Dossier zur Nutzenbewertung gemäß § 35a SGB V

Tisagenlecleucel (Kymriah®)

Novartis Pharma GmbH

Modul 4 A - Separater Anhang 4-H.2 (Teil 1)

Refraktäre oder rezidivierte pädiatrische akute lymphatische B-Zell-Leukämie

Studie CCTL019B2205J (ENSIGN)

Stand: 31.08.2023

Table of Contents

Table 31a
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Full analysis set

Age: <10 years

	All patients N=20			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	14 (70.0)	(45.7, 88.1)	14 (70.0)	(45.7, 88.1)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	14 (70.0)	(45.7, 88.1)	14 (70.0)	(45.7, 88.1)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31a
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Full analysis set

Age: >=10 years to <18 years

	All patients N=34			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	25 (73.5)	(55.6, 87.1)	25 (73.5)	(55.6, 87.1)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	24 (70.6)	(52.5, 84.9)	24 (70.6)	(52.5, 84.9)
With bone marrow 0.01% <= MRD% < 5%	1 (2.9)		1 (2.9)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31a
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Full analysis set

Age: >=18

	All patients N=10			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	6 (60.0)	(26.2, 87.8)	6 (60.0)	(26.2, 87.8)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	5 (50.0)	(18.7, 81.3)	5 (50.0)	(18.7, 81.3)
With bone marrow 0.01% <= MRD% < 5%	1 (10.0)		1 (10.0)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31b
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Gender
Full analysis set

Gender: Male

	All patients N=30			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	23 (76.7)	(57.7, 90.1)	23 (76.7)	(57.7, 90.1)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	22 (73.3)	(54.1, 87.7)	22 (73.3)	(54.1, 87.7)
With bone marrow 0.01% <= MRD% < 5%	1 (3.3)		1 (3.3)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31b
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Gender
Full analysis set

Gender: Female

	All patients N=34			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	22 (64.7)	(46.5, 80.3)	22 (64.7)	(46.5, 80.3)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	21 (61.8)	(43.6, 77.8)	21 (61.8)	(43.6, 77.8)
With bone marrow 0.01% <= MRD% < 5%	1 (2.9)		1 (2.9)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31c
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Full analysis set

Race: White

	All patients N=52			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	36 (69.2)	(54.9, 81.3)	36 (69.2)	(54.9, 81.3)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	34 (65.4)	(50.9, 78.0)	34 (65.4)	(50.9, 78.0)
With bone marrow 0.01% <= MRD% < 5%	2 (3.8)		2 (3.8)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31c
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Full analysis set

Race: Asian

	All patients N=5			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	3 (60.0)	(14.7, 94.7)	3 (60.0)	(14.7, 94.7)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	3 (60.0)	(14.7, 94.7)	3 (60.0)	(14.7, 94.7)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31c
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Full analysis set

Race: Other

	All patients N=7			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	6 (85.7)	(42.1, 99.6)	6 (85.7)	(42.1, 99.6)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	6 (85.7)	(42.1, 99.6)	6 (85.7)	(42.1, 99.6)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31d
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Ethnicity
Full analysis set

Ethnicity: Hispanic or Latino

	All patients N=25			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	23 (92.0)	(74.0, 99.0)	23 (92.0)	(74.0, 99.0)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	23 (92.0)	(74.0, 99.0)	23 (92.0)	(74.0, 99.0)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31d
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Ethnicity
Full analysis set

Ethnicity: Other

	All patients N=39			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	22 (56.4)	(39.6, 72.2)	22 (56.4)	(39.6, 72.2)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	20 (51.3)	(34.8, 67.6)	20 (51.3)	(34.8, 67.6)
With bone marrow 0.01% <= MRD% < 5%	2 (5.1)		2 (5.1)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31e
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Response status at study entry
Full analysis set

Response status at study entry: Primary refractory

	All patients N=7			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	4 (57.1)	(18.4, 90.1)	4 (57.1)	(18.4, 90.1)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	4 (57.1)	(18.4, 90.1)	4 (57.1)	(18.4, 90.1)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31e
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Response status at study entry
Full analysis set

Response status at study entry: Relapsed disease

	All patients N=57			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	41 (71.9)	(58.5, 83.0)	41 (71.9)	(58.5, 83.0)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	39 (68.4)	(54.8, 80.1)	39 (68.4)	(54.8, 80.1)
With bone marrow 0.01% <= MRD% < 5%	2 (3.5)		2 (3.5)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31f
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	2 (100.0)	(15.8, 100.0)	2 (100.0)	(15.8, 100.0)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	2 (100.0)	(15.8, 100.0)	2 (100.0)	(15.8, 100.0)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31f
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	43 (69.4)	(56.3, 80.4)	43 (69.4)	(56.3, 80.4)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	41 (66.1)	(53.0, 77.7)	41 (66.1)	(53.0, 77.7)
With bone marrow 0.01% <= MRD% < 5%	2 (3.2)		2 (3.2)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31g
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	1 (33.3)	(0.8, 90.6)	1 (33.3)	(0.8, 90.6)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	1 (33.3)	(0.8, 90.6)	1 (33.3)	(0.8, 90.6)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31g
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: No

	All patients N=61			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	44 (72.1)	(59.2, 82.9)	44 (72.1)	(59.2, 82.9)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	42 (68.9)	(55.7, 80.1)	42 (68.9)	(55.7, 80.1)
With bone marrow 0.01% <= MRD% < 5%	2 (3.3)		2 (3.3)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31h
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Hypodiploidy
Full analysis set

Hypodiploidy: No

	All patients N=63			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	45 (71.4)	(58.7, 82.1)	45 (71.4)	(58.7, 82.1)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	43 (68.3)	(55.3, 79.4)	43 (68.3)	(55.3, 79.4)
With bone marrow 0.01% <= MRD% < 5%	2 (3.2)		2 (3.2)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31i
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: Yes

	All patients N=4			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	4 (100.0)	(39.8, 100.0)	4 (100.0)	(39.8, 100.0)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	4 (100.0)	(39.8, 100.0)	4 (100.0)	(39.8, 100.0)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31i
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: No

	All patients N=60			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	41 (68.3)	(55.0, 79.7)	41 (68.3)	(55.0, 79.7)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	39 (65.0)	(51.6, 76.9)	39 (65.0)	(51.6, 76.9)
With bone marrow 0.01% <= MRD% < 5%	2 (3.3)		2 (3.3)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31j
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	17 (89.5)	(66.9, 98.7)	17 (89.5)	(66.9, 98.7)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	16 (84.2)	(60.4, 96.6)	16 (84.2)	(60.4, 96.6)
With bone marrow 0.01% <= MRD% < 5%	1 (5.3)		1 (5.3)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31j
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	28 (62.2)	(46.5, 76.2)	28 (62.2)	(46.5, 76.2)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	27 (60.0)	(44.3, 74.3)	27 (60.0)	(44.3, 74.3)
With bone marrow 0.01% <= MRD% < 5%	1 (2.2)		1 (2.2)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31k
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Region
Full analysis set

Region: US

	All patients N=64			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	45 (70.3)	(57.6, 81.1)	45 (70.3)	(57.6, 81.1)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	43 (67.2)	(54.3, 78.4)	43 (67.2)	(54.3, 78.4)
With bone marrow 0.01% <= MRD% < 5%	2 (3.1)		2 (3.1)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31l
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Prior SCT therapy
Full analysis set

Prior SCT therapy: Yes

	All patients N=28			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	19 (67.9)	(47.6, 84.1)	19 (67.9)	(47.6, 84.1)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	18 (64.3)	(44.1, 81.4)	18 (64.3)	(44.1, 81.4)
With bone marrow 0.01% <= MRD% < 5%	1 (3.6)		1 (3.6)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31l
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Prior SCT therapy
Full analysis set

Prior SCT therapy: No

	All patients N=36			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	26 (72.2)	(54.8, 85.8)	26 (72.2)	(54.8, 85.8)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	25 (69.4)	(51.9, 83.7)	25 (69.4)	(51.9, 83.7)
With bone marrow 0.01% <= MRD% < 5%	1 (2.8)		1 (2.8)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31m
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Eligibility for SCT
Full analysis set

Eligibility for SCT: Yes

	All patients N=14			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	ci_irc
Achieved BOR of CR or CRi within 3 months	12 (85.7)	(57.2, 98.2)	12 (85.7)	(57.2, 98.2)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	12 (85.7)	(57.2, 98.2)	12 (85.7)	(57.2, 98.2)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31m
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Eligibility for SCT
Full analysis set

Eligibility for SCT: No

	All patients N=50			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	ci_irc
Achieved BOR of CR or CRi within 3 months	33 (66.0)	(51.2, 78.8)	33 (66.0)	(51.2, 78.8)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	31 (62.0)	(47.2, 75.3)	31 (62.0)	(47.2, 75.3)
With bone marrow 0.01% <= MRD% < 5%	2 (4.0)		2 (4.0)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31n
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: Low

	All patients N=20			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	16 (80.0)	(56.3, 94.3)	16 (80.0)	(56.3, 94.3)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	16 (80.0)	(56.3, 94.3)	16 (80.0)	(56.3, 94.3)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31n
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: High

	All patients N=44			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	29 (65.9)	(50.1, 79.5)	29 (65.9)	(50.1, 79.5)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	27 (61.4)	(45.5, 75.6)	27 (61.4)	(45.5, 75.6)
With bone marrow 0.01% <= MRD% < 5%	2 (4.5)		2 (4.5)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31o
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: Yes

	All patients N=5			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	5 (100.0)	(47.8, 100.0)	5 (100.0)	(47.8, 100.0)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	5 (100.0)	(47.8, 100.0)	5 (100.0)	(47.8, 100.0)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31o
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: No

	All patients N=59			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	40 (67.8)	(54.4, 79.4)	40 (67.8)	(54.4, 79.4)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	38 (64.4)	(50.9, 76.4)	38 (64.4)	(50.9, 76.4)
With bone marrow 0.01% <= MRD% < 5%	2 (3.4)		2 (3.4)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31p
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Down syndrome
Full analysis set

Down syndrome: Yes

	All patients N=4			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	3 (75.0)	(19.4, 99.4)	3 (75.0)	(19.4, 99.4)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	3 (75.0)	(19.4, 99.4)	3 (75.0)	(19.4, 99.4)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31p
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Down syndrome
Full analysis set

Down syndrome: No

	All patients N=60			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	42 (70.0)	(56.8, 81.2)	42 (70.0)	(56.8, 81.2)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	40 (66.7)	(53.3, 78.3)	40 (66.7)	(53.3, 78.3)
With bone marrow 0.01% <= MRD% < 5%	2 (3.3)		2 (3.3)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31q
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: > Median

	All patients N=32			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	23 (71.9)	(53.3, 86.3)	23 (71.9)	(53.3, 86.3)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	23 (71.9)	(53.3, 86.3)	23 (71.9)	(53.3, 86.3)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31q
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	22 (68.8)	(50.0, 83.9)	22 (68.8)	(50.0, 83.9)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	20 (62.5)	(43.7, 78.9)	20 (62.5)	(43.7, 78.9)
With bone marrow 0.01% <= MRD% < 5%	2 (6.3)		2 (6.3)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31r
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 0

	All patients N=7			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	4 (57.1)	(18.4, 90.1)	4 (57.1)	(18.4, 90.1)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	4 (57.1)	(18.4, 90.1)	4 (57.1)	(18.4, 90.1)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31r
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 1

	All patients N=20			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	15 (75.0)	(50.9, 91.3)	15 (75.0)	(50.9, 91.3)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	15 (75.0)	(50.9, 91.3)	15 (75.0)	(50.9, 91.3)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31r
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 2

	All patients N=21			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	14 (66.7)	(43.0, 85.4)	14 (66.7)	(43.0, 85.4)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	13 (61.9)	(38.4, 81.9)	13 (61.9)	(38.4, 81.9)
With bone marrow 0.01% <= MRD% < 5%	1 (4.8)		1 (4.8)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 31r
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: >=3

	All patients N=16			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	12 (75.0)	(47.6, 92.7)	12 (75.0)	(47.6, 92.7)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	11 (68.8)	(41.3, 89.0)	11 (68.8)	(41.3, 89.0)
With bone marrow 0.01% <= MRD% < 5%	1 (6.3)		1 (6.3)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32a
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Enrolled set

Age: <10 years

	All patients N=22			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	14 (63.6)	(45.7, 88.1)	14 (63.6)	(45.7, 88.1)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	14 (63.6)	(45.7, 88.1)	14 (63.6)	(45.7, 88.1)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32a
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=39			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	25 (64.1)	(55.6, 87.1)	25 (64.1)	(55.6, 87.1)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	24 (61.5)	(52.5, 84.9)	24 (61.5)	(52.5, 84.9)
With bone marrow 0.01% <= MRD% < 5%	1 (2.6)		1 (2.6)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32a
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Enrolled set

Age: >=18

	All patients N=14			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	6 (42.9)	(26.2, 87.8)	6 (42.9)	(26.2, 87.8)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	5 (35.7)	(18.7, 81.3)	5 (35.7)	(18.7, 81.3)
With bone marrow 0.01% <= MRD% < 5%	1 (7.1)		1 (7.1)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32b
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Gender
Enrolled set

Gender: Male

	All patients N=40			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	23 (57.5)	(57.7, 90.1)	23 (57.5)	(57.7, 90.1)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	22 (55.0)	(54.1, 87.7)	22 (55.0)	(54.1, 87.7)
With bone marrow 0.01% <= MRD% < 5%	1 (2.5)		1 (2.5)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32b
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Gender
Enrolled set

Gender: Female

	All patients N=35			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	22 (62.9)	(46.5, 80.3)	22 (62.9)	(46.5, 80.3)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	21 (60.0)	(43.6, 77.8)	21 (60.0)	(43.6, 77.8)
With bone marrow 0.01% <= MRD% < 5%	1 (2.9)		1 (2.9)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32c
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Enrolled set

Race: White

	All patients N=60			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	36 (60.0)	(54.9, 81.3)	36 (60.0)	(54.9, 81.3)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	34 (56.7)	(50.9, 78.0)	34 (56.7)	(50.9, 78.0)
With bone marrow 0.01% <= MRD% < 5%	2 (3.3)		2 (3.3)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32c
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Enrolled set

Race: Asian

	All patients N=6			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	3 (50.0)	(14.7, 94.7)	3 (50.0)	(14.7, 94.7)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	3 (50.0)	(14.7, 94.7)	3 (50.0)	(14.7, 94.7)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32c
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Enrolled set

Race: Other

	All patients N=9			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	6 (66.7)	(42.1, 99.6)	6 (66.7)	(42.1, 99.6)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	6 (66.7)	(42.1, 99.6)	6 (66.7)	(42.1, 99.6)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32d
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=30			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	23 (76.7)	(74.0, 99.0)	23 (76.7)	(74.0, 99.0)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	23 (76.7)	(74.0, 99.0)	23 (76.7)	(74.0, 99.0)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32d
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=45			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	22 (48.9)	(39.6, 72.2)	22 (48.9)	(39.6, 72.2)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	20 (44.4)	(34.8, 67.6)	20 (44.4)	(34.8, 67.6)
With bone marrow 0.01% <= MRD% < 5%	2 (4.4)		2 (4.4)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32e
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	4 (50.0)	(18.4, 90.1)	4 (50.0)	(18.4, 90.1)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	4 (50.0)	(18.4, 90.1)	4 (50.0)	(18.4, 90.1)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32e
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=67			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	41 (61.2)	(58.5, 83.0)	41 (61.2)	(58.5, 83.0)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	39 (58.2)	(54.8, 80.1)	39 (58.2)	(54.8, 80.1)
With bone marrow 0.01% <= MRD% < 5%	2 (3.0)		2 (3.0)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32f
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	2 (100.0)	(15.8, 100.0)	2 (100.0)	(15.8, 100.0)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	2 (100.0)	(15.8, 100.0)	2 (100.0)	(15.8, 100.0)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32f
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	43 (58.9)	(56.3, 80.4)	43 (58.9)	(56.3, 80.4)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	41 (56.2)	(53.0, 77.7)	41 (56.2)	(53.0, 77.7)
With bone marrow 0.01% <= MRD% < 5%	2 (2.7)		2 (2.7)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32g
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	1 (33.3)	(0.8, 90.6)	1 (33.3)	(0.8, 90.6)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	1 (33.3)	(0.8, 90.6)	1 (33.3)	(0.8, 90.6)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32g
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=72			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	44 (61.1)	(59.2, 82.9)	44 (61.1)	(59.2, 82.9)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	42 (58.3)	(55.7, 80.1)	42 (58.3)	(55.7, 80.1)
With bone marrow 0.01% <= MRD% < 5%	2 (2.8)		2 (2.8)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32h
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=74			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	45 (60.8)	(58.7, 82.1)	45 (60.8)	(58.7, 82.1)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	43 (58.1)	(55.3, 79.4)	43 (58.1)	(55.3, 79.4)
With bone marrow 0.01% <= MRD% < 5%	2 (2.7)		2 (2.7)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32i
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=4			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	4 (100.0)	(39.8, 100.0)	4 (100.0)	(39.8, 100.0)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	4 (100.0)	(39.8, 100.0)	4 (100.0)	(39.8, 100.0)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32i
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=71			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	41 (57.7)	(55.0, 79.7)	41 (57.7)	(55.0, 79.7)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	39 (54.9)	(51.6, 76.9)	39 (54.9)	(51.6, 76.9)
With bone marrow 0.01% <= MRD% < 5%	2 (2.8)		2 (2.8)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32j
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	17 (77.3)	(66.9, 98.7)	17 (77.3)	(66.9, 98.7)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	16 (72.7)	(60.4, 96.6)	16 (72.7)	(60.4, 96.6)
With bone marrow 0.01% <= MRD% < 5%	1 (4.5)		1 (4.5)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32j
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	28 (52.8)	(46.5, 76.2)	28 (52.8)	(46.5, 76.2)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	27 (50.9)	(44.3, 74.3)	27 (50.9)	(44.3, 74.3)
With bone marrow 0.01% <= MRD% < 5%	1 (1.9)		1 (1.9)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32k
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Region
Enrolled set

Region: US

	All patients N=75			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	45 (60.0)	(57.6, 81.1)	45 (60.0)	(57.6, 81.1)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	43 (57.3)	(54.3, 78.4)	43 (57.3)	(54.3, 78.4)
With bone marrow 0.01% <= MRD% < 5%	2 (2.7)		2 (2.7)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32l
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=32			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	19 (59.4)	(47.6, 84.1)	19 (59.4)	(47.6, 84.1)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	18 (56.3)	(44.1, 81.4)	18 (56.3)	(44.1, 81.4)
With bone marrow 0.01% <= MRD% < 5%	1 (3.1)		1 (3.1)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32l
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=43			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	26 (60.5)	(54.8, 85.8)	26 (60.5)	(54.8, 85.8)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	25 (58.1)	(51.9, 83.7)	25 (58.1)	(51.9, 83.7)
With bone marrow 0.01% <= MRD% < 5%	1 (2.3)		1 (2.3)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32m
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=18			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	12 (66.7)	(57.2, 98.2)	12 (66.7)	(57.2, 98.2)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	12 (66.7)	(57.2, 98.2)	12 (66.7)	(57.2, 98.2)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32m
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=57			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	33 (57.9)	(51.2, 78.8)	33 (57.9)	(51.2, 78.8)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	31 (54.4)	(47.2, 75.3)	31 (54.4)	(47.2, 75.3)
With bone marrow 0.01% <= MRD% < 5%	2 (3.5)		2 (3.5)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32n
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=22			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	16 (72.7)	(56.3, 94.3)	16 (72.7)	(56.3, 94.3)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	16 (72.7)	(56.3, 94.3)	16 (72.7)	(56.3, 94.3)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32n
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=53			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	29 (54.7)	(50.1, 79.5)	29 (54.7)	(50.1, 79.5)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	27 (50.9)	(45.5, 75.6)	27 (50.9)	(45.5, 75.6)
With bone marrow 0.01% <= MRD% < 5%	2 (3.8)		2 (3.8)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32o
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=7			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	5 (71.4)	(47.8, 100.0)	5 (71.4)	(47.8, 100.0)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	5 (71.4)	(47.8, 100.0)	5 (71.4)	(47.8, 100.0)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32o
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=68			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	40 (58.8)	(54.4, 79.4)	40 (58.8)	(54.4, 79.4)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	38 (55.9)	(50.9, 76.4)	38 (55.9)	(50.9, 76.4)
With bone marrow 0.01% <= MRD% < 5%	2 (2.9)		2 (2.9)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32p
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=4			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	3 (75.0)	(19.4, 99.4)	3 (75.0)	(19.4, 99.4)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	3 (75.0)	(19.4, 99.4)	3 (75.0)	(19.4, 99.4)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32p
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Down syndrome
Enrolled set

Down syndrome: No

	All patients N=71			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	42 (59.2)	(56.8, 81.2)	42 (59.2)	(56.8, 81.2)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	40 (56.3)	(53.3, 78.3)	40 (56.3)	(53.3, 78.3)
With bone marrow 0.01% <= MRD% < 5%	2 (2.8)		2 (2.8)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32q
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=32			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	23 (71.9)	(53.3, 86.3)	23 (71.9)	(53.3, 86.3)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	23 (71.9)	(53.3, 86.3)	23 (71.9)	(53.3, 86.3)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32q
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	22 (68.8)	(50.0, 83.9)	22 (68.8)	(50.0, 83.9)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	20 (62.5)	(43.7, 78.9)	20 (62.5)	(43.7, 78.9)
With bone marrow 0.01% <= MRD% < 5%	2 (6.3)		2 (6.3)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32r
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	4 (50.0)	(18.4, 90.1)	4 (50.0)	(18.4, 90.1)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	4 (50.0)	(18.4, 90.1)	4 (50.0)	(18.4, 90.1)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32r
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=23			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	15 (65.2)	(50.9, 91.3)	15 (65.2)	(50.9, 91.3)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	15 (65.2)	(50.9, 91.3)	15 (65.2)	(50.9, 91.3)
With bone marrow 0.01% <= MRD% < 5%	0		0	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32r
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=24			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	14 (58.3)	(43.0, 85.4)	14 (58.3)	(43.0, 85.4)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	13 (54.2)	(38.4, 81.9)	13 (54.2)	(38.4, 81.9)
With bone marrow 0.01% <= MRD% < 5%	1 (4.2)		1 (4.2)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 32r
Bone marrow minimum residual disease (MRD) status by flow cytometry within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=20			
	Local assessment		IRC assessment	
	n (%)	95% CI	n (%)	95% CI
Achieved BOR of CR or CRi within 3 months	12 (60.0)	(47.6, 92.7)	12 (60.0)	(47.6, 92.7)
With bone marrow MRD negative (i.e. MRD% < 0.01%)	11 (55.0)	(41.3, 89.0)	11 (55.0)	(41.3, 89.0)
With bone marrow 0.01% <= MRD% < 5%	1 (5.0)		1 (5.0)	
With bone marrow MRD% >= 5%	0		0	
Bone marrow MRD not available	0		0	

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery; BOR=Best overall response
- The 95% CIs are exact Clopper-Pearson CIs.
- MRD status defined by the minimum MRD% within the corresponding time frame.

Table 170a
Overall survival (OS) by Age
Full analysis set

Age: <10 years	**All patients N=20**
Events/Total (%)	11/20 (55.0)
Maximum follow-up (months)	49.3
Median follow-up (months)	19.42
Percentiles (95% CI) [1]	
25th	7.1 (0.8, 29.9)
50th	29.9 (6.9, 36.8)
75th	36.8 (29.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	95.0 (69.5, 99.3)
Month 6	85.0 (60.4, 94.9)
Month 9	65.0 (40.3, 81.5)
Month 12	60.0 (35.7, 77.6)
Month 15	60.0 (35.7, 77.6)
Month 18	60.0 (35.7, 77.6)
Month 21	60.0 (35.7, 77.6)

Age: <10 years	
	All patients N=20
Month 24	60.0 (35.7, 77.6)
Month 27	60.0 (35.7, 77.6)
Month 30	48.0 (20.5, 71.2)
Month 33	48.0 (20.5, 71.2)
Month 36	32.0 (6.8, 61.7)
Month 39	16.0 (1.0, 48.4)
Month 42	16.0 (1.0, 48.4)
Month 45	16.0 (1.0, 48.4)
Month 48	16.0 (1.0, 48.4)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170a
Overall survival (OS) by Age
Full analysis set

Age: >=10 years to <18 years

	All patients N=34
Events/Total (%)	13/34 (38.2)
Maximum follow-up (months)	48.1
Median follow-up (months)	17.82
Percentiles (95% CI) [1]	
25th	14.8 (4.1, 23.8)
50th	42.4 (23.8, NE)
75th	NE (42.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	94.1 (78.5, 98.5)
Month 6	88.2 (71.6, 95.4)
Month 9	76.5 (58.4, 87.5)
Month 12	76.5 (58.4, 87.5)
Month 15	73.0 (54.4, 85.0)
Month 18	69.3 (50.3, 82.3)
Month 21	69.3 (50.3, 82.3)

Age: >=10 years to <18 years	
	All patients N=34
Month 24	52.0 (26.6, 72.4)
Month 27	52.0 (26.6, 72.4)
Month 30	52.0 (26.6, 72.4)
Month 33	52.0 (26.6, 72.4)
Month 36	52.0 (26.6, 72.4)
Month 39	52.0 (26.6, 72.4)
Month 42	52.0 (26.6, 72.4)
Month 45	26.0 (1.9, 63.4)
Month 48	26.0 (1.9, 63.4)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170a
Overall survival (OS) by Age
Full analysis set

Age: >=18

	All patients N=10
Events/Total (%)	6/10 (60.0)
Maximum follow-up (months)	47.7
Median follow-up (months)	7.36
Percentiles (95% CI) [1]	
25th	4.1 (1.2, 7.4)
50th	7.4 (1.2, NE)
75th	NE (7.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	80.0 (40.9, 94.6)
Month 6	70.0 (32.9, 89.2)
Month 9	36.0 (9.0, 64.8)
Month 12	36.0 (9.0, 64.8)
Month 15	36.0 (9.0, 64.8)
Month 18	36.0 (9.0, 64.8)
Month 21	36.0 (9.0, 64.8)

Age: >=18	
	All patients N=10
Month 24	36.0 (9.0, 64.8)
Month 27	36.0 (9.0, 64.8)
Month 30	36.0 (9.0, 64.8)
Month 33	36.0 (9.0, 64.8)
Month 36	36.0 (9.0, 64.8)
Month 39	36.0 (9.0, 64.8)
Month 42	36.0 (9.0, 64.8)
Month 45	36.0 (9.0, 64.8)
Month 48	NE

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170b
Overall survival (OS) by Gender
Full analysis set

Gender: Male

	All patients N=30
Events/Total (%)	11/30 (36.7)
Maximum follow-up (months)	49.3
Median follow-up (months)	21.08
Percentiles (95% CI) [1]	
25th	23.8 (6.4, 36.8)
50th	36.8 (23.8, NE)
75th	NE (36.8, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	93.3 (75.9, 98.3)
Month 6	93.3 (75.9, 98.3)
Month 9	76.7 (57.2, 88.1)
Month 12	76.7 (57.2, 88.1)
Month 15	76.7 (57.2, 88.1)
Month 18	76.7 (57.2, 88.1)
Month 21	76.7 (57.2, 88.1)

Gender: Male	
	All patients N=30
Month 24	62.7 (37.9, 79.9)
Month 27	62.7 (37.9, 79.9)
Month 30	62.7 (37.9, 79.9)
Month 33	62.7 (37.9, 79.9)
Month 36	62.7 (37.9, 79.9)
Month 39	47.0 (16.3, 73.1)
Month 42	47.0 (16.3, 73.1)
Month 45	31.4 (5.9, 62.3)
Month 48	31.4 (5.9, 62.3)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170b
Overall survival (OS) by Gender
Full analysis set

Gender: Female

	All patients N=34
Events/Total (%)	19/34 (55.9)
Maximum follow-up (months)	48.1
Median follow-up (months)	11.79
Percentiles (95% CI) [1]	
25th	6.6 (3.1, 9.0)
50th	15.1 (7.2, 34.4)
75th	34.4 (29.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	91.2 (75.1, 97.1)
Month 6	76.5 (58.4, 87.5)
Month 9	58.4 (40.1, 72.9)
Month 12	55.3 (37.2, 70.2)
Month 15	51.4 (33.1, 67.0)
Month 18	47.1 (28.8, 63.4)
Month 21	47.1 (28.8, 63.4)

Gender: Female	
	All patients N=34
Month 24	47.1 (28.8, 63.4)
Month 27	47.1 (28.8, 63.4)
Month 30	35.3 (13.5, 58.2)
Month 33	35.3 (13.5, 58.2)
Month 36	17.7 (1.5, 49.1)
Month 39	17.7 (1.5, 49.1)
Month 42	17.7 (1.5, 49.1)
Month 45	17.7 (1.5, 49.1)
Month 48	17.7 (1.5, 49.1)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170c
Overall survival (OS) by Race
Full analysis set

Race: White

	All patients N=52
Events/Total (%)	25/52 (48.1)
Maximum follow-up (months)	49.3
Median follow-up (months)	15.13
Percentiles (95% CI) [1]	
25th	7.1 (3.4, 11.0)
50th	29.9 (11.0, 42.4)
75th	42.4 (36.8, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	90.4 (78.4, 95.9)
Month 6	82.7 (69.4, 90.6)
Month 9	65.2 (50.5, 76.4)
Month 12	63.2 (48.5, 74.7)
Month 15	63.2 (48.5, 74.7)
Month 18	60.8 (45.9, 72.7)
Month 21	60.8 (45.9, 72.7)

Race: White	
	All patients N=52
Month 24	52.7 (36.0, 66.8)
Month 27	52.7 (36.0, 66.8)
Month 30	45.1 (25.8, 62.7)
Month 33	45.1 (25.8, 62.7)
Month 36	45.1 (25.8, 62.7)
Month 39	33.9 (12.5, 56.9)
Month 42	33.9 (12.5, 56.9)
Month 45	22.6 (4.7, 48.4)
Month 48	22.6 (4.7, 48.4)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170c
Overall survival (OS) by Race
Full analysis set

Race: Asian

	All patients N=5
Events/Total (%)	3/5 (60.0)
Maximum follow-up (months)	34.4
Median follow-up (months)	11.96
Percentiles (95% CI) [1]	
25th	9.0 (4.7, 34.4)
50th	34.4 (4.7, 34.4)
75th	34.4 (4.7, 34.4)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	80.0 (20.4, 96.9)
Month 9	60.0 (12.6, 88.2)
Month 12	60.0 (12.6, 88.2)
Month 15	60.0 (12.6, 88.2)
Month 18	60.0 (12.6, 88.2)
Month 21	60.0 (12.6, 88.2)

Race: Asian

	All patients N=5
Month 24	60.0 (12.6, 88.2)
Month 27	60.0 (12.6, 88.2)
Month 30	60.0 (12.6, 88.2)
Month 33	60.0 (12.6, 88.2)
Month 36	0.0 (NE, NE)
Month 39	0.0 (NE, NE)
Month 42	0.0 (NE, NE)
Month 45	0.0 (NE, NE)
Month 48	0.0 (NE, NE)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170c
Overall survival (OS) by Race
Full analysis set

Race: Other

	All patients N=7
Events/Total (%)	2/7 (28.6)
Maximum follow-up (months)	48.1
Median follow-up (months)	17.91
Percentiles (95% CI) [1]	
25th	14.8 (6.6, NE)
50th	NE (6.6, NE)
75th	NE (14.8, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	85.7 (33.4, 97.9)
Month 12	85.7 (33.4, 97.9)
Month 15	68.6 (21.3, 91.2)
Month 18	68.6 (21.3, 91.2)
Month 21	68.6 (21.3, 91.2)

Race: Other	
	All patients N=7
Month 24	68.6 (21.3, 91.2)
Month 27	68.6 (21.3, 91.2)
Month 30	68.6 (21.3, 91.2)
Month 33	68.6 (21.3, 91.2)
Month 36	68.6 (21.3, 91.2)
Month 39	68.6 (21.3, 91.2)
Month 42	68.6 (21.3, 91.2)
Month 45	68.6 (21.3, 91.2)
Month 48	68.6 (21.3, 91.2)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170d
Overall survival (OS) by Ethnicity
Full analysis set

Ethnicity: Hispanic or Latino

	All patients N=25
Events/Total (%)	6/25 (24.0)
Maximum follow-up (months)	24.0
Median follow-up (months)	16.16
Percentiles (95% CI) [1]	
25th	23.8 (4.1, NE)
50th	23.8 (23.8, NE)
75th	NE (23.8, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	96.0 (74.8, 99.4)
Month 9	84.0 (62.8, 93.7)
Month 12	84.0 (62.8, 93.7)
Month 15	84.0 (62.8, 93.7)
Month 18	78.0 (54.2, 90.4)
Month 21	78.0 (54.2, 90.4)

Ethnicity: Hispanic or Latino	
	All patients N=25
Month 24	NE
Month 27	NE
Month 30	NE
Month 33	NE
Month 36	NE
Month 39	NE
Month 42	NE
Month 45	NE
Month 48	NE

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170d
Overall survival (OS) by Ethnicity
Full analysis set

Ethnicity: Other

	All patients N=39
Events/Total (%)	24/39 (61.5)
Maximum follow-up (months)	49.3
Median follow-up (months)	11.96
Percentiles (95% CI) [1]	
25th	6.4 (2.4, 7.4)
50th	23.8 (6.8, 36.8)
75th	42.4 (29.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	87.2 (71.9, 94.5)
Month 6	76.9 (60.3, 87.3)
Month 9	56.1 (39.2, 70.0)
Month 12	53.4 (36.6, 67.6)
Month 15	50.6 (34.0, 65.1)
Month 18	50.6 (34.0, 65.1)
Month 21	50.6 (34.0, 65.1)

Ethnicity: Other	
	All patients N=39
Month 24	47.4 (30.9, 62.3)
Month 27	47.4 (30.9, 62.3)
Month 30	42.2 (25.0, 58.4)
Month 33	42.2 (25.0, 58.4)
Month 36	35.1 (17.2, 53.7)
Month 39	28.1 (11.1, 48.1)
Month 42	28.1 (11.1, 48.1)
Month 45	21.1 (6.2, 41.7)
Month 48	21.1 (6.2, 41.7)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170e
Overall survival (OS) by Response status at study entry
Full analysis set

Response status at study entry: Primary refractory	**All patients N=7**
Events/Total (%)	2/7 (28.6)
Maximum follow-up (months)	29.7
Median follow-up (months)	20.93
Percentiles (95% CI) [1]	
25th	1.2 (0.4, NE)
50th	NE (0.4, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	71.4 (25.8, 92.0)
Month 6	71.4 (25.8, 92.0)
Month 9	71.4 (25.8, 92.0)
Month 12	71.4 (25.8, 92.0)
Month 15	71.4 (25.8, 92.0)
Month 18	71.4 (25.8, 92.0)
Month 21	71.4 (25.8, 92.0)

Response status at study entry: Primary refractory	
	All patients N=7
Month 24	71.4 (25.8, 92.0)
Month 27	71.4 (25.8, 92.0)
Month 30	NE
Month 33	NE
Month 36	NE
Month 39	NE
Month 42	NE
Month 45	NE
Month 48	NE

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170e
Overall survival (OS) by Response status at study entry
Full analysis set

Response status at study entry: Relapsed disease	**All patients N=57**
Events/Total (%)	28/57 (49.1)
Maximum follow-up (months)	49.3
Median follow-up (months)	15.05
Percentiles (95% CI) [1]	
25th	7.4 (4.7, 14.8)
50th	29.9 (14.8, 42.4)
75th	42.4 (34.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	94.7 (84.6, 98.3)
Month 6	86.0 (73.9, 92.7)
Month 9	66.5 (52.6, 77.1)
Month 12	64.7 (50.7, 75.6)
Month 15	62.5 (48.4, 73.8)
Month 18	60.2 (45.9, 71.8)
Month 21	60.2 (45.9, 71.8)

Response status at study entry: Relapsed disease	
	All patients N=57
Month 24	52.2 (36.0, 66.1)
Month 27	52.2 (36.0, 66.1)
Month 30	46.4 (28.6, 62.3)
Month 33	46.4 (28.6, 62.3)
Month 36	38.6 (19.4, 57.6)
Month 39	30.9 (12.3, 51.7)
Month 42	30.9 (12.3, 51.7)
Month 45	23.2 (6.9, 45.0)
Month 48	23.2 (6.9, 45.0)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170f
Overall survival (OS) by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Positive	**All patients N=2**
Events/Total (%)	0/2 (0.0)
Maximum follow-up (months)	23.6
Median follow-up (months)	17.76
Percentiles (95% CI) [1]	
25th	NE
50th	NE
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	100 (100, 100)
Month 12	100 (100, 100)
Month 15	100 (100, 100)
Month 18	100 (100, 100)
Month 21	100 (100, 100)

Philadelphia chromosome/BCR-ABL: Positive	
	All patients N=2
Month 24	NE
Month 27	NE
Month 30	NE
Month 33	NE
Month 36	NE
Month 39	NE
Month 42	NE
Month 45	NE
Month 48	NE

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170f
Overall survival (OS) by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Negative	**All patients N=62**
Events/Total (%)	30/62 (48.4)
Maximum follow-up (months)	49.3
Median follow-up (months)	15.13
Percentiles (95% CI) [1]	
25th	7.2 (4.1, 11.0)
50th	29.9 (14.8, 42.4)
75th	42.4 (34.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	91.9 (81.7, 96.6)
Month 6	83.9 (72.1, 91.0)
Month 9	65.9 (52.7, 76.3)
Month 12	64.3 (51.0, 74.9)
Month 15	62.4 (49.0, 73.2)
Month 18	60.4 (46.9, 71.5)
Month 21	60.4 (46.9, 71.5)

Philadelphia chromosome/BCR-ABL: Negative	
	All patients N=62
Month 24	53.7 (38.7, 66.5)
Month 27	53.7 (38.7, 66.5)
Month 30	47.7 (30.5, 63.1)
Month 33	47.7 (30.5, 63.1)
Month 36	39.8 (20.5, 58.5)
Month 39	31.8 (12.9, 52.7)
Month 42	31.8 (12.9, 52.7)
Month 45	23.9 (7.2, 45.9)
Month 48	23.9 (7.2, 45.9)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170g
Overall survival (OS) by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3
Events/Total (%)	2/3 (66.7)
Maximum follow-up (months)	17.9
Median follow-up (months)	6.90
Percentiles (95% CI) [1]	
25th	1.2 (1.2, NE)
50th	6.9 (1.2, NE)
75th	NE (1.2, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	66.7 (5.4, 94.5)
Month 6	66.7 (5.4, 94.5)
Month 9	33.3 (0.9, 77.4)
Month 12	33.3 (0.9, 77.4)
Month 15	33.3 (0.9, 77.4)
Month 18	NE
Month 21	NE

Mixed-lineage leukemia rearrangement: Yes	
	All patients N=3
Month 24	NE
Month 27	NE
Month 30	NE
Month 33	NE
Month 36	NE
Month 39	NE
Month 42	NE
Month 45	NE
Month 48	NE

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170g
Overall survival (OS) by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: No

	All patients N=61
Events/Total (%)	28/61 (45.9)
Maximum follow-up (months)	49.3
Median follow-up (months)	15.15
Percentiles (95% CI) [1]	
25th	7.4 (4.7, 15.1)
50th	29.9 (15.1, 42.4)
75th	42.4 (34.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	93.4 (83.5, 97.5)
Month 6	85.2 (73.6, 92.0)
Month 9	68.7 (55.4, 78.7)
Month 12	67.0 (53.6, 77.3)
Month 15	65.0 (51.5, 75.6)
Month 18	62.9 (49.2, 73.9)
Month 21	62.9 (49.2, 73.9)

Mixed-lineage leukemia rearrangement: No	
	All patients N=61
Month 24	55.9 (40.6, 68.8)
Month 27	55.9 (40.6, 68.8)
Month 30	49.7 (31.8, 65.3)
Month 33	49.7 (31.8, 65.3)
Month 36	41.4 (21.3, 60.6)
Month 39	33.1 (13.4, 54.6)
Month 42	33.1 (13.4, 54.6)
Month 45	24.9 (7.4, 47.5)
Month 48	24.9 (7.4, 47.5)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170h
Overall survival (OS) by Hypodiploidy
Full analysis set

Hypodiploidy: Yes

	All patients N=1
Events/Total (%)	1/1 (100.0)
Maximum follow-up (months)	23.8
Median follow-up (months)	23.79
Percentiles (95% CI) [1]	
25th	23.8 (NE, NE)
50th	23.8 (NE, NE)
75th	23.8 (NE, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	100 (100, 100)
Month 12	100 (100, 100)
Month 15	100 (100, 100)
Month 18	100 (100, 100)
Month 21	100 (100, 100)

Hypodiploidy: Yes	
	All patients N=1
Month 24	0.0 (NE, NE)
Month 27	0.0 (NE, NE)
Month 30	0.0 (NE, NE)
Month 33	0.0 (NE, NE)
Month 36	0.0 (NE, NE)
Month 39	0.0 (NE, NE)
Month 42	0.0 (NE, NE)
Month 45	0.0 (NE, NE)
Month 48	0.0 (NE, NE)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170h
Overall survival (OS) by Hypodiploidy
Full analysis set

Hypodiploidy: No

	All patients N=63
Events/Total (%)	29/63 (46.0)
Maximum follow-up (months)	49.3
Median follow-up (months)	15.11
Percentiles (95% CI) [1]	
25th	7.2 (4.1, 14.8)
50th	34.4 (14.8, 42.4)
75th	NE (34.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	92.1 (82.0, 96.6)
Month 6	84.1 (72.5, 91.1)
Month 9	66.5 (53.4, 76.7)
Month 12	64.9 (51.7, 75.3)
Month 15	63.0 (49.7, 73.7)
Month 18	60.9 (47.5, 71.9)
Month 21	60.9 (47.5, 71.9)

Hypodiploidy: No	
	All patients N=63
Month 24	57.3 (42.8, 69.4)
Month 27	57.3 (42.8, 69.4)
Month 30	51.0 (33.3, 66.1)
Month 33	51.0 (33.3, 66.1)
Month 36	42.5 (22.1, 61.6)
Month 39	34.0 (13.8, 55.5)
Month 42	34.0 (13.8, 55.5)
Month 45	25.5 (7.6, 48.4)
Month 48	25.5 (7.6, 48.4)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170i
Overall survival (OS) by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: Yes

	All patients N=4
Events/Total (%)	1/4 (25.0)
Maximum follow-up (months)	28.8
Median follow-up (months)	16.53
Percentiles (95% CI) [1]	
25th	15.1 (15.1, NE)
50th	NE (15.1, NE)
75th	NE (15.1, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	100 (100, 100)
Month 12	100 (100, 100)
Month 15	100 (100, 100)
Month 18	66.7 (5.4, 94.5)
Month 21	66.7 (5.4, 94.5)

BCR-ABL1-like: Yes

	All patients N=4
Month 24	66.7 (5.4, 94.5)
Month 27	66.7 (5.4, 94.5)
Month 30	NE
Month 33	NE
Month 36	NE
Month 39	NE
Month 42	NE
Month 45	NE
Month 48	NE

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170i
Overall survival (OS) by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: No

	All patients N=60
Events/Total (%)	29/60 (48.3)
Maximum follow-up (months)	49.3
Median follow-up (months)	15.08
Percentiles (95% CI) [1]	
25th	7.1 (4.1, 11.0)
50th	29.9 (11.0, 42.4)
75th	42.4 (34.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	91.7 (81.1, 96.4)
Month 6	83.3 (71.2, 90.7)
Month 9	64.8 (51.3, 75.4)
Month 12	63.1 (49.5, 73.9)
Month 15	61.1 (47.5, 72.2)
Month 18	61.1 (47.5, 72.2)
Month 21	61.1 (47.5, 72.2)

BCR-ABL1-like: No

	All patients N=60
Month 24	53.9 (38.6, 67.0)
Month 27	53.9 (38.6, 67.0)
Month 30	47.9 (30.4, 63.5)
Month 33	47.9 (30.4, 63.5)
Month 36	40.0 (20.4, 58.9)
Month 39	32.0 (12.9, 53.0)
Month 42	32.0 (12.9, 53.0)
Month 45	24.0 (7.2, 46.1)
Month 48	24.0 (7.2, 46.1)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170j
Overall survival (OS) by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes	**All patients N=19**
Events/Total (%)	9/19 (47.4)
Maximum follow-up (months)	48.1
Median follow-up (months)	21.39
Percentiles (95% CI) [1]	
25th	6.9 (0.8, 34.4)
50th	34.4 (6.9, NE)
75th	42.4 (34.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	94.7 (68.1, 99.2)
Month 6	84.2 (58.7, 94.6)
Month 9	73.7 (47.9, 88.1)
Month 12	68.0 (42.1, 84.2)
Month 15	62.3 (36.7, 80.0)
Month 18	62.3 (36.7, 80.0)
Month 21	62.3 (36.7, 80.0)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19
Month 24	62.3 (36.7, 80.0)
Month 27	62.3 (36.7, 80.0)
Month 30	62.3 (36.7, 80.0)
Month 33	62.3 (36.7, 80.0)
Month 36	41.6 (9.3, 72.3)
Month 39	41.6 (9.3, 72.3)
Month 42	41.6 (9.3, 72.3)
Month 45	20.8 (1.2, 57.5)
Month 48	20.8 (1.2, 57.5)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170j
Overall survival (OS) by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : No	**All patients N=45**
Events/Total (%)	21/45 (46.7)
Maximum follow-up (months)	49.3
Median follow-up (months)	15.05
Percentiles (95% CI) [1]	
25th	7.4 (3.4, 15.1)
50th	23.8 (9.0, NE)
75th	NE (29.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	91.1 (78.0, 96.6)
Month 6	84.4 (70.1, 92.3)
Month 9	64.4 (48.7, 76.5)
Month 12	64.4 (48.7, 76.5)
Month 15	64.4 (48.7, 76.5)
Month 18	61.5 (45.4, 74.1)
Month 21	61.5 (45.4, 74.1)

Complex karyotypes II (>=5 unrelated abnormalities) : No	
	All patients N=45
Month 24	49.2 (29.3, 66.4)
Month 27	49.2 (29.3, 66.4)
Month 30	39.4 (17.4, 60.8)
Month 33	39.4 (17.4, 60.8)
Month 36	39.4 (17.4, 60.8)
Month 39	26.2 (6.0, 52.9)
Month 42	26.2 (6.0, 52.9)
Month 45	26.2 (6.0, 52.9)
Month 48	26.2 (6.0, 52.9)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170k
Overall survival (OS) by Region
Full analysis set

Region: US

	All patients N=64
Events/Total (%)	30/64 (46.9)
Maximum follow-up (months)	49.3
Median follow-up (months)	15.13
Percentiles (95% CI) [1]	
25th	7.3 (4.1, 14.8)
50th	29.9 (15.1, 42.4)
75th	42.4 (34.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	92.2 (82.2, 96.7)
Month 6	84.4 (72.9, 91.3)
Month 9	67.0 (54.0, 77.1)
Month 12	65.4 (52.4, 75.7)
Month 15	63.6 (50.4, 74.1)
Month 18	61.6 (48.2, 72.4)
Month 21	61.6 (48.2, 72.4)

Region: US	
	All patients N=64
Month 24	54.7 (39.8, 67.4)
Month 27	54.7 (39.8, 67.4)
Month 30	48.6 (31.2, 64.0)
Month 33	48.6 (31.2, 64.0)
Month 36	40.5 (20.9, 59.4)
Month 39	32.4 (13.2, 53.5)
Month 42	32.4 (13.2, 53.5)
Month 45	24.3 (7.3, 46.6)
Month 48	24.3 (7.3, 46.6)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170l
Overall survival (OS) by Prior SCT therapy
Full analysis set

Prior SCT therapy: Yes	**All patients N=28**
Events/Total (%)	14/28 (50.0)
Maximum follow-up (months)	48.1
Median follow-up (months)	16.49
Percentiles (95% CI) [1]	
25th	7.8 (2.4, 23.8)
50th	29.9 (14.8, 42.4)
75th	42.4 (29.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	89.3 (70.4, 96.4)
Month 6	85.7 (66.3, 94.4)
Month 9	71.4 (50.9, 84.6)
Month 12	71.4 (50.9, 84.6)
Month 15	67.0 (45.9, 81.3)
Month 18	62.5 (41.2, 78.0)
Month 21	62.5 (41.2, 78.0)

Prior SCT therapy: Yes	
	All patients N=28
Month 24	53.6 (29.1, 72.9)
Month 27	53.6 (29.1, 72.9)
Month 30	42.9 (17.5, 66.2)
Month 33	42.9 (17.5, 66.2)
Month 36	42.9 (17.5, 66.2)
Month 39	32.1 (9.4, 58.0)
Month 42	32.1 (9.4, 58.0)
Month 45	21.4 (3.8, 48.3)
Month 48	21.4 (3.8, 48.3)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170l
Overall survival (OS) by Prior SCT therapy
Full analysis set

Prior SCT therapy: No

	All patients N=36
Events/Total (%)	16/36 (44.4)
Maximum follow-up (months)	49.3
Median follow-up (months)	15.08
Percentiles (95% CI) [1]	
25th	7.3 (3.4, 11.0)
50th	34.4 (8.7, NE)
75th	NE (34.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	94.4 (79.6, 98.6)
Month 6	83.3 (66.6, 92.1)
Month 9	63.5 (45.5, 76.9)
Month 12	60.6 (42.7, 74.5)
Month 15	60.6 (42.7, 74.5)
Month 18	60.6 (42.7, 74.5)
Month 21	60.6 (42.7, 74.5)

Prior SCT therapy: No	
	All patients N=36
Month 24	55.1 (35.7, 70.8)
Month 27	55.1 (35.7, 70.8)
Month 30	55.1 (35.7, 70.8)
Month 33	55.1 (35.7, 70.8)
Month 36	27.5 (2.0, 65.2)
Month 39	27.5 (2.0, 65.2)
Month 42	27.5 (2.0, 65.2)
Month 45	27.5 (2.0, 65.2)
Month 48	27.5 (2.0, 65.2)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170m
Overall survival (OS) by Eligibility for SCT
Full analysis set

Eligibility for SCT: Yes	**All patients N=14**
Events/Total (%)	4/14 (28.6)
Maximum follow-up (months)	34.4
Median follow-up (months)	15.08
Percentiles (95% CI) [1]	
25th	34.4 (3.4, 34.4)
50th	34.4 (7.4, 34.4)
75th	34.4 (NE, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	92.9 (59.1, 99.0)
Month 9	77.9 (45.9, 92.3)
Month 12	77.9 (45.9, 92.3)
Month 15	77.9 (45.9, 92.3)
Month 18	77.9 (45.9, 92.3)
Month 21	77.9 (45.9, 92.3)

Eligibility for SCT: Yes	
	All patients N=14
Month 24	77.9 (45.9, 92.3)
Month 27	77.9 (45.9, 92.3)
Month 30	77.9 (45.9, 92.3)
Month 33	77.9 (45.9, 92.3)
Month 36	0.0 (NE, NE)
Month 39	0.0 (NE, NE)
Month 42	0.0 (NE, NE)
Month 45	0.0 (NE, NE)
Month 48	0.0 (NE, NE)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170m
Overall survival (OS) by Eligibility for SCT
Full analysis set

Eligibility for SCT: No	**All patients N=50**
Events/Total (%)	26/50 (52.0)
Maximum follow-up (months)	49.3
Median follow-up (months)	15.66
Percentiles (95% CI) [1]	
25th	6.8 (4.1, 11.0)
50th	29.9 (9.0, 42.4)
75th	NE (29.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	90.0 (77.6, 95.7)
Month 6	82.0 (68.3, 90.2)
Month 9	64.0 (49.1, 75.6)
Month 12	62.0 (47.1, 73.8)
Month 15	59.7 (44.7, 71.8)
Month 18	57.4 (42.4, 69.8)
Month 21	57.4 (42.4, 69.8)

Eligibility for SCT: No	
	All patients N=50
Month 24	50.2 (34.2, 64.2)
Month 27	50.2 (34.2, 64.2)
Month 30	43.1 (24.6, 60.3)
Month 33	43.1 (24.6, 60.3)
Month 36	43.1 (24.6, 60.3)
Month 39	34.4 (15.0, 54.9)
Month 42	34.4 (15.0, 54.9)
Month 45	25.8 (8.1, 48.2)
Month 48	25.8 (8.1, 48.2)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170n
Overall survival (OS) by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: Low

	All patients N=20
Events/Total (%)	6/20 (30.0)
Maximum follow-up (months)	48.1
Median follow-up (months)	21.31
Percentiles (95% CI) [1]	
25th	29.9 (2.5, 36.8)
50th	36.8 (23.8, NE)
75th	NE (29.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	95.0 (69.5, 99.3)
Month 6	90.0 (65.6, 97.4)
Month 9	84.7 (59.7, 94.8)
Month 12	84.7 (59.7, 94.8)
Month 15	84.7 (59.7, 94.8)
Month 18	84.7 (59.7, 94.8)
Month 21	84.7 (59.7, 94.8)

Baseline bone marrow tumor burden: Low	
	All patients N=20
Month 24	75.3 (44.4, 90.5)
Month 27	75.3 (44.4, 90.5)
Month 30	60.2 (23.6, 83.7)
Month 33	60.2 (23.6, 83.7)
Month 36	60.2 (23.6, 83.7)
Month 39	40.2 (7.3, 72.7)
Month 42	40.2 (7.3, 72.7)
Month 45	40.2 (7.3, 72.7)
Month 48	40.2 (7.3, 72.7)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170n
Overall survival (OS) by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: High	**All patients N=44**
Events/Total (%)	24/44 (54.5)
Maximum follow-up (months)	49.3
Median follow-up (months)	13.55
Percentiles (95% CI) [1]	
25th	6.8 (3.1, 8.8)
50th	23.8 (7.4, 42.4)
75th	42.4 (34.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	90.9 (77.6, 96.5)
Month 6	81.8 (66.9, 90.5)
Month 9	59.1 (43.2, 71.9)
Month 12	56.8 (41.0, 69.9)
Month 15	54.1 (38.3, 67.5)
Month 18	51.1 (35.2, 65.0)
Month 21	51.1 (35.2, 65.0)

Baseline bone marrow tumor burden: High	
	All patients N=44
Month 24	45.4 (28.1, 61.3)
Month 27	45.4 (28.1, 61.3)
Month 30	45.4 (28.1, 61.3)
Month 33	45.4 (28.1, 61.3)
Month 36	30.3 (8.2, 56.6)
Month 39	30.3 (8.2, 56.6)
Month 42	30.3 (8.2, 56.6)
Month 45	15.1 (1.1, 45.4)
Month 48	15.1 (1.1, 45.4)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170o
Overall survival (OS) by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: Yes

	All patients N=5
Events/Total (%)	2/5 (40.0)
Maximum follow-up (months)	36.8
Median follow-up (months)	17.94
Percentiles (95% CI) [1]	
25th	36.8 (6.9, 36.8)
50th	36.8 (6.9, 36.8)
75th	36.8 (6.9, 36.8)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	80.0 (20.4, 96.9)
Month 12	80.0 (20.4, 96.9)
Month 15	80.0 (20.4, 96.9)
Month 18	80.0 (20.4, 96.9)
Month 21	80.0 (20.4, 96.9)

Baseline extramedullary disease presence: Yes	
	All patients N=5
Month 24	80.0 (20.4, 96.9)
Month 27	80.0 (20.4, 96.9)
Month 30	80.0 (20.4, 96.9)
Month 33	80.0 (20.4, 96.9)
Month 36	80.0 (20.4, 96.9)
Month 39	0.0 (NE, NE)
Month 42	0.0 (NE, NE)
Month 45	0.0 (NE, NE)
Month 48	0.0 (NE, NE)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170o
Overall survival (OS) by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: No

	All patients N=59
Events/Total (%)	28/59 (47.5)
Maximum follow-up (months)	49.3
Median follow-up (months)	15.05
Percentiles (95% CI) [1]	
25th	7.2 (4.1, 11.0)
50th	29.9 (14.8, NE)
75th	NE (34.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	91.5 (80.8, 96.4)
Month 6	83.1 (70.8, 90.5)
Month 9	65.9 (52.3, 76.5)
Month 12	64.2 (50.5, 75.0)
Month 15	62.1 (48.3, 73.2)
Month 18	59.9 (45.9, 71.3)
Month 21	59.9 (45.9, 71.3)

Baseline extramedullary disease presence: No	
	All patients N=59
Month 24	52.8 (37.4, 66.1)
Month 27	52.8 (37.4, 66.1)
Month 30	46.2 (28.3, 62.4)
Month 33	46.2 (28.3, 62.4)
Month 36	37.0 (16.8, 57.4)
Month 39	37.0 (16.8, 57.4)
Month 42	37.0 (16.8, 57.4)
Month 45	27.7 (9.0, 50.6)
Month 48	27.7 (9.0, 50.6)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170p
Overall survival (OS) by Down syndrome
Full analysis set

Down syndrome: Yes

	All patients N=4
Events/Total (%)	1/4 (25.0)
Maximum follow-up (months)	49.3
Median follow-up (months)	21.16
Percentiles (95% CI) [1]	
25th	NE (7.4, NE)
50th	NE (7.4, NE)
75th	NE (7.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	75.0 (12.8, 96.1)
Month 12	75.0 (12.8, 96.1)
Month 15	75.0 (12.8, 96.1)
Month 18	75.0 (12.8, 96.1)
Month 21	75.0 (12.8, 96.1)

Down syndrome: Yes	
	All patients N=4
Month 24	75.0 (12.8, 96.1)
Month 27	75.0 (12.8, 96.1)
Month 30	75.0 (12.8, 96.1)
Month 33	75.0 (12.8, 96.1)
Month 36	75.0 (12.8, 96.1)
Month 39	75.0 (12.8, 96.1)
Month 42	75.0 (12.8, 96.1)
Month 45	75.0 (12.8, 96.1)
Month 48	75.0 (12.8, 96.1)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170p
Overall survival (OS) by Down syndrome
Full analysis set

Down syndrome: No

	All patients N=60
Events/Total (%)	29/60 (48.3)
Maximum follow-up (months)	48.1
Median follow-up (months)	15.08
Percentiles (95% CI) [1]	
25th	7.1 (4.1, 14.8)
50th	29.9 (14.8, 42.4)
75th	42.4 (34.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	91.7 (81.1, 96.4)
Month 6	83.3 (71.2, 90.7)
Month 9	66.5 (53.0, 76.9)
Month 12	64.8 (51.3, 75.4)
Month 15	62.8 (49.1, 73.7)
Month 18	60.6 (46.8, 71.9)
Month 21	60.6 (46.8, 71.9)

Down syndrome: No	
	All patients N=60
Month 24	53.5 (38.1, 66.7)
Month 27	53.5 (38.1, 66.7)
Month 30	46.8 (28.7, 63.0)
Month 33	46.8 (28.7, 63.0)
Month 36	37.4 (17.0, 58.0)
Month 39	28.1 (9.1, 51.1)
Month 42	28.1 (9.1, 51.1)
Month 45	18.7 (3.7, 42.8)
Month 48	18.7 (3.7, 42.8)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170q
Overall survival (OS) by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: > Median	**All patients N=32**
Events/Total (%)	12/32 (37.5)
Maximum follow-up (months)	34.4
Median follow-up (months)	17.86
Percentiles (95% CI) [1]	
25th	7.4 (4.7, 29.9)
50th	29.9 (23.8, 34.4)
75th	34.4 (29.9, 34.4)
% Event-free probability estimates (95% CI) [2]	
Month 3	96.9 (79.8, 99.6)
Month 6	90.6 (73.7, 96.9)
Month 9	74.8 (55.8, 86.5)
Month 12	74.8 (55.8, 86.5)
Month 15	71.0 (51.5, 83.8)
Month 18	71.0 (51.5, 83.8)
Month 21	71.0 (51.5, 83.8)

Time since enrollment to CTL019 infusion: > Median	
	All patients N=32
Month 24	63.9 (41.2, 79.8)
Month 27	63.9 (41.2, 79.8)
Month 30	47.9 (17.1, 73.6)
Month 33	47.9 (17.1, 73.6)
Month 36	0.0 (NE, NE)
Month 39	0.0 (NE, NE)
Month 42	0.0 (NE, NE)
Month 45	0.0 (NE, NE)
Month 48	0.0 (NE, NE)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170q
Overall survival (OS) by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: <=Median	**All patients N=32**
Events/Total (%)	18/32 (56.3)
Maximum follow-up (months)	49.3
Median follow-up (months)	12.19
Percentiles (95% CI) [1]	
25th	6.9 (2.4, 9.0)
50th	23.8 (7.2, NE)
75th	NE (36.8, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	87.5 (70.0, 95.1)
Month 6	78.1 (59.5, 88.9)
Month 9	59.4 (40.5, 74.0)
Month 12	56.3 (37.6, 71.3)
Month 15	56.3 (37.6, 71.3)
Month 18	52.2 (33.5, 68.0)
Month 21	52.2 (33.5, 68.0)

Time since enrollment to CTL019 infusion: <=Median	**All patients N=32**
Month 24	45.7 (25.9, 63.5)
Month 27	45.7 (25.9, 63.5)
Month 30	45.7 (25.9, 63.5)
Month 33	45.7 (25.9, 63.5)
Month 36	45.7 (25.9, 63.5)
Month 39	36.6 (15.7, 57.8)
Month 42	36.6 (15.7, 57.8)
Month 45	27.4 (8.5, 50.7)
Month 48	27.4 (8.5, 50.7)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170r
Overall survival (OS) by Number of previous relapses
Full analysis set

Number of previous relapses: 0	**All patients N=7**
Events/Total (%)	2/7 (28.6)
Maximum follow-up (months)	29.7
Median follow-up (months)	20.93
Percentiles (95% CI) [1]	
25th	1.2 (0.4, NE)
50th	NE (0.4, NE)
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	71.4 (25.8, 92.0)
Month 6	71.4 (25.8, 92.0)
Month 9	71.4 (25.8, 92.0)
Month 12	71.4 (25.8, 92.0)
Month 15	71.4 (25.8, 92.0)
Month 18	71.4 (25.8, 92.0)
Month 21	71.4 (25.8, 92.0)

Number of previous relapses: 0	
	All patients N=7
Month 24	71.4 (25.8, 92.0)
Month 27	71.4 (25.8, 92.0)
Month 30	NE
Month 33	NE
Month 36	NE
Month 39	NE
Month 42	NE
Month 45	NE
Month 48	NE

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170r
Overall survival (OS) by Number of previous relapses
Full analysis set

Number of previous relapses: 1

	All patients N=20
Events/Total (%)	11/20 (55.0)
Maximum follow-up (months)	49.3
Median follow-up (months)	14.72
Percentiles (95% CI) [1]	
25th	7.1 (3.4, 15.1)
50th	23.8 (6.9, NE)
75th	36.8 (23.8, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	90.0 (65.6, 97.4)
Month 9	65.0 (40.3, 81.5)
Month 12	65.0 (40.3, 81.5)
Month 15	58.5 (33.5, 76.9)
Month 18	52.0 (27.4, 71.9)
Month 21	52.0 (27.4, 71.9)

Number of previous relapses: 1	
	All patients N=20
Month 24	41.6 (16.7, 65.1)
Month 27	41.6 (16.7, 65.1)
Month 30	41.6 (16.7, 65.1)
Month 33	41.6 (16.7, 65.1)
Month 36	41.6 (16.7, 65.1)
Month 39	20.8 (1.6, 55.1)
Month 42	20.8 (1.6, 55.1)
Month 45	20.8 (1.6, 55.1)
Month 48	20.8 (1.6, 55.1)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170r
Overall survival (OS) by Number of previous relapses
Full analysis set

Number of previous relapses: 2

	All patients N=21
Events/Total (%)	10/21 (47.6)
Maximum follow-up (months)	47.7
Median follow-up (months)	11.63
Percentiles (95% CI) [1]	
25th	7.2 (0.8, 11.0)
50th	34.4 (7.2, NE)
75th	NE (34.4, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	90.5 (67.0, 97.5)
Month 6	81.0 (56.9, 92.4)
Month 9	61.2 (37.1, 78.4)
Month 12	56.1 (32.5, 74.3)
Month 15	56.1 (32.5, 74.3)
Month 18	56.1 (32.5, 74.3)
Month 21	56.1 (32.5, 74.3)

Number of previous relapses: 2	
	All patients N=21
Month 24	56.1 (32.5, 74.3)
Month 27	56.1 (32.5, 74.3)
Month 30	56.1 (32.5, 74.3)
Month 33	56.1 (32.5, 74.3)
Month 36	28.1 (1.9, 66.4)
Month 39	28.1 (1.9, 66.4)
Month 42	28.1 (1.9, 66.4)
Month 45	28.1 (1.9, 66.4)
Month 48	NE

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 170r
Overall survival (OS) by Number of previous relapses
Full analysis set

Number of previous relapses: >=3

	All patients N=16
Events/Total (%)	7/16 (43.8)
Maximum follow-up (months)	48.1
Median follow-up (months)	19.66
Percentiles (95% CI) [1]	
25th	16.3 (2.4, 29.9)
50th	29.9 (8.8, NE)
75th	42.4 (23.8, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	93.8 (63.2, 99.1)
Month 6	87.5 (58.6, 96.7)
Month 9	75.0 (46.3, 89.8)
Month 12	75.0 (46.3, 89.8)
Month 15	75.0 (46.3, 89.8)
Month 18	75.0 (46.3, 89.8)
Month 21	75.0 (46.3, 89.8)

Number of previous relapses: >=3	
	All patients N=16
Month 24	60.0 (24.2, 83.2)
Month 27	60.0 (24.2, 83.2)
Month 30	40.0 (7.4, 72.4)
Month 33	40.0 (7.4, 72.4)
Month 36	40.0 (7.4, 72.4)
Month 39	40.0 (7.4, 72.4)
Month 42	40.0 (7.4, 72.4)
Month 45	20.0 (1.0, 56.8)
Month 48	20.0 (1.0, 56.8)

- Full analysis set (FAS) = All patients who received an infusion of CTL019
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171a
Overall survival (OS) by Age
Enrolled set

Age: <10 years

	All patients N=22
Events/Total (%)	11/22 (50.0)
Maximum follow-up (months)	50.2
Median follow-up (months)	19.04
Percentiles (95% CI) [1]	
25th	8.1 (2.1, 31.2)
50th	31.2 (8.0, 37.7)
75th	37.7 (31.2, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	95.0 (69.5, 99.3)
Month 6	90.0 (65.6, 97.4)
Month 9	70.0 (45.1, 85.3)
Month 12	60.0 (35.7, 77.6)
Month 15	60.0 (35.7, 77.6)
Month 18	60.0 (35.7, 77.6)
Month 21	60.0 (35.7, 77.6)

Age: <10 years	
	All patients N=22
Month 24	60.0 (35.7, 77.6)
Month 27	60.0 (35.7, 77.6)
Month 30	60.0 (35.7, 77.6)
Month 33	48.0 (20.5, 71.2)
Month 36	32.0 (6.8, 61.7)
Month 39	16.0 (1.0, 48.4)
Month 42	16.0 (1.0, 48.4)
Month 45	16.0 (1.0, 48.4)
Month 48	16.0 (1.0, 48.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171a
Overall survival (OS) by Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=39
Events/Total (%)	16/39 (41.0)
Maximum follow-up (months)	49.2
Median follow-up (months)	16.66
Percentiles (95% CI) [1]	
25th	8.6 (1.7, 24.8)
50th	25.9 (16.1, NE)
75th	43.2 (25.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	89.3 (73.8, 95.8)
Month 6	81.1 (64.5, 90.5)
Month 9	73.0 (55.7, 84.5)
Month 12	70.3 (52.8, 82.3)
Month 15	70.3 (52.8, 82.3)
Month 18	64.1 (46.1, 77.4)
Month 21	64.1 (46.1, 77.4)

Age: >=10 years to <18 years	
	All patients N=39
Month 24	64.1 (46.1, 77.4)
Month 27	46.7 (22.7, 67.6)
Month 30	46.7 (22.7, 67.6)
Month 33	46.7 (22.7, 67.6)
Month 36	46.7 (22.7, 67.6)
Month 39	46.7 (22.7, 67.6)
Month 42	46.7 (22.7, 67.6)
Month 45	23.4 (1.8, 59.0)
Month 48	23.4 (1.8, 59.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171a
Overall survival (OS) by Age
Enrolled set

Age: >=18	**All patients N=14**
Events/Total (%)	9/14 (64.3)
Maximum follow-up (months)	48.4
Median follow-up (months)	6.77
Percentiles (95% CI) [1]	
25th	3.4 (0.9, 9.3)
50th	9.3 (1.9, NE)
75th	NE (9.3, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	77.4 (44.9, 92.1)
Month 6	54.2 (25.0, 76.2)
Month 9	54.2 (25.0, 76.2)
Month 12	27.1 (6.8, 53.0)
Month 15	27.1 (6.8, 53.0)
Month 18	27.1 (6.8, 53.0)
Month 21	27.1 (6.8, 53.0)

Age: >=18	
	All patients N=14
Month 24	27.1 (6.8, 53.0)
Month 27	27.1 (6.8, 53.0)
Month 30	27.1 (6.8, 53.0)
Month 33	27.1 (6.8, 53.0)
Month 36	27.1 (6.8, 53.0)
Month 39	27.1 (6.8, 53.0)
Month 42	27.1 (6.8, 53.0)
Month 45	27.1 (6.8, 53.0)
Month 48	27.1 (6.8, 53.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171b
Overall survival (OS) by Gender
Enrolled set

Gender: Male

	All patients N=40
Events/Total (%)	17/40 (42.5)
Maximum follow-up (months)	50.2
Median follow-up (months)	16.76
Percentiles (95% CI) [1]	
25th	7.8 (1.5, 24.8)
50th	37.7 (9.7, NE)
75th	NE (37.7, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	83.6 (67.1, 92.3)
Month 6	78.1 (60.9, 88.4)
Month 9	69.7 (52.0, 82.0)
Month 12	64.1 (46.3, 77.4)
Month 15	64.1 (46.3, 77.4)
Month 18	64.1 (46.3, 77.4)
Month 21	64.1 (46.3, 77.4)

Gender: Male	
	All patients N=40
Month 24	64.1 (46.3, 77.4)
Month 27	52.5 (31.8, 69.5)
Month 30	52.5 (31.8, 69.5)
Month 33	52.5 (31.8, 69.5)
Month 36	52.5 (31.8, 69.5)
Month 39	39.4 (14.6, 63.7)
Month 42	39.4 (14.6, 63.7)
Month 45	26.2 (5.4, 54.2)
Month 48	26.2 (5.4, 54.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171b
Overall survival (OS) by Gender
Enrolled set

Gender: Female

	All patients N=35
Events/Total (%)	19/35 (54.3)
Maximum follow-up (months)	49.2
Median follow-up (months)	12.78
Percentiles (95% CI) [1]	
25th	8.0 (4.0, 10.0)
50th	16.2 (8.6, 35.6)
75th	35.6 (31.2, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	94.1 (78.5, 98.5)
Month 6	79.4 (61.6, 89.6)
Month 9	67.5 (49.1, 80.5)
Month 12	55.2 (37.0, 70.2)
Month 15	55.2 (37.0, 70.2)
Month 18	47.9 (29.9, 63.8)
Month 21	47.9 (29.9, 63.8)

Gender: Female	
	All patients N=35
Month 24	47.9 (29.9, 63.8)
Month 27	47.9 (29.9, 63.8)
Month 30	47.9 (29.9, 63.8)
Month 33	35.9 (13.9, 58.8)
Month 36	18.0 (1.5, 49.6)
Month 39	18.0 (1.5, 49.6)
Month 42	18.0 (1.5, 49.6)
Month 45	18.0 (1.5, 49.6)
Month 48	18.0 (1.5, 49.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171c
Overall survival (OS) by Race
Enrolled set

Race: White

	All patients N=60
Events/Total (%)	29/60 (48.3)
Maximum follow-up (months)	50.2
Median follow-up (months)	13.54
Percentiles (95% CI) [1]	
25th	7.8 (3.4, 10.0)
50th	25.9 (10.0, 43.2)
75th	43.2 (31.2, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	87.6 (75.7, 93.9)
Month 6	76.8 (63.5, 85.8)
Month 9	66.1 (52.1, 76.8)
Month 12	58.7 (44.7, 70.3)
Month 15	58.7 (44.7, 70.3)
Month 18	56.5 (42.4, 68.4)
Month 21	56.5 (42.4, 68.4)

Race: White	
	All patients N=60
Month 24	56.5 (42.4, 68.4)
Month 27	48.4 (32.4, 62.6)
Month 30	48.4 (32.4, 62.6)
Month 33	41.5 (23.5, 58.6)
Month 36	41.5 (23.5, 58.6)
Month 39	31.1 (11.6, 53.1)
Month 42	31.1 (11.6, 53.1)
Month 45	20.7 (4.4, 45.2)
Month 48	20.7 (4.4, 45.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171c
Overall survival (OS) by Race
Enrolled set

Race: Asian

	All patients N=6
Events/Total (%)	3/6 (50.0)
Maximum follow-up (months)	35.6
Median follow-up (months)	11.30
Percentiles (95% CI) [1]	
25th	9.7 (6.4, 35.6)
50th	35.6 (6.4, 35.6)
75th	35.6 (6.4, 35.6)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	80.0 (20.4, 96.9)
Month 12	60.0 (12.6, 88.2)
Month 15	60.0 (12.6, 88.2)
Month 18	60.0 (12.6, 88.2)
Month 21	60.0 (12.6, 88.2)

Race: Asian

	All patients N=6
Month 24	60.0 (12.6, 88.2)
Month 27	60.0 (12.6, 88.2)
Month 30	60.0 (12.6, 88.2)
Month 33	60.0 (12.6, 88.2)
Month 36	0.0 (NE, NE)
Month 39	0.0 (NE, NE)
Month 42	0.0 (NE, NE)
Month 45	0.0 (NE, NE)
Month 48	0.0 (NE, NE)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171c
Overall survival (OS) by Race
Enrolled set

Race: Other

	All patients N=9
Events/Total (%)	4/9 (44.4)
Maximum follow-up (months)	49.2
Median follow-up (months)	16.66
Percentiles (95% CI) [1]	
25th	9.3 (0.9, NE)
50th	NE (0.9, NE)
75th	NE (16.1, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	88.9 (43.3, 98.4)
Month 6	77.8 (36.5, 93.9)
Month 9	77.8 (36.5, 93.9)
Month 12	66.7 (28.2, 87.8)
Month 15	66.7 (28.2, 87.8)
Month 18	55.6 (20.4, 80.5)
Month 21	55.6 (20.4, 80.5)

Race: Other	
	All patients N=9
Month 24	55.6 (20.4, 80.5)
Month 27	55.6 (20.4, 80.5)
Month 30	55.6 (20.4, 80.5)
Month 33	55.6 (20.4, 80.5)
Month 36	55.6 (20.4, 80.5)
Month 39	55.6 (20.4, 80.5)
Month 42	55.6 (20.4, 80.5)
Month 45	55.6 (20.4, 80.5)
Month 48	55.6 (20.4, 80.5)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171d
Overall survival (OS) by Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino	**All patients N=30**
Events/Total (%)	8/30 (26.7)
Maximum follow-up (months)	25.9
Median follow-up (months)	16.28
Percentiles (95% CI) [1]	
25th	16.2 (5.9, 25.9)
50th	25.9 (NE, NE)
75th	25.9 (NE, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	93.1 (75.1, 98.2)
Month 6	89.4 (70.5, 96.5)
Month 9	85.7 (66.1, 94.4)
Month 12	78.2 (57.7, 89.6)
Month 15	78.2 (57.7, 89.6)
Month 18	73.3 (51.6, 86.4)
Month 21	73.3 (51.6, 86.4)

Ethnicity: Hispanic or Latino	
	All patients N=30
Month 24	73.3 (51.6, 86.4)
Month 27	0.0 (NE, NE)
Month 30	0.0 (NE, NE)
Month 33	0.0 (NE, NE)
Month 36	0.0 (NE, NE)
Month 39	0.0 (NE, NE)
Month 42	0.0 (NE, NE)
Month 45	0.0 (NE, NE)
Month 48	0.0 (NE, NE)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171d
Overall survival (OS) by Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=45
Events/Total (%)	28/45 (62.2)
Maximum follow-up (months)	50.2
Median follow-up (months)	9.72
Percentiles (95% CI) [1]	
25th	4.5 (1.9, 8.0)
50th	11.9 (7.8, 35.6)
75th	43.2 (31.2, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	86.0 (71.6, 93.5)
Month 6	72.1 (56.1, 83.1)
Month 9	58.0 (42.0, 71.1)
Month 12	48.4 (32.8, 62.3)
Month 15	48.4 (32.8, 62.3)
Month 18	45.8 (30.4, 59.9)
Month 21	45.8 (30.4, 59.9)

Ethnicity: Other	
	All patients N=45
Month 24	45.8 (30.4, 59.9)
Month 27	43.0 (27.8, 57.3)
Month 30	43.0 (27.8, 57.3)
Month 33	38.2 (22.5, 53.7)
Month 36	31.8 (15.6, 49.3)
Month 39	25.5 (10.1, 44.2)
Month 42	25.5 (10.1, 44.2)
Month 45	19.1 (5.7, 38.3)
Month 48	19.1 (5.7, 38.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171e
Overall survival (OS) by Response status at study entry
Enrolled set

Response status at study entry: Primary refractory	**All patients N=8**
Events/Total (%)	3/8 (37.5)
Maximum follow-up (months)	30.8
Median follow-up (months)	19.61
Percentiles (95% CI) [1]	
25th	1.7 (1.4, NE)
50th	NE (1.4, NE)
75th	NE (1.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	62.5 (22.9, 86.1)
Month 6	62.5 (22.9, 86.1)
Month 9	62.5 (22.9, 86.1)
Month 12	62.5 (22.9, 86.1)
Month 15	62.5 (22.9, 86.1)
Month 18	62.5 (22.9, 86.1)
Month 21	62.5 (22.9, 86.1)

Response status at study entry: Primary refractory	
	All patients N=8
Month 24	62.5 (22.9, 86.1)
Month 27	62.5 (22.9, 86.1)
Month 30	62.5 (22.9, 86.1)
Month 33	NE
Month 36	NE
Month 39	NE
Month 42	NE
Month 45	NE
Month 48	NE

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171e
Overall survival (OS) by Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease	**All patients N=67**
Events/Total (%)	33/67 (49.3)
Maximum follow-up (months)	50.2
Median follow-up (months)	13.47
Percentiles (95% CI) [1]	
25th	8.0 (4.0, 9.7)
50th	25.9 (10.0, 37.7)
75th	43.2 (35.6, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	92.1 (81.9, 96.6)
Month 6	80.7 (68.6, 88.6)
Month 9	69.4 (56.3, 79.3)
Month 12	59.5 (46.2, 70.5)
Month 15	59.5 (46.2, 70.5)
Month 18	55.6 (42.1, 67.1)
Month 21	55.6 (42.1, 67.1)

Response status at study entry: Relapsed disease	
	All patients N=67
Month 24	55.6 (42.1, 67.1)
Month 27	47.9 (32.7, 61.6)
Month 30	47.9 (32.7, 61.6)
Month 33	42.6 (26.2, 58.0)
Month 36	35.5 (17.9, 53.6)
Month 39	28.4 (11.4, 48.1)
Month 42	28.4 (11.4, 48.1)
Month 45	21.3 (6.4, 41.8)
Month 48	21.3 (6.4, 41.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171f
Overall survival (OS) by Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive	**All patients N=2**
Events/Total (%)	0/2 (0.0)
Maximum follow-up (months)	24.7
Median follow-up (months)	18.79
Percentiles (95% CI) [1]	
25th	NE
50th	NE
75th	NE
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	100 (100, 100)
Month 12	100 (100, 100)
Month 15	100 (100, 100)
Month 18	100 (100, 100)
Month 21	100 (100, 100)

Philadelphia chromosome/BCR-ABL: Positive	
	All patients N=2
Month 24	100 (100, 100)
Month 27	NE
Month 30	NE
Month 33	NE
Month 36	NE
Month 39	NE
Month 42	NE
Month 45	NE
Month 48	NE

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171f
Overall survival (OS) by Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative	**All patients N=73**
Events/Total (%)	36/73 (49.3)
Maximum follow-up (months)	50.2
Median follow-up (months)	13.60
Percentiles (95% CI) [1]	
25th	7.8 (3.5, 9.7)
50th	25.9 (10.0, 37.7)
75th	43.2 (35.6, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	88.3 (78.0, 94.0)
Month 6	78.0 (66.2, 86.1)
Month 9	67.7 (55.2, 77.4)
Month 12	58.7 (46.0, 69.3)
Month 15	58.7 (46.0, 69.3)
Month 18	55.3 (42.5, 66.3)
Month 21	55.3 (42.5, 66.3)

Philadelphia chromosome/BCR-ABL: Negative	
	All patients N=73
Month 24	55.3 (42.5, 66.3)
Month 27	48.7 (34.6, 61.4)
Month 30	48.7 (34.6, 61.4)
Month 33	43.3 (27.5, 58.1)
Month 36	36.1 (18.6, 53.9)
Month 39	28.9 (11.8, 48.5)
Month 42	28.9 (11.8, 48.5)
Month 45	21.6 (6.6, 42.2)
Month 48	21.6 (6.6, 42.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171g
Overall survival (OS) by MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3
Events/Total (%)	2/3 (66.7)
Maximum follow-up (months)	19.7
Median follow-up (months)	7.79
Percentiles (95% CI) [1]	
25th	1.9 (1.9, NE)
50th	7.8 (1.9, NE)
75th	NE (1.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	66.7 (5.4, 94.5)
Month 6	66.7 (5.4, 94.5)
Month 9	33.3 (0.9, 77.4)
Month 12	33.3 (0.9, 77.4)
Month 15	33.3 (0.9, 77.4)
Month 18	33.3 (0.9, 77.4)
Month 21	NE

Mixed-lineage leukemia rearrangement: Yes	
	All patients N=3
Month 24	NE
Month 27	NE
Month 30	NE
Month 33	NE
Month 36	NE
Month 39	NE
Month 42	NE
Month 45	NE
Month 48	NE

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171g
Overall survival (OS) by MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No	**All patients N=72**
Events/Total (%)	34/72 (47.2)
Maximum follow-up (months)	50.2
Median follow-up (months)	13.75
Percentiles (95% CI) [1]	
25th	8.0 (3.7, 10.0)
50th	31.2 (10.2, 43.2)
75th	43.2 (35.6, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	89.7 (79.5, 94.9)
Month 6	79.2 (67.4, 87.1)
Month 9	70.2 (57.7, 79.6)
Month 12	61.0 (48.3, 71.6)
Month 15	61.0 (48.3, 71.6)
Month 18	57.5 (44.6, 68.4)
Month 21	57.5 (44.6, 68.4)

Mixed-lineage leukemia rearrangement: No	
	All patients N=72
Month 24	57.5 (44.6, 68.4)
Month 27	50.7 (36.2, 63.5)
Month 30	50.7 (36.2, 63.5)
Month 33	45.1 (28.7, 60.1)
Month 36	37.5 (19.4, 55.7)
Month 39	30.0 (12.3, 50.2)
Month 42	30.0 (12.3, 50.2)
Month 45	22.5 (6.8, 43.7)
Month 48	22.5 (6.8, 43.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171h
Overall survival (OS) by Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=1
Events/Total (%)	1/1 (100.0)
Maximum follow-up (months)	24.8
Median follow-up (months)	24.84
Percentiles (95% CI) [1]	
25th	24.8 (NE, NE)
50th	24.8 (NE, NE)
75th	24.8 (NE, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	100 (100, 100)
Month 12	100 (100, 100)
Month 15	100 (100, 100)
Month 18	100 (100, 100)
Month 21	100 (100, 100)

Hypodiploidy: Yes

	All patients N=1
Month 24	100 (100, 100)
Month 27	0.0 (NE, NE)
Month 30	0.0 (NE, NE)
Month 33	0.0 (NE, NE)
Month 36	0.0 (NE, NE)
Month 39	0.0 (NE, NE)
Month 42	0.0 (NE, NE)
Month 45	0.0 (NE, NE)
Month 48	0.0 (NE, NE)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171h
Overall survival (OS) by Hypodiploidy
Enrolled set

Hypodiploidy: No	**All patients N=74**
Events/Total (%)	35/74 (47.3)
Maximum follow-up (months)	50.2
Median follow-up (months)	13.54
Percentiles (95% CI) [1]	
25th	7.8 (3.5, 9.7)
50th	31.2 (10.0, 43.2)
75th	43.2 (35.6, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	88.5 (78.3, 94.1)
Month 6	78.3 (66.7, 86.3)
Month 9	68.2 (55.8, 77.7)
Month 12	59.3 (46.7, 69.8)
Month 15	59.3 (46.7, 69.8)
Month 18	55.8 (43.2, 66.7)
Month 21	55.8 (43.2, 66.7)

Hypodiploidy: No	
	All patients N=74
Month 24	55.8 (43.2, 66.7)
Month 27	52.1 (38.3, 64.2)
Month 30	52.1 (38.3, 64.2)
Month 33	46.3 (30.1, 61.1)
Month 36	38.6 (20.2, 56.8)
Month 39	30.9 (12.7, 51.2)
Month 42	30.9 (12.7, 51.2)
Month 45	23.2 (7.1, 44.6)
Month 48	23.2 (7.1, 44.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171i
Overall survival (OS) by BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=4
Events/Total (%)	1/4 (25.0)
Maximum follow-up (months)	29.9
Median follow-up (months)	18.96
Percentiles (95% CI) [1]	
25th	16.2 (16.2, NE)
50th	NE (16.2, NE)
75th	NE (16.2, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	100 (100, 100)
Month 12	100 (100, 100)
Month 15	100 (100, 100)
Month 18	66.7 (5.4, 94.5)
Month 21	66.7 (5.4, 94.5)

BCR-ABL1-like: Yes

	All patients N=4
Month 24	66.7 (5.4, 94.5)
Month 27	66.7 (5.4, 94.5)
Month 30	NE
Month 33	NE
Month 36	NE
Month 39	NE
Month 42	NE
Month 45	NE
Month 48	NE

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171i
Overall survival (OS) by BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=71
Events/Total (%)	35/71 (49.3)
Maximum follow-up (months)	50.2
Median follow-up (months)	13.47
Percentiles (95% CI) [1]	
25th	7.8 (3.5, 9.7)
50th	25.9 (9.7, 37.7)
75th	43.2 (35.6, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	88.0 (77.4, 93.8)
Month 6	77.4 (65.3, 85.7)
Month 9	66.7 (54.0, 76.7)
Month 12	57.4 (44.6, 68.3)
Month 15	57.4 (44.6, 68.3)
Month 18	55.7 (42.8, 66.7)
Month 21	55.7 (42.8, 66.7)

BCR-ABL1-like: No

	All patients N=71
Month 24	55.7 (42.8, 66.7)
Month 27	48.6 (34.2, 61.6)
Month 30	48.6 (34.2, 61.6)
Month 33	43.2 (27.2, 58.3)
Month 36	36.0 (18.5, 53.9)
Month 39	28.8 (11.8, 48.5)
Month 42	28.8 (11.8, 48.5)
Month 45	21.6 (6.6, 42.2)
Month 48	21.6 (6.6, 42.2)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171j
Overall survival (OS) by Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22
Events/Total (%)	10/22 (45.5)
Maximum follow-up (months)	49.2
Median follow-up (months)	16.23
Percentiles (95% CI) [1]	
25th	8.0 (0.4, 35.6)
50th	35.6 (8.0, NE)
75th	43.2 (35.6, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	90.4 (66.8, 97.5)
Month 6	80.4 (55.7, 92.2)
Month 9	70.3 (45.5, 85.5)
Month 12	64.9 (40.0, 81.6)
Month 15	64.9 (40.0, 81.6)
Month 18	59.5 (34.9, 77.4)
Month 21	59.5 (34.9, 77.4)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22
Month 24	59.5 (34.9, 77.4)
Month 27	59.5 (34.9, 77.4)
Month 30	59.5 (34.9, 77.4)
Month 33	59.5 (34.9, 77.4)
Month 36	39.7 (9.1, 70.0)
Month 39	39.7 (9.1, 70.0)
Month 42	39.7 (9.1, 70.0)
Month 45	19.8 (1.2, 55.6)
Month 48	19.8 (1.2, 55.6)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171j
Overall survival (OS) by Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No	**All patients N=53**
Events/Total (%)	26/53 (49.1)
Maximum follow-up (months)	50.2
Median follow-up (months)	13.47
Percentiles (95% CI) [1]	
25th	7.8 (3.4, 9.7)
50th	24.8 (9.7, 37.7)
75th	37.7 (31.2, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	88.0 (75.2, 94.4)
Month 6	78.0 (63.8, 87.2)
Month 9	68.0 (53.2, 79.0)
Month 12	58.0 (43.2, 70.2)
Month 15	58.0 (43.2, 70.2)
Month 18	55.5 (40.5, 68.1)
Month 21	55.5 (40.5, 68.1)

Complex karyotypes II (>=5 unrelated abnormalities) : No	
	All patients N=53
Month 24	55.5 (40.5, 68.1)
Month 27	43.7 (25.4, 60.7)
Month 30	43.7 (25.4, 60.7)
Month 33	35.0 (15.4, 55.4)
Month 36	35.0 (15.4, 55.4)
Month 39	23.3 (5.5, 48.1)
Month 42	23.3 (5.5, 48.1)
Month 45	23.3 (5.5, 48.1)
Month 48	23.3 (5.5, 48.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171k
Overall survival (OS) by Region
Enrolled set

Region: US	**All patients N=75**
Events/Total (%)	36/75 (48.0)
Maximum follow-up (months)	50.2
Median follow-up (months)	13.60
Percentiles (95% CI) [1]	
25th	7.8 (3.7, 9.7)
50th	25.9 (10.2, 37.7)
75th	43.2 (35.6, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	88.7 (78.6, 94.2)
Month 6	78.7 (67.1, 86.5)
Month 9	68.6 (56.3, 78.1)
Month 12	59.9 (47.4, 70.3)
Month 15	59.9 (47.4, 70.3)
Month 18	56.5 (43.9, 67.3)
Month 21	56.5 (43.9, 67.3)

Region: US	
	All patients N=75
Month 24	56.5 (43.9, 67.3)
Month 27	49.8 (35.7, 62.4)
Month 30	49.8 (35.7, 62.4)
Month 33	44.3 (28.3, 59.1)
Month 36	36.9 (19.1, 54.8)
Month 39	29.5 (12.1, 49.4)
Month 42	29.5 (12.1, 49.4)
Month 45	22.1 (6.7, 43.0)
Month 48	22.1 (6.7, 43.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171l
Overall survival (OS) by Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes	**All patients N=32**
Events/Total (%)	17/32 (53.1)
Maximum follow-up (months)	49.2
Median follow-up (months)	16.15
Percentiles (95% CI) [1]	
25th	7.8 (1.7, 16.2)
50th	25.9 (9.3, 43.2)
75th	43.2 (31.2, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	87.2 (69.4, 95.0)
Month 6	80.7 (62.0, 90.8)
Month 9	71.0 (51.7, 83.8)
Month 12	64.6 (45.2, 78.6)
Month 15	64.6 (45.2, 78.6)
Month 18	57.0 (37.5, 72.4)
Month 21	57.0 (37.5, 72.4)

Prior SCT therapy: Yes	
	All patients N=32
Month 24	57.0 (37.5, 72.4)
Month 27	48.8 (26.8, 67.7)
Month 30	48.8 (26.8, 67.7)
Month 33	39.1 (16.3, 61.4)
Month 36	39.1 (16.3, 61.4)
Month 39	29.3 (8.8, 53.8)
Month 42	29.3 (8.8, 53.8)
Month 45	19.5 (3.6, 44.8)
Month 48	19.5 (3.6, 44.8)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171l
Overall survival (OS) by Prior SCT therapy
Enrolled set

Prior SCT therapy: No	**All patients N=43**
Events/Total (%)	19/43 (44.2)
Maximum follow-up (months)	50.2
Median follow-up (months)	11.89
Percentiles (95% CI) [1]	
25th	7.8 (3.7, 9.7)
50th	35.6 (8.6, NE)
75th	NE (35.6, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	89.9 (75.2, 96.1)
Month 6	77.0 (60.5, 87.3)
Month 9	66.7 (49.6, 79.1)
Month 12	56.0 (39.0, 69.9)
Month 15	56.0 (39.0, 69.9)
Month 18	56.0 (39.0, 69.9)
Month 21	56.0 (39.0, 69.9)

Prior SCT therapy: No	
	All patients N=43
Month 24	56.0 (39.0, 69.9)
Month 27	50.9 (32.9, 66.4)
Month 30	50.9 (32.9, 66.4)
Month 33	50.9 (32.9, 66.4)
Month 36	25.4 (2.1, 61.7)
Month 39	25.4 (2.1, 61.7)
Month 42	25.4 (2.1, 61.7)
Month 45	25.4 (2.1, 61.7)
Month 48	25.4 (2.1, 61.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171m
Overall survival (OS) by Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes	**All patients N=18**
Events/Total (%)	5/18 (27.8)
Maximum follow-up (months)	35.6
Median follow-up (months)	14.78
Percentiles (95% CI) [1]	
25th	10.2 (1.5, 35.6)
50th	35.6 (8.2, 35.6)
75th	35.6 (NE, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	93.3 (61.3, 99.0)
Month 6	86.7 (56.4, 96.5)
Month 9	80.0 (50.0, 93.1)
Month 12	72.7 (42.5, 88.8)
Month 15	72.7 (42.5, 88.8)
Month 18	72.7 (42.5, 88.8)
Month 21	72.7 (42.5, 88.8)

Eligibility for SCT: Yes	
	All patients N=18
Month 24	72.7 (42.5, 88.8)
Month 27	72.7 (42.5, 88.8)
Month 30	72.7 (42.5, 88.8)
Month 33	72.7 (42.5, 88.8)
Month 36	0.0 (NE, NE)
Month 39	0.0 (NE, NE)
Month 42	0.0 (NE, NE)
Month 45	0.0 (NE, NE)
Month 48	0.0 (NE, NE)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171m
Overall survival (OS) by Eligibility for SCT
Enrolled set

Eligibility for SCT: No	**All patients N=57**
Events/Total (%)	31/57 (54.4)
Maximum follow-up (months)	50.2
Median follow-up (months)	13.60
Percentiles (95% CI) [1]	
25th	6.4 (3.4, 9.3)
50th	24.8 (9.3, 43.2)
75th	43.2 (31.2, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	87.3 (75.2, 93.8)
Month 6	76.4 (62.9, 85.6)
Month 9	65.5 (51.4, 76.4)
Month 12	56.4 (42.3, 68.3)
Month 15	56.4 (42.3, 68.3)
Month 18	52.2 (38.2, 64.5)
Month 21	52.2 (38.2, 64.5)

Eligibility for SCT: No	
	All patients N=57
Month 24	52.2 (38.2, 64.5)
Month 27	45.2 (30.2, 59.0)
Month 30	45.2 (30.2, 59.0)
Month 33	38.7 (22.0, 55.2)
Month 36	38.7 (22.0, 55.2)
Month 39	31.0 (13.6, 50.3)
Month 42	31.0 (13.6, 50.3)
Month 45	23.2 (7.4, 44.1)
Month 48	23.2 (7.4, 44.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171n
Overall survival (OS) by Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low	**All patients N=22**
Events/Total (%)	8/22 (36.4)
Maximum follow-up (months)	49.2
Median follow-up (months)	22.18
Percentiles (95% CI) [1]	
25th	24.8 (1.7, 37.7)
50th	37.7 (24.8, NE)
75th	NE (31.2, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	95.5 (71.9, 99.3)
Month 6	86.4 (63.4, 95.4)
Month 9	77.0 (53.2, 89.7)
Month 12	77.0 (53.2, 89.7)
Month 15	77.0 (53.2, 89.7)
Month 18	77.0 (53.2, 89.7)
Month 21	77.0 (53.2, 89.7)

Baseline bone marrow tumor burden: Low	
	All patients N=22
Month 24	77.0 (53.2, 89.7)
Month 27	68.4 (40.8, 85.2)
Month 30	68.4 (40.8, 85.2)
Month 33	54.8 (22.5, 78.4)
Month 36	54.8 (22.5, 78.4)
Month 39	36.5 (7.2, 68.0)
Month 42	36.5 (7.2, 68.0)
Month 45	36.5 (7.2, 68.0)
Month 48	36.5 (7.2, 68.0)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171n
Overall survival (OS) by Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High	**All patients N=53**
Events/Total (%)	28/53 (52.8)
Maximum follow-up (months)	50.2
Median follow-up (months)	10.22
Percentiles (95% CI) [1]	
25th	7.8 (1.9, 9.3)
50th	16.1 (8.2, 43.2)
75th	43.2 (25.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	85.6 (72.1, 92.9)
Month 6	75.2 (60.4, 85.1)
Month 9	64.7 (49.5, 76.4)
Month 12	52.2 (37.3, 65.1)
Month 15	52.2 (37.3, 65.1)
Month 18	47.3 (32.6, 60.7)
Month 21	47.3 (32.6, 60.7)

Baseline bone marrow tumor burden: High	
	All patients N=53
Month 24	47.3 (32.6, 60.7)
Month 27	41.4 (24.9, 57.1)
Month 30	41.4 (24.9, 57.1)
Month 33	41.4 (24.9, 57.1)
Month 36	27.6 (7.6, 52.6)
Month 39	27.6 (7.6, 52.6)
Month 42	27.6 (7.6, 52.6)
Month 45	13.8 (1.1, 42.3)
Month 48	13.8 (1.1, 42.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171o
Overall survival (OS) by Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=7
Events/Total (%)	2/7 (28.6)
Maximum follow-up (months)	37.7
Median follow-up (months)	19.09
Percentiles (95% CI) [1]	
25th	37.7 (7.8, 37.7)
50th	37.7 (7.8, 37.7)
75th	37.7 (7.8, 37.7)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	80.0 (20.4, 96.9)
Month 12	80.0 (20.4, 96.9)
Month 15	80.0 (20.4, 96.9)
Month 18	80.0 (20.4, 96.9)
Month 21	80.0 (20.4, 96.9)

Baseline extramedullary disease presence: Yes	
	All patients N=7
Month 24	80.0 (20.4, 96.9)
Month 27	80.0 (20.4, 96.9)
Month 30	80.0 (20.4, 96.9)
Month 33	80.0 (20.4, 96.9)
Month 36	80.0 (20.4, 96.9)
Month 39	0.0 (NE, NE)
Month 42	0.0 (NE, NE)
Month 45	0.0 (NE, NE)
Month 48	0.0 (NE, NE)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171o
Overall survival (OS) by Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=68
Events/Total (%)	34/68 (50.0)
Maximum follow-up (months)	50.2
Median follow-up (months)	13.54
Percentiles (95% CI) [1]	
25th	7.8 (3.5, 9.7)
50th	25.9 (10.0, 43.2)
75th	NE (35.6, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	87.8 (77.0, 93.7)
Month 6	77.0 (64.8, 85.4)
Month 9	67.7 (54.9, 77.6)
Month 12	58.3 (45.3, 69.2)
Month 15	58.3 (45.3, 69.2)
Month 18	54.6 (41.5, 65.9)
Month 21	54.6 (41.5, 65.9)

Baseline extramedullary disease presence: No	
	All patients N=68
Month 24	54.6 (41.5, 65.9)
Month 27	47.7 (33.3, 60.8)
Month 30	47.7 (33.3, 60.8)
Month 33	41.7 (25.4, 57.3)
Month 36	33.4 (15.3, 52.7)
Month 39	33.4 (15.3, 52.7)
Month 42	33.4 (15.3, 52.7)
Month 45	25.0 (8.2, 46.4)
Month 48	25.0 (8.2, 46.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171p
Overall survival (OS) by Down syndrome
Enrolled set

Down syndrome: Yes	**All patients N=4**
Events/Total (%)	1/4 (25.0)
Maximum follow-up (months)	50.2
Median follow-up (months)	22.24
Percentiles (95% CI) [1]	
25th	NE (8.6, NE)
50th	NE (8.6, NE)
75th	NE (8.6, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	100 (100, 100)
Month 9	75.0 (12.8, 96.1)
Month 12	75.0 (12.8, 96.1)
Month 15	75.0 (12.8, 96.1)
Month 18	75.0 (12.8, 96.1)
Month 21	75.0 (12.8, 96.1)

Down syndrome: Yes	
	All patients N=4
Month 24	75.0 (12.8, 96.1)
Month 27	75.0 (12.8, 96.1)
Month 30	75.0 (12.8, 96.1)
Month 33	75.0 (12.8, 96.1)
Month 36	75.0 (12.8, 96.1)
Month 39	75.0 (12.8, 96.1)
Month 42	75.0 (12.8, 96.1)
Month 45	75.0 (12.8, 96.1)
Month 48	75.0 (12.8, 96.1)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171p
Overall survival (OS) by Down syndrome
Enrolled set

Down syndrome: No

	All patients N=71
Events/Total (%)	35/71 (49.3)
Maximum follow-up (months)	49.2
Median follow-up (months)	13.47
Percentiles (95% CI) [1]	
25th	7.8 (3.5, 9.7)
50th	25.9 (10.0, 37.7)
75th	43.2 (35.6, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	88.0 (77.4, 93.8)
Month 6	77.4 (65.3, 85.7)
Month 9	68.3 (55.6, 78.0)
Month 12	59.0 (46.1, 69.7)
Month 15	59.0 (46.1, 69.7)
Month 18	55.3 (42.4, 66.5)
Month 21	55.3 (42.4, 66.5)

Down syndrome: No	
	All patients N=71
Month 24	55.3 (42.4, 66.5)
Month 27	48.3 (33.9, 61.4)
Month 30	48.3 (33.9, 61.4)
Month 33	42.3 (25.8, 57.9)
Month 36	33.8 (15.5, 53.2)
Month 39	25.4 (8.3, 46.9)
Month 42	25.4 (8.3, 46.9)
Month 45	16.9 (3.4, 39.3)
Month 48	16.9 (3.4, 39.3)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171q
Overall survival (OS) by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median	**All patients N=32**
Events/Total (%)	12/32 (37.5)
Maximum follow-up (months)	35.6
Median follow-up (months)	19.40
Percentiles (95% CI) [1]	
25th	10.2 (6.4, 31.2)
50th	31.2 (25.9, 35.6)
75th	35.6 (31.2, 35.6)
% Event-free probability estimates (95% CI) [2]	
Month 3	96.9 (79.8, 99.6)
Month 6	93.8 (77.3, 98.4)
Month 9	81.1 (62.7, 91.1)
Month 12	74.6 (55.6, 86.4)
Month 15	74.6 (55.6, 86.4)
Month 18	71.1 (51.7, 83.8)
Month 21	71.1 (51.7, 83.8)

Time since enrollment to CTL019 infusion: > Median	
	All patients N=32
Month 24	71.1 (51.7, 83.8)
Month 27	62.2 (37.4, 79.5)
Month 30	62.2 (37.4, 79.5)
Month 33	46.6 (16.2, 72.6)
Month 36	0.0 (NE, NE)
Month 39	0.0 (NE, NE)
Month 42	0.0 (NE, NE)
Month 45	0.0 (NE, NE)
Month 48	0.0 (NE, NE)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171q
Overall survival (OS) by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median	**All patients N=32**
Events/Total (%)	18/32 (56.3)
Maximum follow-up (months)	50.2
Median follow-up (months)	13.24
Percentiles (95% CI) [1]	
25th	7.8 (3.4, 10.0)
50th	24.8 (8.2, NE)
75th	NE (37.7, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	93.8 (77.3, 98.4)
Month 6	78.1 (59.5, 88.9)
Month 9	68.8 (49.7, 81.8)
Month 12	56.3 (37.6, 71.3)
Month 15	56.3 (37.6, 71.3)
Month 18	52.2 (33.5, 68.0)
Month 21	52.2 (33.5, 68.0)

Time since enrollment to CTL019 infusion: <=Median	**All patients N=32**
Month 24	52.2 (33.5, 68.0)
Month 27	45.7 (25.9, 63.5)
Month 30	45.7 (25.9, 63.5)
Month 33	45.7 (25.9, 63.5)
Month 36	45.7 (25.9, 63.5)
Month 39	36.6 (15.7, 57.8)
Month 42	36.6 (15.7, 57.8)
Month 45	27.4 (8.5, 50.7)
Month 48	27.4 (8.5, 50.7)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171q
Overall survival (OS) by Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=11
Events/Total (%)	6/11 (54.5)
Maximum follow-up (months)	3.7
Median follow-up (months)	1.02
Percentiles (95% CI) [1]	
25th	1.4 (0.4, 1.5)
50th	1.5 (0.4, 3.7)
75th	1.7 (1.4, 3.7)
% Event-free probability estimates (95% CI) [2]	
Month 3	19.0 (0.9, 55.9)
Month 6	0.0 (NE, NE)
Month 9	0.0 (NE, NE)
Month 12	0.0 (NE, NE)
Month 15	0.0 (NE, NE)
Month 18	0.0 (NE, NE)
Month 21	0.0 (NE, NE)

Time since enrollment to CTL019 infusion: Missing	
	All patients N=11
Month 24	0.0 (NE, NE)
Month 27	0.0 (NE, NE)
Month 30	0.0 (NE, NE)
Month 33	0.0 (NE, NE)
Month 36	0.0 (NE, NE)
Month 39	0.0 (NE, NE)
Month 42	0.0 (NE, NE)
Month 45	0.0 (NE, NE)
Month 48	0.0 (NE, NE)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171r
Overall survival (OS) by Number of previous relapses
Enrolled set

Number of previous relapses: 0	**All patients N=8**
Events/Total (%)	3/8 (37.5)
Maximum follow-up (months)	30.8
Median follow-up (months)	19.61
Percentiles (95% CI) [1]	
25th	1.7 (1.4, NE)
50th	NE (1.4, NE)
75th	NE (1.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	62.5 (22.9, 86.1)
Month 6	62.5 (22.9, 86.1)
Month 9	62.5 (22.9, 86.1)
Month 12	62.5 (22.9, 86.1)
Month 15	62.5 (22.9, 86.1)
Month 18	62.5 (22.9, 86.1)
Month 21	62.5 (22.9, 86.1)

Number of previous relapses: 0	
	All patients N=8
Month 24	62.5 (22.9, 86.1)
Month 27	62.5 (22.9, 86.1)
Month 30	62.5 (22.9, 86.1)
Month 33	NE
Month 36	NE
Month 39	NE
Month 42	NE
Month 45	NE
Month 48	NE

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171r
Overall survival (OS) by Number of previous relapses
Enrolled set

Number of previous relapses: 1	**All patients N=23**
Events/Total (%)	12/23 (52.2)
Maximum follow-up (months)	50.2
Median follow-up (months)	13.90
Percentiles (95% CI) [1]	
25th	8.6 (3.7, 16.1)
50th	24.8 (8.6, NE)
75th	37.7 (24.8, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	100 (100, 100)
Month 6	85.7 (62.0, 95.2)
Month 9	71.4 (47.2, 86.0)
Month 12	61.9 (38.1, 78.8)
Month 15	61.9 (38.1, 78.8)
Month 18	50.6 (27.5, 69.9)
Month 21	50.6 (27.5, 69.9)

Number of previous relapses: 1	
	All patients N=23
Month 24	50.6 (27.5, 69.9)
Month 27	40.5 (16.7, 63.4)
Month 30	40.5 (16.7, 63.4)
Month 33	40.5 (16.7, 63.4)
Month 36	40.5 (16.7, 63.4)
Month 39	20.3 (1.6, 53.9)
Month 42	20.3 (1.6, 53.9)
Month 45	20.3 (1.6, 53.9)
Month 48	20.3 (1.6, 53.9)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171r
Overall survival (OS) by Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=24
Events/Total (%)	11/24 (45.8)
Maximum follow-up (months)	48.4
Median follow-up (months)	11.06
Percentiles (95% CI) [1]	
25th	8.0 (0.4, 11.9)
50th	35.6 (8.0, NE)
75th	NE (35.6, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	91.1 (68.8, 97.7)
Month 6	77.4 (54.0, 89.9)
Month 9	68.3 (44.8, 83.5)
Month 12	53.7 (30.9, 71.9)
Month 15	53.7 (30.9, 71.9)
Month 18	53.7 (30.9, 71.9)
Month 21	53.7 (30.9, 71.9)

Number of previous relapses: 2	
	All patients N=24
Month 24	53.7 (30.9, 71.9)
Month 27	53.7 (30.9, 71.9)
Month 30	53.7 (30.9, 71.9)
Month 33	53.7 (30.9, 71.9)
Month 36	26.8 (2.0, 64.4)
Month 39	26.8 (2.0, 64.4)
Month 42	26.8 (2.0, 64.4)
Month 45	26.8 (2.0, 64.4)
Month 48	26.8 (2.0, 64.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 171r
Overall survival (OS) by Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=20
Events/Total (%)	10/20 (50.0)
Maximum follow-up (months)	49.2
Median follow-up (months)	19.98
Percentiles (95% CI) [1]	
25th	6.4 (0.9, 25.9)
50th	31.2 (6.4, NE)
75th	43.2 (25.9, NE)
% Event-free probability estimates (95% CI) [2]	
Month 3	84.4 (59.1, 94.7)
Month 6	79.2 (53.5, 91.6)
Month 9	68.6 (43.0, 84.5)
Month 12	63.3 (38.1, 80.6)
Month 15	63.3 (38.1, 80.6)
Month 18	63.3 (38.1, 80.6)
Month 21	63.3 (38.1, 80.6)

Number of previous relapses: >=3	
	All patients N=20
Month 24	63.3 (38.1, 80.6)
Month 27	50.7 (21.4, 74.1)
Month 30	50.7 (21.4, 74.1)
Month 33	33.8 (7.0, 64.3)
Month 36	33.8 (7.0, 64.3)
Month 39	33.8 (7.0, 64.3)
Month 42	33.8 (7.0, 64.3)
Month 45	16.9 (1.0, 50.4)
Month 48	16.9 (1.0, 50.4)

-Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
[1] Percentiles with 95% CIs are calculated from PROC LIFETEST output using method of Brookmeyer and Crowley (1982).
[2] % Event-free probability estimate is the estimated probability that a patient will remain event-free up to the specified time point. % Event-free probability estimates are obtained from the Kaplan-Meier survival estimates; Greenwood formula is used for CIs of KM estimates.

Table 172a
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Full analysis set

Age: <10 years

	All patients N=20				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	11 (55.0)		11 (55.0)		
CRi	3 (15.0)		3 (15.0)		
No response	4 (20.0)		4 (20.0)		
Unknown (UNK)	2 (10.0)		2 (10.0)		
Overall Remission Rate (ORR: CR+CRi)	14 (70.0)	(45.7,88.1)	14 (70.0)	(45.7,88.1)	0.0368

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172a
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Full analysis set

Age: >=10 years to <18 years

	All patients N=34				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	18 (52.9)		18 (52.9)		
CRi	7 (20.6)		7 (20.6)		
No response	5 (14.7)		5 (14.7)		
Unknown (UNK)	4 (11.8)		4 (11.8)		
Overall Remission Rate (ORR: CR+CRi)	25 (73.5)	(55.6,87.1)	25 (73.5)	(55.6,87.1)	0.0030

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172a
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Full analysis set

Age: >=18

	All patients N=10				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	5 (50.0)		5 (50.0)		
CRi	1 (10.0)		1 (10.0)		
No response	4 (40.0)		4 (40.0)		
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	6 (60.0)	(26.2,87.8)	6 (60.0)	(26.2,87.8)	0.2635

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172b
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Gender
Full analysis set

Gender: Male

	All patients N=30				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	18 (60.0)		18 (60.0)		
CRi	5 (16.7)		5 (16.7)		
No response	5 (16.7)		5 (16.7)		
Unknown (UNK)	2 (6.7)		2 (6.7)		
Overall Remission Rate (ORR: CR+CRi)	23 (76.7)	(57.7,90.1)	23 (76.7)	(57.7,90.1)	0.0017

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172b
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Gender
Full analysis set

Gender: Female

	All patients N=34				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	16 (47.1)		16 (47.1)		
CRi	6 (17.6)		6 (17.6)		
No response	8 (23.5)		8 (23.5)		
Unknown (UNK)	4 (11.8)		4 (11.8)		
Overall Remission Rate (ORR: CR+CRi)	22 (64.7)	(46.5,80.3)	22 (64.7)	(46.5,80.3)	0.0432

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172c
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Full analysis set

Race: White

	All patients N=52				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	27 (51.9)		27 (51.9)		
CRi	9 (17.3)		9 (17.3)		
No response	10 (19.2)		10 (19.2)		
Unknown (UNK)	6 (11.5)		6 (11.5)		
Overall Remission Rate (ORR: CR+CRi)	36 (69.2)	(54.9,81.3)	36 (69.2)	(54.9,81.3)	0.0028

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172c
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Full analysis set

Race: Asian

	All patients N=5				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	3 (60.0)		3 (60.0)		
CRi					
No response	2 (40.0)		2 (40.0)		
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	3 (60.0)	(14.7,94.7)	3 (60.0)	(14.7,94.7)	0.3274

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172c
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Full analysis set

Race: Other

	All patients N=7				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	4 (57.1)		4 (57.1)		
CRi	2 (28.6)		2 (28.6)		
No response	1 (14.3)		1 (14.3)		
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	6 (85.7)	(42.1,99.6)	6 (85.7)	(42.1,99.6)	0.0294

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172d
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Ethnicity
Full analysis set

Ethnicity: Hispanic or Latino

	All patients N=25				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	16 (64.0)		16 (64.0)		
CRi	7 (28.0)		7 (28.0)		
No response	2 (8.0)		2 (8.0)		
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	23 (92.0)	(74.0,99.0)	23 (92.0)	(74.0,99.0)	<.0001

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172d
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Ethnicity
Full analysis set

Ethnicity: Other

	All patients N=39				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	18 (46.2)		18 (46.2)		
CRi	4 (10.3)		4 (10.3)		
No response	11 (28.2)		11 (28.2)		
Unknown (UNK)	6 (15.4)		6 (15.4)		
Overall Remission Rate (ORR: CR+CRi)	22 (56.4)	(39.6,72.2)	22 (56.4)	(39.6,72.2)	0.2117

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172e
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Response status at study entry
Full analysis set

Response status at study entry: Primary refractory

	All patients N=7				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	3 (42.9)		3 (42.9)		
CRi	1 (14.3)		1 (14.3)		
No response	1 (14.3)		1 (14.3)		
Unknown (UNK)	2 (28.6)		2 (28.6)		
Overall Remission Rate (ORR: CR+CRi)	4 (57.1)	(18.4,90.1)	4 (57.1)	(18.4,90.1)	0.3527

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172e
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Response status at study entry
Full analysis set

Response status at study entry: Relapsed disease

	All patients N=57				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	31 (54.4)		31 (54.4)		
CRi	10 (17.5)		10 (17.5)		
No response	12 (21.1)		12 (21.1)		
Unknown (UNK)	4 (7.0)		4 (7.0)		
Overall Remission Rate (ORR: CR+CRi)	41 (71.9)	(58.5,83.0)	41 (71.9)	(58.5,83.0)	0.0005

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172f
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	2 (100)		2 (100)		
CRi					
No response					
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	2 (100)	(0.0,84.2)	2 (100)	(15.8, 100)	0.0786

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172f
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Full analysis set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	32 (51.6)		32 (51.6)		
CRi	11 (17.7)		11 (17.7)		
No response	13 (21.0)		13 (21.0)		
Unknown (UNK)	6 (9.7)		6 (9.7)		
Overall Remission Rate (ORR: CR+CRi)	43 (69.4)	(56.3,80.4)	43 (69.4)	(56.3,80.4)	0.0012

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172g
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	1 (33.3)		1 (33.3)		
CRi					
No response	1 (33.3)		1 (33.3)		
Unknown (UNK)	1 (33.3)		1 (33.3)		
Overall Remission Rate (ORR: CR+CRi)	1 (33.3)	(0.8,90.6)	1 (33.3)	(0.8,90.6)	0.2819

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172g
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by MLL rearrangement
Full analysis set

Mixed-lineage leukemia rearrangement: No

	All patients N=61				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	33 (54.1)		33 (54.1)		
CRi	11 (18.0)		11 (18.0)		
No response	12 (19.7)		12 (19.7)		
Unknown (UNK)	5 (8.2)		5 (8.2)		
Overall Remission Rate (ORR: CR+CRi)	44 (72.1)	(59.2,82.9)	44 (72.1)	(59.2,82.9)	0.0003

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172h
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Hypodiploidy
Full analysis set

Hypodiploidy: Yes

	All patients N=1				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR					
CRi					
No response					
Unknown (UNK)	1 (100)		1 (100)		
Overall Remission Rate (ORR: CR+CRi)		(0.0,97.5)		(2.5, 100)	0.1587

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172h
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Hypodiploidy
Full analysis set

Hypodiploidy: No

	All patients N=63				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	34 (54.0)		34 (54.0)		
CRi	11 (17.5)		11 (17.5)		
No response	13 (20.6)		13 (20.6)		
Unknown (UNK)	5 (7.9)		5 (7.9)		
Overall Remission Rate (ORR: CR+CRi)	45 (71.4)	(58.7,82.1)	45 (71.4)	(58.7,82.1)	0.0003

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172i
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: Yes

	All patients N=4				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	4 (100)		4 (100)		
CRi					
No response					
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	4 (100)	(0.0,60.2)	4 (100)	(39.8, 100)	0.0228

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172i
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by BCR-ABL1-like
Full analysis set

BCR-ABL1-like: No

	All patients N=60				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	30 (50.0)		30 (50.0)		
CRi	11 (18.3)		11 (18.3)		
No response	13 (21.7)		13 (21.7)		
Unknown (UNK)	6 (10.0)		6 (10.0)		
Overall Remission Rate (ORR: CR+CRi)	41 (68.3)	(55.0,79.7)	41 (68.3)	(55.0,79.7)	0.0023

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172j
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	13 (68.4)		13 (68.4)		
CRi	4 (21.1)		4 (21.1)		
No response	1 (5.3)		1 (5.3)		
Unknown (UNK)	1 (5.3)		1 (5.3)		
Overall Remission Rate (ORR: CR+CRi)	17 (89.5)	(66.9,98.7)	17 (89.5)	(66.9,98.7)	0.0003

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172j
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Complex Karyotypes
Full analysis set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	21 (46.7)		21 (46.7)		
CRi	7 (15.6)		7 (15.6)		
No response	12 (26.7)		12 (26.7)		
Unknown (UNK)	5 (11.1)		5 (11.1)		
Overall Remission Rate (ORR: CR+CRi)	28 (62.2)	(46.5,76.2)	28 (62.2)	(46.5,76.2)	0.0505

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172k
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Region
Full analysis set

Region: US

	All patients N=64				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	34 (53.1)		34 (53.1)		
CRi	11 (17.2)		11 (17.2)		
No response	13 (20.3)		13 (20.3)		
Unknown (UNK)	6 (9.4)		6 (9.4)		
Overall Remission Rate (ORR: CR+CRi)	45 (70.3)	(57.6,81.1)	45 (70.3)	(57.6,81.1)	0.0006

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172l
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Prior SCT therapy
Full analysis set

Prior SCT therapy: Yes

	All patients N=28				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	13 (46.4)		13 (46.4)		
CRi	6 (21.4)		6 (21.4)		
No response	7 (25.0)		7 (25.0)		
Unknown (UNK)	2 (7.1)		2 (7.1)		
Overall Remission Rate (ORR: CR+CRi)	19 (67.9)	(47.6,84.1)	19 (67.9)	(47.6,84.1)	0.0294

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172l
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Prior SCT therapy
Full analysis set

Prior SCT therapy: No

	All patients N=36				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	21 (58.3)		21 (58.3)		
CRi	5 (13.9)		5 (13.9)		
No response	6 (16.7)		6 (16.7)		
Unknown (UNK)	4 (11.1)		4 (11.1)		
Overall Remission Rate (ORR: CR+CRi)	26 (72.2)	(54.8,85.8)	26 (72.2)	(54.8,85.8)	0.0038

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172m
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Eligibility for SCT
Full analysis set

Eligibility for SCT: Yes

	All patients N=14				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	8 (57.1)		8 (57.1)		
CRi	4 (28.6)		4 (28.6)		
No response	2 (14.3)		2 (14.3)		
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	12 (85.7)	(57.2,98.2)	12 (85.7)	(57.2,98.2)	0.0038

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172m
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Eligibility for SCT
Full analysis set

Eligibility for SCT: No

	All patients N=50				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	26 (52.0)		26 (52.0)		
CRi	7 (14.0)		7 (14.0)		
No response	11 (22.0)		11 (22.0)		
Unknown (UNK)	6 (12.0)		6 (12.0)		
Overall Remission Rate (ORR: CR+CRi)	33 (66.0)	(51.2,78.8)	33 (66.0)	(51.2,78.8)	0.0118

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172n
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: Low

	All patients N=20				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	14 (70.0)		14 (70.0)		
CRi	2 (10.0)		2 (10.0)		
No response	2 (10.0)		2 (10.0)		
Unknown (UNK)	2 (10.0)		2 (10.0)		
Overall Remission Rate (ORR: CR+CRi)	16 (80.0)	(56.3,94.3)	16 (80.0)	(56.3,94.3)	0.0036

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172n
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Full analysis set

Baseline bone marrow tumor burden: High

	All patients N=44				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	20 (45.5)		20 (45.5)		
CRi	9 (20.5)		9 (20.5)		
No response	11 (25.0)		11 (25.0)		
Unknown (UNK)	4 (9.1)		4 (9.1)		
Overall Remission Rate (ORR: CR+CRi)	29 (65.9)	(50.1,79.5)	29 (65.9)	(50.1,79.5)	0.0174

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172o
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: Yes

	All patients N=5				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	4 (80.0)		4 (80.0)		
CRi	1 (20.0)		1 (20.0)		
No response					
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	5 (100)	(0.0,52.2)	5 (100)	(47.8, 100)	0.0127

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172o
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Full analysis set

Baseline extramedullary disease presence: No

	All patients N=59				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	30 (50.8)		30 (50.8)		
CRi	10 (16.9)		10 (16.9)		
No response	13 (22.0)		13 (22.0)		
Unknown (UNK)	6 (10.2)		6 (10.2)		
Overall Remission Rate (ORR: CR+CRi)	40 (67.8)	(54.4,79.4)	40 (67.8)	(54.4,79.4)	0.0031

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172p
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Down syndrome
Full analysis set

Down syndrome: Yes

	All patients N=4				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	2 (50.0)		2 (50.0)		
CRi	1 (25.0)		1 (25.0)		
No response					
Unknown (UNK)	1 (25.0)		1 (25.0)		
Overall Remission Rate (ORR: CR+CRi)	3 (75.0)	(19.4,99.4)	3 (75.0)	(19.4,99.4)	0.1587

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172p
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Down syndrome
Full analysis set

Down syndrome: No

	All patients N=60				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	32 (53.3)		32 (53.3)		
CRi	10 (16.7)		10 (16.7)		
No response	13 (21.7)		13 (21.7)		
Unknown (UNK)	5 (8.3)		5 (8.3)		
Overall Remission Rate (ORR: CR+CRi)	42 (70.0)	(56.8,81.2)	42 (70.0)	(56.8,81.2)	0.0010

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172q
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	16 (50.0)		16 (50.0)		
CRi	7 (21.9)		7 (21.9)		
No response	6 (18.8)		6 (18.8)		
Unknown (UNK)	3 (9.4)		3 (9.4)		
Overall Remission Rate (ORR: CR+CRi)	23 (71.9)	(53.3,86.3)	23 (71.9)	(53.3,86.3)	0.0067

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172q
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Full analysis set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	18 (56.3)		18 (56.3)		
CRi	4 (12.5)		4 (12.5)		
No response	7 (21.9)		7 (21.9)		
Unknown (UNK)	3 (9.4)		3 (9.4)		
Overall Remission Rate (ORR: CR+CRi)	22 (68.8)	(50.0,83.9)	22 (68.8)	(50.0,83.9)	0.0169

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172r
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 0

	All patients N=7				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	3 (42.9)		3 (42.9)		
CRi	1 (14.3)		1 (14.3)		
No response	1 (14.3)		1 (14.3)		
Unknown (UNK)	2 (28.6)		2 (28.6)		
Overall Remission Rate (ORR: CR+CRi)	4 (57.1)	(18.4,90.1)	4 (57.1)	(18.4,90.1)	0.3527

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172r
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 1

	All patients N=20				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	9 (45.0)		9 (45.0)		
CRi	6 (30.0)		6 (30.0)		
No response	3 (15.0)		3 (15.0)		
Unknown (UNK)	2 (10.0)		2 (10.0)		
Overall Remission Rate (ORR: CR+CRi)	15 (75.0)	(50.9,91.3)	15 (75.0)	(50.9,91.3)	0.0127

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172r
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: 2

	All patients N=21				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	13 (61.9)		13 (61.9)		
CRi	1 (4.8)		1 (4.8)		
No response	5 (23.8)		5 (23.8)		
Unknown (UNK)	2 (9.5)		2 (9.5)		
Overall Remission Rate (ORR: CR+CRi)	14 (66.7)	(43.0,85.4)	14 (66.7)	(43.0,85.4)	0.0633

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 172r
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Full analysis set

Number of previous relapses: >=3

	All patients N=16				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	9 (56.3)		9 (56.3)		
CRi	3 (18.8)		3 (18.8)		
No response	4 (25.0)		4 (25.0)		
Unknown (UNK)					
Overall Remission Rate (ORR: CR+CRi)	12 (75.0)	(47.6,92.7)	12 (75.0)	(47.6,92.7)	0.0228

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173a
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Enrollment set

Age: <10 years

	All patients N=22				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	11 (50.0)		11 (50.0)		
CRi	3 (13.6)		3 (13.6)		
No response	4 (18.2)		4 (18.2)		
Unknown (UNK)	4 (18.2)		4 (18.2)		
Overall Remission Rate (ORR: CR+CRi)	14 (63.6)	(40.7,82.8)	14 (63.6)	(40.7,82.8)	0.1004

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173a
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Enrollment set

Age: >=10 years to <18 years

	All patients N=39				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	18 (46.2)		18 (46.2)		
CRi	7 (17.9)		7 (17.9)		
No response	5 (12.8)		5 (12.8)		
Unknown (UNK)	9 (23.1)		9 (23.1)		
Overall Remission Rate (ORR: CR+CRi)	25 (64.1)	(47.2,78.8)	25 (64.1)	(47.2,78.8)	0.0391

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173a
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Age
Enrollment set

Age: >=18

	All patients N=14				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	5 (35.7)		5 (35.7)		
CRi	1 (7.1)		1 (7.1)		
No response	4 (28.6)		4 (28.6)		
Unknown (UNK)	4 (28.6)		4 (28.6)		
Overall Remission Rate (ORR: CR+CRi)	6 (42.9)	(17.7,71.1)	6 (42.9)	(17.7,71.1)	0.2965

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173b
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Gender
Enrollment set

Gender: Male

	All patients N=40				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	18 (45.0)		18 (45.0)		
CRi	5 (12.5)		5 (12.5)		
No response	5 (12.5)		5 (12.5)		
Unknown (UNK)	12 (30.0)		12 (30.0)		
Overall Remission Rate (ORR: CR+CRi)	23 (57.5)	(40.9,73.0)	23 (57.5)	(40.9,73.0)	0.1714

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173b
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Gender
Enrollment set

Gender: Female

	All patients N=35				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	16 (45.7)		16 (45.7)		
CRi	6 (17.1)		6 (17.1)		
No response	8 (22.9)		8 (22.9)		
Unknown (UNK)	5 (14.3)		5 (14.3)		
Overall Remission Rate (ORR: CR+CRi)	22 (62.9)	(44.9,78.5)	22 (62.9)	(44.9,78.5)	0.0641

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173c
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Enrollment set

Race: White

	All patients N=60				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	27 (45.0)		27 (45.0)		
CRi	9 (15.0)		9 (15.0)		
No response	10 (16.7)		10 (16.7)		
Unknown (UNK)	14 (23.3)		14 (23.3)		
Overall Remission Rate (ORR: CR+CRi)	36 (60.0)	(46.5,72.4)	36 (60.0)	(46.5,72.4)	0.0607

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173c
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Enrollment set

Race: Asian

	All patients N=6				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	3 (50.0)		3 (50.0)		
CRi	0		0		
No response	2 (33.3)		2 (33.3)		
Unknown (UNK)	1 (16.7)		1 (16.7)		
Overall Remission Rate (ORR: CR+CRi)	3 (50.0)	(11.8,88.2)	3 (50.0)	(11.8,88.2)	0.5000

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173c
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Race
Enrollment set

Race: Other

	All patients N=9				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	4 (44.4)		4 (44.4)		
CRi	2 (22.2)		2 (22.2)		
No response	1 (11.1)		1 (11.1)		
Unknown (UNK)	2 (22.2)		2 (22.2)		
Overall Remission Rate (ORR: CR+CRi)	6 (66.7)	(29.9,92.5)	6 (66.7)	(29.9,92.5)	0.1587

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173d
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Ethnicity
Enrollment set

Ethnicity: Hispanic or Latino

	All patients N=30				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	16 (53.3)		16 (53.3)		
CRi	7 (23.3)		7 (23.3)		
No response	2 (6.7)		2 (6.7)		
Unknown (UNK)	5 (16.7)		5 (16.7)		
Overall Remission Rate (ORR: CR+CRi)	23 (76.7)	(57.7,90.1)	23 (76.7)	(57.7,90.1)	0.0017

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173d
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Ethnicity
Enrollment set

Ethnicity: Other

	All patients N=45				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	18 (40.0)		18 (40.0)		
CRi	4 (8.9)		4 (8.9)		
No response	11 (24.4)		11 (24.4)		
Unknown (UNK)	12 (26.7)		12 (26.7)		
Overall Remission Rate (ORR: CR+CRi)	22 (48.9)	(33.7,64.2)	22 (48.9)	(33.7,64.2)	0.4407

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173e
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Response status at study entry
Enrollment set

Response status at study entry: Primary refractory

	All patients N=8				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	3 (37.5)		3 (37.5)		
CRi	1 (12.5)		1 (12.5)		
No response	1 (12.5)		1 (12.5)		
Unknown (UNK)	3 (37.5)		3 (37.5)		
Overall Remission Rate (ORR: CR+CRi)	4 (50.0)	(15.7,84.3)	4 (50.0)	(15.7,84.3)	0.5000

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173e
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Response status at study entry
Enrollment set

Response status at study entry: Relapsed disease

	All patients N=67				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	31 (46.3)		31 (46.3)		
CRi	10 (14.9)		10 (14.9)		
No response	12 (17.9)		12 (17.9)		
Unknown (UNK)	14 (20.9)		14 (20.9)		
Overall Remission Rate (ORR: CR+CRi)	41 (61.2)	(48.5,72.9)	41 (61.2)	(48.5,72.9)	0.0334

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173f
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Enrollment set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	2 (100)		2 (100)		
CRi	0		0		
No response	0		0		
Unknown (UNK)	0		0		
Overall Remission Rate (ORR: CR+CRi)	2 (100)	(0.0,84.2)	2 (100)	(0.0,84.2)	0.0786

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173f
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Philadelphia chromosome/BCR-ABL
Enrollment set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	32 (43.8)		32 (43.8)		
CRi	11 (15.1)		11 (15.1)		
No response	13 (17.8)		13 (17.8)		
Unknown (UNK)	17 (23.3)		17 (23.3)		
Overall Remission Rate (ORR: CR+CRi)	43 (58.9)	(46.8,70.3)	43 (58.9)	(46.8,70.3)	0.0641

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173g
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by MLL rearrangement
Enrollment set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	1 (33.3)		1 (33.3)		
CRi	0		0		
No response	1 (33.3)		1 (33.3)		
Unknown (UNK)	1 (33.3)		1 (33.3)		
Overall Remission Rate (ORR: CR+CRi)	1 (33.3)	(0.8,90.6)	1 (33.3)	(0.8,90.6)	0.2819

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173g
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by MLL rearrangement
Enrollment set

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	33 (45.8)		33 (45.8)		
CRi	11 (15.3)		11 (15.3)		
No response	12 (16.7)		12 (16.7)		
Unknown (UNK)	16 (22.2)		16 (22.2)		
Overall Remission Rate (ORR: CR+CRi)	44 (61.1)	(48.9,72.4)	44 (61.1)	(48.9,72.4)	0.0297

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173h
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Hypodiploidy
Enrollment set

Hypodiploidy: Yes

	All patients N=1				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	0		0		
CRi	0		0		
No response	0		0		
Unknown (UNK)	1 (100)		1 (100)		
Overall Remission Rate (ORR: CR+CRi)	0	(0.0,97.5)	0	(0.0,97.5)	0.1587

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173h
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Hypodiploidy
Enrollment set

Hypodiploidy: No

	All patients N=74				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	34 (45.9)		34 (45.9)		
CRi	11 (14.9)		11 (14.9)		
No response	13 (17.6)		13 (17.6)		
Unknown (UNK)	16 (21.6)		16 (21.6)		
Overall Remission Rate (ORR: CR+CRi)	45 (60.8)	(48.8,72.0)	45 (60.8)	(48.8,72.0)	0.0314

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173i
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by BCR-ABL1-like Enrollment set

BCR-ABL1-like: Yes

	All patients N=4				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	4 (100)		4 (100)		
CRi	0		0		
No response	0		0		
Unknown (UNK)	0		0		
Overall Remission Rate (ORR: CR+CRi)	4 (100)	(0.0,60.2)	4 (100)	(0.0,60.2)	0.0228

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173i
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by BCR-ABL1-like Enrollment set

BCR-ABL1-like: No

	All patients N=71				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	30 (42.3)		30 (42.3)		
CRi	11 (15.5)		11 (15.5)		
No response	13 (18.3)		13 (18.3)		
Unknown (UNK)	17 (23.9)		17 (23.9)		
Overall Remission Rate (ORR: CR+CRi)	41 (57.7)	(45.4,69.4)	41 (57.7)	(45.4,69.4)	0.0959

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173j
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Complex Karyotypes
Enrollment set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	13 (59.1)		13 (59.1)		
CRi	4 (18.2)		4 (18.2)		
No response	1 (4.5)		1 (4.5)		
Unknown (UNK)	4 (18.2)		4 (18.2)		
Overall Remission Rate (ORR: CR+CRi)	17 (77.3)	(54.6,92.2)	17 (77.3)	(54.6,92.2)	0.0053

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173j
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Complex Karyotypes
Enrollment set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	21 (39.6)		21 (39.6)		
CRi	7 (13.2)		7 (13.2)		
No response	12 (22.6)		12 (22.6)		
Unknown (UNK)	13 (24.5)		13 (24.5)		
Overall Remission Rate (ORR: CR+CRi)	28 (52.8)	(38.6,66.7)	28 (52.8)	(38.6,66.7)	0.3401

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173k
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Region
Enrollment set

Region: US

	All patients N=75				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	34 (45.3)		34 (45.3)		
CRi	11 (14.7)		11 (14.7)		
No response	13 (17.3)		13 (17.3)		
Unknown (UNK)	17 (22.7)		17 (22.7)		
Overall Remission Rate (ORR: CR+CRi)	45 (60.0)	(48.0,71.1)	45 (60.0)	(48.0,71.1)	0.0416

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173l
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Prior SCT therapy
Enrollment set

Prior SCT therapy: Yes

	All patients N=32				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	13 (40.6)		13 (40.6)		
CRi	6 (18.8)		6 (18.8)		
No response	7 (21.9)		7 (21.9)		
Unknown (UNK)	6 (18.8)		6 (18.8)		
Overall Remission Rate (ORR: CR+CRi)	19 (59.4)	(40.6,76.3)	19 (59.4)	(40.6,76.3)	0.1444

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 17.3.1
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Prior SCT therapy
Enrollment set

Prior SCT therapy: No

	All patients N=43				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	21 (48.8)		21 (48.8)		
CRi	5 (11.6)		5 (11.6)		
No response	6 (14.0)		6 (14.0)		
Unknown (UNK)	11 (25.6)		11 (25.6)		
Overall Remission Rate (ORR: CR+CRi)	26 (60.5)	(44.4,75.0)	26 (60.5)	(44.4,75.0)	0.0850

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173m
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Eligibility for SCT
Enrollment set

Eligibility for SCT: Yes

	All patients N=18				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	8 (44.4)		8 (44.4)		
CRi	4 (22.2)		4 (22.2)		
No response	2 (11.1)		2 (11.1)		
Unknown (UNK)	4 (22.2)		4 (22.2)		
Overall Remission Rate (ORR: CR+CRi)	12 (66.7)	(41.0,86.7)	12 (66.7)	(41.0,86.7)	0.0786

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173m
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Eligibility for SCT
Enrollment set

Eligibility for SCT: No

	All patients N=57				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	26 (45.6)		26 (45.6)		
CRi	7 (12.3)		7 (12.3)		
No response	11 (19.3)		11 (19.3)		
Unknown (UNK)	13 (22.8)		13 (22.8)		
Overall Remission Rate (ORR: CR+CRi)	33 (57.9)	(44.1,70.9)	33 (57.9)	(44.1,70.9)	0.1166

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173n
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Enrollment set

Baseline bone marrow tumor burden: Low

	All patients N=22				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	14 (63.6)		14 (63.6)		
CRi	2 (9.1)		2 (9.1)		
No response	2 (9.1)		2 (9.1)		
Unknown (UNK)	4 (18.2)		4 (18.2)		
Overall Remission Rate (ORR: CR+CRi)	16 (72.7)	(49.8,89.3)	16 (72.7)	(49.8,89.3)	0.0165

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173n
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline bone marrow tumor burden
Enrollment set

Baseline bone marrow tumor burden: High

	All patients N=53				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	20 (37.7)		20 (37.7)		
CRi	9 (17.0)		9 (17.0)		
No response	11 (20.8)		11 (20.8)		
Unknown (UNK)	13 (24.5)		13 (24.5)		
Overall Remission Rate (ORR: CR+CRi)	29 (54.7)	(40.4,68.4)	29 (54.7)	(40.4,68.4)	0.2461

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173o
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Enrollment set

Baseline extramedullary disease presence: Yes

	All patients N=7				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	4 (57.1)		4 (57.1)		
CRi	1 (14.3)		1 (14.3)		
No response	0		0		
Unknown (UNK)	2 (28.6)		2 (28.6)		
Overall Remission Rate (ORR: CR+CRi)	5 (71.4)	(29.0,96.3)	5 (71.4)	(29.0,96.3)	0.1284

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173o
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Baseline extramedullary disease presence
Enrollment set

Baseline extramedullary disease presence: No

	All patients N=68				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	30 (44.1)		30 (44.1)		
CRi	10 (14.7)		10 (14.7)		
No response	13 (19.1)		13 (19.1)		
Unknown (UNK)	15 (22.1)		15 (22.1)		
Overall Remission Rate (ORR: CR+CRi)	40 (58.8)	(46.2,70.6)	40 (58.8)	(46.2,70.6)	0.0728

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173p
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Down syndrome
Enrollment set

Down syndrome: Yes

	All patients N=4				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	2 (50.0)		2 (50.0)		
CRi	1 (25.0)		1 (25.0)		
No response	0		0		
Unknown (UNK)	1 (25.0)		1 (25.0)		
Overall Remission Rate (ORR: CR+CRi)	3 (75.0)	(19.4,99.4)	3 (75.0)	(19.4,99.4)	0.1587

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173p
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Down syndrome
Enrollment set

Down syndrome: No

	All patients N=71				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	32 (45.1)		32 (45.1)		
CRi	10 (14.1)		10 (14.1)		
No response	13 (18.3)		13 (18.3)		
Unknown (UNK)	16 (22.5)		16 (22.5)		
Overall Remission Rate (ORR: CR+CRi)	42 (59.2)	(46.8,70.7)	42 (59.2)	(46.8,70.7)	0.0614

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173q
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Enrollment set

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	16 (50.0)		16 (50.0)		
CRi	7 (21.9)		7 (21.9)		
No response	6 (18.8)		6 (18.8)		
Unknown (UNK)	3 (9.4)		3 (9.4)		
Overall Remission Rate (ORR: CR+CRi)	23 (71.9)	(53.3,86.3)	23 (71.9)	(53.3,86.3)	0.0067

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173q
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Enrollment set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	18 (56.3)		18 (56.3)		
CRi	4 (12.5)		4 (12.5)		
No response	7 (21.9)		7 (21.9)		
Unknown (UNK)	3 (9.4)		3 (9.4)		
Overall Remission Rate (ORR: CR+CRi)	22 (68.8)	(50.0,83.9)	22 (68.8)	(50.0,83.9)	0.0169

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173q
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Time since enrollment to CTL019 infusion
Enrollment set

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	0		0		
CRi	0		0		
No response	0		0		
Unknown (UNK)	11 (100)		11 (100)		
Overall Remission Rate (ORR: CR+CRi)	0	(0.0,28.5)	0	(0.0,28.5)	0.0005

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173r
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Enrollment set

Number of previous relapses: 0

	All patients N=8				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	3 (37.5)		3 (37.5)		
CRi	1 (12.5)		1 (12.5)		
No response	1 (12.5)		1 (12.5)		
Unknown (UNK)	3 (37.5)		3 (37.5)		
Overall Remission Rate (ORR: CR+CRi)	4 (50.0)	(15.7,84.3)	4 (50.0)	(15.7,84.3)	0.5000

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173r
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Enrollment set

Number of previous relapses: 1

	All patients N=23				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	9 (39.1)		9 (39.1)		
CRi	6 (26.1)		6 (26.1)		
No response	3 (13.0)		3 (13.0)		
Unknown (UNK)	5 (21.7)		5 (21.7)		
Overall Remission Rate (ORR: CR+CRi)	15 (65.2)	(42.7,83.6)	15 (65.2)	(42.7,83.6)	0.0722

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173r
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Enrollment set

Number of previous relapses: 2

	All patients N=24				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	13 (54.2)		13 (54.2)		
CRi	1 (4.2)		1 (4.2)		
No response	5 (20.8)		5 (20.8)		
Unknown (UNK)	5 (20.8)		5 (20.8)		
Overall Remission Rate (ORR: CR+CRi)	14 (58.3)	(36.6,77.9)	14 (58.3)	(36.6,77.9)	0.2071

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 173r
Best overall response (BOR) and overall remission rate (ORR) within 3 months post CTL019 infusion by local investigator assessment and IRC assessment by Number of previous relapses
Enrollment set

Number of previous relapses: >=3

	All patients N=20				
	Local assessment		IRC assessment		
	n (%)	95% CI	n (%)	95% CI	p-value
Best overall response (BOR)					
CR	9 (45.0)		9 (45.0)		
CRi	3 (15.0)		3 (15.0)		
No response	4 (20.0)		4 (20.0)		
Unknown (UNK)	4 (20.0)		4 (20.0)		
Overall Remission Rate (ORR: CR+CRi)	12 (60.0)	(36.1,80.9)	12 (60.0)	(36.1,80.9)	0.1855

- CR=Complete remission; CRi=Complete remission with incomplete blood count recovery
- The 95% exact Clopper-Pearson CIs are displayed.
- No formal significance testing was conducted as the endpoint was met at the interim analysis. Nominal p-value is presented.

Table 174a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: <10 years

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (95.0)	1 (5.0)	4 (20.0)	2 (10.0)	12 (60.0)
Blood and lymphatic system disorders					
-Total	11 (55.0)	2 (10.0)	0	8 (40.0)	1 (5.0)
Anaemia	6 (30.0)	2 (10.0)	0	4 (20.0)	0
Febrile neutropenia	6 (30.0)	0	0	6 (30.0)	0
Coagulopathy	1 (5.0)	1 (5.0)	0	0	0
Disseminated intravascular coagulation	1 (5.0)	0	0	1 (5.0)	0
Thrombocytopenia	1 (5.0)	0	0	0	1 (5.0)
Cardiac disorders					
-Total	8 (40.0)	5 (25.0)	3 (15.0)	0	0
Sinus tachycardia	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Tachycardia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Atrioventricular block second degree	1 (5.0)	1 (5.0)	0	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (5.0)	0	1 (5.0)	0	0
Cardiac dysfunction	1 (5.0)	1 (5.0)	0	0	0
Palpitations	1 (5.0)	1 (5.0)	0	0	0
Pericardial effusion	1 (5.0)	0	1 (5.0)	0	0
Ear and labyrinth disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Ear pain	1 (5.0)	1 (5.0)	0	0	0
Eye disorders					
-Total	4 (20.0)	4 (20.0)	0	0	0
Conjunctival haemorrhage	2 (10.0)	2 (10.0)	0	0	0
Periorbital oedema	2 (10.0)	2 (10.0)	0	0	0
Photophobia	1 (5.0)	1 (5.0)	0	0	0
Retinal haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Gastrointestinal disorders					
-Total	12 (60.0)	4 (20.0)	3 (15.0)	5 (25.0)	0
Nausea	8 (40.0)	3 (15.0)	3 (15.0)	2 (10.0)	0
Vomiting	7 (35.0)	5 (25.0)	2 (10.0)	0	0
Diarrhoea	6 (30.0)	4 (20.0)	2 (10.0)	0	0
Abdominal pain	4 (20.0)	3 (15.0)	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	3 (15.0)	3 (15.0)	0	0	0
Pancreatitis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Abdominal distension	1 (5.0)	0	1 (5.0)	0	0
Abdominal tenderness	1 (5.0)	1 (5.0)	0	0	0
Ascites	1 (5.0)	0	0	1 (5.0)	0
Dysphagia	1 (5.0)	0	0	1 (5.0)	0
Ileus	1 (5.0)	0	0	1 (5.0)	0
Tooth socket haemorrhage	1 (5.0)	1 (5.0)	0	0	0
General disorders and administration site conditions					
-Total	8 (40.0)	2 (10.0)	3 (15.0)	3 (15.0)	0
Pyrexia	4 (20.0)	0	2 (10.0)	2 (10.0)	0
Fatigue	3 (15.0)	3 (15.0)	0	0	0
Catheter site pain	2 (10.0)	0	2 (10.0)	0	0
Oedema peripheral	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Chills	1 (5.0)	1 (5.0)	0	0	0
Face oedema	1 (5.0)	0	0	1 (5.0)	0
Generalised oedema	1 (5.0)	0	1 (5.0)	0	0
Localised oedema	1 (5.0)	0	0	1 (5.0)	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mucosal haemorrhage	1 (5.0)	0	1 (5.0)	0	0
Multiple organ dysfunction syndrome	1 (5.0)	0	0	1 (5.0)	0
Hepatobiliary disorders					
-Total	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Hepatosplenomegaly	1 (5.0)	1 (5.0)	0	0	0
Hyperbilirubinaemia	1 (5.0)	0	0	1 (5.0)	0
Immune system disorders					
-Total	19 (95.0)	1 (5.0)	12 (60.0)	3 (15.0)	3 (15.0)
Cytokine release syndrome	16 (80.0)	2 (10.0)	8 (40.0)	3 (15.0)	3 (15.0)
Hypogammaglobulinaemia	8 (40.0)	1 (5.0)	6 (30.0)	1 (5.0)	0
Haemophagocytic lymphohistiocytosis	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	10 (50.0)	2 (10.0)	4 (20.0)	3 (15.0)	1 (5.0)
Clostridium difficile infection	3 (15.0)	0	3 (15.0)	0	0
Rhinovirus infection	3 (15.0)	3 (15.0)	0	0	0
Clostridium difficile colitis	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Catheter site infection	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis	1 (5.0)	0	1 (5.0)	0	0
Oral candidiasis	1 (5.0)	1 (5.0)	0	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (5.0)	0	0	1 (5.0)	0
Septic embolus	1 (5.0)	0	0	0	1 (5.0)
Staphylococcal infection	1 (5.0)	1 (5.0)	0	0	0
Viral infection	1 (5.0)	0	1 (5.0)	0	0
Viral upper respiratory tract infection	1 (5.0)	0	1 (5.0)	0	0
Vulvovaginal candidiasis	1 (5.0)	1 (5.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	5 (25.0)	3 (15.0)	2 (10.0)	0	0
Procedural pain	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Infusion related reaction	1 (5.0)	0	1 (5.0)	0	0
Procedural complication	1 (5.0)	1 (5.0)	0	0	0
Procedural site reaction	1 (5.0)	1 (5.0)	0	0	0
Stoma site irritation	1 (5.0)	1 (5.0)	0	0	0
Tibia fracture	1 (5.0)	0	1 (5.0)	0	0
Transfusion reaction	1 (5.0)	1 (5.0)	0	0	0
Investigations					
-Total	15 (75.0)	0	2 (10.0)	3 (15.0)	10 (50.0)
White blood cell count decreased	9 (45.0)	2 (10.0)	0	2 (10.0)	5 (25.0)
Neutrophil count decreased	8 (40.0)	0	1 (5.0)	1 (5.0)	6 (30.0)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	7 (35.0)	1 (5.0)	1 (5.0)	3 (15.0)	2 (10.0)
Alanine aminotransferase increased	6 (30.0)	1 (5.0)	1 (5.0)	4 (20.0)	0
Lymphocyte count decreased	4 (20.0)	1 (5.0)	1 (5.0)	1 (5.0)	1 (5.0)
Blood bilirubin increased	3 (15.0)	0	2 (10.0)	1 (5.0)	0
Platelet count decreased	3 (15.0)	0	0	0	3 (15.0)
Blood fibrinogen decreased	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Blood urea increased	2 (10.0)	1 (5.0)	0	1 (5.0)	0
International normalised ratio increased	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Lipase increased	2 (10.0)	0	0	0	2 (10.0)
Prothrombin time prolonged	2 (10.0)	2 (10.0)	0	0	0
Activated partial thromboplastin time prolonged	1 (5.0)	1 (5.0)	0	0	0
Blood creatinine increased	1 (5.0)	0	0	1 (5.0)	0
Blood immunoglobulin g decreased	1 (5.0)	0	1 (5.0)	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Blood lactic acid increased	1 (5.0)	0	0	0	1 (5.0)
Blood phosphorus decreased	1 (5.0)	1 (5.0)	0	0	0
Blood phosphorus increased	1 (5.0)	1 (5.0)	0	0	0
Blood sodium increased	1 (5.0)	0	1 (5.0)	0	0
Blood uric acid increased	1 (5.0)	1 (5.0)	0	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fibrin d dimer increased	1 (5.0)	1 (5.0)	0	0	0
Protein total decreased	1 (5.0)	0	0	1 (5.0)	0
Pulmonary function test decreased	1 (5.0)	0	1 (5.0)	0	0
Serum ferritin increased	1 (5.0)	0	1 (5.0)	0	0
Transaminases increased	1 (5.0)	1 (5.0)	0	0	0
Metabolism and nutrition disorders					
-Total	13 (65.0)	2 (10.0)	4 (20.0)	6 (30.0)	1 (5.0)
Hypokalaemia	7 (35.0)	0	2 (10.0)	5 (25.0)	0
Decreased appetite	6 (30.0)	2 (10.0)	1 (5.0)	3 (15.0)	0
Hypophosphataemia	5 (25.0)	2 (10.0)	0	2 (10.0)	1 (5.0)
Hypertriglyceridaemia	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Hypoalbuminaemia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Hypocalcaemia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Acidosis	1 (5.0)	0	0	1 (5.0)	0
Fluid overload	1 (5.0)	1 (5.0)	0	0	0
Hyperalbuminaemia	1 (5.0)	1 (5.0)	0	0	0
Hypercalcaemia	1 (5.0)	1 (5.0)	0	0	0
Hyperchloraemia	1 (5.0)	1 (5.0)	0	0	0
Hyperglycaemia	1 (5.0)	0	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypermagnesaemia	1 (5.0)	1 (5.0)	0	0	0
Hypernatraemia	1 (5.0)	0	1 (5.0)	0	0
Hyperphosphataemia	1 (5.0)	1 (5.0)	0	0	0
Hypomagnesaemia	1 (5.0)	1 (5.0)	0	0	0
Hyponatraemia	1 (5.0)	0	0	1 (5.0)	0
Malnutrition	1 (5.0)	0	0	1 (5.0)	0
Metabolic alkalosis	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Pain in extremity	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Osteopenia	1 (5.0)	0	1 (5.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (5.0)	0	1 (5.0)	0	0
Skin papilloma	1 (5.0)	0	1 (5.0)	0	0
Nervous system disorders					
-Total	9 (45.0)	6 (30.0)	1 (5.0)	1 (5.0)	1 (5.0)
Headache	7 (35.0)	7 (35.0)	0	0	0
Depressed level of consciousness	1 (5.0)	1 (5.0)	0	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dizziness	1 (5.0)	1 (5.0)	0	0	0
Embolic stroke	1 (5.0)	0	0	0	1 (5.0)
Migraine	1 (5.0)	0	1 (5.0)	0	0
Seizure	1 (5.0)	0	0	1 (5.0)	0
Psychiatric disorders					
-Total	4 (20.0)	2 (10.0)	2 (10.0)	0	0
Confusional state	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Anxiety	1 (5.0)	1 (5.0)	0	0	0
Delirium	1 (5.0)	0	1 (5.0)	0	0
Insomnia	1 (5.0)	0	1 (5.0)	0	0
Irritability	1 (5.0)	1 (5.0)	0	0	0
Renal and urinary disorders					
-Total	4 (20.0)	0	2 (10.0)	2 (10.0)	0
Acute kidney injury	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Dysuria	1 (5.0)	0	1 (5.0)	0	0
Pollakiuria	1 (5.0)	1 (5.0)	0	0	0
Renal impairment	1 (5.0)	0	0	1 (5.0)	0
Reproductive system and breast disorders					
-Total	2 (10.0)	2 (10.0)	0	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal adhesion	2 (10.0)	2 (10.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (45.0)	2 (10.0)	2 (10.0)	3 (15.0)	2 (10.0)
Cough	4 (20.0)	4 (20.0)	0	0	0
Hypoxia	4 (20.0)	0	1 (5.0)	3 (15.0)	0
Pleural effusion	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0
Epistaxis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Pulmonary oedema	2 (10.0)	0	0	2 (10.0)	0
Respiratory distress	1 (5.0)	0	0	0	1 (5.0)
Respiratory failure	1 (5.0)	0	0	0	1 (5.0)
Tachypnoea	1 (5.0)	0	1 (5.0)	0	0
Wheezing	1 (5.0)	0	1 (5.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (40.0)	7 (35.0)	1 (5.0)	0	0
Hyperhidrosis	2 (10.0)	2 (10.0)	0	0	0
Rash	2 (10.0)	2 (10.0)	0	0	0
Rash maculo-papular	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Rash papular	2 (10.0)	2 (10.0)	0	0	0
Dermatitis diaper	1 (5.0)	1 (5.0)	0	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	1 (5.0)	1 (5.0)	0	0	0
Macule	1 (5.0)	1 (5.0)	0	0	0
Petechiae	1 (5.0)	1 (5.0)	0	0	0
Rash erythematous	1 (5.0)	1 (5.0)	0	0	0
Rash follicular	1 (5.0)	1 (5.0)	0	0	0
Rash macular	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	8 (40.0)	2 (10.0)	1 (5.0)	2 (10.0)	3 (15.0)
Hypertension	5 (25.0)	2 (10.0)	3 (15.0)	0	0
Hypotension	5 (25.0)	1 (5.0)	0	1 (5.0)	3 (15.0)
Flushing	2 (10.0)	2 (10.0)	0	0	0
Capillary leak syndrome	1 (5.0)	0	0	0	1 (5.0)
Embolism	1 (5.0)	0	0	1 (5.0)	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=34		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (100)	1 (2.9)	3 (8.8)	8 (23.5)	22 (64.7)
Blood and lymphatic system disorders					
-Total	25 (73.5)	0	3 (8.8)	16 (47.1)	6 (17.6)
Anaemia	18 (52.9)	1 (2.9)	5 (14.7)	11 (32.4)	1 (2.9)
Febrile neutropenia	14 (41.2)	0	0	14 (41.2)	0
Neutropenia	5 (14.7)	0	0	1 (2.9)	4 (11.8)
Thrombocytopenia	4 (11.8)	0	0	2 (5.9)	2 (5.9)
Disseminated intravascular coagulation	3 (8.8)	0	2 (5.9)	1 (2.9)	0
Lymphopenia	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Cardiac disorders					
-Total	10 (29.4)	5 (14.7)	4 (11.8)	1 (2.9)	0
Tachycardia	9 (26.5)	6 (17.6)	2 (5.9)	1 (2.9)	0
Sinus tachycardia	2 (5.9)	1 (2.9)	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pericardial effusion	1 (2.9)	1 (2.9)	0	0	0
Sinus bradycardia	1 (2.9)	1 (2.9)	0	0	0
Ventricular tachycardia	1 (2.9)	0	1 (2.9)	0	0
Ear and labyrinth disorders					
-Total	1 (2.9)	1 (2.9)	0	0	0
Ear pain	1 (2.9)	1 (2.9)	0	0	0
Endocrine disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Adrenal insufficiency	1 (2.9)	0	1 (2.9)	0	0
Eye disorders					
-Total	7 (20.6)	2 (5.9)	5 (14.7)	0	0
Eye pain	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Vision blurred	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Periorbital oedema	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Conjunctival haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Ocular hypertension	1 (2.9)	0	1 (2.9)	0	0
Photophobia	1 (2.9)	0	1 (2.9)	0	0
Retinal haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Uveitis	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	19 (55.9)	6 (17.6)	9 (26.5)	4 (11.8)	0
Vomiting	12 (35.3)	8 (23.5)	2 (5.9)	2 (5.9)	0
Nausea	9 (26.5)	3 (8.8)	6 (17.6)	0	0
Diarrhoea	8 (23.5)	5 (14.7)	2 (5.9)	1 (2.9)	0
Abdominal pain	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Constipation	3 (8.8)	3 (8.8)	0	0	0
Haematemesis	2 (5.9)	2 (5.9)	0	0	0
Stomatitis	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Abdominal distension	1 (2.9)	0	1 (2.9)	0	0
Abdominal pain lower	1 (2.9)	0	1 (2.9)	0	0
Abdominal pain upper	1 (2.9)	0	1 (2.9)	0	0
Anal incontinence	1 (2.9)	1 (2.9)	0	0	0
Dysphagia	1 (2.9)	0	1 (2.9)	0	0
Flatulence	1 (2.9)	1 (2.9)	0	0	0
Gastrointestinal haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Gastrooesophageal reflux disease	1 (2.9)	1 (2.9)	0	0	0
Glossodynia	1 (2.9)	1 (2.9)	0	0	0
Lip pain	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mouth haemorrhage	1 (2.9)	0	0	1 (2.9)	0
General disorders and administration site conditions					
-Total	19 (55.9)	9 (26.5)	5 (14.7)	4 (11.8)	1 (2.9)
Fatigue	8 (23.5)	7 (20.6)	0	1 (2.9)	0
Pyrexia	8 (23.5)	2 (5.9)	4 (11.8)	1 (2.9)	1 (2.9)
Chills	4 (11.8)	4 (11.8)	0	0	0
Pain	3 (8.8)	0	1 (2.9)	2 (5.9)	0
Malaise	2 (5.9)	0	2 (5.9)	0	0
Catheter site extravasation	1 (2.9)	0	1 (2.9)	0	0
Catheter site haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Catheter site pain	1 (2.9)	1 (2.9)	0	0	0
Face oedema	1 (2.9)	0	1 (2.9)	0	0
Generalised oedema	1 (2.9)	0	1 (2.9)	0	0
Injection site haematoma	1 (2.9)	1 (2.9)	0	0	0
Non-cardiac chest pain	1 (2.9)	1 (2.9)	0	0	0
Peripheral swelling	1 (2.9)	0	1 (2.9)	0	0
Physical deconditioning	1 (2.9)	0	0	1 (2.9)	0
Hepatobiliary disorders					

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (11.8)	2 (5.9)	1 (2.9)	1 (2.9)	0
Hepatomegaly	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Hyperbilirubinaemia	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Gallbladder enlargement	1 (2.9)	1 (2.9)	0	0	0
Immune system disorders					
-Total	30 (88.2)	4 (11.8)	13 (38.2)	8 (23.5)	5 (14.7)
Cytokine release syndrome	26 (76.5)	4 (11.8)	12 (35.3)	5 (14.7)	5 (14.7)
Hypogammaglobulinaemia	14 (41.2)	2 (5.9)	9 (26.5)	3 (8.8)	0
Drug hypersensitivity	1 (2.9)	0	1 (2.9)	0	0
Graft versus host disease in skin	1 (2.9)	1 (2.9)	0	0	0
Infections and infestations					
-Total	13 (38.2)	3 (8.8)	8 (23.5)	2 (5.9)	0
Clostridium difficile colitis	2 (5.9)	0	2 (5.9)	0	0
Acute sinusitis	1 (2.9)	0	1 (2.9)	0	0
Body tinea	1 (2.9)	1 (2.9)	0	0	0
Catheter site cellulitis	1 (2.9)	1 (2.9)	0	0	0
Clostridium difficile infection	1 (2.9)	0	1 (2.9)	0	0
Cytomegalovirus infection	1 (2.9)	1 (2.9)	0	0	0
Enterococcal infection	1 (2.9)	1 (2.9)	0	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fungal skin infection	1 (2.9)	1 (2.9)	0	0	0
Gastroenteritis	1 (2.9)	0	0	1 (2.9)	0
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Herpes simplex	1 (2.9)	1 (2.9)	0	0	0
Hypopyon	1 (2.9)	0	1 (2.9)	0	0
Influenza	1 (2.9)	1 (2.9)	0	0	0
Orchitis	1 (2.9)	1 (2.9)	0	0	0
Pharyngitis	1 (2.9)	0	1 (2.9)	0	0
Skin infection	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal infection	1 (2.9)	0	0	1 (2.9)	0
Streptococcal infection	1 (2.9)	0	1 (2.9)	0	0
Upper respiratory tract infection	1 (2.9)	0	1 (2.9)	0	0
Injury, poisoning and procedural complications					
-Total	7 (20.6)	4 (11.8)	2 (5.9)	0	1 (2.9)
Contusion	1 (2.9)	1 (2.9)	0	0	0
Infusion related reaction	1 (2.9)	0	1 (2.9)	0	0
Mouth injury	1 (2.9)	1 (2.9)	0	0	0
Post procedural haemorrhage	1 (2.9)	1 (2.9)	0	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural headache	1 (2.9)	0	1 (2.9)	0	0
Procedural pain	1 (2.9)	0	1 (2.9)	0	0
Skin abrasion	1 (2.9)	1 (2.9)	0	0	0
Subdural haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Tongue injury	1 (2.9)	1 (2.9)	0	0	0
Transfusion reaction	1 (2.9)	1 (2.9)	0	0	0
Transfusion related complication	1 (2.9)	0	0	0	1 (2.9)
Investigations					
-Total	29 (85.3)	4 (11.8)	2 (5.9)	6 (17.6)	17 (50.0)
White blood cell count decreased	17 (50.0)	1 (2.9)	1 (2.9)	6 (17.6)	9 (26.5)
Neutrophil count decreased	16 (47.1)	0	1 (2.9)	3 (8.8)	12 (35.3)
Platelet count decreased	13 (38.2)	2 (5.9)	1 (2.9)	2 (5.9)	8 (23.5)
Alanine aminotransferase increased	12 (35.3)	3 (8.8)	2 (5.9)	7 (20.6)	0
Aspartate aminotransferase increased	9 (26.5)	1 (2.9)	3 (8.8)	4 (11.8)	1 (2.9)
Lymphocyte count decreased	9 (26.5)	0	1 (2.9)	5 (14.7)	3 (8.8)
Blood creatinine increased	8 (23.5)	5 (14.7)	2 (5.9)	1 (2.9)	0
International normalised ratio increased	6 (17.6)	6 (17.6)	0	0	0
Activated partial thromboplastin time prolonged	4 (11.8)	2 (5.9)	2 (5.9)	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	4 (11.8)	2 (5.9)	1 (2.9)	1 (2.9)	0
Prothrombin time prolonged	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Blood immunoglobulin a decreased	3 (8.8)	3 (8.8)	0	0	0
Blood immunoglobulin m decreased	2 (5.9)	2 (5.9)	0	0	0
Blood bicarbonate decreased	1 (2.9)	0	1 (2.9)	0	0
Blood magnesium decreased	1 (2.9)	0	0	1 (2.9)	0
Blood phosphorus increased	1 (2.9)	1 (2.9)	0	0	0
Blood urea increased	1 (2.9)	0	1 (2.9)	0	0
Cardiac murmur	1 (2.9)	1 (2.9)	0	0	0
Culture stool positive	1 (2.9)	1 (2.9)	0	0	0
Haemoglobin decreased	1 (2.9)	0	0	1 (2.9)	0
Norovirus test positive	1 (2.9)	1 (2.9)	0	0	0
Transaminases increased	1 (2.9)	1 (2.9)	0	0	0
Metabolism and nutrition disorders					
-Total	19 (55.9)	3 (8.8)	4 (11.8)	11 (32.4)	1 (2.9)
Decreased appetite	10 (29.4)	2 (5.9)	2 (5.9)	6 (17.6)	0
Hyperphosphataemia	6 (17.6)	6 (17.6)	0	0	0
Hypokalaemia	6 (17.6)	1 (2.9)	3 (8.8)	2 (5.9)	0
Hypernatraemia	3 (8.8)	1 (2.9)	1 (2.9)	0	1 (2.9)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Hypophosphataemia	3 (8.8)	0	0	3 (8.8)	0
Dehydration	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Hyperuricaemia	2 (5.9)	2 (5.9)	0	0	0
Acidosis	1 (2.9)	1 (2.9)	0	0	0
Fluid overload	1 (2.9)	0	1 (2.9)	0	0
Hyperglycaemia	1 (2.9)	0	1 (2.9)	0	0
Hypocalcaemia	1 (2.9)	0	0	1 (2.9)	0
Hyponatraemia	1 (2.9)	0	0	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	0	1 (2.9)	0
Musculoskeletal and connective tissue disorders					
-Total	10 (29.4)	6 (17.6)	3 (8.8)	1 (2.9)	0
Myalgia	5 (14.7)	4 (11.8)	1 (2.9)	0	0
Arthralgia	4 (11.8)	3 (8.8)	0	1 (2.9)	0
Musculoskeletal pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Coccydynia	1 (2.9)	1 (2.9)	0	0	0
Muscle spasms	1 (2.9)	1 (2.9)	0	0	0
Muscular weakness	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal chest pain	1 (2.9)	1 (2.9)	0	0	0
Pain in extremity	1 (2.9)	1 (2.9)	0	0	0
Nervous system disorders					
-Total	20 (58.8)	9 (26.5)	8 (23.5)	3 (8.8)	0
Headache	15 (44.1)	8 (23.5)	5 (14.7)	2 (5.9)	0
Encephalopathy	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Dysarthria	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Seizure	2 (5.9)	0	2 (5.9)	0	0
Tremor	2 (5.9)	2 (5.9)	0	0	0
Asterixis	1 (2.9)	1 (2.9)	0	0	0
Ataxia	1 (2.9)	0	1 (2.9)	0	0
Dizziness	1 (2.9)	1 (2.9)	0	0	0
Myoclonus	1 (2.9)	1 (2.9)	0	0	0
Neuropathy peripheral	1 (2.9)	0	1 (2.9)	0	0
Pleocytosis	1 (2.9)	1 (2.9)	0	0	0
Somnolence	1 (2.9)	1 (2.9)	0	0	0
Product issues					
-Total	1 (2.9)	1 (2.9)	0	0	0
Device occlusion	1 (2.9)	1 (2.9)	0	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	8 (23.5)	4 (11.8)	4 (11.8)	0	0
Anxiety	4 (11.8)	1 (2.9)	3 (8.8)	0	0
Confusional state	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Agitation	2 (5.9)	0	2 (5.9)	0	0
Delirium	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Hallucination	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Adjustment disorder	1 (2.9)	0	1 (2.9)	0	0
Irritability	1 (2.9)	1 (2.9)	0	0	0
Listless	1 (2.9)	1 (2.9)	0	0	0
Mental status changes	1 (2.9)	1 (2.9)	0	0	0
Suicidal ideation	1 (2.9)	1 (2.9)	0	0	0
Renal and urinary disorders					
-Total	5 (14.7)	2 (5.9)	0	1 (2.9)	2 (5.9)
Acute kidney injury	3 (8.8)	1 (2.9)	0	1 (2.9)	1 (2.9)
Haematuria	2 (5.9)	0	1 (2.9)	0	1 (2.9)
Oliguria	2 (5.9)	0	0	2 (5.9)	0
Dysuria	1 (2.9)	1 (2.9)	0	0	0
Renal failure	1 (2.9)	0	0	0	1 (2.9)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	16 (47.1)	8 (23.5)	3 (8.8)	2 (5.9)	3 (8.8)
Epistaxis	4 (11.8)	1 (2.9)	0	2 (5.9)	1 (2.9)
Hypoxia	4 (11.8)	0	2 (5.9)	1 (2.9)	1 (2.9)
Tachypnoea	4 (11.8)	3 (8.8)	0	1 (2.9)	0
Cough	3 (8.8)	3 (8.8)	0	0	0
Pulmonary oedema	3 (8.8)	1 (2.9)	0	1 (2.9)	1 (2.9)
Haemoptysis	2 (5.9)	1 (2.9)	0	0	1 (2.9)
Oropharyngeal pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Pleural effusion	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Respiratory failure	2 (5.9)	0	0	0	2 (5.9)
Atelectasis	1 (2.9)	1 (2.9)	0	0	0
Dyspnoea	1 (2.9)	0	0	1 (2.9)	0
Nasal congestion	1 (2.9)	1 (2.9)	0	0	0
Oropharyngeal plaque	1 (2.9)	1 (2.9)	0	0	0
Pharyngeal ulceration	1 (2.9)	0	1 (2.9)	0	0
Respiratory depression	1 (2.9)	0	1 (2.9)	0	0
Rhinitis allergic	1 (2.9)	1 (2.9)	0	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	1 (2.9)	1 (2.9)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	10 (29.4)	7 (20.6)	2 (5.9)	1 (2.9)	0
Dry skin	4 (11.8)	4 (11.8)	0	0	0
Erythema	2 (5.9)	2 (5.9)	0	0	0
Ecchymosis	1 (2.9)	0	0	1 (2.9)	0
Hyperhidrosis	1 (2.9)	1 (2.9)	0	0	0
Ingrowing nail	1 (2.9)	0	1 (2.9)	0	0
Livedo reticularis	1 (2.9)	1 (2.9)	0	0	0
Night sweats	1 (2.9)	0	1 (2.9)	0	0
Petechiae	1 (2.9)	1 (2.9)	0	0	0
Pruritus	1 (2.9)	1 (2.9)	0	0	0
Rash	1 (2.9)	1 (2.9)	0	0	0
Rash vesicular	1 (2.9)	1 (2.9)	0	0	0
Skin exfoliation	1 (2.9)	1 (2.9)	0	0	0
Skin fissures	1 (2.9)	1 (2.9)	0	0	0
Skin irritation	1 (2.9)	1 (2.9)	0	0	0
Vascular disorders					
-Total	11 (32.4)	0	2 (5.9)	5 (14.7)	4 (11.8)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	9 (26.5)	0	0	5 (14.7)	4 (11.8)
Hypertension	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Haematoma	1 (2.9)	0	1 (2.9)	0	0
Orthostatic hypotension	1 (2.9)	0	1 (2.9)	0	0
Secondary hypertension	1 (2.9)	0	1 (2.9)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=18

			All patients N=10		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (100)	0	0	4 (40.0)	6 (60.0)
Blood and lymphatic system disorders					
-Total	7 (70.0)	0	0	3 (30.0)	4 (40.0)
Anaemia	3 (30.0)	0	0	3 (30.0)	0
Neutropenia	3 (30.0)	0	0	2 (20.0)	1 (10.0)
Thrombocytopenia	3 (30.0)	0	0	0	3 (30.0)
Febrile neutropenia	2 (20.0)	0	0	2 (20.0)	0
Lymphopenia	1 (10.0)	0	1 (10.0)	0	0
Pancytopenia	1 (10.0)	0	0	0	1 (10.0)
Cardiac disorders					
-Total	4 (40.0)	1 (10.0)	2 (20.0)	1 (10.0)	0
Tachycardia	4 (40.0)	1 (10.0)	2 (20.0)	1 (10.0)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (10.0)	0	0	1 (10.0)	0
Ear and labyrinth disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Hypoacusis	1 (10.0)	0	1 (10.0)	0	0
Eye disorders					
-Total	2 (20.0)	0	2 (20.0)	0	0
Papilloedema	1 (10.0)	0	1 (10.0)	0	0
Uveitis	1 (10.0)	0	1 (10.0)	0	0
Visual impairment	1 (10.0)	0	1 (10.0)	0	0
Gastrointestinal disorders					
-Total	5 (50.0)	1 (10.0)	2 (20.0)	2 (20.0)	0
Diarrhoea	4 (40.0)	2 (20.0)	2 (20.0)	0	0
Nausea	4 (40.0)	0	3 (30.0)	1 (10.0)	0
Vomiting	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Abdominal discomfort	1 (10.0)	1 (10.0)	0	0	0
Abdominal pain	1 (10.0)	0	0	1 (10.0)	0
Abdominal pain upper	1 (10.0)	0	1 (10.0)	0	0
Constipation	1 (10.0)	0	1 (10.0)	0	0
Dyspepsia	1 (10.0)	0	1 (10.0)	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Intestinal obstruction	1 (10.0)	0	0	1 (10.0)	0
General disorders and administration site conditions					
-Total	5 (50.0)	1 (10.0)	2 (20.0)	2 (20.0)	0
Pyrexia	4 (40.0)	1 (10.0)	1 (10.0)	2 (20.0)	0
Chills	3 (30.0)	3 (30.0)	0	0	0
Fatigue	2 (20.0)	0	2 (20.0)	0	0
Asthenia	1 (10.0)	1 (10.0)	0	0	0
Facial pain	1 (10.0)	0	1 (10.0)	0	0
Malaise	1 (10.0)	0	1 (10.0)	0	0
Hepatobiliary disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Hepatomegaly	1 (10.0)	0	1 (10.0)	0	0
Immune system disorders					
-Total	8 (80.0)	0	5 (50.0)	0	3 (30.0)
Cytokine release syndrome	8 (80.0)	0	5 (50.0)	0	3 (30.0)
Hypogammaglobulinaemia	3 (30.0)	0	3 (30.0)	0	0
Infections and infestations					
-Total	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Folliculitis	1 (10.0)	0	1 (10.0)	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (10.0)	0	1 (10.0)	0	0
Pneumonia	1 (10.0)	0	1 (10.0)	0	0
Urinary tract infection enterococcal	1 (10.0)	0	0	1 (10.0)	0
Injury, poisoning and procedural complications					
-Total	3 (30.0)	1 (10.0)	1 (10.0)	1 (10.0)	0
Incision site pain	1 (10.0)	1 (10.0)	0	0	0
Limb injury	1 (10.0)	1 (10.0)	0	0	0
Tracheal haemorrhage	1 (10.0)	0	0	1 (10.0)	0
Transfusion reaction	1 (10.0)	0	1 (10.0)	0	0
Investigations					
-Total	8 (80.0)	0	0	4 (40.0)	4 (40.0)
White blood cell count decreased	4 (40.0)	0	0	2 (20.0)	2 (20.0)
Platelet count decreased	3 (30.0)	1 (10.0)	1 (10.0)	0	1 (10.0)
Prothrombin time prolonged	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Aspartate aminotransferase increased	2 (20.0)	1 (10.0)	0	0	1 (10.0)
Blood fibrinogen decreased	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Alanine aminotransferase increased	1 (10.0)	1 (10.0)	0	0	0
Blood immunoglobulin m decreased	1 (10.0)	1 (10.0)	0	0	0
C-reactive protein increased	1 (10.0)	0	0	1 (10.0)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic enzyme increased	1 (10.0)	0	1 (10.0)	0	0
International normalised ratio increased	1 (10.0)	1 (10.0)	0	0	0
Lymphocyte count decreased	1 (10.0)	0	0	0	1 (10.0)
Neutrophil count decreased	1 (10.0)	0	0	0	1 (10.0)
Metabolism and nutrition disorders					
-Total	7 (70.0)	0	2 (20.0)	4 (40.0)	1 (10.0)
Decreased appetite	4 (40.0)	0	1 (10.0)	3 (30.0)	0
Hypokalaemia	3 (30.0)	2 (20.0)	1 (10.0)	0	0
Dehydration	1 (10.0)	0	0	1 (10.0)	0
Fluid overload	1 (10.0)	0	1 (10.0)	0	0
Hyperglycaemia	1 (10.0)	0	0	1 (10.0)	0
Hyperphosphataemia	1 (10.0)	1 (10.0)	0	0	0
Hyperuricaemia	1 (10.0)	0	0	0	1 (10.0)
Hypophosphataemia	1 (10.0)	0	0	1 (10.0)	0
Metabolic acidosis	1 (10.0)	0	1 (10.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Limb discomfort	1 (10.0)	1 (10.0)	0	0	0
Musculoskeletal pain	1 (10.0)	1 (10.0)	0	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	1 (10.0)	0	1 (10.0)	0	0
Nervous system disorders					
-Total	4 (40.0)	2 (20.0)	2 (20.0)	0	0
Dizziness	2 (20.0)	2 (20.0)	0	0	0
Headache	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Idiopathic intracranial hypertension	1 (10.0)	0	1 (10.0)	0	0
Psychiatric disorders					
-Total	4 (40.0)	2 (20.0)	1 (10.0)	1 (10.0)	0
Anxiety	1 (10.0)	0	0	1 (10.0)	0
Confusional state	1 (10.0)	1 (10.0)	0	0	0
Delirium	1 (10.0)	1 (10.0)	0	0	0
Panic attack	1 (10.0)	0	1 (10.0)	0	0
Renal and urinary disorders					
-Total	2 (20.0)	0	0	0	2 (20.0)
Acute kidney injury	2 (20.0)	0	0	0	2 (20.0)
Haematuria	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Reproductive system and breast disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Oedema genital	1 (10.0)	0	1 (10.0)	0	0

Timing: within 8 weeks post infusion, Age: >=18

		All patients N=10			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	3 (30.0)	0	1 (10.0)	0	2 (20.0)
Hypoxia	2 (20.0)	0	0	0	2 (20.0)
Pleural effusion	2 (20.0)	0	2 (20.0)	0	0
Cough	1 (10.0)	1 (10.0)	0	0	0
Dyspnoea	1 (10.0)	0	0	0	1 (10.0)
Epistaxis	1 (10.0)	1 (10.0)	0	0	0
Interstitial lung disease	1 (10.0)	0	0	0	1 (10.0)
Pulmonary oedema	1 (10.0)	0	0	0	1 (10.0)
Skin and subcutaneous tissue disorders					
-Total	3 (30.0)	1 (10.0)	1 (10.0)	1 (10.0)	0
Ingrowing nail	1 (10.0)	0	1 (10.0)	0	0
Petechiae	1 (10.0)	0	1 (10.0)	0	0
Pruritus	1 (10.0)	1 (10.0)	0	0	0
Rash	1 (10.0)	1 (10.0)	0	0	0
Rash maculo-papular	1 (10.0)	0	0	1 (10.0)	0
Vascular disorders					
-Total	5 (50.0)	1 (10.0)	2 (20.0)	1 (10.0)	1 (10.0)
Hypertension	3 (30.0)	0	3 (30.0)	0	0

Timing: within 8 weeks post infusion, Age: >=18

Primary system organ class Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	2 (20.0)	0	0	1 (10.0)	1 (10.0)
Orthostatic hypotension	1 (10.0)	1 (10.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

			All patients N=18		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (83.3)	3 (16.7)	6 (33.3)	5 (27.8)	1 (5.6)
Blood and lymphatic system disorders					
-Total	2 (11.1)	0	1 (5.6)	0	1 (5.6)
Leukopenia	1 (5.6)	0	0	0	1 (5.6)
Thrombocytopenia	1 (5.6)	0	1 (5.6)	0	0
Eye disorders					
-Total	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Conjunctivitis allergic	1 (5.6)	1 (5.6)	0	0	0
Dry eye	1 (5.6)	0	1 (5.6)	0	0
Vision blurred	1 (5.6)	1 (5.6)	0	0	0
Gastrointestinal disorders					
-Total	5 (27.8)	2 (11.1)	2 (11.1)	1 (5.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	4 (22.2)	2 (11.1)	2 (11.1)	0	0
Diarrhoea	3 (16.7)	3 (16.7)	0	0	0
Nausea	2 (11.1)	0	2 (11.1)	0	0
Abdominal pain	1 (5.6)	1 (5.6)	0	0	0
Enterocolitis	1 (5.6)	0	0	1 (5.6)	0
General disorders and administration site conditions					
-Total	7 (38.9)	7 (38.9)	0	0	0
Pyrexia	5 (27.8)	5 (27.8)	0	0	0
Acquired gene mutation	1 (5.6)	1 (5.6)	0	0	0
Crying	1 (5.6)	1 (5.6)	0	0	0
Fatigue	1 (5.6)	1 (5.6)	0	0	0
Malaise	1 (5.6)	1 (5.6)	0	0	0
Immune system disorders					
-Total	3 (16.7)	1 (5.6)	1 (5.6)	1 (5.6)	0
Hypogammaglobulinaemia	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Seasonal allergy	1 (5.6)	1 (5.6)	0	0	0
Infections and infestations					
-Total	11 (61.1)	3 (16.7)	5 (27.8)	3 (16.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Ear infection	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Gastroenteritis	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Corona virus infection	1 (5.6)	0	0	1 (5.6)	0
Cytomegalovirus infection	1 (5.6)	1 (5.6)	0	0	0
Enterovirus infection	1 (5.6)	0	0	1 (5.6)	0
Gastroenteritis viral	1 (5.6)	1 (5.6)	0	0	0
Molluscum contagiosum	1 (5.6)	1 (5.6)	0	0	0
Otitis externa	1 (5.6)	0	1 (5.6)	0	0
Otitis media acute	1 (5.6)	0	1 (5.6)	0	0
Parainfluenzae virus infection	1 (5.6)	0	0	1 (5.6)	0
Paronychia	1 (5.6)	1 (5.6)	0	0	0
Rash pustular	1 (5.6)	0	1 (5.6)	0	0
Respiratory syncytial virus infection	1 (5.6)	0	0	1 (5.6)	0
Rotavirus infection	1 (5.6)	0	0	1 (5.6)	0
Sinusitis	1 (5.6)	0	1 (5.6)	0	0
Tinea capitis	1 (5.6)	1 (5.6)	0	0	0
Urinary tract infection	1 (5.6)	0	1 (5.6)	0	0
Viral upper respiratory tract infection	1 (5.6)	1 (5.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	4 (22.2)	3 (16.7)	1 (5.6)	0	0
Contusion	1 (5.6)	1 (5.6)	0	0	0
Infusion related reaction	1 (5.6)	1 (5.6)	0	0	0
Procedural pain	1 (5.6)	1 (5.6)	0	0	0
Radius fracture	1 (5.6)	0	1 (5.6)	0	0
Skin abrasion	1 (5.6)	1 (5.6)	0	0	0
Investigations					
-Total	5 (27.8)	1 (5.6)	2 (11.1)	2 (11.1)	0
Blood urea increased	1 (5.6)	1 (5.6)	0	0	0
Neutrophil count decreased	1 (5.6)	0	0	1 (5.6)	0
Oxygen saturation decreased	1 (5.6)	1 (5.6)	0	0	0
Weight decreased	1 (5.6)	0	1 (5.6)	0	0
Weight increased	1 (5.6)	0	1 (5.6)	0	0
White blood cell count decreased	1 (5.6)	0	0	1 (5.6)	0
Metabolism and nutrition disorders					
-Total	4 (22.2)	1 (5.6)	1 (5.6)	2 (11.1)	0
Decreased appetite	1 (5.6)	0	1 (5.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (5.6)	0	0	1 (5.6)	0
Hyperalbuminaemia	1 (5.6)	1 (5.6)	0	0	0
Hypercalcaemia	1 (5.6)	1 (5.6)	0	0	0
Tumour lysis syndrome	1 (5.6)	0	0	1 (5.6)	0
Musculoskeletal and connective tissue disorders					
-Total	7 (38.9)	5 (27.8)	2 (11.1)	0	0
Pain in extremity	6 (33.3)	4 (22.2)	2 (11.1)	0	0
Toe walking	1 (5.6)	1 (5.6)	0	0	0
Nervous system disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Dizziness	2 (11.1)	2 (11.1)	0	0	0
Headache	1 (5.6)	0	1 (5.6)	0	0
Renal and urinary disorders					
-Total	1 (5.6)	1 (5.6)	0	0	0
Urinary incontinence	1 (5.6)	1 (5.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (27.8)	3 (16.7)	2 (11.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	2 (11.1)	2 (11.1)	0	0	0
Rhinorrhoea	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Nasal congestion	1 (5.6)	1 (5.6)	0	0	0
Oropharyngeal pain	1 (5.6)	1 (5.6)	0	0	0
Rhinitis allergic	1 (5.6)	0	1 (5.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Papule	1 (5.6)	1 (5.6)	0	0	0
Pruritus	1 (5.6)	1 (5.6)	0	0	0
Rash	1 (5.6)	0	1 (5.6)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (77.4)	0	8 (25.8)	10 (32.3)	6 (19.4)
Blood and lymphatic system disorders					
-Total	9 (29.0)	1 (3.2)	2 (6.5)	3 (9.7)	3 (9.7)
Neutropenia	4 (12.9)	0	0	1 (3.2)	3 (9.7)
Febrile neutropenia	3 (9.7)	0	0	3 (9.7)	0
Anaemia	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Eosinophilia	1 (3.2)	0	0	1 (3.2)	0
Lymphadenopathy	1 (3.2)	0	1 (3.2)	0	0
Lymphopenia	1 (3.2)	0	1 (3.2)	0	0
Thrombocytopenia	1 (3.2)	0	0	1 (3.2)	0
Cardiac disorders					
-Total	1 (3.2)	0	1 (3.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	1 (3.2)	0	1 (3.2)	0	0
Endocrine disorders					
-Total	1 (3.2)	1 (3.2)	0	0	0
Adrenal insufficiency	1 (3.2)	1 (3.2)	0	0	0
Eye disorders					
-Total	2 (6.5)	2 (6.5)	0	0	0
Dry eye	1 (3.2)	1 (3.2)	0	0	0
Ocular hyperaemia	1 (3.2)	1 (3.2)	0	0	0
Gastrointestinal disorders					
-Total	9 (29.0)	7 (22.6)	0	2 (6.5)	0
Diarrhoea	4 (12.9)	3 (9.7)	1 (3.2)	0	0
Vomiting	3 (9.7)	2 (6.5)	0	1 (3.2)	0
Abdominal pain	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Nausea	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Oral pain	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Abdominal pain upper	1 (3.2)	1 (3.2)	0	0	0
Pigmentation lip	1 (3.2)	1 (3.2)	0	0	0
General disorders and administration site conditions					

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (22.6)	4 (12.9)	2 (6.5)	1 (3.2)	0
Pyrexia	3 (9.7)	1 (3.2)	1 (3.2)	1 (3.2)	0
Catheter site pain	1 (3.2)	0	1 (3.2)	0	0
Chills	1 (3.2)	1 (3.2)	0	0	0
Fatigue	1 (3.2)	1 (3.2)	0	0	0
Generalised oedema	1 (3.2)	1 (3.2)	0	0	0
Influenza like illness	1 (3.2)	1 (3.2)	0	0	0
Oedema peripheral	1 (3.2)	1 (3.2)	0	0	0
Pain	1 (3.2)	1 (3.2)	0	0	0
Immune system disorders					
-Total	10 (32.3)	2 (6.5)	8 (25.8)	0	0
Hypogammaglobulinaemia	5 (16.1)	0	5 (16.1)	0	0
Graft versus host disease	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Immunodeficiency common variable	2 (6.5)	0	2 (6.5)	0	0
Graft versus host disease in gastrointestinal tract	1 (3.2)	0	1 (3.2)	0	0
Seasonal allergy	1 (3.2)	1 (3.2)	0	0	0
Infections and infestations					
-Total	17 (54.8)	3 (9.7)	8 (25.8)	6 (19.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	4 (12.9)	1 (3.2)	2 (6.5)	1 (3.2)	0
Urinary tract infection	3 (9.7)	0	1 (3.2)	2 (6.5)	0
Rhinovirus infection	2 (6.5)	2 (6.5)	0	0	0
Cellulitis of male external genital organ	1 (3.2)	0	0	1 (3.2)	0
Escherichia urinary tract infection	1 (3.2)	0	0	1 (3.2)	0
Gastroenteritis	1 (3.2)	0	1 (3.2)	0	0
Gastroenteritis norovirus	1 (3.2)	0	1 (3.2)	0	0
Herpes zoster	1 (3.2)	0	0	1 (3.2)	0
Influenza	1 (3.2)	0	1 (3.2)	0	0
Oral herpes	1 (3.2)	0	1 (3.2)	0	0
Otitis media	1 (3.2)	0	1 (3.2)	0	0
Parainfluenzae virus infection	1 (3.2)	1 (3.2)	0	0	0
Rhinitis	1 (3.2)	1 (3.2)	0	0	0
Sinusitis	1 (3.2)	0	1 (3.2)	0	0
Subcutaneous abscess	1 (3.2)	0	1 (3.2)	0	0
Vascular device infection	1 (3.2)	0	0	1 (3.2)	0
Viral infection	1 (3.2)	1 (3.2)	0	0	0
Viral upper respiratory tract infection	1 (3.2)	0	0	1 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal mycotic infection	1 (3.2)	0	1 (3.2)	0	0
Injury, poisoning and procedural complications					
-Total	3 (9.7)	0	3 (9.7)	0	0
Arthropod bite	1 (3.2)	1 (3.2)	0	0	0
Contusion	1 (3.2)	1 (3.2)	0	0	0
Infusion related reaction	1 (3.2)	0	1 (3.2)	0	0
Procedural nausea	1 (3.2)	0	1 (3.2)	0	0
Procedural pain	1 (3.2)	0	1 (3.2)	0	0
Skin laceration	1 (3.2)	0	1 (3.2)	0	0
Sunburn	1 (3.2)	1 (3.2)	0	0	0
Investigations					
-Total	14 (45.2)	3 (9.7)	2 (6.5)	6 (19.4)	3 (9.7)
Neutrophil count decreased	6 (19.4)	2 (6.5)	0	2 (6.5)	2 (6.5)
White blood cell count decreased	3 (9.7)	1 (3.2)	1 (3.2)	0	1 (3.2)
Alanine aminotransferase increased	2 (6.5)	0	0	2 (6.5)	0
Aspartate aminotransferase increased	2 (6.5)	0	0	2 (6.5)	0
Lymphocyte count decreased	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Platelet count decreased	2 (6.5)	2 (6.5)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (3.2)	0	0	1 (3.2)	0
Blood creatinine increased	1 (3.2)	1 (3.2)	0	0	0
Blood magnesium decreased	1 (3.2)	1 (3.2)	0	0	0
Blood uric acid increased	1 (3.2)	1 (3.2)	0	0	0
Haemoglobin decreased	1 (3.2)	1 (3.2)	0	0	0
Serum ferritin increased	1 (3.2)	0	1 (3.2)	0	0
Weight decreased	1 (3.2)	1 (3.2)	0	0	0
Weight increased	1 (3.2)	1 (3.2)	0	0	0
Metabolism and nutrition disorders					
-Total	6 (19.4)	4 (12.9)	0	1 (3.2)	1 (3.2)
Hyperphosphataemia	2 (6.5)	2 (6.5)	0	0	0
Hypokalaemia	2 (6.5)	1 (3.2)	0	0	1 (3.2)
Decreased appetite	1 (3.2)	1 (3.2)	0	0	0
Hyperglycaemia	1 (3.2)	0	0	1 (3.2)	0
Hypophosphataemia	1 (3.2)	0	0	1 (3.2)	0
Iron overload	1 (3.2)	0	0	1 (3.2)	0
Vitamin d deficiency	1 (3.2)	1 (3.2)	0	0	0
Musculoskeletal and connective tissue disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (25.8)	6 (19.4)	2 (6.5)	0	0
Joint range of motion decreased	2 (6.5)	2 (6.5)	0	0	0
Muscular weakness	2 (6.5)	2 (6.5)	0	0	0
Pain in extremity	2 (6.5)	2 (6.5)	0	0	0
Arthralgia	1 (3.2)	1 (3.2)	0	0	0
Back pain	1 (3.2)	1 (3.2)	0	0	0
Flank pain	1 (3.2)	0	1 (3.2)	0	0
Muscle spasms	1 (3.2)	1 (3.2)	0	0	0
Musculoskeletal chest pain	1 (3.2)	1 (3.2)	0	0	0
Osteonecrosis	1 (3.2)	0	1 (3.2)	0	0
Pain in jaw	1 (3.2)	1 (3.2)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.2)	0	1 (3.2)	0	0
Myelodysplastic syndrome	1 (3.2)	0	1 (3.2)	0	0
Nervous system disorders					
-Total	4 (12.9)	4 (12.9)	0	0	0
Headache	3 (9.7)	3 (9.7)	0	0	0
Peroneal nerve palsy	1 (3.2)	1 (3.2)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Depression	2 (6.5)	2 (6.5)	0	0	0
Anxiety	1 (3.2)	1 (3.2)	0	0	0
Sleep disorder	1 (3.2)	0	1 (3.2)	0	0
Renal and urinary disorders					
-Total	2 (6.5)	0	0	2 (6.5)	0
Acute kidney injury	1 (3.2)	0	0	1 (3.2)	0
Calculus urinary	1 (3.2)	0	1 (3.2)	0	0
Haematuria	1 (3.2)	0	0	1 (3.2)	0
Nephrolithiasis	1 (3.2)	0	0	1 (3.2)	0
Reproductive system and breast disorders					
-Total	1 (3.2)	0	1 (3.2)	0	0
Scrotal pain	1 (3.2)	0	1 (3.2)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	12 (38.7)	7 (22.6)	2 (6.5)	2 (6.5)	1 (3.2)
Cough	5 (16.1)	3 (9.7)	2 (6.5)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	3 (9.7)	3 (9.7)	0	0	0
Epistaxis	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Oropharyngeal pain	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Rhinorrhoea	2 (6.5)	2 (6.5)	0	0	0
Acute respiratory failure	1 (3.2)	0	0	0	1 (3.2)
Dysphonia	1 (3.2)	1 (3.2)	0	0	0
Pharyngeal erythema	1 (3.2)	1 (3.2)	0	0	0
Pharyngeal lesion	1 (3.2)	0	0	1 (3.2)	0
Pulmonary oedema	1 (3.2)	0	0	1 (3.2)	0
Rhinitis allergic	1 (3.2)	1 (3.2)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	13 (41.9)	8 (25.8)	4 (12.9)	1 (3.2)	0
Rash	3 (9.7)	1 (3.2)	2 (6.5)	0	0
Rash maculo-papular	2 (6.5)	2 (6.5)	0	0	0
Alopecia	1 (3.2)	0	1 (3.2)	0	0
Dermatitis	1 (3.2)	1 (3.2)	0	0	0
Dermatitis acneiform	1 (3.2)	0	0	1 (3.2)	0
Dermatitis atopic	1 (3.2)	1 (3.2)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	1 (3.2)	1 (3.2)	0	0	0
Eczema	1 (3.2)	1 (3.2)	0	0	0
Erythema	1 (3.2)	1 (3.2)	0	0	0
Ingrowing nail	1 (3.2)	1 (3.2)	0	0	0
Keloid scar	1 (3.2)	0	1 (3.2)	0	0
Macule	1 (3.2)	1 (3.2)	0	0	0
Petechiae	1 (3.2)	1 (3.2)	0	0	0
Rash erythematous	1 (3.2)	0	1 (3.2)	0	0
Rash pruritic	1 (3.2)	1 (3.2)	0	0	0
Vascular disorders					
-Total	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Hypertension	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Hot flush	1 (3.2)	1 (3.2)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

			All patients N=7		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	1 (14.3)	2 (28.6)	1 (14.3)	3 (42.9)
Gastrointestinal disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Nausea	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Vomiting	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Abdominal pain	1 (14.3)	0	0	1 (14.3)	0
Diarrhoea	1 (14.3)	0	0	1 (14.3)	0
General disorders and administration site conditions					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Pyrexia	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Influenza like illness	1 (14.3)	1 (14.3)	0	0	0
Immune system disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (14.3)	0	1 (14.3)	0	0
Hypogammaglobulinaemia	1 (14.3)	0	1 (14.3)	0	0
Infections and infestations					
-Total	5 (71.4)	0	2 (28.6)	1 (14.3)	2 (28.6)
Influenza	2 (28.6)	0	2 (28.6)	0	0
Bacterial sepsis	1 (14.3)	0	0	0	1 (14.3)
Cholecystitis infective	1 (14.3)	0	0	1 (14.3)	0
Sepsis	1 (14.3)	0	0	0	1 (14.3)
Injury, poisoning and procedural complications					
-Total	1 (14.3)	0	1 (14.3)	0	0
Foot fracture	1 (14.3)	0	1 (14.3)	0	0
Investigations					
-Total	4 (57.1)	2 (28.6)	1 (14.3)	0	1 (14.3)
Weight decreased	2 (28.6)	0	2 (28.6)	0	0
Aspartate aminotransferase increased	1 (14.3)	1 (14.3)	0	0	0
Haemoglobin decreased	1 (14.3)	1 (14.3)	0	0	0
Neutrophil count decreased	1 (14.3)	0	0	0	1 (14.3)
Platelet count decreased	1 (14.3)	1 (14.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transaminases increased	1 (14.3)	1 (14.3)	0	0	0
White blood cell count decreased	1 (14.3)	1 (14.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Arthralgia	1 (14.3)	0	1 (14.3)	0	0
Nervous system disorders					
-Total	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Dizziness	1 (14.3)	1 (14.3)	0	0	0
Headache	1 (14.3)	1 (14.3)	0	0	0
Peroneal nerve palsy	1 (14.3)	0	1 (14.3)	0	0
Reproductive system and breast disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Vaginal haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Rhinitis allergic	1 (14.3)	1 (14.3)	0	0	0
Skin and subcutaneous tissue disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (14.3)	1 (14.3)	0	0	0
Erythema	1 (14.3)	1 (14.3)	0	0	0
Hyperhidrosis	1 (14.3)	1 (14.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: <10 years

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (54.5)	0	2 (18.2)	2 (18.2)	2 (18.2)
Ear and labyrinth disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Tympanic membrane perforation	1 (9.1)	0	1 (9.1)	0	0
Gastrointestinal disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Abdominal pain	1 (9.1)	0	1 (9.1)	0	0
Diarrhoea	1 (9.1)	0	1 (9.1)	0	0
General disorders and administration site conditions					
-Total	1 (9.1)	0	0	1 (9.1)	0
Cyst	1 (9.1)	0	0	1 (9.1)	0
Immune system disorders					

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (9.1)	0	1 (9.1)	0	0
Chronic graft versus host disease	1 (9.1)	0	1 (9.1)	0	0
Infections and infestations					
-Total	5 (45.5)	0	2 (18.2)	2 (18.2)	1 (9.1)
Otitis media acute	2 (18.2)	0	2 (18.2)	0	0
Campylobacter infection	1 (9.1)	0	0	1 (9.1)	0
Clostridium difficile infection	1 (9.1)	0	0	1 (9.1)	0
Haemophilus infection	1 (9.1)	0	1 (9.1)	0	0
Otitis media	1 (9.1)	0	0	1 (9.1)	0
Pneumonia	1 (9.1)	0	1 (9.1)	0	0
Respiratory tract infection	1 (9.1)	0	0	0	1 (9.1)
Respiratory tract infection viral	1 (9.1)	0	0	1 (9.1)	0
Sinusitis	1 (9.1)	0	1 (9.1)	0	0
Skin infection	1 (9.1)	0	1 (9.1)	0	0
Urinary tract infection	1 (9.1)	0	1 (9.1)	0	0
Vulvovaginal candidiasis	1 (9.1)	0	1 (9.1)	0	0
Metabolism and nutrition disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Vitamin d deficiency	1 (9.1)	1 (9.1)	0	0	0

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (9.1)	0	0	0	1 (9.1)
Glioblastoma multiforme	1 (9.1)	0	0	0	1 (9.1)
Nervous system disorders					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Dizziness	1 (9.1)	1 (9.1)	0	0	0
Headache	1 (9.1)	0	1 (9.1)	0	0
Seizure	1 (9.1)	0	0	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Oropharyngeal pain	1 (9.1)	1 (9.1)	0	0	0
Rhinorrhoea	1 (9.1)	1 (9.1)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

			All patients N=22		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (68.2)	4 (18.2)	4 (18.2)	5 (22.7)	2 (9.1)
Blood and lymphatic system disorders					
-Total	2 (9.1)	1 (4.5)	0	0	1 (4.5)
Febrile neutropenia	1 (4.5)	0	0	0	1 (4.5)
Thrombocytopenia	1 (4.5)	1 (4.5)	0	0	0
Gastrointestinal disorders					
-Total	2 (9.1)	0	2 (9.1)	0	0
Diarrhoea	1 (4.5)	0	1 (4.5)	0	0
Nausea	1 (4.5)	0	1 (4.5)	0	0
General disorders and administration site conditions					
-Total	1 (4.5)	0	1 (4.5)	0	0
Chills	1 (4.5)	0	1 (4.5)	0	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (4.5)	0	1 (4.5)	0	0
Immune system disorders					
-Total	1 (4.5)	0	1 (4.5)	0	0
Immunodeficiency	1 (4.5)	0	1 (4.5)	0	0
Infections and infestations					
-Total	5 (22.7)	2 (9.1)	2 (9.1)	1 (4.5)	0
Otitis media	2 (9.1)	0	2 (9.1)	0	0
Cellulitis of male external genital organ	1 (4.5)	0	0	1 (4.5)	0
Gingivitis	1 (4.5)	1 (4.5)	0	0	0
Meningitis aseptic	1 (4.5)	0	1 (4.5)	0	0
Pneumonia	1 (4.5)	0	1 (4.5)	0	0
Sinusitis	1 (4.5)	0	1 (4.5)	0	0
Upper respiratory tract infection	1 (4.5)	1 (4.5)	0	0	0
Urinary tract infection	1 (4.5)	0	0	1 (4.5)	0
Viral infection	1 (4.5)	1 (4.5)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (4.5)	0	0	1 (4.5)	0
Procedural pain	1 (4.5)	0	0	1 (4.5)	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	7 (31.8)	1 (4.5)	2 (9.1)	3 (13.6)	1 (4.5)
White blood cell count decreased	4 (18.2)	1 (4.5)	0	2 (9.1)	1 (4.5)
Lymphocyte count decreased	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Alanine aminotransferase increased	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Neutrophil count decreased	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Aspartate aminotransferase increased	1 (4.5)	1 (4.5)	0	0	0
Blood alkaline phosphatase increased	1 (4.5)	1 (4.5)	0	0	0
Blood lactate dehydrogenase increased	1 (4.5)	1 (4.5)	0	0	0
C-reactive protein increased	1 (4.5)	1 (4.5)	0	0	0
Platelet count decreased	1 (4.5)	0	0	1 (4.5)	0
Metabolism and nutrition disorders					
-Total	1 (4.5)	0	0	1 (4.5)	0
Hypokalaemia	1 (4.5)	0	0	1 (4.5)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (4.5)	0	1 (4.5)	0	0
Neck pain	1 (4.5)	0	1 (4.5)	0	0
Nervous system disorders					

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.5)	1 (4.5)	0	0	0
Disturbance in attention	1 (4.5)	1 (4.5)	0	0	0
Renal and urinary disorders					
-Total	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Acute kidney injury	1 (4.5)	0	0	1 (4.5)	0
Haematuria	1 (4.5)	1 (4.5)	0	0	0
Reproductive system and breast disorders					
-Total	1 (4.5)	0	0	1 (4.5)	0
Ovarian failure	1 (4.5)	0	0	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (13.6)	3 (13.6)	0	0	0
Cough	2 (9.1)	2 (9.1)	0	0	0
Epistaxis	1 (4.5)	1 (4.5)	0	0	0
Rhinitis allergic	1 (4.5)	1 (4.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (13.6)	3 (13.6)	0	0	0
Acne	1 (4.5)	1 (4.5)	0	0	0
Papule	1 (4.5)	1 (4.5)	0	0	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	1 (4.5)	1 (4.5)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=18

		All patients N=1			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Infections and infestations					
-Total	1 (100)	0	1 (100)	0	0
Sinusitis	1 (100)	0	1 (100)	0	0
Upper respiratory tract infection	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	0	0	1 (100)	0
Alanine aminotransferase increased	1 (100)	0	0	1 (100)	0
Aspartate aminotransferase increased	1 (100)	0	0	1 (100)	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: <10 years

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (100)	0	3 (15.0)	3 (15.0)	14 (70.0)
Blood and lymphatic system disorders					
-Total	13 (65.0)	2 (10.0)	1 (5.0)	8 (40.0)	2 (10.0)
Anaemia	6 (30.0)	2 (10.0)	0	4 (20.0)	0
Febrile neutropenia	6 (30.0)	0	0	6 (30.0)	0
Thrombocytopenia	2 (10.0)	0	1 (5.0)	0	1 (5.0)
Coagulopathy	1 (5.0)	1 (5.0)	0	0	0
Disseminated intravascular coagulation	1 (5.0)	0	0	1 (5.0)	0
Leukopenia	1 (5.0)	0	0	0	1 (5.0)
Cardiac disorders					
-Total	8 (40.0)	5 (25.0)	3 (15.0)	0	0
Sinus tachycardia	3 (15.0)	2 (10.0)	1 (5.0)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Atrioventricular block second degree	1 (5.0)	1 (5.0)	0	0	0
Bradycardia	1 (5.0)	0	1 (5.0)	0	0
Cardiac dysfunction	1 (5.0)	1 (5.0)	0	0	0
Palpitations	1 (5.0)	1 (5.0)	0	0	0
Pericardial effusion	1 (5.0)	0	1 (5.0)	0	0
Ear and labyrinth disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Ear pain	1 (5.0)	1 (5.0)	0	0	0
Tympanic membrane perforation	1 (5.0)	0	1 (5.0)	0	0
Eye disorders					
-Total	7 (35.0)	6 (30.0)	1 (5.0)	0	0
Conjunctival haemorrhage	2 (10.0)	2 (10.0)	0	0	0
Periorbital oedema	2 (10.0)	2 (10.0)	0	0	0
Conjunctivitis allergic	1 (5.0)	1 (5.0)	0	0	0
Dry eye	1 (5.0)	0	1 (5.0)	0	0
Photophobia	1 (5.0)	1 (5.0)	0	0	0
Retinal haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Vision blurred	1 (5.0)	1 (5.0)	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	13 (65.0)	3 (15.0)	4 (20.0)	6 (30.0)	0
Nausea	9 (45.0)	2 (10.0)	5 (25.0)	2 (10.0)	0
Vomiting	9 (45.0)	5 (25.0)	4 (20.0)	0	0
Diarrhoea	8 (40.0)	5 (25.0)	3 (15.0)	0	0
Abdominal pain	4 (20.0)	2 (10.0)	2 (10.0)	0	0
Constipation	3 (15.0)	3 (15.0)	0	0	0
Pancreatitis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Abdominal distension	1 (5.0)	0	1 (5.0)	0	0
Abdominal tenderness	1 (5.0)	1 (5.0)	0	0	0
Ascites	1 (5.0)	0	0	1 (5.0)	0
Dysphagia	1 (5.0)	0	0	1 (5.0)	0
Enterocolitis	1 (5.0)	0	0	1 (5.0)	0
Ileus	1 (5.0)	0	0	1 (5.0)	0
Tooth socket haemorrhage	1 (5.0)	1 (5.0)	0	0	0
General disorders and administration site conditions					
-Total	12 (60.0)	5 (25.0)	3 (15.0)	4 (20.0)	0
Pyrexia	7 (35.0)	3 (15.0)	2 (10.0)	2 (10.0)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	4 (20.0)	4 (20.0)	0	0	0
Catheter site pain	2 (10.0)	0	2 (10.0)	0	0
Oedema peripheral	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Acquired gene mutation	1 (5.0)	1 (5.0)	0	0	0
Chills	1 (5.0)	1 (5.0)	0	0	0
Crying	1 (5.0)	1 (5.0)	0	0	0
Cyst	1 (5.0)	0	0	1 (5.0)	0
Face oedema	1 (5.0)	0	0	1 (5.0)	0
Generalised oedema	1 (5.0)	0	1 (5.0)	0	0
Localised oedema	1 (5.0)	0	0	1 (5.0)	0
Malaise	1 (5.0)	1 (5.0)	0	0	0
Mucosal haemorrhage	1 (5.0)	0	1 (5.0)	0	0
Multiple organ dysfunction syndrome	1 (5.0)	0	0	1 (5.0)	0
Hepatobiliary disorders					
-Total	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Hepatosplenomegaly	1 (5.0)	1 (5.0)	0	0	0
Hyperbilirubinaemia	1 (5.0)	0	0	1 (5.0)	0
Immune system disorders					
-Total	19 (95.0)	1 (5.0)	12 (60.0)	3 (15.0)	3 (15.0)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	16 (80.0)	2 (10.0)	8 (40.0)	3 (15.0)	3 (15.0)
Hypogammaglobulinaemia	10 (50.0)	1 (5.0)	7 (35.0)	2 (10.0)	0
Chronic graft versus host disease	1 (5.0)	0	1 (5.0)	0	0
Haemophagocytic lymphohistiocytosis	1 (5.0)	0	1 (5.0)	0	0
Seasonal allergy	1 (5.0)	1 (5.0)	0	0	0
Infections and infestations					
-Total	17 (85.0)	3 (15.0)	6 (30.0)	6 (30.0)	2 (10.0)
Clostridium difficile infection	4 (20.0)	0	3 (15.0)	1 (5.0)	0
Gastroenteritis	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Rhinovirus infection	3 (15.0)	3 (15.0)	0	0	0
Upper respiratory tract infection	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Clostridium difficile colitis	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Ear infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Otitis media acute	2 (10.0)	0	2 (10.0)	0	0
Pneumonia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Sinusitis	2 (10.0)	0	2 (10.0)	0	0
Urinary tract infection	2 (10.0)	0	2 (10.0)	0	0
Viral upper respiratory tract infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Vulvovaginal candidiasis	2 (10.0)	1 (5.0)	1 (5.0)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (5.0)	0	0	1 (5.0)	0
Catheter site infection	1 (5.0)	0	0	1 (5.0)	0
Corona virus infection	1 (5.0)	0	0	1 (5.0)	0
Cytomegalovirus infection	1 (5.0)	1 (5.0)	0	0	0
Enterovirus infection	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis viral	1 (5.0)	1 (5.0)	0	0	0
Haemophilus infection	1 (5.0)	0	1 (5.0)	0	0
Molluscum contagiosum	1 (5.0)	1 (5.0)	0	0	0
Oral candidiasis	1 (5.0)	1 (5.0)	0	0	0
Otitis externa	1 (5.0)	0	1 (5.0)	0	0
Otitis media	1 (5.0)	0	0	1 (5.0)	0
Parainfluenzae virus infection	1 (5.0)	0	0	1 (5.0)	0
Paronychia	1 (5.0)	1 (5.0)	0	0	0
Rash pustular	1 (5.0)	0	1 (5.0)	0	0
Respiratory syncytial virus infection	1 (5.0)	0	0	1 (5.0)	0
Respiratory tract infection	1 (5.0)	0	0	0	1 (5.0)
Respiratory tract infection viral	1 (5.0)	0	0	1 (5.0)	0
Rotavirus infection	1 (5.0)	0	0	1 (5.0)	0
Septic embolus	1 (5.0)	0	0	0	1 (5.0)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	1 (5.0)	0	1 (5.0)	0	0
Staphylococcal infection	1 (5.0)	1 (5.0)	0	0	0
Tinea capitis	1 (5.0)	1 (5.0)	0	0	0
Viral infection	1 (5.0)	0	1 (5.0)	0	0
Injury, poisoning and procedural complications					
-Total	8 (40.0)	6 (30.0)	2 (10.0)	0	0
Procedural pain	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Infusion related reaction	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Contusion	1 (5.0)	1 (5.0)	0	0	0
Procedural complication	1 (5.0)	1 (5.0)	0	0	0
Procedural site reaction	1 (5.0)	1 (5.0)	0	0	0
Radius fracture	1 (5.0)	0	1 (5.0)	0	0
Skin abrasion	1 (5.0)	1 (5.0)	0	0	0
Stoma site irritation	1 (5.0)	1 (5.0)	0	0	0
Tibia fracture	1 (5.0)	0	1 (5.0)	0	0
Transfusion reaction	1 (5.0)	1 (5.0)	0	0	0
Investigations					
-Total	16 (80.0)	0	2 (10.0)	4 (20.0)	10 (50.0)
White blood cell count decreased	10 (50.0)	2 (10.0)	0	3 (15.0)	5 (25.0)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	8 (40.0)	0	1 (5.0)	1 (5.0)	6 (30.0)
Aspartate aminotransferase increased	7 (35.0)	1 (5.0)	1 (5.0)	3 (15.0)	2 (10.0)
Alanine aminotransferase increased	6 (30.0)	1 (5.0)	1 (5.0)	4 (20.0)	0
Lymphocyte count decreased	4 (20.0)	1 (5.0)	1 (5.0)	1 (5.0)	1 (5.0)
Blood bilirubin increased	3 (15.0)	0	2 (10.0)	1 (5.0)	0
Platelet count decreased	3 (15.0)	0	0	0	3 (15.0)
Blood fibrinogen decreased	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Blood urea increased	2 (10.0)	1 (5.0)	0	1 (5.0)	0
International normalised ratio increased	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Lipase increased	2 (10.0)	0	0	0	2 (10.0)
Prothrombin time prolonged	2 (10.0)	2 (10.0)	0	0	0
Activated partial thromboplastin time prolonged	1 (5.0)	1 (5.0)	0	0	0
Blood creatinine increased	1 (5.0)	0	0	1 (5.0)	0
Blood immunoglobulin g decreased	1 (5.0)	0	1 (5.0)	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Blood lactic acid increased	1 (5.0)	0	0	0	1 (5.0)
Blood phosphorus decreased	1 (5.0)	1 (5.0)	0	0	0
Blood phosphorus increased	1 (5.0)	1 (5.0)	0	0	0
Blood sodium increased	1 (5.0)	0	1 (5.0)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	1 (5.0)	1 (5.0)	0	0	0
Fibrin d dimer increased	1 (5.0)	1 (5.0)	0	0	0
Oxygen saturation decreased	1 (5.0)	1 (5.0)	0	0	0
Protein total decreased	1 (5.0)	0	0	1 (5.0)	0
Pulmonary function test decreased	1 (5.0)	0	1 (5.0)	0	0
Serum ferritin increased	1 (5.0)	0	1 (5.0)	0	0
Transaminases increased	1 (5.0)	1 (5.0)	0	0	0
Weight decreased	1 (5.0)	0	1 (5.0)	0	0
Weight increased	1 (5.0)	0	1 (5.0)	0	0
Metabolism and nutrition disorders					
-Total	14 (70.0)	3 (15.0)	3 (15.0)	7 (35.0)	1 (5.0)
Decreased appetite	7 (35.0)	2 (10.0)	2 (10.0)	3 (15.0)	0
Hypokalaemia	7 (35.0)	0	2 (10.0)	5 (25.0)	0
Hypophosphataemia	5 (25.0)	2 (10.0)	0	2 (10.0)	1 (5.0)
Hypertriglyceridaemia	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Hypoalbuminaemia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Hypocalcaemia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Acidosis	1 (5.0)	0	0	1 (5.0)	0
Dehydration	1 (5.0)	0	0	1 (5.0)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fluid overload	1 (5.0)	1 (5.0)	0	0	0
Hyperalbuminaemia	1 (5.0)	1 (5.0)	0	0	0
Hypercalcaemia	1 (5.0)	1 (5.0)	0	0	0
Hyperchloraemia	1 (5.0)	1 (5.0)	0	0	0
Hyperglycaemia	1 (5.0)	0	1 (5.0)	0	0
Hypermagnesaemia	1 (5.0)	1 (5.0)	0	0	0
Hypernatraemia	1 (5.0)	0	1 (5.0)	0	0
Hyperphosphataemia	1 (5.0)	1 (5.0)	0	0	0
Hypomagnesaemia	1 (5.0)	1 (5.0)	0	0	0
Hyponatraemia	1 (5.0)	0	0	1 (5.0)	0
Malnutrition	1 (5.0)	0	0	1 (5.0)	0
Metabolic alkalosis	1 (5.0)	1 (5.0)	0	0	0
Tumour lysis syndrome	1 (5.0)	0	0	1 (5.0)	0
Vitamin d deficiency	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	9 (45.0)	5 (25.0)	4 (20.0)	0	0
Pain in extremity	7 (35.0)	4 (20.0)	3 (15.0)	0	0
Osteopenia	1 (5.0)	0	1 (5.0)	0	0
Toe walking	1 (5.0)	1 (5.0)	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (10.0)	0	1 (5.0)	0	1 (5.0)
Glioblastoma multiforme	1 (5.0)	0	0	0	1 (5.0)
Skin papilloma	1 (5.0)	0	1 (5.0)	0	0
Nervous system disorders					
-Total	10 (50.0)	6 (30.0)	1 (5.0)	2 (10.0)	1 (5.0)
Headache	7 (35.0)	6 (30.0)	1 (5.0)	0	0
Dizziness	2 (10.0)	2 (10.0)	0	0	0
Seizure	2 (10.0)	0	0	2 (10.0)	0
Depressed level of consciousness	1 (5.0)	1 (5.0)	0	0	0
Embolic stroke	1 (5.0)	0	0	0	1 (5.0)
Migraine	1 (5.0)	0	1 (5.0)	0	0
Psychiatric disorders					
-Total	4 (20.0)	2 (10.0)	2 (10.0)	0	0
Confusional state	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Anxiety	1 (5.0)	1 (5.0)	0	0	0
Delirium	1 (5.0)	0	1 (5.0)	0	0
Insomnia	1 (5.0)	0	1 (5.0)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	1 (5.0)	1 (5.0)	0	0	0
Renal and urinary disorders					
-Total	5 (25.0)	1 (5.0)	2 (10.0)	2 (10.0)	0
Acute kidney injury	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Dysuria	1 (5.0)	0	1 (5.0)	0	0
Pollakiuria	1 (5.0)	1 (5.0)	0	0	0
Renal impairment	1 (5.0)	0	0	1 (5.0)	0
Urinary incontinence	1 (5.0)	1 (5.0)	0	0	0
Reproductive system and breast disorders					
-Total	2 (10.0)	2 (10.0)	0	0	0
Vulvovaginal adhesion	2 (10.0)	2 (10.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	12 (60.0)	3 (15.0)	4 (20.0)	3 (15.0)	2 (10.0)
Cough	5 (25.0)	5 (25.0)	0	0	0
Hypoxia	4 (20.0)	0	1 (5.0)	3 (15.0)	0
Pleural effusion	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0
Rhinorrhoea	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Epistaxis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Oropharyngeal pain	2 (10.0)	2 (10.0)	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	2 (10.0)	0	0	2 (10.0)	0
Nasal congestion	1 (5.0)	1 (5.0)	0	0	0
Respiratory distress	1 (5.0)	0	0	0	1 (5.0)
Respiratory failure	1 (5.0)	0	0	0	1 (5.0)
Rhinitis allergic	1 (5.0)	0	1 (5.0)	0	0
Tachypnoea	1 (5.0)	0	1 (5.0)	0	0
Wheezing	1 (5.0)	0	1 (5.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (45.0)	7 (35.0)	2 (10.0)	0	0
Rash	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Hyperhidrosis	2 (10.0)	2 (10.0)	0	0	0
Rash maculo-papular	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Rash papular	2 (10.0)	2 (10.0)	0	0	0
Dermatitis diaper	1 (5.0)	1 (5.0)	0	0	0
Erythema	1 (5.0)	1 (5.0)	0	0	0
Macule	1 (5.0)	1 (5.0)	0	0	0
Papule	1 (5.0)	1 (5.0)	0	0	0
Petechiae	1 (5.0)	1 (5.0)	0	0	0
Pruritus	1 (5.0)	1 (5.0)	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash erythematous	1 (5.0)	1 (5.0)	0	0	0
Rash follicular	1 (5.0)	1 (5.0)	0	0	0
Rash macular	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	8 (40.0)	2 (10.0)	1 (5.0)	2 (10.0)	3 (15.0)
Hypertension	5 (25.0)	2 (10.0)	3 (15.0)	0	0
Hypotension	5 (25.0)	1 (5.0)	0	1 (5.0)	3 (15.0)
Flushing	2 (10.0)	2 (10.0)	0	0	0
Capillary leak syndrome	1 (5.0)	0	0	0	1 (5.0)
Embolism	1 (5.0)	0	0	1 (5.0)	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=34		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (100)	0	2 (5.9)	7 (20.6)	25 (73.5)
Blood and lymphatic system disorders					
-Total	28 (82.4)	0	2 (5.9)	16 (47.1)	10 (29.4)
Anaemia	18 (52.9)	1 (2.9)	4 (11.8)	12 (35.3)	1 (2.9)
Febrile neutropenia	16 (47.1)	0	0	15 (44.1)	1 (2.9)
Neutropenia	8 (23.5)	0	0	1 (2.9)	7 (20.6)
Thrombocytopenia	5 (14.7)	0	0	3 (8.8)	2 (5.9)
Disseminated intravascular coagulation	3 (8.8)	0	2 (5.9)	1 (2.9)	0
Lymphopenia	3 (8.8)	0	1 (2.9)	1 (2.9)	1 (2.9)
Eosinophilia	1 (2.9)	0	0	1 (2.9)	0
Lymphadenopathy	1 (2.9)	0	1 (2.9)	0	0
Cardiac disorders					

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (32.4)	5 (14.7)	5 (14.7)	1 (2.9)	0
Tachycardia	9 (26.5)	6 (17.6)	2 (5.9)	1 (2.9)	0
Sinus tachycardia	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Pericardial effusion	1 (2.9)	1 (2.9)	0	0	0
Sinus bradycardia	1 (2.9)	1 (2.9)	0	0	0
Ventricular tachycardia	1 (2.9)	0	1 (2.9)	0	0
Ear and labyrinth disorders					
-Total	1 (2.9)	1 (2.9)	0	0	0
Ear pain	1 (2.9)	1 (2.9)	0	0	0
Endocrine disorders					
-Total	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Adrenal insufficiency	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Eye disorders					
-Total	9 (26.5)	4 (11.8)	5 (14.7)	0	0
Eye pain	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Vision blurred	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Periorbital oedema	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Conjunctival haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Dry eye	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ocular hyperaemia	1 (2.9)	1 (2.9)	0	0	0
Ocular hypertension	1 (2.9)	0	1 (2.9)	0	0
Photophobia	1 (2.9)	0	1 (2.9)	0	0
Retinal haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Uveitis	1 (2.9)	0	1 (2.9)	0	0
Gastrointestinal disorders					
-Total	25 (73.5)	9 (26.5)	11 (32.4)	5 (14.7)	0
Vomiting	14 (41.2)	10 (29.4)	2 (5.9)	2 (5.9)	0
Nausea	12 (35.3)	4 (11.8)	7 (20.6)	1 (2.9)	0
Diarrhoea	11 (32.4)	6 (17.6)	4 (11.8)	1 (2.9)	0
Abdominal pain	6 (17.6)	4 (11.8)	2 (5.9)	0	0
Constipation	3 (8.8)	3 (8.8)	0	0	0
Abdominal pain upper	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Haematemesis	2 (5.9)	2 (5.9)	0	0	0
Oral pain	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Stomatitis	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Abdominal distension	1 (2.9)	0	1 (2.9)	0	0
Abdominal pain lower	1 (2.9)	0	1 (2.9)	0	0
Anal incontinence	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphagia	1 (2.9)	0	1 (2.9)	0	0
Flatulence	1 (2.9)	1 (2.9)	0	0	0
Gastrointestinal haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Gastrooesophageal reflux disease	1 (2.9)	1 (2.9)	0	0	0
Glossodynia	1 (2.9)	1 (2.9)	0	0	0
Lip pain	1 (2.9)	0	1 (2.9)	0	0
Mouth haemorrhage	1 (2.9)	0	0	1 (2.9)	0
Pigmentation lip	1 (2.9)	1 (2.9)	0	0	0
General disorders and administration site conditions					
-Total	23 (67.6)	9 (26.5)	8 (23.5)	5 (14.7)	1 (2.9)
Pyrexia	12 (35.3)	3 (8.8)	6 (17.6)	2 (5.9)	1 (2.9)
Fatigue	9 (26.5)	8 (23.5)	0	1 (2.9)	0
Chills	6 (17.6)	5 (14.7)	1 (2.9)	0	0
Pain	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Catheter site pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Generalised oedema	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Malaise	2 (5.9)	0	2 (5.9)	0	0
Catheter site extravasation	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Face oedema	1 (2.9)	0	1 (2.9)	0	0
Influenza like illness	1 (2.9)	1 (2.9)	0	0	0
Injection site haematoma	1 (2.9)	1 (2.9)	0	0	0
Non-cardiac chest pain	1 (2.9)	1 (2.9)	0	0	0
Oedema peripheral	1 (2.9)	1 (2.9)	0	0	0
Peripheral swelling	1 (2.9)	0	1 (2.9)	0	0
Physical deconditioning	1 (2.9)	0	0	1 (2.9)	0
Hepatobiliary disorders					
-Total	4 (11.8)	2 (5.9)	1 (2.9)	1 (2.9)	0
Hepatomegaly	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Hyperbilirubinaemia	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Gallbladder enlargement	1 (2.9)	1 (2.9)	0	0	0
Immune system disorders					
-Total	31 (91.2)	4 (11.8)	14 (41.2)	8 (23.5)	5 (14.7)
Cytokine release syndrome	26 (76.5)	4 (11.8)	12 (35.3)	5 (14.7)	5 (14.7)
Hypogammaglobulinaemia	19 (55.9)	2 (5.9)	14 (41.2)	3 (8.8)	0
Graft versus host disease	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Immunodeficiency common variable	2 (5.9)	0	2 (5.9)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug hypersensitivity	1 (2.9)	0	1 (2.9)	0	0
Graft versus host disease in gastrointestinal tract	1 (2.9)	0	1 (2.9)	0	0
Graft versus host disease in skin	1 (2.9)	1 (2.9)	0	0	0
Immunodeficiency	1 (2.9)	0	1 (2.9)	0	0
Seasonal allergy	1 (2.9)	1 (2.9)	0	0	0
Infections and infestations					
-Total	22 (64.7)	4 (11.8)	11 (32.4)	7 (20.6)	0
Upper respiratory tract infection	5 (14.7)	2 (5.9)	2 (5.9)	1 (2.9)	0
Otitis media	3 (8.8)	0	3 (8.8)	0	0
Urinary tract infection	3 (8.8)	0	1 (2.9)	2 (5.9)	0
Clostridium difficile colitis	2 (5.9)	0	2 (5.9)	0	0
Gastroenteritis	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Influenza	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Rhinovirus infection	2 (5.9)	2 (5.9)	0	0	0
Viral infection	2 (5.9)	2 (5.9)	0	0	0
Acute sinusitis	1 (2.9)	0	1 (2.9)	0	0
Body tinea	1 (2.9)	1 (2.9)	0	0	0
Catheter site cellulitis	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (2.9)	0	0	1 (2.9)	0
Clostridium difficile infection	1 (2.9)	0	1 (2.9)	0	0
Cytomegalovirus infection	1 (2.9)	1 (2.9)	0	0	0
Enterococcal infection	1 (2.9)	1 (2.9)	0	0	0
Escherichia urinary tract infection	1 (2.9)	0	0	1 (2.9)	0
Fungal skin infection	1 (2.9)	1 (2.9)	0	0	0
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Gingivitis	1 (2.9)	1 (2.9)	0	0	0
Herpes simplex	1 (2.9)	1 (2.9)	0	0	0
Herpes zoster	1 (2.9)	0	0	1 (2.9)	0
Hypopyon	1 (2.9)	0	1 (2.9)	0	0
Meningitis aseptic	1 (2.9)	0	1 (2.9)	0	0
Oral herpes	1 (2.9)	0	1 (2.9)	0	0
Orchitis	1 (2.9)	1 (2.9)	0	0	0
Parainfluenzae virus infection	1 (2.9)	1 (2.9)	0	0	0
Pharyngitis	1 (2.9)	0	1 (2.9)	0	0
Pneumonia	1 (2.9)	0	1 (2.9)	0	0
Rhinitis	1 (2.9)	1 (2.9)	0	0	0
Sinusitis	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal infection	1 (2.9)	0	0	1 (2.9)	0
Streptococcal infection	1 (2.9)	0	1 (2.9)	0	0
Subcutaneous abscess	1 (2.9)	0	1 (2.9)	0	0
Vascular device infection	1 (2.9)	0	0	1 (2.9)	0
Viral upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Vulvovaginal mycotic infection	1 (2.9)	0	1 (2.9)	0	0
Injury, poisoning and procedural complications					
-Total	10 (29.4)	4 (11.8)	4 (11.8)	1 (2.9)	1 (2.9)
Contusion	2 (5.9)	2 (5.9)	0	0	0
Infusion related reaction	2 (5.9)	0	2 (5.9)	0	0
Procedural pain	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Arthropod bite	1 (2.9)	1 (2.9)	0	0	0
Mouth injury	1 (2.9)	1 (2.9)	0	0	0
Post procedural haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Procedural headache	1 (2.9)	0	1 (2.9)	0	0
Procedural nausea	1 (2.9)	0	1 (2.9)	0	0
Skin abrasion	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin laceration	1 (2.9)	0	1 (2.9)	0	0
Subdural haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Sunburn	1 (2.9)	1 (2.9)	0	0	0
Tongue injury	1 (2.9)	1 (2.9)	0	0	0
Transfusion reaction	1 (2.9)	1 (2.9)	0	0	0
Transfusion related complication	1 (2.9)	0	0	0	1 (2.9)
Investigations					
-Total	31 (91.2)	2 (5.9)	3 (8.8)	7 (20.6)	19 (55.9)
White blood cell count decreased	21 (61.8)	2 (5.9)	1 (2.9)	7 (20.6)	11 (32.4)
Neutrophil count decreased	18 (52.9)	1 (2.9)	1 (2.9)	3 (8.8)	13 (38.2)
Platelet count decreased	14 (41.2)	2 (5.9)	1 (2.9)	3 (8.8)	8 (23.5)
Alanine aminotransferase increased	13 (38.2)	3 (8.8)	1 (2.9)	9 (26.5)	0
Lymphocyte count decreased	11 (32.4)	0	2 (5.9)	6 (17.6)	3 (8.8)
Aspartate aminotransferase increased	10 (29.4)	2 (5.9)	3 (8.8)	4 (11.8)	1 (2.9)
Blood creatinine increased	8 (23.5)	5 (14.7)	2 (5.9)	1 (2.9)	0
International normalised ratio increased	6 (17.6)	6 (17.6)	0	0	0
Blood bilirubin increased	5 (14.7)	2 (5.9)	1 (2.9)	2 (5.9)	0
Activated partial thromboplastin time prolonged	4 (11.8)	2 (5.9)	2 (5.9)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prothrombin time prolonged	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Blood immunoglobulin a decreased	3 (8.8)	3 (8.8)	0	0	0
Blood immunoglobulin m decreased	2 (5.9)	2 (5.9)	0	0	0
Blood magnesium decreased	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Haemoglobin decreased	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Blood alkaline phosphatase increased	1 (2.9)	1 (2.9)	0	0	0
Blood bicarbonate decreased	1 (2.9)	0	1 (2.9)	0	0
Blood lactate dehydrogenase increased	1 (2.9)	1 (2.9)	0	0	0
Blood phosphorus increased	1 (2.9)	1 (2.9)	0	0	0
Blood urea increased	1 (2.9)	0	1 (2.9)	0	0
Blood uric acid increased	1 (2.9)	1 (2.9)	0	0	0
C-reactive protein increased	1 (2.9)	1 (2.9)	0	0	0
Cardiac murmur	1 (2.9)	1 (2.9)	0	0	0
Culture stool positive	1 (2.9)	1 (2.9)	0	0	0
Norovirus test positive	1 (2.9)	1 (2.9)	0	0	0
Serum ferritin increased	1 (2.9)	0	1 (2.9)	0	0
Transaminases increased	1 (2.9)	1 (2.9)	0	0	0
Weight decreased	1 (2.9)	1 (2.9)	0	0	0
Weight increased	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	22 (64.7)	5 (14.7)	3 (8.8)	12 (35.3)	2 (5.9)
Decreased appetite	11 (32.4)	3 (8.8)	2 (5.9)	6 (17.6)	0
Hypokalaemia	9 (26.5)	2 (5.9)	3 (8.8)	3 (8.8)	1 (2.9)
Hyperphosphataemia	6 (17.6)	6 (17.6)	0	0	0
Hypophosphataemia	4 (11.8)	0	0	4 (11.8)	0
Hypernatraemia	3 (8.8)	1 (2.9)	1 (2.9)	0	1 (2.9)
Hypoalbuminaemia	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Dehydration	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Hyperuricaemia	2 (5.9)	2 (5.9)	0	0	0
Acidosis	1 (2.9)	1 (2.9)	0	0	0
Fluid overload	1 (2.9)	0	1 (2.9)	0	0
Hyperglycaemia	1 (2.9)	0	0	1 (2.9)	0
Hypocalcaemia	1 (2.9)	0	0	1 (2.9)	0
Hyponatraemia	1 (2.9)	0	0	1 (2.9)	0
Iron overload	1 (2.9)	0	0	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	0	0	1 (2.9)	0
Vitamin d deficiency	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	14 (41.2)	8 (23.5)	5 (14.7)	1 (2.9)	0
Myalgia	5 (14.7)	4 (11.8)	1 (2.9)	0	0
Arthralgia	4 (11.8)	3 (8.8)	0	1 (2.9)	0
Muscular weakness	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Pain in extremity	3 (8.8)	3 (8.8)	0	0	0
Joint range of motion decreased	2 (5.9)	2 (5.9)	0	0	0
Muscle spasms	2 (5.9)	2 (5.9)	0	0	0
Musculoskeletal chest pain	2 (5.9)	2 (5.9)	0	0	0
Musculoskeletal pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Back pain	1 (2.9)	1 (2.9)	0	0	0
Coccydynia	1 (2.9)	1 (2.9)	0	0	0
Flank pain	1 (2.9)	0	1 (2.9)	0	0
Neck pain	1 (2.9)	0	1 (2.9)	0	0
Osteonecrosis	1 (2.9)	0	1 (2.9)	0	0
Pain in jaw	1 (2.9)	1 (2.9)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.9)	0	1 (2.9)	0	0
Myelodysplastic syndrome	1 (2.9)	0	1 (2.9)	0	0
Nervous system disorders					
-Total	20 (58.8)	9 (26.5)	8 (23.5)	3 (8.8)	0
Headache	15 (44.1)	8 (23.5)	5 (14.7)	2 (5.9)	0
Encephalopathy	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Dysarthria	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Seizure	2 (5.9)	0	2 (5.9)	0	0
Tremor	2 (5.9)	2 (5.9)	0	0	0
Asterixis	1 (2.9)	1 (2.9)	0	0	0
Ataxia	1 (2.9)	0	1 (2.9)	0	0
Disturbance in attention	1 (2.9)	1 (2.9)	0	0	0
Dizziness	1 (2.9)	1 (2.9)	0	0	0
Myoclonus	1 (2.9)	1 (2.9)	0	0	0
Neuropathy peripheral	1 (2.9)	0	1 (2.9)	0	0
Peroneal nerve palsy	1 (2.9)	1 (2.9)	0	0	0
Pleocytosis	1 (2.9)	1 (2.9)	0	0	0
Somnolence	1 (2.9)	1 (2.9)	0	0	0
Product issues					

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.9)	1 (2.9)	0	0	0
Device occlusion	1 (2.9)	1 (2.9)	0	0	0
Psychiatric disorders					
-Total	9 (26.5)	4 (11.8)	5 (14.7)	0	0
Anxiety	5 (14.7)	2 (5.9)	3 (8.8)	0	0
Confusional state	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Agitation	2 (5.9)	0	2 (5.9)	0	0
Delirium	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Depression	2 (5.9)	2 (5.9)	0	0	0
Hallucination	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Adjustment disorder	1 (2.9)	0	1 (2.9)	0	0
Irritability	1 (2.9)	1 (2.9)	0	0	0
Listless	1 (2.9)	1 (2.9)	0	0	0
Mental status changes	1 (2.9)	1 (2.9)	0	0	0
Sleep disorder	1 (2.9)	0	1 (2.9)	0	0
Suicidal ideation	1 (2.9)	1 (2.9)	0	0	0
Renal and urinary disorders					
-Total	8 (23.5)	2 (5.9)	0	4 (11.8)	2 (5.9)
Acute kidney injury	5 (14.7)	1 (2.9)	0	3 (8.8)	1 (2.9)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	3 (8.8)	0	1 (2.9)	1 (2.9)	1 (2.9)
Oliguria	2 (5.9)	0	0	2 (5.9)	0
Calculus urinary	1 (2.9)	0	1 (2.9)	0	0
Dysuria	1 (2.9)	1 (2.9)	0	0	0
Nephrolithiasis	1 (2.9)	0	0	1 (2.9)	0
Renal failure	1 (2.9)	0	0	0	1 (2.9)
Reproductive system and breast disorders					
-Total	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Ovarian failure	1 (2.9)	0	0	1 (2.9)	0
Scrotal pain	1 (2.9)	0	1 (2.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	22 (64.7)	10 (29.4)	4 (11.8)	4 (11.8)	4 (11.8)
Cough	8 (23.5)	6 (17.6)	2 (5.9)	0	0
Epistaxis	7 (20.6)	3 (8.8)	0	3 (8.8)	1 (2.9)
Hypoxia	4 (11.8)	0	2 (5.9)	1 (2.9)	1 (2.9)
Nasal congestion	4 (11.8)	4 (11.8)	0	0	0
Oropharyngeal pain	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Pulmonary oedema	4 (11.8)	1 (2.9)	0	2 (5.9)	1 (2.9)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	4 (11.8)	3 (8.8)	0	1 (2.9)	0
Rhinorrhoea	3 (8.8)	3 (8.8)	0	0	0
Haemoptysis	2 (5.9)	1 (2.9)	0	0	1 (2.9)
Pleural effusion	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Respiratory failure	2 (5.9)	0	0	0	2 (5.9)
Rhinitis allergic	2 (5.9)	2 (5.9)	0	0	0
Acute respiratory failure	1 (2.9)	0	0	0	1 (2.9)
Atelectasis	1 (2.9)	1 (2.9)	0	0	0
Dysphonia	1 (2.9)	1 (2.9)	0	0	0
Dyspnoea	1 (2.9)	0	0	1 (2.9)	0
Oropharyngeal plaque	1 (2.9)	1 (2.9)	0	0	0
Pharyngeal erythema	1 (2.9)	1 (2.9)	0	0	0
Pharyngeal lesion	1 (2.9)	0	0	1 (2.9)	0
Pharyngeal ulceration	1 (2.9)	0	1 (2.9)	0	0
Respiratory depression	1 (2.9)	0	1 (2.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	18 (52.9)	10 (29.4)	6 (17.6)	2 (5.9)	0
Dry skin	5 (14.7)	5 (14.7)	0	0	0
Rash	4 (11.8)	2 (5.9)	2 (5.9)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	3 (8.8)	3 (8.8)	0	0	0
Ingrowing nail	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Petechiae	2 (5.9)	2 (5.9)	0	0	0
Pruritus	2 (5.9)	2 (5.9)	0	0	0
Rash maculo-papular	2 (5.9)	2 (5.9)	0	0	0
Acne	1 (2.9)	1 (2.9)	0	0	0
Alopecia	1 (2.9)	0	1 (2.9)	0	0
Dermatitis	1 (2.9)	1 (2.9)	0	0	0
Dermatitis acneiform	1 (2.9)	0	0	1 (2.9)	0
Dermatitis atopic	1 (2.9)	1 (2.9)	0	0	0
Ecchymosis	1 (2.9)	0	0	1 (2.9)	0
Eczema	1 (2.9)	1 (2.9)	0	0	0
Hyperhidrosis	1 (2.9)	1 (2.9)	0	0	0
Keloid scar	1 (2.9)	0	1 (2.9)	0	0
Livedo reticularis	1 (2.9)	1 (2.9)	0	0	0
Macule	1 (2.9)	1 (2.9)	0	0	0
Night sweats	1 (2.9)	0	1 (2.9)	0	0
Papule	1 (2.9)	1 (2.9)	0	0	0
Rash erythematous	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash pruritic	1 (2.9)	1 (2.9)	0	0	0
Rash vesicular	1 (2.9)	1 (2.9)	0	0	0
Skin exfoliation	1 (2.9)	1 (2.9)	0	0	0
Skin fissures	1 (2.9)	1 (2.9)	0	0	0
Skin irritation	1 (2.9)	1 (2.9)	0	0	0
Vascular disorders					
-Total	12 (35.3)	0	3 (8.8)	5 (14.7)	4 (11.8)
Hypotension	9 (26.5)	0	0	5 (14.7)	4 (11.8)
Hypertension	4 (11.8)	1 (2.9)	2 (5.9)	1 (2.9)	0
Haematoma	1 (2.9)	0	1 (2.9)	0	0
Hot flush	1 (2.9)	1 (2.9)	0	0	0
Orthostatic hypotension	1 (2.9)	0	1 (2.9)	0	0
Secondary hypertension	1 (2.9)	0	1 (2.9)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174a
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (100)	0	0	2 (20.0)	8 (80.0)
Blood and lymphatic system disorders					
-Total	7 (70.0)	0	0	3 (30.0)	4 (40.0)
Anaemia	3 (30.0)	0	0	3 (30.0)	0
Neutropenia	3 (30.0)	0	0	2 (20.0)	1 (10.0)
Thrombocytopenia	3 (30.0)	0	0	0	3 (30.0)
Febrile neutropenia	2 (20.0)	0	0	2 (20.0)	0
Lymphopenia	1 (10.0)	0	1 (10.0)	0	0
Pancytopenia	1 (10.0)	0	0	0	1 (10.0)
Cardiac disorders					
-Total	4 (40.0)	1 (10.0)	2 (20.0)	1 (10.0)	0
Tachycardia	4 (40.0)	1 (10.0)	2 (20.0)	1 (10.0)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (10.0)	0	0	1 (10.0)	0
Ear and labyrinth disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Hypoacusis	1 (10.0)	0	1 (10.0)	0	0
Eye disorders					
-Total	2 (20.0)	0	2 (20.0)	0	0
Papilloedema	1 (10.0)	0	1 (10.0)	0	0
Uveitis	1 (10.0)	0	1 (10.0)	0	0
Visual impairment	1 (10.0)	0	1 (10.0)	0	0
Gastrointestinal disorders					
-Total	5 (50.0)	1 (10.0)	2 (20.0)	2 (20.0)	0
Diarrhoea	5 (50.0)	2 (20.0)	2 (20.0)	1 (10.0)	0
Nausea	4 (40.0)	0	2 (20.0)	2 (20.0)	0
Vomiting	4 (40.0)	1 (10.0)	2 (20.0)	1 (10.0)	0
Abdominal discomfort	1 (10.0)	1 (10.0)	0	0	0
Abdominal pain	1 (10.0)	0	0	1 (10.0)	0
Abdominal pain upper	1 (10.0)	0	1 (10.0)	0	0
Constipation	1 (10.0)	0	1 (10.0)	0	0
Dyspepsia	1 (10.0)	0	1 (10.0)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Intestinal obstruction	1 (10.0)	0	0	1 (10.0)	0
General disorders and administration site conditions					
-Total	7 (70.0)	2 (20.0)	3 (30.0)	2 (20.0)	0
Pyrexia	6 (60.0)	2 (20.0)	2 (20.0)	2 (20.0)	0
Chills	3 (30.0)	3 (30.0)	0	0	0
Fatigue	2 (20.0)	0	2 (20.0)	0	0
Asthenia	1 (10.0)	1 (10.0)	0	0	0
Facial pain	1 (10.0)	0	1 (10.0)	0	0
Influenza like illness	1 (10.0)	1 (10.0)	0	0	0
Malaise	1 (10.0)	0	1 (10.0)	0	0
Hepatobiliary disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Hepatomegaly	1 (10.0)	0	1 (10.0)	0	0
Immune system disorders					
-Total	8 (80.0)	0	5 (50.0)	0	3 (30.0)
Cytokine release syndrome	8 (80.0)	0	5 (50.0)	0	3 (30.0)
Hypogammaglobulinaemia	3 (30.0)	0	3 (30.0)	0	0
Infections and infestations					

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (70.0)	0	4 (40.0)	1 (10.0)	2 (20.0)
Influenza	2 (20.0)	0	2 (20.0)	0	0
Bacterial sepsis	1 (10.0)	0	0	0	1 (10.0)
Cholecystitis infective	1 (10.0)	0	0	1 (10.0)	0
Folliculitis	1 (10.0)	0	1 (10.0)	0	0
Human herpesvirus 6 infection	1 (10.0)	0	1 (10.0)	0	0
Pneumonia	1 (10.0)	0	1 (10.0)	0	0
Sepsis	1 (10.0)	0	0	0	1 (10.0)
Sinusitis	1 (10.0)	0	1 (10.0)	0	0
Upper respiratory tract infection	1 (10.0)	0	1 (10.0)	0	0
Urinary tract infection enterococcal	1 (10.0)	0	0	1 (10.0)	0
Injury, poisoning and procedural complications					
-Total	4 (40.0)	1 (10.0)	2 (20.0)	1 (10.0)	0
Foot fracture	1 (10.0)	0	1 (10.0)	0	0
Incision site pain	1 (10.0)	1 (10.0)	0	0	0
Limb injury	1 (10.0)	1 (10.0)	0	0	0
Tracheal haemorrhage	1 (10.0)	0	0	1 (10.0)	0
Transfusion reaction	1 (10.0)	0	1 (10.0)	0	0
Investigations					

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (90.0)	0	0	4 (40.0)	5 (50.0)
White blood cell count decreased	4 (40.0)	0	0	2 (20.0)	2 (20.0)
Aspartate aminotransferase increased	3 (30.0)	1 (10.0)	0	1 (10.0)	1 (10.0)
Platelet count decreased	3 (30.0)	1 (10.0)	1 (10.0)	0	1 (10.0)
Prothrombin time prolonged	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Alanine aminotransferase increased	2 (20.0)	1 (10.0)	0	1 (10.0)	0
Blood fibrinogen decreased	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Neutrophil count decreased	2 (20.0)	0	0	0	2 (20.0)
Weight decreased	2 (20.0)	0	2 (20.0)	0	0
Blood immunoglobulin m decreased	1 (10.0)	1 (10.0)	0	0	0
C-reactive protein increased	1 (10.0)	0	0	1 (10.0)	0
Haemoglobin decreased	1 (10.0)	1 (10.0)	0	0	0
Hepatic enzyme increased	1 (10.0)	0	1 (10.0)	0	0
International normalised ratio increased	1 (10.0)	1 (10.0)	0	0	0
Lymphocyte count decreased	1 (10.0)	0	0	0	1 (10.0)
Transaminases increased	1 (10.0)	1 (10.0)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (70.0)	0	2 (20.0)	4 (40.0)	1 (10.0)
Decreased appetite	4 (40.0)	0	1 (10.0)	3 (30.0)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	3 (30.0)	2 (20.0)	1 (10.0)	0	0
Dehydration	1 (10.0)	0	0	1 (10.0)	0
Fluid overload	1 (10.0)	0	1 (10.0)	0	0
Hyperglycaemia	1 (10.0)	0	0	1 (10.0)	0
Hyperphosphataemia	1 (10.0)	1 (10.0)	0	0	0
Hyperuricaemia	1 (10.0)	0	0	0	1 (10.0)
Hypophosphataemia	1 (10.0)	0	0	1 (10.0)	0
Metabolic acidosis	1 (10.0)	0	1 (10.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Arthralgia	1 (10.0)	0	1 (10.0)	0	0
Limb discomfort	1 (10.0)	1 (10.0)	0	0	0
Musculoskeletal pain	1 (10.0)	1 (10.0)	0	0	0
Pain in extremity	1 (10.0)	0	1 (10.0)	0	0
Nervous system disorders					
-Total	5 (50.0)	2 (20.0)	3 (30.0)	0	0
Dizziness	3 (30.0)	3 (30.0)	0	0	0
Headache	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Idiopathic intracranial hypertension	1 (10.0)	0	1 (10.0)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Peroneal nerve palsy	1 (10.0)	0	1 (10.0)	0	0
Psychiatric disorders					
-Total	4 (40.0)	2 (20.0)	1 (10.0)	1 (10.0)	0
Anxiety	1 (10.0)	0	0	1 (10.0)	0
Confusional state	1 (10.0)	1 (10.0)	0	0	0
Delirium	1 (10.0)	1 (10.0)	0	0	0
Panic attack	1 (10.0)	0	1 (10.0)	0	0
Renal and urinary disorders					
-Total	2 (20.0)	0	0	0	2 (20.0)
Acute kidney injury	2 (20.0)	0	0	0	2 (20.0)
Haematuria	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Reproductive system and breast disorders					
-Total	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Oedema genital	1 (10.0)	0	1 (10.0)	0	0
Vaginal haemorrhage	1 (10.0)	0	0	1 (10.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (40.0)	1 (10.0)	1 (10.0)	0	2 (20.0)
Hypoxia	2 (20.0)	0	0	0	2 (20.0)
Pleural effusion	2 (20.0)	0	2 (20.0)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	1 (10.0)	1 (10.0)	0	0	0
Dyspnoea	1 (10.0)	0	0	0	1 (10.0)
Epistaxis	1 (10.0)	1 (10.0)	0	0	0
Interstitial lung disease	1 (10.0)	0	0	0	1 (10.0)
Pulmonary oedema	1 (10.0)	0	0	0	1 (10.0)
Rhinitis allergic	1 (10.0)	1 (10.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (30.0)	1 (10.0)	1 (10.0)	1 (10.0)	0
Erythema	1 (10.0)	1 (10.0)	0	0	0
Hyperhidrosis	1 (10.0)	1 (10.0)	0	0	0
Ingrowing nail	1 (10.0)	0	1 (10.0)	0	0
Petechiae	1 (10.0)	0	1 (10.0)	0	0
Pruritus	1 (10.0)	1 (10.0)	0	0	0
Rash	1 (10.0)	1 (10.0)	0	0	0
Rash maculo-papular	1 (10.0)	0	0	1 (10.0)	0
Vascular disorders					
-Total	5 (50.0)	1 (10.0)	2 (20.0)	1 (10.0)	1 (10.0)
Hypertension	3 (30.0)	0	3 (30.0)	0	0
Hypotension	2 (20.0)	0	0	1 (10.0)	1 (10.0)

Timing: Any time post CTL019 infusion, Age: >=18

Primary system organ class Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Orthostatic hypotension	1 (10.0)	1 (10.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174b
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Male

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (96.7)	2 (6.7)	4 (13.3)	7 (23.3)	16 (53.3)
Blood and lymphatic system disorders					
-Total	18 (60.0)	1 (3.3)	0	13 (43.3)	4 (13.3)
Anaemia	13 (43.3)	3 (10.0)	2 (6.7)	8 (26.7)	0
Febrile neutropenia	10 (33.3)	0	0	10 (33.3)	0
Neutropenia	4 (13.3)	0	0	2 (6.7)	2 (6.7)
Thrombocytopenia	4 (13.3)	0	0	1 (3.3)	3 (10.0)
Disseminated intravascular coagulation	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Lymphopenia	1 (3.3)	0	0	1 (3.3)	0
Cardiac disorders					
-Total	9 (30.0)	4 (13.3)	3 (10.0)	2 (6.7)	0
Tachycardia	7 (23.3)	3 (10.0)	2 (6.7)	2 (6.7)	0
Bradycardia	1 (3.3)	0	1 (3.3)	0	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (3.3)	0	0	1 (3.3)	0
Palpitations	1 (3.3)	1 (3.3)	0	0	0
Pericardial effusion	1 (3.3)	0	1 (3.3)	0	0
Sinus bradycardia	1 (3.3)	1 (3.3)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.3)	0	1 (3.3)	0	0
Hypoacusis	1 (3.3)	0	1 (3.3)	0	0
Eye disorders					
-Total	5 (16.7)	3 (10.0)	2 (6.7)	0	0
Eye pain	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Periorbital oedema	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Conjunctival haemorrhage	1 (3.3)	1 (3.3)	0	0	0
Retinal haemorrhage	1 (3.3)	1 (3.3)	0	0	0
Vision blurred	1 (3.3)	1 (3.3)	0	0	0
Gastrointestinal disorders					
-Total	12 (40.0)	4 (13.3)	4 (13.3)	4 (13.3)	0
Vomiting	7 (23.3)	5 (16.7)	2 (6.7)	0	0
Diarrhoea	6 (20.0)	3 (10.0)	3 (10.0)	0	0
Nausea	5 (16.7)	2 (6.7)	2 (6.7)	1 (3.3)	0

Timing: within 8 weeks post infusion, Gender: Male

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Haematemesis	2 (6.7)	2 (6.7)	0	0	0
Abdominal distension	1 (3.3)	0	1 (3.3)	0	0
Anal incontinence	1 (3.3)	1 (3.3)	0	0	0
Constipation	1 (3.3)	1 (3.3)	0	0	0
Dysphagia	1 (3.3)	0	0	1 (3.3)	0
Gastrointestinal haemorrhage	1 (3.3)	1 (3.3)	0	0	0
Ileus	1 (3.3)	0	0	1 (3.3)	0
Mouth haemorrhage	1 (3.3)	0	0	1 (3.3)	0
Pancreatitis	1 (3.3)	0	1 (3.3)	0	0
Stomatitis	1 (3.3)	0	1 (3.3)	0	0
General disorders and administration site conditions					
-Total	12 (40.0)	2 (6.7)	4 (13.3)	6 (20.0)	0
Pyrexia	6 (20.0)	0	3 (10.0)	3 (10.0)	0
Chills	4 (13.3)	4 (13.3)	0	0	0
Fatigue	3 (10.0)	2 (6.7)	0	1 (3.3)	0
Pain	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Face oedema	2 (6.7)	0	1 (3.3)	1 (3.3)	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Generalised oedema	2 (6.7)	0	2 (6.7)	0	0
Asthenia	1 (3.3)	1 (3.3)	0	0	0
Catheter site extravasation	1 (3.3)	0	1 (3.3)	0	0
Catheter site pain	1 (3.3)	0	1 (3.3)	0	0
Localised oedema	1 (3.3)	0	0	1 (3.3)	0
Malaise	1 (3.3)	0	1 (3.3)	0	0
Mucosal haemorrhage	1 (3.3)	0	1 (3.3)	0	0
Multiple organ dysfunction syndrome	1 (3.3)	0	0	1 (3.3)	0
Non-cardiac chest pain	1 (3.3)	1 (3.3)	0	0	0
Oedema peripheral	1 (3.3)	0	0	1 (3.3)	0
Peripheral swelling	1 (3.3)	0	1 (3.3)	0	0
Hepatobiliary disorders					
-Total	5 (16.7)	1 (3.3)	2 (6.7)	2 (6.7)	0
Hepatomegaly	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Hyperbilirubinaemia	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Immune system disorders					
-Total	26 (86.7)	4 (13.3)	12 (40.0)	4 (13.3)	6 (20.0)
Cytokine release syndrome	23 (76.7)	4 (13.3)	10 (33.3)	3 (10.0)	6 (20.0)
Hypogammaglobulinaemia	12 (40.0)	1 (3.3)	10 (33.3)	1 (3.3)	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Drug hypersensitivity	1 (3.3)	0	1 (3.3)	0	0
Graft versus host disease in skin	1 (3.3)	1 (3.3)	0	0	0
Infections and infestations					
-Total	8 (26.7)	2 (6.7)	4 (13.3)	2 (6.7)	0
Acute sinusitis	1 (3.3)	0	1 (3.3)	0	0
Body tinea	1 (3.3)	1 (3.3)	0	0	0
Clostridium difficile colitis	1 (3.3)	0	0	1 (3.3)	0
Clostridium difficile infection	1 (3.3)	0	1 (3.3)	0	0
Fungal skin infection	1 (3.3)	1 (3.3)	0	0	0
Gastroenteritis	1 (3.3)	0	0	1 (3.3)	0
Orchitis	1 (3.3)	1 (3.3)	0	0	0
Pharyngitis	1 (3.3)	0	1 (3.3)	0	0
Skin infection	1 (3.3)	0	1 (3.3)	0	0
Streptococcal infection	1 (3.3)	0	1 (3.3)	0	0
Upper respiratory tract infection	1 (3.3)	0	1 (3.3)	0	0
Viral infection	1 (3.3)	0	1 (3.3)	0	0
Injury, poisoning and procedural complications					
-Total	4 (13.3)	2 (6.7)	1 (3.3)	1 (3.3)	0
Infusion related reaction	1 (3.3)	0	1 (3.3)	0	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mouth injury	1 (3.3)	1 (3.3)	0	0	0
Procedural complication	1 (3.3)	1 (3.3)	0	0	0
Procedural headache	1 (3.3)	0	1 (3.3)	0	0
Skin abrasion	1 (3.3)	1 (3.3)	0	0	0
Tongue injury	1 (3.3)	1 (3.3)	0	0	0
Tracheal haemorrhage	1 (3.3)	0	0	1 (3.3)	0
Investigations					
-Total	22 (73.3)	3 (10.0)	2 (6.7)	4 (13.3)	13 (43.3)
White blood cell count decreased	12 (40.0)	2 (6.7)	0	4 (13.3)	6 (20.0)
Neutrophil count decreased	11 (36.7)	0	1 (3.3)	2 (6.7)	8 (26.7)
Aspartate aminotransferase increased	8 (26.7)	0	2 (6.7)	3 (10.0)	3 (10.0)
Platelet count decreased	8 (26.7)	2 (6.7)	1 (3.3)	1 (3.3)	4 (13.3)
Alanine aminotransferase increased	7 (23.3)	2 (6.7)	0	5 (16.7)	0
Lymphocyte count decreased	5 (16.7)	1 (3.3)	1 (3.3)	1 (3.3)	2 (6.7)
Blood creatinine increased	4 (13.3)	2 (6.7)	0	2 (6.7)	0
International normalised ratio increased	4 (13.3)	4 (13.3)	0	0	0
Activated partial thromboplastin time prolonged	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Blood bilirubin increased	3 (10.0)	2 (6.7)	0	1 (3.3)	0
Blood fibrinogen decreased	2 (6.7)	0	1 (3.3)	0	1 (3.3)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	2 (6.7)	2 (6.7)	0	0	0
Blood phosphorus increased	2 (6.7)	2 (6.7)	0	0	0
Blood urea increased	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Prothrombin time prolonged	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Blood bicarbonate decreased	1 (3.3)	0	1 (3.3)	0	0
Blood immunoglobulin a decreased	1 (3.3)	1 (3.3)	0	0	0
Blood phosphorus decreased	1 (3.3)	1 (3.3)	0	0	0
Blood uric acid increased	1 (3.3)	1 (3.3)	0	0	0
C-reactive protein increased	1 (3.3)	0	0	1 (3.3)	0
Cardiac murmur	1 (3.3)	1 (3.3)	0	0	0
Fibrin d dimer increased	1 (3.3)	1 (3.3)	0	0	0
Lipase increased	1 (3.3)	0	0	0	1 (3.3)
Norovirus test positive	1 (3.3)	1 (3.3)	0	0	0
Protein total decreased	1 (3.3)	0	0	1 (3.3)	0
Metabolism and nutrition disorders					
-Total	14 (46.7)	2 (6.7)	1 (3.3)	10 (33.3)	1 (3.3)
Decreased appetite	9 (30.0)	2 (6.7)	1 (3.3)	6 (20.0)	0
Hypokalaemia	7 (23.3)	3 (10.0)	1 (3.3)	3 (10.0)	0
Hypophosphataemia	5 (16.7)	1 (3.3)	0	4 (13.3)	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	2 (6.7)	2 (6.7)	0	0	0
Hypoalbuminaemia	2 (6.7)	0	2 (6.7)	0	0
Hypocalcaemia	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Acidosis	1 (3.3)	0	0	1 (3.3)	0
Dehydration	1 (3.3)	0	0	1 (3.3)	0
Fluid overload	1 (3.3)	0	1 (3.3)	0	0
Hyperalbuminaemia	1 (3.3)	1 (3.3)	0	0	0
Hypercalcaemia	1 (3.3)	1 (3.3)	0	0	0
Hyperchloraemia	1 (3.3)	1 (3.3)	0	0	0
Hyperglycaemia	1 (3.3)	0	1 (3.3)	0	0
Hypermagnesaemia	1 (3.3)	1 (3.3)	0	0	0
Hypernatraemia	1 (3.3)	0	1 (3.3)	0	0
Hypertriglyceridaemia	1 (3.3)	0	0	1 (3.3)	0
Hyperuricaemia	1 (3.3)	0	0	0	1 (3.3)
Hyponatraemia	1 (3.3)	0	0	1 (3.3)	0
Metabolic alkalosis	1 (3.3)	1 (3.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (16.7)	2 (6.7)	2 (6.7)	1 (3.3)	0
Arthralgia	2 (6.7)	1 (3.3)	0	1 (3.3)	0

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Myalgia	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Muscle spasms	1 (3.3)	1 (3.3)	0	0	0
Muscular weakness	1 (3.3)	0	1 (3.3)	0	0
Musculoskeletal pain	1 (3.3)	1 (3.3)	0	0	0
Nervous system disorders					
-Total	15 (50.0)	9 (30.0)	5 (16.7)	1 (3.3)	0
Headache	11 (36.7)	8 (26.7)	2 (6.7)	1 (3.3)	0
Encephalopathy	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Dizziness	1 (3.3)	1 (3.3)	0	0	0
Dysarthria	1 (3.3)	0	1 (3.3)	0	0
Seizure	1 (3.3)	0	1 (3.3)	0	0
Somnolence	1 (3.3)	1 (3.3)	0	0	0
Psychiatric disorders					
-Total	7 (23.3)	4 (13.3)	3 (10.0)	0	0
Confusional state	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Anxiety	2 (6.7)	0	2 (6.7)	0	0
Delirium	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Irritability	2 (6.7)	2 (6.7)	0	0	0
Agitation	1 (3.3)	0	1 (3.3)	0	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hallucination	1 (3.3)	0	1 (3.3)	0	0
Insomnia	1 (3.3)	0	1 (3.3)	0	0
Listless	1 (3.3)	1 (3.3)	0	0	0
Mental status changes	1 (3.3)	1 (3.3)	0	0	0
Renal and urinary disorders					
-Total	5 (16.7)	1 (3.3)	1 (3.3)	1 (3.3)	2 (6.7)
Acute kidney injury	3 (10.0)	0	1 (3.3)	0	2 (6.7)
Haematuria	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Dysuria	1 (3.3)	1 (3.3)	0	0	0
Oliguria	1 (3.3)	0	0	1 (3.3)	0
Renal impairment	1 (3.3)	0	0	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	13 (43.3)	6 (20.0)	3 (10.0)	1 (3.3)	3 (10.0)
Hypoxia	5 (16.7)	0	2 (6.7)	1 (3.3)	2 (6.7)
Pleural effusion	5 (16.7)	1 (3.3)	3 (10.0)	1 (3.3)	0
Cough	4 (13.3)	4 (13.3)	0	0	0
Epistaxis	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Pulmonary oedema	3 (10.0)	0	0	2 (6.7)	1 (3.3)
Dyspnoea	2 (6.7)	0	0	1 (3.3)	1 (3.3)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Atelectasis	1 (3.3)	1 (3.3)	0	0	0
Interstitial lung disease	1 (3.3)	0	0	0	1 (3.3)
Nasal congestion	1 (3.3)	1 (3.3)	0	0	0
Oropharyngeal plaque	1 (3.3)	1 (3.3)	0	0	0
Pharyngeal ulceration	1 (3.3)	0	1 (3.3)	0	0
Respiratory depression	1 (3.3)	0	1 (3.3)	0	0
Respiratory distress	1 (3.3)	0	0	0	1 (3.3)
Rhinitis allergic	1 (3.3)	1 (3.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (36.7)	9 (30.0)	1 (3.3)	1 (3.3)	0
Erythema	2 (6.7)	2 (6.7)	0	0	0
Rash	2 (6.7)	2 (6.7)	0	0	0
Rash maculo-papular	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Dermatitis diaper	1 (3.3)	1 (3.3)	0	0	0
Dry skin	1 (3.3)	1 (3.3)	0	0	0
Hyperhidrosis	1 (3.3)	1 (3.3)	0	0	0
Ingrowing nail	1 (3.3)	0	1 (3.3)	0	0
Livedo reticularis	1 (3.3)	1 (3.3)	0	0	0

Timing: within 8 weeks post infusion, Gender: Male

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Night sweats	1 (3.3)	0	1 (3.3)	0	0
Pruritus	1 (3.3)	1 (3.3)	0	0	0
Rash papular	1 (3.3)	1 (3.3)	0	0	0
Skin irritation	1 (3.3)	1 (3.3)	0	0	0
Vascular disorders					
-Total	10 (33.3)	0	1 (3.3)	5 (16.7)	4 (13.3)
Hypotension	9 (30.0)	0	0	5 (16.7)	4 (13.3)
Hypertension	6 (20.0)	1 (3.3)	4 (13.3)	1 (3.3)	0
Capillary leak syndrome	1 (3.3)	0	0	0	1 (3.3)
Flushing	1 (3.3)	1 (3.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174b
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Female

			All patients N=34		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (100)	0	3 (8.8)	7 (20.6)	24 (70.6)
Blood and lymphatic system disorders					
-Total	25 (73.5)	1 (2.9)	3 (8.8)	14 (41.2)	7 (20.6)
Anaemia	14 (41.2)	0	3 (8.8)	10 (29.4)	1 (2.9)
Febrile neutropenia	12 (35.3)	0	0	12 (35.3)	0
Neutropenia	4 (11.8)	0	0	1 (2.9)	3 (8.8)
Thrombocytopenia	4 (11.8)	0	0	1 (2.9)	3 (8.8)
Disseminated intravascular coagulation	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Lymphopenia	2 (5.9)	0	1 (2.9)	0	1 (2.9)
Coagulopathy	1 (2.9)	1 (2.9)	0	0	0
Pancytopenia	1 (2.9)	0	0	0	1 (2.9)
Cardiac disorders					
-Total	13 (38.2)	7 (20.6)	6 (17.6)	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	8 (23.5)	5 (14.7)	3 (8.8)	0	0
Sinus tachycardia	5 (14.7)	3 (8.8)	2 (5.9)	0	0
Atrioventricular block second degree	1 (2.9)	1 (2.9)	0	0	0
Cardiac dysfunction	1 (2.9)	1 (2.9)	0	0	0
Pericardial effusion	1 (2.9)	1 (2.9)	0	0	0
Ventricular tachycardia	1 (2.9)	0	1 (2.9)	0	0
Ear and labyrinth disorders					
-Total	2 (5.9)	2 (5.9)	0	0	0
Ear pain	2 (5.9)	2 (5.9)	0	0	0
Endocrine disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Adrenal insufficiency	1 (2.9)	0	1 (2.9)	0	0
Eye disorders					
-Total	8 (23.5)	3 (8.8)	5 (14.7)	0	0
Conjunctival haemorrhage	2 (5.9)	2 (5.9)	0	0	0
Periorbital oedema	2 (5.9)	2 (5.9)	0	0	0
Photophobia	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Uveitis	2 (5.9)	0	2 (5.9)	0	0
Vision blurred	2 (5.9)	0	2 (5.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye pain	1 (2.9)	0	1 (2.9)	0	0
Ocular hypertension	1 (2.9)	0	1 (2.9)	0	0
Papilloedema	1 (2.9)	0	1 (2.9)	0	0
Retinal haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Visual impairment	1 (2.9)	0	1 (2.9)	0	0
Gastrointestinal disorders					
-Total	24 (70.6)	7 (20.6)	10 (29.4)	7 (20.6)	0
Nausea	16 (47.1)	4 (11.8)	10 (29.4)	2 (5.9)	0
Vomiting	15 (44.1)	8 (23.5)	4 (11.8)	3 (8.8)	0
Diarrhoea	12 (35.3)	8 (23.5)	3 (8.8)	1 (2.9)	0
Abdominal pain	7 (20.6)	5 (14.7)	1 (2.9)	1 (2.9)	0
Constipation	6 (17.6)	5 (14.7)	1 (2.9)	0	0
Abdominal pain upper	2 (5.9)	0	2 (5.9)	0	0
Abdominal discomfort	1 (2.9)	1 (2.9)	0	0	0
Abdominal distension	1 (2.9)	0	1 (2.9)	0	0
Abdominal pain lower	1 (2.9)	0	1 (2.9)	0	0
Abdominal tenderness	1 (2.9)	1 (2.9)	0	0	0
Ascites	1 (2.9)	0	0	1 (2.9)	0
Dyspepsia	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

			All patients N=34		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphagia	1 (2.9)	0	1 (2.9)	0	0
Flatulence	1 (2.9)	1 (2.9)	0	0	0
Gastrooesophageal reflux disease	1 (2.9)	1 (2.9)	0	0	0
Glossodynia	1 (2.9)	1 (2.9)	0	0	0
Intestinal obstruction	1 (2.9)	0	0	1 (2.9)	0
Lip pain	1 (2.9)	0	1 (2.9)	0	0
Pancreatitis	1 (2.9)	0	0	1 (2.9)	0
Stomatitis	1 (2.9)	1 (2.9)	0	0	0
Tooth socket haemorrhage	1 (2.9)	1 (2.9)	0	0	0
General disorders and administration site conditions					
-Total	20 (58.8)	10 (29.4)	6 (17.6)	3 (8.8)	1 (2.9)
Fatigue	10 (29.4)	8 (23.5)	2 (5.9)	0	0
Pyrexia	10 (29.4)	3 (8.8)	4 (11.8)	2 (5.9)	1 (2.9)
Chills	4 (11.8)	4 (11.8)	0	0	0
Catheter site pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Malaise	2 (5.9)	0	2 (5.9)	0	0
Catheter site haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Facial pain	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injection site haematoma	1 (2.9)	1 (2.9)	0	0	0
Oedema peripheral	1 (2.9)	1 (2.9)	0	0	0
Physical deconditioning	1 (2.9)	0	0	1 (2.9)	0
Hepatobiliary disorders					
-Total	2 (5.9)	2 (5.9)	0	0	0
Gallbladder enlargement	1 (2.9)	1 (2.9)	0	0	0
Hepatosplenomegaly	1 (2.9)	1 (2.9)	0	0	0
Immune system disorders					
-Total	31 (91.2)	1 (2.9)	18 (52.9)	7 (20.6)	5 (14.7)
Cytokine release syndrome	27 (79.4)	2 (5.9)	15 (44.1)	5 (14.7)	5 (14.7)
Hypogammaglobulinaemia	13 (38.2)	2 (5.9)	8 (23.5)	3 (8.8)	0
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	1 (2.9)	0	0
Infections and infestations					
-Total	18 (52.9)	3 (8.8)	10 (29.4)	4 (11.8)	1 (2.9)
Clostridium difficile colitis	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Clostridium difficile infection	3 (8.8)	0	3 (8.8)	0	0
Rhinovirus infection	3 (8.8)	3 (8.8)	0	0	0
Pneumonia	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Staphylococcal infection	2 (5.9)	1 (2.9)	0	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site cellulitis	1 (2.9)	1 (2.9)	0	0	0
Catheter site infection	1 (2.9)	0	0	1 (2.9)	0
Cytomegalovirus infection	1 (2.9)	1 (2.9)	0	0	0
Enterococcal infection	1 (2.9)	1 (2.9)	0	0	0
Folliculitis	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Herpes simplex	1 (2.9)	1 (2.9)	0	0	0
Human herpesvirus 6 infection	1 (2.9)	0	1 (2.9)	0	0
Hypopyon	1 (2.9)	0	1 (2.9)	0	0
Influenza	1 (2.9)	1 (2.9)	0	0	0
Oral candidiasis	1 (2.9)	1 (2.9)	0	0	0
Septic embolus	1 (2.9)	0	0	0	1 (2.9)
Urinary tract infection enterococcal	1 (2.9)	0	0	1 (2.9)	0
Viral upper respiratory tract infection	1 (2.9)	0	1 (2.9)	0	0
Vulvovaginal candidiasis	1 (2.9)	1 (2.9)	0	0	0
Injury, poisoning and procedural complications					
-Total	11 (32.4)	6 (17.6)	4 (11.8)	0	1 (2.9)
Procedural pain	3 (8.8)	1 (2.9)	2 (5.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion reaction	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Contusion	1 (2.9)	1 (2.9)	0	0	0
Incision site pain	1 (2.9)	1 (2.9)	0	0	0
Infusion related reaction	1 (2.9)	0	1 (2.9)	0	0
Limb injury	1 (2.9)	1 (2.9)	0	0	0
Post procedural haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Procedural site reaction	1 (2.9)	1 (2.9)	0	0	0
Stoma site irritation	1 (2.9)	1 (2.9)	0	0	0
Subdural haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Tibia fracture	1 (2.9)	0	1 (2.9)	0	0
Transfusion related complication	1 (2.9)	0	0	0	1 (2.9)
Investigations					
-Total	30 (88.2)	1 (2.9)	2 (5.9)	9 (26.5)	18 (52.9)
White blood cell count decreased	18 (52.9)	1 (2.9)	1 (2.9)	6 (17.6)	10 (29.4)
Neutrophil count decreased	14 (41.2)	0	1 (2.9)	2 (5.9)	11 (32.4)
Alanine aminotransferase increased	12 (35.3)	3 (8.8)	3 (8.8)	6 (17.6)	0
Platelet count decreased	11 (32.4)	1 (2.9)	1 (2.9)	1 (2.9)	8 (23.5)
Aspartate aminotransferase increased	10 (29.4)	3 (8.8)	2 (5.9)	4 (11.8)	1 (2.9)
Lymphocyte count decreased	9 (26.5)	0	1 (2.9)	5 (14.7)	3 (8.8)

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prothrombin time prolonged	7 (20.6)	4 (11.8)	2 (5.9)	1 (2.9)	0
Blood creatinine increased	5 (14.7)	3 (8.8)	2 (5.9)	0	0
International normalised ratio increased	5 (14.7)	4 (11.8)	0	1 (2.9)	0
Blood bilirubin increased	4 (11.8)	0	3 (8.8)	1 (2.9)	0
Activated partial thromboplastin time prolonged	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Blood fibrinogen decreased	2 (5.9)	0	0	2 (5.9)	0
Blood immunoglobulin a decreased	2 (5.9)	2 (5.9)	0	0	0
Blood immunoglobulin m decreased	2 (5.9)	2 (5.9)	0	0	0
Transaminases increased	2 (5.9)	2 (5.9)	0	0	0
Blood immunoglobulin g decreased	1 (2.9)	0	1 (2.9)	0	0
Blood lactic acid increased	1 (2.9)	0	0	0	1 (2.9)
Blood magnesium decreased	1 (2.9)	0	0	1 (2.9)	0
Blood sodium increased	1 (2.9)	0	1 (2.9)	0	0
Blood urea increased	1 (2.9)	1 (2.9)	0	0	0
Culture stool positive	1 (2.9)	1 (2.9)	0	0	0
Haemoglobin decreased	1 (2.9)	0	0	1 (2.9)	0
Hepatic enzyme increased	1 (2.9)	0	1 (2.9)	0	0
Lipase increased	1 (2.9)	0	0	0	1 (2.9)
Pulmonary function test decreased	1 (2.9)	0	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

			All patients N=34		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	1 (2.9)	0	1 (2.9)	0	0
Metabolism and nutrition disorders					
-Total	25 (73.5)	3 (8.8)	9 (26.5)	11 (32.4)	2 (5.9)
Decreased appetite	11 (32.4)	2 (5.9)	3 (8.8)	6 (17.6)	0
Hypokalaemia	9 (26.5)	0	5 (14.7)	4 (11.8)	0
Hyperphosphataemia	6 (17.6)	6 (17.6)	0	0	0
Hypophosphataemia	4 (11.8)	1 (2.9)	0	2 (5.9)	1 (2.9)
Hypernatraemia	3 (8.8)	1 (2.9)	1 (2.9)	0	1 (2.9)
Hypoalbuminaemia	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Dehydration	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Fluid overload	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Hyperglycaemia	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Hyperuricaemia	2 (5.9)	2 (5.9)	0	0	0
Acidosis	1 (2.9)	1 (2.9)	0	0	0
Hypertriglyceridaemia	1 (2.9)	1 (2.9)	0	0	0
Hypocalcaemia	1 (2.9)	0	1 (2.9)	0	0
Hypomagnesaemia	1 (2.9)	1 (2.9)	0	0	0
Hyponatraemia	1 (2.9)	0	0	1 (2.9)	0
Malnutrition	1 (2.9)	0	0	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	1 (2.9)	0	1 (2.9)	0	0
Tumour lysis syndrome	1 (2.9)	0	0	1 (2.9)	0
Musculoskeletal and connective tissue disorders					
-Total	10 (29.4)	6 (17.6)	4 (11.8)	0	0
Pain in extremity	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Myalgia	3 (8.8)	3 (8.8)	0	0	0
Arthralgia	2 (5.9)	2 (5.9)	0	0	0
Musculoskeletal pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Coccydynia	1 (2.9)	1 (2.9)	0	0	0
Limb discomfort	1 (2.9)	1 (2.9)	0	0	0
Musculoskeletal chest pain	1 (2.9)	1 (2.9)	0	0	0
Osteopenia	1 (2.9)	0	1 (2.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.9)	0	1 (2.9)	0	0
Skin papilloma	1 (2.9)	0	1 (2.9)	0	0
Nervous system disorders					
-Total	18 (52.9)	8 (23.5)	6 (17.6)	3 (8.8)	1 (2.9)
Headache	13 (38.2)	8 (23.5)	4 (11.8)	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dizziness	3 (8.8)	3 (8.8)	0	0	0
Encephalopathy	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Seizure	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Tremor	2 (5.9)	2 (5.9)	0	0	0
Asterixis	1 (2.9)	1 (2.9)	0	0	0
Ataxia	1 (2.9)	0	1 (2.9)	0	0
Depressed level of consciousness	1 (2.9)	1 (2.9)	0	0	0
Dysarthria	1 (2.9)	1 (2.9)	0	0	0
Embolic stroke	1 (2.9)	0	0	0	1 (2.9)
Idiopathic intracranial hypertension	1 (2.9)	0	1 (2.9)	0	0
Migraine	1 (2.9)	0	1 (2.9)	0	0
Myoclonus	1 (2.9)	1 (2.9)	0	0	0
Neuropathy peripheral	1 (2.9)	0	1 (2.9)	0	0
Pleocytosis	1 (2.9)	1 (2.9)	0	0	0
Product issues					
-Total	1 (2.9)	1 (2.9)	0	0	0
Device occlusion	1 (2.9)	1 (2.9)	0	0	0
Psychiatric disorders					
-Total	9 (26.5)	4 (11.8)	4 (11.8)	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	4 (11.8)	2 (5.9)	1 (2.9)	1 (2.9)	0
Confusional state	2 (5.9)	0	2 (5.9)	0	0
Delirium	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Adjustment disorder	1 (2.9)	0	1 (2.9)	0	0
Agitation	1 (2.9)	0	1 (2.9)	0	0
Hallucination	1 (2.9)	1 (2.9)	0	0	0
Panic attack	1 (2.9)	0	1 (2.9)	0	0
Suicidal ideation	1 (2.9)	1 (2.9)	0	0	0
Renal and urinary disorders					
-Total	6 (17.6)	1 (2.9)	1 (2.9)	2 (5.9)	2 (5.9)
Acute kidney injury	4 (11.8)	1 (2.9)	0	2 (5.9)	1 (2.9)
Haematuria	2 (5.9)	0	1 (2.9)	0	1 (2.9)
Dysuria	1 (2.9)	0	1 (2.9)	0	0
Oliguria	1 (2.9)	0	0	1 (2.9)	0
Pollakiuria	1 (2.9)	1 (2.9)	0	0	0
Renal failure	1 (2.9)	0	0	0	1 (2.9)
Reproductive system and breast disorders					
-Total	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Vulvovaginal adhesion	2 (5.9)	2 (5.9)	0	0	0

Timing: within 8 weeks post infusion, Gender: Female

			All patients N=34		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema genital	1 (2.9)	0	1 (2.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	15 (44.1)	4 (11.8)	3 (8.8)	4 (11.8)	4 (11.8)
Hypoxia	5 (14.7)	0	1 (2.9)	3 (8.8)	1 (2.9)
Cough	4 (11.8)	4 (11.8)	0	0	0
Epistaxis	3 (8.8)	1 (2.9)	0	1 (2.9)	1 (2.9)
Pleural effusion	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Pulmonary oedema	3 (8.8)	1 (2.9)	0	1 (2.9)	1 (2.9)
Respiratory failure	3 (8.8)	0	0	0	3 (8.8)
Tachypnoea	3 (8.8)	2 (5.9)	0	1 (2.9)	0
Haemoptysis	2 (5.9)	1 (2.9)	0	0	1 (2.9)
Oropharyngeal pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Rhinorrhoea	1 (2.9)	1 (2.9)	0	0	0
Wheezing	1 (2.9)	0	1 (2.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	10 (29.4)	6 (17.6)	3 (8.8)	1 (2.9)	0
Dry skin	3 (8.8)	3 (8.8)	0	0	0
Petechiae	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Hyperhidrosis	2 (5.9)	2 (5.9)	0	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	2 (5.9)	2 (5.9)	0	0	0
Ecchymosis	1 (2.9)	0	0	1 (2.9)	0
Erythema	1 (2.9)	1 (2.9)	0	0	0
Ingrowing nail	1 (2.9)	0	1 (2.9)	0	0
Macule	1 (2.9)	1 (2.9)	0	0	0
Pruritus	1 (2.9)	1 (2.9)	0	0	0
Rash erythematous	1 (2.9)	1 (2.9)	0	0	0
Rash follicular	1 (2.9)	1 (2.9)	0	0	0
Rash macular	1 (2.9)	1 (2.9)	0	0	0
Rash maculo-papular	1 (2.9)	0	1 (2.9)	0	0
Rash papular	1 (2.9)	1 (2.9)	0	0	0
Rash vesicular	1 (2.9)	1 (2.9)	0	0	0
Skin exfoliation	1 (2.9)	1 (2.9)	0	0	0
Skin fissures	1 (2.9)	1 (2.9)	0	0	0
Vascular disorders					
-Total	14 (41.2)	3 (8.8)	4 (11.8)	3 (8.8)	4 (11.8)
Hypotension	7 (20.6)	1 (2.9)	0	2 (5.9)	4 (11.8)
Hypertension	4 (11.8)	1 (2.9)	3 (8.8)	0	0
Orthostatic hypotension	2 (5.9)	1 (2.9)	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

Primary system organ class Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Embolism	1 (2.9)	0	0	1 (2.9)	0
Flushing	1 (2.9)	1 (2.9)	0	0	0
Haematoma	1 (2.9)	0	1 (2.9)	0	0
Secondary hypertension	1 (2.9)	0	1 (2.9)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174b
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=27		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (74.1)	2 (7.4)	6 (22.2)	8 (29.6)	4 (14.8)
Blood and lymphatic system disorders					
-Total	7 (25.9)	1 (3.7)	0	2 (7.4)	4 (14.8)
Neutropenia	4 (14.8)	0	0	1 (3.7)	3 (11.1)
Febrile neutropenia	2 (7.4)	0	0	2 (7.4)	0
Anaemia	1 (3.7)	1 (3.7)	0	0	0
Eosinophilia	1 (3.7)	0	0	1 (3.7)	0
Leukopenia	1 (3.7)	0	0	0	1 (3.7)
Thrombocytopenia	1 (3.7)	0	0	1 (3.7)	0
Cardiac disorders					
-Total	1 (3.7)	0	1 (3.7)	0	0
Sinus tachycardia	1 (3.7)	0	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (3.7)	1 (3.7)	0	0	0
Adrenal insufficiency	1 (3.7)	1 (3.7)	0	0	0
Eye disorders					
-Total	2 (7.4)	2 (7.4)	0	0	0
Ocular hyperaemia	1 (3.7)	1 (3.7)	0	0	0
Vision blurred	1 (3.7)	1 (3.7)	0	0	0
Gastrointestinal disorders					
-Total	6 (22.2)	4 (14.8)	0	2 (7.4)	0
Vomiting	3 (11.1)	3 (11.1)	0	0	0
Oral pain	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Abdominal pain	1 (3.7)	1 (3.7)	0	0	0
Abdominal pain upper	1 (3.7)	1 (3.7)	0	0	0
Diarrhoea	1 (3.7)	1 (3.7)	0	0	0
Enterocolitis	1 (3.7)	0	0	1 (3.7)	0
Nausea	1 (3.7)	0	1 (3.7)	0	0
Pigmentation lip	1 (3.7)	1 (3.7)	0	0	0
General disorders and administration site conditions					

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (22.2)	4 (14.8)	2 (7.4)	0	0
Pyrexia	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Acquired gene mutation	1 (3.7)	1 (3.7)	0	0	0
Catheter site pain	1 (3.7)	0	1 (3.7)	0	0
Chills	1 (3.7)	1 (3.7)	0	0	0
Fatigue	1 (3.7)	1 (3.7)	0	0	0
Influenza like illness	1 (3.7)	1 (3.7)	0	0	0
Pain	1 (3.7)	1 (3.7)	0	0	0
Immune system disorders					
-Total	7 (25.9)	2 (7.4)	4 (14.8)	1 (3.7)	0
Hypogammaglobulinaemia	4 (14.8)	0	3 (11.1)	1 (3.7)	0
Graft versus host disease	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Seasonal allergy	1 (3.7)	1 (3.7)	0	0	0
Infections and infestations					
-Total	14 (51.9)	2 (7.4)	7 (25.9)	5 (18.5)	0
Upper respiratory tract infection	4 (14.8)	2 (7.4)	2 (7.4)	0	0
Gastroenteritis	2 (7.4)	0	2 (7.4)	0	0
Influenza	2 (7.4)	0	2 (7.4)	0	0
Cellulitis of male external genital organ	1 (3.7)	0	0	1 (3.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (3.7)	0	0	1 (3.7)	0
Corona virus infection	1 (3.7)	0	0	1 (3.7)	0
Herpes zoster	1 (3.7)	0	0	1 (3.7)	0
Otitis media	1 (3.7)	0	1 (3.7)	0	0
Rash pustular	1 (3.7)	0	1 (3.7)	0	0
Respiratory syncytial virus infection	1 (3.7)	0	0	1 (3.7)	0
Rhinovirus infection	1 (3.7)	1 (3.7)	0	0	0
Subcutaneous abscess	1 (3.7)	0	1 (3.7)	0	0
Urinary tract infection	1 (3.7)	0	0	1 (3.7)	0
Viral infection	1 (3.7)	1 (3.7)	0	0	0
Viral upper respiratory tract infection	1 (3.7)	0	0	1 (3.7)	0
Injury, poisoning and procedural complications					
-Total	3 (11.1)	0	3 (11.1)	0	0
Contusion	1 (3.7)	1 (3.7)	0	0	0
Foot fracture	1 (3.7)	0	1 (3.7)	0	0
Infusion related reaction	1 (3.7)	0	1 (3.7)	0	0
Procedural nausea	1 (3.7)	0	1 (3.7)	0	0
Skin laceration	1 (3.7)	0	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sunburn	1 (3.7)	1 (3.7)	0	0	0
Investigations					
-Total	11 (40.7)	4 (14.8)	2 (7.4)	3 (11.1)	2 (7.4)
Neutrophil count decreased	3 (11.1)	1 (3.7)	0	1 (3.7)	1 (3.7)
White blood cell count decreased	3 (11.1)	2 (7.4)	0	0	1 (3.7)
Alanine aminotransferase increased	1 (3.7)	0	0	1 (3.7)	0
Blood bilirubin increased	1 (3.7)	0	0	1 (3.7)	0
Blood magnesium decreased	1 (3.7)	1 (3.7)	0	0	0
Blood urea increased	1 (3.7)	1 (3.7)	0	0	0
Lymphocyte count decreased	1 (3.7)	0	1 (3.7)	0	0
Platelet count decreased	1 (3.7)	1 (3.7)	0	0	0
Serum ferritin increased	1 (3.7)	0	1 (3.7)	0	0
Transaminases increased	1 (3.7)	1 (3.7)	0	0	0
Weight decreased	1 (3.7)	1 (3.7)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (14.8)	3 (11.1)	0	1 (3.7)	0
Hyperalbuminaemia	1 (3.7)	1 (3.7)	0	0	0
Hypercalcaemia	1 (3.7)	1 (3.7)	0	0	0
Hyperphosphataemia	1 (3.7)	1 (3.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Iron overload	1 (3.7)	0	0	1 (3.7)	0
Vitamin d deficiency	1 (3.7)	1 (3.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (18.5)	3 (11.1)	2 (7.4)	0	0
Pain in extremity	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Arthralgia	1 (3.7)	1 (3.7)	0	0	0
Back pain	1 (3.7)	1 (3.7)	0	0	0
Joint range of motion decreased	1 (3.7)	1 (3.7)	0	0	0
Muscle spasms	1 (3.7)	1 (3.7)	0	0	0
Muscular weakness	1 (3.7)	1 (3.7)	0	0	0
Osteonecrosis	1 (3.7)	0	1 (3.7)	0	0
Pain in jaw	1 (3.7)	1 (3.7)	0	0	0
Nervous system disorders					
-Total	5 (18.5)	4 (14.8)	1 (3.7)	0	0
Headache	3 (11.1)	3 (11.1)	0	0	0
Peroneal nerve palsy	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Psychiatric disorders					
-Total	2 (7.4)	1 (3.7)	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Depression	2 (7.4)	2 (7.4)	0	0	0
Anxiety	1 (3.7)	1 (3.7)	0	0	0
Sleep disorder	1 (3.7)	0	1 (3.7)	0	0
Reproductive system and breast disorders					
-Total	1 (3.7)	0	1 (3.7)	0	0
Scrotal pain	1 (3.7)	0	1 (3.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (25.9)	2 (7.4)	3 (11.1)	2 (7.4)	0
Cough	2 (7.4)	0	2 (7.4)	0	0
Nasal congestion	2 (7.4)	2 (7.4)	0	0	0
Rhinorrhoea	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Dysphonia	1 (3.7)	1 (3.7)	0	0	0
Epistaxis	1 (3.7)	0	0	1 (3.7)	0
Oropharyngeal pain	1 (3.7)	0	1 (3.7)	0	0
Pharyngeal erythema	1 (3.7)	1 (3.7)	0	0	0
Pharyngeal lesion	1 (3.7)	0	0	1 (3.7)	0
Pulmonary oedema	1 (3.7)	0	0	1 (3.7)	0
Skin and subcutaneous tissue disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (33.3)	5 (18.5)	3 (11.1)	1 (3.7)	0
Erythema	2 (7.4)	2 (7.4)	0	0	0
Rash maculo-papular	2 (7.4)	2 (7.4)	0	0	0
Alopecia	1 (3.7)	0	1 (3.7)	0	0
Dermatitis acneiform	1 (3.7)	0	0	1 (3.7)	0
Hyperhidrosis	1 (3.7)	1 (3.7)	0	0	0
Ingrowing nail	1 (3.7)	1 (3.7)	0	0	0
Keloid scar	1 (3.7)	0	1 (3.7)	0	0
Macule	1 (3.7)	1 (3.7)	0	0	0
Papule	1 (3.7)	1 (3.7)	0	0	0
Rash	1 (3.7)	0	1 (3.7)	0	0
Rash erythematous	1 (3.7)	0	1 (3.7)	0	0
Vascular disorders					
-Total	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Hypertension	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Hot flush	1 (3.7)	1 (3.7)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174b
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

			All patients N=29		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (89.7)	2 (6.9)	10 (34.5)	8 (27.6)	6 (20.7)
Blood and lymphatic system disorders					
-Total	4 (13.8)	0	3 (10.3)	1 (3.4)	0
Anaemia	1 (3.4)	0	0	1 (3.4)	0
Febrile neutropenia	1 (3.4)	0	0	1 (3.4)	0
Lymphadenopathy	1 (3.4)	0	1 (3.4)	0	0
Lymphopenia	1 (3.4)	0	1 (3.4)	0	0
Thrombocytopenia	1 (3.4)	0	1 (3.4)	0	0
Eye disorders					
-Total	3 (10.3)	2 (6.9)	1 (3.4)	0	0
Dry eye	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Conjunctivitis allergic	1 (3.4)	1 (3.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	10 (34.5)	5 (17.2)	3 (10.3)	2 (6.9)	0
Diarrhoea	7 (24.1)	5 (17.2)	1 (3.4)	1 (3.4)	0
Vomiting	6 (20.7)	2 (6.9)	2 (6.9)	2 (6.9)	0
Nausea	5 (17.2)	1 (3.4)	2 (6.9)	2 (6.9)	0
Abdominal pain	3 (10.3)	1 (3.4)	1 (3.4)	1 (3.4)	0
General disorders and administration site conditions					
-Total	11 (37.9)	9 (31.0)	1 (3.4)	1 (3.4)	0
Pyrexia	8 (27.6)	6 (20.7)	1 (3.4)	1 (3.4)	0
Crying	1 (3.4)	1 (3.4)	0	0	0
Fatigue	1 (3.4)	1 (3.4)	0	0	0
Generalised oedema	1 (3.4)	1 (3.4)	0	0	0
Influenza like illness	1 (3.4)	1 (3.4)	0	0	0
Malaise	1 (3.4)	1 (3.4)	0	0	0
Oedema peripheral	1 (3.4)	1 (3.4)	0	0	0
Immune system disorders					
-Total	7 (24.1)	1 (3.4)	6 (20.7)	0	0
Hypogammaglobulinaemia	4 (13.8)	0	4 (13.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency common variable	2 (6.9)	0	2 (6.9)	0	0
Graft versus host disease in gastrointestinal tract	1 (3.4)	0	1 (3.4)	0	0
Seasonal allergy	1 (3.4)	1 (3.4)	0	0	0
Infections and infestations					
-Total	19 (65.5)	4 (13.8)	8 (27.6)	5 (17.2)	2 (6.9)
Upper respiratory tract infection	3 (10.3)	1 (3.4)	1 (3.4)	1 (3.4)	0
Urinary tract infection	3 (10.3)	0	2 (6.9)	1 (3.4)	0
Ear infection	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Parainfluenzae virus infection	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Sinusitis	2 (6.9)	0	2 (6.9)	0	0
Bacterial sepsis	1 (3.4)	0	0	0	1 (3.4)
Cytomegalovirus infection	1 (3.4)	1 (3.4)	0	0	0
Enterovirus infection	1 (3.4)	0	0	1 (3.4)	0
Escherichia urinary tract infection	1 (3.4)	0	0	1 (3.4)	0
Gastroenteritis	1 (3.4)	1 (3.4)	0	0	0
Gastroenteritis norovirus	1 (3.4)	0	1 (3.4)	0	0
Gastroenteritis viral	1 (3.4)	1 (3.4)	0	0	0
Influenza	1 (3.4)	0	1 (3.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Molluscum contagiosum	1 (3.4)	1 (3.4)	0	0	0
Oral herpes	1 (3.4)	0	1 (3.4)	0	0
Otitis externa	1 (3.4)	0	1 (3.4)	0	0
Otitis media acute	1 (3.4)	0	1 (3.4)	0	0
Paronychia	1 (3.4)	1 (3.4)	0	0	0
Rhinitis	1 (3.4)	1 (3.4)	0	0	0
Rhinovirus infection	1 (3.4)	1 (3.4)	0	0	0
Rotavirus infection	1 (3.4)	0	0	1 (3.4)	0
Sepsis	1 (3.4)	0	0	0	1 (3.4)
Tinea capitis	1 (3.4)	1 (3.4)	0	0	0
Vascular device infection	1 (3.4)	0	0	1 (3.4)	0
Viral upper respiratory tract infection	1 (3.4)	1 (3.4)	0	0	0
Vulvovaginal mycotic infection	1 (3.4)	0	1 (3.4)	0	0
Injury, poisoning and procedural complications					
-Total	5 (17.2)	3 (10.3)	2 (6.9)	0	0
Procedural pain	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Arthropod bite	1 (3.4)	1 (3.4)	0	0	0
Contusion	1 (3.4)	1 (3.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infusion related reaction	1 (3.4)	1 (3.4)	0	0	0
Radius fracture	1 (3.4)	0	1 (3.4)	0	0
Skin abrasion	1 (3.4)	1 (3.4)	0	0	0
Investigations					
-Total	12 (41.4)	2 (6.9)	3 (10.3)	5 (17.2)	2 (6.9)
Neutrophil count decreased	5 (17.2)	1 (3.4)	0	2 (6.9)	2 (6.9)
Aspartate aminotransferase increased	3 (10.3)	1 (3.4)	0	2 (6.9)	0
Weight decreased	3 (10.3)	0	3 (10.3)	0	0
Haemoglobin decreased	2 (6.9)	2 (6.9)	0	0	0
Platelet count decreased	2 (6.9)	2 (6.9)	0	0	0
Weight increased	2 (6.9)	1 (3.4)	1 (3.4)	0	0
White blood cell count decreased	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Alanine aminotransferase increased	1 (3.4)	0	0	1 (3.4)	0
Blood creatinine increased	1 (3.4)	1 (3.4)	0	0	0
Blood uric acid increased	1 (3.4)	1 (3.4)	0	0	0
Lymphocyte count decreased	1 (3.4)	1 (3.4)	0	0	0
Oxygen saturation decreased	1 (3.4)	1 (3.4)	0	0	0
Metabolism and nutrition disorders					
-Total	6 (20.7)	2 (6.9)	1 (3.4)	2 (6.9)	1 (3.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Hypokalaemia	2 (6.9)	1 (3.4)	0	0	1 (3.4)
Dehydration	1 (3.4)	0	0	1 (3.4)	0
Hyperglycaemia	1 (3.4)	0	0	1 (3.4)	0
Hyperphosphataemia	1 (3.4)	1 (3.4)	0	0	0
Hypophosphataemia	1 (3.4)	0	0	1 (3.4)	0
Tumour lysis syndrome	1 (3.4)	0	0	1 (3.4)	0
Musculoskeletal and connective tissue disorders					
-Total	11 (37.9)	8 (27.6)	3 (10.3)	0	0
Pain in extremity	6 (20.7)	5 (17.2)	1 (3.4)	0	0
Arthralgia	1 (3.4)	0	1 (3.4)	0	0
Flank pain	1 (3.4)	0	1 (3.4)	0	0
Joint range of motion decreased	1 (3.4)	1 (3.4)	0	0	0
Muscular weakness	1 (3.4)	1 (3.4)	0	0	0
Musculoskeletal chest pain	1 (3.4)	1 (3.4)	0	0	0
Toe walking	1 (3.4)	1 (3.4)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

			All patients N=29		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.4)	0	1 (3.4)	0	0
Myelodysplastic syndrome	1 (3.4)	0	1 (3.4)	0	0
Nervous system disorders					
-Total	3 (10.3)	2 (6.9)	1 (3.4)	0	0
Dizziness	3 (10.3)	3 (10.3)	0	0	0
Headache	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Renal and urinary disorders					
-Total	3 (10.3)	1 (3.4)	0	2 (6.9)	0
Acute kidney injury	1 (3.4)	0	0	1 (3.4)	0
Calculus urinary	1 (3.4)	0	1 (3.4)	0	0
Haematuria	1 (3.4)	0	0	1 (3.4)	0
Nephrolithiasis	1 (3.4)	0	0	1 (3.4)	0
Urinary incontinence	1 (3.4)	1 (3.4)	0	0	0
Reproductive system and breast disorders					
-Total	1 (3.4)	0	0	1 (3.4)	0
Vaginal haemorrhage	1 (3.4)	0	0	1 (3.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (37.9)	9 (31.0)	1 (3.4)	0	1 (3.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	5 (17.2)	5 (17.2)	0	0	0
Rhinitis allergic	3 (10.3)	2 (6.9)	1 (3.4)	0	0
Nasal congestion	2 (6.9)	2 (6.9)	0	0	0
Oropharyngeal pain	2 (6.9)	2 (6.9)	0	0	0
Rhinorrhoea	2 (6.9)	2 (6.9)	0	0	0
Acute respiratory failure	1 (3.4)	0	0	0	1 (3.4)
Epistaxis	1 (3.4)	1 (3.4)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (24.1)	5 (17.2)	2 (6.9)	0	0
Rash	3 (10.3)	1 (3.4)	2 (6.9)	0	0
Dermatitis	1 (3.4)	1 (3.4)	0	0	0
Dermatitis atopic	1 (3.4)	1 (3.4)	0	0	0
Dry skin	1 (3.4)	1 (3.4)	0	0	0
Eczema	1 (3.4)	1 (3.4)	0	0	0
Petechiae	1 (3.4)	1 (3.4)	0	0	0
Pruritus	1 (3.4)	1 (3.4)	0	0	0
Rash pruritic	1 (3.4)	1 (3.4)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174b
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (60.0)	3 (15.0)	3 (15.0)	4 (20.0)	2 (10.0)
Blood and lymphatic system disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Thrombocytopenia	1 (5.0)	1 (5.0)	0	0	0
Ear and labyrinth disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Tympanic membrane perforation	1 (5.0)	0	1 (5.0)	0	0
Gastrointestinal disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Diarrhoea	1 (5.0)	0	1 (5.0)	0	0
Immune system disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0

Timing: >1 year post-CTL019 infusion, Gender: Male

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chronic graft versus host disease	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0
Otitis media	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Sinusitis	2 (10.0)	0	2 (10.0)	0	0
Cellulitis of male external genital organ	1 (5.0)	0	0	1 (5.0)	0
Gingivitis	1 (5.0)	1 (5.0)	0	0	0
Haemophilus infection	1 (5.0)	0	1 (5.0)	0	0
Otitis media acute	1 (5.0)	0	1 (5.0)	0	0
Pneumonia	1 (5.0)	0	1 (5.0)	0	0
Upper respiratory tract infection	1 (5.0)	0	1 (5.0)	0	0
Urinary tract infection	1 (5.0)	0	0	1 (5.0)	0
Viral infection	1 (5.0)	1 (5.0)	0	0	0
Investigations					
-Total	6 (30.0)	1 (5.0)	1 (5.0)	3 (15.0)	1 (5.0)
Alanine aminotransferase increased	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Lymphocyte count decreased	2 (10.0)	1 (5.0)	0	1 (5.0)	0
White blood cell count decreased	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Aspartate aminotransferase increased	1 (5.0)	0	0	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Gender: Male

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	1 (5.0)	1 (5.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Vitamin d deficiency	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Neck pain	1 (5.0)	0	1 (5.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (5.0)	0	0	0	1 (5.0)
Glioblastoma multiforme	1 (5.0)	0	0	0	1 (5.0)
Nervous system disorders					
-Total	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Disturbance in attention	1 (5.0)	1 (5.0)	0	0	0
Seizure	1 (5.0)	0	0	1 (5.0)	0
Skin and subcutaneous tissue disorders					
-Total	2 (10.0)	2 (10.0)	0	0	0
Acne	1 (5.0)	1 (5.0)	0	0	0
Papule	1 (5.0)	1 (5.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174b
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Female

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (71.4)	1 (7.1)	3 (21.4)	4 (28.6)	2 (14.3)
Blood and lymphatic system disorders					
-Total	1 (7.1)	0	0	0	1 (7.1)
Febrile neutropenia	1 (7.1)	0	0	0	1 (7.1)
Gastrointestinal disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Abdominal pain	1 (7.1)	0	1 (7.1)	0	0
Diarrhoea	1 (7.1)	0	1 (7.1)	0	0
Nausea	1 (7.1)	0	1 (7.1)	0	0
General disorders and administration site conditions					
-Total	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Chills	1 (7.1)	0	1 (7.1)	0	0

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cyst	1 (7.1)	0	0	1 (7.1)	0
Pyrexia	1 (7.1)	0	1 (7.1)	0	0
Immune system disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0
Immunodeficiency	1 (7.1)	0	1 (7.1)	0	0
Infections and infestations					
-Total	7 (50.0)	1 (7.1)	4 (28.6)	1 (7.1)	1 (7.1)
Campylobacter infection	1 (7.1)	0	0	1 (7.1)	0
Clostridium difficile infection	1 (7.1)	0	0	1 (7.1)	0
Meningitis aseptic	1 (7.1)	0	1 (7.1)	0	0
Otitis media	1 (7.1)	0	1 (7.1)	0	0
Otitis media acute	1 (7.1)	0	1 (7.1)	0	0
Pneumonia	1 (7.1)	0	1 (7.1)	0	0
Respiratory tract infection	1 (7.1)	0	0	0	1 (7.1)
Respiratory tract infection viral	1 (7.1)	0	0	1 (7.1)	0
Sinusitis	1 (7.1)	0	1 (7.1)	0	0
Skin infection	1 (7.1)	0	1 (7.1)	0	0
Upper respiratory tract infection	1 (7.1)	1 (7.1)	0	0	0
Urinary tract infection	1 (7.1)	0	1 (7.1)	0	0

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal candidiasis	1 (7.1)	0	1 (7.1)	0	0
Injury, poisoning and procedural complications					
-Total	1 (7.1)	0	0	1 (7.1)	0
Procedural pain	1 (7.1)	0	0	1 (7.1)	0
Investigations					
-Total	2 (14.3)	0	1 (7.1)	1 (7.1)	0
White blood cell count decreased	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Alanine aminotransferase increased	1 (7.1)	0	0	1 (7.1)	0
Aspartate aminotransferase increased	1 (7.1)	1 (7.1)	0	0	0
Blood alkaline phosphatase increased	1 (7.1)	1 (7.1)	0	0	0
Blood lactate dehydrogenase increased	1 (7.1)	1 (7.1)	0	0	0
C-reactive protein increased	1 (7.1)	1 (7.1)	0	0	0
Lymphocyte count decreased	1 (7.1)	1 (7.1)	0	0	0
Neutrophil count decreased	1 (7.1)	0	1 (7.1)	0	0
Platelet count decreased	1 (7.1)	0	0	1 (7.1)	0
Metabolism and nutrition disorders					
-Total	1 (7.1)	0	0	1 (7.1)	0
Hypokalaemia	1 (7.1)	0	0	1 (7.1)	0
Nervous system disorders					

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (7.1)	0	1 (7.1)	0	0
Dizziness	1 (7.1)	1 (7.1)	0	0	0
Headache	1 (7.1)	0	1 (7.1)	0	0
Renal and urinary disorders					
-Total	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Acute kidney injury	1 (7.1)	0	0	1 (7.1)	0
Haematuria	1 (7.1)	1 (7.1)	0	0	0
Reproductive system and breast disorders					
-Total	1 (7.1)	0	0	1 (7.1)	0
Ovarian failure	1 (7.1)	0	0	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (28.6)	4 (28.6)	0	0	0
Cough	2 (14.3)	2 (14.3)	0	0	0
Epistaxis	1 (7.1)	1 (7.1)	0	0	0
Oropharyngeal pain	1 (7.1)	1 (7.1)	0	0	0
Rhinitis allergic	1 (7.1)	1 (7.1)	0	0	0
Rhinorrhoea	1 (7.1)	1 (7.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0

Timing: >1 year post-CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pruritus	1 (7.1)	1 (7.1)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174b
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Male

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (100)	0	4 (13.3)	6 (20.0)	20 (66.7)
Blood and lymphatic system disorders					
-Total	22 (73.3)	1 (3.3)	0	13 (43.3)	8 (26.7)
Anaemia	13 (43.3)	3 (10.0)	2 (6.7)	8 (26.7)	0
Febrile neutropenia	10 (33.3)	0	0	10 (33.3)	0
Neutropenia	7 (23.3)	0	0	2 (6.7)	5 (16.7)
Thrombocytopenia	5 (16.7)	0	0	2 (6.7)	3 (10.0)
Disseminated intravascular coagulation	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Eosinophilia	1 (3.3)	0	0	1 (3.3)	0
Leukopenia	1 (3.3)	0	0	0	1 (3.3)
Lymphopenia	1 (3.3)	0	0	1 (3.3)	0
Cardiac disorders					

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (33.3)	4 (13.3)	4 (13.3)	2 (6.7)	0
Tachycardia	7 (23.3)	3 (10.0)	2 (6.7)	2 (6.7)	0
Bradycardia	1 (3.3)	0	1 (3.3)	0	0
Left ventricular dysfunction	1 (3.3)	0	0	1 (3.3)	0
Palpitations	1 (3.3)	1 (3.3)	0	0	0
Pericardial effusion	1 (3.3)	0	1 (3.3)	0	0
Sinus bradycardia	1 (3.3)	1 (3.3)	0	0	0
Sinus tachycardia	1 (3.3)	0	1 (3.3)	0	0
Ear and labyrinth disorders					
-Total	2 (6.7)	0	2 (6.7)	0	0
Hypoacusis	1 (3.3)	0	1 (3.3)	0	0
Tympanic membrane perforation	1 (3.3)	0	1 (3.3)	0	0
Endocrine disorders					
-Total	1 (3.3)	1 (3.3)	0	0	0
Adrenal insufficiency	1 (3.3)	1 (3.3)	0	0	0
Eye disorders					
-Total	7 (23.3)	5 (16.7)	2 (6.7)	0	0
Eye pain	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Periorbital oedema	2 (6.7)	1 (3.3)	1 (3.3)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vision blurred	2 (6.7)	2 (6.7)	0	0	0
Conjunctival haemorrhage	1 (3.3)	1 (3.3)	0	0	0
Ocular hyperaemia	1 (3.3)	1 (3.3)	0	0	0
Retinal haemorrhage	1 (3.3)	1 (3.3)	0	0	0
Gastrointestinal disorders					
-Total	17 (56.7)	6 (20.0)	5 (16.7)	6 (20.0)	0
Vomiting	10 (33.3)	8 (26.7)	2 (6.7)	0	0
Diarrhoea	7 (23.3)	3 (10.0)	4 (13.3)	0	0
Nausea	6 (20.0)	2 (6.7)	3 (10.0)	1 (3.3)	0
Abdominal pain	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Haematemesis	2 (6.7)	2 (6.7)	0	0	0
Oral pain	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Abdominal distension	1 (3.3)	0	1 (3.3)	0	0
Abdominal pain upper	1 (3.3)	1 (3.3)	0	0	0
Anal incontinence	1 (3.3)	1 (3.3)	0	0	0
Constipation	1 (3.3)	1 (3.3)	0	0	0
Dysphagia	1 (3.3)	0	0	1 (3.3)	0
Enterocolitis	1 (3.3)	0	0	1 (3.3)	0
Gastrointestinal haemorrhage	1 (3.3)	1 (3.3)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ileus	1 (3.3)	0	0	1 (3.3)	0
Mouth haemorrhage	1 (3.3)	0	0	1 (3.3)	0
Pancreatitis	1 (3.3)	0	1 (3.3)	0	0
Pigmentation lip	1 (3.3)	1 (3.3)	0	0	0
Stomatitis	1 (3.3)	0	1 (3.3)	0	0
General disorders and administration site conditions					
-Total	17 (56.7)	5 (16.7)	6 (20.0)	6 (20.0)	0
Pyrexia	8 (26.7)	1 (3.3)	4 (13.3)	3 (10.0)	0
Chills	5 (16.7)	5 (16.7)	0	0	0
Fatigue	4 (13.3)	3 (10.0)	0	1 (3.3)	0
Pain	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Catheter site pain	2 (6.7)	0	2 (6.7)	0	0
Face oedema	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Generalised oedema	2 (6.7)	0	2 (6.7)	0	0
Acquired gene mutation	1 (3.3)	1 (3.3)	0	0	0
Asthenia	1 (3.3)	1 (3.3)	0	0	0
Catheter site extravasation	1 (3.3)	0	1 (3.3)	0	0
Influenza like illness	1 (3.3)	1 (3.3)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised oedema	1 (3.3)	0	0	1 (3.3)	0
Malaise	1 (3.3)	0	1 (3.3)	0	0
Mucosal haemorrhage	1 (3.3)	0	1 (3.3)	0	0
Multiple organ dysfunction syndrome	1 (3.3)	0	0	1 (3.3)	0
Non-cardiac chest pain	1 (3.3)	1 (3.3)	0	0	0
Oedema peripheral	1 (3.3)	0	0	1 (3.3)	0
Peripheral swelling	1 (3.3)	0	1 (3.3)	0	0
Hepatobiliary disorders					
-Total	5 (16.7)	1 (3.3)	2 (6.7)	2 (6.7)	0
Hepatomegaly	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Hyperbilirubinaemia	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Immune system disorders					
-Total	27 (90.0)	4 (13.3)	13 (43.3)	4 (13.3)	6 (20.0)
Cytokine release syndrome	23 (76.7)	4 (13.3)	10 (33.3)	3 (10.0)	6 (20.0)
Hypogammaglobulinaemia	16 (53.3)	1 (3.3)	13 (43.3)	2 (6.7)	0
Graft versus host disease	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Chronic graft versus host disease	1 (3.3)	0	1 (3.3)	0	0
Drug hypersensitivity	1 (3.3)	0	1 (3.3)	0	0
Graft versus host disease in skin	1 (3.3)	1 (3.3)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seasonal allergy	1 (3.3)	1 (3.3)	0	0	0
Infections and infestations					
-Total	20 (66.7)	4 (13.3)	9 (30.0)	7 (23.3)	0
Upper respiratory tract infection	5 (16.7)	2 (6.7)	3 (10.0)	0	0
Gastroenteritis	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Otitis media	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Viral infection	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Influenza	2 (6.7)	0	2 (6.7)	0	0
Sinusitis	2 (6.7)	0	2 (6.7)	0	0
Acute sinusitis	1 (3.3)	0	1 (3.3)	0	0
Body tinea	1 (3.3)	1 (3.3)	0	0	0
Cellulitis of male external genital organ	1 (3.3)	0	0	1 (3.3)	0
Cholecystitis infective	1 (3.3)	0	0	1 (3.3)	0
Clostridium difficile colitis	1 (3.3)	0	0	1 (3.3)	0
Clostridium difficile infection	1 (3.3)	0	1 (3.3)	0	0
Corona virus infection	1 (3.3)	0	0	1 (3.3)	0
Fungal skin infection	1 (3.3)	1 (3.3)	0	0	0
Gingivitis	1 (3.3)	1 (3.3)	0	0	0
Haemophilus infection	1 (3.3)	0	1 (3.3)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Herpes zoster	1 (3.3)	0	0	1 (3.3)	0
Orchitis	1 (3.3)	1 (3.3)	0	0	0
Otitis media acute	1 (3.3)	0	1 (3.3)	0	0
Pharyngitis	1 (3.3)	0	1 (3.3)	0	0
Pneumonia	1 (3.3)	0	1 (3.3)	0	0
Rash pustular	1 (3.3)	0	1 (3.3)	0	0
Respiratory syncytial virus infection	1 (3.3)	0	0	1 (3.3)	0
Rhinovirus infection	1 (3.3)	1 (3.3)	0	0	0
Skin infection	1 (3.3)	0	1 (3.3)	0	0
Streptococcal infection	1 (3.3)	0	1 (3.3)	0	0
Subcutaneous abscess	1 (3.3)	0	1 (3.3)	0	0
Urinary tract infection	1 (3.3)	0	0	1 (3.3)	0
Viral upper respiratory tract infection	1 (3.3)	0	0	1 (3.3)	0
Injury, poisoning and procedural complications					
-Total	7 (23.3)	2 (6.7)	4 (13.3)	1 (3.3)	0
Infusion related reaction	2 (6.7)	0	2 (6.7)	0	0
Contusion	1 (3.3)	1 (3.3)	0	0	0
Foot fracture	1 (3.3)	0	1 (3.3)	0	0
Mouth injury	1 (3.3)	1 (3.3)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural complication	1 (3.3)	1 (3.3)	0	0	0
Procedural headache	1 (3.3)	0	1 (3.3)	0	0
Procedural nausea	1 (3.3)	0	1 (3.3)	0	0
Skin abrasion	1 (3.3)	1 (3.3)	0	0	0
Skin laceration	1 (3.3)	0	1 (3.3)	0	0
Sunburn	1 (3.3)	1 (3.3)	0	0	0
Tongue injury	1 (3.3)	1 (3.3)	0	0	0
Tracheal haemorrhage	1 (3.3)	0	0	1 (3.3)	0
Investigations					
-Total	25 (83.3)	1 (3.3)	3 (10.0)	6 (20.0)	15 (50.0)
White blood cell count decreased	15 (50.0)	3 (10.0)	0	4 (13.3)	8 (26.7)
Neutrophil count decreased	13 (43.3)	1 (3.3)	1 (3.3)	2 (6.7)	9 (30.0)
Aspartate aminotransferase increased	9 (30.0)	0	2 (6.7)	4 (13.3)	3 (10.0)
Alanine aminotransferase increased	8 (26.7)	2 (6.7)	0	6 (20.0)	0
Platelet count decreased	8 (26.7)	2 (6.7)	1 (3.3)	1 (3.3)	4 (13.3)
Lymphocyte count decreased	7 (23.3)	1 (3.3)	2 (6.7)	2 (6.7)	2 (6.7)
Blood bilirubin increased	4 (13.3)	2 (6.7)	0	2 (6.7)	0
Blood creatinine increased	4 (13.3)	2 (6.7)	0	2 (6.7)	0
International normalised ratio increased	4 (13.3)	4 (13.3)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Blood fibrinogen decreased	2 (6.7)	0	1 (3.3)	0	1 (3.3)
Blood immunoglobulin m decreased	2 (6.7)	2 (6.7)	0	0	0
Blood phosphorus increased	2 (6.7)	2 (6.7)	0	0	0
Blood urea increased	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Prothrombin time prolonged	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Blood bicarbonate decreased	1 (3.3)	0	1 (3.3)	0	0
Blood immunoglobulin a decreased	1 (3.3)	1 (3.3)	0	0	0
Blood magnesium decreased	1 (3.3)	1 (3.3)	0	0	0
Blood phosphorus decreased	1 (3.3)	1 (3.3)	0	0	0
Blood uric acid increased	1 (3.3)	1 (3.3)	0	0	0
C-reactive protein increased	1 (3.3)	0	0	1 (3.3)	0
Cardiac murmur	1 (3.3)	1 (3.3)	0	0	0
Fibrin d dimer increased	1 (3.3)	1 (3.3)	0	0	0
Lipase increased	1 (3.3)	0	0	0	1 (3.3)
Norovirus test positive	1 (3.3)	1 (3.3)	0	0	0
Protein total decreased	1 (3.3)	0	0	1 (3.3)	0
Serum ferritin increased	1 (3.3)	0	1 (3.3)	0	0
Transaminases increased	1 (3.3)	1 (3.3)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Weight decreased	1 (3.3)	1 (3.3)	0	0	0
Metabolism and nutrition disorders					
-Total	16 (53.3)	4 (13.3)	1 (3.3)	10 (33.3)	1 (3.3)
Decreased appetite	9 (30.0)	2 (6.7)	1 (3.3)	6 (20.0)	0
Hypokalaemia	7 (23.3)	3 (10.0)	1 (3.3)	3 (10.0)	0
Hypophosphataemia	5 (16.7)	1 (3.3)	0	4 (13.3)	0
Hyperphosphataemia	2 (6.7)	2 (6.7)	0	0	0
Hypoalbuminaemia	2 (6.7)	0	2 (6.7)	0	0
Hypocalcaemia	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Vitamin d deficiency	2 (6.7)	2 (6.7)	0	0	0
Acidosis	1 (3.3)	0	0	1 (3.3)	0
Dehydration	1 (3.3)	0	0	1 (3.3)	0
Fluid overload	1 (3.3)	0	1 (3.3)	0	0
Hyperalbuminaemia	1 (3.3)	1 (3.3)	0	0	0
Hypercalcaemia	1 (3.3)	1 (3.3)	0	0	0
Hyperchloraemia	1 (3.3)	1 (3.3)	0	0	0
Hyperglycaemia	1 (3.3)	0	1 (3.3)	0	0
Hypermagnesaemia	1 (3.3)	1 (3.3)	0	0	0
Hypernatraemia	1 (3.3)	0	1 (3.3)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertriglyceridaemia	1 (3.3)	0	0	1 (3.3)	0
Hyperuricaemia	1 (3.3)	0	0	0	1 (3.3)
Hyponatraemia	1 (3.3)	0	0	1 (3.3)	0
Iron overload	1 (3.3)	0	0	1 (3.3)	0
Metabolic alkalosis	1 (3.3)	1 (3.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	9 (30.0)	4 (13.3)	4 (13.3)	1 (3.3)	0
Arthralgia	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Muscle spasms	2 (6.7)	2 (6.7)	0	0	0
Muscular weakness	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Myalgia	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Pain in extremity	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Back pain	1 (3.3)	1 (3.3)	0	0	0
Joint range of motion decreased	1 (3.3)	1 (3.3)	0	0	0
Musculoskeletal pain	1 (3.3)	1 (3.3)	0	0	0
Neck pain	1 (3.3)	0	1 (3.3)	0	0
Osteonecrosis	1 (3.3)	0	1 (3.3)	0	0
Pain in jaw	1 (3.3)	1 (3.3)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.3)	0	0	0	1 (3.3)
Glioblastoma multiforme	1 (3.3)	0	0	0	1 (3.3)
Nervous system disorders					
-Total	17 (56.7)	9 (30.0)	6 (20.0)	2 (6.7)	0
Headache	11 (36.7)	8 (26.7)	2 (6.7)	1 (3.3)	0
Encephalopathy	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Peroneal nerve palsy	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Seizure	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Disturbance in attention	1 (3.3)	1 (3.3)	0	0	0
Dizziness	1 (3.3)	1 (3.3)	0	0	0
Dysarthria	1 (3.3)	0	1 (3.3)	0	0
Somnolence	1 (3.3)	1 (3.3)	0	0	0
Psychiatric disorders					
-Total	8 (26.7)	4 (13.3)	4 (13.3)	0	0
Confusional state	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Anxiety	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Delirium	2 (6.7)	1 (3.3)	1 (3.3)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Depression	2 (6.7)	2 (6.7)	0	0	0
Irritability	2 (6.7)	2 (6.7)	0	0	0
Agitation	1 (3.3)	0	1 (3.3)	0	0
Hallucination	1 (3.3)	0	1 (3.3)	0	0
Insomnia	1 (3.3)	0	1 (3.3)	0	0
Listless	1 (3.3)	1 (3.3)	0	0	0
Mental status changes	1 (3.3)	1 (3.3)	0	0	0
Sleep disorder	1 (3.3)	0	1 (3.3)	0	0
Renal and urinary disorders					
-Total	5 (16.7)	1 (3.3)	1 (3.3)	1 (3.3)	2 (6.7)
Acute kidney injury	3 (10.0)	0	1 (3.3)	0	2 (6.7)
Haematuria	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Dysuria	1 (3.3)	1 (3.3)	0	0	0
Oliguria	1 (3.3)	0	0	1 (3.3)	0
Renal impairment	1 (3.3)	0	0	1 (3.3)	0
Reproductive system and breast disorders					
-Total	1 (3.3)	0	1 (3.3)	0	0
Scrotal pain	1 (3.3)	0	1 (3.3)	0	0
Respiratory, thoracic and mediastinal disorders					

Timing: Any time post CTL019 infusion, Gender: Male

			All patients N=30		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	16 (53.3)	5 (16.7)	5 (16.7)	3 (10.0)	3 (10.0)
Cough	6 (20.0)	4 (13.3)	2 (6.7)	0	0
Epistaxis	5 (16.7)	1 (3.3)	1 (3.3)	3 (10.0)	0
Hypoxia	5 (16.7)	0	2 (6.7)	1 (3.3)	2 (6.7)
Pleural effusion	5 (16.7)	1 (3.3)	3 (10.0)	1 (3.3)	0
Pulmonary oedema	4 (13.3)	0	0	3 (10.0)	1 (3.3)
Nasal congestion	3 (10.0)	3 (10.0)	0	0	0
Dyspnoea	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Rhinorrhoea	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Tachypnoea	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Atelectasis	1 (3.3)	1 (3.3)	0	0	0
Dysphonia	1 (3.3)	1 (3.3)	0	0	0
Interstitial lung disease	1 (3.3)	0	0	0	1 (3.3)
Oropharyngeal pain	1 (3.3)	0	1 (3.3)	0	0
Oropharyngeal plaque	1 (3.3)	1 (3.3)	0	0	0
Pharyngeal erythema	1 (3.3)	1 (3.3)	0	0	0
Pharyngeal lesion	1 (3.3)	0	0	1 (3.3)	0
Pharyngeal ulceration	1 (3.3)	0	1 (3.3)	0	0
Respiratory depression	1 (3.3)	0	1 (3.3)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory distress	1 (3.3)	0	0	0	1 (3.3)
Rhinitis allergic	1 (3.3)	1 (3.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	16 (53.3)	10 (33.3)	4 (13.3)	2 (6.7)	0
Erythema	4 (13.3)	4 (13.3)	0	0	0
Rash maculo-papular	4 (13.3)	3 (10.0)	0	1 (3.3)	0
Rash	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Hyperhidrosis	2 (6.7)	2 (6.7)	0	0	0
Ingrowing nail	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Papule	2 (6.7)	2 (6.7)	0	0	0
Acne	1 (3.3)	1 (3.3)	0	0	0
Alopecia	1 (3.3)	0	1 (3.3)	0	0
Dermatitis acneiform	1 (3.3)	0	0	1 (3.3)	0
Dermatitis diaper	1 (3.3)	1 (3.3)	0	0	0
Dry skin	1 (3.3)	1 (3.3)	0	0	0
Keloid scar	1 (3.3)	0	1 (3.3)	0	0
Livedo reticularis	1 (3.3)	1 (3.3)	0	0	0
Macule	1 (3.3)	1 (3.3)	0	0	0
Night sweats	1 (3.3)	0	1 (3.3)	0	0

Timing: Any time post CTL019 infusion, Gender: Male

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pruritus	1 (3.3)	1 (3.3)	0	0	0
Rash erythematous	1 (3.3)	0	1 (3.3)	0	0
Rash papular	1 (3.3)	1 (3.3)	0	0	0
Skin irritation	1 (3.3)	1 (3.3)	0	0	0
Vascular disorders					
-Total	11 (36.7)	0	2 (6.7)	5 (16.7)	4 (13.3)
Hypotension	9 (30.0)	0	0	5 (16.7)	4 (13.3)
Hypertension	8 (26.7)	2 (6.7)	5 (16.7)	1 (3.3)	0
Capillary leak syndrome	1 (3.3)	0	0	0	1 (3.3)
Flushing	1 (3.3)	1 (3.3)	0	0	0
Hot flush	1 (3.3)	1 (3.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174b
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Female

			All patients N=34		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (100)	0	1 (2.9)	6 (17.6)	27 (79.4)
Blood and lymphatic system disorders					
-Total	26 (76.5)	1 (2.9)	3 (8.8)	14 (41.2)	8 (23.5)
Anaemia	14 (41.2)	0	2 (5.9)	11 (32.4)	1 (2.9)
Febrile neutropenia	14 (41.2)	0	0	13 (38.2)	1 (2.9)
Thrombocytopenia	5 (14.7)	0	1 (2.9)	1 (2.9)	3 (8.8)
Neutropenia	4 (11.8)	0	0	1 (2.9)	3 (8.8)
Lymphopenia	3 (8.8)	0	2 (5.9)	0	1 (2.9)
Disseminated intravascular coagulation	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Coagulopathy	1 (2.9)	1 (2.9)	0	0	0
Lymphadenopathy	1 (2.9)	0	1 (2.9)	0	0
Pancytopenia	1 (2.9)	0	0	0	1 (2.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	13 (38.2)	7 (20.6)	6 (17.6)	0	0
Tachycardia	8 (23.5)	5 (14.7)	3 (8.8)	0	0
Sinus tachycardia	5 (14.7)	3 (8.8)	2 (5.9)	0	0
Atrioventricular block second degree	1 (2.9)	1 (2.9)	0	0	0
Cardiac dysfunction	1 (2.9)	1 (2.9)	0	0	0
Pericardial effusion	1 (2.9)	1 (2.9)	0	0	0
Ventricular tachycardia	1 (2.9)	0	1 (2.9)	0	0
Ear and labyrinth disorders					
-Total	2 (5.9)	2 (5.9)	0	0	0
Ear pain	2 (5.9)	2 (5.9)	0	0	0
Endocrine disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Adrenal insufficiency	1 (2.9)	0	1 (2.9)	0	0
Eye disorders					
-Total	11 (32.4)	5 (14.7)	6 (17.6)	0	0
Conjunctival haemorrhage	2 (5.9)	2 (5.9)	0	0	0
Dry eye	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Periorbital oedema	2 (5.9)	2 (5.9)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Photophobia	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Uveitis	2 (5.9)	0	2 (5.9)	0	0
Vision blurred	2 (5.9)	0	2 (5.9)	0	0
Conjunctivitis allergic	1 (2.9)	1 (2.9)	0	0	0
Eye pain	1 (2.9)	0	1 (2.9)	0	0
Ocular hypertension	1 (2.9)	0	1 (2.9)	0	0
Papilloedema	1 (2.9)	0	1 (2.9)	0	0
Retinal haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Visual impairment	1 (2.9)	0	1 (2.9)	0	0
Gastrointestinal disorders					
-Total	26 (76.5)	7 (20.6)	12 (35.3)	7 (20.6)	0
Nausea	19 (55.9)	4 (11.8)	11 (32.4)	4 (11.8)	0
Diarrhoea	17 (50.0)	10 (29.4)	5 (14.7)	2 (5.9)	0
Vomiting	17 (50.0)	8 (23.5)	6 (17.6)	3 (8.8)	0
Abdominal pain	8 (23.5)	4 (11.8)	3 (8.8)	1 (2.9)	0
Constipation	6 (17.6)	5 (14.7)	1 (2.9)	0	0
Abdominal pain upper	2 (5.9)	0	2 (5.9)	0	0
Abdominal discomfort	1 (2.9)	1 (2.9)	0	0	0
Abdominal distension	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain lower	1 (2.9)	0	1 (2.9)	0	0
Abdominal tenderness	1 (2.9)	1 (2.9)	0	0	0
Ascites	1 (2.9)	0	0	1 (2.9)	0
Dyspepsia	1 (2.9)	0	1 (2.9)	0	0
Dysphagia	1 (2.9)	0	1 (2.9)	0	0
Flatulence	1 (2.9)	1 (2.9)	0	0	0
Gastrooesophageal reflux disease	1 (2.9)	1 (2.9)	0	0	0
Glossodynia	1 (2.9)	1 (2.9)	0	0	0
Intestinal obstruction	1 (2.9)	0	0	1 (2.9)	0
Lip pain	1 (2.9)	0	1 (2.9)	0	0
Pancreatitis	1 (2.9)	0	0	1 (2.9)	0
Stomatitis	1 (2.9)	1 (2.9)	0	0	0
Tooth socket haemorrhage	1 (2.9)	1 (2.9)	0	0	0
General disorders and administration site conditions					
-Total	25 (73.5)	11 (32.4)	8 (23.5)	5 (14.7)	1 (2.9)
Pyrexia	17 (50.0)	7 (20.6)	6 (17.6)	3 (8.8)	1 (2.9)
Fatigue	11 (32.4)	9 (26.5)	2 (5.9)	0	0
Chills	5 (14.7)	4 (11.8)	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Catheter site pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Oedema peripheral	2 (5.9)	2 (5.9)	0	0	0
Catheter site haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Crying	1 (2.9)	1 (2.9)	0	0	0
Cyst	1 (2.9)	0	0	1 (2.9)	0
Facial pain	1 (2.9)	0	1 (2.9)	0	0
Generalised oedema	1 (2.9)	1 (2.9)	0	0	0
Influenza like illness	1 (2.9)	1 (2.9)	0	0	0
Injection site haematoma	1 (2.9)	1 (2.9)	0	0	0
Physical deconditioning	1 (2.9)	0	0	1 (2.9)	0
Hepatobiliary disorders					
-Total	2 (5.9)	2 (5.9)	0	0	0
Gallbladder enlargement	1 (2.9)	1 (2.9)	0	0	0
Hepatosplenomegaly	1 (2.9)	1 (2.9)	0	0	0
Immune system disorders					
-Total	31 (91.2)	1 (2.9)	18 (52.9)	7 (20.6)	5 (14.7)
Cytokine release syndrome	27 (79.4)	2 (5.9)	15 (44.1)	5 (14.7)	5 (14.7)
Hypogammaglobulinaemia	16 (47.1)	2 (5.9)	11 (32.4)	3 (8.8)	0

Timing: Any time post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Immunodeficiency common variable	2 (5.9)	0	2 (5.9)	0	0
Graft versus host disease in gastrointestinal tract	1 (2.9)	0	1 (2.9)	0	0
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	1 (2.9)	0	0
Immunodeficiency	1 (2.9)	0	1 (2.9)	0	0
Seasonal allergy	1 (2.9)	1 (2.9)	0	0	0
Infections and infestations					
-Total	26 (76.5)	3 (8.8)	12 (35.3)	7 (20.6)	4 (11.8)
Clostridium difficile infection	4 (11.8)	0	3 (8.8)	1 (2.9)	0
Rhinovirus infection	4 (11.8)	4 (11.8)	0	0	0
Upper respiratory tract infection	4 (11.8)	2 (5.9)	1 (2.9)	1 (2.9)	0
Urinary tract infection	4 (11.8)	0	3 (8.8)	1 (2.9)	0
Clostridium difficile colitis	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Pneumonia	3 (8.8)	0	2 (5.9)	1 (2.9)	0
Cytomegalovirus infection	2 (5.9)	2 (5.9)	0	0	0
Ear infection	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Gastroenteritis	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Influenza	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Parainfluenzae virus infection	2 (5.9)	1 (2.9)	0	1 (2.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sinusitis	2 (5.9)	0	2 (5.9)	0	0
Staphylococcal infection	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Viral upper respiratory tract infection	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Vulvovaginal candidiasis	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Bacterial sepsis	1 (2.9)	0	0	0	1 (2.9)
Campylobacter infection	1 (2.9)	0	0	1 (2.9)	0
Catheter site cellulitis	1 (2.9)	1 (2.9)	0	0	0
Catheter site infection	1 (2.9)	0	0	1 (2.9)	0
Enterococcal infection	1 (2.9)	1 (2.9)	0	0	0
Enterovirus infection	1 (2.9)	0	0	1 (2.9)	0
Escherichia urinary tract infection	1 (2.9)	0	0	1 (2.9)	0
Folliculitis	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis viral	1 (2.9)	1 (2.9)	0	0	0
Herpes simplex	1 (2.9)	1 (2.9)	0	0	0
Human herpesvirus 6 infection	1 (2.9)	0	1 (2.9)	0	0
Hypopyon	1 (2.9)	0	1 (2.9)	0	0
Meningitis aseptic	1 (2.9)	0	1 (2.9)	0	0
Molluscum contagiosum	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral candidiasis	1 (2.9)	1 (2.9)	0	0	0
Oral herpes	1 (2.9)	0	1 (2.9)	0	0
Otitis externa	1 (2.9)	0	1 (2.9)	0	0
Otitis media	1 (2.9)	0	1 (2.9)	0	0
Otitis media acute	1 (2.9)	0	1 (2.9)	0	0
Paronychia	1 (2.9)	1 (2.9)	0	0	0
Respiratory tract infection	1 (2.9)	0	0	0	1 (2.9)
Respiratory tract infection viral	1 (2.9)	0	0	1 (2.9)	0
Rhinitis	1 (2.9)	1 (2.9)	0	0	0
Rotavirus infection	1 (2.9)	0	0	1 (2.9)	0
Sepsis	1 (2.9)	0	0	0	1 (2.9)
Septic embolus	1 (2.9)	0	0	0	1 (2.9)
Skin infection	1 (2.9)	0	1 (2.9)	0	0
Tinea capitis	1 (2.9)	1 (2.9)	0	0	0
Urinary tract infection enterococcal	1 (2.9)	0	0	1 (2.9)	0
Vascular device infection	1 (2.9)	0	0	1 (2.9)	0
Vulvovaginal mycotic infection	1 (2.9)	0	1 (2.9)	0	0
Injury, poisoning and procedural complications					
-Total	15 (44.1)	9 (26.5)	4 (11.8)	1 (2.9)	1 (2.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural pain	5 (14.7)	2 (5.9)	2 (5.9)	1 (2.9)	0
Transfusion reaction	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Contusion	2 (5.9)	2 (5.9)	0	0	0
Infusion related reaction	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Arthropod bite	1 (2.9)	1 (2.9)	0	0	0
Incision site pain	1 (2.9)	1 (2.9)	0	0	0
Limb injury	1 (2.9)	1 (2.9)	0	0	0
Post procedural haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Procedural site reaction	1 (2.9)	1 (2.9)	0	0	0
Radius fracture	1 (2.9)	0	1 (2.9)	0	0
Skin abrasion	1 (2.9)	1 (2.9)	0	0	0
Stoma site irritation	1 (2.9)	1 (2.9)	0	0	0
Subdural haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Tibia fracture	1 (2.9)	0	1 (2.9)	0	0
Transfusion related complication	1 (2.9)	0	0	0	1 (2.9)
Investigations					
-Total	31 (91.2)	1 (2.9)	2 (5.9)	9 (26.5)	19 (55.9)
White blood cell count decreased	20 (58.8)	1 (2.9)	1 (2.9)	8 (23.5)	10 (29.4)
Neutrophil count decreased	15 (44.1)	0	1 (2.9)	2 (5.9)	12 (35.3)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	13 (38.2)	3 (8.8)	2 (5.9)	8 (23.5)	0
Platelet count decreased	12 (35.3)	1 (2.9)	1 (2.9)	2 (5.9)	8 (23.5)
Aspartate aminotransferase increased	11 (32.4)	4 (11.8)	2 (5.9)	4 (11.8)	1 (2.9)
Lymphocyte count decreased	9 (26.5)	0	1 (2.9)	5 (14.7)	3 (8.8)
Prothrombin time prolonged	7 (20.6)	4 (11.8)	2 (5.9)	1 (2.9)	0
Blood creatinine increased	5 (14.7)	3 (8.8)	2 (5.9)	0	0
International normalised ratio increased	5 (14.7)	4 (11.8)	0	1 (2.9)	0
Blood bilirubin increased	4 (11.8)	0	3 (8.8)	1 (2.9)	0
Haemoglobin decreased	3 (8.8)	2 (5.9)	0	1 (2.9)	0
Weight decreased	3 (8.8)	0	3 (8.8)	0	0
Activated partial thromboplastin time prolonged	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Blood fibrinogen decreased	2 (5.9)	0	0	2 (5.9)	0
Blood immunoglobulin a decreased	2 (5.9)	2 (5.9)	0	0	0
Blood immunoglobulin m decreased	2 (5.9)	2 (5.9)	0	0	0
Transaminases increased	2 (5.9)	2 (5.9)	0	0	0
Weight increased	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Blood alkaline phosphatase increased	1 (2.9)	1 (2.9)	0	0	0
Blood immunoglobulin g decreased	1 (2.9)	0	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood lactate dehydrogenase increased	1 (2.9)	1 (2.9)	0	0	0
Blood lactic acid increased	1 (2.9)	0	0	0	1 (2.9)
Blood magnesium decreased	1 (2.9)	0	0	1 (2.9)	0
Blood sodium increased	1 (2.9)	0	1 (2.9)	0	0
Blood urea increased	1 (2.9)	1 (2.9)	0	0	0
Blood uric acid increased	1 (2.9)	1 (2.9)	0	0	0
C-reactive protein increased	1 (2.9)	1 (2.9)	0	0	0
Culture stool positive	1 (2.9)	1 (2.9)	0	0	0
Hepatic enzyme increased	1 (2.9)	0	1 (2.9)	0	0
Lipase increased	1 (2.9)	0	0	0	1 (2.9)
Oxygen saturation decreased	1 (2.9)	1 (2.9)	0	0	0
Pulmonary function test decreased	1 (2.9)	0	1 (2.9)	0	0
Serum ferritin increased	1 (2.9)	0	1 (2.9)	0	0
Metabolism and nutrition disorders					
-Total	27 (79.4)	4 (11.8)	7 (20.6)	13 (38.2)	3 (8.8)
Decreased appetite	13 (38.2)	3 (8.8)	4 (11.8)	6 (17.6)	0
Hypokalaemia	12 (35.3)	1 (2.9)	5 (14.7)	5 (14.7)	1 (2.9)
Hyperphosphataemia	6 (17.6)	6 (17.6)	0	0	0
Hypophosphataemia	5 (14.7)	1 (2.9)	0	3 (8.8)	1 (2.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	3 (8.8)	1 (2.9)	0	2 (5.9)	0
Hypernatraemia	3 (8.8)	1 (2.9)	1 (2.9)	0	1 (2.9)
Hypoalbuminaemia	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Fluid overload	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Hyperglycaemia	2 (5.9)	0	0	2 (5.9)	0
Hyperuricaemia	2 (5.9)	2 (5.9)	0	0	0
Tumour lysis syndrome	2 (5.9)	0	0	2 (5.9)	0
Acidosis	1 (2.9)	1 (2.9)	0	0	0
Hypertriglyceridaemia	1 (2.9)	1 (2.9)	0	0	0
Hypocalcaemia	1 (2.9)	0	1 (2.9)	0	0
Hypomagnesaemia	1 (2.9)	1 (2.9)	0	0	0
Hyponatraemia	1 (2.9)	0	0	1 (2.9)	0
Malnutrition	1 (2.9)	0	0	1 (2.9)	0
Metabolic acidosis	1 (2.9)	0	1 (2.9)	0	0
Musculoskeletal and connective tissue disorders					
-Total	16 (47.1)	10 (29.4)	6 (17.6)	0	0
Pain in extremity	9 (26.5)	6 (17.6)	3 (8.8)	0	0
Arthralgia	3 (8.8)	2 (5.9)	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	3 (8.8)	3 (8.8)	0	0	0
Musculoskeletal chest pain	2 (5.9)	2 (5.9)	0	0	0
Musculoskeletal pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Coccydynia	1 (2.9)	1 (2.9)	0	0	0
Flank pain	1 (2.9)	0	1 (2.9)	0	0
Joint range of motion decreased	1 (2.9)	1 (2.9)	0	0	0
Limb discomfort	1 (2.9)	1 (2.9)	0	0	0
Muscular weakness	1 (2.9)	1 (2.9)	0	0	0
Osteopenia	1 (2.9)	0	1 (2.9)	0	0
Toe walking	1 (2.9)	1 (2.9)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (5.9)	0	2 (5.9)	0	0
Myelodysplastic syndrome	1 (2.9)	0	1 (2.9)	0	0
Skin papilloma	1 (2.9)	0	1 (2.9)	0	0
Nervous system disorders					
-Total	18 (52.9)	8 (23.5)	6 (17.6)	3 (8.8)	1 (2.9)
Headache	13 (38.2)	7 (20.6)	5 (14.7)	1 (2.9)	0
Dizziness	5 (14.7)	5 (14.7)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Seizure	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Tremor	2 (5.9)	2 (5.9)	0	0	0
Asterixis	1 (2.9)	1 (2.9)	0	0	0
Ataxia	1 (2.9)	0	1 (2.9)	0	0
Depressed level of consciousness	1 (2.9)	1 (2.9)	0	0	0
Dysarthria	1 (2.9)	1 (2.9)	0	0	0
Embolic stroke	1 (2.9)	0	0	0	1 (2.9)
Idiopathic intracranial hypertension	1 (2.9)	0	1 (2.9)	0	0
Migraine	1 (2.9)	0	1 (2.9)	0	0
Myoclonus	1 (2.9)	1 (2.9)	0	0	0
Neuropathy peripheral	1 (2.9)	0	1 (2.9)	0	0
Pleocytosis	1 (2.9)	1 (2.9)	0	0	0
Product issues					
-Total	1 (2.9)	1 (2.9)	0	0	0
Device occlusion	1 (2.9)	1 (2.9)	0	0	0
Psychiatric disorders					
-Total	9 (26.5)	4 (11.8)	4 (11.8)	1 (2.9)	0
Anxiety	4 (11.8)	2 (5.9)	1 (2.9)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	2 (5.9)	0	2 (5.9)	0	0
Delirium	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Adjustment disorder	1 (2.9)	0	1 (2.9)	0	0
Agitation	1 (2.9)	0	1 (2.9)	0	0
Hallucination	1 (2.9)	1 (2.9)	0	0	0
Panic attack	1 (2.9)	0	1 (2.9)	0	0
Suicidal ideation	1 (2.9)	1 (2.9)	0	0	0
Renal and urinary disorders					
-Total	10 (29.4)	2 (5.9)	1 (2.9)	5 (14.7)	2 (5.9)
Acute kidney injury	6 (17.6)	1 (2.9)	0	4 (11.8)	1 (2.9)
Haematuria	3 (8.8)	0	1 (2.9)	1 (2.9)	1 (2.9)
Calculus urinary	1 (2.9)	0	1 (2.9)	0	0
Dysuria	1 (2.9)	0	1 (2.9)	0	0
Nephrolithiasis	1 (2.9)	0	0	1 (2.9)	0
Oliguria	1 (2.9)	0	0	1 (2.9)	0
Pollakiuria	1 (2.9)	1 (2.9)	0	0	0
Renal failure	1 (2.9)	0	0	0	1 (2.9)
Urinary incontinence	1 (2.9)	1 (2.9)	0	0	0
Reproductive system and breast disorders					

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (14.7)	2 (5.9)	1 (2.9)	2 (5.9)	0
Vulvovaginal adhesion	2 (5.9)	2 (5.9)	0	0	0
Oedema genital	1 (2.9)	0	1 (2.9)	0	0
Ovarian failure	1 (2.9)	0	0	1 (2.9)	0
Vaginal haemorrhage	1 (2.9)	0	0	1 (2.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	22 (64.7)	9 (26.5)	4 (11.8)	4 (11.8)	5 (14.7)
Cough	8 (23.5)	8 (23.5)	0	0	0
Epistaxis	5 (14.7)	3 (8.8)	0	1 (2.9)	1 (2.9)
Hypoxia	5 (14.7)	0	1 (2.9)	3 (8.8)	1 (2.9)
Oropharyngeal pain	5 (14.7)	4 (11.8)	1 (2.9)	0	0
Rhinorrhoea	4 (11.8)	4 (11.8)	0	0	0
Pleural effusion	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Pulmonary oedema	3 (8.8)	1 (2.9)	0	1 (2.9)	1 (2.9)
Respiratory failure	3 (8.8)	0	0	0	3 (8.8)
Rhinitis allergic	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Tachypnoea	3 (8.8)	2 (5.9)	0	1 (2.9)	0
Haemoptysis	2 (5.9)	1 (2.9)	0	0	1 (2.9)
Nasal congestion	2 (5.9)	2 (5.9)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

Primary system organ class Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute respiratory failure	1 (2.9)	0	0	0	1 (2.9)
Wheezing	1 (2.9)	0	1 (2.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	14 (41.2)	8 (23.5)	5 (14.7)	1 (2.9)	0
Rash	5 (14.7)	3 (8.8)	2 (5.9)	0	0
Dry skin	4 (11.8)	4 (11.8)	0	0	0
Petechiae	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Pruritus	3 (8.8)	3 (8.8)	0	0	0
Hyperhidrosis	2 (5.9)	2 (5.9)	0	0	0
Dermatitis	1 (2.9)	1 (2.9)	0	0	0
Dermatitis atopic	1 (2.9)	1 (2.9)	0	0	0
Ecchymosis	1 (2.9)	0	0	1 (2.9)	0
Eczema	1 (2.9)	1 (2.9)	0	0	0
Erythema	1 (2.9)	1 (2.9)	0	0	0
Ingrowing nail	1 (2.9)	0	1 (2.9)	0	0
Macule	1 (2.9)	1 (2.9)	0	0	0
Rash erythematous	1 (2.9)	1 (2.9)	0	0	0
Rash follicular	1 (2.9)	1 (2.9)	0	0	0
Rash macular	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash maculo-papular	1 (2.9)	0	1 (2.9)	0	0
Rash papular	1 (2.9)	1 (2.9)	0	0	0
Rash pruritic	1 (2.9)	1 (2.9)	0	0	0
Rash vesicular	1 (2.9)	1 (2.9)	0	0	0
Skin exfoliation	1 (2.9)	1 (2.9)	0	0	0
Skin fissures	1 (2.9)	1 (2.9)	0	0	0
Vascular disorders					
-Total	14 (41.2)	3 (8.8)	4 (11.8)	3 (8.8)	4 (11.8)
Hypotension	7 (20.6)	1 (2.9)	0	2 (5.9)	4 (11.8)
Hypertension	4 (11.8)	1 (2.9)	3 (8.8)	0	0
Orthostatic hypotension	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Embolism	1 (2.9)	0	0	1 (2.9)	0
Flushing	1 (2.9)	1 (2.9)	0	0	0
Haematoma	1 (2.9)	0	1 (2.9)	0	0
Secondary hypertension	1 (2.9)	0	1 (2.9)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: White

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (98.1)	2 (3.8)	5 (9.6)	10 (19.2)	34 (65.4)
Blood and lymphatic system disorders					
-Total	35 (67.3)	2 (3.8)	0	23 (44.2)	10 (19.2)
Anaemia	21 (40.4)	3 (5.8)	3 (5.8)	14 (26.9)	1 (1.9)
Febrile neutropenia	19 (36.5)	0	0	19 (36.5)	0
Neutropenia	8 (15.4)	0	0	3 (5.8)	5 (9.6)
Thrombocytopenia	8 (15.4)	0	0	2 (3.8)	6 (11.5)
Disseminated intravascular coagulation	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Lymphopenia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Coagulopathy	1 (1.9)	1 (1.9)	0	0	0
Pancytopenia	1 (1.9)	0	0	0	1 (1.9)
Cardiac disorders					
-Total	18 (34.6)	8 (15.4)	8 (15.4)	2 (3.8)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	12 (23.1)	5 (9.6)	5 (9.6)	2 (3.8)	0
Sinus tachycardia	5 (9.6)	3 (5.8)	2 (3.8)	0	0
Pericardial effusion	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Bradycardia	1 (1.9)	0	1 (1.9)	0	0
Cardiac dysfunction	1 (1.9)	1 (1.9)	0	0	0
Left ventricular dysfunction	1 (1.9)	0	0	1 (1.9)	0
Palpitations	1 (1.9)	1 (1.9)	0	0	0
Sinus bradycardia	1 (1.9)	1 (1.9)	0	0	0
Ear and labyrinth disorders					
-Total	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Ear pain	2 (3.8)	2 (3.8)	0	0	0
Hypoacusis	1 (1.9)	0	1 (1.9)	0	0
Eye disorders					
-Total	11 (21.2)	6 (11.5)	5 (9.6)	0	0
Eye pain	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Periorbital oedema	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Conjunctival haemorrhage	2 (3.8)	2 (3.8)	0	0	0
Photophobia	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Retinal haemorrhage	2 (3.8)	2 (3.8)	0	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vision blurred	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Ocular hypertension	1 (1.9)	0	1 (1.9)	0	0
Papilloedema	1 (1.9)	0	1 (1.9)	0	0
Uveitis	1 (1.9)	0	1 (1.9)	0	0
Visual impairment	1 (1.9)	0	1 (1.9)	0	0
Gastrointestinal disorders					
-Total	29 (55.8)	9 (17.3)	9 (17.3)	11 (21.2)	0
Vomiting	17 (32.7)	8 (15.4)	6 (11.5)	3 (5.8)	0
Diarrhoea	16 (30.8)	11 (21.2)	4 (7.7)	1 (1.9)	0
Nausea	16 (30.8)	4 (7.7)	9 (17.3)	3 (5.8)	0
Abdominal pain	8 (15.4)	5 (9.6)	2 (3.8)	1 (1.9)	0
Constipation	6 (11.5)	5 (9.6)	1 (1.9)	0	0
Abdominal distension	2 (3.8)	0	2 (3.8)	0	0
Haematemesis	2 (3.8)	2 (3.8)	0	0	0
Pancreatitis	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Stomatitis	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Abdominal discomfort	1 (1.9)	1 (1.9)	0	0	0
Abdominal pain lower	1 (1.9)	0	1 (1.9)	0	0
Abdominal pain upper	1 (1.9)	0	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Race: White

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal tenderness	1 (1.9)	1 (1.9)	0	0	0
Anal incontinence	1 (1.9)	1 (1.9)	0	0	0
Ascites	1 (1.9)	0	0	1 (1.9)	0
Dyspepsia	1 (1.9)	0	1 (1.9)	0	0
Dysphagia	1 (1.9)	0	0	1 (1.9)	0
Gastrointestinal haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Gastrooesophageal reflux disease	1 (1.9)	1 (1.9)	0	0	0
Glossodynia	1 (1.9)	1 (1.9)	0	0	0
Ileus	1 (1.9)	0	0	1 (1.9)	0
Intestinal obstruction	1 (1.9)	0	0	1 (1.9)	0
Mouth haemorrhage	1 (1.9)	0	0	1 (1.9)	0
Tooth socket haemorrhage	1 (1.9)	1 (1.9)	0	0	0
General disorders and administration site conditions					
-Total	24 (46.2)	8 (15.4)	7 (13.5)	8 (15.4)	1 (1.9)
Pyrexia	14 (26.9)	2 (3.8)	6 (11.5)	5 (9.6)	1 (1.9)
Fatigue	9 (17.3)	6 (11.5)	2 (3.8)	1 (1.9)	0
Chills	8 (15.4)	8 (15.4)	0	0	0
Catheter site pain	2 (3.8)	0	2 (3.8)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Generalised oedema	2 (3.8)	0	2 (3.8)	0	0
Malaise	2 (3.8)	0	2 (3.8)	0	0
Oedema peripheral	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Pain	2 (3.8)	0	0	2 (3.8)	0
Asthenia	1 (1.9)	1 (1.9)	0	0	0
Catheter site extravasation	1 (1.9)	0	1 (1.9)	0	0
Facial pain	1 (1.9)	0	1 (1.9)	0	0
Localised oedema	1 (1.9)	0	0	1 (1.9)	0
Mucosal haemorrhage	1 (1.9)	0	1 (1.9)	0	0
Multiple organ dysfunction syndrome	1 (1.9)	0	0	1 (1.9)	0
Non-cardiac chest pain	1 (1.9)	1 (1.9)	0	0	0
Peripheral swelling	1 (1.9)	0	1 (1.9)	0	0
Hepatobiliary disorders					
-Total	6 (11.5)	2 (3.8)	2 (3.8)	2 (3.8)	0
Hepatomegaly	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Hyperbilirubinaemia	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Hepatosplenomegaly	1 (1.9)	1 (1.9)	0	0	0
Immune system disorders					

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	46 (88.5)	4 (7.7)	22 (42.3)	10 (19.2)	10 (19.2)
Cytokine release syndrome	40 (76.9)	4 (7.7)	19 (36.5)	7 (13.5)	10 (19.2)
Hypogammaglobulinaemia	20 (38.5)	1 (1.9)	15 (28.8)	4 (7.7)	0
Drug hypersensitivity	1 (1.9)	0	1 (1.9)	0	0
Graft versus host disease in skin	1 (1.9)	1 (1.9)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.9)	0	1 (1.9)	0	0
Infections and infestations					
-Total	21 (40.4)	4 (7.7)	11 (21.2)	5 (9.6)	1 (1.9)
Clostridium difficile colitis	3 (5.8)	1 (1.9)	1 (1.9)	1 (1.9)	0
Clostridium difficile infection	3 (5.8)	0	3 (5.8)	0	0
Rhinovirus infection	3 (5.8)	3 (5.8)	0	0	0
Pneumonia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Staphylococcal infection	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Acute sinusitis	1 (1.9)	0	1 (1.9)	0	0
Body tinea	1 (1.9)	1 (1.9)	0	0	0
Catheter site infection	1 (1.9)	0	0	1 (1.9)	0
Enterococcal infection	1 (1.9)	1 (1.9)	0	0	0
Folliculitis	1 (1.9)	0	1 (1.9)	0	0
Fungal skin infection	1 (1.9)	1 (1.9)	0	0	0

Timing: within 8 weeks post infusion, Race: White

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Human herpesvirus 6 infection	1 (1.9)	0	1 (1.9)	0	0
Hypopyon	1 (1.9)	0	1 (1.9)	0	0
Influenza	1 (1.9)	1 (1.9)	0	0	0
Oral candidiasis	1 (1.9)	1 (1.9)	0	0	0
Orchitis	1 (1.9)	1 (1.9)	0	0	0
Septic embolus	1 (1.9)	0	0	0	1 (1.9)
Skin infection	1 (1.9)	0	1 (1.9)	0	0
Upper respiratory tract infection	1 (1.9)	0	1 (1.9)	0	0
Urinary tract infection enterococcal	1 (1.9)	0	0	1 (1.9)	0
Viral infection	1 (1.9)	0	1 (1.9)	0	0
Vulvovaginal candidiasis	1 (1.9)	1 (1.9)	0	0	0
Injury, poisoning and procedural complications					
-Total	12 (23.1)	7 (13.5)	4 (7.7)	1 (1.9)	0
Infusion related reaction	2 (3.8)	0	2 (3.8)	0	0
Procedural pain	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Transfusion reaction	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Contusion	1 (1.9)	1 (1.9)	0	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Incision site pain	1 (1.9)	1 (1.9)	0	0	0
Limb injury	1 (1.9)	1 (1.9)	0	0	0
Mouth injury	1 (1.9)	1 (1.9)	0	0	0
Procedural complication	1 (1.9)	1 (1.9)	0	0	0
Procedural headache	1 (1.9)	0	1 (1.9)	0	0
Procedural site reaction	1 (1.9)	1 (1.9)	0	0	0
Skin abrasion	1 (1.9)	1 (1.9)	0	0	0
Stoma site irritation	1 (1.9)	1 (1.9)	0	0	0
Subdural haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Tibia fracture	1 (1.9)	0	1 (1.9)	0	0
Tongue injury	1 (1.9)	1 (1.9)	0	0	0
Tracheal haemorrhage	1 (1.9)	0	0	1 (1.9)	0
Investigations					
-Total	43 (82.7)	4 (7.7)	3 (5.8)	10 (19.2)	26 (50.0)
White blood cell count decreased	23 (44.2)	3 (5.8)	0	7 (13.5)	13 (25.0)
Neutrophil count decreased	20 (38.5)	0	1 (1.9)	4 (7.7)	15 (28.8)
Platelet count decreased	17 (32.7)	3 (5.8)	2 (3.8)	2 (3.8)	10 (19.2)
Alanine aminotransferase increased	16 (30.8)	4 (7.7)	2 (3.8)	10 (19.2)	0
Aspartate aminotransferase increased	14 (26.9)	2 (3.8)	3 (5.8)	5 (9.6)	4 (7.7)

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	11 (21.2)	1 (1.9)	1 (1.9)	5 (9.6)	4 (7.7)
Blood bilirubin increased	7 (13.5)	2 (3.8)	3 (5.8)	2 (3.8)	0
Blood creatinine increased	7 (13.5)	4 (7.7)	1 (1.9)	2 (3.8)	0
International normalised ratio increased	7 (13.5)	6 (11.5)	0	1 (1.9)	0
Prothrombin time prolonged	7 (13.5)	4 (7.7)	2 (3.8)	1 (1.9)	0
Activated partial thromboplastin time prolonged	4 (7.7)	2 (3.8)	2 (3.8)	0	0
Blood fibrinogen decreased	4 (7.7)	0	1 (1.9)	2 (3.8)	1 (1.9)
Blood immunoglobulin m decreased	3 (5.8)	3 (5.8)	0	0	0
Blood urea increased	3 (5.8)	1 (1.9)	1 (1.9)	1 (1.9)	0
Blood phosphorus increased	2 (3.8)	2 (3.8)	0	0	0
Lipase increased	2 (3.8)	0	0	0	2 (3.8)
Transaminases increased	2 (3.8)	2 (3.8)	0	0	0
Blood bicarbonate decreased	1 (1.9)	0	1 (1.9)	0	0
Blood immunoglobulin a decreased	1 (1.9)	1 (1.9)	0	0	0
Blood immunoglobulin g decreased	1 (1.9)	0	1 (1.9)	0	0
Blood lactic acid increased	1 (1.9)	0	0	0	1 (1.9)
Blood magnesium decreased	1 (1.9)	0	0	1 (1.9)	0
Blood phosphorus decreased	1 (1.9)	1 (1.9)	0	0	0
Blood sodium increased	1 (1.9)	0	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	1 (1.9)	1 (1.9)	0	0	0
C-reactive protein increased	1 (1.9)	0	0	1 (1.9)	0
Cardiac murmur	1 (1.9)	1 (1.9)	0	0	0
Fibrin d dimer increased	1 (1.9)	1 (1.9)	0	0	0
Norovirus test positive	1 (1.9)	1 (1.9)	0	0	0
Protein total decreased	1 (1.9)	0	0	1 (1.9)	0
Pulmonary function test decreased	1 (1.9)	0	1 (1.9)	0	0
Serum ferritin increased	1 (1.9)	0	1 (1.9)	0	0
Metabolism and nutrition disorders					
-Total	33 (63.5)	2 (3.8)	10 (19.2)	18 (34.6)	3 (5.8)
Decreased appetite	18 (34.6)	3 (5.8)	4 (7.7)	11 (21.2)	0
Hypokalaemia	16 (30.8)	3 (5.8)	6 (11.5)	7 (13.5)	0
Hypophosphataemia	9 (17.3)	2 (3.8)	0	6 (11.5)	1 (1.9)
Hyperphosphataemia	6 (11.5)	6 (11.5)	0	0	0
Hypoalbuminaemia	5 (9.6)	1 (1.9)	3 (5.8)	1 (1.9)	0
Fluid overload	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Hyperglycaemia	3 (5.8)	0	2 (3.8)	1 (1.9)	0
Hypernatraemia	3 (5.8)	0	2 (3.8)	0	1 (1.9)
Hypocalcaemia	3 (5.8)	1 (1.9)	1 (1.9)	1 (1.9)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Hypertriglyceridaemia	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Hyperuricaemia	2 (3.8)	1 (1.9)	0	0	1 (1.9)
Hyponatraemia	2 (3.8)	0	0	2 (3.8)	0
Acidosis	1 (1.9)	0	0	1 (1.9)	0
Hyperalbuminaemia	1 (1.9)	1 (1.9)	0	0	0
Hypercalcaemia	1 (1.9)	1 (1.9)	0	0	0
Hyperchloraemia	1 (1.9)	1 (1.9)	0	0	0
Hypermagnesaemia	1 (1.9)	1 (1.9)	0	0	0
Hypomagnesaemia	1 (1.9)	1 (1.9)	0	0	0
Malnutrition	1 (1.9)	0	0	1 (1.9)	0
Metabolic acidosis	1 (1.9)	0	1 (1.9)	0	0
Metabolic alkalosis	1 (1.9)	1 (1.9)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	11 (21.2)	5 (9.6)	5 (9.6)	1 (1.9)	0
Arthralgia	3 (5.8)	2 (3.8)	0	1 (1.9)	0
Musculoskeletal pain	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Myalgia	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Pain in extremity	2 (3.8)	1 (1.9)	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Limb discomfort	1 (1.9)	1 (1.9)	0	0	0
Muscle spasms	1 (1.9)	1 (1.9)	0	0	0
Muscular weakness	1 (1.9)	0	1 (1.9)	0	0
Musculoskeletal chest pain	1 (1.9)	1 (1.9)	0	0	0
Osteopenia	1 (1.9)	0	1 (1.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.9)	0	1 (1.9)	0	0
Skin papilloma	1 (1.9)	0	1 (1.9)	0	0
Nervous system disorders					
-Total	27 (51.9)	14 (26.9)	8 (15.4)	4 (7.7)	1 (1.9)
Headache	19 (36.5)	14 (26.9)	3 (5.8)	2 (3.8)	0
Dizziness	4 (7.7)	4 (7.7)	0	0	0
Encephalopathy	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Seizure	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Depressed level of consciousness	1 (1.9)	1 (1.9)	0	0	0
Dysarthria	1 (1.9)	0	1 (1.9)	0	0
Embolic stroke	1 (1.9)	0	0	0	1 (1.9)
Idiopathic intracranial hypertension	1 (1.9)	0	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Migraine	1 (1.9)	0	1 (1.9)	0	0
Somnolence	1 (1.9)	1 (1.9)	0	0	0
Tremor	1 (1.9)	1 (1.9)	0	0	0
Product issues					
-Total	1 (1.9)	1 (1.9)	0	0	0
Device occlusion	1 (1.9)	1 (1.9)	0	0	0
Psychiatric disorders					
-Total	15 (28.8)	8 (15.4)	6 (11.5)	1 (1.9)	0
Confusional state	6 (11.5)	3 (5.8)	3 (5.8)	0	0
Anxiety	5 (9.6)	2 (3.8)	2 (3.8)	1 (1.9)	0
Delirium	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Hallucination	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Irritability	2 (3.8)	2 (3.8)	0	0	0
Agitation	1 (1.9)	0	1 (1.9)	0	0
Insomnia	1 (1.9)	0	1 (1.9)	0	0
Listless	1 (1.9)	1 (1.9)	0	0	0
Mental status changes	1 (1.9)	1 (1.9)	0	0	0
Panic attack	1 (1.9)	0	1 (1.9)	0	0
Renal and urinary disorders					

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (15.4)	1 (1.9)	1 (1.9)	2 (3.8)	4 (7.7)
Acute kidney injury	5 (9.6)	0	1 (1.9)	1 (1.9)	3 (5.8)
Haematuria	4 (7.7)	0	2 (3.8)	1 (1.9)	1 (1.9)
Oliguria	2 (3.8)	0	0	2 (3.8)	0
Dysuria	1 (1.9)	1 (1.9)	0	0	0
Renal failure	1 (1.9)	0	0	0	1 (1.9)
Renal impairment	1 (1.9)	0	0	1 (1.9)	0
Reproductive system and breast disorders					
-Total	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Vulvovaginal adhesion	2 (3.8)	2 (3.8)	0	0	0
Oedema genital	1 (1.9)	0	1 (1.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	26 (50.0)	10 (19.2)	6 (11.5)	4 (7.7)	6 (11.5)
Hypoxia	10 (19.2)	0	3 (5.8)	4 (7.7)	3 (5.8)
Cough	8 (15.4)	8 (15.4)	0	0	0
Pleural effusion	8 (15.4)	2 (3.8)	4 (7.7)	2 (3.8)	0
Epistaxis	6 (11.5)	2 (3.8)	1 (1.9)	2 (3.8)	1 (1.9)
Pulmonary oedema	5 (9.6)	1 (1.9)	0	3 (5.8)	1 (1.9)
Tachypnoea	5 (9.6)	3 (5.8)	1 (1.9)	1 (1.9)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Respiratory failure	2 (3.8)	0	0	0	2 (3.8)
Atelectasis	1 (1.9)	1 (1.9)	0	0	0
Haemoptysis	1 (1.9)	0	0	0	1 (1.9)
Interstitial lung disease	1 (1.9)	0	0	0	1 (1.9)
Nasal congestion	1 (1.9)	1 (1.9)	0	0	0
Oropharyngeal pain	1 (1.9)	1 (1.9)	0	0	0
Oropharyngeal plaque	1 (1.9)	1 (1.9)	0	0	0
Pharyngeal ulceration	1 (1.9)	0	1 (1.9)	0	0
Respiratory depression	1 (1.9)	0	1 (1.9)	0	0
Respiratory distress	1 (1.9)	0	0	0	1 (1.9)
Rhinitis allergic	1 (1.9)	1 (1.9)	0	0	0
Rhinorrhoea	1 (1.9)	1 (1.9)	0	0	0
Wheezing	1 (1.9)	0	1 (1.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	19 (36.5)	14 (26.9)	4 (7.7)	1 (1.9)	0
Rash	4 (7.7)	4 (7.7)	0	0	0
Petechiae	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Rash maculo-papular	3 (5.8)	1 (1.9)	1 (1.9)	1 (1.9)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	2 (3.8)	2 (3.8)	0	0	0
Erythema	2 (3.8)	2 (3.8)	0	0	0
Hyperhidrosis	2 (3.8)	2 (3.8)	0	0	0
Ingrowing nail	2 (3.8)	0	2 (3.8)	0	0
Rash papular	2 (3.8)	2 (3.8)	0	0	0
Dermatitis diaper	1 (1.9)	1 (1.9)	0	0	0
Livedo reticularis	1 (1.9)	1 (1.9)	0	0	0
Macule	1 (1.9)	1 (1.9)	0	0	0
Night sweats	1 (1.9)	0	1 (1.9)	0	0
Pruritus	1 (1.9)	1 (1.9)	0	0	0
Rash erythematous	1 (1.9)	1 (1.9)	0	0	0
Rash follicular	1 (1.9)	1 (1.9)	0	0	0
Rash macular	1 (1.9)	1 (1.9)	0	0	0
Skin irritation	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					
-Total	20 (38.5)	3 (5.8)	3 (5.8)	7 (13.5)	7 (13.5)
Hypotension	15 (28.8)	1 (1.9)	0	7 (13.5)	7 (13.5)
Hypertension	9 (17.3)	2 (3.8)	6 (11.5)	1 (1.9)	0
Flushing	2 (3.8)	2 (3.8)	0	0	0

Timing: within 8 weeks post infusion, Race: White

Primary system organ class Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Capillary leak syndrome	1 (1.9)	0	0	0	1 (1.9)
Haematoma	1 (1.9)	0	1 (1.9)	0	0
Orthostatic hypotension	1 (1.9)	1 (1.9)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Asian

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	0	2 (40.0)	2 (40.0)	1 (20.0)
Blood and lymphatic system disorders					
-Total	3 (60.0)	0	1 (20.0)	2 (40.0)	0
Anaemia	3 (60.0)	0	1 (20.0)	2 (40.0)	0
Febrile neutropenia	1 (20.0)	0	0	1 (20.0)	0
Cardiac disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Atrioventricular block second degree	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Diarrhoea	1 (20.0)	0	1 (20.0)	0	0
Nausea	1 (20.0)	1 (20.0)	0	0	0
Vomiting	1 (20.0)	1 (20.0)	0	0	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	4 (80.0)	2 (40.0)	2 (40.0)	0	0
Fatigue	3 (60.0)	3 (60.0)	0	0	0
Pain	1 (20.0)	0	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	1 (20.0)	0	0
Immune system disorders					
-Total	5 (100)	0	5 (100)	0	0
Cytokine release syndrome	4 (80.0)	0	4 (80.0)	0	0
Hypogammaglobulinaemia	3 (60.0)	1 (20.0)	2 (40.0)	0	0
Infections and infestations					
-Total	2 (40.0)	0	1 (20.0)	1 (20.0)	0
Gastroenteritis	1 (20.0)	0	0	1 (20.0)	0
Pharyngitis	1 (20.0)	0	1 (20.0)	0	0
Streptococcal infection	1 (20.0)	0	1 (20.0)	0	0
Viral upper respiratory tract infection	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	3 (60.0)	0	1 (20.0)	1 (20.0)	1 (20.0)
Neutrophil count decreased	2 (40.0)	0	1 (20.0)	0	1 (20.0)

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	2 (40.0)	0	1 (20.0)	1 (20.0)	0
Aspartate aminotransferase increased	1 (20.0)	0	0	1 (20.0)	0
Blood immunoglobulin a decreased	1 (20.0)	1 (20.0)	0	0	0
International normalised ratio increased	1 (20.0)	1 (20.0)	0	0	0
Lymphocyte count decreased	1 (20.0)	0	1 (20.0)	0	0
Metabolism and nutrition disorders					
-Total	3 (60.0)	2 (40.0)	0	1 (20.0)	0
Decreased appetite	1 (20.0)	1 (20.0)	0	0	0
Dehydration	1 (20.0)	0	0	1 (20.0)	0
Hyperphosphataemia	1 (20.0)	1 (20.0)	0	0	0
Hyperuricaemia	1 (20.0)	1 (20.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Pain in extremity	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Arthralgia	1 (20.0)	1 (20.0)	0	0	0
Myalgia	1 (20.0)	1 (20.0)	0	0	0
Nervous system disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0
Headache	2 (40.0)	2 (40.0)	0	0	0

Timing: within 8 weeks post infusion, Race: Asian

Primary system organ class Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Renal and urinary disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Dysuria	1 (20.0)	0	1 (20.0)	0	0
Pollakiuria	1 (20.0)	1 (20.0)	0	0	0
Vascular disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Embolism	1 (20.0)	0	0	1 (20.0)	0
Hypertension	1 (20.0)	0	1 (20.0)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Other

			All patients N=7		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	0	2 (28.6)	5 (71.4)
Blood and lymphatic system disorders					
-Total	5 (71.4)	0	2 (28.6)	2 (28.6)	1 (14.3)
Anaemia	3 (42.9)	0	1 (14.3)	2 (28.6)	0
Febrile neutropenia	2 (28.6)	0	0	2 (28.6)	0
Disseminated intravascular coagulation	1 (14.3)	0	1 (14.3)	0	0
Lymphopenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Tachycardia	3 (42.9)	3 (42.9)	0	0	0
Ventricular tachycardia	1 (14.3)	0	1 (14.3)	0	0
Endocrine disorders					

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (14.3)	0	1 (14.3)	0	0
Adrenal insufficiency	1 (14.3)	0	1 (14.3)	0	0
Eye disorders					
-Total	2 (28.6)	0	2 (28.6)	0	0
Conjunctival haemorrhage	1 (14.3)	1 (14.3)	0	0	0
Periorbital oedema	1 (14.3)	1 (14.3)	0	0	0
Uveitis	1 (14.3)	0	1 (14.3)	0	0
Vision blurred	1 (14.3)	0	1 (14.3)	0	0
Gastrointestinal disorders					
-Total	5 (71.4)	1 (14.3)	4 (57.1)	0	0
Nausea	4 (57.1)	1 (14.3)	3 (42.9)	0	0
Vomiting	4 (57.1)	4 (57.1)	0	0	0
Abdominal pain	1 (14.3)	1 (14.3)	0	0	0
Abdominal pain upper	1 (14.3)	0	1 (14.3)	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Diarrhoea	1 (14.3)	0	1 (14.3)	0	0
Dysphagia	1 (14.3)	0	1 (14.3)	0	0
Flatulence	1 (14.3)	1 (14.3)	0	0	0
Lip pain	1 (14.3)	0	1 (14.3)	0	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	4 (57.1)	2 (28.6)	1 (14.3)	1 (14.3)	0
Catheter site haemorrhage	1 (14.3)	1 (14.3)	0	0	0
Catheter site pain	1 (14.3)	1 (14.3)	0	0	0
Fatigue	1 (14.3)	1 (14.3)	0	0	0
Injection site haematoma	1 (14.3)	1 (14.3)	0	0	0
Malaise	1 (14.3)	0	1 (14.3)	0	0
Physical deconditioning	1 (14.3)	0	0	1 (14.3)	0
Pyrexia	1 (14.3)	1 (14.3)	0	0	0
Hepatobiliary disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Gallbladder enlargement	1 (14.3)	1 (14.3)	0	0	0
Immune system disorders					
-Total	6 (85.7)	1 (14.3)	3 (42.9)	1 (14.3)	1 (14.3)
Cytokine release syndrome	6 (85.7)	2 (28.6)	2 (28.6)	1 (14.3)	1 (14.3)
Hypogammaglobulinaemia	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Infections and infestations					
-Total	3 (42.9)	1 (14.3)	2 (28.6)	0	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site cellulitis	1 (14.3)	1 (14.3)	0	0	0
Clostridium difficile colitis	1 (14.3)	0	1 (14.3)	0	0
Clostridium difficile infection	1 (14.3)	0	1 (14.3)	0	0
Cytomegalovirus infection	1 (14.3)	1 (14.3)	0	0	0
Herpes simplex	1 (14.3)	1 (14.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (42.9)	1 (14.3)	1 (14.3)	0	1 (14.3)
Post procedural haemorrhage	1 (14.3)	1 (14.3)	0	0	0
Procedural pain	1 (14.3)	0	1 (14.3)	0	0
Transfusion reaction	1 (14.3)	1 (14.3)	0	0	0
Transfusion related complication	1 (14.3)	0	0	0	1 (14.3)
Investigations					
-Total	6 (85.7)	0	0	2 (28.6)	4 (57.1)
White blood cell count decreased	5 (71.4)	0	0	2 (28.6)	3 (42.9)
Alanine aminotransferase increased	3 (42.9)	1 (14.3)	1 (14.3)	1 (14.3)	0
Aspartate aminotransferase increased	3 (42.9)	1 (14.3)	1 (14.3)	1 (14.3)	0
Neutrophil count decreased	3 (42.9)	0	0	0	3 (42.9)
Blood creatinine increased	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Lymphocyte count decreased	2 (28.6)	0	0	1 (14.3)	1 (14.3)

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	2 (28.6)	0	0	0	2 (28.6)
Prothrombin time prolonged	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0	0	0
Blood immunoglobulin a decreased	1 (14.3)	1 (14.3)	0	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0
Culture stool positive	1 (14.3)	1 (14.3)	0	0	0
Haemoglobin decreased	1 (14.3)	0	0	1 (14.3)	0
Hepatic enzyme increased	1 (14.3)	0	1 (14.3)	0	0
International normalised ratio increased	1 (14.3)	1 (14.3)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (42.9)	1 (14.3)	0	2 (28.6)	0
Acidosis	1 (14.3)	1 (14.3)	0	0	0
Decreased appetite	1 (14.3)	0	0	1 (14.3)	0
Hypernatraemia	1 (14.3)	1 (14.3)	0	0	0
Hyperphosphataemia	1 (14.3)	1 (14.3)	0	0	0
Tumour lysis syndrome	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Coccydynia	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	1 (14.3)	1 (14.3)	0	0	0
Nervous system disorders					
-Total	4 (57.1)	1 (14.3)	3 (42.9)	0	0
Headache	3 (42.9)	0	3 (42.9)	0	0
Asterixis	1 (14.3)	1 (14.3)	0	0	0
Ataxia	1 (14.3)	0	1 (14.3)	0	0
Dysarthria	1 (14.3)	1 (14.3)	0	0	0
Encephalopathy	1 (14.3)	1 (14.3)	0	0	0
Myoclonus	1 (14.3)	1 (14.3)	0	0	0
Neuropathy peripheral	1 (14.3)	0	1 (14.3)	0	0
Pleocytosis	1 (14.3)	1 (14.3)	0	0	0
Seizure	1 (14.3)	0	1 (14.3)	0	0
Tremor	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Adjustment disorder	1 (14.3)	0	1 (14.3)	0	0
Agitation	1 (14.3)	0	1 (14.3)	0	0
Anxiety	1 (14.3)	0	1 (14.3)	0	0
Delirium	1 (14.3)	0	1 (14.3)	0	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Suicidal ideation	1 (14.3)	1 (14.3)	0	0	0
Renal and urinary disorders					
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Acute kidney injury	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Epistaxis	1 (14.3)	0	0	1 (14.3)	0
Haemoptysis	1 (14.3)	1 (14.3)	0	0	0
Oropharyngeal pain	1 (14.3)	0	1 (14.3)	0	0
Pulmonary oedema	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Skin and subcutaneous tissue disorders					
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Dry skin	2 (28.6)	2 (28.6)	0	0	0
Ecchymosis	1 (14.3)	0	0	1 (14.3)	0
Erythema	1 (14.3)	1 (14.3)	0	0	0
Hyperhidrosis	1 (14.3)	1 (14.3)	0	0	0
Pruritus	1 (14.3)	1 (14.3)	0	0	0
Rash vesicular	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Race: Other

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin exfoliation	1 (14.3)	1 (14.3)	0	0	0
Skin fissures	1 (14.3)	1 (14.3)	0	0	0
Vascular disorders					
-Total	3 (42.9)	0	2 (28.6)	0	1 (14.3)
Hypotension	1 (14.3)	0	0	0	1 (14.3)
Orthostatic hypotension	1 (14.3)	0	1 (14.3)	0	0
Secondary hypertension	1 (14.3)	0	1 (14.3)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

			All patients N=44		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (81.8)	2 (4.5)	12 (27.3)	15 (34.1)	7 (15.9)
Blood and lymphatic system disorders					
-Total	7 (15.9)	1 (2.3)	1 (2.3)	2 (4.5)	3 (6.8)
Neutropenia	3 (6.8)	0	0	1 (2.3)	2 (4.5)
Thrombocytopenia	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Anaemia	1 (2.3)	1 (2.3)	0	0	0
Eosinophilia	1 (2.3)	0	0	1 (2.3)	0
Febrile neutropenia	1 (2.3)	0	0	1 (2.3)	0
Leukopenia	1 (2.3)	0	0	0	1 (2.3)
Cardiac disorders					
-Total	1 (2.3)	0	1 (2.3)	0	0
Sinus tachycardia	1 (2.3)	0	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (2.3)	1 (2.3)	0	0	0
Adrenal insufficiency	1 (2.3)	1 (2.3)	0	0	0
Eye disorders					
-Total	4 (9.1)	3 (6.8)	1 (2.3)	0	0
Conjunctivitis allergic	1 (2.3)	1 (2.3)	0	0	0
Dry eye	1 (2.3)	0	1 (2.3)	0	0
Ocular hyperaemia	1 (2.3)	1 (2.3)	0	0	0
Vision blurred	1 (2.3)	1 (2.3)	0	0	0
Gastrointestinal disorders					
-Total	14 (31.8)	7 (15.9)	3 (6.8)	4 (9.1)	0
Vomiting	9 (20.5)	5 (11.4)	2 (4.5)	2 (4.5)	0
Diarrhoea	7 (15.9)	5 (11.4)	1 (2.3)	1 (2.3)	0
Nausea	5 (11.4)	0	3 (6.8)	2 (4.5)	0
Abdominal pain	4 (9.1)	2 (4.5)	1 (2.3)	1 (2.3)	0
Oral pain	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Abdominal pain upper	1 (2.3)	1 (2.3)	0	0	0
Enterocolitis	1 (2.3)	0	0	1 (2.3)	0
Pigmentation lip	1 (2.3)	1 (2.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	14 (31.8)	10 (22.7)	3 (6.8)	1 (2.3)	0
Pyrexia	7 (15.9)	4 (9.1)	2 (4.5)	1 (2.3)	0
Fatigue	2 (4.5)	2 (4.5)	0	0	0
Influenza like illness	2 (4.5)	2 (4.5)	0	0	0
Acquired gene mutation	1 (2.3)	1 (2.3)	0	0	0
Catheter site pain	1 (2.3)	0	1 (2.3)	0	0
Chills	1 (2.3)	1 (2.3)	0	0	0
Crying	1 (2.3)	1 (2.3)	0	0	0
Generalised oedema	1 (2.3)	1 (2.3)	0	0	0
Malaise	1 (2.3)	1 (2.3)	0	0	0
Oedema peripheral	1 (2.3)	1 (2.3)	0	0	0
Pain	1 (2.3)	1 (2.3)	0	0	0
Immune system disorders					
-Total	10 (22.7)	2 (4.5)	7 (15.9)	1 (2.3)	0
Hypogammaglobulinaemia	7 (15.9)	0	6 (13.6)	1 (2.3)	0
Graft versus host disease	2 (4.5)	1 (2.3)	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease in gastrointestinal tract	1 (2.3)	0	1 (2.3)	0	0
Seasonal allergy	1 (2.3)	1 (2.3)	0	0	0
Infections and infestations					
-Total	26 (59.1)	5 (11.4)	12 (27.3)	8 (18.2)	1 (2.3)
Upper respiratory tract infection	7 (15.9)	3 (6.8)	3 (6.8)	1 (2.3)	0
Gastroenteritis	3 (6.8)	1 (2.3)	2 (4.5)	0	0
Influenza	3 (6.8)	0	3 (6.8)	0	0
Urinary tract infection	3 (6.8)	0	1 (2.3)	2 (4.5)	0
Ear infection	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Parainfluenzae virus infection	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Rhinovirus infection	2 (4.5)	2 (4.5)	0	0	0
Sinusitis	2 (4.5)	0	2 (4.5)	0	0
Viral upper respiratory tract infection	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Bacterial sepsis	1 (2.3)	0	0	0	1 (2.3)
Cellulitis of male external genital organ	1 (2.3)	0	0	1 (2.3)	0
Cholecystitis infective	1 (2.3)	0	0	1 (2.3)	0
Corona virus infection	1 (2.3)	0	0	1 (2.3)	0
Cytomegalovirus infection	1 (2.3)	1 (2.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterovirus infection	1 (2.3)	0	0	1 (2.3)	0
Escherichia urinary tract infection	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis norovirus	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis viral	1 (2.3)	1 (2.3)	0	0	0
Otitis externa	1 (2.3)	0	1 (2.3)	0	0
Otitis media	1 (2.3)	0	1 (2.3)	0	0
Otitis media acute	1 (2.3)	0	1 (2.3)	0	0
Paronychia	1 (2.3)	1 (2.3)	0	0	0
Rash pustular	1 (2.3)	0	1 (2.3)	0	0
Respiratory syncytial virus infection	1 (2.3)	0	0	1 (2.3)	0
Rotavirus infection	1 (2.3)	0	0	1 (2.3)	0
Subcutaneous abscess	1 (2.3)	0	1 (2.3)	0	0
Tinea capitis	1 (2.3)	1 (2.3)	0	0	0
Viral infection	1 (2.3)	1 (2.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	7 (15.9)	3 (6.8)	4 (9.1)	0	0
Contusion	2 (4.5)	2 (4.5)	0	0	0
Infusion related reaction	2 (4.5)	1 (2.3)	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Foot fracture	1 (2.3)	0	1 (2.3)	0	0
Procedural nausea	1 (2.3)	0	1 (2.3)	0	0
Procedural pain	1 (2.3)	1 (2.3)	0	0	0
Radius fracture	1 (2.3)	0	1 (2.3)	0	0
Skin abrasion	1 (2.3)	1 (2.3)	0	0	0
Skin laceration	1 (2.3)	0	1 (2.3)	0	0
Sunburn	1 (2.3)	1 (2.3)	0	0	0
Investigations					
-Total	19 (43.2)	4 (9.1)	5 (11.4)	8 (18.2)	2 (4.5)
Neutrophil count decreased	5 (11.4)	1 (2.3)	0	3 (6.8)	1 (2.3)
White blood cell count decreased	5 (11.4)	2 (4.5)	1 (2.3)	1 (2.3)	1 (2.3)
Weight decreased	4 (9.1)	1 (2.3)	3 (6.8)	0	0
Aspartate aminotransferase increased	3 (6.8)	1 (2.3)	0	2 (4.5)	0
Platelet count decreased	3 (6.8)	3 (6.8)	0	0	0
Alanine aminotransferase increased	2 (4.5)	0	0	2 (4.5)	0
Weight increased	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Blood bilirubin increased	1 (2.3)	0	0	1 (2.3)	0
Blood magnesium decreased	1 (2.3)	1 (2.3)	0	0	0
Blood urea increased	1 (2.3)	1 (2.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

		All patients N=44			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoglobin decreased	1 (2.3)	1 (2.3)	0	0	0
Lymphocyte count decreased	1 (2.3)	0	1 (2.3)	0	0
Oxygen saturation decreased	1 (2.3)	1 (2.3)	0	0	0
Serum ferritin increased	1 (2.3)	0	1 (2.3)	0	0
Transaminases increased	1 (2.3)	1 (2.3)	0	0	0
Metabolism and nutrition disorders					
-Total	8 (18.2)	3 (6.8)	1 (2.3)	3 (6.8)	1 (2.3)
Hyperphosphataemia	2 (4.5)	2 (4.5)	0	0	0
Decreased appetite	1 (2.3)	0	1 (2.3)	0	0
Dehydration	1 (2.3)	0	0	1 (2.3)	0
Hyperalbuminaemia	1 (2.3)	1 (2.3)	0	0	0
Hypercalcaemia	1 (2.3)	1 (2.3)	0	0	0
Hyperglycaemia	1 (2.3)	0	0	1 (2.3)	0
Hypokalaemia	1 (2.3)	0	0	0	1 (2.3)
Hypophosphataemia	1 (2.3)	0	0	1 (2.3)	0
Iron overload	1 (2.3)	0	0	1 (2.3)	0
Tumour lysis syndrome	1 (2.3)	0	0	1 (2.3)	0
Vitamin d deficiency	1 (2.3)	1 (2.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

			All patients N=44		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	10 (22.7)	6 (13.6)	4 (9.1)	0	0
Pain in extremity	5 (11.4)	3 (6.8)	2 (4.5)	0	0
Arthralgia	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Back pain	1 (2.3)	1 (2.3)	0	0	0
Flank pain	1 (2.3)	0	1 (2.3)	0	0
Joint range of motion decreased	1 (2.3)	1 (2.3)	0	0	0
Muscle spasms	1 (2.3)	1 (2.3)	0	0	0
Muscular weakness	1 (2.3)	1 (2.3)	0	0	0
Pain in jaw	1 (2.3)	1 (2.3)	0	0	0
Toe walking	1 (2.3)	1 (2.3)	0	0	0
Nervous system disorders					
-Total	8 (18.2)	6 (13.6)	2 (4.5)	0	0
Headache	5 (11.4)	4 (9.1)	1 (2.3)	0	0
Dizziness	3 (6.8)	3 (6.8)	0	0	0
Peroneal nerve palsy	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Psychiatric disorders					
-Total	2 (4.5)	1 (2.3)	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

		All patients N=44			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Depression	2 (4.5)	2 (4.5)	0	0	0
Anxiety	1 (2.3)	1 (2.3)	0	0	0
Sleep disorder	1 (2.3)	0	1 (2.3)	0	0
Renal and urinary disorders					
-Total	3 (6.8)	1 (2.3)	0	2 (4.5)	0
Acute kidney injury	1 (2.3)	0	0	1 (2.3)	0
Calculus urinary	1 (2.3)	0	1 (2.3)	0	0
Haematuria	1 (2.3)	0	0	1 (2.3)	0
Nephrolithiasis	1 (2.3)	0	0	1 (2.3)	0
Urinary incontinence	1 (2.3)	1 (2.3)	0	0	0
Reproductive system and breast disorders					
-Total	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Scrotal pain	1 (2.3)	0	1 (2.3)	0	0
Vaginal haemorrhage	1 (2.3)	0	0	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	13 (29.5)	7 (15.9)	4 (9.1)	1 (2.3)	1 (2.3)
Cough	4 (9.1)	2 (4.5)	2 (4.5)	0	0
Nasal congestion	3 (6.8)	3 (6.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Rhinorrhoea	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Epistaxis	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Rhinitis allergic	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Acute respiratory failure	1 (2.3)	0	0	0	1 (2.3)
Dysphonia	1 (2.3)	1 (2.3)	0	0	0
Pharyngeal erythema	1 (2.3)	1 (2.3)	0	0	0
Pharyngeal lesion	1 (2.3)	0	0	1 (2.3)	0
Skin and subcutaneous tissue disorders					
-Total	10 (22.7)	6 (13.6)	3 (6.8)	1 (2.3)	0
Erythema	2 (4.5)	2 (4.5)	0	0	0
Rash maculo-papular	2 (4.5)	2 (4.5)	0	0	0
Alopecia	1 (2.3)	0	1 (2.3)	0	0
Dermatitis acneiform	1 (2.3)	0	0	1 (2.3)	0
Hyperhidrosis	1 (2.3)	1 (2.3)	0	0	0
Ingrowing nail	1 (2.3)	1 (2.3)	0	0	0
Keloid scar	1 (2.3)	0	1 (2.3)	0	0
Macule	1 (2.3)	1 (2.3)	0	0	0
Papule	1 (2.3)	1 (2.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=44 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Petechiae	1 (2.3)	1 (2.3)	0	0	0
Pruritus	1 (2.3)	1 (2.3)	0	0	0
Rash	1 (2.3)	0	1 (2.3)	0	0
Rash erythematous	1 (2.3)	0	1 (2.3)	0	0
Rash pruritic	1 (2.3)	1 (2.3)	0	0	0
Vascular disorders					
-Total	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Hypertension	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Hot flush	1 (2.3)	1 (2.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	2 (40.0)	1 (20.0)	0	1 (20.0)
Blood and lymphatic system disorders					
-Total	2 (40.0)	0	1 (20.0)	0	1 (20.0)
Febrile neutropenia	1 (20.0)	0	0	1 (20.0)	0
Lymphopenia	1 (20.0)	0	1 (20.0)	0	0
Neutropenia	1 (20.0)	0	0	0	1 (20.0)
General disorders and administration site conditions					
-Total	2 (40.0)	2 (40.0)	0	0	0
Pyrexia	2 (40.0)	2 (40.0)	0	0	0
Infections and infestations					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Herpes zoster	1 (20.0)	0	0	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Molluscum contagiosum	1 (20.0)	1 (20.0)	0	0	0
Investigations					
-Total	2 (40.0)	1 (20.0)	0	0	1 (20.0)
Neutrophil count decreased	2 (40.0)	1 (20.0)	0	0	1 (20.0)
Blood uric acid increased	1 (20.0)	1 (20.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (60.0)	2 (40.0)	1 (20.0)	0	0
Joint range of motion decreased	1 (20.0)	1 (20.0)	0	0	0
Osteonecrosis	1 (20.0)	0	1 (20.0)	0	0
Pain in extremity	1 (20.0)	1 (20.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Pulmonary oedema	1 (20.0)	0	0	1 (20.0)	0
Skin and subcutaneous tissue disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Rash	1 (20.0)	0	1 (20.0)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

			All patients N=7		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	3 (42.9)	1 (14.3)	2 (28.6)
Blood and lymphatic system disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Anaemia	1 (14.3)	0	0	1 (14.3)	0
Febrile neutropenia	1 (14.3)	0	0	1 (14.3)	0
Lymphadenopathy	1 (14.3)	0	1 (14.3)	0	0
Eye disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Dry eye	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Diarrhoea	1 (14.3)	1 (14.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (14.3)	1 (14.3)	0	0	0
General disorders and administration site conditions					
-Total	1 (14.3)	1 (14.3)	0	0	0
Pyrexia	1 (14.3)	1 (14.3)	0	0	0
Immune system disorders					
-Total	4 (57.1)	1 (14.3)	3 (42.9)	0	0
Immunodeficiency common variable	2 (28.6)	0	2 (28.6)	0	0
Hypogammaglobulinaemia	1 (14.3)	0	1 (14.3)	0	0
Seasonal allergy	1 (14.3)	1 (14.3)	0	0	0
Infections and infestations					
-Total	5 (71.4)	0	3 (42.9)	1 (14.3)	1 (14.3)
Oral herpes	1 (14.3)	0	1 (14.3)	0	0
Rhinitis	1 (14.3)	1 (14.3)	0	0	0
Sepsis	1 (14.3)	0	0	0	1 (14.3)
Urinary tract infection	1 (14.3)	0	1 (14.3)	0	0
Vascular device infection	1 (14.3)	0	0	1 (14.3)	0
Vulvovaginal mycotic infection	1 (14.3)	0	1 (14.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	1 (14.3)	0	1 (14.3)	0	0
Arthropod bite	1 (14.3)	1 (14.3)	0	0	0
Procedural pain	1 (14.3)	0	1 (14.3)	0	0
Investigations					
-Total	2 (28.6)	1 (14.3)	0	0	1 (14.3)
Blood creatinine increased	1 (14.3)	1 (14.3)	0	0	0
Haemoglobin decreased	1 (14.3)	1 (14.3)	0	0	0
Lymphocyte count decreased	1 (14.3)	1 (14.3)	0	0	0
Neutrophil count decreased	1 (14.3)	0	0	0	1 (14.3)
Metabolism and nutrition disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Decreased appetite	1 (14.3)	1 (14.3)	0	0	0
Hypokalaemia	1 (14.3)	1 (14.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (42.9)	3 (42.9)	0	0	0
Pain in extremity	2 (28.6)	2 (28.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	1 (14.3)	1 (14.3)	0	0	0
Musculoskeletal chest pain	1 (14.3)	1 (14.3)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (14.3)	0	1 (14.3)	0	0
Myelodysplastic syndrome	1 (14.3)	0	1 (14.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (57.1)	4 (57.1)	0	0	0
Cough	3 (42.9)	3 (42.9)	0	0	0
Nasal congestion	1 (14.3)	1 (14.3)	0	0	0
Rhinitis allergic	1 (14.3)	1 (14.3)	0	0	0
Rhinorrhoea	1 (14.3)	1 (14.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (71.4)	4 (57.1)	1 (14.3)	0	0
Rash	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Dermatitis	1 (14.3)	1 (14.3)	0	0	0
Dermatitis atopic	1 (14.3)	1 (14.3)	0	0	0
Dry skin	1 (14.3)	1 (14.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eczema	1 (14.3)	1 (14.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: White

			All patients N=28		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (57.1)	4 (14.3)	4 (14.3)	6 (21.4)	2 (7.1)
Blood and lymphatic system disorders					
-Total	1 (3.6)	1 (3.6)	0	0	0
Thrombocytopenia	1 (3.6)	1 (3.6)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.6)	0	1 (3.6)	0	0
Tympanic membrane perforation	1 (3.6)	0	1 (3.6)	0	0
Gastrointestinal disorders					
-Total	2 (7.1)	0	2 (7.1)	0	0
Diarrhoea	2 (7.1)	0	2 (7.1)	0	0
Abdominal pain	1 (3.6)	0	1 (3.6)	0	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.6)	0	0	1 (3.6)	0
Cyst	1 (3.6)	0	0	1 (3.6)	0
Immune system disorders					
-Total	1 (3.6)	0	1 (3.6)	0	0
Chronic graft versus host disease	1 (3.6)	0	1 (3.6)	0	0
Infections and infestations					
-Total	7 (25.0)	0	4 (14.3)	3 (10.7)	0
Sinusitis	3 (10.7)	0	3 (10.7)	0	0
Otitis media	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Otitis media acute	2 (7.1)	0	2 (7.1)	0	0
Pneumonia	2 (7.1)	0	2 (7.1)	0	0
Urinary tract infection	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Campylobacter infection	1 (3.6)	0	0	1 (3.6)	0
Cellulitis of male external genital organ	1 (3.6)	0	0	1 (3.6)	0
Clostridium difficile infection	1 (3.6)	0	0	1 (3.6)	0
Haemophilus infection	1 (3.6)	0	1 (3.6)	0	0
Respiratory tract infection viral	1 (3.6)	0	0	1 (3.6)	0
Skin infection	1 (3.6)	0	1 (3.6)	0	0
Upper respiratory tract infection	1 (3.6)	0	1 (3.6)	0	0

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal candidiasis	1 (3.6)	0	1 (3.6)	0	0
Investigations					
-Total	5 (17.9)	1 (3.6)	1 (3.6)	2 (7.1)	1 (3.6)
Alanine aminotransferase increased	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Lymphocyte count decreased	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Aspartate aminotransferase increased	1 (3.6)	0	0	1 (3.6)	0
Neutrophil count decreased	1 (3.6)	1 (3.6)	0	0	0
White blood cell count decreased	1 (3.6)	0	0	0	1 (3.6)
Metabolism and nutrition disorders					
-Total	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Hypokalaemia	1 (3.6)	0	0	1 (3.6)	0
Vitamin d deficiency	1 (3.6)	1 (3.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (3.6)	0	1 (3.6)	0	0
Neck pain	1 (3.6)	0	1 (3.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.6)	0	0	0	1 (3.6)
Glioblastoma multiforme	1 (3.6)	0	0	0	1 (3.6)

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Disturbance in attention	1 (3.6)	1 (3.6)	0	0	0
Dizziness	1 (3.6)	1 (3.6)	0	0	0
Headache	1 (3.6)	0	1 (3.6)	0	0
Seizure	1 (3.6)	0	0	1 (3.6)	0
Renal and urinary disorders					
-Total	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Acute kidney injury	1 (3.6)	0	0	1 (3.6)	0
Haematuria	1 (3.6)	1 (3.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (3.6)	1 (3.6)	0	0	0
Oropharyngeal pain	1 (3.6)	1 (3.6)	0	0	0
Rhinorrhoea	1 (3.6)	1 (3.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (7.1)	2 (7.1)	0	0	0
Acne	1 (3.6)	1 (3.6)	0	0	0
Papule	1 (3.6)	1 (3.6)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Asian

		All patients N=2			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Infections and infestations					
-Total	2 (100)	1 (50.0)	0	0	1 (50.0)
Gingivitis	1 (50.0)	1 (50.0)	0	0	0
Respiratory tract infection	1 (50.0)	0	0	0	1 (50.0)
Viral infection	1 (50.0)	1 (50.0)	0	0	0
Investigations					
-Total	1 (50.0)	0	0	1 (50.0)	0
White blood cell count decreased	1 (50.0)	0	0	1 (50.0)	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Other

			All patients N=4		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	2 (50.0)	1 (25.0)	1 (25.0)
Blood and lymphatic system disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Febrile neutropenia	1 (25.0)	0	0	0	1 (25.0)
Gastrointestinal disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Nausea	1 (25.0)	0	1 (25.0)	0	0
General disorders and administration site conditions					
-Total	1 (25.0)	0	1 (25.0)	0	0
Chills	1 (25.0)	0	1 (25.0)	0	0
Pyrexia	1 (25.0)	0	1 (25.0)	0	0
Immune system disorders					

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (25.0)	0	1 (25.0)	0	0
Immunodeficiency	1 (25.0)	0	1 (25.0)	0	0
Infections and infestations					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Meningitis aseptic	1 (25.0)	0	1 (25.0)	0	0
Otitis media	1 (25.0)	0	1 (25.0)	0	0
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (25.0)	0	0	1 (25.0)	0
Procedural pain	1 (25.0)	0	0	1 (25.0)	0
Investigations					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
White blood cell count decreased	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Alanine aminotransferase increased	1 (25.0)	0	0	1 (25.0)	0
Aspartate aminotransferase increased	1 (25.0)	1 (25.0)	0	0	0
Blood alkaline phosphatase increased	1 (25.0)	1 (25.0)	0	0	0
Blood lactate dehydrogenase increased	1 (25.0)	1 (25.0)	0	0	0
C-reactive protein increased	1 (25.0)	1 (25.0)	0	0	0
Lymphocyte count decreased	1 (25.0)	1 (25.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Race: Other

		All patients N=4			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	1 (25.0)	0	1 (25.0)	0	0
Platelet count decreased	1 (25.0)	0	0	1 (25.0)	0
Reproductive system and breast disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Ovarian failure	1 (25.0)	0	0	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (75.0)	3 (75.0)	0	0	0
Cough	2 (50.0)	2 (50.0)	0	0	0
Epistaxis	1 (25.0)	1 (25.0)	0	0	0
Rhinitis allergic	1 (25.0)	1 (25.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Pruritus	1 (25.0)	1 (25.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: White

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (100)	0	4 (7.7)	10 (19.2)	38 (73.1)
Blood and lymphatic system disorders					
-Total	40 (76.9)	2 (3.8)	1 (1.9)	24 (46.2)	13 (25.0)
Anaemia	21 (40.4)	3 (5.8)	3 (5.8)	14 (26.9)	1 (1.9)
Febrile neutropenia	19 (36.5)	0	0	19 (36.5)	0
Neutropenia	10 (19.2)	0	0	3 (5.8)	7 (13.5)
Thrombocytopenia	10 (19.2)	0	1 (1.9)	3 (5.8)	6 (11.5)
Disseminated intravascular coagulation	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Lymphopenia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Coagulopathy	1 (1.9)	1 (1.9)	0	0	0
Eosinophilia	1 (1.9)	0	0	1 (1.9)	0
Leukopenia	1 (1.9)	0	0	0	1 (1.9)

Timing: Any time post CTL019 infusion, Race: White

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	1 (1.9)	0	0	0	1 (1.9)
Cardiac disorders					
-Total	19 (36.5)	8 (15.4)	9 (17.3)	2 (3.8)	0
Tachycardia	12 (23.1)	5 (9.6)	5 (9.6)	2 (3.8)	0
Sinus tachycardia	6 (11.5)	3 (5.8)	3 (5.8)	0	0
Pericardial effusion	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Bradycardia	1 (1.9)	0	1 (1.9)	0	0
Cardiac dysfunction	1 (1.9)	1 (1.9)	0	0	0
Left ventricular dysfunction	1 (1.9)	0	0	1 (1.9)	0
Palpitations	1 (1.9)	1 (1.9)	0	0	0
Sinus bradycardia	1 (1.9)	1 (1.9)	0	0	0
Ear and labyrinth disorders					
-Total	4 (7.7)	2 (3.8)	2 (3.8)	0	0
Ear pain	2 (3.8)	2 (3.8)	0	0	0
Hypoacusis	1 (1.9)	0	1 (1.9)	0	0
Tympanic membrane perforation	1 (1.9)	0	1 (1.9)	0	0
Endocrine disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Adrenal insufficiency	1 (1.9)	1 (1.9)	0	0	0

Timing: Any time post CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eye disorders					
-Total	15 (28.8)	9 (17.3)	6 (11.5)	0	0
Eye pain	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Periorbital oedema	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Vision blurred	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Conjunctival haemorrhage	2 (3.8)	2 (3.8)	0	0	0
Photophobia	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Retinal haemorrhage	2 (3.8)	2 (3.8)	0	0	0
Conjunctivitis allergic	1 (1.9)	1 (1.9)	0	0	0
Dry eye	1 (1.9)	0	1 (1.9)	0	0
Ocular hyperaemia	1 (1.9)	1 (1.9)	0	0	0
Ocular hypertension	1 (1.9)	0	1 (1.9)	0	0
Papilloedema	1 (1.9)	0	1 (1.9)	0	0
Uveitis	1 (1.9)	0	1 (1.9)	0	0
Visual impairment	1 (1.9)	0	1 (1.9)	0	0
Gastrointestinal disorders					
-Total	35 (67.3)	11 (21.2)	11 (21.2)	13 (25.0)	0
Vomiting	22 (42.3)	11 (21.2)	8 (15.4)	3 (5.8)	0
Diarrhoea	21 (40.4)	12 (23.1)	7 (13.5)	2 (3.8)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	18 (34.6)	3 (5.8)	10 (19.2)	5 (9.6)	0
Abdominal pain	10 (19.2)	5 (9.6)	4 (7.7)	1 (1.9)	0
Constipation	6 (11.5)	5 (9.6)	1 (1.9)	0	0
Abdominal distension	2 (3.8)	0	2 (3.8)	0	0
Abdominal pain upper	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Haematemesis	2 (3.8)	2 (3.8)	0	0	0
Oral pain	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Pancreatitis	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Stomatitis	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Abdominal discomfort	1 (1.9)	1 (1.9)	0	0	0
Abdominal pain lower	1 (1.9)	0	1 (1.9)	0	0
Abdominal tenderness	1 (1.9)	1 (1.9)	0	0	0
Anal incontinence	1 (1.9)	1 (1.9)	0	0	0
Ascites	1 (1.9)	0	0	1 (1.9)	0
Dyspepsia	1 (1.9)	0	1 (1.9)	0	0
Dysphagia	1 (1.9)	0	0	1 (1.9)	0
Enterocolitis	1 (1.9)	0	0	1 (1.9)	0
Gastrointestinal haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Gastrooesophageal reflux disease	1 (1.9)	1 (1.9)	0	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Glossodynia	1 (1.9)	1 (1.9)	0	0	0
Ileus	1 (1.9)	0	0	1 (1.9)	0
Intestinal obstruction	1 (1.9)	0	0	1 (1.9)	0
Mouth haemorrhage	1 (1.9)	0	0	1 (1.9)	0
Pigmentation lip	1 (1.9)	1 (1.9)	0	0	0
Tooth socket haemorrhage	1 (1.9)	1 (1.9)	0	0	0
General disorders and administration site conditions					
-Total	32 (61.5)	11 (21.2)	10 (19.2)	10 (19.2)	1 (1.9)
Pyrexia	20 (38.5)	5 (9.6)	8 (15.4)	6 (11.5)	1 (1.9)
Fatigue	11 (21.2)	8 (15.4)	2 (3.8)	1 (1.9)	0
Chills	9 (17.3)	9 (17.3)	0	0	0
Catheter site pain	3 (5.8)	0	3 (5.8)	0	0
Generalised oedema	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Malaise	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Oedema peripheral	3 (5.8)	2 (3.8)	0	1 (1.9)	0
Pain	3 (5.8)	1 (1.9)	0	2 (3.8)	0
Face oedema	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Influenza like illness	2 (3.8)	2 (3.8)	0	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acquired gene mutation	1 (1.9)	1 (1.9)	0	0	0
Asthenia	1 (1.9)	1 (1.9)	0	0	0
Catheter site extravasation	1 (1.9)	0	1 (1.9)	0	0
Crying	1 (1.9)	1 (1.9)	0	0	0
Cyst	1 (1.9)	0	0	1 (1.9)	0
Facial pain	1 (1.9)	0	1 (1.9)	0	0
Localised oedema	1 (1.9)	0	0	1 (1.9)	0
Mucosal haemorrhage	1 (1.9)	0	1 (1.9)	0	0
Multiple organ dysfunction syndrome	1 (1.9)	0	0	1 (1.9)	0
Non-cardiac chest pain	1 (1.9)	1 (1.9)	0	0	0
Peripheral swelling	1 (1.9)	0	1 (1.9)	0	0
Hepatobiliary disorders					
-Total	6 (11.5)	2 (3.8)	2 (3.8)	2 (3.8)	0
Hepatomegaly	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Hyperbilirubinaemia	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Hepatosplenomegaly	1 (1.9)	1 (1.9)	0	0	0
Immune system disorders					
-Total	47 (90.4)	4 (7.7)	23 (44.2)	10 (19.2)	10 (19.2)
Cytokine release syndrome	40 (76.9)	4 (7.7)	19 (36.5)	7 (13.5)	10 (19.2)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	26 (50.0)	1 (1.9)	20 (38.5)	5 (9.6)	0
Graft versus host disease	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Chronic graft versus host disease	1 (1.9)	0	1 (1.9)	0	0
Drug hypersensitivity	1 (1.9)	0	1 (1.9)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.9)	0	1 (1.9)	0	0
Graft versus host disease in skin	1 (1.9)	1 (1.9)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.9)	0	1 (1.9)	0	0
Seasonal allergy	1 (1.9)	1 (1.9)	0	0	0
Infections and infestations					
-Total	38 (73.1)	7 (13.5)	17 (32.7)	12 (23.1)	2 (3.8)
Upper respiratory tract infection	8 (15.4)	3 (5.8)	4 (7.7)	1 (1.9)	0
Rhinovirus infection	5 (9.6)	5 (9.6)	0	0	0
Clostridium difficile infection	4 (7.7)	0	3 (5.8)	1 (1.9)	0
Gastroenteritis	4 (7.7)	1 (1.9)	3 (5.8)	0	0
Influenza	4 (7.7)	1 (1.9)	3 (5.8)	0	0
Pneumonia	4 (7.7)	0	3 (5.8)	1 (1.9)	0
Sinusitis	4 (7.7)	0	4 (7.7)	0	0
Urinary tract infection	4 (7.7)	0	2 (3.8)	2 (3.8)	0
Clostridium difficile colitis	3 (5.8)	1 (1.9)	1 (1.9)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Race: White

Primary system organ class Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=52 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Otitis media	3 (5.8)	0	2 (3.8)	1 (1.9)	0
Ear infection	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Otitis media acute	2 (3.8)	0	2 (3.8)	0	0
Parainfluenzae virus infection	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Skin infection	2 (3.8)	0	2 (3.8)	0	0
Staphylococcal infection	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Viral infection	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Viral upper respiratory tract infection	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Vulvovaginal candidiasis	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Acute sinusitis	1 (1.9)	0	1 (1.9)	0	0
Bacterial sepsis	1 (1.9)	0	0	0	1 (1.9)
Body tinea	1 (1.9)	1 (1.9)	0	0	0
Campylobacter infection	1 (1.9)	0	0	1 (1.9)	0
Catheter site infection	1 (1.9)	0	0	1 (1.9)	0
Cellulitis of male external genital organ	1 (1.9)	0	0	1 (1.9)	0
Cholecystitis infective	1 (1.9)	0	0	1 (1.9)	0
Corona virus infection	1 (1.9)	0	0	1 (1.9)	0
Cytomegalovirus infection	1 (1.9)	1 (1.9)	0	0	0
Enterococcal infection	1 (1.9)	1 (1.9)	0	0	0

Timing: Any time post CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Folliculitis	1 (1.9)	0	1 (1.9)	0	0
Fungal skin infection	1 (1.9)	1 (1.9)	0	0	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis viral	1 (1.9)	1 (1.9)	0	0	0
Haemophilus infection	1 (1.9)	0	1 (1.9)	0	0
Human herpesvirus 6 infection	1 (1.9)	0	1 (1.9)	0	0
Hypopyon	1 (1.9)	0	1 (1.9)	0	0
Oral candidiasis	1 (1.9)	1 (1.9)	0	0	0
Orchitis	1 (1.9)	1 (1.9)	0	0	0
Otitis externa	1 (1.9)	0	1 (1.9)	0	0
Paronychia	1 (1.9)	1 (1.9)	0	0	0
Rash pustular	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus infection	1 (1.9)	0	0	1 (1.9)	0
Respiratory tract infection viral	1 (1.9)	0	0	1 (1.9)	0
Rotavirus infection	1 (1.9)	0	0	1 (1.9)	0
Septic embolus	1 (1.9)	0	0	0	1 (1.9)
Subcutaneous abscess	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tinea capitis	1 (1.9)	1 (1.9)	0	0	0
Urinary tract infection enterococcal	1 (1.9)	0	0	1 (1.9)	0
Injury, poisoning and procedural complications					
-Total	18 (34.6)	10 (19.2)	7 (13.5)	1 (1.9)	0
Infusion related reaction	4 (7.7)	1 (1.9)	3 (5.8)	0	0
Contusion	3 (5.8)	3 (5.8)	0	0	0
Procedural pain	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Skin abrasion	2 (3.8)	2 (3.8)	0	0	0
Transfusion reaction	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Foot fracture	1 (1.9)	0	1 (1.9)	0	0
Incision site pain	1 (1.9)	1 (1.9)	0	0	0
Limb injury	1 (1.9)	1 (1.9)	0	0	0
Mouth injury	1 (1.9)	1 (1.9)	0	0	0
Procedural complication	1 (1.9)	1 (1.9)	0	0	0
Procedural headache	1 (1.9)	0	1 (1.9)	0	0
Procedural nausea	1 (1.9)	0	1 (1.9)	0	0
Procedural site reaction	1 (1.9)	1 (1.9)	0	0	0
Radius fracture	1 (1.9)	0	1 (1.9)	0	0
Skin laceration	1 (1.9)	0	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stoma site irritation	1 (1.9)	1 (1.9)	0	0	0
Subdural haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Sunburn	1 (1.9)	1 (1.9)	0	0	0
Tibia fracture	1 (1.9)	0	1 (1.9)	0	0
Tongue injury	1 (1.9)	1 (1.9)	0	0	0
Tracheal haemorrhage	1 (1.9)	0	0	1 (1.9)	0
Investigations					
-Total	46 (88.5)	2 (3.8)	4 (7.7)	12 (23.1)	28 (53.8)
White blood cell count decreased	26 (50.0)	4 (7.7)	0	7 (13.5)	15 (28.8)
Neutrophil count decreased	22 (42.3)	1 (1.9)	1 (1.9)	4 (7.7)	16 (30.8)
Alanine aminotransferase increased	17 (32.7)	4 (7.7)	1 (1.9)	12 (23.1)	0
Platelet count decreased	17 (32.7)	3 (5.8)	2 (3.8)	2 (3.8)	10 (19.2)
Aspartate aminotransferase increased	15 (28.8)	2 (3.8)	3 (5.8)	6 (11.5)	4 (7.7)
Lymphocyte count decreased	13 (25.0)	1 (1.9)	2 (3.8)	6 (11.5)	4 (7.7)
Blood bilirubin increased	8 (15.4)	2 (3.8)	3 (5.8)	3 (5.8)	0
Blood creatinine increased	7 (13.5)	4 (7.7)	1 (1.9)	2 (3.8)	0
International normalised ratio increased	7 (13.5)	6 (11.5)	0	1 (1.9)	0
Prothrombin time prolonged	7 (13.5)	4 (7.7)	2 (3.8)	1 (1.9)	0
Activated partial thromboplastin time prolonged	4 (7.7)	2 (3.8)	2 (3.8)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	4 (7.7)	0	1 (1.9)	2 (3.8)	1 (1.9)
Weight decreased	4 (7.7)	1 (1.9)	3 (5.8)	0	0
Blood immunoglobulin m decreased	3 (5.8)	3 (5.8)	0	0	0
Blood urea increased	3 (5.8)	1 (1.9)	1 (1.9)	1 (1.9)	0
Transaminases increased	3 (5.8)	3 (5.8)	0	0	0
Blood magnesium decreased	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Blood phosphorus increased	2 (3.8)	2 (3.8)	0	0	0
Lipase increased	2 (3.8)	0	0	0	2 (3.8)
Serum ferritin increased	2 (3.8)	0	2 (3.8)	0	0
Weight increased	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Blood bicarbonate decreased	1 (1.9)	0	1 (1.9)	0	0
Blood immunoglobulin a decreased	1 (1.9)	1 (1.9)	0	0	0
Blood immunoglobulin g decreased	1 (1.9)	0	1 (1.9)	0	0
Blood lactic acid increased	1 (1.9)	0	0	0	1 (1.9)
Blood phosphorus decreased	1 (1.9)	1 (1.9)	0	0	0
Blood sodium increased	1 (1.9)	0	1 (1.9)	0	0
Blood uric acid increased	1 (1.9)	1 (1.9)	0	0	0
C-reactive protein increased	1 (1.9)	0	0	1 (1.9)	0
Cardiac murmur	1 (1.9)	1 (1.9)	0	0	0

Timing: Any time post CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fibrin d dimer increased	1 (1.9)	1 (1.9)	0	0	0
Haemoglobin decreased	1 (1.9)	1 (1.9)	0	0	0
Norovirus test positive	1 (1.9)	1 (1.9)	0	0	0
Oxygen saturation decreased	1 (1.9)	1 (1.9)	0	0	0
Protein total decreased	1 (1.9)	0	0	1 (1.9)	0
Pulmonary function test decreased	1 (1.9)	0	1 (1.9)	0	0
Metabolism and nutrition disorders					
-Total	36 (69.2)	4 (7.7)	8 (15.4)	20 (38.5)	4 (7.7)
Decreased appetite	19 (36.5)	3 (5.8)	5 (9.6)	11 (21.2)	0
Hypokalaemia	18 (34.6)	3 (5.8)	6 (11.5)	8 (15.4)	1 (1.9)
Hypophosphataemia	10 (19.2)	2 (3.8)	0	7 (13.5)	1 (1.9)
Hyperphosphataemia	6 (11.5)	6 (11.5)	0	0	0
Hypoalbuminaemia	5 (9.6)	1 (1.9)	3 (5.8)	1 (1.9)	0
Dehydration	3 (5.8)	1 (1.9)	0	2 (3.8)	0
Fluid overload	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Hyperglycaemia	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Hypernatraemia	3 (5.8)	0	2 (3.8)	0	1 (1.9)
Hypocalcaemia	3 (5.8)	1 (1.9)	1 (1.9)	1 (1.9)	0
Hypertriglyceridaemia	2 (3.8)	1 (1.9)	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperuricaemia	2 (3.8)	1 (1.9)	0	0	1 (1.9)
Hyponatraemia	2 (3.8)	0	0	2 (3.8)	0
Vitamin d deficiency	2 (3.8)	2 (3.8)	0	0	0
Acidosis	1 (1.9)	0	0	1 (1.9)	0
Hyperalbuminaemia	1 (1.9)	1 (1.9)	0	0	0
Hypercalcaemia	1 (1.9)	1 (1.9)	0	0	0
Hyperchloraemia	1 (1.9)	1 (1.9)	0	0	0
Hypermagnesaemia	1 (1.9)	1 (1.9)	0	0	0
Hypomagnesaemia	1 (1.9)	1 (1.9)	0	0	0
Iron overload	1 (1.9)	0	0	1 (1.9)	0
Malnutrition	1 (1.9)	0	0	1 (1.9)	0
Metabolic acidosis	1 (1.9)	0	1 (1.9)	0	0
Metabolic alkalosis	1 (1.9)	1 (1.9)	0	0	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0
Musculoskeletal and connective tissue disorders					
-Total	18 (34.6)	9 (17.3)	8 (15.4)	1 (1.9)	0
Pain in extremity	6 (11.5)	3 (5.8)	3 (5.8)	0	0
Arthralgia	4 (7.7)	2 (3.8)	1 (1.9)	1 (1.9)	0
Musculoskeletal pain	3 (5.8)	2 (3.8)	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Muscle spasms	2 (3.8)	2 (3.8)	0	0	0
Muscular weakness	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Back pain	1 (1.9)	1 (1.9)	0	0	0
Flank pain	1 (1.9)	0	1 (1.9)	0	0
Joint range of motion decreased	1 (1.9)	1 (1.9)	0	0	0
Limb discomfort	1 (1.9)	1 (1.9)	0	0	0
Musculoskeletal chest pain	1 (1.9)	1 (1.9)	0	0	0
Neck pain	1 (1.9)	0	1 (1.9)	0	0
Osteopenia	1 (1.9)	0	1 (1.9)	0	0
Pain in jaw	1 (1.9)	1 (1.9)	0	0	0
Toe walking	1 (1.9)	1 (1.9)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (3.8)	0	1 (1.9)	0	1 (1.9)
Glioblastoma multiforme	1 (1.9)	0	0	0	1 (1.9)
Skin papilloma	1 (1.9)	0	1 (1.9)	0	0
Nervous system disorders					
-Total	29 (55.8)	14 (26.9)	9 (17.3)	5 (9.6)	1 (1.9)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	19 (36.5)	13 (25.0)	4 (7.7)	2 (3.8)	0
Dizziness	6 (11.5)	6 (11.5)	0	0	0
Encephalopathy	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Seizure	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Peroneal nerve palsy	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Depressed level of consciousness	1 (1.9)	1 (1.9)	0	0	0
Disturbance in attention	1 (1.9)	1 (1.9)	0	0	0
Dysarthria	1 (1.9)	0	1 (1.9)	0	0
Embolic stroke	1 (1.9)	0	0	0	1 (1.9)
Idiopathic intracranial hypertension	1 (1.9)	0	1 (1.9)	0	0
Migraine	1 (1.9)	0	1 (1.9)	0	0
Somnolence	1 (1.9)	1 (1.9)	0	0	0
Tremor	1 (1.9)	1 (1.9)	0	0	0
Product issues					
-Total	1 (1.9)	1 (1.9)	0	0	0
Device occlusion	1 (1.9)	1 (1.9)	0	0	0
Psychiatric disorders					
-Total	16 (30.8)	8 (15.4)	7 (13.5)	1 (1.9)	0
Anxiety	6 (11.5)	3 (5.8)	2 (3.8)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Confusional state	6 (11.5)	3 (5.8)	3 (5.8)	0	0
Delirium	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Depression	2 (3.8)	2 (3.8)	0	0	0
Hallucination	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Irritability	2 (3.8)	2 (3.8)	0	0	0
Agitation	1 (1.9)	0	1 (1.9)	0	0
Insomnia	1 (1.9)	0	1 (1.9)	0	0
Listless	1 (1.9)	1 (1.9)	0	0	0
Mental status changes	1 (1.9)	1 (1.9)	0	0	0
Panic attack	1 (1.9)	0	1 (1.9)	0	0
Sleep disorder	1 (1.9)	0	1 (1.9)	0	0
Renal and urinary disorders					
-Total	12 (23.1)	2 (3.8)	1 (1.9)	5 (9.6)	4 (7.7)
Acute kidney injury	7 (13.5)	0	1 (1.9)	3 (5.8)	3 (5.8)
Haematuria	5 (9.6)	0	2 (3.8)	2 (3.8)	1 (1.9)
Oliguria	2 (3.8)	0	0	2 (3.8)	0
Calculus urinary	1 (1.9)	0	1 (1.9)	0	0
Dysuria	1 (1.9)	1 (1.9)	0	0	0
Nephrolithiasis	1 (1.9)	0	0	1 (1.9)	0

Timing: Any time post CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Renal failure	1 (1.9)	0	0	0	1 (1.9)
Renal impairment	1 (1.9)	0	0	1 (1.9)	0
Urinary incontinence	1 (1.9)	1 (1.9)	0	0	0
Reproductive system and breast disorders					
-Total	5 (9.6)	2 (3.8)	2 (3.8)	1 (1.9)	0
Vulvovaginal adhesion	2 (3.8)	2 (3.8)	0	0	0
Oedema genital	1 (1.9)	0	1 (1.9)	0	0
Scrotal pain	1 (1.9)	0	1 (1.9)	0	0
Vaginal haemorrhage	1 (1.9)	0	0	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	32 (61.5)	11 (21.2)	9 (17.3)	5 (9.6)	7 (13.5)
Cough	11 (21.2)	9 (17.3)	2 (3.8)	0	0
Hypoxia	10 (19.2)	0	3 (5.8)	4 (7.7)	3 (5.8)
Epistaxis	8 (15.4)	3 (5.8)	1 (1.9)	3 (5.8)	1 (1.9)
Pleural effusion	8 (15.4)	2 (3.8)	4 (7.7)	2 (3.8)	0
Oropharyngeal pain	5 (9.6)	4 (7.7)	1 (1.9)	0	0
Pulmonary oedema	5 (9.6)	1 (1.9)	0	3 (5.8)	1 (1.9)
Rhinorrhoea	5 (9.6)	4 (7.7)	1 (1.9)	0	0
Tachypnoea	5 (9.6)	3 (5.8)	1 (1.9)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nasal congestion	4 (7.7)	4 (7.7)	0	0	0
Rhinitis allergic	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Dyspnoea	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Respiratory failure	2 (3.8)	0	0	0	2 (3.8)
Acute respiratory failure	1 (1.9)	0	0	0	1 (1.9)
Atelectasis	1 (1.9)	1 (1.9)	0	0	0
Dysphonia	1 (1.9)	1 (1.9)	0	0	0
Haemoptysis	1 (1.9)	0	0	0	1 (1.9)
Interstitial lung disease	1 (1.9)	0	0	0	1 (1.9)
Oropharyngeal plaque	1 (1.9)	1 (1.9)	0	0	0
Pharyngeal erythema	1 (1.9)	1 (1.9)	0	0	0
Pharyngeal lesion	1 (1.9)	0	0	1 (1.9)	0
Pharyngeal ulceration	1 (1.9)	0	1 (1.9)	0	0
Respiratory depression	1 (1.9)	0	1 (1.9)	0	0
Respiratory distress	1 (1.9)	0	0	0	1 (1.9)
Wheezing	1 (1.9)	0	1 (1.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	24 (46.2)	15 (28.8)	7 (13.5)	2 (3.8)	0
Rash	5 (9.6)	4 (7.7)	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash maculo-papular	5 (9.6)	3 (5.8)	1 (1.9)	1 (1.9)	0
Erythema	4 (7.7)	4 (7.7)	0	0	0
Petechiae	4 (7.7)	3 (5.8)	1 (1.9)	0	0
Hyperhidrosis	3 (5.8)	3 (5.8)	0	0	0
Ingrowing nail	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Dry skin	2 (3.8)	2 (3.8)	0	0	0
Macule	2 (3.8)	2 (3.8)	0	0	0
Papule	2 (3.8)	2 (3.8)	0	0	0
Pruritus	2 (3.8)	2 (3.8)	0	0	0
Rash erythematous	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Rash papular	2 (3.8)	2 (3.8)	0	0	0
Acne	1 (1.9)	1 (1.9)	0	0	0
Alopecia	1 (1.9)	0	1 (1.9)	0	0
Dermatitis acneiform	1 (1.9)	0	0	1 (1.9)	0
Dermatitis diaper	1 (1.9)	1 (1.9)	0	0	0
Keloid scar	1 (1.9)	0	1 (1.9)	0	0
Livedo reticularis	1 (1.9)	1 (1.9)	0	0	0
Night sweats	1 (1.9)	0	1 (1.9)	0	0
Rash follicular	1 (1.9)	1 (1.9)	0	0	0

Timing: Any time post CTL019 infusion, Race: White

Primary system organ class Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash macular	1 (1.9)	1 (1.9)	0	0	0
Rash pruritic	1 (1.9)	1 (1.9)	0	0	0
Skin irritation	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					
-Total	21 (40.4)	3 (5.8)	4 (7.7)	7 (13.5)	7 (13.5)
Hypotension	15 (28.8)	1 (1.9)	0	7 (13.5)	7 (13.5)
Hypertension	11 (21.2)	3 (5.8)	7 (13.5)	1 (1.9)	0
Flushing	2 (3.8)	2 (3.8)	0	0	0
Capillary leak syndrome	1 (1.9)	0	0	0	1 (1.9)
Haematoma	1 (1.9)	0	1 (1.9)	0	0
Hot flush	1 (1.9)	1 (1.9)	0	0	0
Orthostatic hypotension	1 (1.9)	1 (1.9)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	0	1 (20.0)	1 (20.0)	3 (60.0)
Blood and lymphatic system disorders					
-Total	3 (60.0)	0	1 (20.0)	1 (20.0)	1 (20.0)
Anaemia	3 (60.0)	0	1 (20.0)	2 (40.0)	0
Febrile neutropenia	1 (20.0)	0	0	1 (20.0)	0
Lymphopenia	1 (20.0)	0	1 (20.0)	0	0
Neutropenia	1 (20.0)	0	0	0	1 (20.0)
Cardiac disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Atrioventricular block second degree	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0

Timing: Any time post CTL019 infusion, Race: Asian

		All patients N=5			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (20.0)	0	1 (20.0)	0	0
Nausea	1 (20.0)	1 (20.0)	0	0	0
Vomiting	1 (20.0)	1 (20.0)	0	0	0
General disorders and administration site conditions					
-Total	5 (100)	3 (60.0)	2 (40.0)	0	0
Fatigue	3 (60.0)	3 (60.0)	0	0	0
Pyrexia	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Pain	1 (20.0)	0	1 (20.0)	0	0
Immune system disorders					
-Total	5 (100)	0	5 (100)	0	0
Cytokine release syndrome	4 (80.0)	0	4 (80.0)	0	0
Hypogammaglobulinaemia	3 (60.0)	1 (20.0)	2 (40.0)	0	0
Infections and infestations					
-Total	3 (60.0)	0	1 (20.0)	1 (20.0)	1 (20.0)
Gastroenteritis	1 (20.0)	0	0	1 (20.0)	0
Gingivitis	1 (20.0)	1 (20.0)	0	0	0
Herpes zoster	1 (20.0)	0	0	1 (20.0)	0
Molluscum contagiosum	1 (20.0)	1 (20.0)	0	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis	1 (20.0)	0	1 (20.0)	0	0
Respiratory tract infection	1 (20.0)	0	0	0	1 (20.0)
Streptococcal infection	1 (20.0)	0	1 (20.0)	0	0
Viral infection	1 (20.0)	1 (20.0)	0	0	0
Viral upper respiratory tract infection	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	4 (80.0)	0	1 (20.0)	1 (20.0)	2 (40.0)
Neutrophil count decreased	3 (60.0)	0	1 (20.0)	0	2 (40.0)
White blood cell count decreased	3 (60.0)	0	1 (20.0)	2 (40.0)	0
Aspartate aminotransferase increased	1 (20.0)	0	0	1 (20.0)	0
Blood immunoglobulin a decreased	1 (20.0)	1 (20.0)	0	0	0
Blood uric acid increased	1 (20.0)	1 (20.0)	0	0	0
International normalised ratio increased	1 (20.0)	1 (20.0)	0	0	0
Lymphocyte count decreased	1 (20.0)	0	1 (20.0)	0	0
Metabolism and nutrition disorders					
-Total	3 (60.0)	2 (40.0)	0	1 (20.0)	0
Decreased appetite	1 (20.0)	1 (20.0)	0	0	0
Dehydration	1 (20.0)	0	0	1 (20.0)	0
Hyperphosphataemia	1 (20.0)	1 (20.0)	0	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	1 (20.0)	1 (20.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (80.0)	2 (40.0)	2 (40.0)	0	0
Pain in extremity	3 (60.0)	2 (40.0)	1 (20.0)	0	0
Arthralgia	1 (20.0)	1 (20.0)	0	0	0
Joint range of motion decreased	1 (20.0)	1 (20.0)	0	0	0
Myalgia	1 (20.0)	1 (20.0)	0	0	0
Osteonecrosis	1 (20.0)	0	1 (20.0)	0	0
Nervous system disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0
Headache	2 (40.0)	2 (40.0)	0	0	0
Renal and urinary disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Dysuria	1 (20.0)	0	1 (20.0)	0	0
Pollakiuria	1 (20.0)	1 (20.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Pulmonary oedema	1 (20.0)	0	0	1 (20.0)	0
Skin and subcutaneous tissue disorders					

Timing: Any time post CTL019 infusion, Race: Asian

Primary system organ class Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (20.0)	0	1 (20.0)	0	0
Rash	1 (20.0)	0	1 (20.0)	0	0
Vascular disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Embolism	1 (20.0)	0	0	1 (20.0)	0
Hypertension	1 (20.0)	0	1 (20.0)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174c
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Other

			All patients N=7		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	0	1 (14.3)	6 (85.7)
Blood and lymphatic system disorders					
-Total	5 (71.4)	0	1 (14.3)	2 (28.6)	2 (28.6)
Febrile neutropenia	4 (57.1)	0	0	3 (42.9)	1 (14.3)
Anaemia	3 (42.9)	0	0	3 (42.9)	0
Disseminated intravascular coagulation	1 (14.3)	0	1 (14.3)	0	0
Lymphadenopathy	1 (14.3)	0	1 (14.3)	0	0
Lymphopenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Tachycardia	3 (42.9)	3 (42.9)	0	0	0
Ventricular tachycardia	1 (14.3)	0	1 (14.3)	0	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Adrenal insufficiency	1 (14.3)	0	1 (14.3)	0	0
Eye disorders					
-Total	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Conjunctival haemorrhage	1 (14.3)	1 (14.3)	0	0	0
Dry eye	1 (14.3)	1 (14.3)	0	0	0
Periorbital oedema	1 (14.3)	1 (14.3)	0	0	0
Uveitis	1 (14.3)	0	1 (14.3)	0	0
Vision blurred	1 (14.3)	0	1 (14.3)	0	0
Gastrointestinal disorders					
-Total	6 (85.7)	1 (14.3)	5 (71.4)	0	0
Nausea	6 (85.7)	2 (28.6)	4 (57.1)	0	0
Vomiting	4 (57.1)	4 (57.1)	0	0	0
Diarrhoea	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Abdominal pain	1 (14.3)	1 (14.3)	0	0	0
Abdominal pain upper	1 (14.3)	0	1 (14.3)	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Dysphagia	1 (14.3)	0	1 (14.3)	0	0

Timing: Any time post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Flatulence	1 (14.3)	1 (14.3)	0	0	0
Lip pain	1 (14.3)	0	1 (14.3)	0	0
General disorders and administration site conditions					
-Total	5 (71.4)	2 (28.6)	2 (28.6)	1 (14.3)	0
Pyrexia	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Catheter site haemorrhage	1 (14.3)	1 (14.3)	0	0	0
Catheter site pain	1 (14.3)	1 (14.3)	0	0	0
Chills	1 (14.3)	0	1 (14.3)	0	0
Fatigue	1 (14.3)	1 (14.3)	0	0	0
Injection site haematoma	1 (14.3)	1 (14.3)	0	0	0
Malaise	1 (14.3)	0	1 (14.3)	0	0
Physical deconditioning	1 (14.3)	0	0	1 (14.3)	0
Hepatobiliary disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Gallbladder enlargement	1 (14.3)	1 (14.3)	0	0	0
Immune system disorders					
-Total	6 (85.7)	1 (14.3)	3 (42.9)	1 (14.3)	1 (14.3)
Cytokine release syndrome	6 (85.7)	2 (28.6)	2 (28.6)	1 (14.3)	1 (14.3)

Timing: Any time post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypogammaglobulinaemia	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Immunodeficiency common variable	2 (28.6)	0	2 (28.6)	0	0
Immunodeficiency	1 (14.3)	0	1 (14.3)	0	0
Seasonal allergy	1 (14.3)	1 (14.3)	0	0	0
Infections and infestations					
-Total	5 (71.4)	0	3 (42.9)	1 (14.3)	1 (14.3)
Catheter site cellulitis	1 (14.3)	1 (14.3)	0	0	0
Clostridium difficile colitis	1 (14.3)	0	1 (14.3)	0	0
Clostridium difficile infection	1 (14.3)	0	1 (14.3)	0	0
Cytomegalovirus infection	1 (14.3)	1 (14.3)	0	0	0
Herpes simplex	1 (14.3)	1 (14.3)	0	0	0
Meningitis aseptic	1 (14.3)	0	1 (14.3)	0	0
Oral herpes	1 (14.3)	0	1 (14.3)	0	0
Otitis media	1 (14.3)	0	1 (14.3)	0	0
Rhinitis	1 (14.3)	1 (14.3)	0	0	0
Sepsis	1 (14.3)	0	0	0	1 (14.3)
Upper respiratory tract infection	1 (14.3)	1 (14.3)	0	0	0
Urinary tract infection	1 (14.3)	0	1 (14.3)	0	0
Vascular device infection	1 (14.3)	0	0	1 (14.3)	0

Timing: Any time post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulvovaginal mycotic infection	1 (14.3)	0	1 (14.3)	0	0
Injury, poisoning and procedural complications					
-Total	4 (57.1)	1 (14.3)	1 (14.3)	1 (14.3)	1 (14.3)
Procedural pain	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Arthropod bite	1 (14.3)	1 (14.3)	0	0	0
Post procedural haemorrhage	1 (14.3)	1 (14.3)	0	0	0
Transfusion reaction	1 (14.3)	1 (14.3)	0	0	0
Transfusion related complication	1 (14.3)	0	0	0	1 (14.3)
Investigations					
-Total	6 (85.7)	0	0	2 (28.6)	4 (57.1)
White blood cell count decreased	6 (85.7)	0	0	3 (42.9)	3 (42.9)
Alanine aminotransferase increased	4 (57.1)	1 (14.3)	1 (14.3)	2 (28.6)	0
Aspartate aminotransferase increased	4 (57.1)	2 (28.6)	1 (14.3)	1 (14.3)	0
Neutrophil count decreased	3 (42.9)	0	0	0	3 (42.9)
Platelet count decreased	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Blood creatinine increased	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Haemoglobin decreased	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Lymphocyte count decreased	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Prothrombin time prolonged	2 (28.6)	1 (14.3)	1 (14.3)	0	0

Timing: Any time post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0	0	0
Blood alkaline phosphatase increased	1 (14.3)	1 (14.3)	0	0	0
Blood immunoglobulin a decreased	1 (14.3)	1 (14.3)	0	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0
Blood lactate dehydrogenase increased	1 (14.3)	1 (14.3)	0	0	0
C-reactive protein increased	1 (14.3)	1 (14.3)	0	0	0
Culture stool positive	1 (14.3)	1 (14.3)	0	0	0
Hepatic enzyme increased	1 (14.3)	0	1 (14.3)	0	0
International normalised ratio increased	1 (14.3)	1 (14.3)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (57.1)	2 (28.6)	0	2 (28.6)	0
Decreased appetite	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Acidosis	1 (14.3)	1 (14.3)	0	0	0
Hypernatraemia	1 (14.3)	1 (14.3)	0	0	0
Hyperphosphataemia	1 (14.3)	1 (14.3)	0	0	0
Hypokalaemia	1 (14.3)	1 (14.3)	0	0	0
Tumour lysis syndrome	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (42.9)	3 (42.9)	0	0	0

Timing: Any time post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain in extremity	2 (28.6)	2 (28.6)	0	0	0
Coccydynia	1 (14.3)	1 (14.3)	0	0	0
Muscular weakness	1 (14.3)	1 (14.3)	0	0	0
Musculoskeletal chest pain	1 (14.3)	1 (14.3)	0	0	0
Myalgia	1 (14.3)	1 (14.3)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (14.3)	0	1 (14.3)	0	0
Myelodysplastic syndrome	1 (14.3)	0	1 (14.3)	0	0
Nervous system disorders					
-Total	4 (57.1)	1 (14.3)	3 (42.9)	0	0
Headache	3 (42.9)	0	3 (42.9)	0	0
Asterixis	1 (14.3)	1 (14.3)	0	0	0
Ataxia	1 (14.3)	0	1 (14.3)	0	0
Dysarthria	1 (14.3)	1 (14.3)	0	0	0
Encephalopathy	1 (14.3)	1 (14.3)	0	0	0
Myoclonus	1 (14.3)	1 (14.3)	0	0	0
Neuropathy peripheral	1 (14.3)	0	1 (14.3)	0	0
Pleocytosis	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Seizure	1 (14.3)	0	1 (14.3)	0	0
Tremor	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Adjustment disorder	1 (14.3)	0	1 (14.3)	0	0
Agitation	1 (14.3)	0	1 (14.3)	0	0
Anxiety	1 (14.3)	0	1 (14.3)	0	0
Delirium	1 (14.3)	0	1 (14.3)	0	0
Suicidal ideation	1 (14.3)	1 (14.3)	0	0	0
Renal and urinary disorders					
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Acute kidney injury	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Reproductive system and breast disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Ovarian failure	1 (14.3)	0	0	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (71.4)	3 (42.9)	0	1 (14.3)	1 (14.3)
Cough	3 (42.9)	3 (42.9)	0	0	0
Epistaxis	2 (28.6)	1 (14.3)	0	1 (14.3)	0

Timing: Any time post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemoptysis	1 (14.3)	1 (14.3)	0	0	0
Nasal congestion	1 (14.3)	1 (14.3)	0	0	0
Oropharyngeal pain	1 (14.3)	0	1 (14.3)	0	0
Pulmonary oedema	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Rhinitis allergic	1 (14.3)	1 (14.3)	0	0	0
Rhinorrhoea	1 (14.3)	1 (14.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (71.4)	3 (42.9)	1 (14.3)	1 (14.3)	0
Dry skin	3 (42.9)	3 (42.9)	0	0	0
Pruritus	2 (28.6)	2 (28.6)	0	0	0
Rash	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Dermatitis	1 (14.3)	1 (14.3)	0	0	0
Dermatitis atopic	1 (14.3)	1 (14.3)	0	0	0
Ecchymosis	1 (14.3)	0	0	1 (14.3)	0
Eczema	1 (14.3)	1 (14.3)	0	0	0
Erythema	1 (14.3)	1 (14.3)	0	0	0
Hyperhidrosis	1 (14.3)	1 (14.3)	0	0	0
Rash vesicular	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Race: Other

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin exfoliation	1 (14.3)	1 (14.3)	0	0	0
Skin fissures	1 (14.3)	1 (14.3)	0	0	0
Vascular disorders					
-Total	3 (42.9)	0	2 (28.6)	0	1 (14.3)
Hypotension	1 (14.3)	0	0	0	1 (14.3)
Orthostatic hypotension	1 (14.3)	0	1 (14.3)	0	0
Secondary hypertension	1 (14.3)	0	1 (14.3)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174d
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=25		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (100)	1 (4.0)	2 (8.0)	5 (20.0)	17 (68.0)
Blood and lymphatic system disorders					
-Total	19 (76.0)	0	2 (8.0)	15 (60.0)	2 (8.0)
Febrile neutropenia	14 (56.0)	0	0	14 (56.0)	0
Anaemia	11 (44.0)	2 (8.0)	3 (12.0)	6 (24.0)	0
Disseminated intravascular coagulation	2 (8.0)	0	1 (4.0)	1 (4.0)	0
Lymphopenia	2 (8.0)	0	1 (4.0)	1 (4.0)	0
Neutropenia	2 (8.0)	0	0	2 (8.0)	0
Thrombocytopenia	2 (8.0)	0	0	0	2 (8.0)
Cardiac disorders					
-Total	8 (32.0)	5 (20.0)	3 (12.0)	0	0
Tachycardia	7 (28.0)	6 (24.0)	1 (4.0)	0	0
Cardiac dysfunction	1 (4.0)	1 (4.0)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	1 (4.0)	0	1 (4.0)	0	0
Ventricular tachycardia	1 (4.0)	0	1 (4.0)	0	0
Endocrine disorders					
-Total	1 (4.0)	0	1 (4.0)	0	0
Adrenal insufficiency	1 (4.0)	0	1 (4.0)	0	0
Eye disorders					
-Total	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Conjunctival haemorrhage	1 (4.0)	1 (4.0)	0	0	0
Eye pain	1 (4.0)	1 (4.0)	0	0	0
Periorbital oedema	1 (4.0)	1 (4.0)	0	0	0
Vision blurred	1 (4.0)	0	1 (4.0)	0	0
Gastrointestinal disorders					
-Total	12 (48.0)	3 (12.0)	6 (24.0)	3 (12.0)	0
Nausea	7 (28.0)	1 (4.0)	6 (24.0)	0	0
Vomiting	6 (24.0)	4 (16.0)	1 (4.0)	1 (4.0)	0
Diarrhoea	5 (20.0)	3 (12.0)	1 (4.0)	1 (4.0)	0
Abdominal pain	3 (12.0)	3 (12.0)	0	0	0
Constipation	2 (8.0)	2 (8.0)	0	0	0
Abdominal distension	1 (4.0)	0	1 (4.0)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=25		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain upper	1 (4.0)	0	1 (4.0)	0	0
Abdominal tenderness	1 (4.0)	1 (4.0)	0	0	0
Ascites	1 (4.0)	0	0	1 (4.0)	0
Dysphagia	1 (4.0)	0	1 (4.0)	0	0
Flatulence	1 (4.0)	1 (4.0)	0	0	0
Gastrooesophageal reflux disease	1 (4.0)	1 (4.0)	0	0	0
Glossodynia	1 (4.0)	1 (4.0)	0	0	0
Pancreatitis	1 (4.0)	0	0	1 (4.0)	0
General disorders and administration site conditions					
-Total	8 (32.0)	4 (16.0)	1 (4.0)	3 (12.0)	0
Pyrexia	3 (12.0)	1 (4.0)	0	2 (8.0)	0
Chills	2 (8.0)	2 (8.0)	0	0	0
Fatigue	2 (8.0)	2 (8.0)	0	0	0
Malaise	1 (4.0)	0	1 (4.0)	0	0
Physical deconditioning	1 (4.0)	0	0	1 (4.0)	0
Hepatobiliary disorders					
-Total	1 (4.0)	1 (4.0)	0	0	0
Gallbladder enlargement	1 (4.0)	1 (4.0)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	23 (92.0)	2 (8.0)	14 (56.0)	4 (16.0)	3 (12.0)
Cytokine release syndrome	20 (80.0)	2 (8.0)	12 (48.0)	3 (12.0)	3 (12.0)
Hypogammaglobulinaemia	12 (48.0)	0	11 (44.0)	1 (4.0)	0
Drug hypersensitivity	1 (4.0)	0	1 (4.0)	0	0
Graft versus host disease in skin	1 (4.0)	1 (4.0)	0	0	0
Infections and infestations					
-Total	8 (32.0)	1 (4.0)	6 (24.0)	1 (4.0)	0
Clostridium difficile infection	2 (8.0)	0	2 (8.0)	0	0
Cytomegalovirus infection	1 (4.0)	1 (4.0)	0	0	0
Enterococcal infection	1 (4.0)	1 (4.0)	0	0	0
Fungal skin infection	1 (4.0)	1 (4.0)	0	0	0
Gastroenteritis	1 (4.0)	0	1 (4.0)	0	0
Gastroenteritis norovirus	1 (4.0)	0	1 (4.0)	0	0
Influenza	1 (4.0)	1 (4.0)	0	0	0
Skin infection	1 (4.0)	0	1 (4.0)	0	0
Staphylococcal infection	1 (4.0)	0	0	1 (4.0)	0
Viral infection	1 (4.0)	0	1 (4.0)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	6 (24.0)	5 (20.0)	1 (4.0)	0	0
Procedural pain	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Contusion	1 (4.0)	1 (4.0)	0	0	0
Infusion related reaction	1 (4.0)	0	1 (4.0)	0	0
Post procedural haemorrhage	1 (4.0)	1 (4.0)	0	0	0
Procedural site reaction	1 (4.0)	1 (4.0)	0	0	0
Skin abrasion	1 (4.0)	1 (4.0)	0	0	0
Subdural haemorrhage	1 (4.0)	1 (4.0)	0	0	0
Investigations					
-Total	22 (88.0)	1 (4.0)	1 (4.0)	5 (20.0)	15 (60.0)
White blood cell count decreased	15 (60.0)	0	0	6 (24.0)	9 (36.0)
Neutrophil count decreased	13 (52.0)	0	0	2 (8.0)	11 (44.0)
Platelet count decreased	9 (36.0)	3 (12.0)	2 (8.0)	0	4 (16.0)
Alanine aminotransferase increased	7 (28.0)	1 (4.0)	0	6 (24.0)	0
Lymphocyte count decreased	7 (28.0)	1 (4.0)	0	4 (16.0)	2 (8.0)
Aspartate aminotransferase increased	4 (16.0)	1 (4.0)	0	3 (12.0)	0
Blood creatinine increased	4 (16.0)	4 (16.0)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Blood bilirubin increased	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Blood immunoglobulin m decreased	2 (8.0)	2 (8.0)	0	0	0
Prothrombin time prolonged	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Blood fibrinogen decreased	1 (4.0)	0	0	1 (4.0)	0
Blood immunoglobulin a decreased	1 (4.0)	1 (4.0)	0	0	0
Blood immunoglobulin g decreased	1 (4.0)	0	1 (4.0)	0	0
Blood sodium increased	1 (4.0)	0	1 (4.0)	0	0
Blood urea increased	1 (4.0)	1 (4.0)	0	0	0
C-reactive protein increased	1 (4.0)	0	0	1 (4.0)	0
Fibrin d dimer increased	1 (4.0)	1 (4.0)	0	0	0
International normalised ratio increased	1 (4.0)	1 (4.0)	0	0	0
Lipase increased	1 (4.0)	0	0	0	1 (4.0)
Pulmonary function test decreased	1 (4.0)	0	1 (4.0)	0	0
Metabolism and nutrition disorders					
-Total	15 (60.0)	1 (4.0)	6 (24.0)	5 (20.0)	3 (12.0)
Decreased appetite	7 (28.0)	1 (4.0)	3 (12.0)	3 (12.0)	0
Hypokalaemia	6 (24.0)	1 (4.0)	3 (12.0)	2 (8.0)	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=25		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	4 (16.0)	4 (16.0)	0	0	0
Hypernatraemia	2 (8.0)	1 (4.0)	0	0	1 (4.0)
Hyperuricaemia	2 (8.0)	1 (4.0)	0	0	1 (4.0)
Acidosis	1 (4.0)	1 (4.0)	0	0	0
Dehydration	1 (4.0)	1 (4.0)	0	0	0
Hyperglycaemia	1 (4.0)	0	1 (4.0)	0	0
Hypertriglyceridaemia	1 (4.0)	1 (4.0)	0	0	0
Hypoalbuminaemia	1 (4.0)	0	0	1 (4.0)	0
Hypomagnesaemia	1 (4.0)	1 (4.0)	0	0	0
Hypophosphataemia	1 (4.0)	0	0	0	1 (4.0)
Tumour lysis syndrome	1 (4.0)	0	0	1 (4.0)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (8.0)	0	2 (8.0)	0	0
Arthralgia	2 (8.0)	2 (8.0)	0	0	0
Muscular weakness	1 (4.0)	0	1 (4.0)	0	0
Musculoskeletal chest pain	1 (4.0)	1 (4.0)	0	0	0
Musculoskeletal pain	1 (4.0)	0	1 (4.0)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (4.0)	0	1 (4.0)	0	0
Skin papilloma	1 (4.0)	0	1 (4.0)	0	0
Nervous system disorders					
-Total	13 (52.0)	6 (24.0)	6 (24.0)	1 (4.0)	0
Headache	10 (40.0)	6 (24.0)	4 (16.0)	0	0
Dysarthria	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Seizure	2 (8.0)	0	2 (8.0)	0	0
Asterixis	1 (4.0)	1 (4.0)	0	0	0
Ataxia	1 (4.0)	0	1 (4.0)	0	0
Dizziness	1 (4.0)	1 (4.0)	0	0	0
Encephalopathy	1 (4.0)	0	0	1 (4.0)	0
Neuropathy peripheral	1 (4.0)	0	1 (4.0)	0	0
Pleocytosis	1 (4.0)	1 (4.0)	0	0	0
Somnolence	1 (4.0)	1 (4.0)	0	0	0
Tremor	1 (4.0)	1 (4.0)	0	0	0
Product issues					
-Total	1 (4.0)	1 (4.0)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=25		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device occlusion	1 (4.0)	1 (4.0)	0	0	0
Psychiatric disorders					
-Total	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Adjustment disorder	1 (4.0)	0	1 (4.0)	0	0
Agitation	1 (4.0)	0	1 (4.0)	0	0
Anxiety	1 (4.0)	0	1 (4.0)	0	0
Confusional state	1 (4.0)	1 (4.0)	0	0	0
Delirium	1 (4.0)	0	1 (4.0)	0	0
Hallucination	1 (4.0)	1 (4.0)	0	0	0
Suicidal ideation	1 (4.0)	1 (4.0)	0	0	0
Renal and urinary disorders					
-Total	3 (12.0)	1 (4.0)	0	2 (8.0)	0
Acute kidney injury	2 (8.0)	0	0	2 (8.0)	0
Dysuria	1 (4.0)	1 (4.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (44.0)	7 (28.0)	2 (8.0)	0	2 (8.0)
Pulmonary oedema	3 (12.0)	1 (4.0)	0	1 (4.0)	1 (4.0)
Tachypnoea	3 (12.0)	3 (12.0)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	2 (8.0)	0	0	0	2 (8.0)
Cough	1 (4.0)	1 (4.0)	0	0	0
Epistaxis	1 (4.0)	1 (4.0)	0	0	0
Haemoptysis	1 (4.0)	1 (4.0)	0	0	0
Hypoxia	1 (4.0)	0	1 (4.0)	0	0
Nasal congestion	1 (4.0)	1 (4.0)	0	0	0
Oropharyngeal pain	1 (4.0)	0	1 (4.0)	0	0
Oropharyngeal plaque	1 (4.0)	1 (4.0)	0	0	0
Pleural effusion	1 (4.0)	0	0	1 (4.0)	0
Rhinorrhoea	1 (4.0)	1 (4.0)	0	0	0
Wheezing	1 (4.0)	0	1 (4.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (36.0)	7 (28.0)	1 (4.0)	1 (4.0)	0
Dry skin	2 (8.0)	2 (8.0)	0	0	0
Dermatitis diaper	1 (4.0)	1 (4.0)	0	0	0
Ecchymosis	1 (4.0)	0	0	1 (4.0)	0
Erythema	1 (4.0)	1 (4.0)	0	0	0
Ingrowing nail	1 (4.0)	0	1 (4.0)	0	0
Petechiae	1 (4.0)	1 (4.0)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	1 (4.0)	1 (4.0)	0	0	0
Rash	1 (4.0)	1 (4.0)	0	0	0
Rash follicular	1 (4.0)	1 (4.0)	0	0	0
Rash papular	1 (4.0)	1 (4.0)	0	0	0
Skin exfoliation	1 (4.0)	1 (4.0)	0	0	0
Skin fissures	1 (4.0)	1 (4.0)	0	0	0
Skin irritation	1 (4.0)	1 (4.0)	0	0	0
Vascular disorders					
-Total	10 (40.0)	1 (4.0)	4 (16.0)	4 (16.0)	1 (4.0)
Hypotension	5 (20.0)	0	0	4 (16.0)	1 (4.0)
Hypertension	2 (8.0)	0	2 (8.0)	0	0
Orthostatic hypotension	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Secondary hypertension	1 (4.0)	0	1 (4.0)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174d
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Other

			All patients N=39		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (97.4)	1 (2.6)	5 (12.8)	9 (23.1)	23 (59.0)
Blood and lymphatic system disorders					
-Total	24 (61.5)	2 (5.1)	1 (2.6)	12 (30.8)	9 (23.1)
Anaemia	16 (41.0)	1 (2.6)	2 (5.1)	12 (30.8)	1 (2.6)
Febrile neutropenia	8 (20.5)	0	0	8 (20.5)	0
Neutropenia	6 (15.4)	0	0	1 (2.6)	5 (12.8)
Thrombocytopenia	6 (15.4)	0	0	2 (5.1)	4 (10.3)
Disseminated intravascular coagulation	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Coagulopathy	1 (2.6)	1 (2.6)	0	0	0
Lymphopenia	1 (2.6)	0	0	0	1 (2.6)
Pancytopenia	1 (2.6)	0	0	0	1 (2.6)
Cardiac disorders					
-Total	14 (35.9)	6 (15.4)	6 (15.4)	2 (5.1)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	8 (20.5)	2 (5.1)	4 (10.3)	2 (5.1)	0
Sinus tachycardia	4 (10.3)	3 (7.7)	1 (2.6)	0	0
Pericardial effusion	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Atrioventricular block second degree	1 (2.6)	1 (2.6)	0	0	0
Bradycardia	1 (2.6)	0	1 (2.6)	0	0
Left ventricular dysfunction	1 (2.6)	0	0	1 (2.6)	0
Palpitations	1 (2.6)	1 (2.6)	0	0	0
Sinus bradycardia	1 (2.6)	1 (2.6)	0	0	0
Ear and labyrinth disorders					
-Total	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Ear pain	2 (5.1)	2 (5.1)	0	0	0
Hypoacusis	1 (2.6)	0	1 (2.6)	0	0
Eye disorders					
-Total	11 (28.2)	5 (12.8)	6 (15.4)	0	0
Periorbital oedema	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Conjunctival haemorrhage	2 (5.1)	2 (5.1)	0	0	0
Eye pain	2 (5.1)	0	2 (5.1)	0	0
Photophobia	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Retinal haemorrhage	2 (5.1)	2 (5.1)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Uveitis	2 (5.1)	0	2 (5.1)	0	0
Vision blurred	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Ocular hypertension	1 (2.6)	0	1 (2.6)	0	0
Papilloedema	1 (2.6)	0	1 (2.6)	0	0
Visual impairment	1 (2.6)	0	1 (2.6)	0	0
Gastrointestinal disorders					
-Total	24 (61.5)	8 (20.5)	8 (20.5)	8 (20.5)	0
Vomiting	16 (41.0)	9 (23.1)	5 (12.8)	2 (5.1)	0
Nausea	14 (35.9)	5 (12.8)	6 (15.4)	3 (7.7)	0
Diarrhoea	13 (33.3)	8 (20.5)	5 (12.8)	0	0
Abdominal pain	6 (15.4)	3 (7.7)	2 (5.1)	1 (2.6)	0
Constipation	5 (12.8)	4 (10.3)	1 (2.6)	0	0
Haematemesis	2 (5.1)	2 (5.1)	0	0	0
Stomatitis	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Abdominal discomfort	1 (2.6)	1 (2.6)	0	0	0
Abdominal distension	1 (2.6)	0	1 (2.6)	0	0
Abdominal pain lower	1 (2.6)	0	1 (2.6)	0	0
Abdominal pain upper	1 (2.6)	0	1 (2.6)	0	0
Anal incontinence	1 (2.6)	1 (2.6)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspepsia	1 (2.6)	0	1 (2.6)	0	0
Dysphagia	1 (2.6)	0	0	1 (2.6)	0
Gastrointestinal haemorrhage	1 (2.6)	1 (2.6)	0	0	0
Ileus	1 (2.6)	0	0	1 (2.6)	0
Intestinal obstruction	1 (2.6)	0	0	1 (2.6)	0
Lip pain	1 (2.6)	0	1 (2.6)	0	0
Mouth haemorrhage	1 (2.6)	0	0	1 (2.6)	0
Pancreatitis	1 (2.6)	0	1 (2.6)	0	0
Tooth socket haemorrhage	1 (2.6)	1 (2.6)	0	0	0
General disorders and administration site conditions					
-Total	24 (61.5)	8 (20.5)	9 (23.1)	6 (15.4)	1 (2.6)
Pyrexia	13 (33.3)	2 (5.1)	7 (17.9)	3 (7.7)	1 (2.6)
Fatigue	11 (28.2)	8 (20.5)	2 (5.1)	1 (2.6)	0
Chills	6 (15.4)	6 (15.4)	0	0	0
Catheter site pain	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Pain	3 (7.7)	0	1 (2.6)	2 (5.1)	0
Face oedema	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Generalised oedema	2 (5.1)	0	2 (5.1)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	2 (5.1)	0	2 (5.1)	0	0
Oedema peripheral	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Asthenia	1 (2.6)	1 (2.6)	0	0	0
Catheter site extravasation	1 (2.6)	0	1 (2.6)	0	0
Catheter site haemorrhage	1 (2.6)	1 (2.6)	0	0	0
Facial pain	1 (2.6)	0	1 (2.6)	0	0
Injection site haematoma	1 (2.6)	1 (2.6)	0	0	0
Localised oedema	1 (2.6)	0	0	1 (2.6)	0
Mucosal haemorrhage	1 (2.6)	0	1 (2.6)	0	0
Multiple organ dysfunction syndrome	1 (2.6)	0	0	1 (2.6)	0
Non-cardiac chest pain	1 (2.6)	1 (2.6)	0	0	0
Peripheral swelling	1 (2.6)	0	1 (2.6)	0	0
Hepatobiliary disorders					
-Total	6 (15.4)	2 (5.1)	2 (5.1)	2 (5.1)	0
Hepatomegaly	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Hyperbilirubinaemia	3 (7.7)	0	1 (2.6)	2 (5.1)	0
Hepatosplenomegaly	1 (2.6)	1 (2.6)	0	0	0
Immune system disorders					
-Total	34 (87.2)	3 (7.7)	16 (41.0)	7 (17.9)	8 (20.5)

Timing: within 8 weeks post infusion, Ethnicity: Other

			All patients N=39		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	30 (76.9)	4 (10.3)	13 (33.3)	5 (12.8)	8 (20.5)
Hypogammaglobulinaemia	13 (33.3)	3 (7.7)	7 (17.9)	3 (7.7)	0
Haemophagocytic lymphohistiocytosis	1 (2.6)	0	1 (2.6)	0	0
Infections and infestations					
-Total	18 (46.2)	4 (10.3)	8 (20.5)	5 (12.8)	1 (2.6)
Clostridium difficile colitis	4 (10.3)	1 (2.6)	2 (5.1)	1 (2.6)	0
Rhinovirus infection	3 (7.7)	3 (7.7)	0	0	0
Clostridium difficile infection	2 (5.1)	0	2 (5.1)	0	0
Pneumonia	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Acute sinusitis	1 (2.6)	0	1 (2.6)	0	0
Body tinea	1 (2.6)	1 (2.6)	0	0	0
Catheter site cellulitis	1 (2.6)	1 (2.6)	0	0	0
Catheter site infection	1 (2.6)	0	0	1 (2.6)	0
Folliculitis	1 (2.6)	0	1 (2.6)	0	0
Gastroenteritis	1 (2.6)	0	0	1 (2.6)	0
Herpes simplex	1 (2.6)	1 (2.6)	0	0	0
Human herpesvirus 6 infection	1 (2.6)	0	1 (2.6)	0	0
Hypopyon	1 (2.6)	0	1 (2.6)	0	0
Oral candidiasis	1 (2.6)	1 (2.6)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Orchitis	1 (2.6)	1 (2.6)	0	0	0
Pharyngitis	1 (2.6)	0	1 (2.6)	0	0
Septic embolus	1 (2.6)	0	0	0	1 (2.6)
Staphylococcal infection	1 (2.6)	1 (2.6)	0	0	0
Streptococcal infection	1 (2.6)	0	1 (2.6)	0	0
Upper respiratory tract infection	1 (2.6)	0	1 (2.6)	0	0
Urinary tract infection enterococcal	1 (2.6)	0	0	1 (2.6)	0
Viral upper respiratory tract infection	1 (2.6)	0	1 (2.6)	0	0
Vulvovaginal candidiasis	1 (2.6)	1 (2.6)	0	0	0
Injury, poisoning and procedural complications					
-Total	9 (23.1)	3 (7.7)	4 (10.3)	1 (2.6)	1 (2.6)
Transfusion reaction	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Incision site pain	1 (2.6)	1 (2.6)	0	0	0
Infusion related reaction	1 (2.6)	0	1 (2.6)	0	0
Limb injury	1 (2.6)	1 (2.6)	0	0	0
Mouth injury	1 (2.6)	1 (2.6)	0	0	0
Procedural complication	1 (2.6)	1 (2.6)	0	0	0
Procedural headache	1 (2.6)	0	1 (2.6)	0	0
Procedural pain	1 (2.6)	0	1 (2.6)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stoma site irritation	1 (2.6)	1 (2.6)	0	0	0
Tibia fracture	1 (2.6)	0	1 (2.6)	0	0
Tongue injury	1 (2.6)	1 (2.6)	0	0	0
Tracheal haemorrhage	1 (2.6)	0	0	1 (2.6)	0
Transfusion related complication	1 (2.6)	0	0	0	1 (2.6)
Investigations					
-Total	30 (76.9)	3 (7.7)	3 (7.7)	8 (20.5)	16 (41.0)
White blood cell count decreased	15 (38.5)	3 (7.7)	1 (2.6)	4 (10.3)	7 (17.9)
Aspartate aminotransferase increased	14 (35.9)	2 (5.1)	4 (10.3)	4 (10.3)	4 (10.3)
Alanine aminotransferase increased	12 (30.8)	4 (10.3)	3 (7.7)	5 (12.8)	0
Neutrophil count decreased	12 (30.8)	0	2 (5.1)	2 (5.1)	8 (20.5)
Platelet count decreased	10 (25.6)	0	0	2 (5.1)	8 (20.5)
International normalised ratio increased	8 (20.5)	7 (17.9)	0	1 (2.6)	0
Lymphocyte count decreased	7 (17.9)	0	2 (5.1)	2 (5.1)	3 (7.7)
Prothrombin time prolonged	7 (17.9)	4 (10.3)	2 (5.1)	1 (2.6)	0
Blood bilirubin increased	5 (12.8)	1 (2.6)	2 (5.1)	2 (5.1)	0
Blood creatinine increased	5 (12.8)	1 (2.6)	2 (5.1)	2 (5.1)	0
Blood fibrinogen decreased	3 (7.7)	0	1 (2.6)	1 (2.6)	1 (2.6)
Activated partial thromboplastin time prolonged	2 (5.1)	1 (2.6)	1 (2.6)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	2 (5.1)	2 (5.1)	0	0	0
Blood immunoglobulin m decreased	2 (5.1)	2 (5.1)	0	0	0
Blood phosphorus increased	2 (5.1)	2 (5.1)	0	0	0
Blood urea increased	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Transaminases increased	2 (5.1)	2 (5.1)	0	0	0
Blood bicarbonate decreased	1 (2.6)	0	1 (2.6)	0	0
Blood lactic acid increased	1 (2.6)	0	0	0	1 (2.6)
Blood magnesium decreased	1 (2.6)	0	0	1 (2.6)	0
Blood phosphorus decreased	1 (2.6)	1 (2.6)	0	0	0
Blood uric acid increased	1 (2.6)	1 (2.6)	0	0	0
Cardiac murmur	1 (2.6)	1 (2.6)	0	0	0
Culture stool positive	1 (2.6)	1 (2.6)	0	0	0
Haemoglobin decreased	1 (2.6)	0	0	1 (2.6)	0
Hepatic enzyme increased	1 (2.6)	0	1 (2.6)	0	0
Lipase increased	1 (2.6)	0	0	0	1 (2.6)
Norovirus test positive	1 (2.6)	1 (2.6)	0	0	0
Protein total decreased	1 (2.6)	0	0	1 (2.6)	0
Serum ferritin increased	1 (2.6)	0	1 (2.6)	0	0
Metabolism and nutrition disorders					

Timing: within 8 weeks post infusion, Ethnicity: Other

			All patients N=39		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	24 (61.5)	4 (10.3)	4 (10.3)	16 (41.0)	0
Decreased appetite	13 (33.3)	3 (7.7)	1 (2.6)	9 (23.1)	0
Hypokalaemia	10 (25.6)	2 (5.1)	3 (7.7)	5 (12.8)	0
Hypophosphataemia	8 (20.5)	2 (5.1)	0	6 (15.4)	0
Hyperphosphataemia	4 (10.3)	4 (10.3)	0	0	0
Hypoalbuminaemia	4 (10.3)	1 (2.6)	3 (7.7)	0	0
Fluid overload	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Hypocalcaemia	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Dehydration	2 (5.1)	0	0	2 (5.1)	0
Hyperglycaemia	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Hypernatraemia	2 (5.1)	0	2 (5.1)	0	0
Hyponatraemia	2 (5.1)	0	0	2 (5.1)	0
Acidosis	1 (2.6)	0	0	1 (2.6)	0
Hyperalbuminaemia	1 (2.6)	1 (2.6)	0	0	0
Hypercalcaemia	1 (2.6)	1 (2.6)	0	0	0
Hyperchloraemia	1 (2.6)	1 (2.6)	0	0	0
Hypermagnesaemia	1 (2.6)	1 (2.6)	0	0	0
Hypertriglyceridaemia	1 (2.6)	0	0	1 (2.6)	0
Hyperuricaemia	1 (2.6)	1 (2.6)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

			All patients N=39		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malnutrition	1 (2.6)	0	0	1 (2.6)	0
Metabolic acidosis	1 (2.6)	0	1 (2.6)	0	0
Metabolic alkalosis	1 (2.6)	1 (2.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	13 (33.3)	8 (20.5)	4 (10.3)	1 (2.6)	0
Myalgia	5 (12.8)	4 (10.3)	1 (2.6)	0	0
Pain in extremity	4 (10.3)	2 (5.1)	2 (5.1)	0	0
Arthralgia	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Musculoskeletal pain	2 (5.1)	2 (5.1)	0	0	0
Coccydynia	1 (2.6)	1 (2.6)	0	0	0
Limb discomfort	1 (2.6)	1 (2.6)	0	0	0
Muscle spasms	1 (2.6)	1 (2.6)	0	0	0
Osteopenia	1 (2.6)	0	1 (2.6)	0	0
Nervous system disorders					
-Total	20 (51.3)	11 (28.2)	5 (12.8)	3 (7.7)	1 (2.6)
Headache	14 (35.9)	10 (25.6)	2 (5.1)	2 (5.1)	0
Dizziness	3 (7.7)	3 (7.7)	0	0	0
Encephalopathy	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Depressed level of consciousness	1 (2.6)	1 (2.6)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

			All patients N=39		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Embolic stroke	1 (2.6)	0	0	0	1 (2.6)
Idiopathic intracranial hypertension	1 (2.6)	0	1 (2.6)	0	0
Migraine	1 (2.6)	0	1 (2.6)	0	0
Myoclonus	1 (2.6)	1 (2.6)	0	0	0
Seizure	1 (2.6)	0	0	1 (2.6)	0
Tremor	1 (2.6)	1 (2.6)	0	0	0
Psychiatric disorders					
-Total	13 (33.3)	6 (15.4)	6 (15.4)	1 (2.6)	0
Anxiety	5 (12.8)	2 (5.1)	2 (5.1)	1 (2.6)	0
Confusional state	5 (12.8)	2 (5.1)	3 (7.7)	0	0
Delirium	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Irritability	2 (5.1)	2 (5.1)	0	0	0
Agitation	1 (2.6)	0	1 (2.6)	0	0
Hallucination	1 (2.6)	0	1 (2.6)	0	0
Insomnia	1 (2.6)	0	1 (2.6)	0	0
Listless	1 (2.6)	1 (2.6)	0	0	0
Mental status changes	1 (2.6)	1 (2.6)	0	0	0
Panic attack	1 (2.6)	0	1 (2.6)	0	0
Renal and urinary disorders					

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (20.5)	1 (2.6)	2 (5.1)	1 (2.6)	4 (10.3)
Acute kidney injury	5 (12.8)	1 (2.6)	1 (2.6)	0	3 (7.7)
Haematuria	4 (10.3)	0	2 (5.1)	1 (2.6)	1 (2.6)
Oliguria	2 (5.1)	0	0	2 (5.1)	0
Dysuria	1 (2.6)	0	1 (2.6)	0	0
Pollakiuria	1 (2.6)	1 (2.6)	0	0	0
Renal failure	1 (2.6)	0	0	0	1 (2.6)
Renal impairment	1 (2.6)	0	0	1 (2.6)	0
Reproductive system and breast disorders					
-Total	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Vulvovaginal adhesion	2 (5.1)	2 (5.1)	0	0	0
Oedema genital	1 (2.6)	0	1 (2.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	17 (43.6)	3 (7.7)	4 (10.3)	5 (12.8)	5 (12.8)
Hypoxia	9 (23.1)	0	2 (5.1)	4 (10.3)	3 (7.7)
Cough	7 (17.9)	7 (17.9)	0	0	0
Pleural effusion	7 (17.9)	2 (5.1)	4 (10.3)	1 (2.6)	0
Epistaxis	6 (15.4)	1 (2.6)	1 (2.6)	3 (7.7)	1 (2.6)
Pulmonary oedema	3 (7.7)	0	0	2 (5.1)	1 (2.6)

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Tachypnoea	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Atelectasis	1 (2.6)	1 (2.6)	0	0	0
Haemoptysis	1 (2.6)	0	0	0	1 (2.6)
Interstitial lung disease	1 (2.6)	0	0	0	1 (2.6)
Oropharyngeal pain	1 (2.6)	1 (2.6)	0	0	0
Pharyngeal ulceration	1 (2.6)	0	1 (2.6)	0	0
Respiratory depression	1 (2.6)	0	1 (2.6)	0	0
Respiratory distress	1 (2.6)	0	0	0	1 (2.6)
Respiratory failure	1 (2.6)	0	0	0	1 (2.6)
Rhinitis allergic	1 (2.6)	1 (2.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	12 (30.8)	8 (20.5)	3 (7.7)	1 (2.6)	0
Hyperhidrosis	3 (7.7)	3 (7.7)	0	0	0
Rash	3 (7.7)	3 (7.7)	0	0	0
Rash maculo-papular	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Dry skin	2 (5.1)	2 (5.1)	0	0	0
Erythema	2 (5.1)	2 (5.1)	0	0	0
Petechiae	2 (5.1)	1 (2.6)	1 (2.6)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

			All patients N=39		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ingrowing nail	1 (2.6)	0	1 (2.6)	0	0
Livedo reticularis	1 (2.6)	1 (2.6)	0	0	0
Macule	1 (2.6)	1 (2.6)	0	0	0
Night sweats	1 (2.6)	0	1 (2.6)	0	0
Pruritus	1 (2.6)	1 (2.6)	0	0	0
Rash erythematous	1 (2.6)	1 (2.6)	0	0	0
Rash macular	1 (2.6)	1 (2.6)	0	0	0
Rash papular	1 (2.6)	1 (2.6)	0	0	0
Rash vesicular	1 (2.6)	1 (2.6)	0	0	0
Vascular disorders					
-Total	14 (35.9)	2 (5.1)	1 (2.6)	4 (10.3)	7 (17.9)
Hypotension	11 (28.2)	1 (2.6)	0	3 (7.7)	7 (17.9)
Hypertension	8 (20.5)	2 (5.1)	5 (12.8)	1 (2.6)	0
Flushing	2 (5.1)	2 (5.1)	0	0	0
Capillary leak syndrome	1 (2.6)	0	0	0	1 (2.6)
Embolism	1 (2.6)	0	0	1 (2.6)	0
Haematoma	1 (2.6)	0	1 (2.6)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174d
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=23		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (95.7)	1 (4.3)	8 (34.8)	9 (39.1)	4 (17.4)
Blood and lymphatic system disorders					
-Total	5 (21.7)	1 (4.3)	1 (4.3)	2 (8.7)	1 (4.3)
Anaemia	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Febrile neutropenia	2 (8.7)	0	0	2 (8.7)	0
Neutropenia	2 (8.7)	0	0	1 (4.3)	1 (4.3)
Eosinophilia	1 (4.3)	0	0	1 (4.3)	0
Lymphadenopathy	1 (4.3)	0	1 (4.3)	0	0
Cardiac disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Sinus tachycardia	1 (4.3)	0	1 (4.3)	0	0
Eye disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (17.4)	3 (13.0)	1 (4.3)	0	0
Dry eye	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Conjunctivitis allergic	1 (4.3)	1 (4.3)	0	0	0
Ocular hyperaemia	1 (4.3)	1 (4.3)	0	0	0
Gastrointestinal disorders					
-Total	9 (39.1)	5 (21.7)	2 (8.7)	2 (8.7)	0
Vomiting	6 (26.1)	4 (17.4)	1 (4.3)	1 (4.3)	0
Diarrhoea	3 (13.0)	2 (8.7)	1 (4.3)	0	0
Nausea	3 (13.0)	0	2 (8.7)	1 (4.3)	0
Abdominal pain	1 (4.3)	0	1 (4.3)	0	0
Enterocolitis	1 (4.3)	0	0	1 (4.3)	0
Oral pain	1 (4.3)	1 (4.3)	0	0	0
Pigmentation lip	1 (4.3)	1 (4.3)	0	0	0
General disorders and administration site conditions					
-Total	7 (30.4)	5 (21.7)	2 (8.7)	0	0
Pyrexia	3 (13.0)	2 (8.7)	1 (4.3)	0	0
Influenza like illness	2 (8.7)	2 (8.7)	0	0	0
Catheter site pain	1 (4.3)	0	1 (4.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	1 (4.3)	1 (4.3)	0	0	0
Fatigue	1 (4.3)	1 (4.3)	0	0	0
Generalised oedema	1 (4.3)	1 (4.3)	0	0	0
Oedema peripheral	1 (4.3)	1 (4.3)	0	0	0
Pain	1 (4.3)	1 (4.3)	0	0	0
Immune system disorders					
-Total	8 (34.8)	2 (8.7)	6 (26.1)	0	0
Hypogammaglobulinaemia	4 (17.4)	0	4 (17.4)	0	0
Immunodeficiency common variable	2 (8.7)	0	2 (8.7)	0	0
Graft versus host disease	1 (4.3)	1 (4.3)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (4.3)	0	1 (4.3)	0	0
Seasonal allergy	1 (4.3)	1 (4.3)	0	0	0
Infections and infestations					
-Total	16 (69.6)	2 (8.7)	10 (43.5)	4 (17.4)	0
Upper respiratory tract infection	4 (17.4)	2 (8.7)	2 (8.7)	0	0
Urinary tract infection	4 (17.4)	0	2 (8.7)	2 (8.7)	0
Influenza	3 (13.0)	0	3 (13.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (4.3)	0	0	1 (4.3)	0
Corona virus infection	1 (4.3)	0	0	1 (4.3)	0
Cytomegalovirus infection	1 (4.3)	1 (4.3)	0	0	0
Ear infection	1 (4.3)	1 (4.3)	0	0	0
Escherichia urinary tract infection	1 (4.3)	0	0	1 (4.3)	0
Gastroenteritis	1 (4.3)	0	1 (4.3)	0	0
Gastroenteritis norovirus	1 (4.3)	0	1 (4.3)	0	0
Otitis externa	1 (4.3)	0	1 (4.3)	0	0
Otitis media	1 (4.3)	0	1 (4.3)	0	0
Otitis media acute	1 (4.3)	0	1 (4.3)	0	0
Parainfluenzae virus infection	1 (4.3)	1 (4.3)	0	0	0
Paronychia	1 (4.3)	1 (4.3)	0	0	0
Respiratory syncytial virus infection	1 (4.3)	0	0	1 (4.3)	0
Rhinovirus infection	1 (4.3)	1 (4.3)	0	0	0
Sinusitis	1 (4.3)	0	1 (4.3)	0	0
Subcutaneous abscess	1 (4.3)	0	1 (4.3)	0	0
Tinea capitis	1 (4.3)	1 (4.3)	0	0	0
Viral upper respiratory tract infection	1 (4.3)	0	0	1 (4.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal mycotic infection	1 (4.3)	0	1 (4.3)	0	0
Injury, poisoning and procedural complications					
-Total	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Arthropod bite	1 (4.3)	1 (4.3)	0	0	0
Procedural pain	1 (4.3)	0	1 (4.3)	0	0
Skin abrasion	1 (4.3)	1 (4.3)	0	0	0
Skin laceration	1 (4.3)	0	1 (4.3)	0	0
Investigations					
-Total	10 (43.5)	2 (8.7)	2 (8.7)	5 (21.7)	1 (4.3)
Neutrophil count decreased	5 (21.7)	1 (4.3)	0	3 (13.0)	1 (4.3)
Aspartate aminotransferase increased	3 (13.0)	1 (4.3)	0	2 (8.7)	0
Platelet count decreased	3 (13.0)	3 (13.0)	0	0	0
White blood cell count decreased	3 (13.0)	2 (8.7)	1 (4.3)	0	0
Alanine aminotransferase increased	1 (4.3)	0	0	1 (4.3)	0
Blood magnesium decreased	1 (4.3)	1 (4.3)	0	0	0
Haemoglobin decreased	1 (4.3)	1 (4.3)	0	0	0
Lymphocyte count decreased	1 (4.3)	0	1 (4.3)	0	0
Serum ferritin increased	1 (4.3)	0	1 (4.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight decreased	1 (4.3)	0	1 (4.3)	0	0
Weight increased	1 (4.3)	1 (4.3)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (30.4)	3 (13.0)	1 (4.3)	2 (8.7)	1 (4.3)
Hyperphosphataemia	2 (8.7)	2 (8.7)	0	0	0
Hypokalaemia	2 (8.7)	1 (4.3)	0	0	1 (4.3)
Decreased appetite	1 (4.3)	0	1 (4.3)	0	0
Hyperglycaemia	1 (4.3)	0	0	1 (4.3)	0
Hypophosphataemia	1 (4.3)	0	0	1 (4.3)	0
Iron overload	1 (4.3)	0	0	1 (4.3)	0
Tumour lysis syndrome	1 (4.3)	0	0	1 (4.3)	0
Vitamin d deficiency	1 (4.3)	1 (4.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (30.4)	6 (26.1)	1 (4.3)	0	0
Pain in extremity	3 (13.0)	3 (13.0)	0	0	0
Back pain	1 (4.3)	1 (4.3)	0	0	0
Flank pain	1 (4.3)	0	1 (4.3)	0	0
Joint range of motion decreased	1 (4.3)	1 (4.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscle spasms	1 (4.3)	1 (4.3)	0	0	0
Muscular weakness	1 (4.3)	1 (4.3)	0	0	0
Toe walking	1 (4.3)	1 (4.3)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (4.3)	0	1 (4.3)	0	0
Myelodysplastic syndrome	1 (4.3)	0	1 (4.3)	0	0
Nervous system disorders					
-Total	3 (13.0)	3 (13.0)	0	0	0
Headache	3 (13.0)	3 (13.0)	0	0	0
Dizziness	1 (4.3)	1 (4.3)	0	0	0
Psychiatric disorders					
-Total	1 (4.3)	1 (4.3)	0	0	0
Depression	1 (4.3)	1 (4.3)	0	0	0
Renal and urinary disorders					
-Total	2 (8.7)	0	0	2 (8.7)	0
Acute kidney injury	1 (4.3)	0	0	1 (4.3)	0
Calculus urinary	1 (4.3)	0	1 (4.3)	0	0
Haematuria	1 (4.3)	0	0	1 (4.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nephrolithiasis	1 (4.3)	0	0	1 (4.3)	0
Reproductive system and breast disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Scrotal pain	1 (4.3)	0	1 (4.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	12 (52.2)	7 (30.4)	4 (17.4)	0	1 (4.3)
Cough	4 (17.4)	2 (8.7)	2 (8.7)	0	0
Nasal congestion	4 (17.4)	4 (17.4)	0	0	0
Rhinorrhoea	4 (17.4)	3 (13.0)	1 (4.3)	0	0
Oropharyngeal pain	2 (8.7)	2 (8.7)	0	0	0
Rhinitis allergic	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Acute respiratory failure	1 (4.3)	0	0	0	1 (4.3)
Epistaxis	1 (4.3)	1 (4.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (39.1)	6 (26.1)	2 (8.7)	1 (4.3)	0
Rash maculo-papular	2 (8.7)	2 (8.7)	0	0	0
Dermatitis	1 (4.3)	1 (4.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dermatitis acneiform	1 (4.3)	0	0	1 (4.3)	0
Dry skin	1 (4.3)	1 (4.3)	0	0	0
Eczema	1 (4.3)	1 (4.3)	0	0	0
Ingrowing nail	1 (4.3)	1 (4.3)	0	0	0
Keloid scar	1 (4.3)	0	1 (4.3)	0	0
Macule	1 (4.3)	1 (4.3)	0	0	0
Petechiae	1 (4.3)	1 (4.3)	0	0	0
Rash	1 (4.3)	0	1 (4.3)	0	0
Rash pruritic	1 (4.3)	1 (4.3)	0	0	0
Vascular disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Hypertension	1 (4.3)	0	1 (4.3)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174d
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (72.7)	3 (9.1)	8 (24.2)	7 (21.2)	6 (18.2)
Blood and lymphatic system disorders					
-Total	6 (18.2)	0	2 (6.1)	1 (3.0)	3 (9.1)
Neutropenia	2 (6.1)	0	0	0	2 (6.1)
Thrombocytopenia	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Febrile neutropenia	1 (3.0)	0	0	1 (3.0)	0
Leukopenia	1 (3.0)	0	0	0	1 (3.0)
Lymphopenia	1 (3.0)	0	1 (3.0)	0	0
Endocrine disorders					
-Total	1 (3.0)	1 (3.0)	0	0	0
Adrenal insufficiency	1 (3.0)	1 (3.0)	0	0	0
Eye disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.0)	1 (3.0)	0	0	0
Vision blurred	1 (3.0)	1 (3.0)	0	0	0
Gastrointestinal disorders					
-Total	7 (21.2)	4 (12.1)	1 (3.0)	2 (6.1)	0
Diarrhoea	5 (15.2)	4 (12.1)	0	1 (3.0)	0
Abdominal pain	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Nausea	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Vomiting	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Abdominal pain upper	1 (3.0)	1 (3.0)	0	0	0
Oral pain	1 (3.0)	0	0	1 (3.0)	0
General disorders and administration site conditions					
-Total	10 (30.3)	8 (24.2)	1 (3.0)	1 (3.0)	0
Pyrexia	7 (21.2)	5 (15.2)	1 (3.0)	1 (3.0)	0
Acquired gene mutation	1 (3.0)	1 (3.0)	0	0	0
Crying	1 (3.0)	1 (3.0)	0	0	0
Fatigue	1 (3.0)	1 (3.0)	0	0	0
Malaise	1 (3.0)	1 (3.0)	0	0	0
Immune system disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (18.2)	1 (3.0)	4 (12.1)	1 (3.0)	0
Hypogammaglobulinaemia	4 (12.1)	0	3 (9.1)	1 (3.0)	0
Graft versus host disease	1 (3.0)	0	1 (3.0)	0	0
Seasonal allergy	1 (3.0)	1 (3.0)	0	0	0
Infections and infestations					
-Total	17 (51.5)	4 (12.1)	5 (15.2)	6 (18.2)	2 (6.1)
Upper respiratory tract infection	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Gastroenteritis	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Bacterial sepsis	1 (3.0)	0	0	0	1 (3.0)
Cholecystitis infective	1 (3.0)	0	0	1 (3.0)	0
Ear infection	1 (3.0)	0	1 (3.0)	0	0
Enterovirus infection	1 (3.0)	0	0	1 (3.0)	0
Gastroenteritis viral	1 (3.0)	1 (3.0)	0	0	0
Herpes zoster	1 (3.0)	0	0	1 (3.0)	0
Molluscum contagiosum	1 (3.0)	1 (3.0)	0	0	0
Oral herpes	1 (3.0)	0	1 (3.0)	0	0
Parainfluenzae virus infection	1 (3.0)	0	0	1 (3.0)	0
Rash pustular	1 (3.0)	0	1 (3.0)	0	0
Rhinitis	1 (3.0)	1 (3.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (3.0)	1 (3.0)	0	0	0
Rotavirus infection	1 (3.0)	0	0	1 (3.0)	0
Sepsis	1 (3.0)	0	0	0	1 (3.0)
Sinusitis	1 (3.0)	0	1 (3.0)	0	0
Vascular device infection	1 (3.0)	0	0	1 (3.0)	0
Viral infection	1 (3.0)	1 (3.0)	0	0	0
Viral upper respiratory tract infection	1 (3.0)	1 (3.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	5 (15.2)	2 (6.1)	3 (9.1)	0	0
Contusion	2 (6.1)	2 (6.1)	0	0	0
Infusion related reaction	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Foot fracture	1 (3.0)	0	1 (3.0)	0	0
Procedural nausea	1 (3.0)	0	1 (3.0)	0	0
Procedural pain	1 (3.0)	1 (3.0)	0	0	0
Radius fracture	1 (3.0)	0	1 (3.0)	0	0
Sunburn	1 (3.0)	1 (3.0)	0	0	0
Investigations					
-Total	13 (39.4)	4 (12.1)	3 (9.1)	3 (9.1)	3 (9.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	3 (9.1)	1 (3.0)	0	0	2 (6.1)
Weight decreased	3 (9.1)	1 (3.0)	2 (6.1)	0	0
White blood cell count decreased	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Alanine aminotransferase increased	1 (3.0)	0	0	1 (3.0)	0
Blood bilirubin increased	1 (3.0)	0	0	1 (3.0)	0
Blood creatinine increased	1 (3.0)	1 (3.0)	0	0	0
Blood urea increased	1 (3.0)	1 (3.0)	0	0	0
Blood uric acid increased	1 (3.0)	1 (3.0)	0	0	0
Haemoglobin decreased	1 (3.0)	1 (3.0)	0	0	0
Lymphocyte count decreased	1 (3.0)	1 (3.0)	0	0	0
Oxygen saturation decreased	1 (3.0)	1 (3.0)	0	0	0
Transaminases increased	1 (3.0)	1 (3.0)	0	0	0
Weight increased	1 (3.0)	0	1 (3.0)	0	0
Metabolism and nutrition disorders					
-Total	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Decreased appetite	1 (3.0)	1 (3.0)	0	0	0
Dehydration	1 (3.0)	0	0	1 (3.0)	0
Hyperalbuminaemia	1 (3.0)	1 (3.0)	0	0	0
Hypercalcaemia	1 (3.0)	1 (3.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	9 (27.3)	5 (15.2)	4 (12.1)	0	0
Pain in extremity	5 (15.2)	3 (9.1)	2 (6.1)	0	0
Arthralgia	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Joint range of motion decreased	1 (3.0)	1 (3.0)	0	0	0
Muscular weakness	1 (3.0)	1 (3.0)	0	0	0
Musculoskeletal chest pain	1 (3.0)	1 (3.0)	0	0	0
Osteonecrosis	1 (3.0)	0	1 (3.0)	0	0
Pain in jaw	1 (3.0)	1 (3.0)	0	0	0
Nervous system disorders					
-Total	5 (15.2)	3 (9.1)	2 (6.1)	0	0
Dizziness	2 (6.1)	2 (6.1)	0	0	0
Headache	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Peroneal nerve palsy	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Psychiatric disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Anxiety	1 (3.0)	1 (3.0)	0	0	0
Depression	1 (3.0)	1 (3.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sleep disorder	1 (3.0)	0	1 (3.0)	0	0
Renal and urinary disorders					
-Total	1 (3.0)	1 (3.0)	0	0	0
Urinary incontinence	1 (3.0)	1 (3.0)	0	0	0
Reproductive system and breast disorders					
-Total	1 (3.0)	0	0	1 (3.0)	0
Vaginal haemorrhage	1 (3.0)	0	0	1 (3.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (18.2)	4 (12.1)	0	2 (6.1)	0
Cough	3 (9.1)	3 (9.1)	0	0	0
Dysphonia	1 (3.0)	1 (3.0)	0	0	0
Epistaxis	1 (3.0)	0	0	1 (3.0)	0
Oropharyngeal pain	1 (3.0)	0	1 (3.0)	0	0
Pharyngeal erythema	1 (3.0)	1 (3.0)	0	0	0
Pharyngeal lesion	1 (3.0)	0	0	1 (3.0)	0
Pulmonary oedema	1 (3.0)	0	0	1 (3.0)	0
Rhinitis allergic	1 (3.0)	1 (3.0)	0	0	0
Skin and subcutaneous tissue disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (21.2)	4 (12.1)	3 (9.1)	0	0
Rash	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Erythema	2 (6.1)	2 (6.1)	0	0	0
Alopecia	1 (3.0)	0	1 (3.0)	0	0
Dermatitis atopic	1 (3.0)	1 (3.0)	0	0	0
Hyperhidrosis	1 (3.0)	1 (3.0)	0	0	0
Papule	1 (3.0)	1 (3.0)	0	0	0
Pruritus	1 (3.0)	1 (3.0)	0	0	0
Rash erythematous	1 (3.0)	0	1 (3.0)	0	0
Vascular disorders					
-Total	1 (3.0)	1 (3.0)	0	0	0
Hot flush	1 (3.0)	1 (3.0)	0	0	0
Hypertension	1 (3.0)	1 (3.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174d
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (64.7)	3 (17.6)	3 (17.6)	3 (17.6)	2 (11.8)
Blood and lymphatic system disorders					
-Total	1 (5.9)	0	0	0	1 (5.9)
Febrile neutropenia	1 (5.9)	0	0	0	1 (5.9)
Gastrointestinal disorders					
-Total	2 (11.8)	0	2 (11.8)	0	0
Diarrhoea	1 (5.9)	0	1 (5.9)	0	0
Nausea	1 (5.9)	0	1 (5.9)	0	0
General disorders and administration site conditions					
-Total	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Chills	1 (5.9)	0	1 (5.9)	0	0
Cyst	1 (5.9)	0	0	1 (5.9)	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (5.9)	0	1 (5.9)	0	0
Immune system disorders					
-Total	1 (5.9)	0	1 (5.9)	0	0
Immunodeficiency	1 (5.9)	0	1 (5.9)	0	0
Infections and infestations					
-Total	4 (23.5)	0	3 (17.6)	1 (5.9)	0
Otitis media	2 (11.8)	0	2 (11.8)	0	0
Cellulitis of male external genital organ	1 (5.9)	0	0	1 (5.9)	0
Meningitis aseptic	1 (5.9)	0	1 (5.9)	0	0
Otitis media acute	1 (5.9)	0	1 (5.9)	0	0
Skin infection	1 (5.9)	0	1 (5.9)	0	0
Urinary tract infection	1 (5.9)	0	0	1 (5.9)	0
Injury, poisoning and procedural complications					
-Total	1 (5.9)	0	0	1 (5.9)	0
Procedural pain	1 (5.9)	0	0	1 (5.9)	0
Investigations					
-Total	4 (23.5)	1 (5.9)	1 (5.9)	1 (5.9)	1 (5.9)
Alanine aminotransferase increased	2 (11.8)	0	1 (5.9)	1 (5.9)	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Aspartate aminotransferase increased	1 (5.9)	1 (5.9)	0	0	0
Blood alkaline phosphatase increased	1 (5.9)	1 (5.9)	0	0	0
Blood lactate dehydrogenase increased	1 (5.9)	1 (5.9)	0	0	0
C-reactive protein increased	1 (5.9)	1 (5.9)	0	0	0
Lymphocyte count decreased	1 (5.9)	1 (5.9)	0	0	0
Neutrophil count decreased	1 (5.9)	1 (5.9)	0	0	0
Platelet count decreased	1 (5.9)	0	0	1 (5.9)	0
Renal and urinary disorders					
-Total	1 (5.9)	1 (5.9)	0	0	0
Haematuria	1 (5.9)	1 (5.9)	0	0	0
Reproductive system and breast disorders					
-Total	1 (5.9)	0	0	1 (5.9)	0
Ovarian failure	1 (5.9)	0	0	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (11.8)	2 (11.8)	0	0	0
Cough	1 (5.9)	1 (5.9)	0	0	0
Epistaxis	1 (5.9)	1 (5.9)	0	0	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	2 (11.8)	2 (11.8)	0	0	0
Papule	1 (5.9)	1 (5.9)	0	0	0
Pruritus	1 (5.9)	1 (5.9)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174d
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

			All patients N=17		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (64.7)	1 (5.9)	3 (17.6)	5 (29.4)	2 (11.8)
Blood and lymphatic system disorders					
-Total	1 (5.9)	1 (5.9)	0	0	0
Thrombocytopenia	1 (5.9)	1 (5.9)	0	0	0
Ear and labyrinth disorders					
-Total	1 (5.9)	0	1 (5.9)	0	0
Tympanic membrane perforation	1 (5.9)	0	1 (5.9)	0	0
Gastrointestinal disorders					
-Total	1 (5.9)	0	1 (5.9)	0	0
Abdominal pain	1 (5.9)	0	1 (5.9)	0	0
Diarrhoea	1 (5.9)	0	1 (5.9)	0	0
Immune system disorders					

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.9)	0	1 (5.9)	0	0
Chronic graft versus host disease	1 (5.9)	0	1 (5.9)	0	0
Infections and infestations					
-Total	7 (41.2)	2 (11.8)	2 (11.8)	2 (11.8)	1 (5.9)
Sinusitis	3 (17.6)	0	3 (17.6)	0	0
Pneumonia	2 (11.8)	0	2 (11.8)	0	0
Upper respiratory tract infection	2 (11.8)	1 (5.9)	1 (5.9)	0	0
Campylobacter infection	1 (5.9)	0	0	1 (5.9)	0
Clostridium difficile infection	1 (5.9)	0	0	1 (5.9)	0
Gingivitis	1 (5.9)	1 (5.9)	0	0	0
Haemophilus infection	1 (5.9)	0	1 (5.9)	0	0
Otitis media	1 (5.9)	0	0	1 (5.9)	0
Otitis media acute	1 (5.9)	0	1 (5.9)	0	0
Respiratory tract infection	1 (5.9)	0	0	0	1 (5.9)
Respiratory tract infection viral	1 (5.9)	0	0	1 (5.9)	0
Urinary tract infection	1 (5.9)	0	1 (5.9)	0	0
Viral infection	1 (5.9)	1 (5.9)	0	0	0
Vulvovaginal candidiasis	1 (5.9)	0	1 (5.9)	0	0
Investigations					

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (23.5)	0	1 (5.9)	3 (17.6)	0
Lymphocyte count decreased	2 (11.8)	1 (5.9)	0	1 (5.9)	0
White blood cell count decreased	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Alanine aminotransferase increased	1 (5.9)	0	0	1 (5.9)	0
Aspartate aminotransferase increased	1 (5.9)	0	0	1 (5.9)	0
Neutrophil count decreased	1 (5.9)	0	1 (5.9)	0	0
Metabolism and nutrition disorders					
-Total	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Hypokalaemia	1 (5.9)	0	0	1 (5.9)	0
Vitamin d deficiency	1 (5.9)	1 (5.9)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (5.9)	0	1 (5.9)	0	0
Neck pain	1 (5.9)	0	1 (5.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (5.9)	0	0	0	1 (5.9)
Glioblastoma multiforme	1 (5.9)	0	0	0	1 (5.9)
Nervous system disorders					
-Total	3 (17.6)	1 (5.9)	1 (5.9)	1 (5.9)	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=17				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disturbance in attention	1 (5.9)	1 (5.9)	0	0	0
Dizziness	1 (5.9)	1 (5.9)	0	0	0
Headache	1 (5.9)	0	1 (5.9)	0	0
Seizure	1 (5.9)	0	0	1 (5.9)	0
Renal and urinary disorders					
-Total	1 (5.9)	0	0	1 (5.9)	0
Acute kidney injury	1 (5.9)	0	0	1 (5.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (11.8)	2 (11.8)	0	0	0
Cough	1 (5.9)	1 (5.9)	0	0	0
Oropharyngeal pain	1 (5.9)	1 (5.9)	0	0	0
Rhinitis allergic	1 (5.9)	1 (5.9)	0	0	0
Rhinorrhoea	1 (5.9)	1 (5.9)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (5.9)	1 (5.9)	0	0	0
Acne	1 (5.9)	1 (5.9)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174d
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=25		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (100)	0	1 (4.0)	5 (20.0)	19 (76.0)
Blood and lymphatic system disorders					
-Total	20 (80.0)	0	1 (4.0)	15 (60.0)	4 (16.0)
Febrile neutropenia	16 (64.0)	0	0	15 (60.0)	1 (4.0)
Anaemia	11 (44.0)	2 (8.0)	2 (8.0)	7 (28.0)	0
Neutropenia	3 (12.0)	0	0	2 (8.0)	1 (4.0)
Disseminated intravascular coagulation	2 (8.0)	0	1 (4.0)	1 (4.0)	0
Lymphopenia	2 (8.0)	0	1 (4.0)	1 (4.0)	0
Thrombocytopenia	2 (8.0)	0	0	0	2 (8.0)
Eosinophilia	1 (4.0)	0	0	1 (4.0)	0
Lymphadenopathy	1 (4.0)	0	1 (4.0)	0	0
Cardiac disorders					

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (36.0)	5 (20.0)	4 (16.0)	0	0
Tachycardia	7 (28.0)	6 (24.0)	1 (4.0)	0	0
Sinus tachycardia	2 (8.0)	0	2 (8.0)	0	0
Cardiac dysfunction	1 (4.0)	1 (4.0)	0	0	0
Ventricular tachycardia	1 (4.0)	0	1 (4.0)	0	0
Endocrine disorders					
-Total	1 (4.0)	0	1 (4.0)	0	0
Adrenal insufficiency	1 (4.0)	0	1 (4.0)	0	0
Eye disorders					
-Total	6 (24.0)	4 (16.0)	2 (8.0)	0	0
Dry eye	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Conjunctival haemorrhage	1 (4.0)	1 (4.0)	0	0	0
Conjunctivitis allergic	1 (4.0)	1 (4.0)	0	0	0
Eye pain	1 (4.0)	1 (4.0)	0	0	0
Ocular hyperaemia	1 (4.0)	1 (4.0)	0	0	0
Periorbital oedema	1 (4.0)	1 (4.0)	0	0	0
Vision blurred	1 (4.0)	0	1 (4.0)	0	0
Gastrointestinal disorders					
-Total	17 (68.0)	5 (20.0)	8 (32.0)	4 (16.0)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	11 (44.0)	8 (32.0)	2 (8.0)	1 (4.0)	0
Nausea	10 (40.0)	1 (4.0)	8 (32.0)	1 (4.0)	0
Diarrhoea	8 (32.0)	4 (16.0)	3 (12.0)	1 (4.0)	0
Abdominal pain	4 (16.0)	3 (12.0)	1 (4.0)	0	0
Constipation	2 (8.0)	2 (8.0)	0	0	0
Abdominal distension	1 (4.0)	0	1 (4.0)	0	0
Abdominal pain upper	1 (4.0)	0	1 (4.0)	0	0
Abdominal tenderness	1 (4.0)	1 (4.0)	0	0	0
Ascites	1 (4.0)	0	0	1 (4.0)	0
Dysphagia	1 (4.0)	0	1 (4.0)	0	0
Enterocolitis	1 (4.0)	0	0	1 (4.0)	0
Flatulence	1 (4.0)	1 (4.0)	0	0	0
Gastrooesophageal reflux disease	1 (4.0)	1 (4.0)	0	0	0
Glossodynia	1 (4.0)	1 (4.0)	0	0	0
Oral pain	1 (4.0)	1 (4.0)	0	0	0
Pancreatitis	1 (4.0)	0	0	1 (4.0)	0
Pigmentation lip	1 (4.0)	1 (4.0)	0	0	0
General disorders and administration site conditions					

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (56.0)	6 (24.0)	4 (16.0)	4 (16.0)	0
Pyrexia	7 (28.0)	3 (12.0)	2 (8.0)	2 (8.0)	0
Chills	4 (16.0)	3 (12.0)	1 (4.0)	0	0
Fatigue	3 (12.0)	3 (12.0)	0	0	0
Influenza like illness	2 (8.0)	2 (8.0)	0	0	0
Catheter site pain	1 (4.0)	0	1 (4.0)	0	0
Cyst	1 (4.0)	0	0	1 (4.0)	0
Generalised oedema	1 (4.0)	1 (4.0)	0	0	0
Malaise	1 (4.0)	0	1 (4.0)	0	0
Oedema peripheral	1 (4.0)	1 (4.0)	0	0	0
Pain	1 (4.0)	1 (4.0)	0	0	0
Physical deconditioning	1 (4.0)	0	0	1 (4.0)	0
Hepatobiliary disorders					
-Total	1 (4.0)	1 (4.0)	0	0	0
Gallbladder enlargement	1 (4.0)	1 (4.0)	0	0	0
Immune system disorders					
-Total	24 (96.0)	2 (8.0)	15 (60.0)	4 (16.0)	3 (12.0)
Cytokine release syndrome	20 (80.0)	2 (8.0)	12 (48.0)	3 (12.0)	3 (12.0)
Hypogammaglobulinaemia	15 (60.0)	0	14 (56.0)	1 (4.0)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency common variable	2 (8.0)	0	2 (8.0)	0	0
Drug hypersensitivity	1 (4.0)	0	1 (4.0)	0	0
Graft versus host disease	1 (4.0)	1 (4.0)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (4.0)	0	1 (4.0)	0	0
Graft versus host disease in skin	1 (4.0)	1 (4.0)	0	0	0
Immunodeficiency	1 (4.0)	0	1 (4.0)	0	0
Seasonal allergy	1 (4.0)	1 (4.0)	0	0	0
Infections and infestations					
-Total	18 (72.0)	2 (8.0)	11 (44.0)	5 (20.0)	0
Influenza	4 (16.0)	1 (4.0)	3 (12.0)	0	0
Upper respiratory tract infection	4 (16.0)	2 (8.0)	2 (8.0)	0	0
Urinary tract infection	4 (16.0)	0	2 (8.0)	2 (8.0)	0
Otitis media	3 (12.0)	0	3 (12.0)	0	0
Clostridium difficile infection	2 (8.0)	0	2 (8.0)	0	0
Cytomegalovirus infection	2 (8.0)	2 (8.0)	0	0	0
Gastroenteritis	2 (8.0)	0	2 (8.0)	0	0
Skin infection	2 (8.0)	0	2 (8.0)	0	0
Cellulitis of male external genital organ	1 (4.0)	0	0	1 (4.0)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	1 (4.0)	0	0	1 (4.0)	0
Ear infection	1 (4.0)	1 (4.0)	0	0	0
Enterococcal infection	1 (4.0)	1 (4.0)	0	0	0
Escherichia urinary tract infection	1 (4.0)	0	0	1 (4.0)	0
Fungal skin infection	1 (4.0)	1 (4.0)	0	0	0
Gastroenteritis norovirus	1 (4.0)	0	1 (4.0)	0	0
Meningitis aseptic	1 (4.0)	0	1 (4.0)	0	0
Otitis externa	1 (4.0)	0	1 (4.0)	0	0
Otitis media acute	1 (4.0)	0	1 (4.0)	0	0
Parainfluenzae virus infection	1 (4.0)	1 (4.0)	0	0	0
Paronychia	1 (4.0)	1 (4.0)	0	0	0
Respiratory syncytial virus infection	1 (4.0)	0	0	1 (4.0)	0
Rhinovirus infection	1 (4.0)	1 (4.0)	0	0	0
Sinusitis	1 (4.0)	0	1 (4.0)	0	0
Staphylococcal infection	1 (4.0)	0	0	1 (4.0)	0
Subcutaneous abscess	1 (4.0)	0	1 (4.0)	0	0
Tinea capitis	1 (4.0)	1 (4.0)	0	0	0
Viral infection	1 (4.0)	0	1 (4.0)	0	0
Viral upper respiratory tract infection	1 (4.0)	0	0	1 (4.0)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal mycotic infection	1 (4.0)	0	1 (4.0)	0	0
Injury, poisoning and procedural complications					
-Total	9 (36.0)	6 (24.0)	2 (8.0)	1 (4.0)	0
Procedural pain	3 (12.0)	1 (4.0)	1 (4.0)	1 (4.0)	0
Skin abrasion	2 (8.0)	2 (8.0)	0	0	0
Arthropod bite	1 (4.0)	1 (4.0)	0	0	0
Contusion	1 (4.0)	1 (4.0)	0	0	0
Infusion related reaction	1 (4.0)	0	1 (4.0)	0	0
Post procedural haemorrhage	1 (4.0)	1 (4.0)	0	0	0
Procedural site reaction	1 (4.0)	1 (4.0)	0	0	0
Skin laceration	1 (4.0)	0	1 (4.0)	0	0
Subdural haemorrhage	1 (4.0)	1 (4.0)	0	0	0
Investigations					
-Total	22 (88.0)	0	2 (8.0)	4 (16.0)	16 (64.0)
White blood cell count decreased	17 (68.0)	1 (4.0)	0	6 (24.0)	10 (40.0)
Neutrophil count decreased	15 (60.0)	1 (4.0)	0	2 (8.0)	12 (48.0)
Platelet count decreased	10 (40.0)	3 (12.0)	2 (8.0)	1 (4.0)	4 (16.0)
Alanine aminotransferase increased	8 (32.0)	1 (4.0)	0	7 (28.0)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	8 (32.0)	1 (4.0)	1 (4.0)	4 (16.0)	2 (8.0)
Aspartate aminotransferase increased	5 (20.0)	2 (8.0)	0	3 (12.0)	0
Blood creatinine increased	4 (16.0)	4 (16.0)	0	0	0
Activated partial thromboplastin time prolonged	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Blood bilirubin increased	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Blood immunoglobulin m decreased	2 (8.0)	2 (8.0)	0	0	0
C-reactive protein increased	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Prothrombin time prolonged	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Blood alkaline phosphatase increased	1 (4.0)	1 (4.0)	0	0	0
Blood fibrinogen decreased	1 (4.0)	0	0	1 (4.0)	0
Blood immunoglobulin a decreased	1 (4.0)	1 (4.0)	0	0	0
Blood immunoglobulin g decreased	1 (4.0)	0	1 (4.0)	0	0
Blood lactate dehydrogenase increased	1 (4.0)	1 (4.0)	0	0	0
Blood magnesium decreased	1 (4.0)	1 (4.0)	0	0	0
Blood sodium increased	1 (4.0)	0	1 (4.0)	0	0
Blood urea increased	1 (4.0)	1 (4.0)	0	0	0
Fibrin d dimer increased	1 (4.0)	1 (4.0)	0	0	0
Haemoglobin decreased	1 (4.0)	1 (4.0)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=25 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
International normalised ratio increased	1 (4.0)	1 (4.0)	0	0	0
Lipase increased	1 (4.0)	0	0	0	1 (4.0)
Pulmonary function test decreased	1 (4.0)	0	1 (4.0)	0	0
Serum ferritin increased	1 (4.0)	0	1 (4.0)	0	0
Weight decreased	1 (4.0)	0	1 (4.0)	0	0
Weight increased	1 (4.0)	1 (4.0)	0	0	0
Metabolism and nutrition disorders					
-Total	17 (68.0)	3 (12.0)	5 (20.0)	5 (20.0)	4 (16.0)
Decreased appetite	8 (32.0)	1 (4.0)	4 (16.0)	3 (12.0)	0
Hypokalaemia	8 (32.0)	2 (8.0)	3 (12.0)	2 (8.0)	1 (4.0)
Hyperphosphataemia	4 (16.0)	4 (16.0)	0	0	0
Hypernatraemia	2 (8.0)	1 (4.0)	0	0	1 (4.0)
Hyperuricaemia	2 (8.0)	1 (4.0)	0	0	1 (4.0)
Hypophosphataemia	2 (8.0)	0	0	1 (4.0)	1 (4.0)
Tumour lysis syndrome	2 (8.0)	0	0	2 (8.0)	0
Acidosis	1 (4.0)	1 (4.0)	0	0	0
Dehydration	1 (4.0)	1 (4.0)	0	0	0
Hyperglycaemia	1 (4.0)	0	0	1 (4.0)	0
Hypertriglyceridaemia	1 (4.0)	1 (4.0)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	1 (4.0)	0	0	1 (4.0)	0
Hypomagnesaemia	1 (4.0)	1 (4.0)	0	0	0
Iron overload	1 (4.0)	0	0	1 (4.0)	0
Vitamin d deficiency	1 (4.0)	1 (4.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	9 (36.0)	6 (24.0)	3 (12.0)	0	0
Pain in extremity	3 (12.0)	3 (12.0)	0	0	0
Arthralgia	2 (8.0)	2 (8.0)	0	0	0
Muscular weakness	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Back pain	1 (4.0)	1 (4.0)	0	0	0
Flank pain	1 (4.0)	0	1 (4.0)	0	0
Joint range of motion decreased	1 (4.0)	1 (4.0)	0	0	0
Muscle spasms	1 (4.0)	1 (4.0)	0	0	0
Musculoskeletal chest pain	1 (4.0)	1 (4.0)	0	0	0
Musculoskeletal pain	1 (4.0)	0	1 (4.0)	0	0
Toe walking	1 (4.0)	1 (4.0)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (8.0)	0	2 (8.0)	0	0
Myelodysplastic syndrome	1 (4.0)	0	1 (4.0)	0	0
Skin papilloma	1 (4.0)	0	1 (4.0)	0	0
Nervous system disorders					
-Total	13 (52.0)	6 (24.0)	6 (24.0)	1 (4.0)	0
Headache	10 (40.0)	6 (24.0)	4 (16.0)	0	0
Dizziness	2 (8.0)	2 (8.0)	0	0	0
Dysarthria	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Seizure	2 (8.0)	0	2 (8.0)	0	0
Asterixis	1 (4.0)	1 (4.0)	0	0	0
Ataxia	1 (4.0)	0	1 (4.0)	0	0
Encephalopathy	1 (4.0)	0	0	1 (4.0)	0
Neuropathy peripheral	1 (4.0)	0	1 (4.0)	0	0
Pleocytosis	1 (4.0)	1 (4.0)	0	0	0
Somnolence	1 (4.0)	1 (4.0)	0	0	0
Tremor	1 (4.0)	1 (4.0)	0	0	0
Product issues					
-Total	1 (4.0)	1 (4.0)	0	0	0
Device occlusion	1 (4.0)	1 (4.0)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	4 (16.0)	3 (12.0)	1 (4.0)	0	0
Adjustment disorder	1 (4.0)	0	1 (4.0)	0	0
Agitation	1 (4.0)	0	1 (4.0)	0	0
Anxiety	1 (4.0)	0	1 (4.0)	0	0
Confusional state	1 (4.0)	1 (4.0)	0	0	0
Delirium	1 (4.0)	0	1 (4.0)	0	0
Depression	1 (4.0)	1 (4.0)	0	0	0
Hallucination	1 (4.0)	1 (4.0)	0	0	0
Suicidal ideation	1 (4.0)	1 (4.0)	0	0	0
Renal and urinary disorders					
-Total	5 (20.0)	1 (4.0)	0	4 (16.0)	0
Acute kidney injury	3 (12.0)	0	0	3 (12.0)	0
Calculus urinary	1 (4.0)	0	1 (4.0)	0	0
Dysuria	1 (4.0)	1 (4.0)	0	0	0
Haematuria	1 (4.0)	0	0	1 (4.0)	0
Nephrolithiasis	1 (4.0)	0	0	1 (4.0)	0
Reproductive system and breast disorders					
-Total	2 (8.0)	0	1 (4.0)	1 (4.0)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ovarian failure	1 (4.0)	0	0	1 (4.0)	0
Scrotal pain	1 (4.0)	0	1 (4.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	19 (76.0)	11 (44.0)	5 (20.0)	0	3 (12.0)
Cough	5 (20.0)	3 (12.0)	2 (8.0)	0	0
Nasal congestion	5 (20.0)	5 (20.0)	0	0	0
Rhinorrhoea	5 (20.0)	4 (16.0)	1 (4.0)	0	0
Epistaxis	3 (12.0)	3 (12.0)	0	0	0
Oropharyngeal pain	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Pulmonary oedema	3 (12.0)	1 (4.0)	0	1 (4.0)	1 (4.0)
Tachypnoea	3 (12.0)	3 (12.0)	0	0	0
Respiratory failure	2 (8.0)	0	0	0	2 (8.0)
Rhinitis allergic	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Acute respiratory failure	1 (4.0)	0	0	0	1 (4.0)
Haemoptysis	1 (4.0)	1 (4.0)	0	0	0
Hypoxia	1 (4.0)	0	1 (4.0)	0	0
Oropharyngeal plaque	1 (4.0)	1 (4.0)	0	0	0
Pleural effusion	1 (4.0)	0	0	1 (4.0)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wheezing	1 (4.0)	0	1 (4.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	15 (60.0)	10 (40.0)	3 (12.0)	2 (8.0)	0
Dry skin	3 (12.0)	3 (12.0)	0	0	0
Ingrowing nail	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Petechiae	2 (8.0)	2 (8.0)	0	0	0
Pruritus	2 (8.0)	2 (8.0)	0	0	0
Rash	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Rash maculo-papular	2 (8.0)	2 (8.0)	0	0	0
Dermatitis	1 (4.0)	1 (4.0)	0	0	0
Dermatitis acneiform	1 (4.0)	0	0	1 (4.0)	0
Dermatitis diaper	1 (4.0)	1 (4.0)	0	0	0
Ecchymosis	1 (4.0)	0	0	1 (4.0)	0
Eczema	1 (4.0)	1 (4.0)	0	0	0
Erythema	1 (4.0)	1 (4.0)	0	0	0
Keloid scar	1 (4.0)	0	1 (4.0)	0	0
Macule	1 (4.0)	1 (4.0)	0	0	0
Papule	1 (4.0)	1 (4.0)	0	0	0
Rash follicular	1 (4.0)	1 (4.0)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=25 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash papular	1 (4.0)	1 (4.0)	0	0	0
Rash pruritic	1 (4.0)	1 (4.0)	0	0	0
Skin exfoliation	1 (4.0)	1 (4.0)	0	0	0
Skin fissures	1 (4.0)	1 (4.0)	0	0	0
Skin irritation	1 (4.0)	1 (4.0)	0	0	0
Vascular disorders					
-Total	11 (44.0)	1 (4.0)	5 (20.0)	4 (16.0)	1 (4.0)
Hypotension	5 (20.0)	0	0	4 (16.0)	1 (4.0)
Hypertension	3 (12.0)	0	3 (12.0)	0	0
Orthostatic hypotension	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Secondary hypertension	1 (4.0)	0	1 (4.0)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174d
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Other

			All patients N=39		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (100)	0	4 (10.3)	7 (17.9)	28 (71.8)
Blood and lymphatic system disorders					
-Total	28 (71.8)	2 (5.1)	2 (5.1)	12 (30.8)	12 (30.8)
Anaemia	16 (41.0)	1 (2.6)	2 (5.1)	12 (30.8)	1 (2.6)
Febrile neutropenia	8 (20.5)	0	0	8 (20.5)	0
Neutropenia	8 (20.5)	0	0	1 (2.6)	7 (17.9)
Thrombocytopenia	8 (20.5)	0	1 (2.6)	3 (7.7)	4 (10.3)
Disseminated intravascular coagulation	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Lymphopenia	2 (5.1)	0	1 (2.6)	0	1 (2.6)
Coagulopathy	1 (2.6)	1 (2.6)	0	0	0
Leukopenia	1 (2.6)	0	0	0	1 (2.6)
Pancytopenia	1 (2.6)	0	0	0	1 (2.6)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	14 (35.9)	6 (15.4)	6 (15.4)	2 (5.1)	0
Tachycardia	8 (20.5)	2 (5.1)	4 (10.3)	2 (5.1)	0
Sinus tachycardia	4 (10.3)	3 (7.7)	1 (2.6)	0	0
Pericardial effusion	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Atrioventricular block second degree	1 (2.6)	1 (2.6)	0	0	0
Bradycardia	1 (2.6)	0	1 (2.6)	0	0
Left ventricular dysfunction	1 (2.6)	0	0	1 (2.6)	0
Palpitations	1 (2.6)	1 (2.6)	0	0	0
Sinus bradycardia	1 (2.6)	1 (2.6)	0	0	0
Ear and labyrinth disorders					
-Total	4 (10.3)	2 (5.1)	2 (5.1)	0	0
Ear pain	2 (5.1)	2 (5.1)	0	0	0
Hypoacusis	1 (2.6)	0	1 (2.6)	0	0
Tympanic membrane perforation	1 (2.6)	0	1 (2.6)	0	0
Endocrine disorders					
-Total	1 (2.6)	1 (2.6)	0	0	0
Adrenal insufficiency	1 (2.6)	1 (2.6)	0	0	0
Eye disorders					

Timing: Any time post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	12 (30.8)	6 (15.4)	6 (15.4)	0	0
Periorbital oedema	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Vision blurred	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Conjunctival haemorrhage	2 (5.1)	2 (5.1)	0	0	0
Eye pain	2 (5.1)	0	2 (5.1)	0	0
Photophobia	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Retinal haemorrhage	2 (5.1)	2 (5.1)	0	0	0
Uveitis	2 (5.1)	0	2 (5.1)	0	0
Ocular hypertension	1 (2.6)	0	1 (2.6)	0	0
Papilloedema	1 (2.6)	0	1 (2.6)	0	0
Visual impairment	1 (2.6)	0	1 (2.6)	0	0
Gastrointestinal disorders					
-Total	26 (66.7)	8 (20.5)	9 (23.1)	9 (23.1)	0
Diarrhoea	16 (41.0)	9 (23.1)	6 (15.4)	1 (2.6)	0
Vomiting	16 (41.0)	8 (20.5)	6 (15.4)	2 (5.1)	0
Nausea	15 (38.5)	5 (12.8)	6 (15.4)	4 (10.3)	0
Abdominal pain	7 (17.9)	3 (7.7)	3 (7.7)	1 (2.6)	0
Constipation	5 (12.8)	4 (10.3)	1 (2.6)	0	0
Abdominal pain upper	2 (5.1)	1 (2.6)	1 (2.6)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematemesis	2 (5.1)	2 (5.1)	0	0	0
Stomatitis	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Abdominal discomfort	1 (2.6)	1 (2.6)	0	0	0
Abdominal distension	1 (2.6)	0	1 (2.6)	0	0
Abdominal pain lower	1 (2.6)	0	1 (2.6)	0	0
Anal incontinence	1 (2.6)	1 (2.6)	0	0	0
Dyspepsia	1 (2.6)	0	1 (2.6)	0	0
Dysphagia	1 (2.6)	0	0	1 (2.6)	0
Gastrointestinal haemorrhage	1 (2.6)	1 (2.6)	0	0	0
Ileus	1 (2.6)	0	0	1 (2.6)	0
Intestinal obstruction	1 (2.6)	0	0	1 (2.6)	0
Lip pain	1 (2.6)	0	1 (2.6)	0	0
Mouth haemorrhage	1 (2.6)	0	0	1 (2.6)	0
Oral pain	1 (2.6)	0	0	1 (2.6)	0
Pancreatitis	1 (2.6)	0	1 (2.6)	0	0
Tooth socket haemorrhage	1 (2.6)	1 (2.6)	0	0	0
General disorders and administration site conditions					
-Total	28 (71.8)	10 (25.6)	10 (25.6)	7 (17.9)	1 (2.6)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	18 (46.2)	5 (12.8)	8 (20.5)	4 (10.3)	1 (2.6)
Fatigue	12 (30.8)	9 (23.1)	2 (5.1)	1 (2.6)	0
Chills	6 (15.4)	6 (15.4)	0	0	0
Catheter site pain	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Malaise	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Pain	3 (7.7)	0	1 (2.6)	2 (5.1)	0
Face oedema	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Generalised oedema	2 (5.1)	0	2 (5.1)	0	0
Oedema peripheral	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Acquired gene mutation	1 (2.6)	1 (2.6)	0	0	0
Asthenia	1 (2.6)	1 (2.6)	0	0	0
Catheter site extravasation	1 (2.6)	0	1 (2.6)	0	0
Catheter site haemorrhage	1 (2.6)	1 (2.6)	0	0	0
Crying	1 (2.6)	1 (2.6)	0	0	0
Facial pain	1 (2.6)	0	1 (2.6)	0	0
Injection site haematoma	1 (2.6)	1 (2.6)	0	0	0
Localised oedema	1 (2.6)	0	0	1 (2.6)	0
Mucosal haemorrhage	1 (2.6)	0	1 (2.6)	0	0
Multiple organ dysfunction syndrome	1 (2.6)	0	0	1 (2.6)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Non-cardiac chest pain	1 (2.6)	1 (2.6)	0	0	0
Peripheral swelling	1 (2.6)	0	1 (2.6)	0	0
Hepatobiliary disorders					
-Total	6 (15.4)	2 (5.1)	2 (5.1)	2 (5.1)	0
Hepatomegaly	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Hyperbilirubinaemia	3 (7.7)	0	1 (2.6)	2 (5.1)	0
Hepatosplenomegaly	1 (2.6)	1 (2.6)	0	0	0
Immune system disorders					
-Total	34 (87.2)	3 (7.7)	16 (41.0)	7 (17.9)	8 (20.5)
Cytokine release syndrome	30 (76.9)	4 (10.3)	13 (33.3)	5 (12.8)	8 (20.5)
Hypogammaglobulinaemia	17 (43.6)	3 (7.7)	10 (25.6)	4 (10.3)	0
Chronic graft versus host disease	1 (2.6)	0	1 (2.6)	0	0
Graft versus host disease	1 (2.6)	0	1 (2.6)	0	0
Haemophagocytic lymphohistiocytosis	1 (2.6)	0	1 (2.6)	0	0
Seasonal allergy	1 (2.6)	1 (2.6)	0	0	0
Infections and infestations					
-Total	28 (71.8)	5 (12.8)	10 (25.6)	9 (23.1)	4 (10.3)
Upper respiratory tract infection	5 (12.8)	2 (5.1)	2 (5.1)	1 (2.6)	0
Clostridium difficile colitis	4 (10.3)	1 (2.6)	2 (5.1)	1 (2.6)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	4 (10.3)	0	3 (7.7)	1 (2.6)	0
Rhinovirus infection	4 (10.3)	4 (10.3)	0	0	0
Clostridium difficile infection	3 (7.7)	0	2 (5.1)	1 (2.6)	0
Gastroenteritis	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Sinusitis	3 (7.7)	0	3 (7.7)	0	0
Viral infection	2 (5.1)	2 (5.1)	0	0	0
Viral upper respiratory tract infection	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Vulvovaginal candidiasis	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Acute sinusitis	1 (2.6)	0	1 (2.6)	0	0
Bacterial sepsis	1 (2.6)	0	0	0	1 (2.6)
Body tinea	1 (2.6)	1 (2.6)	0	0	0
Campylobacter infection	1 (2.6)	0	0	1 (2.6)	0
Catheter site cellulitis	1 (2.6)	1 (2.6)	0	0	0
Catheter site infection	1 (2.6)	0	0	1 (2.6)	0
Cholecystitis infective	1 (2.6)	0	0	1 (2.6)	0
Ear infection	1 (2.6)	0	1 (2.6)	0	0
Enterovirus infection	1 (2.6)	0	0	1 (2.6)	0
Folliculitis	1 (2.6)	0	1 (2.6)	0	0
Gastroenteritis viral	1 (2.6)	1 (2.6)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gingivitis	1 (2.6)	1 (2.6)	0	0	0
Haemophilus infection	1 (2.6)	0	1 (2.6)	0	0
Herpes simplex	1 (2.6)	1 (2.6)	0	0	0
Herpes zoster	1 (2.6)	0	0	1 (2.6)	0
Human herpesvirus 6 infection	1 (2.6)	0	1 (2.6)	0	0
Hypopyon	1 (2.6)	0	1 (2.6)	0	0
Molluscum contagiosum	1 (2.6)	1 (2.6)	0	0	0
Oral candidiasis	1 (2.6)	1 (2.6)	0	0	0
Oral herpes	1 (2.6)	0	1 (2.6)	0	0
Orchitis	1 (2.6)	1 (2.6)	0	0	0
Otitis media	1 (2.6)	0	0	1 (2.6)	0
Otitis media acute	1 (2.6)	0	1 (2.6)	0	0
Parainfluenzae virus infection	1 (2.6)	0	0	1 (2.6)	0
Pharyngitis	1 (2.6)	0	1 (2.6)	0	0
Rash pustular	1 (2.6)	0	1 (2.6)	0	0
Respiratory tract infection	1 (2.6)	0	0	0	1 (2.6)
Respiratory tract infection viral	1 (2.6)	0	0	1 (2.6)	0
Rhinitis	1 (2.6)	1 (2.6)	0	0	0
Rotavirus infection	1 (2.6)	0	0	1 (2.6)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (2.6)	0	0	0	1 (2.6)
Septic embolus	1 (2.6)	0	0	0	1 (2.6)
Staphylococcal infection	1 (2.6)	1 (2.6)	0	0	0
Streptococcal infection	1 (2.6)	0	1 (2.6)	0	0
Urinary tract infection	1 (2.6)	0	1 (2.6)	0	0
Urinary tract infection enterococcal	1 (2.6)	0	0	1 (2.6)	0
Vascular device infection	1 (2.6)	0	0	1 (2.6)	0
Injury, poisoning and procedural complications					
-Total	13 (33.3)	5 (12.8)	6 (15.4)	1 (2.6)	1 (2.6)
Infusion related reaction	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Transfusion reaction	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Contusion	2 (5.1)	2 (5.1)	0	0	0
Procedural pain	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Foot fracture	1 (2.6)	0	1 (2.6)	0	0
Incision site pain	1 (2.6)	1 (2.6)	0	0	0
Limb injury	1 (2.6)	1 (2.6)	0	0	0
Mouth injury	1 (2.6)	1 (2.6)	0	0	0
Procedural complication	1 (2.6)	1 (2.6)	0	0	0
Procedural headache	1 (2.6)	0	1 (2.6)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural nausea	1 (2.6)	0	1 (2.6)	0	0
Radius fracture	1 (2.6)	0	1 (2.6)	0	0
Stoma site irritation	1 (2.6)	1 (2.6)	0	0	0
Sunburn	1 (2.6)	1 (2.6)	0	0	0
Tibia fracture	1 (2.6)	0	1 (2.6)	0	0
Tongue injury	1 (2.6)	1 (2.6)	0	0	0
Tracheal haemorrhage	1 (2.6)	0	0	1 (2.6)	0
Transfusion related complication	1 (2.6)	0	0	0	1 (2.6)
Investigations					
-Total	34 (87.2)	2 (5.1)	3 (7.7)	11 (28.2)	18 (46.2)
White blood cell count decreased	18 (46.2)	3 (7.7)	1 (2.6)	6 (15.4)	8 (20.5)
Aspartate aminotransferase increased	15 (38.5)	2 (5.1)	4 (10.3)	5 (12.8)	4 (10.3)
Alanine aminotransferase increased	13 (33.3)	4 (10.3)	2 (5.1)	7 (17.9)	0
Neutrophil count decreased	13 (33.3)	0	2 (5.1)	2 (5.1)	9 (23.1)
Platelet count decreased	10 (25.6)	0	0	2 (5.1)	8 (20.5)
International normalised ratio increased	8 (20.5)	7 (17.9)	0	1 (2.6)	0
Lymphocyte count decreased	8 (20.5)	0	2 (5.1)	3 (7.7)	3 (7.7)
Prothrombin time prolonged	7 (17.9)	4 (10.3)	2 (5.1)	1 (2.6)	0
Blood bilirubin increased	6 (15.4)	1 (2.6)	2 (5.1)	3 (7.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	5 (12.8)	1 (2.6)	2 (5.1)	2 (5.1)	0
Blood fibrinogen decreased	3 (7.7)	0	1 (2.6)	1 (2.6)	1 (2.6)
Transaminases increased	3 (7.7)	3 (7.7)	0	0	0
Weight decreased	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Activated partial thromboplastin time prolonged	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Blood immunoglobulin a decreased	2 (5.1)	2 (5.1)	0	0	0
Blood immunoglobulin m decreased	2 (5.1)	2 (5.1)	0	0	0
Blood phosphorus increased	2 (5.1)	2 (5.1)	0	0	0
Blood urea increased	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Blood uric acid increased	2 (5.1)	2 (5.1)	0	0	0
Haemoglobin decreased	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Blood bicarbonate decreased	1 (2.6)	0	1 (2.6)	0	0
Blood lactic acid increased	1 (2.6)	0	0	0	1 (2.6)
Blood magnesium decreased	1 (2.6)	0	0	1 (2.6)	0
Blood phosphorus decreased	1 (2.6)	1 (2.6)	0	0	0
Cardiac murmur	1 (2.6)	1 (2.6)	0	0	0
Culture stool positive	1 (2.6)	1 (2.6)	0	0	0
Hepatic enzyme increased	1 (2.6)	0	1 (2.6)	0	0
Lipase increased	1 (2.6)	0	0	0	1 (2.6)

Timing: Any time post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Norovirus test positive	1 (2.6)	1 (2.6)	0	0	0
Oxygen saturation decreased	1 (2.6)	1 (2.6)	0	0	0
Protein total decreased	1 (2.6)	0	0	1 (2.6)	0
Serum ferritin increased	1 (2.6)	0	1 (2.6)	0	0
Weight increased	1 (2.6)	0	1 (2.6)	0	0
Metabolism and nutrition disorders					
-Total	26 (66.7)	5 (12.8)	3 (7.7)	18 (46.2)	0
Decreased appetite	14 (35.9)	4 (10.3)	1 (2.6)	9 (23.1)	0
Hypokalaemia	11 (28.2)	2 (5.1)	3 (7.7)	6 (15.4)	0
Hypophosphataemia	8 (20.5)	2 (5.1)	0	6 (15.4)	0
Hyperphosphataemia	4 (10.3)	4 (10.3)	0	0	0
Hypoalbuminaemia	4 (10.3)	1 (2.6)	3 (7.7)	0	0
Dehydration	3 (7.7)	0	0	3 (7.7)	0
Fluid overload	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Hypocalcaemia	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Hyperglycaemia	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Hypernatraemia	2 (5.1)	0	2 (5.1)	0	0
Hyponatraemia	2 (5.1)	0	0	2 (5.1)	0
Acidosis	1 (2.6)	0	0	1 (2.6)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperalbuminaemia	1 (2.6)	1 (2.6)	0	0	0
Hypercalcaemia	1 (2.6)	1 (2.6)	0	0	0
Hyperchloraemia	1 (2.6)	1 (2.6)	0	0	0
Hypermagnesaemia	1 (2.6)	1 (2.6)	0	0	0
Hypertriglyceridaemia	1 (2.6)	0	0	1 (2.6)	0
Hyperuricaemia	1 (2.6)	1 (2.6)	0	0	0
Malnutrition	1 (2.6)	0	0	1 (2.6)	0
Metabolic acidosis	1 (2.6)	0	1 (2.6)	0	0
Metabolic alkalosis	1 (2.6)	1 (2.6)	0	0	0
Vitamin d deficiency	1 (2.6)	1 (2.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	16 (41.0)	8 (20.5)	7 (17.9)	1 (2.6)	0
Pain in extremity	8 (20.5)	4 (10.3)	4 (10.3)	0	0
Myalgia	5 (12.8)	4 (10.3)	1 (2.6)	0	0
Arthralgia	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Musculoskeletal pain	2 (5.1)	2 (5.1)	0	0	0
Coccydynia	1 (2.6)	1 (2.6)	0	0	0
Joint range of motion decreased	1 (2.6)	1 (2.6)	0	0	0
Limb discomfort	1 (2.6)	1 (2.6)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscle spasms	1 (2.6)	1 (2.6)	0	0	0
Muscular weakness	1 (2.6)	1 (2.6)	0	0	0
Musculoskeletal chest pain	1 (2.6)	1 (2.6)	0	0	0
Neck pain	1 (2.6)	0	1 (2.6)	0	0
Osteonecrosis	1 (2.6)	0	1 (2.6)	0	0
Osteopenia	1 (2.6)	0	1 (2.6)	0	0
Pain in jaw	1 (2.6)	1 (2.6)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.6)	0	0	0	1 (2.6)
Glioblastoma multiforme	1 (2.6)	0	0	0	1 (2.6)
Nervous system disorders					
-Total	22 (56.4)	11 (28.2)	6 (15.4)	4 (10.3)	1 (2.6)
Headache	14 (35.9)	9 (23.1)	3 (7.7)	2 (5.1)	0
Dizziness	4 (10.3)	4 (10.3)	0	0	0
Encephalopathy	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Peroneal nerve palsy	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Seizure	2 (5.1)	0	0	2 (5.1)	0
Depressed level of consciousness	1 (2.6)	1 (2.6)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disturbance in attention	1 (2.6)	1 (2.6)	0	0	0
Embolic stroke	1 (2.6)	0	0	0	1 (2.6)
Idiopathic intracranial hypertension	1 (2.6)	0	1 (2.6)	0	0
Migraine	1 (2.6)	0	1 (2.6)	0	0
Myoclonus	1 (2.6)	1 (2.6)	0	0	0
Tremor	1 (2.6)	1 (2.6)	0	0	0
Psychiatric disorders					
-Total	13 (33.3)	5 (12.8)	7 (17.9)	1 (2.6)	0
Anxiety	6 (15.4)	3 (7.7)	2 (5.1)	1 (2.6)	0
Confusional state	5 (12.8)	2 (5.1)	3 (7.7)	0	0
Delirium	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Irritability	2 (5.1)	2 (5.1)	0	0	0
Agitation	1 (2.6)	0	1 (2.6)	0	0
Depression	1 (2.6)	1 (2.6)	0	0	0
Hallucination	1 (2.6)	0	1 (2.6)	0	0
Insomnia	1 (2.6)	0	1 (2.6)	0	0
Listless	1 (2.6)	1 (2.6)	0	0	0
Mental status changes	1 (2.6)	1 (2.6)	0	0	0
Panic attack	1 (2.6)	0	1 (2.6)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sleep disorder	1 (2.6)	0	1 (2.6)	0	0
Renal and urinary disorders					
-Total	10 (25.6)	2 (5.1)	2 (5.1)	2 (5.1)	4 (10.3)
Acute kidney injury	6 (15.4)	1 (2.6)	1 (2.6)	1 (2.6)	3 (7.7)
Haematuria	4 (10.3)	0	2 (5.1)	1 (2.6)	1 (2.6)
Oliguria	2 (5.1)	0	0	2 (5.1)	0
Dysuria	1 (2.6)	0	1 (2.6)	0	0
Pollakiuria	1 (2.6)	1 (2.6)	0	0	0
Renal failure	1 (2.6)	0	0	0	1 (2.6)
Renal impairment	1 (2.6)	0	0	1 (2.6)	0
Urinary incontinence	1 (2.6)	1 (2.6)	0	0	0
Reproductive system and breast disorders					
-Total	4 (10.3)	2 (5.1)	1 (2.6)	1 (2.6)	0
Vulvovaginal adhesion	2 (5.1)	2 (5.1)	0	0	0
Oedema genital	1 (2.6)	0	1 (2.6)	0	0
Vaginal haemorrhage	1 (2.6)	0	0	1 (2.6)	0
Respiratory, thoracic and mediastinal disorders					
-Total	19 (48.7)	3 (7.7)	4 (10.3)	7 (17.9)	5 (12.8)
Cough	9 (23.1)	9 (23.1)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	9 (23.1)	0	2 (5.1)	4 (10.3)	3 (7.7)
Epistaxis	7 (17.9)	1 (2.6)	1 (2.6)	4 (10.3)	1 (2.6)
Pleural effusion	7 (17.9)	2 (5.1)	4 (10.3)	1 (2.6)	0
Pulmonary oedema	4 (10.3)	0	0	3 (7.7)	1 (2.6)
Oropharyngeal pain	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Dyspnoea	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Rhinitis allergic	2 (5.1)	2 (5.1)	0	0	0
Tachypnoea	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Atelectasis	1 (2.6)	1 (2.6)	0	0	0
Dysphonia	1 (2.6)	1 (2.6)	0	0	0
Haemoptysis	1 (2.6)	0	0	0	1 (2.6)
Interstitial lung disease	1 (2.6)	0	0	0	1 (2.6)
Pharyngeal erythema	1 (2.6)	1 (2.6)	0	0	0
Pharyngeal lesion	1 (2.6)	0	0	1 (2.6)	0
Pharyngeal ulceration	1 (2.6)	0	1 (2.6)	0	0
Respiratory depression	1 (2.6)	0	1 (2.6)	0	0
Respiratory distress	1 (2.6)	0	0	0	1 (2.6)
Respiratory failure	1 (2.6)	0	0	0	1 (2.6)
Rhinorrhoea	1 (2.6)	1 (2.6)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	15 (38.5)	8 (20.5)	6 (15.4)	1 (2.6)	0
Rash	6 (15.4)	4 (10.3)	2 (5.1)	0	0
Erythema	4 (10.3)	4 (10.3)	0	0	0
Hyperhidrosis	4 (10.3)	4 (10.3)	0	0	0
Rash maculo-papular	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Dry skin	2 (5.1)	2 (5.1)	0	0	0
Petechiae	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Pruritus	2 (5.1)	2 (5.1)	0	0	0
Rash erythematous	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Acne	1 (2.6)	1 (2.6)	0	0	0
Alopecia	1 (2.6)	0	1 (2.6)	0	0
Dermatitis atopic	1 (2.6)	1 (2.6)	0	0	0
Ingrowing nail	1 (2.6)	0	1 (2.6)	0	0
Livedo reticularis	1 (2.6)	1 (2.6)	0	0	0
Macule	1 (2.6)	1 (2.6)	0	0	0
Night sweats	1 (2.6)	0	1 (2.6)	0	0
Papule	1 (2.6)	1 (2.6)	0	0	0
Rash macular	1 (2.6)	1 (2.6)	0	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

Primary system organ class Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash papular	1 (2.6)	1 (2.6)	0	0	0
Rash vesicular	1 (2.6)	1 (2.6)	0	0	0
Vascular disorders					
-Total	14 (35.9)	2 (5.1)	1 (2.6)	4 (10.3)	7 (17.9)
Hypotension	11 (28.2)	1 (2.6)	0	3 (7.7)	7 (17.9)
Hypertension	9 (23.1)	3 (7.7)	5 (12.8)	1 (2.6)	0
Flushing	2 (5.1)	2 (5.1)	0	0	0
Capillary leak syndrome	1 (2.6)	0	0	0	1 (2.6)
Embolism	1 (2.6)	0	0	1 (2.6)	0
Haematoma	1 (2.6)	0	1 (2.6)	0	0
Hot flush	1 (2.6)	1 (2.6)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174e
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

			All patients N=7		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	1 (14.3)	0	6 (85.7)
Blood and lymphatic system disorders					
-Total	5 (71.4)	1 (14.3)	0	2 (28.6)	2 (28.6)
Anaemia	4 (57.1)	2 (28.6)	0	1 (14.3)	1 (14.3)
Febrile neutropenia	2 (28.6)	0	0	2 (28.6)	0
Neutropenia	2 (28.6)	0	0	0	2 (28.6)
Thrombocytopenia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Cardiac disorders					
-Total	3 (42.9)	2 (28.6)	0	1 (14.3)	0
Tachycardia	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0
Palpitations	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pericardial effusion	1 (14.3)	1 (14.3)	0	0	0
Eye disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Eye pain	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal disorders					
-Total	4 (57.1)	2 (28.6)	1 (14.3)	1 (14.3)	0
Diarrhoea	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Nausea	3 (42.9)	1 (14.3)	1 (14.3)	1 (14.3)	0
Vomiting	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
General disorders and administration site conditions					
-Total	3 (42.9)	0	0	2 (28.6)	1 (14.3)
Pyrexia	3 (42.9)	0	1 (14.3)	1 (14.3)	1 (14.3)
Asthenia	1 (14.3)	1 (14.3)	0	0	0
Chills	1 (14.3)	1 (14.3)	0	0	0
Pain	1 (14.3)	0	0	1 (14.3)	0
Hepatobiliary disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	1 (14.3)	0	1 (14.3)	0	0
Immune system disorders					
-Total	7 (100)	0	4 (57.1)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)	0	0
Infections and infestations					
-Total	2 (28.6)	0	2 (28.6)	0	0
Gastroenteritis	1 (14.3)	0	1 (14.3)	0	0
Viral infection	1 (14.3)	0	1 (14.3)	0	0
Injury, poisoning and procedural complications					
-Total	1 (14.3)	0	0	1 (14.3)	0
Tracheal haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Investigations					
-Total	7 (100)	1 (14.3)	1 (14.3)	1 (14.3)	4 (57.1)
Neutrophil count decreased	4 (57.1)	0	1 (14.3)	0	3 (42.9)
White blood cell count decreased	4 (57.1)	1 (14.3)	0	1 (14.3)	2 (28.6)
Lymphocyte count decreased	2 (28.6)	1 (14.3)	1 (14.3)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0	0	0
Aspartate aminotransferase increased	1 (14.3)	0	0	0	1 (14.3)
Blood creatinine increased	1 (14.3)	0	1 (14.3)	0	0
Blood fibrinogen decreased	1 (14.3)	0	1 (14.3)	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0
Blood magnesium decreased	1 (14.3)	0	0	1 (14.3)	0
Blood phosphorus increased	1 (14.3)	1 (14.3)	0	0	0
Blood uric acid increased	1 (14.3)	1 (14.3)	0	0	0
Cardiac murmur	1 (14.3)	1 (14.3)	0	0	0
Fibrin d dimer increased	1 (14.3)	1 (14.3)	0	0	0
International normalised ratio increased	1 (14.3)	1 (14.3)	0	0	0
Prothrombin time prolonged	1 (14.3)	0	1 (14.3)	0	0
Metabolism and nutrition disorders					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Decreased appetite	3 (42.9)	1 (14.3)	1 (14.3)	1 (14.3)	0
Hypokalaemia	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Hypernatraemia	1 (14.3)	0	1 (14.3)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	1 (14.3)	1 (14.3)	0	0	0
Hypophosphataemia	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Arthralgia	1 (14.3)	0	0	1 (14.3)	0
Nervous system disorders					
-Total	4 (57.1)	4 (57.1)	0	0	0
Headache	3 (42.9)	3 (42.9)	0	0	0
Dizziness	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Confusional state	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Delirium	1 (14.3)	1 (14.3)	0	0	0
Renal and urinary disorders					
-Total	2 (28.6)	0	0	0	2 (28.6)
Haematuria	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Acute kidney injury	1 (14.3)	0	0	0	1 (14.3)
Oliguria	1 (14.3)	0	0	1 (14.3)	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	1 (14.3)	0	0	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders					
-Total	3 (42.9)	1 (14.3)	0	0	2 (28.6)
Cough	2 (28.6)	2 (28.6)	0	0	0
Hypoxia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Dyspnoea	1 (14.3)	0	0	0	1 (14.3)
Epistaxis	1 (14.3)	0	0	0	1 (14.3)
Haemoptysis	1 (14.3)	0	0	0	1 (14.3)
Interstitial lung disease	1 (14.3)	0	0	0	1 (14.3)
Pleural effusion	1 (14.3)	0	1 (14.3)	0	0
Pulmonary oedema	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Skin and subcutaneous tissue disorders					
-Total	4 (57.1)	4 (57.1)	0	0	0
Dermatitis diaper	1 (14.3)	1 (14.3)	0	0	0
Dry skin	1 (14.3)	1 (14.3)	0	0	0
Erythema	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Livedo reticularis	1 (14.3)	1 (14.3)	0	0	0
Rash maculo-papular	1 (14.3)	1 (14.3)	0	0	0
Vascular disorders					
-Total	4 (57.1)	0	0	2 (28.6)	2 (28.6)
Hypotension	4 (57.1)	0	0	2 (28.6)	2 (28.6)
Haematoma	1 (14.3)	0	1 (14.3)	0	0
Hypertension	1 (14.3)	0	1 (14.3)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174e
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=57		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (98.2)	2 (3.5)	6 (10.5)	14 (24.6)	34 (59.6)
Blood and lymphatic system disorders					
-Total	38 (66.7)	1 (1.8)	3 (5.3)	25 (43.9)	9 (15.8)
Anaemia	23 (40.4)	1 (1.8)	5 (8.8)	17 (29.8)	0
Febrile neutropenia	20 (35.1)	0	0	20 (35.1)	0
Neutropenia	6 (10.5)	0	0	3 (5.3)	3 (5.3)
Thrombocytopenia	6 (10.5)	0	0	1 (1.8)	5 (8.8)
Disseminated intravascular coagulation	4 (7.0)	0	2 (3.5)	2 (3.5)	0
Lymphopenia	3 (5.3)	0	1 (1.8)	1 (1.8)	1 (1.8)
Coagulopathy	1 (1.8)	1 (1.8)	0	0	0
Pancytopenia	1 (1.8)	0	0	0	1 (1.8)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	19 (33.3)	9 (15.8)	9 (15.8)	1 (1.8)	0
Tachycardia	13 (22.8)	7 (12.3)	5 (8.8)	1 (1.8)	0
Sinus tachycardia	5 (8.8)	3 (5.3)	2 (3.5)	0	0
Atrioventricular block second degree	1 (1.8)	1 (1.8)	0	0	0
Bradycardia	1 (1.8)	0	1 (1.8)	0	0
Cardiac dysfunction	1 (1.8)	1 (1.8)	0	0	0
Pericardial effusion	1 (1.8)	0	1 (1.8)	0	0
Sinus bradycardia	1 (1.8)	1 (1.8)	0	0	0
Ventricular tachycardia	1 (1.8)	0	1 (1.8)	0	0
Ear and labyrinth disorders					
-Total	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Ear pain	2 (3.5)	2 (3.5)	0	0	0
Hypoacusis	1 (1.8)	0	1 (1.8)	0	0
Endocrine disorders					
-Total	1 (1.8)	0	1 (1.8)	0	0
Adrenal insufficiency	1 (1.8)	0	1 (1.8)	0	0
Eye disorders					

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (21.1)	5 (8.8)	7 (12.3)	0	0
Periorbital oedema	4 (7.0)	3 (5.3)	1 (1.8)	0	0
Conjunctival haemorrhage	3 (5.3)	3 (5.3)	0	0	0
Vision blurred	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Eye pain	2 (3.5)	0	2 (3.5)	0	0
Photophobia	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Retinal haemorrhage	2 (3.5)	2 (3.5)	0	0	0
Uveitis	2 (3.5)	0	2 (3.5)	0	0
Ocular hypertension	1 (1.8)	0	1 (1.8)	0	0
Papilloedema	1 (1.8)	0	1 (1.8)	0	0
Visual impairment	1 (1.8)	0	1 (1.8)	0	0
Gastrointestinal disorders					
-Total	32 (56.1)	9 (15.8)	13 (22.8)	10 (17.5)	0
Vomiting	19 (33.3)	12 (21.1)	4 (7.0)	3 (5.3)	0
Nausea	18 (31.6)	5 (8.8)	11 (19.3)	2 (3.5)	0
Diarrhoea	15 (26.3)	9 (15.8)	5 (8.8)	1 (1.8)	0
Abdominal pain	9 (15.8)	6 (10.5)	2 (3.5)	1 (1.8)	0
Constipation	6 (10.5)	5 (8.8)	1 (1.8)	0	0
Abdominal distension	2 (3.5)	0	2 (3.5)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=57		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain upper	2 (3.5)	0	2 (3.5)	0	0
Dysphagia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Haematemesis	2 (3.5)	2 (3.5)	0	0	0
Pancreatitis	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Stomatitis	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Abdominal discomfort	1 (1.8)	1 (1.8)	0	0	0
Abdominal pain lower	1 (1.8)	0	1 (1.8)	0	0
Abdominal tenderness	1 (1.8)	1 (1.8)	0	0	0
Anal incontinence	1 (1.8)	1 (1.8)	0	0	0
Ascites	1 (1.8)	0	0	1 (1.8)	0
Dyspepsia	1 (1.8)	0	1 (1.8)	0	0
Flatulence	1 (1.8)	1 (1.8)	0	0	0
Gastrointestinal haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Gastrooesophageal reflux disease	1 (1.8)	1 (1.8)	0	0	0
Glossodynia	1 (1.8)	1 (1.8)	0	0	0
Ileus	1 (1.8)	0	0	1 (1.8)	0
Intestinal obstruction	1 (1.8)	0	0	1 (1.8)	0
Lip pain	1 (1.8)	0	1 (1.8)	0	0
Mouth haemorrhage	1 (1.8)	0	0	1 (1.8)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tooth socket haemorrhage	1 (1.8)	1 (1.8)	0	0	0
General disorders and administration site conditions					
-Total	29 (50.9)	12 (21.1)	10 (17.5)	7 (12.3)	0
Fatigue	13 (22.8)	10 (17.5)	2 (3.5)	1 (1.8)	0
Pyrexia	13 (22.8)	3 (5.3)	6 (10.5)	4 (7.0)	0
Chills	7 (12.3)	7 (12.3)	0	0	0
Catheter site pain	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Malaise	3 (5.3)	0	3 (5.3)	0	0
Face oedema	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Generalised oedema	2 (3.5)	0	2 (3.5)	0	0
Oedema peripheral	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Pain	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Catheter site extravasation	1 (1.8)	0	1 (1.8)	0	0
Catheter site haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Facial pain	1 (1.8)	0	1 (1.8)	0	0
Injection site haematoma	1 (1.8)	1 (1.8)	0	0	0
Localised oedema	1 (1.8)	0	0	1 (1.8)	0
Mucosal haemorrhage	1 (1.8)	0	1 (1.8)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	1 (1.8)	0	0	1 (1.8)	0
Non-cardiac chest pain	1 (1.8)	1 (1.8)	0	0	0
Peripheral swelling	1 (1.8)	0	1 (1.8)	0	0
Physical deconditioning	1 (1.8)	0	0	1 (1.8)	0
Hepatobiliary disorders					
-Total	6 (10.5)	3 (5.3)	1 (1.8)	2 (3.5)	0
Hyperbilirubinaemia	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Hepatomegaly	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Gallbladder enlargement	1 (1.8)	1 (1.8)	0	0	0
Hepatosplenomegaly	1 (1.8)	1 (1.8)	0	0	0
Immune system disorders					
-Total	50 (87.7)	5 (8.8)	26 (45.6)	11 (19.3)	8 (14.0)
Cytokine release syndrome	45 (78.9)	6 (10.5)	23 (40.4)	8 (14.0)	8 (14.0)
Hypogammaglobulinaemia	21 (36.8)	3 (5.3)	14 (24.6)	4 (7.0)	0
Drug hypersensitivity	1 (1.8)	0	1 (1.8)	0	0
Graft versus host disease in skin	1 (1.8)	1 (1.8)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.8)	0	1 (1.8)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	24 (42.1)	5 (8.8)	12 (21.1)	6 (10.5)	1 (1.8)
Clostridium difficile colitis	4 (7.0)	1 (1.8)	2 (3.5)	1 (1.8)	0
Clostridium difficile infection	4 (7.0)	0	4 (7.0)	0	0
Rhinovirus infection	3 (5.3)	3 (5.3)	0	0	0
Pneumonia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Staphylococcal infection	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Acute sinusitis	1 (1.8)	0	1 (1.8)	0	0
Body tinea	1 (1.8)	1 (1.8)	0	0	0
Catheter site cellulitis	1 (1.8)	1 (1.8)	0	0	0
Catheter site infection	1 (1.8)	0	0	1 (1.8)	0
Cytomegalovirus infection	1 (1.8)	1 (1.8)	0	0	0
Enterococcal infection	1 (1.8)	1 (1.8)	0	0	0
Folliculitis	1 (1.8)	0	1 (1.8)	0	0
Fungal skin infection	1 (1.8)	1 (1.8)	0	0	0
Gastroenteritis	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	0	1 (1.8)	0	0
Herpes simplex	1 (1.8)	1 (1.8)	0	0	0
Human herpesvirus 6 infection	1 (1.8)	0	1 (1.8)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypopyon	1 (1.8)	0	1 (1.8)	0	0
Influenza	1 (1.8)	1 (1.8)	0	0	0
Oral candidiasis	1 (1.8)	1 (1.8)	0	0	0
Orchitis	1 (1.8)	1 (1.8)	0	0	0
Pharyngitis	1 (1.8)	0	1 (1.8)	0	0
Septic embolus	1 (1.8)	0	0	0	1 (1.8)
Skin infection	1 (1.8)	0	1 (1.8)	0	0
Streptococcal infection	1 (1.8)	0	1 (1.8)	0	0
Upper respiratory tract infection	1 (1.8)	0	1 (1.8)	0	0
Urinary tract infection enterococcal	1 (1.8)	0	0	1 (1.8)	0
Viral upper respiratory tract infection	1 (1.8)	0	1 (1.8)	0	0
Vulvovaginal candidiasis	1 (1.8)	1 (1.8)	0	0	0
Injury, poisoning and procedural complications					
-Total	14 (24.6)	8 (14.0)	5 (8.8)	0	1 (1.8)
Procedural pain	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Transfusion reaction	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Infusion related reaction	2 (3.5)	0	2 (3.5)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Contusion	1 (1.8)	1 (1.8)	0	0	0
Incision site pain	1 (1.8)	1 (1.8)	0	0	0
Limb injury	1 (1.8)	1 (1.8)	0	0	0
Mouth injury	1 (1.8)	1 (1.8)	0	0	0
Post procedural haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Procedural complication	1 (1.8)	1 (1.8)	0	0	0
Procedural headache	1 (1.8)	0	1 (1.8)	0	0
Procedural site reaction	1 (1.8)	1 (1.8)	0	0	0
Skin abrasion	1 (1.8)	1 (1.8)	0	0	0
Stoma site irritation	1 (1.8)	1 (1.8)	0	0	0
Subdural haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Tibia fracture	1 (1.8)	0	1 (1.8)	0	0
Tongue injury	1 (1.8)	1 (1.8)	0	0	0
Transfusion related complication	1 (1.8)	0	0	0	1 (1.8)
Investigations					
-Total	45 (78.9)	3 (5.3)	3 (5.3)	12 (21.1)	27 (47.4)
White blood cell count decreased	26 (45.6)	2 (3.5)	1 (1.8)	9 (15.8)	14 (24.6)
Neutrophil count decreased	21 (36.8)	0	1 (1.8)	4 (7.0)	16 (28.1)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=57		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	19 (33.3)	5 (8.8)	3 (5.3)	11 (19.3)	0
Platelet count decreased	19 (33.3)	3 (5.3)	2 (3.5)	2 (3.5)	12 (21.1)
Aspartate aminotransferase increased	17 (29.8)	3 (5.3)	4 (7.0)	7 (12.3)	3 (5.3)
Lymphocyte count decreased	12 (21.1)	0	1 (1.8)	6 (10.5)	5 (8.8)
Blood creatinine increased	8 (14.0)	5 (8.8)	1 (1.8)	2 (3.5)	0
International normalised ratio increased	8 (14.0)	7 (12.3)	0	1 (1.8)	0
Prothrombin time prolonged	8 (14.0)	5 (8.8)	2 (3.5)	1 (1.8)	0
Blood bilirubin increased	7 (12.3)	2 (3.5)	3 (5.3)	2 (3.5)	0
Activated partial thromboplastin time prolonged	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Blood fibrinogen decreased	3 (5.3)	0	0	2 (3.5)	1 (1.8)
Blood immunoglobulin a decreased	3 (5.3)	3 (5.3)	0	0	0
Blood immunoglobulin m decreased	3 (5.3)	3 (5.3)	0	0	0
Blood urea increased	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Lipase increased	2 (3.5)	0	0	0	2 (3.5)
Transaminases increased	2 (3.5)	2 (3.5)	0	0	0
Blood bicarbonate decreased	1 (1.8)	0	1 (1.8)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (1.8)	0	1 (1.8)	0	0
Blood lactic acid increased	1 (1.8)	0	0	0	1 (1.8)
Blood phosphorus decreased	1 (1.8)	1 (1.8)	0	0	0
Blood phosphorus increased	1 (1.8)	1 (1.8)	0	0	0
Blood sodium increased	1 (1.8)	0	1 (1.8)	0	0
C-reactive protein increased	1 (1.8)	0	0	1 (1.8)	0
Culture stool positive	1 (1.8)	1 (1.8)	0	0	0
Haemoglobin decreased	1 (1.8)	0	0	1 (1.8)	0
Hepatic enzyme increased	1 (1.8)	0	1 (1.8)	0	0
Norovirus test positive	1 (1.8)	1 (1.8)	0	0	0
Protein total decreased	1 (1.8)	0	0	1 (1.8)	0
Pulmonary function test decreased	1 (1.8)	0	1 (1.8)	0	0
Serum ferritin increased	1 (1.8)	0	1 (1.8)	0	0
Metabolism and nutrition disorders					
-Total	35 (61.4)	4 (7.0)	8 (14.0)	20 (35.1)	3 (5.3)
Decreased appetite	17 (29.8)	3 (5.3)	3 (5.3)	11 (19.3)	0
Hypokalaemia	14 (24.6)	2 (3.5)	5 (8.8)	7 (12.3)	0
Hyperphosphataemia	8 (14.0)	8 (14.0)	0	0	0
Hypophosphataemia	8 (14.0)	2 (3.5)	0	5 (8.8)	1 (1.8)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	4 (7.0)	0	3 (5.3)	1 (1.8)	0
Dehydration	3 (5.3)	1 (1.8)	0	2 (3.5)	0
Fluid overload	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Hyperglycaemia	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Hypernatraemia	3 (5.3)	1 (1.8)	1 (1.8)	0	1 (1.8)
Hyperuricaemia	3 (5.3)	2 (3.5)	0	0	1 (1.8)
Hypocalcaemia	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Acidosis	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Hypertriglyceridaemia	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Hyponatraemia	2 (3.5)	0	0	2 (3.5)	0
Hyperalbuminaemia	1 (1.8)	1 (1.8)	0	0	0
Hypercalcaemia	1 (1.8)	1 (1.8)	0	0	0
Hyperchloraemia	1 (1.8)	1 (1.8)	0	0	0
Hypermagnesaemia	1 (1.8)	1 (1.8)	0	0	0
Hypomagnesaemia	1 (1.8)	1 (1.8)	0	0	0
Malnutrition	1 (1.8)	0	0	1 (1.8)	0
Metabolic acidosis	1 (1.8)	0	1 (1.8)	0	0
Metabolic alkalosis	1 (1.8)	1 (1.8)	0	0	0
Tumour lysis syndrome	1 (1.8)	0	0	1 (1.8)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	14 (24.6)	8 (14.0)	6 (10.5)	0	0
Myalgia	5 (8.8)	4 (7.0)	1 (1.8)	0	0
Pain in extremity	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Arthralgia	3 (5.3)	3 (5.3)	0	0	0
Musculoskeletal pain	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Coccydynia	1 (1.8)	1 (1.8)	0	0	0
Limb discomfort	1 (1.8)	1 (1.8)	0	0	0
Muscle spasms	1 (1.8)	1 (1.8)	0	0	0
Muscular weakness	1 (1.8)	0	1 (1.8)	0	0
Musculoskeletal chest pain	1 (1.8)	1 (1.8)	0	0	0
Osteopenia	1 (1.8)	0	1 (1.8)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.8)	0	1 (1.8)	0	0
Skin papilloma	1 (1.8)	0	1 (1.8)	0	0
Nervous system disorders					
-Total	29 (50.9)	13 (22.8)	11 (19.3)	4 (7.0)	1 (1.8)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	21 (36.8)	13 (22.8)	6 (10.5)	2 (3.5)	0
Encephalopathy	4 (7.0)	1 (1.8)	1 (1.8)	2 (3.5)	0
Dizziness	3 (5.3)	3 (5.3)	0	0	0
Seizure	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Dysarthria	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Tremor	2 (3.5)	2 (3.5)	0	0	0
Asterixis	1 (1.8)	1 (1.8)	0	0	0
Ataxia	1 (1.8)	0	1 (1.8)	0	0
Depressed level of consciousness	1 (1.8)	1 (1.8)	0	0	0
Embolic stroke	1 (1.8)	0	0	0	1 (1.8)
Idiopathic intracranial hypertension	1 (1.8)	0	1 (1.8)	0	0
Migraine	1 (1.8)	0	1 (1.8)	0	0
Myoclonus	1 (1.8)	1 (1.8)	0	0	0
Neuropathy peripheral	1 (1.8)	0	1 (1.8)	0	0
Pleocytosis	1 (1.8)	1 (1.8)	0	0	0
Somnolence	1 (1.8)	1 (1.8)	0	0	0
Product issues					
-Total	1 (1.8)	1 (1.8)	0	0	0
Device occlusion	1 (1.8)	1 (1.8)	0	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=57		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	13 (22.8)	6 (10.5)	6 (10.5)	1 (1.8)	0
Anxiety	6 (10.5)	2 (3.5)	3 (5.3)	1 (1.8)	0
Confusional state	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Delirium	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Agitation	2 (3.5)	0	2 (3.5)	0	0
Hallucination	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Irritability	2 (3.5)	2 (3.5)	0	0	0
Adjustment disorder	1 (1.8)	0	1 (1.8)	0	0
Insomnia	1 (1.8)	0	1 (1.8)	0	0
Listless	1 (1.8)	1 (1.8)	0	0	0
Mental status changes	1 (1.8)	1 (1.8)	0	0	0
Panic attack	1 (1.8)	0	1 (1.8)	0	0
Suicidal ideation	1 (1.8)	1 (1.8)	0	0	0
Renal and urinary disorders					
-Total	9 (15.8)	2 (3.5)	2 (3.5)	3 (5.3)	2 (3.5)
Acute kidney injury	6 (10.5)	1 (1.8)	1 (1.8)	2 (3.5)	2 (3.5)
Dysuria	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Haematuria	2 (3.5)	0	2 (3.5)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oliguria	1 (1.8)	0	0	1 (1.8)	0
Pollakiuria	1 (1.8)	1 (1.8)	0	0	0
Renal impairment	1 (1.8)	0	0	1 (1.8)	0
Reproductive system and breast disorders					
-Total	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Vulvovaginal adhesion	2 (3.5)	2 (3.5)	0	0	0
Oedema genital	1 (1.8)	0	1 (1.8)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	25 (43.9)	9 (15.8)	6 (10.5)	5 (8.8)	5 (8.8)
Hypoxia	8 (14.0)	0	3 (5.3)	3 (5.3)	2 (3.5)
Pleural effusion	7 (12.3)	2 (3.5)	3 (5.3)	2 (3.5)	0
Cough	6 (10.5)	6 (10.5)	0	0	0
Epistaxis	6 (10.5)	2 (3.5)	1 (1.8)	3 (5.3)	0
Pulmonary oedema	5 (8.8)	1 (1.8)	0	3 (5.3)	1 (1.8)
Tachypnoea	5 (8.8)	3 (5.3)	1 (1.8)	1 (1.8)	0
Oropharyngeal pain	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Respiratory failure	2 (3.5)	0	0	0	2 (3.5)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atelectasis	1 (1.8)	1 (1.8)	0	0	0
Dyspnoea	1 (1.8)	0	0	1 (1.8)	0
Haemoptysis	1 (1.8)	1 (1.8)	0	0	0
Nasal congestion	1 (1.8)	1 (1.8)	0	0	0
Oropharyngeal plaque	1 (1.8)	1 (1.8)	0	0	0
Pharyngeal ulceration	1 (1.8)	0	1 (1.8)	0	0
Respiratory depression	1 (1.8)	0	1 (1.8)	0	0
Respiratory distress	1 (1.8)	0	0	0	1 (1.8)
Rhinitis allergic	1 (1.8)	1 (1.8)	0	0	0
Rhinorrhoea	1 (1.8)	1 (1.8)	0	0	0
Wheezing	1 (1.8)	0	1 (1.8)	0	0
Skin and subcutaneous tissue disorders					
-Total	17 (29.8)	11 (19.3)	4 (7.0)	2 (3.5)	0
Rash	4 (7.0)	4 (7.0)	0	0	0
Dry skin	3 (5.3)	3 (5.3)	0	0	0
Hyperhidrosis	3 (5.3)	3 (5.3)	0	0	0
Petechiae	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Erythema	2 (3.5)	2 (3.5)	0	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=57		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ingrowing nail	2 (3.5)	0	2 (3.5)	0	0
Pruritus	2 (3.5)	2 (3.5)	0	0	0
Rash maculo-papular	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Rash papular	2 (3.5)	2 (3.5)	0	0	0
Ecchymosis	1 (1.8)	0	0	1 (1.8)	0
Macule	1 (1.8)	1 (1.8)	0	0	0
Night sweats	1 (1.8)	0	1 (1.8)	0	0
Rash erythematous	1 (1.8)	1 (1.8)	0	0	0
Rash follicular	1 (1.8)	1 (1.8)	0	0	0
Rash macular	1 (1.8)	1 (1.8)	0	0	0
Rash vesicular	1 (1.8)	1 (1.8)	0	0	0
Skin exfoliation	1 (1.8)	1 (1.8)	0	0	0
Skin fissures	1 (1.8)	1 (1.8)	0	0	0
Skin irritation	1 (1.8)	1 (1.8)	0	0	0
Vascular disorders					
-Total	20 (35.1)	3 (5.3)	5 (8.8)	6 (10.5)	6 (10.5)
Hypotension	12 (21.1)	1 (1.8)	0	5 (8.8)	6 (10.5)
Hypertension	9 (15.8)	2 (3.5)	6 (10.5)	1 (1.8)	0
Flushing	2 (3.5)	2 (3.5)	0	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Orthostatic hypotension	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Capillary leak syndrome	1 (1.8)	0	0	0	1 (1.8)
Embolism	1 (1.8)	0	0	1 (1.8)	0
Secondary hypertension	1 (1.8)	0	1 (1.8)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174e
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	2 (40.0)	2 (40.0)	0
Endocrine disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Adrenal insufficiency	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal disorders					
-Total	4 (80.0)	2 (40.0)	0	2 (40.0)	0
Diarrhoea	2 (40.0)	2 (40.0)	0	0	0
Oral pain	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Vomiting	2 (40.0)	2 (40.0)	0	0	0
Abdominal pain	1 (20.0)	1 (20.0)	0	0	0
Enterocolitis	1 (20.0)	0	0	1 (20.0)	0
Nausea	1 (20.0)	0	1 (20.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	3 (60.0)	2 (40.0)	1 (20.0)	0	0
Catheter site pain	1 (20.0)	0	1 (20.0)	0	0
Fatigue	1 (20.0)	1 (20.0)	0	0	0
Pyrexia	1 (20.0)	1 (20.0)	0	0	0
Immune system disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Graft versus host disease	1 (20.0)	0	1 (20.0)	0	0
Infections and infestations					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Upper respiratory tract infection	2 (40.0)	0	2 (40.0)	0	0
Corona virus infection	1 (20.0)	0	0	1 (20.0)	0
Ear infection	1 (20.0)	1 (20.0)	0	0	0
Respiratory syncytial virus infection	1 (20.0)	0	0	1 (20.0)	0
Rhinovirus infection	1 (20.0)	1 (20.0)	0	0	0
Tinea capitis	1 (20.0)	1 (20.0)	0	0	0
Viral infection	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	1 (20.0)	0	1 (20.0)	0	0
Contusion	1 (20.0)	1 (20.0)	0	0	0
Infusion related reaction	1 (20.0)	0	1 (20.0)	0	0
Procedural nausea	1 (20.0)	0	1 (20.0)	0	0
Sunburn	1 (20.0)	1 (20.0)	0	0	0
Investigations					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Blood bilirubin increased	1 (20.0)	0	0	1 (20.0)	0
Blood magnesium decreased	1 (20.0)	1 (20.0)	0	0	0
Weight decreased	1 (20.0)	1 (20.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (60.0)	3 (60.0)	0	0	0
Pain in extremity	2 (40.0)	2 (40.0)	0	0	0
Arthralgia	1 (20.0)	1 (20.0)	0	0	0
Muscular weakness	1 (20.0)	1 (20.0)	0	0	0
Pain in jaw	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0
Headache	1 (20.0)	1 (20.0)	0	0	0
Peroneal nerve palsy	1 (20.0)	1 (20.0)	0	0	0
Psychiatric disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Anxiety	1 (20.0)	1 (20.0)	0	0	0
Depression	1 (20.0)	1 (20.0)	0	0	0
Sleep disorder	1 (20.0)	0	1 (20.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (80.0)	2 (40.0)	1 (20.0)	1 (20.0)	0
Rhinorrhoea	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Cough	1 (20.0)	1 (20.0)	0	0	0
Epistaxis	1 (20.0)	0	0	1 (20.0)	0
Nasal congestion	1 (20.0)	1 (20.0)	0	0	0
Oropharyngeal pain	1 (20.0)	0	1 (20.0)	0	0
Pharyngeal erythema	1 (20.0)	1 (20.0)	0	0	0
Pharyngeal lesion	1 (20.0)	0	0	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Alopecia	1 (20.0)	0	1 (20.0)	0	0
Erythema	1 (20.0)	1 (20.0)	0	0	0
Rash erythematous	1 (20.0)	0	1 (20.0)	0	0
Vascular disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Hypertension	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Hot flush	1 (20.0)	1 (20.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174e
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=51		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (82.4)	4 (7.8)	14 (27.5)	14 (27.5)	10 (19.6)
Blood and lymphatic system disorders					
-Total	11 (21.6)	1 (2.0)	3 (5.9)	3 (5.9)	4 (7.8)
Neutropenia	4 (7.8)	0	0	1 (2.0)	3 (5.9)
Febrile neutropenia	3 (5.9)	0	0	3 (5.9)	0
Anaemia	2 (3.9)	1 (2.0)	0	1 (2.0)	0
Thrombocytopenia	2 (3.9)	0	1 (2.0)	1 (2.0)	0
Eosinophilia	1 (2.0)	0	0	1 (2.0)	0
Leukopenia	1 (2.0)	0	0	0	1 (2.0)
Lymphadenopathy	1 (2.0)	0	1 (2.0)	0	0
Lymphopenia	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	1 (2.0)	0	1 (2.0)	0	0
Sinus tachycardia	1 (2.0)	0	1 (2.0)	0	0
Eye disorders					
-Total	5 (9.8)	4 (7.8)	1 (2.0)	0	0
Dry eye	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Conjunctivitis allergic	1 (2.0)	1 (2.0)	0	0	0
Ocular hyperaemia	1 (2.0)	1 (2.0)	0	0	0
Vision blurred	1 (2.0)	1 (2.0)	0	0	0
Gastrointestinal disorders					
-Total	12 (23.5)	7 (13.7)	3 (5.9)	2 (3.9)	0
Vomiting	7 (13.7)	3 (5.9)	2 (3.9)	2 (3.9)	0
Diarrhoea	6 (11.8)	4 (7.8)	1 (2.0)	1 (2.0)	0
Nausea	5 (9.8)	1 (2.0)	2 (3.9)	2 (3.9)	0
Abdominal pain	3 (5.9)	1 (2.0)	1 (2.0)	1 (2.0)	0
Abdominal pain upper	1 (2.0)	1 (2.0)	0	0	0
Pigmentation lip	1 (2.0)	1 (2.0)	0	0	0
General disorders and administration site conditions					

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (27.5)	11 (21.6)	2 (3.9)	1 (2.0)	0
Pyrexia	9 (17.6)	6 (11.8)	2 (3.9)	1 (2.0)	0
Influenza like illness	2 (3.9)	2 (3.9)	0	0	0
Acquired gene mutation	1 (2.0)	1 (2.0)	0	0	0
Chills	1 (2.0)	1 (2.0)	0	0	0
Crying	1 (2.0)	1 (2.0)	0	0	0
Fatigue	1 (2.0)	1 (2.0)	0	0	0
Generalised oedema	1 (2.0)	1 (2.0)	0	0	0
Malaise	1 (2.0)	1 (2.0)	0	0	0
Oedema peripheral	1 (2.0)	1 (2.0)	0	0	0
Pain	1 (2.0)	1 (2.0)	0	0	0
Immune system disorders					
-Total	13 (25.5)	3 (5.9)	9 (17.6)	1 (2.0)	0
Hypogammaglobulinaemia	8 (15.7)	0	7 (13.7)	1 (2.0)	0
Immunodeficiency common variable	2 (3.9)	0	2 (3.9)	0	0
Seasonal allergy	2 (3.9)	2 (3.9)	0	0	0
Graft versus host disease	1 (2.0)	1 (2.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease in gastrointestinal tract	1 (2.0)	0	1 (2.0)	0	0
Infections and infestations					
-Total	29 (56.9)	5 (9.8)	13 (25.5)	9 (17.6)	2 (3.9)
Upper respiratory tract infection	5 (9.8)	3 (5.9)	1 (2.0)	1 (2.0)	0
Urinary tract infection	4 (7.8)	0	2 (3.9)	2 (3.9)	0
Gastroenteritis	3 (5.9)	1 (2.0)	2 (3.9)	0	0
Influenza	3 (5.9)	0	3 (5.9)	0	0
Parainfluenzae virus infection	2 (3.9)	1 (2.0)	0	1 (2.0)	0
Sinusitis	2 (3.9)	0	2 (3.9)	0	0
Viral upper respiratory tract infection	2 (3.9)	1 (2.0)	0	1 (2.0)	0
Bacterial sepsis	1 (2.0)	0	0	0	1 (2.0)
Cellulitis of male external genital organ	1 (2.0)	0	0	1 (2.0)	0
Cholecystitis infective	1 (2.0)	0	0	1 (2.0)	0
Cytomegalovirus infection	1 (2.0)	1 (2.0)	0	0	0
Ear infection	1 (2.0)	0	1 (2.0)	0	0
Enterovirus infection	1 (2.0)	0	0	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia urinary tract infection	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis norovirus	1 (2.0)	0	1 (2.0)	0	0
Gastroenteritis viral	1 (2.0)	1 (2.0)	0	0	0
Herpes zoster	1 (2.0)	0	0	1 (2.0)	0
Molluscum contagiosum	1 (2.0)	1 (2.0)	0	0	0
Oral herpes	1 (2.0)	0	1 (2.0)	0	0
Otitis externa	1 (2.0)	0	1 (2.0)	0	0
Otitis media	1 (2.0)	0	1 (2.0)	0	0
Otitis media acute	1 (2.0)	0	1 (2.0)	0	0
Paronychia	1 (2.0)	1 (2.0)	0	0	0
Rash pustular	1 (2.0)	0	1 (2.0)	0	0
Rhinitis	1 (2.0)	1 (2.0)	0	0	0
Rhinovirus infection	1 (2.0)	1 (2.0)	0	0	0
Rotavirus infection	1 (2.0)	0	0	1 (2.0)	0
Sepsis	1 (2.0)	0	0	0	1 (2.0)
Subcutaneous abscess	1 (2.0)	0	1 (2.0)	0	0
Vascular device infection	1 (2.0)	0	0	1 (2.0)	0
Vulvovaginal mycotic infection	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	7 (13.7)	3 (5.9)	4 (7.8)	0	0
Procedural pain	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Arthropod bite	1 (2.0)	1 (2.0)	0	0	0
Contusion	1 (2.0)	1 (2.0)	0	0	0
Foot fracture	1 (2.0)	0	1 (2.0)	0	0
Infusion related reaction	1 (2.0)	1 (2.0)	0	0	0
Radius fracture	1 (2.0)	0	1 (2.0)	0	0
Skin abrasion	1 (2.0)	1 (2.0)	0	0	0
Skin laceration	1 (2.0)	0	1 (2.0)	0	0
Investigations					
-Total	21 (41.2)	5 (9.8)	5 (9.8)	7 (13.7)	4 (7.8)
Neutrophil count decreased	8 (15.7)	2 (3.9)	0	3 (5.9)	3 (5.9)
White blood cell count decreased	5 (9.8)	2 (3.9)	1 (2.0)	1 (2.0)	1 (2.0)
Aspartate aminotransferase increased	3 (5.9)	1 (2.0)	0	2 (3.9)	0
Platelet count decreased	3 (5.9)	3 (5.9)	0	0	0
Weight decreased	3 (5.9)	0	3 (5.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	2 (3.9)	0	0	2 (3.9)	0
Haemoglobin decreased	2 (3.9)	2 (3.9)	0	0	0
Lymphocyte count decreased	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Weight increased	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Blood creatinine increased	1 (2.0)	1 (2.0)	0	0	0
Blood urea increased	1 (2.0)	1 (2.0)	0	0	0
Blood uric acid increased	1 (2.0)	1 (2.0)	0	0	0
Oxygen saturation decreased	1 (2.0)	1 (2.0)	0	0	0
Serum ferritin increased	1 (2.0)	0	1 (2.0)	0	0
Transaminases increased	1 (2.0)	1 (2.0)	0	0	0
Metabolism and nutrition disorders					
-Total	10 (19.6)	5 (9.8)	1 (2.0)	3 (5.9)	1 (2.0)
Decreased appetite	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Hyperphosphataemia	2 (3.9)	2 (3.9)	0	0	0
Hypokalaemia	2 (3.9)	1 (2.0)	0	0	1 (2.0)
Dehydration	1 (2.0)	0	0	1 (2.0)	0
Hyperalbuminaemia	1 (2.0)	1 (2.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypercalcaemia	1 (2.0)	1 (2.0)	0	0	0
Hyperglycaemia	1 (2.0)	0	0	1 (2.0)	0
Hypophosphataemia	1 (2.0)	0	0	1 (2.0)	0
Iron overload	1 (2.0)	0	0	1 (2.0)	0
Tumour lysis syndrome	1 (2.0)	0	0	1 (2.0)	0
Vitamin d deficiency	1 (2.0)	1 (2.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	13 (25.5)	8 (15.7)	5 (9.8)	0	0
Pain in extremity	6 (11.8)	4 (7.8)	2 (3.9)	0	0
Joint range of motion decreased	2 (3.9)	2 (3.9)	0	0	0
Arthralgia	1 (2.0)	0	1 (2.0)	0	0
Back pain	1 (2.0)	1 (2.0)	0	0	0
Flank pain	1 (2.0)	0	1 (2.0)	0	0
Muscle spasms	1 (2.0)	1 (2.0)	0	0	0
Muscular weakness	1 (2.0)	1 (2.0)	0	0	0
Musculoskeletal chest pain	1 (2.0)	1 (2.0)	0	0	0
Osteonecrosis	1 (2.0)	0	1 (2.0)	0	0
Toe walking	1 (2.0)	1 (2.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.0)	0	1 (2.0)	0	0
Myelodysplastic syndrome	1 (2.0)	0	1 (2.0)	0	0
Nervous system disorders					
-Total	6 (11.8)	4 (7.8)	2 (3.9)	0	0
Headache	4 (7.8)	3 (5.9)	1 (2.0)	0	0
Dizziness	3 (5.9)	3 (5.9)	0	0	0
Peroneal nerve palsy	1 (2.0)	0	1 (2.0)	0	0
Psychiatric disorders					
-Total	1 (2.0)	1 (2.0)	0	0	0
Depression	1 (2.0)	1 (2.0)	0	0	0
Renal and urinary disorders					
-Total	3 (5.9)	1 (2.0)	0	2 (3.9)	0
Acute kidney injury	1 (2.0)	0	0	1 (2.0)	0
Calculus urinary	1 (2.0)	0	1 (2.0)	0	0
Haematuria	1 (2.0)	0	0	1 (2.0)	0
Nephrolithiasis	1 (2.0)	0	0	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary incontinence	1 (2.0)	1 (2.0)	0	0	0
Reproductive system and breast disorders					
-Total	2 (3.9)	0	1 (2.0)	1 (2.0)	0
Scrotal pain	1 (2.0)	0	1 (2.0)	0	0
Vaginal haemorrhage	1 (2.0)	0	0	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	14 (27.5)	9 (17.6)	3 (5.9)	1 (2.0)	1 (2.0)
Cough	6 (11.8)	4 (7.8)	2 (3.9)	0	0
Nasal congestion	3 (5.9)	3 (5.9)	0	0	0
Rhinitis allergic	3 (5.9)	2 (3.9)	1 (2.0)	0	0
Oropharyngeal pain	2 (3.9)	2 (3.9)	0	0	0
Rhinorrhoea	2 (3.9)	2 (3.9)	0	0	0
Acute respiratory failure	1 (2.0)	0	0	0	1 (2.0)
Dysphonia	1 (2.0)	1 (2.0)	0	0	0
Epistaxis	1 (2.0)	1 (2.0)	0	0	0
Pulmonary oedema	1 (2.0)	0	0	1 (2.0)	0
Skin and subcutaneous tissue disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (29.4)	10 (19.6)	4 (7.8)	1 (2.0)	0
Rash	4 (7.8)	1 (2.0)	3 (5.9)	0	0
Rash maculo-papular	2 (3.9)	2 (3.9)	0	0	0
Dermatitis	1 (2.0)	1 (2.0)	0	0	0
Dermatitis acneiform	1 (2.0)	0	0	1 (2.0)	0
Dermatitis atopic	1 (2.0)	1 (2.0)	0	0	0
Dry skin	1 (2.0)	1 (2.0)	0	0	0
Eczema	1 (2.0)	1 (2.0)	0	0	0
Erythema	1 (2.0)	1 (2.0)	0	0	0
Hyperhidrosis	1 (2.0)	1 (2.0)	0	0	0
Ingrowing nail	1 (2.0)	1 (2.0)	0	0	0
Keloid scar	1 (2.0)	0	1 (2.0)	0	0
Macule	1 (2.0)	1 (2.0)	0	0	0
Papule	1 (2.0)	1 (2.0)	0	0	0
Petechiae	1 (2.0)	1 (2.0)	0	0	0
Pruritus	1 (2.0)	1 (2.0)	0	0	0
Rash pruritic	1 (2.0)	1 (2.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174e
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (40.0)	0	1 (20.0)	0	1 (20.0)
Infections and infestations					
-Total	1 (20.0)	0	1 (20.0)	0	0
Skin infection	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	1 (20.0)	0	0	0	1 (20.0)
White blood cell count decreased	1 (20.0)	0	0	0	1 (20.0)

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174e
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=29		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (69.0)	4 (13.8)	5 (17.2)	8 (27.6)	3 (10.3)
Blood and lymphatic system disorders					
-Total	2 (6.9)	1 (3.4)	0	0	1 (3.4)
Febrile neutropenia	1 (3.4)	0	0	0	1 (3.4)
Thrombocytopenia	1 (3.4)	1 (3.4)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.4)	0	1 (3.4)	0	0
Tympanic membrane perforation	1 (3.4)	0	1 (3.4)	0	0
Gastrointestinal disorders					
-Total	3 (10.3)	0	3 (10.3)	0	0
Diarrhoea	2 (6.9)	0	2 (6.9)	0	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (3.4)	0	1 (3.4)	0	0
Nausea	1 (3.4)	0	1 (3.4)	0	0
General disorders and administration site conditions					
-Total	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Chills	1 (3.4)	0	1 (3.4)	0	0
Cyst	1 (3.4)	0	0	1 (3.4)	0
Pyrexia	1 (3.4)	0	1 (3.4)	0	0
Immune system disorders					
-Total	2 (6.9)	0	2 (6.9)	0	0
Chronic graft versus host disease	1 (3.4)	0	1 (3.4)	0	0
Immunodeficiency	1 (3.4)	0	1 (3.4)	0	0
Infections and infestations					
-Total	10 (34.5)	2 (6.9)	4 (13.8)	3 (10.3)	1 (3.4)
Otitis media	3 (10.3)	0	2 (6.9)	1 (3.4)	0
Sinusitis	3 (10.3)	0	3 (10.3)	0	0
Otitis media acute	2 (6.9)	0	2 (6.9)	0	0
Pneumonia	2 (6.9)	0	2 (6.9)	0	0
Upper respiratory tract infection	2 (6.9)	1 (3.4)	1 (3.4)	0	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Campylobacter infection	1 (3.4)	0	0	1 (3.4)	0
Cellulitis of male external genital organ	1 (3.4)	0	0	1 (3.4)	0
Clostridium difficile infection	1 (3.4)	0	0	1 (3.4)	0
Gingivitis	1 (3.4)	1 (3.4)	0	0	0
Haemophilus infection	1 (3.4)	0	1 (3.4)	0	0
Meningitis aseptic	1 (3.4)	0	1 (3.4)	0	0
Respiratory tract infection	1 (3.4)	0	0	0	1 (3.4)
Respiratory tract infection viral	1 (3.4)	0	0	1 (3.4)	0
Viral infection	1 (3.4)	1 (3.4)	0	0	0
Vulvovaginal candidiasis	1 (3.4)	0	1 (3.4)	0	0
Injury, poisoning and procedural complications					
-Total	1 (3.4)	0	0	1 (3.4)	0
Procedural pain	1 (3.4)	0	0	1 (3.4)	0
Investigations					
-Total	7 (24.1)	1 (3.4)	2 (6.9)	4 (13.8)	0
Alanine aminotransferase increased	3 (10.3)	0	1 (3.4)	2 (6.9)	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	3 (10.3)	2 (6.9)	0	1 (3.4)	0
White blood cell count decreased	3 (10.3)	1 (3.4)	0	2 (6.9)	0
Aspartate aminotransferase increased	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Neutrophil count decreased	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Blood alkaline phosphatase increased	1 (3.4)	1 (3.4)	0	0	0
Blood lactate dehydrogenase increased	1 (3.4)	1 (3.4)	0	0	0
C-reactive protein increased	1 (3.4)	1 (3.4)	0	0	0
Platelet count decreased	1 (3.4)	0	0	1 (3.4)	0
Metabolism and nutrition disorders					
-Total	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Hypokalaemia	1 (3.4)	0	0	1 (3.4)	0
Vitamin d deficiency	1 (3.4)	1 (3.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (3.4)	0	1 (3.4)	0	0
Neck pain	1 (3.4)	0	1 (3.4)	0	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.4)	0	0	0	1 (3.4)
Glioblastoma multiforme	1 (3.4)	0	0	0	1 (3.4)
Nervous system disorders					
-Total	3 (10.3)	1 (3.4)	1 (3.4)	1 (3.4)	0
Disturbance in attention	1 (3.4)	1 (3.4)	0	0	0
Dizziness	1 (3.4)	1 (3.4)	0	0	0
Headache	1 (3.4)	0	1 (3.4)	0	0
Seizure	1 (3.4)	0	0	1 (3.4)	0
Renal and urinary disorders					
-Total	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Acute kidney injury	1 (3.4)	0	0	1 (3.4)	0
Haematuria	1 (3.4)	1 (3.4)	0	0	0
Reproductive system and breast disorders					
-Total	1 (3.4)	0	0	1 (3.4)	0
Ovarian failure	1 (3.4)	0	0	1 (3.4)	0
Respiratory, thoracic and mediastinal disorders					

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (13.8)	4 (13.8)	0	0	0
Cough	2 (6.9)	2 (6.9)	0	0	0
Epistaxis	1 (3.4)	1 (3.4)	0	0	0
Oropharyngeal pain	1 (3.4)	1 (3.4)	0	0	0
Rhinitis allergic	1 (3.4)	1 (3.4)	0	0	0
Rhinorrhoea	1 (3.4)	1 (3.4)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (10.3)	3 (10.3)	0	0	0
Acne	1 (3.4)	1 (3.4)	0	0	0
Papule	1 (3.4)	1 (3.4)	0	0	0
Pruritus	1 (3.4)	1 (3.4)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174e
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

			All patients N=7		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	1 (14.3)	0	6 (85.7)
Blood and lymphatic system disorders					
-Total	5 (71.4)	1 (14.3)	0	2 (28.6)	2 (28.6)
Anaemia	4 (57.1)	2 (28.6)	0	1 (14.3)	1 (14.3)
Febrile neutropenia	2 (28.6)	0	0	2 (28.6)	0
Neutropenia	2 (28.6)	0	0	0	2 (28.6)
Thrombocytopenia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Cardiac disorders					
-Total	3 (42.9)	2 (28.6)	0	1 (14.3)	0
Tachycardia	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Palpitations	1 (14.3)	1 (14.3)	0	0	0
Pericardial effusion	1 (14.3)	1 (14.3)	0	0	0
Endocrine disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Adrenal insufficiency	1 (14.3)	1 (14.3)	0	0	0
Eye disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Eye pain	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal disorders					
-Total	6 (85.7)	2 (28.6)	1 (14.3)	3 (42.9)	0
Vomiting	5 (71.4)	3 (42.9)	2 (28.6)	0	0
Diarrhoea	4 (57.1)	3 (42.9)	1 (14.3)	0	0
Nausea	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Oral pain	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Abdominal pain	1 (14.3)	1 (14.3)	0	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Enterocolitis	1 (14.3)	0	0	1 (14.3)	0
General disorders and administration site conditions					

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (71.4)	1 (14.3)	1 (14.3)	2 (28.6)	1 (14.3)
Pyrexia	4 (57.1)	1 (14.3)	1 (14.3)	1 (14.3)	1 (14.3)
Asthenia	1 (14.3)	1 (14.3)	0	0	0
Catheter site pain	1 (14.3)	0	1 (14.3)	0	0
Chills	1 (14.3)	1 (14.3)	0	0	0
Fatigue	1 (14.3)	1 (14.3)	0	0	0
Pain	1 (14.3)	0	0	1 (14.3)	0
Hepatobiliary disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Hepatomegaly	1 (14.3)	0	1 (14.3)	0	0
Immune system disorders					
-Total	7 (100)	0	4 (57.1)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)	0	0
Graft versus host disease	1 (14.3)	0	1 (14.3)	0	0
Infections and infestations					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Upper respiratory tract infection	2 (28.6)	0	2 (28.6)	0	0
Viral infection	2 (28.6)	1 (14.3)	1 (14.3)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	1 (14.3)	0	0	1 (14.3)	0
Ear infection	1 (14.3)	1 (14.3)	0	0	0
Gastroenteritis	1 (14.3)	0	1 (14.3)	0	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	1 (14.3)	0	0	0
Skin infection	1 (14.3)	0	1 (14.3)	0	0
Tinea capitis	1 (14.3)	1 (14.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Contusion	1 (14.3)	1 (14.3)	0	0	0
Infusion related reaction	1 (14.3)	0	1 (14.3)	0	0
Procedural nausea	1 (14.3)	0	1 (14.3)	0	0
Sunburn	1 (14.3)	1 (14.3)	0	0	0
Tracheal haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Investigations					
-Total	7 (100)	0	1 (14.3)	2 (28.6)	4 (57.1)
Neutrophil count decreased	4 (57.1)	0	1 (14.3)	0	3 (42.9)

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	4 (57.1)	1 (14.3)	0	0	3 (42.9)
Blood magnesium decreased	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Lymphocyte count decreased	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0	0	0
Aspartate aminotransferase increased	1 (14.3)	0	0	0	1 (14.3)
Blood bilirubin increased	1 (14.3)	0	0	1 (14.3)	0
Blood creatinine increased	1 (14.3)	0	1 (14.3)	0	0
Blood fibrinogen decreased	1 (14.3)	0	1 (14.3)	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0
Blood phosphorus increased	1 (14.3)	1 (14.3)	0	0	0
Blood uric acid increased	1 (14.3)	1 (14.3)	0	0	0
Cardiac murmur	1 (14.3)	1 (14.3)	0	0	0
Fibrin d dimer increased	1 (14.3)	1 (14.3)	0	0	0
International normalised ratio increased	1 (14.3)	1 (14.3)	0	0	0
Prothrombin time prolonged	1 (14.3)	0	1 (14.3)	0	0
Weight decreased	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Decreased appetite	3 (42.9)	1 (14.3)	1 (14.3)	1 (14.3)	0
Hypokalaemia	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Hypernatraemia	1 (14.3)	0	1 (14.3)	0	0
Hypoalbuminaemia	1 (14.3)	1 (14.3)	0	0	0
Hypophosphataemia	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (42.9)	2 (28.6)	0	1 (14.3)	0
Pain in extremity	2 (28.6)	2 (28.6)	0	0	0
Arthralgia	1 (14.3)	0	0	1 (14.3)	0
Muscular weakness	1 (14.3)	1 (14.3)	0	0	0
Pain in jaw	1 (14.3)	1 (14.3)	0	0	0
Nervous system disorders					
-Total	4 (57.1)	4 (57.1)	0	0	0
Headache	3 (42.9)	3 (42.9)	0	0	0
Dizziness	1 (14.3)	1 (14.3)	0	0	0
Peroneal nerve palsy	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Confusional state	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Anxiety	1 (14.3)	1 (14.3)	0	0	0
Delirium	1 (14.3)	1 (14.3)	0	0	0
Depression	1 (14.3)	1 (14.3)	0	0	0
Sleep disorder	1 (14.3)	0	1 (14.3)	0	0
Renal and urinary disorders					
-Total	2 (28.6)	0	0	0	2 (28.6)
Haematuria	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Acute kidney injury	1 (14.3)	0	0	0	1 (14.3)
Oliguria	1 (14.3)	0	0	1 (14.3)	0
Renal failure	1 (14.3)	0	0	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders					
-Total	6 (85.7)	2 (28.6)	1 (14.3)	1 (14.3)	2 (28.6)
Cough	3 (42.9)	3 (42.9)	0	0	0
Epistaxis	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Hypoxia	2 (28.6)	0	0	1 (14.3)	1 (14.3)

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Dyspnoea	1 (14.3)	0	0	0	1 (14.3)
Haemoptysis	1 (14.3)	0	0	0	1 (14.3)
Interstitial lung disease	1 (14.3)	0	0	0	1 (14.3)
Nasal congestion	1 (14.3)	1 (14.3)	0	0	0
Oropharyngeal pain	1 (14.3)	0	1 (14.3)	0	0
Pharyngeal erythema	1 (14.3)	1 (14.3)	0	0	0
Pharyngeal lesion	1 (14.3)	0	0	1 (14.3)	0
Pleural effusion	1 (14.3)	0	1 (14.3)	0	0
Pulmonary oedema	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Skin and subcutaneous tissue disorders					
-Total	4 (57.1)	3 (42.9)	1 (14.3)	0	0
Erythema	2 (28.6)	2 (28.6)	0	0	0
Alopecia	1 (14.3)	0	1 (14.3)	0	0
Dermatitis diaper	1 (14.3)	1 (14.3)	0	0	0
Dry skin	1 (14.3)	1 (14.3)	0	0	0
Livedo reticularis	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash erythematous	1 (14.3)	0	1 (14.3)	0	0
Rash maculo-papular	1 (14.3)	1 (14.3)	0	0	0
Vascular disorders					
-Total	5 (71.4)	0	1 (14.3)	2 (28.6)	2 (28.6)
Hypotension	4 (57.1)	0	0	2 (28.6)	2 (28.6)
Hypertension	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Haematoma	1 (14.3)	0	1 (14.3)	0	0
Hot flush	1 (14.3)	1 (14.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174e
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=57		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	57 (100)	0	4 (7.0)	12 (21.1)	41 (71.9)
Blood and lymphatic system disorders					
-Total	43 (75.4)	1 (1.8)	3 (5.3)	25 (43.9)	14 (24.6)
Anaemia	23 (40.4)	1 (1.8)	4 (7.0)	18 (31.6)	0
Febrile neutropenia	22 (38.6)	0	0	21 (36.8)	1 (1.8)
Neutropenia	9 (15.8)	0	0	3 (5.3)	6 (10.5)
Thrombocytopenia	8 (14.0)	0	1 (1.8)	2 (3.5)	5 (8.8)
Disseminated intravascular coagulation	4 (7.0)	0	2 (3.5)	2 (3.5)	0
Lymphopenia	4 (7.0)	0	2 (3.5)	1 (1.8)	1 (1.8)
Coagulopathy	1 (1.8)	1 (1.8)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eosinophilia	1 (1.8)	0	0	1 (1.8)	0
Leukopenia	1 (1.8)	0	0	0	1 (1.8)
Lymphadenopathy	1 (1.8)	0	1 (1.8)	0	0
Pancytopenia	1 (1.8)	0	0	0	1 (1.8)
Cardiac disorders					
-Total	20 (35.1)	9 (15.8)	10 (17.5)	1 (1.8)	0
Tachycardia	13 (22.8)	7 (12.3)	5 (8.8)	1 (1.8)	0
Sinus tachycardia	6 (10.5)	3 (5.3)	3 (5.3)	0	0
Atrioventricular block second degree	1 (1.8)	1 (1.8)	0	0	0
Bradycardia	1 (1.8)	0	1 (1.8)	0	0
Cardiac dysfunction	1 (1.8)	1 (1.8)	0	0	0
Pericardial effusion	1 (1.8)	0	1 (1.8)	0	0
Sinus bradycardia	1 (1.8)	1 (1.8)	0	0	0
Ventricular tachycardia	1 (1.8)	0	1 (1.8)	0	0
Ear and labyrinth disorders					
-Total	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Ear pain	2 (3.5)	2 (3.5)	0	0	0
Hypoacusis	1 (1.8)	0	1 (1.8)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tympanic membrane perforation	1 (1.8)	0	1 (1.8)	0	0
Endocrine disorders					
-Total	1 (1.8)	0	1 (1.8)	0	0
Adrenal insufficiency	1 (1.8)	0	1 (1.8)	0	0
Eye disorders					
-Total	17 (29.8)	9 (15.8)	8 (14.0)	0	0
Periorbital oedema	4 (7.0)	3 (5.3)	1 (1.8)	0	0
Vision blurred	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Conjunctival haemorrhage	3 (5.3)	3 (5.3)	0	0	0
Dry eye	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Eye pain	2 (3.5)	0	2 (3.5)	0	0
Photophobia	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Retinal haemorrhage	2 (3.5)	2 (3.5)	0	0	0
Uveitis	2 (3.5)	0	2 (3.5)	0	0
Conjunctivitis allergic	1 (1.8)	1 (1.8)	0	0	0
Ocular hyperaemia	1 (1.8)	1 (1.8)	0	0	0
Ocular hypertension	1 (1.8)	0	1 (1.8)	0	0
Papilloedema	1 (1.8)	0	1 (1.8)	0	0
Visual impairment	1 (1.8)	0	1 (1.8)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	37 (64.9)	11 (19.3)	16 (28.1)	10 (17.5)	0
Vomiting	22 (38.6)	13 (22.8)	6 (10.5)	3 (5.3)	0
Nausea	21 (36.8)	5 (8.8)	12 (21.1)	4 (7.0)	0
Diarrhoea	20 (35.1)	10 (17.5)	8 (14.0)	2 (3.5)	0
Abdominal pain	10 (17.5)	5 (8.8)	4 (7.0)	1 (1.8)	0
Constipation	6 (10.5)	5 (8.8)	1 (1.8)	0	0
Abdominal pain upper	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Abdominal distension	2 (3.5)	0	2 (3.5)	0	0
Dysphagia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Haematemesis	2 (3.5)	2 (3.5)	0	0	0
Pancreatitis	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Stomatitis	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Abdominal discomfort	1 (1.8)	1 (1.8)	0	0	0
Abdominal pain lower	1 (1.8)	0	1 (1.8)	0	0
Abdominal tenderness	1 (1.8)	1 (1.8)	0	0	0
Anal incontinence	1 (1.8)	1 (1.8)	0	0	0
Ascites	1 (1.8)	0	0	1 (1.8)	0
Dyspepsia	1 (1.8)	0	1 (1.8)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flatulence	1 (1.8)	1 (1.8)	0	0	0
Gastrointestinal haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Gastrooesophageal reflux disease	1 (1.8)	1 (1.8)	0	0	0
Glossodynia	1 (1.8)	1 (1.8)	0	0	0
Ileus	1 (1.8)	0	0	1 (1.8)	0
Intestinal obstruction	1 (1.8)	0	0	1 (1.8)	0
Lip pain	1 (1.8)	0	1 (1.8)	0	0
Mouth haemorrhage	1 (1.8)	0	0	1 (1.8)	0
Pigmentation lip	1 (1.8)	1 (1.8)	0	0	0
Tooth socket haemorrhage	1 (1.8)	1 (1.8)	0	0	0
General disorders and administration site conditions					
-Total	37 (64.9)	15 (26.3)	13 (22.8)	9 (15.8)	0
Pyrexia	21 (36.8)	7 (12.3)	9 (15.8)	5 (8.8)	0
Fatigue	14 (24.6)	11 (19.3)	2 (3.5)	1 (1.8)	0
Chills	9 (15.8)	8 (14.0)	1 (1.8)	0	0
Malaise	4 (7.0)	1 (1.8)	3 (5.3)	0	0
Catheter site pain	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Generalised oedema	3 (5.3)	1 (1.8)	2 (3.5)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=57		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	3 (5.3)	2 (3.5)	0	1 (1.8)	0
Pain	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Face oedema	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Influenza like illness	2 (3.5)	2 (3.5)	0	0	0
Acquired gene mutation	1 (1.8)	1 (1.8)	0	0	0
Catheter site extravasation	1 (1.8)	0	1 (1.8)	0	0
Catheter site haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Crying	1 (1.8)	1 (1.8)	0	0	0
Cyst	1 (1.8)	0	0	1 (1.8)	0
Facial pain	1 (1.8)	0	1 (1.8)	0	0
Injection site haematoma	1 (1.8)	1 (1.8)	0	0	0
Localised oedema	1 (1.8)	0	0	1 (1.8)	0
Mucosal haemorrhage	1 (1.8)	0	1 (1.8)	0	0
Multiple organ dysfunction syndrome	1 (1.8)	0	0	1 (1.8)	0
Non-cardiac chest pain	1 (1.8)	1 (1.8)	0	0	0
Peripheral swelling	1 (1.8)	0	1 (1.8)	0	0
Physical deconditioning	1 (1.8)	0	0	1 (1.8)	0
Hepatobiliary disorders					

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (10.5)	3 (5.3)	1 (1.8)	2 (3.5)	0
Hyperbilirubinaemia	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Hepatomegaly	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Gallbladder enlargement	1 (1.8)	1 (1.8)	0	0	0
Hepatosplenomegaly	1 (1.8)	1 (1.8)	0	0	0
Immune system disorders					
-Total	51 (89.5)	5 (8.8)	27 (47.4)	11 (19.3)	8 (14.0)
Cytokine release syndrome	45 (78.9)	6 (10.5)	23 (40.4)	8 (14.0)	8 (14.0)
Hypogammaglobulinaemia	28 (49.1)	3 (5.3)	20 (35.1)	5 (8.8)	0
Immunodeficiency common variable	2 (3.5)	0	2 (3.5)	0	0
Seasonal allergy	2 (3.5)	2 (3.5)	0	0	0
Chronic graft versus host disease	1 (1.8)	0	1 (1.8)	0	0
Drug hypersensitivity	1 (1.8)	0	1 (1.8)	0	0
Graft versus host disease	1 (1.8)	1 (1.8)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (1.8)	0	1 (1.8)	0	0
Graft versus host disease in skin	1 (1.8)	1 (1.8)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.8)	0	1 (1.8)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency	1 (1.8)	0	1 (1.8)	0	0
Infections and infestations					
-Total	42 (73.7)	6 (10.5)	19 (33.3)	13 (22.8)	4 (7.0)
Upper respiratory tract infection	7 (12.3)	4 (7.0)	2 (3.5)	1 (1.8)	0
Clostridium difficile infection	5 (8.8)	0	4 (7.0)	1 (1.8)	0
Urinary tract infection	5 (8.8)	0	3 (5.3)	2 (3.5)	0
Clostridium difficile colitis	4 (7.0)	1 (1.8)	2 (3.5)	1 (1.8)	0
Gastroenteritis	4 (7.0)	1 (1.8)	2 (3.5)	1 (1.8)	0
Influenza	4 (7.0)	1 (1.8)	3 (5.3)	0	0
Otitis media	4 (7.0)	0	3 (5.3)	1 (1.8)	0
Pneumonia	4 (7.0)	0	3 (5.3)	1 (1.8)	0
Rhinovirus infection	4 (7.0)	4 (7.0)	0	0	0
Sinusitis	4 (7.0)	0	4 (7.0)	0	0
Viral upper respiratory tract infection	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Cytomegalovirus infection	2 (3.5)	2 (3.5)	0	0	0
Otitis media acute	2 (3.5)	0	2 (3.5)	0	0
Parainfluenzae virus infection	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Staphylococcal infection	2 (3.5)	1 (1.8)	0	1 (1.8)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal candidiasis	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Acute sinusitis	1 (1.8)	0	1 (1.8)	0	0
Bacterial sepsis	1 (1.8)	0	0	0	1 (1.8)
Body tinea	1 (1.8)	1 (1.8)	0	0	0
Campylobacter infection	1 (1.8)	0	0	1 (1.8)	0
Catheter site cellulitis	1 (1.8)	1 (1.8)	0	0	0
Catheter site infection	1 (1.8)	0	0	1 (1.8)	0
Cellulitis of male external genital organ	1 (1.8)	0	0	1 (1.8)	0
Cholecystitis infective	1 (1.8)	0	0	1 (1.8)	0
Ear infection	1 (1.8)	0	1 (1.8)	0	0
Enterococcal infection	1 (1.8)	1 (1.8)	0	0	0
Enterovirus infection	1 (1.8)	0	0	1 (1.8)	0
Escherichia urinary tract infection	1 (1.8)	0	0	1 (1.8)	0
Folliculitis	1 (1.8)	0	1 (1.8)	0	0
Fungal skin infection	1 (1.8)	1 (1.8)	0	0	0
Gastroenteritis norovirus	1 (1.8)	0	1 (1.8)	0	0
Gastroenteritis viral	1 (1.8)	1 (1.8)	0	0	0
Gingivitis	1 (1.8)	1 (1.8)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophilus infection	1 (1.8)	0	1 (1.8)	0	0
Herpes simplex	1 (1.8)	1 (1.8)	0	0	0
Herpes zoster	1 (1.8)	0	0	1 (1.8)	0
Human herpesvirus 6 infection	1 (1.8)	0	1 (1.8)	0	0
Hypopyon	1 (1.8)	0	1 (1.8)	0	0
Meningitis aseptic	1 (1.8)	0	1 (1.8)	0	0
Molluscum contagiosum	1 (1.8)	1 (1.8)	0	0	0
Oral candidiasis	1 (1.8)	1 (1.8)	0	0	0
Oral herpes	1 (1.8)	0	1 (1.8)	0	0
Orchitis	1 (1.8)	1 (1.8)	0	0	0
Otitis externa	1 (1.8)	0	1 (1.8)	0	0
Paronychia	1 (1.8)	1 (1.8)	0	0	0
Pharyngitis	1 (1.8)	0	1 (1.8)	0	0
Rash pustular	1 (1.8)	0	1 (1.8)	0	0
Respiratory tract infection	1 (1.8)	0	0	0	1 (1.8)
Respiratory tract infection viral	1 (1.8)	0	0	1 (1.8)	0
Rhinitis	1 (1.8)	1 (1.8)	0	0	0
Rotavirus infection	1 (1.8)	0	0	1 (1.8)	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic embolus	1 (1.8)	0	0	0	1 (1.8)
Skin infection	1 (1.8)	0	1 (1.8)	0	0
Streptococcal infection	1 (1.8)	0	1 (1.8)	0	0
Subcutaneous abscess	1 (1.8)	0	1 (1.8)	0	0
Urinary tract infection enterococcal	1 (1.8)	0	0	1 (1.8)	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Viral infection	1 (1.8)	1 (1.8)	0	0	0
Vulvovaginal mycotic infection	1 (1.8)	0	1 (1.8)	0	0
Injury, poisoning and procedural complications					
-Total	20 (35.1)	11 (19.3)	7 (12.3)	1 (1.8)	1 (1.8)
Procedural pain	5 (8.8)	2 (3.5)	2 (3.5)	1 (1.8)	0
Infusion related reaction	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Transfusion reaction	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Contusion	2 (3.5)	2 (3.5)	0	0	0
Skin abrasion	2 (3.5)	2 (3.5)	0	0	0
Arthropod bite	1 (1.8)	1 (1.8)	0	0	0
Foot fracture	1 (1.8)	0	1 (1.8)	0	0
Incision site pain	1 (1.8)	1 (1.8)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Limb injury	1 (1.8)	1 (1.8)	0	0	0
Mouth injury	1 (1.8)	1 (1.8)	0	0	0
Post procedural haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Procedural complication	1 (1.8)	1 (1.8)	0	0	0
Procedural headache	1 (1.8)	0	1 (1.8)	0	0
Procedural site reaction	1 (1.8)	1 (1.8)	0	0	0
Radius fracture	1 (1.8)	0	1 (1.8)	0	0
Skin laceration	1 (1.8)	0	1 (1.8)	0	0
Stoma site irritation	1 (1.8)	1 (1.8)	0	0	0
Subdural haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Tibia fracture	1 (1.8)	0	1 (1.8)	0	0
Tongue injury	1 (1.8)	1 (1.8)	0	0	0
Transfusion related complication	1 (1.8)	0	0	0	1 (1.8)
Investigations					
-Total	49 (86.0)	2 (3.5)	4 (7.0)	13 (22.8)	30 (52.6)
White blood cell count decreased	31 (54.4)	3 (5.3)	1 (1.8)	12 (21.1)	15 (26.3)
Neutrophil count decreased	24 (42.1)	1 (1.8)	1 (1.8)	4 (7.0)	18 (31.6)
Alanine aminotransferase increased	21 (36.8)	5 (8.8)	2 (3.5)	14 (24.6)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	20 (35.1)	3 (5.3)	2 (3.5)	3 (5.3)	12 (21.1)
Aspartate aminotransferase increased	19 (33.3)	4 (7.0)	4 (7.0)	8 (14.0)	3 (5.3)
Lymphocyte count decreased	14 (24.6)	0	2 (3.5)	7 (12.3)	5 (8.8)
Blood creatinine increased	8 (14.0)	5 (8.8)	1 (1.8)	2 (3.5)	0
International normalised ratio increased	8 (14.0)	7 (12.3)	0	1 (1.8)	0
Prothrombin time prolonged	8 (14.0)	5 (8.8)	2 (3.5)	1 (1.8)	0
Blood bilirubin increased	7 (12.3)	2 (3.5)	3 (5.3)	2 (3.5)	0
Activated partial thromboplastin time prolonged	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Blood fibrinogen decreased	3 (5.3)	0	0	2 (3.5)	1 (1.8)
Blood immunoglobulin a decreased	3 (5.3)	3 (5.3)	0	0	0
Blood immunoglobulin m decreased	3 (5.3)	3 (5.3)	0	0	0
Blood urea increased	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Haemoglobin decreased	3 (5.3)	2 (3.5)	0	1 (1.8)	0
Transaminases increased	3 (5.3)	3 (5.3)	0	0	0
Weight decreased	3 (5.3)	0	3 (5.3)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Lipase increased	2 (3.5)	0	0	0	2 (3.5)
Serum ferritin increased	2 (3.5)	0	2 (3.5)	0	0
Weight increased	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Blood alkaline phosphatase increased	1 (1.8)	1 (1.8)	0	0	0
Blood bicarbonate decreased	1 (1.8)	0	1 (1.8)	0	0
Blood immunoglobulin g decreased	1 (1.8)	0	1 (1.8)	0	0
Blood lactate dehydrogenase increased	1 (1.8)	1 (1.8)	0	0	0
Blood lactic acid increased	1 (1.8)	0	0	0	1 (1.8)
Blood phosphorus decreased	1 (1.8)	1 (1.8)	0	0	0
Blood phosphorus increased	1 (1.8)	1 (1.8)	0	0	0
Blood sodium increased	1 (1.8)	0	1 (1.8)	0	0
Blood uric acid increased	1 (1.8)	1 (1.8)	0	0	0
Culture stool positive	1 (1.8)	1 (1.8)	0	0	0
Hepatic enzyme increased	1 (1.8)	0	1 (1.8)	0	0
Norovirus test positive	1 (1.8)	1 (1.8)	0	0	0
Oxygen saturation decreased	1 (1.8)	1 (1.8)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Protein total decreased	1 (1.8)	0	0	1 (1.8)	0
Pulmonary function test decreased	1 (1.8)	0	1 (1.8)	0	0
Metabolism and nutrition disorders					
-Total	39 (68.4)	7 (12.3)	6 (10.5)	22 (38.6)	4 (7.0)
Decreased appetite	19 (33.3)	4 (7.0)	4 (7.0)	11 (19.3)	0
Hypokalaemia	17 (29.8)	3 (5.3)	5 (8.8)	8 (14.0)	1 (1.8)
Hypophosphataemia	9 (15.8)	2 (3.5)	0	6 (10.5)	1 (1.8)
Hyperphosphataemia	8 (14.0)	8 (14.0)	0	0	0
Dehydration	4 (7.0)	1 (1.8)	0	3 (5.3)	0
Hypoalbuminaemia	4 (7.0)	0	3 (5.3)	1 (1.8)	0
Fluid overload	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Hyperglycaemia	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Hypernatraemia	3 (5.3)	1 (1.8)	1 (1.8)	0	1 (1.8)
Hyperuricaemia	3 (5.3)	2 (3.5)	0	0	1 (1.8)
Hypocalcaemia	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Acidosis	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Hypertriglyceridaemia	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Hyponatraemia	2 (3.5)	0	0	2 (3.5)	0
Tumour lysis syndrome	2 (3.5)	0	0	2 (3.5)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vitamin d deficiency	2 (3.5)	2 (3.5)	0	0	0
Hyperalbuminaemia	1 (1.8)	1 (1.8)	0	0	0
Hypercalcaemia	1 (1.8)	1 (1.8)	0	0	0
Hyperchloraemia	1 (1.8)	1 (1.8)	0	0	0
Hypermagnesaemia	1 (1.8)	1 (1.8)	0	0	0
Hypomagnesaemia	1 (1.8)	1 (1.8)	0	0	0
Iron overload	1 (1.8)	0	0	1 (1.8)	0
Malnutrition	1 (1.8)	0	0	1 (1.8)	0
Metabolic acidosis	1 (1.8)	0	1 (1.8)	0	0
Metabolic alkalosis	1 (1.8)	1 (1.8)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	22 (38.6)	12 (21.1)	10 (17.5)	0	0
Pain in extremity	9 (15.8)	5 (8.8)	4 (7.0)	0	0
Myalgia	5 (8.8)	4 (7.0)	1 (1.8)	0	0
Arthralgia	4 (7.0)	3 (5.3)	1 (1.8)	0	0
Musculoskeletal pain	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Joint range of motion decreased	2 (3.5)	2 (3.5)	0	0	0
Muscle spasms	2 (3.5)	2 (3.5)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Musculoskeletal chest pain	2 (3.5)	2 (3.5)	0	0	0
Back pain	1 (1.8)	1 (1.8)	0	0	0
Coccydynia	1 (1.8)	1 (1.8)	0	0	0
Flank pain	1 (1.8)	0	1 (1.8)	0	0
Limb discomfort	1 (1.8)	1 (1.8)	0	0	0
Neck pain	1 (1.8)	0	1 (1.8)	0	0
Osteonecrosis	1 (1.8)	0	1 (1.8)	0	0
Osteopenia	1 (1.8)	0	1 (1.8)	0	0
Toe walking	1 (1.8)	1 (1.8)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (5.3)	0	2 (3.5)	0	1 (1.8)
Glioblastoma multiforme	1 (1.8)	0	0	0	1 (1.8)
Myelodysplastic syndrome	1 (1.8)	0	1 (1.8)	0	0
Skin papilloma	1 (1.8)	0	1 (1.8)	0	0
Nervous system disorders					
-Total	31 (54.4)	13 (22.8)	12 (21.1)	5 (8.8)	1 (1.8)
Headache	21 (36.8)	12 (21.1)	7 (12.3)	2 (3.5)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dizziness	5 (8.8)	5 (8.8)	0	0	0
Encephalopathy	4 (7.0)	1 (1.8)	1 (1.8)	2 (3.5)	0
Seizure	4 (7.0)	0	2 (3.5)	2 (3.5)	0
Dysarthria	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Tremor	2 (3.5)	2 (3.5)	0	0	0
Asterixis	1 (1.8)	1 (1.8)	0	0	0
Ataxia	1 (1.8)	0	1 (1.8)	0	0
Depressed level of consciousness	1 (1.8)	1 (1.8)	0	0	0
Disturbance in attention	1 (1.8)	1 (1.8)	0	0	0
Embolic stroke	1 (1.8)	0	0	0	1 (1.8)
Idiopathic intracranial hypertension	1 (1.8)	0	1 (1.8)	0	0
Migraine	1 (1.8)	0	1 (1.8)	0	0
Myoclonus	1 (1.8)	1 (1.8)	0	0	0
Neuropathy peripheral	1 (1.8)	0	1 (1.8)	0	0
Peroneal nerve palsy	1 (1.8)	0	1 (1.8)	0	0
Pleocytosis	1 (1.8)	1 (1.8)	0	0	0
Somnolence	1 (1.8)	1 (1.8)	0	0	0
Product issues					
-Total	1 (1.8)	1 (1.8)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device occlusion	1 (1.8)	1 (1.8)	0	0	0
Psychiatric disorders					
-Total	14 (24.6)	7 (12.3)	6 (10.5)	1 (1.8)	0
Anxiety	6 (10.5)	2 (3.5)	3 (5.3)	1 (1.8)	0
Confusional state	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Delirium	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Agitation	2 (3.5)	0	2 (3.5)	0	0
Hallucination	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Irritability	2 (3.5)	2 (3.5)	0	0	0
Adjustment disorder	1 (1.8)	0	1 (1.8)	0	0
Depression	1 (1.8)	1 (1.8)	0	0	0
Insomnia	1 (1.8)	0	1 (1.8)	0	0
Listless	1 (1.8)	1 (1.8)	0	0	0
Mental status changes	1 (1.8)	1 (1.8)	0	0	0
Panic attack	1 (1.8)	0	1 (1.8)	0	0
Suicidal ideation	1 (1.8)	1 (1.8)	0	0	0
Renal and urinary disorders					
-Total	13 (22.8)	3 (5.3)	2 (3.5)	6 (10.5)	2 (3.5)
Acute kidney injury	8 (14.0)	1 (1.8)	1 (1.8)	4 (7.0)	2 (3.5)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Dysuria	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Calculus urinary	1 (1.8)	0	1 (1.8)	0	0
Nephrolithiasis	1 (1.8)	0	0	1 (1.8)	0
Oliguria	1 (1.8)	0	0	1 (1.8)	0
Pollakiuria	1 (1.8)	1 (1.8)	0	0	0
Renal impairment	1 (1.8)	0	0	1 (1.8)	0
Urinary incontinence	1 (1.8)	1 (1.8)	0	0	0
Reproductive system and breast disorders					
-Total	6 (10.5)	2 (3.5)	2 (3.5)	2 (3.5)	0
Vulvovaginal adhesion	2 (3.5)	2 (3.5)	0	0	0
Oedema genital	1 (1.8)	0	1 (1.8)	0	0
Ovarian failure	1 (1.8)	0	0	1 (1.8)	0
Scrotal pain	1 (1.8)	0	1 (1.8)	0	0
Vaginal haemorrhage	1 (1.8)	0	0	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders					
-Total	32 (56.1)	12 (21.1)	8 (14.0)	6 (10.5)	6 (10.5)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	11 (19.3)	9 (15.8)	2 (3.5)	0	0
Epistaxis	8 (14.0)	4 (7.0)	1 (1.8)	3 (5.3)	0
Hypoxia	8 (14.0)	0	3 (5.3)	3 (5.3)	2 (3.5)
Pleural effusion	7 (12.3)	2 (3.5)	3 (5.3)	2 (3.5)	0
Pulmonary oedema	6 (10.5)	1 (1.8)	0	4 (7.0)	1 (1.8)
Oropharyngeal pain	5 (8.8)	4 (7.0)	1 (1.8)	0	0
Tachypnoea	5 (8.8)	3 (5.3)	1 (1.8)	1 (1.8)	0
Nasal congestion	4 (7.0)	4 (7.0)	0	0	0
Rhinitis allergic	4 (7.0)	3 (5.3)	1 (1.8)	0	0
Rhinorrhoea	4 (7.0)	4 (7.0)	0	0	0
Respiratory failure	2 (3.5)	0	0	0	2 (3.5)
Acute respiratory failure	1 (1.8)	0	0	0	1 (1.8)
Atelectasis	1 (1.8)	1 (1.8)	0	0	0
Dysphonia	1 (1.8)	1 (1.8)	0	0	0
Dyspnoea	1 (1.8)	0	0	1 (1.8)	0
Haemoptysis	1 (1.8)	1 (1.8)	0	0	0
Oropharyngeal plaque	1 (1.8)	1 (1.8)	0	0	0
Pharyngeal ulceration	1 (1.8)	0	1 (1.8)	0	0
Respiratory depression	1 (1.8)	0	1 (1.8)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	1 (1.8)	0	0	0	1 (1.8)
Wheezing	1 (1.8)	0	1 (1.8)	0	0
Skin and subcutaneous tissue disorders					
-Total	26 (45.6)	15 (26.3)	8 (14.0)	3 (5.3)	0
Rash	8 (14.0)	5 (8.8)	3 (5.3)	0	0
Dry skin	4 (7.0)	4 (7.0)	0	0	0
Hyperhidrosis	4 (7.0)	4 (7.0)	0	0	0
Petechiae	4 (7.0)	3 (5.3)	1 (1.8)	0	0
Pruritus	4 (7.0)	4 (7.0)	0	0	0
Rash maculo-papular	4 (7.0)	2 (3.5)	1 (1.8)	1 (1.8)	0
Erythema	3 (5.3)	3 (5.3)	0	0	0
Ingrowing nail	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Macule	2 (3.5)	2 (3.5)	0	0	0
Papule	2 (3.5)	2 (3.5)	0	0	0
Rash papular	2 (3.5)	2 (3.5)	0	0	0
Acne	1 (1.8)	1 (1.8)	0	0	0
Dermatitis	1 (1.8)	1 (1.8)	0	0	0
Dermatitis acneiform	1 (1.8)	0	0	1 (1.8)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dermatitis atopic	1 (1.8)	1 (1.8)	0	0	0
Ecchymosis	1 (1.8)	0	0	1 (1.8)	0
Eczema	1 (1.8)	1 (1.8)	0	0	0
Keloid scar	1 (1.8)	0	1 (1.8)	0	0
Night sweats	1 (1.8)	0	1 (1.8)	0	0
Rash erythematous	1 (1.8)	1 (1.8)	0	0	0
Rash follicular	1 (1.8)	1 (1.8)	0	0	0
Rash macular	1 (1.8)	1 (1.8)	0	0	0
Rash pruritic	1 (1.8)	1 (1.8)	0	0	0
Rash vesicular	1 (1.8)	1 (1.8)	0	0	0
Skin exfoliation	1 (1.8)	1 (1.8)	0	0	0
Skin fissures	1 (1.8)	1 (1.8)	0	0	0
Skin irritation	1 (1.8)	1 (1.8)	0	0	0
Vascular disorders					
-Total	20 (35.1)	3 (5.3)	5 (8.8)	6 (10.5)	6 (10.5)
Hypotension	12 (21.1)	1 (1.8)	0	5 (8.8)	6 (10.5)
Hypertension	9 (15.8)	2 (3.5)	6 (10.5)	1 (1.8)	0
Flushing	2 (3.5)	2 (3.5)	0	0	0
Orthostatic hypotension	2 (3.5)	1 (1.8)	1 (1.8)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Capillary leak syndrome	1 (1.8)	0	0	0	1 (1.8)
Embolism	1 (1.8)	0	0	1 (1.8)	0
Secondary hypertension	1 (1.8)	0	1 (1.8)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174f
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	1 (50.0)	1 (50.0)	0	0
Blood and lymphatic system disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Anaemia	1 (50.0)	0	1 (50.0)	0	0
General disorders and administration site conditions					
-Total	1 (50.0)	1 (50.0)	0	0	0
Fatigue	1 (50.0)	1 (50.0)	0	0	0
Immune system disorders					
-Total	2 (100)	1 (50.0)	1 (50.0)	0	0
Graft versus host disease in skin	1 (50.0)	1 (50.0)	0	0	0
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	1 (50.0)	1 (50.0)	0	0	0
Skin abrasion	1 (50.0)	1 (50.0)	0	0	0
Investigations					
-Total	1 (50.0)	0	1 (50.0)	0	0
Blood immunoglobulin a decreased	1 (50.0)	1 (50.0)	0	0	0
International normalised ratio increased	1 (50.0)	1 (50.0)	0	0	0
Lymphocyte count decreased	1 (50.0)	0	1 (50.0)	0	0
Neutrophil count decreased	1 (50.0)	0	1 (50.0)	0	0
White blood cell count decreased	1 (50.0)	0	1 (50.0)	0	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Hyperphosphataemia	1 (50.0)	1 (50.0)	0	0	0
Hyperuricaemia	1 (50.0)	1 (50.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Arthralgia	1 (50.0)	1 (50.0)	0	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	1 (50.0)	1 (50.0)	0	0	0
Pain in extremity	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					
-Total	2 (100)	2 (100)	0	0	0
Headache	2 (100)	2 (100)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Cough	1 (50.0)	1 (50.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Skin irritation	1 (50.0)	1 (50.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174f
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	61 (98.4)	1 (1.6)	6 (9.7)	14 (22.6)	40 (64.5)
Blood and lymphatic system disorders					
-Total	42 (67.7)	2 (3.2)	2 (3.2)	27 (43.5)	11 (17.7)
Anaemia	26 (41.9)	3 (4.8)	4 (6.5)	18 (29.0)	1 (1.6)
Febrile neutropenia	22 (35.5)	0	0	22 (35.5)	0
Neutropenia	8 (12.9)	0	0	3 (4.8)	5 (8.1)
Thrombocytopenia	8 (12.9)	0	0	2 (3.2)	6 (9.7)
Disseminated intravascular coagulation	4 (6.5)	0	2 (3.2)	2 (3.2)	0
Lymphopenia	3 (4.8)	0	1 (1.6)	1 (1.6)	1 (1.6)
Coagulopathy	1 (1.6)	1 (1.6)	0	0	0
Pancytopenia	1 (1.6)	0	0	0	1 (1.6)
Cardiac disorders					

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	22 (35.5)	11 (17.7)	9 (14.5)	2 (3.2)	0
Tachycardia	15 (24.2)	8 (12.9)	5 (8.1)	2 (3.2)	0
Sinus tachycardia	5 (8.1)	3 (4.8)	2 (3.2)	0	0
Pericardial effusion	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Atrioventricular block second degree	1 (1.6)	1 (1.6)	0	0	0
Bradycardia	1 (1.6)	0	1 (1.6)	0	0
Cardiac dysfunction	1 (1.6)	1 (1.6)	0	0	0
Left ventricular dysfunction	1 (1.6)	0	0	1 (1.6)	0
Palpitations	1 (1.6)	1 (1.6)	0	0	0
Sinus bradycardia	1 (1.6)	1 (1.6)	0	0	0
Ventricular tachycardia	1 (1.6)	0	1 (1.6)	0	0
Ear and labyrinth disorders					
-Total	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Ear pain	2 (3.2)	2 (3.2)	0	0	0
Hypoacusis	1 (1.6)	0	1 (1.6)	0	0
Endocrine disorders					
-Total	1 (1.6)	0	1 (1.6)	0	0
Adrenal insufficiency	1 (1.6)	0	1 (1.6)	0	0
Eye disorders					

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (21.0)	6 (9.7)	7 (11.3)	0	0
Periorbital oedema	4 (6.5)	3 (4.8)	1 (1.6)	0	0
Conjunctival haemorrhage	3 (4.8)	3 (4.8)	0	0	0
Eye pain	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Vision blurred	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Photophobia	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Retinal haemorrhage	2 (3.2)	2 (3.2)	0	0	0
Uveitis	2 (3.2)	0	2 (3.2)	0	0
Ocular hypertension	1 (1.6)	0	1 (1.6)	0	0
Papilloedema	1 (1.6)	0	1 (1.6)	0	0
Visual impairment	1 (1.6)	0	1 (1.6)	0	0
Gastrointestinal disorders					
-Total	36 (58.1)	11 (17.7)	14 (22.6)	11 (17.7)	0
Vomiting	22 (35.5)	13 (21.0)	6 (9.7)	3 (4.8)	0
Nausea	21 (33.9)	6 (9.7)	12 (19.4)	3 (4.8)	0
Diarrhoea	18 (29.0)	11 (17.7)	6 (9.7)	1 (1.6)	0
Abdominal pain	9 (14.5)	6 (9.7)	2 (3.2)	1 (1.6)	0
Constipation	7 (11.3)	6 (9.7)	1 (1.6)	0	0
Abdominal distension	2 (3.2)	0	2 (3.2)	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain upper	2 (3.2)	0	2 (3.2)	0	0
Dysphagia	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Haematemesis	2 (3.2)	2 (3.2)	0	0	0
Pancreatitis	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Stomatitis	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Abdominal discomfort	1 (1.6)	1 (1.6)	0	0	0
Abdominal pain lower	1 (1.6)	0	1 (1.6)	0	0
Abdominal tenderness	1 (1.6)	1 (1.6)	0	0	0
Anal incontinence	1 (1.6)	1 (1.6)	0	0	0
Ascites	1 (1.6)	0	0	1 (1.6)	0
Dyspepsia	1 (1.6)	0	1 (1.6)	0	0
Flatulence	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Gastrooesophageal reflux disease	1 (1.6)	1 (1.6)	0	0	0
Glossodynia	1 (1.6)	1 (1.6)	0	0	0
Ileus	1 (1.6)	0	0	1 (1.6)	0
Intestinal obstruction	1 (1.6)	0	0	1 (1.6)	0
Lip pain	1 (1.6)	0	1 (1.6)	0	0
Mouth haemorrhage	1 (1.6)	0	0	1 (1.6)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tooth socket haemorrhage	1 (1.6)	1 (1.6)	0	0	0
General disorders and administration site conditions					
-Total	31 (50.0)	11 (17.7)	10 (16.1)	9 (14.5)	1 (1.6)
Pyrexia	16 (25.8)	3 (4.8)	7 (11.3)	5 (8.1)	1 (1.6)
Fatigue	12 (19.4)	9 (14.5)	2 (3.2)	1 (1.6)	0
Chills	8 (12.9)	8 (12.9)	0	0	0
Catheter site pain	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Malaise	3 (4.8)	0	3 (4.8)	0	0
Pain	3 (4.8)	0	1 (1.6)	2 (3.2)	0
Face oedema	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Generalised oedema	2 (3.2)	0	2 (3.2)	0	0
Oedema peripheral	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Asthenia	1 (1.6)	1 (1.6)	0	0	0
Catheter site extravasation	1 (1.6)	0	1 (1.6)	0	0
Catheter site haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Facial pain	1 (1.6)	0	1 (1.6)	0	0
Injection site haematoma	1 (1.6)	1 (1.6)	0	0	0
Localised oedema	1 (1.6)	0	0	1 (1.6)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mucosal haemorrhage	1 (1.6)	0	1 (1.6)	0	0
Multiple organ dysfunction syndrome	1 (1.6)	0	0	1 (1.6)	0
Non-cardiac chest pain	1 (1.6)	1 (1.6)	0	0	0
Peripheral swelling	1 (1.6)	0	1 (1.6)	0	0
Physical deconditioning	1 (1.6)	0	0	1 (1.6)	0
Hepatobiliary disorders					
-Total	7 (11.3)	3 (4.8)	2 (3.2)	2 (3.2)	0
Hepatomegaly	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Hyperbilirubinaemia	3 (4.8)	0	1 (1.6)	2 (3.2)	0
Gallbladder enlargement	1 (1.6)	1 (1.6)	0	0	0
Hepatosplenomegaly	1 (1.6)	1 (1.6)	0	0	0
Immune system disorders					
-Total	55 (88.7)	4 (6.5)	29 (46.8)	11 (17.7)	11 (17.7)
Cytokine release syndrome	50 (80.6)	6 (9.7)	25 (40.3)	8 (12.9)	11 (17.7)
Hypogammaglobulinaemia	24 (38.7)	3 (4.8)	17 (27.4)	4 (6.5)	0
Drug hypersensitivity	1 (1.6)	0	1 (1.6)	0	0
Haemophagocytic lymphohistiocytosis	1 (1.6)	0	1 (1.6)	0	0
Infections and infestations					

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	26 (41.9)	5 (8.1)	14 (22.6)	6 (9.7)	1 (1.6)
Clostridium difficile colitis	4 (6.5)	1 (1.6)	2 (3.2)	1 (1.6)	0
Clostridium difficile infection	4 (6.5)	0	4 (6.5)	0	0
Rhinovirus infection	3 (4.8)	3 (4.8)	0	0	0
Gastroenteritis	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Pneumonia	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Staphylococcal infection	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Body tinea	1 (1.6)	1 (1.6)	0	0	0
Catheter site cellulitis	1 (1.6)	1 (1.6)	0	0	0
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cytomegalovirus infection	1 (1.6)	1 (1.6)	0	0	0
Enterococcal infection	1 (1.6)	1 (1.6)	0	0	0
Folliculitis	1 (1.6)	0	1 (1.6)	0	0
Fungal skin infection	1 (1.6)	1 (1.6)	0	0	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Herpes simplex	1 (1.6)	1 (1.6)	0	0	0
Human herpesvirus 6 infection	1 (1.6)	0	1 (1.6)	0	0
Hypopyon	1 (1.6)	0	1 (1.6)	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	1 (1.6)	0	0	0
Orchitis	1 (1.6)	1 (1.6)	0	0	0
Pharyngitis	1 (1.6)	0	1 (1.6)	0	0
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Skin infection	1 (1.6)	0	1 (1.6)	0	0
Streptococcal infection	1 (1.6)	0	1 (1.6)	0	0
Upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Urinary tract infection enterococcal	1 (1.6)	0	0	1 (1.6)	0
Viral infection	1 (1.6)	0	1 (1.6)	0	0
Viral upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Vulvovaginal candidiasis	1 (1.6)	1 (1.6)	0	0	0
Injury, poisoning and procedural complications					
-Total	14 (22.6)	7 (11.3)	5 (8.1)	1 (1.6)	1 (1.6)
Procedural pain	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Transfusion reaction	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Infusion related reaction	2 (3.2)	0	2 (3.2)	0	0
Contusion	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Incision site pain	1 (1.6)	1 (1.6)	0	0	0
Limb injury	1 (1.6)	1 (1.6)	0	0	0
Mouth injury	1 (1.6)	1 (1.6)	0	0	0
Post procedural haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Procedural complication	1 (1.6)	1 (1.6)	0	0	0
Procedural headache	1 (1.6)	0	1 (1.6)	0	0
Procedural site reaction	1 (1.6)	1 (1.6)	0	0	0
Stoma site irritation	1 (1.6)	1 (1.6)	0	0	0
Subdural haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Tibia fracture	1 (1.6)	0	1 (1.6)	0	0
Tongue injury	1 (1.6)	1 (1.6)	0	0	0
Tracheal haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Transfusion related complication	1 (1.6)	0	0	0	1 (1.6)
Investigations					
-Total	51 (82.3)	4 (6.5)	3 (4.8)	13 (21.0)	31 (50.0)
White blood cell count decreased	29 (46.8)	3 (4.8)	0	10 (16.1)	16 (25.8)
Neutrophil count decreased	24 (38.7)	0	1 (1.6)	4 (6.5)	19 (30.6)
Alanine aminotransferase increased	19 (30.6)	5 (8.1)	3 (4.8)	11 (17.7)	0
Platelet count decreased	19 (30.6)	3 (4.8)	2 (3.2)	2 (3.2)	12 (19.4)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	18 (29.0)	3 (4.8)	4 (6.5)	7 (11.3)	4 (6.5)
Lymphocyte count decreased	13 (21.0)	1 (1.6)	1 (1.6)	6 (9.7)	5 (8.1)
Blood creatinine increased	9 (14.5)	5 (8.1)	2 (3.2)	2 (3.2)	0
Prothrombin time prolonged	9 (14.5)	5 (8.1)	3 (4.8)	1 (1.6)	0
International normalised ratio increased	8 (12.9)	7 (11.3)	0	1 (1.6)	0
Blood bilirubin increased	7 (11.3)	2 (3.2)	3 (4.8)	2 (3.2)	0
Activated partial thromboplastin time prolonged	5 (8.1)	3 (4.8)	2 (3.2)	0	0
Blood fibrinogen decreased	4 (6.5)	0	1 (1.6)	2 (3.2)	1 (1.6)
Blood immunoglobulin m decreased	4 (6.5)	4 (6.5)	0	0	0
Blood urea increased	3 (4.8)	1 (1.6)	1 (1.6)	1 (1.6)	0
Blood immunoglobulin a decreased	2 (3.2)	2 (3.2)	0	0	0
Blood phosphorus increased	2 (3.2)	2 (3.2)	0	0	0
Lipase increased	2 (3.2)	0	0	0	2 (3.2)
Transaminases increased	2 (3.2)	2 (3.2)	0	0	0
Blood bicarbonate decreased	1 (1.6)	0	1 (1.6)	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Blood lactic acid increased	1 (1.6)	0	0	0	1 (1.6)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood magnesium decreased	1 (1.6)	0	0	1 (1.6)	0
Blood phosphorus decreased	1 (1.6)	1 (1.6)	0	0	0
Blood sodium increased	1 (1.6)	0	1 (1.6)	0	0
Blood uric acid increased	1 (1.6)	1 (1.6)	0	0	0
C-reactive protein increased	1 (1.6)	0	0	1 (1.6)	0
Cardiac murmur	1 (1.6)	1 (1.6)	0	0	0
Culture stool positive	1 (1.6)	1 (1.6)	0	0	0
Fibrin d dimer increased	1 (1.6)	1 (1.6)	0	0	0
Haemoglobin decreased	1 (1.6)	0	0	1 (1.6)	0
Hepatic enzyme increased	1 (1.6)	0	1 (1.6)	0	0
Norovirus test positive	1 (1.6)	1 (1.6)	0	0	0
Protein total decreased	1 (1.6)	0	0	1 (1.6)	0
Pulmonary function test decreased	1 (1.6)	0	1 (1.6)	0	0
Serum ferritin increased	1 (1.6)	0	1 (1.6)	0	0
Metabolism and nutrition disorders					
-Total	38 (61.3)	4 (6.5)	10 (16.1)	21 (33.9)	3 (4.8)
Decreased appetite	20 (32.3)	4 (6.5)	4 (6.5)	12 (19.4)	0
Hypokalaemia	16 (25.8)	3 (4.8)	6 (9.7)	7 (11.3)	0
Hypophosphataemia	9 (14.5)	2 (3.2)	0	6 (9.7)	1 (1.6)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	7 (11.3)	7 (11.3)	0	0	0
Hypoalbuminaemia	5 (8.1)	1 (1.6)	3 (4.8)	1 (1.6)	0
Hypernatraemia	4 (6.5)	1 (1.6)	2 (3.2)	0	1 (1.6)
Dehydration	3 (4.8)	1 (1.6)	0	2 (3.2)	0
Fluid overload	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Hyperglycaemia	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Hypocalcaemia	3 (4.8)	1 (1.6)	1 (1.6)	1 (1.6)	0
Acidosis	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Hypertriglyceridaemia	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Hyperuricaemia	2 (3.2)	1 (1.6)	0	0	1 (1.6)
Hyponatraemia	2 (3.2)	0	0	2 (3.2)	0
Hyperalbuminaemia	1 (1.6)	1 (1.6)	0	0	0
Hypercalcaemia	1 (1.6)	1 (1.6)	0	0	0
Hyperchloraemia	1 (1.6)	1 (1.6)	0	0	0
Hypermagnesaemia	1 (1.6)	1 (1.6)	0	0	0
Hypomagnesaemia	1 (1.6)	1 (1.6)	0	0	0
Malnutrition	1 (1.6)	0	0	1 (1.6)	0
Metabolic acidosis	1 (1.6)	0	1 (1.6)	0	0
Metabolic alkalosis	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0
Musculoskeletal and connective tissue disorders					
-Total	14 (22.6)	7 (11.3)	6 (9.7)	1 (1.6)	0
Myalgia	4 (6.5)	3 (4.8)	1 (1.6)	0	0
Arthralgia	3 (4.8)	2 (3.2)	0	1 (1.6)	0
Musculoskeletal pain	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Pain in extremity	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Coccydynia	1 (1.6)	1 (1.6)	0	0	0
Limb discomfort	1 (1.6)	1 (1.6)	0	0	0
Muscle spasms	1 (1.6)	1 (1.6)	0	0	0
Muscular weakness	1 (1.6)	0	1 (1.6)	0	0
Musculoskeletal chest pain	1 (1.6)	1 (1.6)	0	0	0
Osteopenia	1 (1.6)	0	1 (1.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.6)	0	1 (1.6)	0	0
Skin papilloma	1 (1.6)	0	1 (1.6)	0	0
Nervous system disorders					

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	31 (50.0)	15 (24.2)	11 (17.7)	4 (6.5)	1 (1.6)
Headache	22 (35.5)	14 (22.6)	6 (9.7)	2 (3.2)	0
Dizziness	4 (6.5)	4 (6.5)	0	0	0
Encephalopathy	4 (6.5)	1 (1.6)	1 (1.6)	2 (3.2)	0
Seizure	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Dysarthria	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Tremor	2 (3.2)	2 (3.2)	0	0	0
Asterixis	1 (1.6)	1 (1.6)	0	0	0
Ataxia	1 (1.6)	0	1 (1.6)	0	0
Depressed level of consciousness	1 (1.6)	1 (1.6)	0	0	0
Embolic stroke	1 (1.6)	0	0	0	1 (1.6)
Idiopathic intracranial hypertension	1 (1.6)	0	1 (1.6)	0	0
Migraine	1 (1.6)	0	1 (1.6)	0	0
Myoclonus	1 (1.6)	1 (1.6)	0	0	0
Neuropathy peripheral	1 (1.6)	0	1 (1.6)	0	0
Pleocytosis	1 (1.6)	1 (1.6)	0	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0
Product issues					
-Total	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device occlusion	1 (1.6)	1 (1.6)	0	0	0
Psychiatric disorders					
-Total	16 (25.8)	8 (12.9)	7 (11.3)	1 (1.6)	0
Anxiety	6 (9.7)	2 (3.2)	3 (4.8)	1 (1.6)	0
Confusional state	6 (9.7)	3 (4.8)	3 (4.8)	0	0
Delirium	4 (6.5)	2 (3.2)	2 (3.2)	0	0
Agitation	2 (3.2)	0	2 (3.2)	0	0
Hallucination	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Irritability	2 (3.2)	2 (3.2)	0	0	0
Adjustment disorder	1 (1.6)	0	1 (1.6)	0	0
Insomnia	1 (1.6)	0	1 (1.6)	0	0
Listless	1 (1.6)	1 (1.6)	0	0	0
Mental status changes	1 (1.6)	1 (1.6)	0	0	0
Panic attack	1 (1.6)	0	1 (1.6)	0	0
Suicidal ideation	1 (1.6)	1 (1.6)	0	0	0
Renal and urinary disorders					
-Total	11 (17.7)	2 (3.2)	2 (3.2)	3 (4.8)	4 (6.5)
Acute kidney injury	7 (11.3)	1 (1.6)	1 (1.6)	2 (3.2)	3 (4.8)
Haematuria	4 (6.5)	0	2 (3.2)	1 (1.6)	1 (1.6)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysuria	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Oliguria	2 (3.2)	0	0	2 (3.2)	0
Pollakiuria	1 (1.6)	1 (1.6)	0	0	0
Renal failure	1 (1.6)	0	0	0	1 (1.6)
Renal impairment	1 (1.6)	0	0	1 (1.6)	0
Reproductive system and breast disorders					
-Total	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Vulvovaginal adhesion	2 (3.2)	2 (3.2)	0	0	0
Oedema genital	1 (1.6)	0	1 (1.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	27 (43.5)	9 (14.5)	6 (9.7)	5 (8.1)	7 (11.3)
Hypoxia	10 (16.1)	0	3 (4.8)	4 (6.5)	3 (4.8)
Pleural effusion	8 (12.9)	2 (3.2)	4 (6.5)	2 (3.2)	0
Cough	7 (11.3)	7 (11.3)	0	0	0
Epistaxis	7 (11.3)	2 (3.2)	1 (1.6)	3 (4.8)	1 (1.6)
Pulmonary oedema	6 (9.7)	1 (1.6)	0	3 (4.8)	2 (3.2)
Tachypnoea	5 (8.1)	3 (4.8)	1 (1.6)	1 (1.6)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	3 (4.8)	0	0	0	3 (4.8)
Dyspnoea	2 (3.2)	0	0	1 (1.6)	1 (1.6)
Haemoptysis	2 (3.2)	1 (1.6)	0	0	1 (1.6)
Oropharyngeal pain	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Atelectasis	1 (1.6)	1 (1.6)	0	0	0
Interstitial lung disease	1 (1.6)	0	0	0	1 (1.6)
Nasal congestion	1 (1.6)	1 (1.6)	0	0	0
Oropharyngeal plaque	1 (1.6)	1 (1.6)	0	0	0
Pharyngeal ulceration	1 (1.6)	0	1 (1.6)	0	0
Respiratory depression	1 (1.6)	0	1 (1.6)	0	0
Respiratory distress	1 (1.6)	0	0	0	1 (1.6)
Rhinitis allergic	1 (1.6)	1 (1.6)	0	0	0
Rhinorrhoea	1 (1.6)	1 (1.6)	0	0	0
Wheezing	1 (1.6)	0	1 (1.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	20 (32.3)	14 (22.6)	4 (6.5)	2 (3.2)	0
Dry skin	4 (6.5)	4 (6.5)	0	0	0
Rash	4 (6.5)	4 (6.5)	0	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	3 (4.8)	3 (4.8)	0	0	0
Hyperhidrosis	3 (4.8)	3 (4.8)	0	0	0
Petechiae	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Rash maculo-papular	3 (4.8)	1 (1.6)	1 (1.6)	1 (1.6)	0
Ingrowing nail	2 (3.2)	0	2 (3.2)	0	0
Pruritus	2 (3.2)	2 (3.2)	0	0	0
Rash papular	2 (3.2)	2 (3.2)	0	0	0
Dermatitis diaper	1 (1.6)	1 (1.6)	0	0	0
Ecchymosis	1 (1.6)	0	0	1 (1.6)	0
Livedo reticularis	1 (1.6)	1 (1.6)	0	0	0
Macule	1 (1.6)	1 (1.6)	0	0	0
Night sweats	1 (1.6)	0	1 (1.6)	0	0
Rash erythematous	1 (1.6)	1 (1.6)	0	0	0
Rash follicular	1 (1.6)	1 (1.6)	0	0	0
Rash macular	1 (1.6)	1 (1.6)	0	0	0
Rash vesicular	1 (1.6)	1 (1.6)	0	0	0
Skin exfoliation	1 (1.6)	1 (1.6)	0	0	0
Skin fissures	1 (1.6)	1 (1.6)	0	0	0
Vascular disorders					

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	24 (38.7)	3 (4.8)	5 (8.1)	8 (12.9)	8 (12.9)
Hypotension	16 (25.8)	1 (1.6)	0	7 (11.3)	8 (12.9)
Hypertension	10 (16.1)	2 (3.2)	7 (11.3)	1 (1.6)	0
Flushing	2 (3.2)	2 (3.2)	0	0	0
Orthostatic hypotension	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Capillary leak syndrome	1 (1.6)	0	0	0	1 (1.6)
Embolism	1 (1.6)	0	0	1 (1.6)	0
Haematoma	1 (1.6)	0	1 (1.6)	0	0
Secondary hypertension	1 (1.6)	0	1 (1.6)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174f
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	1 (50.0)	0	1 (50.0)
Blood and lymphatic system disorders					
-Total	2 (100)	0	1 (50.0)	0	1 (50.0)
Eosinophilia	1 (50.0)	0	0	1 (50.0)	0
Lymphopenia	1 (50.0)	0	1 (50.0)	0	0
Neutropenia	1 (50.0)	0	0	0	1 (50.0)
Cardiac disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Sinus tachycardia	1 (50.0)	0	1 (50.0)	0	0
Gastrointestinal disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pigmentation lip	1 (50.0)	1 (50.0)	0	0	0
General disorders and administration site conditions					
-Total	1 (50.0)	0	1 (50.0)	0	0
Chills	1 (50.0)	1 (50.0)	0	0	0
Pain	1 (50.0)	1 (50.0)	0	0	0
Pyrexia	1 (50.0)	0	1 (50.0)	0	0
Immune system disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Graft versus host disease	1 (50.0)	1 (50.0)	0	0	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	0	0	1 (50.0)	0
Urinary tract infection	1 (50.0)	0	0	1 (50.0)	0
Investigations					
-Total	1 (50.0)	1 (50.0)	0	0	0
Blood uric acid increased	1 (50.0)	1 (50.0)	0	0	0
Neutrophil count decreased	1 (50.0)	1 (50.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Vitamin d deficiency	1 (50.0)	1 (50.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (100)	2 (100)	0	0	0
Joint range of motion decreased	2 (100)	2 (100)	0	0	0
Back pain	1 (50.0)	1 (50.0)	0	0	0
Muscle spasms	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Headache	1 (50.0)	1 (50.0)	0	0	0
Reproductive system and breast disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Scrotal pain	1 (50.0)	0	1 (50.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Macule	1 (50.0)	1 (50.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash maculo-papular	1 (50.0)	1 (50.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174f
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	44 (81.5)	4 (7.4)	15 (27.8)	16 (29.6)	9 (16.7)
Blood and lymphatic system disorders					
-Total	9 (16.7)	1 (1.9)	2 (3.7)	3 (5.6)	3 (5.6)
Febrile neutropenia	3 (5.6)	0	0	3 (5.6)	0
Neutropenia	3 (5.6)	0	0	1 (1.9)	2 (3.7)
Anaemia	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Thrombocytopenia	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Leukopenia	1 (1.9)	0	0	0	1 (1.9)
Lymphadenopathy	1 (1.9)	0	1 (1.9)	0	0
Endocrine disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	1 (1.9)	1 (1.9)	0	0	0
Eye disorders					
-Total	5 (9.3)	4 (7.4)	1 (1.9)	0	0
Dry eye	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Conjunctivitis allergic	1 (1.9)	1 (1.9)	0	0	0
Ocular hyperaemia	1 (1.9)	1 (1.9)	0	0	0
Vision blurred	1 (1.9)	1 (1.9)	0	0	0
Gastrointestinal disorders					
-Total	15 (27.8)	8 (14.8)	3 (5.6)	4 (7.4)	0
Vomiting	9 (16.7)	5 (9.3)	2 (3.7)	2 (3.7)	0
Diarrhoea	8 (14.8)	6 (11.1)	1 (1.9)	1 (1.9)	0
Nausea	6 (11.1)	1 (1.9)	3 (5.6)	2 (3.7)	0
Abdominal pain	4 (7.4)	2 (3.7)	1 (1.9)	1 (1.9)	0
Oral pain	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Abdominal pain upper	1 (1.9)	1 (1.9)	0	0	0
Enterocolitis	1 (1.9)	0	0	1 (1.9)	0
General disorders and administration site conditions					
-Total	16 (29.6)	13 (24.1)	2 (3.7)	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	9 (16.7)	7 (13.0)	1 (1.9)	1 (1.9)	0
Fatigue	2 (3.7)	2 (3.7)	0	0	0
Influenza like illness	2 (3.7)	2 (3.7)	0	0	0
Acquired gene mutation	1 (1.9)	1 (1.9)	0	0	0
Catheter site pain	1 (1.9)	0	1 (1.9)	0	0
Crying	1 (1.9)	1 (1.9)	0	0	0
Generalised oedema	1 (1.9)	1 (1.9)	0	0	0
Malaise	1 (1.9)	1 (1.9)	0	0	0
Oedema peripheral	1 (1.9)	1 (1.9)	0	0	0
Immune system disorders					
-Total	13 (24.1)	2 (3.7)	10 (18.5)	1 (1.9)	0
Hypogammaglobulinaemia	8 (14.8)	0	7 (13.0)	1 (1.9)	0
Immunodeficiency common variable	2 (3.7)	0	2 (3.7)	0	0
Seasonal allergy	2 (3.7)	2 (3.7)	0	0	0
Graft versus host disease	1 (1.9)	0	1 (1.9)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.9)	0	1 (1.9)	0	0
Infections and infestations					

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	32 (59.3)	6 (11.1)	15 (27.8)	9 (16.7)	2 (3.7)
Upper respiratory tract infection	7 (13.0)	3 (5.6)	3 (5.6)	1 (1.9)	0
Gastroenteritis	3 (5.6)	1 (1.9)	2 (3.7)	0	0
Influenza	3 (5.6)	0	3 (5.6)	0	0
Urinary tract infection	3 (5.6)	0	2 (3.7)	1 (1.9)	0
Ear infection	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Parainfluenzae virus infection	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Rhinovirus infection	2 (3.7)	2 (3.7)	0	0	0
Sinusitis	2 (3.7)	0	2 (3.7)	0	0
Viral upper respiratory tract infection	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Bacterial sepsis	1 (1.9)	0	0	0	1 (1.9)
Cholecystitis infective	1 (1.9)	0	0	1 (1.9)	0
Corona virus infection	1 (1.9)	0	0	1 (1.9)	0
Cytomegalovirus infection	1 (1.9)	1 (1.9)	0	0	0
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis viral	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	1 (1.9)	0	0	1 (1.9)	0
Molluscum contagiosum	1 (1.9)	1 (1.9)	0	0	0
Oral herpes	1 (1.9)	0	1 (1.9)	0	0
Otitis externa	1 (1.9)	0	1 (1.9)	0	0
Otitis media	1 (1.9)	0	1 (1.9)	0	0
Otitis media acute	1 (1.9)	0	1 (1.9)	0	0
Paronychia	1 (1.9)	1 (1.9)	0	0	0
Rash pustular	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus infection	1 (1.9)	0	0	1 (1.9)	0
Rhinitis	1 (1.9)	1 (1.9)	0	0	0
Rotavirus infection	1 (1.9)	0	0	1 (1.9)	0
Sepsis	1 (1.9)	0	0	0	1 (1.9)
Subcutaneous abscess	1 (1.9)	0	1 (1.9)	0	0
Tinea capitis	1 (1.9)	1 (1.9)	0	0	0
Vascular device infection	1 (1.9)	0	0	1 (1.9)	0
Viral infection	1 (1.9)	1 (1.9)	0	0	0
Vulvovaginal mycotic infection	1 (1.9)	0	1 (1.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	8 (14.8)	3 (5.6)	5 (9.3)	0	0
Contusion	2 (3.7)	2 (3.7)	0	0	0
Infusion related reaction	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Procedural pain	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Arthropod bite	1 (1.9)	1 (1.9)	0	0	0
Foot fracture	1 (1.9)	0	1 (1.9)	0	0
Procedural nausea	1 (1.9)	0	1 (1.9)	0	0
Radius fracture	1 (1.9)	0	1 (1.9)	0	0
Skin abrasion	1 (1.9)	1 (1.9)	0	0	0
Skin laceration	1 (1.9)	0	1 (1.9)	0	0
Sunburn	1 (1.9)	1 (1.9)	0	0	0
Investigations					
-Total	22 (40.7)	5 (9.3)	5 (9.3)	8 (14.8)	4 (7.4)
Neutrophil count decreased	7 (13.0)	1 (1.9)	0	3 (5.6)	3 (5.6)
White blood cell count decreased	5 (9.3)	2 (3.7)	1 (1.9)	1 (1.9)	1 (1.9)
Weight decreased	4 (7.4)	1 (1.9)	3 (5.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	3 (5.6)	1 (1.9)	0	2 (3.7)	0
Platelet count decreased	3 (5.6)	3 (5.6)	0	0	0
Alanine aminotransferase increased	2 (3.7)	0	0	2 (3.7)	0
Haemoglobin decreased	2 (3.7)	2 (3.7)	0	0	0
Lymphocyte count decreased	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Weight increased	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Blood bilirubin increased	1 (1.9)	0	0	1 (1.9)	0
Blood creatinine increased	1 (1.9)	1 (1.9)	0	0	0
Blood magnesium decreased	1 (1.9)	1 (1.9)	0	0	0
Blood urea increased	1 (1.9)	1 (1.9)	0	0	0
Oxygen saturation decreased	1 (1.9)	1 (1.9)	0	0	0
Serum ferritin increased	1 (1.9)	0	1 (1.9)	0	0
Transaminases increased	1 (1.9)	1 (1.9)	0	0	0
Metabolism and nutrition disorders					
-Total	9 (16.7)	4 (7.4)	1 (1.9)	3 (5.6)	1 (1.9)
Decreased appetite	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Hyperphosphataemia	2 (3.7)	2 (3.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	2 (3.7)	1 (1.9)	0	0	1 (1.9)
Dehydration	1 (1.9)	0	0	1 (1.9)	0
Hyperalbuminaemia	1 (1.9)	1 (1.9)	0	0	0
Hypercalcaemia	1 (1.9)	1 (1.9)	0	0	0
Hyperglycaemia	1 (1.9)	0	0	1 (1.9)	0
Hypophosphataemia	1 (1.9)	0	0	1 (1.9)	0
Iron overload	1 (1.9)	0	0	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0
Musculoskeletal and connective tissue disorders					
-Total	14 (25.9)	9 (16.7)	5 (9.3)	0	0
Pain in extremity	8 (14.8)	6 (11.1)	2 (3.7)	0	0
Arthralgia	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Muscular weakness	2 (3.7)	2 (3.7)	0	0	0
Flank pain	1 (1.9)	0	1 (1.9)	0	0
Musculoskeletal chest pain	1 (1.9)	1 (1.9)	0	0	0
Osteonecrosis	1 (1.9)	0	1 (1.9)	0	0
Pain in jaw	1 (1.9)	1 (1.9)	0	0	0
Toe walking	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.9)	0	1 (1.9)	0	0
Myelodysplastic syndrome	1 (1.9)	0	1 (1.9)	0	0
Nervous system disorders					
-Total	7 (13.0)	5 (9.3)	2 (3.7)	0	0
Headache	4 (7.4)	3 (5.6)	1 (1.9)	0	0
Dizziness	3 (5.6)	3 (5.6)	0	0	0
Peroneal nerve palsy	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Psychiatric disorders					
-Total	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Depression	2 (3.7)	2 (3.7)	0	0	0
Anxiety	1 (1.9)	1 (1.9)	0	0	0
Sleep disorder	1 (1.9)	0	1 (1.9)	0	0
Renal and urinary disorders					
-Total	3 (5.6)	1 (1.9)	0	2 (3.7)	0
Acute kidney injury	1 (1.9)	0	0	1 (1.9)	0
Calculus urinary	1 (1.9)	0	1 (1.9)	0	0
Haematuria	1 (1.9)	0	0	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nephrolithiasis	1 (1.9)	0	0	1 (1.9)	0
Urinary incontinence	1 (1.9)	1 (1.9)	0	0	0
Reproductive system and breast disorders					
-Total	1 (1.9)	0	0	1 (1.9)	0
Vaginal haemorrhage	1 (1.9)	0	0	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	18 (33.3)	11 (20.4)	4 (7.4)	2 (3.7)	1 (1.9)
Cough	7 (13.0)	5 (9.3)	2 (3.7)	0	0
Nasal congestion	4 (7.4)	4 (7.4)	0	0	0
Rhinorrhoea	4 (7.4)	3 (5.6)	1 (1.9)	0	0
Oropharyngeal pain	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Rhinitis allergic	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Epistaxis	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Acute respiratory failure	1 (1.9)	0	0	0	1 (1.9)
Dysphonia	1 (1.9)	1 (1.9)	0	0	0
Pharyngeal erythema	1 (1.9)	1 (1.9)	0	0	0
Pharyngeal lesion	1 (1.9)	0	0	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	1 (1.9)	0	0	1 (1.9)	0
Skin and subcutaneous tissue disorders					
-Total	15 (27.8)	9 (16.7)	5 (9.3)	1 (1.9)	0
Rash	4 (7.4)	1 (1.9)	3 (5.6)	0	0
Erythema	2 (3.7)	2 (3.7)	0	0	0
Alopecia	1 (1.9)	0	1 (1.9)	0	0
Dermatitis	1 (1.9)	1 (1.9)	0	0	0
Dermatitis acneiform	1 (1.9)	0	0	1 (1.9)	0
Dermatitis atopic	1 (1.9)	1 (1.9)	0	0	0
Dry skin	1 (1.9)	1 (1.9)	0	0	0
Eczema	1 (1.9)	1 (1.9)	0	0	0
Hyperhidrosis	1 (1.9)	1 (1.9)	0	0	0
Ingrowing nail	1 (1.9)	1 (1.9)	0	0	0
Keloid scar	1 (1.9)	0	1 (1.9)	0	0
Papule	1 (1.9)	1 (1.9)	0	0	0
Petechiae	1 (1.9)	1 (1.9)	0	0	0
Pruritus	1 (1.9)	1 (1.9)	0	0	0
Rash erythematous	1 (1.9)	0	1 (1.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash maculo-papular	1 (1.9)	1 (1.9)	0	0	0
Rash pruritic	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					
-Total	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Hypertension	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Hot flush	1 (1.9)	1 (1.9)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174f
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=1		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Diarrhoea	1 (100)	0	1 (100)	0	0
Infections and infestations					
-Total	1 (100)	0	0	1 (100)	0
Cellulitis of male external genital organ	1 (100)	0	0	1 (100)	0
Otitis media	1 (100)	0	1 (100)	0	0
Urinary tract infection	1 (100)	0	0	1 (100)	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174f
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (63.6)	4 (12.1)	6 (18.2)	7 (21.2)	4 (12.1)
Blood and lymphatic system disorders					
-Total	2 (6.1)	1 (3.0)	0	0	1 (3.0)
Febrile neutropenia	1 (3.0)	0	0	0	1 (3.0)
Thrombocytopenia	1 (3.0)	1 (3.0)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Tympanic membrane perforation	1 (3.0)	0	1 (3.0)	0	0
Gastrointestinal disorders					
-Total	2 (6.1)	0	2 (6.1)	0	0
Abdominal pain	1 (3.0)	0	1 (3.0)	0	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (3.0)	0	1 (3.0)	0	0
Nausea	1 (3.0)	0	1 (3.0)	0	0
General disorders and administration site conditions					
-Total	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Chills	1 (3.0)	0	1 (3.0)	0	0
Cyst	1 (3.0)	0	0	1 (3.0)	0
Pyrexia	1 (3.0)	0	1 (3.0)	0	0
Immune system disorders					
-Total	2 (6.1)	0	2 (6.1)	0	0
Chronic graft versus host disease	1 (3.0)	0	1 (3.0)	0	0
Immunodeficiency	1 (3.0)	0	1 (3.0)	0	0
Infections and infestations					
-Total	10 (30.3)	2 (6.1)	5 (15.2)	2 (6.1)	1 (3.0)
Sinusitis	3 (9.1)	0	3 (9.1)	0	0
Otitis media	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Otitis media acute	2 (6.1)	0	2 (6.1)	0	0
Pneumonia	2 (6.1)	0	2 (6.1)	0	0
Upper respiratory tract infection	2 (6.1)	1 (3.0)	1 (3.0)	0	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (3.0)	0	0	1 (3.0)	0
Clostridium difficile infection	1 (3.0)	0	0	1 (3.0)	0
Gingivitis	1 (3.0)	1 (3.0)	0	0	0
Haemophilus infection	1 (3.0)	0	1 (3.0)	0	0
Meningitis aseptic	1 (3.0)	0	1 (3.0)	0	0
Respiratory tract infection	1 (3.0)	0	0	0	1 (3.0)
Respiratory tract infection viral	1 (3.0)	0	0	1 (3.0)	0
Skin infection	1 (3.0)	0	1 (3.0)	0	0
Urinary tract infection	1 (3.0)	0	1 (3.0)	0	0
Viral infection	1 (3.0)	1 (3.0)	0	0	0
Vulvovaginal candidiasis	1 (3.0)	0	1 (3.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (3.0)	0	0	1 (3.0)	0
Procedural pain	1 (3.0)	0	0	1 (3.0)	0
Investigations					
-Total	8 (24.2)	1 (3.0)	2 (6.1)	4 (12.1)	1 (3.0)
White blood cell count decreased	4 (12.1)	1 (3.0)	0	2 (6.1)	1 (3.0)
Alanine aminotransferase increased	3 (9.1)	0	1 (3.0)	2 (6.1)	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Aspartate aminotransferase increased	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Neutrophil count decreased	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Blood alkaline phosphatase increased	1 (3.0)	1 (3.0)	0	0	0
Blood lactate dehydrogenase increased	1 (3.0)	1 (3.0)	0	0	0
C-reactive protein increased	1 (3.0)	1 (3.0)	0	0	0
Platelet count decreased	1 (3.0)	0	0	1 (3.0)	0
Metabolism and nutrition disorders					
-Total	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Hypokalaemia	1 (3.0)	0	0	1 (3.0)	0
Vitamin d deficiency	1 (3.0)	1 (3.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Neck pain	1 (3.0)	0	1 (3.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.0)	0	0	0	1 (3.0)
Glioblastoma multiforme	1 (3.0)	0	0	0	1 (3.0)
Nervous system disorders					
-Total	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Disturbance in attention	1 (3.0)	1 (3.0)	0	0	0
Dizziness	1 (3.0)	1 (3.0)	0	0	0
Headache	1 (3.0)	0	1 (3.0)	0	0
Seizure	1 (3.0)	0	0	1 (3.0)	0
Renal and urinary disorders					
-Total	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Acute kidney injury	1 (3.0)	0	0	1 (3.0)	0
Haematuria	1 (3.0)	1 (3.0)	0	0	0
Reproductive system and breast disorders					
-Total	1 (3.0)	0	0	1 (3.0)	0
Ovarian failure	1 (3.0)	0	0	1 (3.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (12.1)	4 (12.1)	0	0	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	2 (6.1)	2 (6.1)	0	0	0
Epistaxis	1 (3.0)	1 (3.0)	0	0	0
Oropharyngeal pain	1 (3.0)	1 (3.0)	0	0	0
Rhinitis allergic	1 (3.0)	1 (3.0)	0	0	0
Rhinorrhoea	1 (3.0)	1 (3.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (9.1)	3 (9.1)	0	0	0
Acne	1 (3.0)	1 (3.0)	0	0	0
Papule	1 (3.0)	1 (3.0)	0	0	0
Pruritus	1 (3.0)	1 (3.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174f
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	1 (50.0)	0	1 (50.0)
Blood and lymphatic system disorders					
-Total	2 (100)	0	1 (50.0)	0	1 (50.0)
Anaemia	1 (50.0)	0	1 (50.0)	0	0
Eosinophilia	1 (50.0)	0	0	1 (50.0)	0
Lymphopenia	1 (50.0)	0	1 (50.0)	0	0
Neutropenia	1 (50.0)	0	0	0	1 (50.0)
Cardiac disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Sinus tachycardia	1 (50.0)	0	1 (50.0)	0	0
Gastrointestinal disorders					

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	1 (50.0)	0	0
Diarrhoea	1 (50.0)	0	1 (50.0)	0	0
Pigmentation lip	1 (50.0)	1 (50.0)	0	0	0
General disorders and administration site conditions					
-Total	2 (100)	1 (50.0)	1 (50.0)	0	0
Chills	1 (50.0)	1 (50.0)	0	0	0
Fatigue	1 (50.0)	1 (50.0)	0	0	0
Pain	1 (50.0)	1 (50.0)	0	0	0
Pyrexia	1 (50.0)	0	1 (50.0)	0	0
Immune system disorders					
-Total	2 (100)	1 (50.0)	1 (50.0)	0	0
Graft versus host disease	1 (50.0)	1 (50.0)	0	0	0
Graft versus host disease in skin	1 (50.0)	1 (50.0)	0	0	0
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	0	0	1 (50.0)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (50.0)	0	1 (50.0)	0	0
Urinary tract infection	1 (50.0)	0	0	1 (50.0)	0
Injury, poisoning and procedural complications					
-Total	1 (50.0)	1 (50.0)	0	0	0
Skin abrasion	1 (50.0)	1 (50.0)	0	0	0
Investigations					
-Total	1 (50.0)	0	1 (50.0)	0	0
Blood immunoglobulin a decreased	1 (50.0)	1 (50.0)	0	0	0
Blood uric acid increased	1 (50.0)	1 (50.0)	0	0	0
International normalised ratio increased	1 (50.0)	1 (50.0)	0	0	0
Lymphocyte count decreased	1 (50.0)	0	1 (50.0)	0	0
Neutrophil count decreased	1 (50.0)	0	1 (50.0)	0	0
White blood cell count decreased	1 (50.0)	0	1 (50.0)	0	0
Metabolism and nutrition disorders					
-Total	2 (100)	2 (100)	0	0	0
Hyperphosphataemia	1 (50.0)	1 (50.0)	0	0	0
Hyperuricaemia	1 (50.0)	1 (50.0)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vitamin d deficiency	1 (50.0)	1 (50.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (100)	2 (100)	0	0	0
Joint range of motion decreased	2 (100)	2 (100)	0	0	0
Arthralgia	1 (50.0)	1 (50.0)	0	0	0
Back pain	1 (50.0)	1 (50.0)	0	0	0
Muscle spasms	1 (50.0)	1 (50.0)	0	0	0
Myalgia	1 (50.0)	1 (50.0)	0	0	0
Pain in extremity	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					
-Total	2 (100)	2 (100)	0	0	0
Headache	2 (100)	2 (100)	0	0	0
Reproductive system and breast disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Scrotal pain	1 (50.0)	0	1 (50.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	1 (50.0)	1 (50.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Macule	1 (50.0)	1 (50.0)	0	0	0
Rash maculo-papular	1 (50.0)	1 (50.0)	0	0	0
Skin irritation	1 (50.0)	1 (50.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174f
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	62 (100)	0	4 (6.5)	12 (19.4)	46 (74.2)
Blood and lymphatic system disorders					
-Total	46 (74.2)	2 (3.2)	2 (3.2)	27 (43.5)	15 (24.2)
Anaemia	26 (41.9)	3 (4.8)	3 (4.8)	19 (30.6)	1 (1.6)
Febrile neutropenia	24 (38.7)	0	0	23 (37.1)	1 (1.6)
Neutropenia	10 (16.1)	0	0	3 (4.8)	7 (11.3)
Thrombocytopenia	10 (16.1)	0	1 (1.6)	3 (4.8)	6 (9.7)
Disseminated intravascular coagulation	4 (6.5)	0	2 (3.2)	2 (3.2)	0
Lymphopenia	3 (4.8)	0	1 (1.6)	1 (1.6)	1 (1.6)
Coagulopathy	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (1.6)	0	0	0	1 (1.6)
Lymphadenopathy	1 (1.6)	0	1 (1.6)	0	0
Pancytopenia	1 (1.6)	0	0	0	1 (1.6)
Cardiac disorders					
-Total	22 (35.5)	11 (17.7)	9 (14.5)	2 (3.2)	0
Tachycardia	15 (24.2)	8 (12.9)	5 (8.1)	2 (3.2)	0
Sinus tachycardia	5 (8.1)	3 (4.8)	2 (3.2)	0	0
Pericardial effusion	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Atrioventricular block second degree	1 (1.6)	1 (1.6)	0	0	0
Bradycardia	1 (1.6)	0	1 (1.6)	0	0
Cardiac dysfunction	1 (1.6)	1 (1.6)	0	0	0
Left ventricular dysfunction	1 (1.6)	0	0	1 (1.6)	0
Palpitations	1 (1.6)	1 (1.6)	0	0	0
Sinus bradycardia	1 (1.6)	1 (1.6)	0	0	0
Ventricular tachycardia	1 (1.6)	0	1 (1.6)	0	0
Ear and labyrinth disorders					
-Total	4 (6.5)	2 (3.2)	2 (3.2)	0	0
Ear pain	2 (3.2)	2 (3.2)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoacusis	1 (1.6)	0	1 (1.6)	0	0
Tympanic membrane perforation	1 (1.6)	0	1 (1.6)	0	0
Endocrine disorders					
-Total	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Adrenal insufficiency	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Eye disorders					
-Total	18 (29.0)	10 (16.1)	8 (12.9)	0	0
Periorbital oedema	4 (6.5)	3 (4.8)	1 (1.6)	0	0
Vision blurred	4 (6.5)	2 (3.2)	2 (3.2)	0	0
Conjunctival haemorrhage	3 (4.8)	3 (4.8)	0	0	0
Eye pain	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Dry eye	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Photophobia	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Retinal haemorrhage	2 (3.2)	2 (3.2)	0	0	0
Uveitis	2 (3.2)	0	2 (3.2)	0	0
Conjunctivitis allergic	1 (1.6)	1 (1.6)	0	0	0
Ocular hyperaemia	1 (1.6)	1 (1.6)	0	0	0
Ocular hypertension	1 (1.6)	0	1 (1.6)	0	0
Papilloedema	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Visual impairment	1 (1.6)	0	1 (1.6)	0	0
Gastrointestinal disorders					
-Total	42 (67.7)	13 (21.0)	16 (25.8)	13 (21.0)	0
Vomiting	27 (43.5)	16 (25.8)	8 (12.9)	3 (4.8)	0
Nausea	25 (40.3)	6 (9.7)	14 (22.6)	5 (8.1)	0
Diarrhoea	23 (37.1)	13 (21.0)	8 (12.9)	2 (3.2)	0
Abdominal pain	11 (17.7)	6 (9.7)	4 (6.5)	1 (1.6)	0
Constipation	7 (11.3)	6 (9.7)	1 (1.6)	0	0
Abdominal pain upper	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Abdominal distension	2 (3.2)	0	2 (3.2)	0	0
Dysphagia	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Haematemesis	2 (3.2)	2 (3.2)	0	0	0
Oral pain	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Pancreatitis	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Stomatitis	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Abdominal discomfort	1 (1.6)	1 (1.6)	0	0	0
Abdominal pain lower	1 (1.6)	0	1 (1.6)	0	0
Abdominal tenderness	1 (1.6)	1 (1.6)	0	0	0
Anal incontinence	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	1 (1.6)	0	0	1 (1.6)	0
Dyspepsia	1 (1.6)	0	1 (1.6)	0	0
Enterocolitis	1 (1.6)	0	0	1 (1.6)	0
Flatulence	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Gastrooesophageal reflux disease	1 (1.6)	1 (1.6)	0	0	0
Glossodynia	1 (1.6)	1 (1.6)	0	0	0
Ileus	1 (1.6)	0	0	1 (1.6)	0
Intestinal obstruction	1 (1.6)	0	0	1 (1.6)	0
Lip pain	1 (1.6)	0	1 (1.6)	0	0
Mouth haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Tooth socket haemorrhage	1 (1.6)	1 (1.6)	0	0	0
General disorders and administration site conditions					
-Total	40 (64.5)	15 (24.2)	13 (21.0)	11 (17.7)	1 (1.6)
Pyrexia	24 (38.7)	8 (12.9)	9 (14.5)	6 (9.7)	1 (1.6)
Fatigue	14 (22.6)	11 (17.7)	2 (3.2)	1 (1.6)	0
Chills	9 (14.5)	8 (12.9)	1 (1.6)	0	0
Catheter site pain	4 (6.5)	1 (1.6)	3 (4.8)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	4 (6.5)	1 (1.6)	3 (4.8)	0	0
Generalised oedema	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Oedema peripheral	3 (4.8)	2 (3.2)	0	1 (1.6)	0
Pain	3 (4.8)	0	1 (1.6)	2 (3.2)	0
Face oedema	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Influenza like illness	2 (3.2)	2 (3.2)	0	0	0
Acquired gene mutation	1 (1.6)	1 (1.6)	0	0	0
Asthenia	1 (1.6)	1 (1.6)	0	0	0
Catheter site extravasation	1 (1.6)	0	1 (1.6)	0	0
Catheter site haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Crying	1 (1.6)	1 (1.6)	0	0	0
Cyst	1 (1.6)	0	0	1 (1.6)	0
Facial pain	1 (1.6)	0	1 (1.6)	0	0
Injection site haematoma	1 (1.6)	1 (1.6)	0	0	0
Localised oedema	1 (1.6)	0	0	1 (1.6)	0
Mucosal haemorrhage	1 (1.6)	0	1 (1.6)	0	0
Multiple organ dysfunction syndrome	1 (1.6)	0	0	1 (1.6)	0
Non-cardiac chest pain	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Peripheral swelling	1 (1.6)	0	1 (1.6)	0	0
Physical deconditioning	1 (1.6)	0	0	1 (1.6)	0
Hepatobiliary disorders					
-Total	7 (11.3)	3 (4.8)	2 (3.2)	2 (3.2)	0
Hepatomegaly	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Hyperbilirubinaemia	3 (4.8)	0	1 (1.6)	2 (3.2)	0
Gallbladder enlargement	1 (1.6)	1 (1.6)	0	0	0
Hepatosplenomegaly	1 (1.6)	1 (1.6)	0	0	0
Immune system disorders					
-Total	56 (90.3)	4 (6.5)	30 (48.4)	11 (17.7)	11 (17.7)
Cytokine release syndrome	50 (80.6)	6 (9.7)	25 (40.3)	8 (12.9)	11 (17.7)
Hypogammaglobulinaemia	31 (50.0)	3 (4.8)	23 (37.1)	5 (8.1)	0
Immunodeficiency common variable	2 (3.2)	0	2 (3.2)	0	0
Seasonal allergy	2 (3.2)	2 (3.2)	0	0	0
Chronic graft versus host disease	1 (1.6)	0	1 (1.6)	0	0
Drug hypersensitivity	1 (1.6)	0	1 (1.6)	0	0
Graft versus host disease	1 (1.6)	0	1 (1.6)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (1.6)	0	1 (1.6)	0	0
Immunodeficiency	1 (1.6)	0	1 (1.6)	0	0
Infections and infestations					
-Total	45 (72.6)	7 (11.3)	21 (33.9)	13 (21.0)	4 (6.5)
Upper respiratory tract infection	9 (14.5)	4 (6.5)	4 (6.5)	1 (1.6)	0
Clostridium difficile infection	5 (8.1)	0	4 (6.5)	1 (1.6)	0
Gastroenteritis	5 (8.1)	1 (1.6)	3 (4.8)	1 (1.6)	0
Rhinovirus infection	5 (8.1)	5 (8.1)	0	0	0
Clostridium difficile colitis	4 (6.5)	1 (1.6)	2 (3.2)	1 (1.6)	0
Influenza	4 (6.5)	1 (1.6)	3 (4.8)	0	0
Pneumonia	4 (6.5)	0	3 (4.8)	1 (1.6)	0
Sinusitis	4 (6.5)	0	4 (6.5)	0	0
Urinary tract infection	4 (6.5)	0	3 (4.8)	1 (1.6)	0
Otitis media	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Viral infection	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Viral upper respiratory tract infection	3 (4.8)	1 (1.6)	1 (1.6)	1 (1.6)	0
Cytomegalovirus infection	2 (3.2)	2 (3.2)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Otitis media acute	2 (3.2)	0	2 (3.2)	0	0
Parainfluenzae virus infection	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Skin infection	2 (3.2)	0	2 (3.2)	0	0
Staphylococcal infection	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Vulvovaginal candidiasis	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Bacterial sepsis	1 (1.6)	0	0	0	1 (1.6)
Body tinea	1 (1.6)	1 (1.6)	0	0	0
Campylobacter infection	1 (1.6)	0	0	1 (1.6)	0
Catheter site cellulitis	1 (1.6)	1 (1.6)	0	0	0
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cholecystitis infective	1 (1.6)	0	0	1 (1.6)	0
Corona virus infection	1 (1.6)	0	0	1 (1.6)	0
Enterococcal infection	1 (1.6)	1 (1.6)	0	0	0
Enterovirus infection	1 (1.6)	0	0	1 (1.6)	0
Escherichia urinary tract infection	1 (1.6)	0	0	1 (1.6)	0
Folliculitis	1 (1.6)	0	1 (1.6)	0	0
Fungal skin infection	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Gastroenteritis viral	1 (1.6)	1 (1.6)	0	0	0
Gingivitis	1 (1.6)	1 (1.6)	0	0	0
Haemophilus infection	1 (1.6)	0	1 (1.6)	0	0
Herpes simplex	1 (1.6)	1 (1.6)	0	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	0	1 (1.6)	0	0
Hypopyon	1 (1.6)	0	1 (1.6)	0	0
Meningitis aseptic	1 (1.6)	0	1 (1.6)	0	0
Molluscum contagiosum	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	1 (1.6)	0	0	0
Oral herpes	1 (1.6)	0	1 (1.6)	0	0
Orchitis	1 (1.6)	1 (1.6)	0	0	0
Otitis externa	1 (1.6)	0	1 (1.6)	0	0
Paronychia	1 (1.6)	1 (1.6)	0	0	0
Pharyngitis	1 (1.6)	0	1 (1.6)	0	0
Rash pustular	1 (1.6)	0	1 (1.6)	0	0
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection	1 (1.6)	0	0	0	1 (1.6)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (1.6)	0	0	1 (1.6)	0
Rhinitis	1 (1.6)	1 (1.6)	0	0	0
Rotavirus infection	1 (1.6)	0	0	1 (1.6)	0
Sepsis	1 (1.6)	0	0	0	1 (1.6)
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Streptococcal infection	1 (1.6)	0	1 (1.6)	0	0
Subcutaneous abscess	1 (1.6)	0	1 (1.6)	0	0
Tinea capitis	1 (1.6)	1 (1.6)	0	0	0
Urinary tract infection enterococcal	1 (1.6)	0	0	1 (1.6)	0
Vascular device infection	1 (1.6)	0	0	1 (1.6)	0
Vulvovaginal mycotic infection	1 (1.6)	0	1 (1.6)	0	0
Injury, poisoning and procedural complications					
-Total	21 (33.9)	10 (16.1)	8 (12.9)	2 (3.2)	1 (1.6)
Procedural pain	5 (8.1)	2 (3.2)	2 (3.2)	1 (1.6)	0
Infusion related reaction	4 (6.5)	1 (1.6)	3 (4.8)	0	0
Contusion	3 (4.8)	3 (4.8)	0	0	0
Transfusion reaction	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Arthropod bite	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Foot fracture	1 (1.6)	0	1 (1.6)	0	0
Incision site pain	1 (1.6)	1 (1.6)	0	0	0
Limb injury	1 (1.6)	1 (1.6)	0	0	0
Mouth injury	1 (1.6)	1 (1.6)	0	0	0
Post procedural haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Procedural complication	1 (1.6)	1 (1.6)	0	0	0
Procedural headache	1 (1.6)	0	1 (1.6)	0	0
Procedural nausea	1 (1.6)	0	1 (1.6)	0	0
Procedural site reaction	1 (1.6)	1 (1.6)	0	0	0
Radius fracture	1 (1.6)	0	1 (1.6)	0	0
Skin abrasion	1 (1.6)	1 (1.6)	0	0	0
Skin laceration	1 (1.6)	0	1 (1.6)	0	0
Stoma site irritation	1 (1.6)	1 (1.6)	0	0	0
Subdural haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Sunburn	1 (1.6)	1 (1.6)	0	0	0
Tibia fracture	1 (1.6)	0	1 (1.6)	0	0
Tongue injury	1 (1.6)	1 (1.6)	0	0	0
Tracheal haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Transfusion related complication	1 (1.6)	0	0	0	1 (1.6)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	55 (88.7)	2 (3.2)	4 (6.5)	15 (24.2)	34 (54.8)
White blood cell count decreased	34 (54.8)	4 (6.5)	0	12 (19.4)	18 (29.0)
Neutrophil count decreased	27 (43.5)	1 (1.6)	1 (1.6)	4 (6.5)	21 (33.9)
Alanine aminotransferase increased	21 (33.9)	5 (8.1)	2 (3.2)	14 (22.6)	0
Aspartate aminotransferase increased	20 (32.3)	4 (6.5)	4 (6.5)	8 (12.9)	4 (6.5)
Platelet count decreased	20 (32.3)	3 (4.8)	2 (3.2)	3 (4.8)	12 (19.4)
Lymphocyte count decreased	15 (24.2)	1 (1.6)	2 (3.2)	7 (11.3)	5 (8.1)
Blood creatinine increased	9 (14.5)	5 (8.1)	2 (3.2)	2 (3.2)	0
Prothrombin time prolonged	9 (14.5)	5 (8.1)	3 (4.8)	1 (1.6)	0
Blood bilirubin increased	8 (12.9)	2 (3.2)	3 (4.8)	3 (4.8)	0
International normalised ratio increased	8 (12.9)	7 (11.3)	0	1 (1.6)	0
Activated partial thromboplastin time prolonged	5 (8.1)	3 (4.8)	2 (3.2)	0	0
Blood fibrinogen decreased	4 (6.5)	0	1 (1.6)	2 (3.2)	1 (1.6)
Blood immunoglobulin m decreased	4 (6.5)	4 (6.5)	0	0	0
Weight decreased	4 (6.5)	1 (1.6)	3 (4.8)	0	0
Blood urea increased	3 (4.8)	1 (1.6)	1 (1.6)	1 (1.6)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoglobin decreased	3 (4.8)	2 (3.2)	0	1 (1.6)	0
Transaminases increased	3 (4.8)	3 (4.8)	0	0	0
Blood immunoglobulin a decreased	2 (3.2)	2 (3.2)	0	0	0
Blood magnesium decreased	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Blood phosphorus increased	2 (3.2)	2 (3.2)	0	0	0
C-reactive protein increased	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Lipase increased	2 (3.2)	0	0	0	2 (3.2)
Serum ferritin increased	2 (3.2)	0	2 (3.2)	0	0
Weight increased	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Blood alkaline phosphatase increased	1 (1.6)	1 (1.6)	0	0	0
Blood bicarbonate decreased	1 (1.6)	0	1 (1.6)	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Blood lactate dehydrogenase increased	1 (1.6)	1 (1.6)	0	0	0
Blood lactic acid increased	1 (1.6)	0	0	0	1 (1.6)
Blood phosphorus decreased	1 (1.6)	1 (1.6)	0	0	0
Blood sodium increased	1 (1.6)	0	1 (1.6)	0	0
Blood uric acid increased	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac murmur	1 (1.6)	1 (1.6)	0	0	0
Culture stool positive	1 (1.6)	1 (1.6)	0	0	0
Fibrin d dimer increased	1 (1.6)	1 (1.6)	0	0	0
Hepatic enzyme increased	1 (1.6)	0	1 (1.6)	0	0
Norovirus test positive	1 (1.6)	1 (1.6)	0	0	0
Oxygen saturation decreased	1 (1.6)	1 (1.6)	0	0	0
Protein total decreased	1 (1.6)	0	0	1 (1.6)	0
Pulmonary function test decreased	1 (1.6)	0	1 (1.6)	0	0
Metabolism and nutrition disorders					
-Total	41 (66.1)	6 (9.7)	8 (12.9)	23 (37.1)	4 (6.5)
Decreased appetite	22 (35.5)	5 (8.1)	5 (8.1)	12 (19.4)	0
Hypokalaemia	19 (30.6)	4 (6.5)	6 (9.7)	8 (12.9)	1 (1.6)
Hypophosphataemia	10 (16.1)	2 (3.2)	0	7 (11.3)	1 (1.6)
Hyperphosphataemia	7 (11.3)	7 (11.3)	0	0	0
Hypoalbuminaemia	5 (8.1)	1 (1.6)	3 (4.8)	1 (1.6)	0
Dehydration	4 (6.5)	1 (1.6)	0	3 (4.8)	0
Hypernatraemia	4 (6.5)	1 (1.6)	2 (3.2)	0	1 (1.6)
Fluid overload	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Hyperglycaemia	3 (4.8)	0	1 (1.6)	2 (3.2)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	3 (4.8)	1 (1.6)	1 (1.6)	1 (1.6)	0
Acidosis	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Hypertriglyceridaemia	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Hyperuricaemia	2 (3.2)	1 (1.6)	0	0	1 (1.6)
Hyponatraemia	2 (3.2)	0	0	2 (3.2)	0
Tumour lysis syndrome	2 (3.2)	0	0	2 (3.2)	0
Hyperalbuminaemia	1 (1.6)	1 (1.6)	0	0	0
Hypercalcaemia	1 (1.6)	1 (1.6)	0	0	0
Hyperchloraemia	1 (1.6)	1 (1.6)	0	0	0
Hypermagnesaemia	1 (1.6)	1 (1.6)	0	0	0
Hypomagnesaemia	1 (1.6)	1 (1.6)	0	0	0
Iron overload	1 (1.6)	0	0	1 (1.6)	0
Malnutrition	1 (1.6)	0	0	1 (1.6)	0
Metabolic acidosis	1 (1.6)	0	1 (1.6)	0	0
Metabolic alkalosis	1 (1.6)	1 (1.6)	0	0	0
Vitamin d deficiency	1 (1.6)	1 (1.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	23 (37.1)	12 (19.4)	10 (16.1)	1 (1.6)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	10 (16.1)	6 (9.7)	4 (6.5)	0	0
Arthralgia	4 (6.5)	2 (3.2)	1 (1.6)	1 (1.6)	0
Myalgia	4 (6.5)	3 (4.8)	1 (1.6)	0	0
Muscular weakness	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Musculoskeletal pain	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Musculoskeletal chest pain	2 (3.2)	2 (3.2)	0	0	0
Coccydynia	1 (1.6)	1 (1.6)	0	0	0
Flank pain	1 (1.6)	0	1 (1.6)	0	0
Limb discomfort	1 (1.6)	1 (1.6)	0	0	0
Muscle spasms	1 (1.6)	1 (1.6)	0	0	0
Neck pain	1 (1.6)	0	1 (1.6)	0	0
Osteonecrosis	1 (1.6)	0	1 (1.6)	0	0
Osteopenia	1 (1.6)	0	1 (1.6)	0	0
Pain in jaw	1 (1.6)	1 (1.6)	0	0	0
Toe walking	1 (1.6)	1 (1.6)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (4.8)	0	2 (3.2)	0	1 (1.6)
Glioblastoma multiforme	1 (1.6)	0	0	0	1 (1.6)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myelodysplastic syndrome	1 (1.6)	0	1 (1.6)	0	0
Skin papilloma	1 (1.6)	0	1 (1.6)	0	0
Nervous system disorders					
-Total	33 (53.2)	15 (24.2)	12 (19.4)	5 (8.1)	1 (1.6)
Headache	22 (35.5)	13 (21.0)	7 (11.3)	2 (3.2)	0
Dizziness	6 (9.7)	6 (9.7)	0	0	0
Encephalopathy	4 (6.5)	1 (1.6)	1 (1.6)	2 (3.2)	0
Seizure	4 (6.5)	0	2 (3.2)	2 (3.2)	0
Dysarthria	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Peroneal nerve palsy	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Tremor	2 (3.2)	2 (3.2)	0	0	0
Asterixis	1 (1.6)	1 (1.6)	0	0	0
Ataxia	1 (1.6)	0	1 (1.6)	0	0
Depressed level of consciousness	1 (1.6)	1 (1.6)	0	0	0
Disturbance in attention	1 (1.6)	1 (1.6)	0	0	0
Embolic stroke	1 (1.6)	0	0	0	1 (1.6)
Idiopathic intracranial hypertension	1 (1.6)	0	1 (1.6)	0	0
Migraine	1 (1.6)	0	1 (1.6)	0	0
Myoclonus	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neuropathy peripheral	1 (1.6)	0	1 (1.6)	0	0
Pleocytosis	1 (1.6)	1 (1.6)	0	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0
Product issues					
-Total	1 (1.6)	1 (1.6)	0	0	0
Device occlusion	1 (1.6)	1 (1.6)	0	0	0
Psychiatric disorders					
-Total	17 (27.4)	8 (12.9)	8 (12.9)	1 (1.6)	0
Anxiety	7 (11.3)	3 (4.8)	3 (4.8)	1 (1.6)	0
Confusional state	6 (9.7)	3 (4.8)	3 (4.8)	0	0
Delirium	4 (6.5)	2 (3.2)	2 (3.2)	0	0
Agitation	2 (3.2)	0	2 (3.2)	0	0
Depression	2 (3.2)	2 (3.2)	0	0	0
Hallucination	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Irritability	2 (3.2)	2 (3.2)	0	0	0
Adjustment disorder	1 (1.6)	0	1 (1.6)	0	0
Insomnia	1 (1.6)	0	1 (1.6)	0	0
Listless	1 (1.6)	1 (1.6)	0	0	0
Mental status changes	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Panic attack	1 (1.6)	0	1 (1.6)	0	0
Sleep disorder	1 (1.6)	0	1 (1.6)	0	0
Suicidal ideation	1 (1.6)	1 (1.6)	0	0	0
Renal and urinary disorders					
-Total	15 (24.2)	3 (4.8)	2 (3.2)	6 (9.7)	4 (6.5)
Acute kidney injury	9 (14.5)	1 (1.6)	1 (1.6)	4 (6.5)	3 (4.8)
Haematuria	5 (8.1)	0	2 (3.2)	2 (3.2)	1 (1.6)
Dysuria	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Oliguria	2 (3.2)	0	0	2 (3.2)	0
Calculus urinary	1 (1.6)	0	1 (1.6)	0	0
Nephrolithiasis	1 (1.6)	0	0	1 (1.6)	0
Pollakiuria	1 (1.6)	1 (1.6)	0	0	0
Renal failure	1 (1.6)	0	0	0	1 (1.6)
Renal impairment	1 (1.6)	0	0	1 (1.6)	0
Urinary incontinence	1 (1.6)	1 (1.6)	0	0	0
Reproductive system and breast disorders					
-Total	5 (8.1)	2 (3.2)	1 (1.6)	2 (3.2)	0
Vulvovaginal adhesion	2 (3.2)	2 (3.2)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema genital	1 (1.6)	0	1 (1.6)	0	0
Ovarian failure	1 (1.6)	0	0	1 (1.6)	0
Vaginal haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Respiratory, thoracic and mediastinal disorders					
-Total	37 (59.7)	13 (21.0)	9 (14.5)	7 (11.3)	8 (12.9)
Cough	13 (21.0)	11 (17.7)	2 (3.2)	0	0
Epistaxis	10 (16.1)	4 (6.5)	1 (1.6)	4 (6.5)	1 (1.6)
Hypoxia	10 (16.1)	0	3 (4.8)	4 (6.5)	3 (4.8)
Pleural effusion	8 (12.9)	2 (3.2)	4 (6.5)	2 (3.2)	0
Pulmonary oedema	7 (11.3)	1 (1.6)	0	4 (6.5)	2 (3.2)
Oropharyngeal pain	6 (9.7)	4 (6.5)	2 (3.2)	0	0
Rhinorrhoea	6 (9.7)	5 (8.1)	1 (1.6)	0	0
Nasal congestion	5 (8.1)	5 (8.1)	0	0	0
Tachypnoea	5 (8.1)	3 (4.8)	1 (1.6)	1 (1.6)	0
Rhinitis allergic	4 (6.5)	3 (4.8)	1 (1.6)	0	0
Respiratory failure	3 (4.8)	0	0	0	3 (4.8)
Dyspnoea	2 (3.2)	0	0	1 (1.6)	1 (1.6)
Haemoptysis	2 (3.2)	1 (1.6)	0	0	1 (1.6)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory failure	1 (1.6)	0	0	0	1 (1.6)
Atelectasis	1 (1.6)	1 (1.6)	0	0	0
Dysphonia	1 (1.6)	1 (1.6)	0	0	0
Interstitial lung disease	1 (1.6)	0	0	0	1 (1.6)
Oropharyngeal plaque	1 (1.6)	1 (1.6)	0	0	0
Pharyngeal erythema	1 (1.6)	1 (1.6)	0	0	0
Pharyngeal lesion	1 (1.6)	0	0	1 (1.6)	0
Pharyngeal ulceration	1 (1.6)	0	1 (1.6)	0	0
Respiratory depression	1 (1.6)	0	1 (1.6)	0	0
Respiratory distress	1 (1.6)	0	0	0	1 (1.6)
Wheezing	1 (1.6)	0	1 (1.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	29 (46.8)	17 (27.4)	9 (14.5)	3 (4.8)	0
Rash	8 (12.9)	5 (8.1)	3 (4.8)	0	0
Dry skin	5 (8.1)	5 (8.1)	0	0	0
Erythema	5 (8.1)	5 (8.1)	0	0	0
Hyperhidrosis	4 (6.5)	4 (6.5)	0	0	0
Petechiae	4 (6.5)	3 (4.8)	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	4 (6.5)	4 (6.5)	0	0	0
Rash maculo-papular	4 (6.5)	2 (3.2)	1 (1.6)	1 (1.6)	0
Ingrowing nail	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Papule	2 (3.2)	2 (3.2)	0	0	0
Rash erythematous	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Rash papular	2 (3.2)	2 (3.2)	0	0	0
Acne	1 (1.6)	1 (1.6)	0	0	0
Alopecia	1 (1.6)	0	1 (1.6)	0	0
Dermatitis	1 (1.6)	1 (1.6)	0	0	0
Dermatitis acneiform	1 (1.6)	0	0	1 (1.6)	0
Dermatitis atopic	1 (1.6)	1 (1.6)	0	0	0
Dermatitis diaper	1 (1.6)	1 (1.6)	0	0	0
Ecchymosis	1 (1.6)	0	0	1 (1.6)	0
Eczema	1 (1.6)	1 (1.6)	0	0	0
Keloid scar	1 (1.6)	0	1 (1.6)	0	0
Livedo reticularis	1 (1.6)	1 (1.6)	0	0	0
Macule	1 (1.6)	1 (1.6)	0	0	0
Night sweats	1 (1.6)	0	1 (1.6)	0	0
Rash follicular	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash macular	1 (1.6)	1 (1.6)	0	0	0
Rash pruritic	1 (1.6)	1 (1.6)	0	0	0
Rash vesicular	1 (1.6)	1 (1.6)	0	0	0
Skin exfoliation	1 (1.6)	1 (1.6)	0	0	0
Skin fissures	1 (1.6)	1 (1.6)	0	0	0
Vascular disorders					
-Total	25 (40.3)	3 (4.8)	6 (9.7)	8 (12.9)	8 (12.9)
Hypotension	16 (25.8)	1 (1.6)	0	7 (11.3)	8 (12.9)
Hypertension	12 (19.4)	3 (4.8)	8 (12.9)	1 (1.6)	0
Flushing	2 (3.2)	2 (3.2)	0	0	0
Orthostatic hypotension	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Capillary leak syndrome	1 (1.6)	0	0	0	1 (1.6)
Embolism	1 (1.6)	0	0	1 (1.6)	0
Haematoma	1 (1.6)	0	1 (1.6)	0	0
Hot flush	1 (1.6)	1 (1.6)	0	0	0
Secondary hypertension	1 (1.6)	0	1 (1.6)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174g
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=3		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Anaemia	2 (66.7)	0	0	2 (66.7)	0
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	0	0	1 (33.3)
Cardiac disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Bradycardia	1 (33.3)	0	1 (33.3)	0	0
Left ventricular dysfunction	1 (33.3)	0	0	1 (33.3)	0
Pericardial effusion	1 (33.3)	0	1 (33.3)	0	0
Tachycardia	1 (33.3)	0	0	1 (33.3)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Conjunctival haemorrhage	1 (33.3)	1 (33.3)	0	0	0
Periorbital oedema	1 (33.3)	1 (33.3)	0	0	0
Gastrointestinal disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Diarrhoea	1 (33.3)	0	1 (33.3)	0	0
Dysphagia	1 (33.3)	0	0	1 (33.3)	0
Nausea	1 (33.3)	0	0	1 (33.3)	0
Vomiting	1 (33.3)	0	1 (33.3)	0	0
General disorders and administration site conditions					
-Total	2 (66.7)	0	0	2 (66.7)	0
Asthenia	1 (33.3)	1 (33.3)	0	0	0
Chills	1 (33.3)	1 (33.3)	0	0	0
Face oedema	1 (33.3)	0	0	1 (33.3)	0
Localised oedema	1 (33.3)	0	0	1 (33.3)	0
Mucosal haemorrhage	1 (33.3)	0	1 (33.3)	0	0
Multiple organ dysfunction syndrome	1 (33.3)	0	0	1 (33.3)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=3		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	1 (33.3)	0	0	1 (33.3)	0
Pyrexia	1 (33.3)	0	0	1 (33.3)	0
Hepatobiliary disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Hepatomegaly	1 (33.3)	0	1 (33.3)	0	0
Hyperbilirubinaemia	1 (33.3)	0	0	1 (33.3)	0
Immune system disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	0	0	2 (66.7)
Injury, poisoning and procedural complications					
-Total	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Procedural complication	1 (33.3)	1 (33.3)	0	0	0
Tracheal haemorrhage	1 (33.3)	0	0	1 (33.3)	0
Investigations					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Aspartate aminotransferase increased	2 (66.7)	0	0	0	2 (66.7)
Blood fibrinogen decreased	2 (66.7)	0	1 (33.3)	0	1 (33.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (33.3)	0	0	1 (33.3)	0
Blood creatinine increased	1 (33.3)	0	0	1 (33.3)	0
Blood phosphorus decreased	1 (33.3)	1 (33.3)	0	0	0
Blood urea increased	1 (33.3)	0	0	1 (33.3)	0
International normalised ratio increased	1 (33.3)	1 (33.3)	0	0	0
Neutrophil count decreased	1 (33.3)	0	0	1 (33.3)	0
Platelet count decreased	1 (33.3)	0	0	1 (33.3)	0
Protein total decreased	1 (33.3)	0	0	1 (33.3)	0
Prothrombin time prolonged	1 (33.3)	0	1 (33.3)	0	0
White blood cell count decreased	1 (33.3)	0	0	1 (33.3)	0
Metabolism and nutrition disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Hypokalaemia	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Hypophosphataemia	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Acidosis	1 (33.3)	0	0	1 (33.3)	0
Decreased appetite	1 (33.3)	0	0	1 (33.3)	0
Hyperalbuminaemia	1 (33.3)	1 (33.3)	0	0	0
Hypercalcaemia	1 (33.3)	1 (33.3)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperchloraemia	1 (33.3)	1 (33.3)	0	0	0
Hypermagnesaemia	1 (33.3)	1 (33.3)	0	0	0
Hypernatraemia	1 (33.3)	0	1 (33.3)	0	0
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)	0	0
Metabolic alkalosis	1 (33.3)	1 (33.3)	0	0	0
Nervous system disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Dizziness	1 (33.3)	1 (33.3)	0	0	0
Psychiatric disorders					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Confusional state	1 (33.3)	1 (33.3)	0	0	0
Delirium	1 (33.3)	0	1 (33.3)	0	0
Insomnia	1 (33.3)	0	1 (33.3)	0	0
Irritability	1 (33.3)	1 (33.3)	0	0	0
Renal and urinary disorders					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Acute kidney injury	1 (33.3)	0	0	0	1 (33.3)
Haematuria	1 (33.3)	0	0	1 (33.3)	0
Renal impairment	1 (33.3)	0	0	1 (33.3)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=3		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Pleural effusion	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Pulmonary oedema	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Cough	1 (33.3)	1 (33.3)	0	0	0
Dyspnoea	1 (33.3)	0	0	0	1 (33.3)
Epistaxis	1 (33.3)	0	1 (33.3)	0	0
Hypoxia	1 (33.3)	0	0	0	1 (33.3)
Interstitial lung disease	1 (33.3)	0	0	0	1 (33.3)
Respiratory distress	1 (33.3)	0	0	0	1 (33.3)
Skin and subcutaneous tissue disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Hyperhidrosis	1 (33.3)	1 (33.3)	0	0	0
Rash papular	1 (33.3)	1 (33.3)	0	0	0
Vascular disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Hypertension	2 (66.7)	0	2 (66.7)	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=3		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	2 (66.7)	0	0	0	2 (66.7)
Capillary leak syndrome	1 (33.3)	0	0	0	1 (33.3)
Flushing	1 (33.3)	1 (33.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174g
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	60 (98.4)	2 (3.3)	7 (11.5)	13 (21.3)	38 (62.3)
Blood and lymphatic system disorders					
-Total	41 (67.2)	2 (3.3)	3 (4.9)	26 (42.6)	10 (16.4)
Anaemia	25 (41.0)	3 (4.9)	5 (8.2)	16 (26.2)	1 (1.6)
Febrile neutropenia	22 (36.1)	0	0	22 (36.1)	0
Neutropenia	7 (11.5)	0	0	3 (4.9)	4 (6.6)
Thrombocytopenia	7 (11.5)	0	0	2 (3.3)	5 (8.2)
Disseminated intravascular coagulation	4 (6.6)	0	2 (3.3)	2 (3.3)	0
Lymphopenia	3 (4.9)	0	1 (1.6)	1 (1.6)	1 (1.6)
Coagulopathy	1 (1.6)	1 (1.6)	0	0	0
Pancytopenia	1 (1.6)	0	0	0	1 (1.6)
Cardiac disorders					

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	20 (32.8)	11 (18.0)	8 (13.1)	1 (1.6)	0
Tachycardia	14 (23.0)	8 (13.1)	5 (8.2)	1 (1.6)	0
Sinus tachycardia	5 (8.2)	3 (4.9)	2 (3.3)	0	0
Atrioventricular block second degree	1 (1.6)	1 (1.6)	0	0	0
Cardiac dysfunction	1 (1.6)	1 (1.6)	0	0	0
Palpitations	1 (1.6)	1 (1.6)	0	0	0
Pericardial effusion	1 (1.6)	1 (1.6)	0	0	0
Sinus bradycardia	1 (1.6)	1 (1.6)	0	0	0
Ventricular tachycardia	1 (1.6)	0	1 (1.6)	0	0
Ear and labyrinth disorders					
-Total	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Ear pain	2 (3.3)	2 (3.3)	0	0	0
Hypoacusis	1 (1.6)	0	1 (1.6)	0	0
Endocrine disorders					
-Total	1 (1.6)	0	1 (1.6)	0	0
Adrenal insufficiency	1 (1.6)	0	1 (1.6)	0	0
Eye disorders					
-Total	12 (19.7)	5 (8.2)	7 (11.5)	0	0
Eye pain	3 (4.9)	1 (1.6)	2 (3.3)	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Periorbital oedema	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Vision blurred	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Conjunctival haemorrhage	2 (3.3)	2 (3.3)	0	0	0
Photophobia	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Retinal haemorrhage	2 (3.3)	2 (3.3)	0	0	0
Uveitis	2 (3.3)	0	2 (3.3)	0	0
Ocular hypertension	1 (1.6)	0	1 (1.6)	0	0
Papilloedema	1 (1.6)	0	1 (1.6)	0	0
Visual impairment	1 (1.6)	0	1 (1.6)	0	0
Gastrointestinal disorders					
-Total	34 (55.7)	11 (18.0)	14 (23.0)	9 (14.8)	0
Vomiting	21 (34.4)	13 (21.3)	5 (8.2)	3 (4.9)	0
Nausea	20 (32.8)	6 (9.8)	12 (19.7)	2 (3.3)	0
Diarrhoea	17 (27.9)	11 (18.0)	5 (8.2)	1 (1.6)	0
Abdominal pain	9 (14.8)	6 (9.8)	2 (3.3)	1 (1.6)	0
Constipation	7 (11.5)	6 (9.8)	1 (1.6)	0	0
Abdominal distension	2 (3.3)	0	2 (3.3)	0	0
Abdominal pain upper	2 (3.3)	0	2 (3.3)	0	0
Haematemesis	2 (3.3)	2 (3.3)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Stomatitis	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Abdominal discomfort	1 (1.6)	1 (1.6)	0	0	0
Abdominal pain lower	1 (1.6)	0	1 (1.6)	0	0
Abdominal tenderness	1 (1.6)	1 (1.6)	0	0	0
Anal incontinence	1 (1.6)	1 (1.6)	0	0	0
Ascites	1 (1.6)	0	0	1 (1.6)	0
Dyspepsia	1 (1.6)	0	1 (1.6)	0	0
Dysphagia	1 (1.6)	0	1 (1.6)	0	0
Flatulence	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Gastrooesophageal reflux disease	1 (1.6)	1 (1.6)	0	0	0
Glossodynia	1 (1.6)	1 (1.6)	0	0	0
Ileus	1 (1.6)	0	0	1 (1.6)	0
Intestinal obstruction	1 (1.6)	0	0	1 (1.6)	0
Lip pain	1 (1.6)	0	1 (1.6)	0	0
Mouth haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Tooth socket haemorrhage	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	30 (49.2)	12 (19.7)	10 (16.4)	7 (11.5)	1 (1.6)
Pyrexia	15 (24.6)	3 (4.9)	7 (11.5)	4 (6.6)	1 (1.6)
Fatigue	13 (21.3)	10 (16.4)	2 (3.3)	1 (1.6)	0
Chills	7 (11.5)	7 (11.5)	0	0	0
Catheter site pain	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Malaise	3 (4.9)	0	3 (4.9)	0	0
Pain	3 (4.9)	0	1 (1.6)	2 (3.3)	0
Generalised oedema	2 (3.3)	0	2 (3.3)	0	0
Catheter site extravasation	1 (1.6)	0	1 (1.6)	0	0
Catheter site haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Face oedema	1 (1.6)	0	1 (1.6)	0	0
Facial pain	1 (1.6)	0	1 (1.6)	0	0
Injection site haematoma	1 (1.6)	1 (1.6)	0	0	0
Non-cardiac chest pain	1 (1.6)	1 (1.6)	0	0	0
Oedema peripheral	1 (1.6)	1 (1.6)	0	0	0
Peripheral swelling	1 (1.6)	0	1 (1.6)	0	0
Physical deconditioning	1 (1.6)	0	0	1 (1.6)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	5 (8.2)	3 (4.9)	1 (1.6)	1 (1.6)	0
Hepatomegaly	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Hyperbilirubinaemia	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Gallbladder enlargement	1 (1.6)	1 (1.6)	0	0	0
Hepatosplenomegaly	1 (1.6)	1 (1.6)	0	0	0
Immune system disorders					
-Total	55 (90.2)	5 (8.2)	30 (49.2)	11 (18.0)	9 (14.8)
Cytokine release syndrome	48 (78.7)	6 (9.8)	25 (41.0)	8 (13.1)	9 (14.8)
Hypogammaglobulinaemia	25 (41.0)	3 (4.9)	18 (29.5)	4 (6.6)	0
Drug hypersensitivity	1 (1.6)	0	1 (1.6)	0	0
Graft versus host disease in skin	1 (1.6)	1 (1.6)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.6)	0	1 (1.6)	0	0
Infections and infestations					
-Total	26 (42.6)	5 (8.2)	14 (23.0)	6 (9.8)	1 (1.6)
Clostridium difficile colitis	4 (6.6)	1 (1.6)	2 (3.3)	1 (1.6)	0
Clostridium difficile infection	4 (6.6)	0	4 (6.6)	0	0
Rhinovirus infection	3 (4.9)	3 (4.9)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Pneumonia	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Staphylococcal infection	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Body tinea	1 (1.6)	1 (1.6)	0	0	0
Catheter site cellulitis	1 (1.6)	1 (1.6)	0	0	0
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cytomegalovirus infection	1 (1.6)	1 (1.6)	0	0	0
Enterococcal infection	1 (1.6)	1 (1.6)	0	0	0
Folliculitis	1 (1.6)	0	1 (1.6)	0	0
Fungal skin infection	1 (1.6)	1 (1.6)	0	0	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Herpes simplex	1 (1.6)	1 (1.6)	0	0	0
Human herpesvirus 6 infection	1 (1.6)	0	1 (1.6)	0	0
Hypopyon	1 (1.6)	0	1 (1.6)	0	0
Influenza	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	1 (1.6)	0	0	0
Orchitis	1 (1.6)	1 (1.6)	0	0	0
Pharyngitis	1 (1.6)	0	1 (1.6)	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Skin infection	1 (1.6)	0	1 (1.6)	0	0
Streptococcal infection	1 (1.6)	0	1 (1.6)	0	0
Upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Urinary tract infection enterococcal	1 (1.6)	0	0	1 (1.6)	0
Viral infection	1 (1.6)	0	1 (1.6)	0	0
Viral upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Vulvovaginal candidiasis	1 (1.6)	1 (1.6)	0	0	0
Injury, poisoning and procedural complications					
-Total	13 (21.3)	7 (11.5)	5 (8.2)	0	1 (1.6)
Procedural pain	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Transfusion reaction	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Infusion related reaction	2 (3.3)	0	2 (3.3)	0	0
Contusion	1 (1.6)	1 (1.6)	0	0	0
Incision site pain	1 (1.6)	1 (1.6)	0	0	0
Limb injury	1 (1.6)	1 (1.6)	0	0	0
Mouth injury	1 (1.6)	1 (1.6)	0	0	0
Post procedural haemorrhage	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural headache	1 (1.6)	0	1 (1.6)	0	0
Procedural site reaction	1 (1.6)	1 (1.6)	0	0	0
Skin abrasion	1 (1.6)	1 (1.6)	0	0	0
Stoma site irritation	1 (1.6)	1 (1.6)	0	0	0
Subdural haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Tibia fracture	1 (1.6)	0	1 (1.6)	0	0
Tongue injury	1 (1.6)	1 (1.6)	0	0	0
Transfusion related complication	1 (1.6)	0	0	0	1 (1.6)
Investigations					
-Total	49 (80.3)	4 (6.6)	4 (6.6)	12 (19.7)	29 (47.5)
White blood cell count decreased	29 (47.5)	3 (4.9)	1 (1.6)	9 (14.8)	16 (26.2)
Neutrophil count decreased	24 (39.3)	0	2 (3.3)	3 (4.9)	19 (31.1)
Alanine aminotransferase increased	18 (29.5)	5 (8.2)	3 (4.9)	10 (16.4)	0
Platelet count decreased	18 (29.5)	3 (4.9)	2 (3.3)	1 (1.6)	12 (19.7)
Aspartate aminotransferase increased	16 (26.2)	3 (4.9)	4 (6.6)	7 (11.5)	2 (3.3)
Lymphocyte count decreased	14 (23.0)	1 (1.6)	2 (3.3)	6 (9.8)	5 (8.2)
Blood creatinine increased	8 (13.1)	5 (8.2)	2 (3.3)	1 (1.6)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	8 (13.1)	7 (11.5)	0	1 (1.6)	0
Prothrombin time prolonged	8 (13.1)	5 (8.2)	2 (3.3)	1 (1.6)	0
Blood bilirubin increased	7 (11.5)	2 (3.3)	3 (4.9)	2 (3.3)	0
Activated partial thromboplastin time prolonged	5 (8.2)	3 (4.9)	2 (3.3)	0	0
Blood immunoglobulin m decreased	4 (6.6)	4 (6.6)	0	0	0
Blood immunoglobulin a decreased	3 (4.9)	3 (4.9)	0	0	0
Blood fibrinogen decreased	2 (3.3)	0	0	2 (3.3)	0
Blood phosphorus increased	2 (3.3)	2 (3.3)	0	0	0
Blood urea increased	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Lipase increased	2 (3.3)	0	0	0	2 (3.3)
Transaminases increased	2 (3.3)	2 (3.3)	0	0	0
Blood bicarbonate decreased	1 (1.6)	0	1 (1.6)	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Blood lactic acid increased	1 (1.6)	0	0	0	1 (1.6)
Blood magnesium decreased	1 (1.6)	0	0	1 (1.6)	0
Blood sodium increased	1 (1.6)	0	1 (1.6)	0	0
Blood uric acid increased	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	1 (1.6)	0	0	1 (1.6)	0
Cardiac murmur	1 (1.6)	1 (1.6)	0	0	0
Culture stool positive	1 (1.6)	1 (1.6)	0	0	0
Fibrin d dimer increased	1 (1.6)	1 (1.6)	0	0	0
Haemoglobin decreased	1 (1.6)	0	0	1 (1.6)	0
Hepatic enzyme increased	1 (1.6)	0	1 (1.6)	0	0
Norovirus test positive	1 (1.6)	1 (1.6)	0	0	0
Pulmonary function test decreased	1 (1.6)	0	1 (1.6)	0	0
Serum ferritin increased	1 (1.6)	0	1 (1.6)	0	0
Metabolism and nutrition disorders					
-Total	37 (60.7)	5 (8.2)	10 (16.4)	19 (31.1)	3 (4.9)
Decreased appetite	19 (31.1)	4 (6.6)	4 (6.6)	11 (18.0)	0
Hypokalaemia	14 (23.0)	2 (3.3)	6 (9.8)	6 (9.8)	0
Hyperphosphataemia	8 (13.1)	8 (13.1)	0	0	0
Hypophosphataemia	7 (11.5)	1 (1.6)	0	5 (8.2)	1 (1.6)
Hypoalbuminaemia	4 (6.6)	1 (1.6)	2 (3.3)	1 (1.6)	0
Dehydration	3 (4.9)	1 (1.6)	0	2 (3.3)	0
Fluid overload	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Hyperglycaemia	3 (4.9)	0	2 (3.3)	1 (1.6)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	3 (4.9)	1 (1.6)	1 (1.6)	0	1 (1.6)
Hyperuricaemia	3 (4.9)	2 (3.3)	0	0	1 (1.6)
Hypocalcaemia	3 (4.9)	1 (1.6)	1 (1.6)	1 (1.6)	0
Hypertriglyceridaemia	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Hyponatraemia	2 (3.3)	0	0	2 (3.3)	0
Acidosis	1 (1.6)	1 (1.6)	0	0	0
Hypomagnesaemia	1 (1.6)	1 (1.6)	0	0	0
Malnutrition	1 (1.6)	0	0	1 (1.6)	0
Metabolic acidosis	1 (1.6)	0	1 (1.6)	0	0
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0
Musculoskeletal and connective tissue disorders					
-Total	15 (24.6)	8 (13.1)	6 (9.8)	1 (1.6)	0
Myalgia	5 (8.2)	4 (6.6)	1 (1.6)	0	0
Arthralgia	4 (6.6)	3 (4.9)	0	1 (1.6)	0
Pain in extremity	4 (6.6)	2 (3.3)	2 (3.3)	0	0
Musculoskeletal pain	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Coccydynia	1 (1.6)	1 (1.6)	0	0	0
Limb discomfort	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscle spasms	1 (1.6)	1 (1.6)	0	0	0
Muscular weakness	1 (1.6)	0	1 (1.6)	0	0
Musculoskeletal chest pain	1 (1.6)	1 (1.6)	0	0	0
Osteopenia	1 (1.6)	0	1 (1.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.6)	0	1 (1.6)	0	0
Skin papilloma	1 (1.6)	0	1 (1.6)	0	0
Nervous system disorders					
-Total	32 (52.5)	16 (26.2)	11 (18.0)	4 (6.6)	1 (1.6)
Headache	24 (39.3)	16 (26.2)	6 (9.8)	2 (3.3)	0
Encephalopathy	4 (6.6)	1 (1.6)	1 (1.6)	2 (3.3)	0
Dizziness	3 (4.9)	3 (4.9)	0	0	0
Seizure	3 (4.9)	0	2 (3.3)	1 (1.6)	0
Dysarthria	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Tremor	2 (3.3)	2 (3.3)	0	0	0
Asterixis	1 (1.6)	1 (1.6)	0	0	0
Ataxia	1 (1.6)	0	1 (1.6)	0	0
Depressed level of consciousness	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Embolic stroke	1 (1.6)	0	0	0	1 (1.6)
Idiopathic intracranial hypertension	1 (1.6)	0	1 (1.6)	0	0
Migraine	1 (1.6)	0	1 (1.6)	0	0
Myoclonus	1 (1.6)	1 (1.6)	0	0	0
Neuropathy peripheral	1 (1.6)	0	1 (1.6)	0	0
Pleocytosis	1 (1.6)	1 (1.6)	0	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0
Product issues					
-Total	1 (1.6)	1 (1.6)	0	0	0
Device occlusion	1 (1.6)	1 (1.6)	0	0	0
Psychiatric disorders					
-Total	14 (23.0)	7 (11.5)	6 (9.8)	1 (1.6)	0
Anxiety	6 (9.8)	2 (3.3)	3 (4.9)	1 (1.6)	0
Confusional state	5 (8.2)	2 (3.3)	3 (4.9)	0	0
Delirium	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Agitation	2 (3.3)	0	2 (3.3)	0	0
Hallucination	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Adjustment disorder	1 (1.6)	0	1 (1.6)	0	0
Irritability	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Listless	1 (1.6)	1 (1.6)	0	0	0
Mental status changes	1 (1.6)	1 (1.6)	0	0	0
Panic attack	1 (1.6)	0	1 (1.6)	0	0
Suicidal ideation	1 (1.6)	1 (1.6)	0	0	0
Renal and urinary disorders					
-Total	9 (14.8)	2 (3.3)	2 (3.3)	2 (3.3)	3 (4.9)
Acute kidney injury	6 (9.8)	1 (1.6)	1 (1.6)	2 (3.3)	2 (3.3)
Haematuria	3 (4.9)	0	2 (3.3)	0	1 (1.6)
Dysuria	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Oliguria	2 (3.3)	0	0	2 (3.3)	0
Pollakiuria	1 (1.6)	1 (1.6)	0	0	0
Renal failure	1 (1.6)	0	0	0	1 (1.6)
Reproductive system and breast disorders					
-Total	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Vulvovaginal adhesion	2 (3.3)	2 (3.3)	0	0	0
Oedema genital	1 (1.6)	0	1 (1.6)	0	0
Respiratory, thoracic and mediastinal disorders					

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	26 (42.6)	10 (16.4)	6 (9.8)	5 (8.2)	5 (8.2)
Hypoxia	9 (14.8)	0	3 (4.9)	4 (6.6)	2 (3.3)
Cough	7 (11.5)	7 (11.5)	0	0	0
Epistaxis	6 (9.8)	2 (3.3)	0	3 (4.9)	1 (1.6)
Pleural effusion	6 (9.8)	2 (3.3)	3 (4.9)	1 (1.6)	0
Tachypnoea	5 (8.2)	3 (4.9)	1 (1.6)	1 (1.6)	0
Pulmonary oedema	4 (6.6)	1 (1.6)	0	2 (3.3)	1 (1.6)
Respiratory failure	3 (4.9)	0	0	0	3 (4.9)
Haemoptysis	2 (3.3)	1 (1.6)	0	0	1 (1.6)
Oropharyngeal pain	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Atelectasis	1 (1.6)	1 (1.6)	0	0	0
Dyspnoea	1 (1.6)	0	0	1 (1.6)	0
Nasal congestion	1 (1.6)	1 (1.6)	0	0	0
Oropharyngeal plaque	1 (1.6)	1 (1.6)	0	0	0
Pharyngeal ulceration	1 (1.6)	0	1 (1.6)	0	0
Respiratory depression	1 (1.6)	0	1 (1.6)	0	0
Rhinitis allergic	1 (1.6)	1 (1.6)	0	0	0
Rhinorrhoea	1 (1.6)	1 (1.6)	0	0	0
Wheezing	1 (1.6)	0	1 (1.6)	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	20 (32.8)	14 (23.0)	4 (6.6)	2 (3.3)	0
Dry skin	4 (6.6)	4 (6.6)	0	0	0
Rash	4 (6.6)	4 (6.6)	0	0	0
Erythema	3 (4.9)	3 (4.9)	0	0	0
Petechiae	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Rash maculo-papular	3 (4.9)	1 (1.6)	1 (1.6)	1 (1.6)	0
Hyperhidrosis	2 (3.3)	2 (3.3)	0	0	0
Ingrowing nail	2 (3.3)	0	2 (3.3)	0	0
Pruritus	2 (3.3)	2 (3.3)	0	0	0
Dermatitis diaper	1 (1.6)	1 (1.6)	0	0	0
Ecchymosis	1 (1.6)	0	0	1 (1.6)	0
Livedo reticularis	1 (1.6)	1 (1.6)	0	0	0
Macule	1 (1.6)	1 (1.6)	0	0	0
Night sweats	1 (1.6)	0	1 (1.6)	0	0
Rash erythematous	1 (1.6)	1 (1.6)	0	0	0
Rash follicular	1 (1.6)	1 (1.6)	0	0	0
Rash macular	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash papular	1 (1.6)	1 (1.6)	0	0	0
Rash vesicular	1 (1.6)	1 (1.6)	0	0	0
Skin exfoliation	1 (1.6)	1 (1.6)	0	0	0
Skin fissures	1 (1.6)	1 (1.6)	0	0	0
Skin irritation	1 (1.6)	1 (1.6)	0	0	0
Vascular disorders					
-Total	22 (36.1)	3 (4.9)	5 (8.2)	8 (13.1)	6 (9.8)
Hypotension	14 (23.0)	1 (1.6)	0	7 (11.5)	6 (9.8)
Hypertension	8 (13.1)	2 (3.3)	5 (8.2)	1 (1.6)	0
Orthostatic hypotension	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Embolism	1 (1.6)	0	0	1 (1.6)	0
Flushing	1 (1.6)	1 (1.6)	0	0	0
Haematoma	1 (1.6)	0	1 (1.6)	0	0
Secondary hypertension	1 (1.6)	0	1 (1.6)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174g
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	0	0	1 (50.0)
Blood and lymphatic system disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Leukopenia	1 (50.0)	0	0	0	1 (50.0)
Immune system disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Hypogammaglobulinaemia	1 (50.0)	0	0	1 (50.0)	0
Infections and infestations					
-Total	1 (50.0)	1 (50.0)	0	0	0
Upper respiratory tract infection	1 (50.0)	1 (50.0)	0	0	0
Investigations					

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=2		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	1 (50.0)	0	0	0
Blood urea increased	1 (50.0)	1 (50.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Hyperalbuminaemia	1 (50.0)	1 (50.0)	0	0	0
Hypercalcaemia	1 (50.0)	1 (50.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Papule	1 (50.0)	1 (50.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174g
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (83.3)	4 (7.4)	16 (29.6)	16 (29.6)	9 (16.7)
Blood and lymphatic system disorders					
-Total	10 (18.5)	1 (1.9)	3 (5.6)	3 (5.6)	3 (5.6)
Neutropenia	4 (7.4)	0	0	1 (1.9)	3 (5.6)
Febrile neutropenia	3 (5.6)	0	0	3 (5.6)	0
Anaemia	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Thrombocytopenia	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Eosinophilia	1 (1.9)	0	0	1 (1.9)	0
Lymphadenopathy	1 (1.9)	0	1 (1.9)	0	0
Lymphopenia	1 (1.9)	0	1 (1.9)	0	0
Cardiac disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.9)	0	1 (1.9)	0	0
Sinus tachycardia	1 (1.9)	0	1 (1.9)	0	0
Endocrine disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Adrenal insufficiency	1 (1.9)	1 (1.9)	0	0	0
Eye disorders					
-Total	5 (9.3)	4 (7.4)	1 (1.9)	0	0
Dry eye	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Conjunctivitis allergic	1 (1.9)	1 (1.9)	0	0	0
Ocular hyperaemia	1 (1.9)	1 (1.9)	0	0	0
Vision blurred	1 (1.9)	1 (1.9)	0	0	0
Gastrointestinal disorders					
-Total	16 (29.6)	9 (16.7)	3 (5.6)	4 (7.4)	0
Vomiting	9 (16.7)	5 (9.3)	2 (3.7)	2 (3.7)	0
Diarrhoea	8 (14.8)	6 (11.1)	1 (1.9)	1 (1.9)	0
Nausea	6 (11.1)	1 (1.9)	3 (5.6)	2 (3.7)	0
Abdominal pain	4 (7.4)	2 (3.7)	1 (1.9)	1 (1.9)	0
Oral pain	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Abdominal pain upper	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterocolitis	1 (1.9)	0	0	1 (1.9)	0
Pigmentation lip	1 (1.9)	1 (1.9)	0	0	0
General disorders and administration site conditions					
-Total	17 (31.5)	13 (24.1)	3 (5.6)	1 (1.9)	0
Pyrexia	10 (18.5)	7 (13.0)	2 (3.7)	1 (1.9)	0
Fatigue	2 (3.7)	2 (3.7)	0	0	0
Influenza like illness	2 (3.7)	2 (3.7)	0	0	0
Acquired gene mutation	1 (1.9)	1 (1.9)	0	0	0
Catheter site pain	1 (1.9)	0	1 (1.9)	0	0
Chills	1 (1.9)	1 (1.9)	0	0	0
Crying	1 (1.9)	1 (1.9)	0	0	0
Generalised oedema	1 (1.9)	1 (1.9)	0	0	0
Malaise	1 (1.9)	1 (1.9)	0	0	0
Oedema peripheral	1 (1.9)	1 (1.9)	0	0	0
Pain	1 (1.9)	1 (1.9)	0	0	0
Immune system disorders					
-Total	13 (24.1)	3 (5.6)	10 (18.5)	0	0
Hypogammaglobulinaemia	7 (13.0)	0	7 (13.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Immunodeficiency common variable	2 (3.7)	0	2 (3.7)	0	0
Seasonal allergy	2 (3.7)	2 (3.7)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (1.9)	0	1 (1.9)	0	0
Infections and infestations					
-Total	32 (59.3)	5 (9.3)	15 (27.8)	10 (18.5)	2 (3.7)
Upper respiratory tract infection	6 (11.1)	2 (3.7)	3 (5.6)	1 (1.9)	0
Urinary tract infection	4 (7.4)	0	2 (3.7)	2 (3.7)	0
Gastroenteritis	3 (5.6)	1 (1.9)	2 (3.7)	0	0
Influenza	3 (5.6)	0	3 (5.6)	0	0
Ear infection	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Parainfluenzae virus infection	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Rhinovirus infection	2 (3.7)	2 (3.7)	0	0	0
Sinusitis	2 (3.7)	0	2 (3.7)	0	0
Viral upper respiratory tract infection	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Bacterial sepsis	1 (1.9)	0	0	0	1 (1.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (1.9)	0	0	1 (1.9)	0
Cholecystitis infective	1 (1.9)	0	0	1 (1.9)	0
Corona virus infection	1 (1.9)	0	0	1 (1.9)	0
Cytomegalovirus infection	1 (1.9)	1 (1.9)	0	0	0
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis viral	1 (1.9)	1 (1.9)	0	0	0
Herpes zoster	1 (1.9)	0	0	1 (1.9)	0
Molluscum contagiosum	1 (1.9)	1 (1.9)	0	0	0
Oral herpes	1 (1.9)	0	1 (1.9)	0	0
Otitis externa	1 (1.9)	0	1 (1.9)	0	0
Otitis media	1 (1.9)	0	1 (1.9)	0	0
Otitis media acute	1 (1.9)	0	1 (1.9)	0	0
Paronychia	1 (1.9)	1 (1.9)	0	0	0
Rash pustular	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus infection	1 (1.9)	0	0	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	1 (1.9)	1 (1.9)	0	0	0
Rotavirus infection	1 (1.9)	0	0	1 (1.9)	0
Sepsis	1 (1.9)	0	0	0	1 (1.9)
Subcutaneous abscess	1 (1.9)	0	1 (1.9)	0	0
Tinea capitis	1 (1.9)	1 (1.9)	0	0	0
Vascular device infection	1 (1.9)	0	0	1 (1.9)	0
Viral infection	1 (1.9)	1 (1.9)	0	0	0
Vulvovaginal mycotic infection	1 (1.9)	0	1 (1.9)	0	0
Injury, poisoning and procedural complications					
-Total	8 (14.8)	3 (5.6)	5 (9.3)	0	0
Contusion	2 (3.7)	2 (3.7)	0	0	0
Infusion related reaction	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Procedural pain	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Arthropod bite	1 (1.9)	1 (1.9)	0	0	0
Foot fracture	1 (1.9)	0	1 (1.9)	0	0
Procedural nausea	1 (1.9)	0	1 (1.9)	0	0
Radius fracture	1 (1.9)	0	1 (1.9)	0	0
Skin abrasion	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin laceration	1 (1.9)	0	1 (1.9)	0	0
Sunburn	1 (1.9)	1 (1.9)	0	0	0
Investigations					
-Total	22 (40.7)	5 (9.3)	5 (9.3)	8 (14.8)	4 (7.4)
Neutrophil count decreased	8 (14.8)	2 (3.7)	0	3 (5.6)	3 (5.6)
White blood cell count decreased	5 (9.3)	2 (3.7)	1 (1.9)	1 (1.9)	1 (1.9)
Weight decreased	4 (7.4)	1 (1.9)	3 (5.6)	0	0
Aspartate aminotransferase increased	3 (5.6)	1 (1.9)	0	2 (3.7)	0
Platelet count decreased	3 (5.6)	3 (5.6)	0	0	0
Alanine aminotransferase increased	2 (3.7)	0	0	2 (3.7)	0
Haemoglobin decreased	2 (3.7)	2 (3.7)	0	0	0
Lymphocyte count decreased	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Weight increased	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Blood bilirubin increased	1 (1.9)	0	0	1 (1.9)	0
Blood creatinine increased	1 (1.9)	1 (1.9)	0	0	0
Blood magnesium decreased	1 (1.9)	1 (1.9)	0	0	0
Blood uric acid increased	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oxygen saturation decreased	1 (1.9)	1 (1.9)	0	0	0
Serum ferritin increased	1 (1.9)	0	1 (1.9)	0	0
Transaminases increased	1 (1.9)	1 (1.9)	0	0	0
Metabolism and nutrition disorders					
-Total	9 (16.7)	4 (7.4)	1 (1.9)	3 (5.6)	1 (1.9)
Decreased appetite	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Hyperphosphataemia	2 (3.7)	2 (3.7)	0	0	0
Hypokalaemia	2 (3.7)	1 (1.9)	0	0	1 (1.9)
Dehydration	1 (1.9)	0	0	1 (1.9)	0
Hyperglycaemia	1 (1.9)	0	0	1 (1.9)	0
Hypophosphataemia	1 (1.9)	0	0	1 (1.9)	0
Iron overload	1 (1.9)	0	0	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0
Vitamin d deficiency	1 (1.9)	1 (1.9)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	16 (29.6)	11 (20.4)	5 (9.3)	0	0
Pain in extremity	8 (14.8)	6 (11.1)	2 (3.7)	0	0
Arthralgia	2 (3.7)	1 (1.9)	1 (1.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Joint range of motion decreased	2 (3.7)	2 (3.7)	0	0	0
Muscular weakness	2 (3.7)	2 (3.7)	0	0	0
Back pain	1 (1.9)	1 (1.9)	0	0	0
Flank pain	1 (1.9)	0	1 (1.9)	0	0
Muscle spasms	1 (1.9)	1 (1.9)	0	0	0
Musculoskeletal chest pain	1 (1.9)	1 (1.9)	0	0	0
Osteonecrosis	1 (1.9)	0	1 (1.9)	0	0
Pain in jaw	1 (1.9)	1 (1.9)	0	0	0
Toe walking	1 (1.9)	1 (1.9)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.9)	0	1 (1.9)	0	0
Myelodysplastic syndrome	1 (1.9)	0	1 (1.9)	0	0
Nervous system disorders					
-Total	8 (14.8)	6 (11.1)	2 (3.7)	0	0
Headache	5 (9.3)	4 (7.4)	1 (1.9)	0	0
Dizziness	3 (5.6)	3 (5.6)	0	0	0
Peroneal nerve palsy	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Psychiatric disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Depression	2 (3.7)	2 (3.7)	0	0	0
Anxiety	1 (1.9)	1 (1.9)	0	0	0
Sleep disorder	1 (1.9)	0	1 (1.9)	0	0
Renal and urinary disorders					
-Total	3 (5.6)	1 (1.9)	0	2 (3.7)	0
Acute kidney injury	1 (1.9)	0	0	1 (1.9)	0
Calculus urinary	1 (1.9)	0	1 (1.9)	0	0
Haematuria	1 (1.9)	0	0	1 (1.9)	0
Nephrolithiasis	1 (1.9)	0	0	1 (1.9)	0
Urinary incontinence	1 (1.9)	1 (1.9)	0	0	0
Reproductive system and breast disorders					
-Total	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Scrotal pain	1 (1.9)	0	1 (1.9)	0	0
Vaginal haemorrhage	1 (1.9)	0	0	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	18 (33.3)	11 (20.4)	4 (7.4)	2 (3.7)	1 (1.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	7 (13.0)	5 (9.3)	2 (3.7)	0	0
Nasal congestion	4 (7.4)	4 (7.4)	0	0	0
Rhinorrhoea	4 (7.4)	3 (5.6)	1 (1.9)	0	0
Oropharyngeal pain	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Rhinitis allergic	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Epistaxis	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Acute respiratory failure	1 (1.9)	0	0	0	1 (1.9)
Dysphonia	1 (1.9)	1 (1.9)	0	0	0
Pharyngeal erythema	1 (1.9)	1 (1.9)	0	0	0
Pharyngeal lesion	1 (1.9)	0	0	1 (1.9)	0
Pulmonary oedema	1 (1.9)	0	0	1 (1.9)	0
Skin and subcutaneous tissue disorders					
-Total	15 (27.8)	9 (16.7)	5 (9.3)	1 (1.9)	0
Rash	4 (7.4)	1 (1.9)	3 (5.6)	0	0
Erythema	2 (3.7)	2 (3.7)	0	0	0
Rash maculo-papular	2 (3.7)	2 (3.7)	0	0	0
Alopecia	1 (1.9)	0	1 (1.9)	0	0
Dermatitis	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dermatitis acneiform	1 (1.9)	0	0	1 (1.9)	0
Dermatitis atopic	1 (1.9)	1 (1.9)	0	0	0
Dry skin	1 (1.9)	1 (1.9)	0	0	0
Eczema	1 (1.9)	1 (1.9)	0	0	0
Hyperhidrosis	1 (1.9)	1 (1.9)	0	0	0
Ingrowing nail	1 (1.9)	1 (1.9)	0	0	0
Keloid scar	1 (1.9)	0	1 (1.9)	0	0
Macule	1 (1.9)	1 (1.9)	0	0	0
Petechiae	1 (1.9)	1 (1.9)	0	0	0
Pruritus	1 (1.9)	1 (1.9)	0	0	0
Rash erythematous	1 (1.9)	0	1 (1.9)	0	0
Rash pruritic	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					
-Total	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Hypertension	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Hot flush	1 (1.9)	1 (1.9)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174g
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (66.7)	4 (12.1)	6 (18.2)	8 (24.2)	4 (12.1)
Blood and lymphatic system disorders					
-Total	2 (6.1)	1 (3.0)	0	0	1 (3.0)
Febrile neutropenia	1 (3.0)	0	0	0	1 (3.0)
Thrombocytopenia	1 (3.0)	1 (3.0)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Tympanic membrane perforation	1 (3.0)	0	1 (3.0)	0	0
Gastrointestinal disorders					
-Total	3 (9.1)	0	3 (9.1)	0	0
Diarrhoea	2 (6.1)	0	2 (6.1)	0	0
Abdominal pain	1 (3.0)	0	1 (3.0)	0	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (3.0)	0	1 (3.0)	0	0
General disorders and administration site conditions					
-Total	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Chills	1 (3.0)	0	1 (3.0)	0	0
Cyst	1 (3.0)	0	0	1 (3.0)	0
Pyrexia	1 (3.0)	0	1 (3.0)	0	0
Immune system disorders					
-Total	2 (6.1)	0	2 (6.1)	0	0
Chronic graft versus host disease	1 (3.0)	0	1 (3.0)	0	0
Immunodeficiency	1 (3.0)	0	1 (3.0)	0	0
Infections and infestations					
-Total	11 (33.3)	2 (6.1)	5 (15.2)	3 (9.1)	1 (3.0)
Otitis media	3 (9.1)	0	2 (6.1)	1 (3.0)	0
Sinusitis	3 (9.1)	0	3 (9.1)	0	0
Otitis media acute	2 (6.1)	0	2 (6.1)	0	0
Pneumonia	2 (6.1)	0	2 (6.1)	0	0
Upper respiratory tract infection	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Urinary tract infection	2 (6.1)	0	1 (3.0)	1 (3.0)	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (3.0)	0	0	1 (3.0)	0
Cellulitis of male external genital organ	1 (3.0)	0	0	1 (3.0)	0
Clostridium difficile infection	1 (3.0)	0	0	1 (3.0)	0
Gingivitis	1 (3.0)	1 (3.0)	0	0	0
Haemophilus infection	1 (3.0)	0	1 (3.0)	0	0
Meningitis aseptic	1 (3.0)	0	1 (3.0)	0	0
Respiratory tract infection	1 (3.0)	0	0	0	1 (3.0)
Respiratory tract infection viral	1 (3.0)	0	0	1 (3.0)	0
Skin infection	1 (3.0)	0	1 (3.0)	0	0
Viral infection	1 (3.0)	1 (3.0)	0	0	0
Vulvovaginal candidiasis	1 (3.0)	0	1 (3.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (3.0)	0	0	1 (3.0)	0
Procedural pain	1 (3.0)	0	0	1 (3.0)	0
Investigations					
-Total	8 (24.2)	1 (3.0)	2 (6.1)	4 (12.1)	1 (3.0)
White blood cell count decreased	4 (12.1)	1 (3.0)	0	2 (6.1)	1 (3.0)

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	3 (9.1)	0	1 (3.0)	2 (6.1)	0
Lymphocyte count decreased	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Aspartate aminotransferase increased	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Neutrophil count decreased	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Blood alkaline phosphatase increased	1 (3.0)	1 (3.0)	0	0	0
Blood lactate dehydrogenase increased	1 (3.0)	1 (3.0)	0	0	0
C-reactive protein increased	1 (3.0)	1 (3.0)	0	0	0
Platelet count decreased	1 (3.0)	0	0	1 (3.0)	0
Metabolism and nutrition disorders					
-Total	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Hypokalaemia	1 (3.0)	0	0	1 (3.0)	0
Vitamin d deficiency	1 (3.0)	1 (3.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Neck pain	1 (3.0)	0	1 (3.0)	0	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.0)	0	0	0	1 (3.0)
Glioblastoma multiforme	1 (3.0)	0	0	0	1 (3.0)
Nervous system disorders					
-Total	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Disturbance in attention	1 (3.0)	1 (3.0)	0	0	0
Dizziness	1 (3.0)	1 (3.0)	0	0	0
Headache	1 (3.0)	0	1 (3.0)	0	0
Seizure	1 (3.0)	0	0	1 (3.0)	0
Renal and urinary disorders					
-Total	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Acute kidney injury	1 (3.0)	0	0	1 (3.0)	0
Haematuria	1 (3.0)	1 (3.0)	0	0	0
Reproductive system and breast disorders					
-Total	1 (3.0)	0	0	1 (3.0)	0
Ovarian failure	1 (3.0)	0	0	1 (3.0)	0
Respiratory, thoracic and mediastinal disorders					

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (12.1)	4 (12.1)	0	0	0
Cough	2 (6.1)	2 (6.1)	0	0	0
Epistaxis	1 (3.0)	1 (3.0)	0	0	0
Oropharyngeal pain	1 (3.0)	1 (3.0)	0	0	0
Rhinitis allergic	1 (3.0)	1 (3.0)	0	0	0
Rhinorrhoea	1 (3.0)	1 (3.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (9.1)	3 (9.1)	0	0	0
Acne	1 (3.0)	1 (3.0)	0	0	0
Papule	1 (3.0)	1 (3.0)	0	0	0
Pruritus	1 (3.0)	1 (3.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174g
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=3		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Anaemia	2 (66.7)	0	0	2 (66.7)	0
Leukopenia	1 (33.3)	0	0	0	1 (33.3)
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	0	0	1 (33.3)
Cardiac disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Bradycardia	1 (33.3)	0	1 (33.3)	0	0
Left ventricular dysfunction	1 (33.3)	0	0	1 (33.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pericardial effusion	1 (33.3)	0	1 (33.3)	0	0
Tachycardia	1 (33.3)	0	0	1 (33.3)	0
Eye disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Conjunctival haemorrhage	1 (33.3)	1 (33.3)	0	0	0
Periorbital oedema	1 (33.3)	1 (33.3)	0	0	0
Gastrointestinal disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Diarrhoea	1 (33.3)	0	1 (33.3)	0	0
Dysphagia	1 (33.3)	0	0	1 (33.3)	0
Nausea	1 (33.3)	0	0	1 (33.3)	0
Vomiting	1 (33.3)	0	1 (33.3)	0	0
General disorders and administration site conditions					
-Total	2 (66.7)	0	0	2 (66.7)	0
Asthenia	1 (33.3)	1 (33.3)	0	0	0
Chills	1 (33.3)	1 (33.3)	0	0	0
Face oedema	1 (33.3)	0	0	1 (33.3)	0
Localised oedema	1 (33.3)	0	0	1 (33.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mucosal haemorrhage	1 (33.3)	0	1 (33.3)	0	0
Multiple organ dysfunction syndrome	1 (33.3)	0	0	1 (33.3)	0
Oedema peripheral	1 (33.3)	0	0	1 (33.3)	0
Pyrexia	1 (33.3)	0	0	1 (33.3)	0
Hepatobiliary disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Hepatomegaly	1 (33.3)	0	1 (33.3)	0	0
Hyperbilirubinaemia	1 (33.3)	0	0	1 (33.3)	0
Immune system disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	0	0	2 (66.7)
Hypogammaglobulinaemia	1 (33.3)	0	0	1 (33.3)	0
Infections and infestations					
-Total	1 (33.3)	1 (33.3)	0	0	0
Upper respiratory tract infection	1 (33.3)	1 (33.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (66.7)	1 (33.3)	0	1 (33.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural complication	1 (33.3)	1 (33.3)	0	0	0
Tracheal haemorrhage	1 (33.3)	0	0	1 (33.3)	0
Investigations					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Aspartate aminotransferase increased	2 (66.7)	0	0	0	2 (66.7)
Blood fibrinogen decreased	2 (66.7)	0	1 (33.3)	0	1 (33.3)
Alanine aminotransferase increased	1 (33.3)	0	0	1 (33.3)	0
Blood creatinine increased	1 (33.3)	0	0	1 (33.3)	0
Blood phosphorus decreased	1 (33.3)	1 (33.3)	0	0	0
Blood urea increased	1 (33.3)	0	0	1 (33.3)	0
International normalised ratio increased	1 (33.3)	1 (33.3)	0	0	0
Neutrophil count decreased	1 (33.3)	0	0	1 (33.3)	0
Platelet count decreased	1 (33.3)	0	0	1 (33.3)	0
Protein total decreased	1 (33.3)	0	0	1 (33.3)	0
Prothrombin time prolonged	1 (33.3)	0	1 (33.3)	0	0
White blood cell count decreased	1 (33.3)	0	0	1 (33.3)	0
Metabolism and nutrition disorders					

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (66.7)	0	0	2 (66.7)	0
Hypokalaemia	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Hypophosphataemia	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Acidosis	1 (33.3)	0	0	1 (33.3)	0
Decreased appetite	1 (33.3)	0	0	1 (33.3)	0
Hyperalbuminaemia	1 (33.3)	1 (33.3)	0	0	0
Hypercalcaemia	1 (33.3)	1 (33.3)	0	0	0
Hyperchloraemia	1 (33.3)	1 (33.3)	0	0	0
Hypermagnesaemia	1 (33.3)	1 (33.3)	0	0	0
Hypernatraemia	1 (33.3)	0	1 (33.3)	0	0
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)	0	0
Metabolic alkalosis	1 (33.3)	1 (33.3)	0	0	0
Nervous system disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Dizziness	1 (33.3)	1 (33.3)	0	0	0
Psychiatric disorders					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Confusional state	1 (33.3)	1 (33.3)	0	0	0
Delirium	1 (33.3)	0	1 (33.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Insomnia	1 (33.3)	0	1 (33.3)	0	0
Irritability	1 (33.3)	1 (33.3)	0	0	0
Renal and urinary disorders					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Acute kidney injury	1 (33.3)	0	0	0	1 (33.3)
Haematuria	1 (33.3)	0	0	1 (33.3)	0
Renal impairment	1 (33.3)	0	0	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Pleural effusion	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Pulmonary oedema	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Cough	1 (33.3)	1 (33.3)	0	0	0
Dyspnoea	1 (33.3)	0	0	0	1 (33.3)
Epistaxis	1 (33.3)	0	1 (33.3)	0	0
Hypoxia	1 (33.3)	0	0	0	1 (33.3)
Interstitial lung disease	1 (33.3)	0	0	0	1 (33.3)
Respiratory distress	1 (33.3)	0	0	0	1 (33.3)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Hyperhidrosis	1 (33.3)	1 (33.3)	0	0	0
Papule	1 (33.3)	1 (33.3)	0	0	0
Rash papular	1 (33.3)	1 (33.3)	0	0	0
Vascular disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Hypertension	2 (66.7)	0	2 (66.7)	0	0
Hypotension	2 (66.7)	0	0	0	2 (66.7)
Capillary leak syndrome	1 (33.3)	0	0	0	1 (33.3)
Flushing	1 (33.3)	1 (33.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174g
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	61 (100)	0	5 (8.2)	11 (18.0)	45 (73.8)
Blood and lymphatic system disorders					
-Total	45 (73.8)	2 (3.3)	3 (4.9)	26 (42.6)	14 (23.0)
Anaemia	25 (41.0)	3 (4.9)	4 (6.6)	17 (27.9)	1 (1.6)
Febrile neutropenia	24 (39.3)	0	0	23 (37.7)	1 (1.6)
Neutropenia	10 (16.4)	0	0	3 (4.9)	7 (11.5)
Thrombocytopenia	9 (14.8)	0	1 (1.6)	3 (4.9)	5 (8.2)
Disseminated intravascular coagulation	4 (6.6)	0	2 (3.3)	2 (3.3)	0
Lymphopenia	4 (6.6)	0	2 (3.3)	1 (1.6)	1 (1.6)
Coagulopathy	1 (1.6)	1 (1.6)	0	0	0
Eosinophilia	1 (1.6)	0	0	1 (1.6)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphadenopathy	1 (1.6)	0	1 (1.6)	0	0
Pancytopenia	1 (1.6)	0	0	0	1 (1.6)
Cardiac disorders					
-Total	21 (34.4)	11 (18.0)	9 (14.8)	1 (1.6)	0
Tachycardia	14 (23.0)	8 (13.1)	5 (8.2)	1 (1.6)	0
Sinus tachycardia	6 (9.8)	3 (4.9)	3 (4.9)	0	0
Atrioventricular block second degree	1 (1.6)	1 (1.6)	0	0	0
Cardiac dysfunction	1 (1.6)	1 (1.6)	0	0	0
Palpitations	1 (1.6)	1 (1.6)	0	0	0
Pericardial effusion	1 (1.6)	1 (1.6)	0	0	0
Sinus bradycardia	1 (1.6)	1 (1.6)	0	0	0
Ventricular tachycardia	1 (1.6)	0	1 (1.6)	0	0
Ear and labyrinth disorders					
-Total	4 (6.6)	2 (3.3)	2 (3.3)	0	0
Ear pain	2 (3.3)	2 (3.3)	0	0	0
Hypoacusis	1 (1.6)	0	1 (1.6)	0	0
Tympanic membrane perforation	1 (1.6)	0	1 (1.6)	0	0
Endocrine disorders					
-Total	2 (3.3)	1 (1.6)	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Eye disorders					
-Total	17 (27.9)	9 (14.8)	8 (13.1)	0	0
Vision blurred	4 (6.6)	2 (3.3)	2 (3.3)	0	0
Eye pain	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Periorbital oedema	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Conjunctival haemorrhage	2 (3.3)	2 (3.3)	0	0	0
Dry eye	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Photophobia	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Retinal haemorrhage	2 (3.3)	2 (3.3)	0	0	0
Uveitis	2 (3.3)	0	2 (3.3)	0	0
Conjunctivitis allergic	1 (1.6)	1 (1.6)	0	0	0
Ocular hyperaemia	1 (1.6)	1 (1.6)	0	0	0
Ocular hypertension	1 (1.6)	0	1 (1.6)	0	0
Papilloedema	1 (1.6)	0	1 (1.6)	0	0
Visual impairment	1 (1.6)	0	1 (1.6)	0	0
Gastrointestinal disorders					
-Total	41 (67.2)	13 (21.3)	17 (27.9)	11 (18.0)	0
Vomiting	26 (42.6)	16 (26.2)	7 (11.5)	3 (4.9)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	24 (39.3)	6 (9.8)	14 (23.0)	4 (6.6)	0
Diarrhoea	23 (37.7)	13 (21.3)	8 (13.1)	2 (3.3)	0
Abdominal pain	11 (18.0)	6 (9.8)	4 (6.6)	1 (1.6)	0
Constipation	7 (11.5)	6 (9.8)	1 (1.6)	0	0
Abdominal pain upper	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Abdominal distension	2 (3.3)	0	2 (3.3)	0	0
Haematemesis	2 (3.3)	2 (3.3)	0	0	0
Oral pain	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Pancreatitis	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Stomatitis	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Abdominal discomfort	1 (1.6)	1 (1.6)	0	0	0
Abdominal pain lower	1 (1.6)	0	1 (1.6)	0	0
Abdominal tenderness	1 (1.6)	1 (1.6)	0	0	0
Anal incontinence	1 (1.6)	1 (1.6)	0	0	0
Ascites	1 (1.6)	0	0	1 (1.6)	0
Dyspepsia	1 (1.6)	0	1 (1.6)	0	0
Dysphagia	1 (1.6)	0	1 (1.6)	0	0
Enterocolitis	1 (1.6)	0	0	1 (1.6)	0
Flatulence	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Gastrooesophageal reflux disease	1 (1.6)	1 (1.6)	0	0	0
Glossodynia	1 (1.6)	1 (1.6)	0	0	0
Ileus	1 (1.6)	0	0	1 (1.6)	0
Intestinal obstruction	1 (1.6)	0	0	1 (1.6)	0
Lip pain	1 (1.6)	0	1 (1.6)	0	0
Mouth haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Pigmentation lip	1 (1.6)	1 (1.6)	0	0	0
Tooth socket haemorrhage	1 (1.6)	1 (1.6)	0	0	0
General disorders and administration site conditions					
-Total	40 (65.6)	16 (26.2)	14 (23.0)	9 (14.8)	1 (1.6)
Pyrexia	24 (39.3)	8 (13.1)	10 (16.4)	5 (8.2)	1 (1.6)
Fatigue	15 (24.6)	12 (19.7)	2 (3.3)	1 (1.6)	0
Chills	9 (14.8)	8 (13.1)	1 (1.6)	0	0
Catheter site pain	4 (6.6)	1 (1.6)	3 (4.9)	0	0
Malaise	4 (6.6)	1 (1.6)	3 (4.9)	0	0
Pain	4 (6.6)	1 (1.6)	1 (1.6)	2 (3.3)	0
Generalised oedema	3 (4.9)	1 (1.6)	2 (3.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza like illness	2 (3.3)	2 (3.3)	0	0	0
Oedema peripheral	2 (3.3)	2 (3.3)	0	0	0
Acquired gene mutation	1 (1.6)	1 (1.6)	0	0	0
Catheter site extravasation	1 (1.6)	0	1 (1.6)	0	0
Catheter site haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Crying	1 (1.6)	1 (1.6)	0	0	0
Cyst	1 (1.6)	0	0	1 (1.6)	0
Face oedema	1 (1.6)	0	1 (1.6)	0	0
Facial pain	1 (1.6)	0	1 (1.6)	0	0
Injection site haematoma	1 (1.6)	1 (1.6)	0	0	0
Non-cardiac chest pain	1 (1.6)	1 (1.6)	0	0	0
Peripheral swelling	1 (1.6)	0	1 (1.6)	0	0
Physical deconditioning	1 (1.6)	0	0	1 (1.6)	0
Hepatobiliary disorders					
-Total	5 (8.2)	3 (4.9)	1 (1.6)	1 (1.6)	0
Hepatomegaly	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Hyperbilirubinaemia	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Gallbladder enlargement	1 (1.6)	1 (1.6)	0	0	0
Hepatosplenomegaly	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	56 (91.8)	5 (8.2)	31 (50.8)	11 (18.0)	9 (14.8)
Cytokine release syndrome	48 (78.7)	6 (9.8)	25 (41.0)	8 (13.1)	9 (14.8)
Hypogammaglobulinaemia	31 (50.8)	3 (4.9)	24 (39.3)	4 (6.6)	0
Graft versus host disease	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Immunodeficiency common variable	2 (3.3)	0	2 (3.3)	0	0
Seasonal allergy	2 (3.3)	2 (3.3)	0	0	0
Chronic graft versus host disease	1 (1.6)	0	1 (1.6)	0	0
Drug hypersensitivity	1 (1.6)	0	1 (1.6)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.6)	0	1 (1.6)	0	0
Graft versus host disease in skin	1 (1.6)	1 (1.6)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.6)	0	1 (1.6)	0	0
Immunodeficiency	1 (1.6)	0	1 (1.6)	0	0
Infections and infestations					
-Total	45 (73.8)	6 (9.8)	21 (34.4)	14 (23.0)	4 (6.6)
Upper respiratory tract infection	8 (13.1)	3 (4.9)	4 (6.6)	1 (1.6)	0
Clostridium difficile infection	5 (8.2)	0	4 (6.6)	1 (1.6)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	5 (8.2)	1 (1.6)	3 (4.9)	1 (1.6)	0
Rhinovirus infection	5 (8.2)	5 (8.2)	0	0	0
Urinary tract infection	5 (8.2)	0	3 (4.9)	2 (3.3)	0
Clostridium difficile colitis	4 (6.6)	1 (1.6)	2 (3.3)	1 (1.6)	0
Influenza	4 (6.6)	1 (1.6)	3 (4.9)	0	0
Otitis media	4 (6.6)	0	3 (4.9)	1 (1.6)	0
Pneumonia	4 (6.6)	0	3 (4.9)	1 (1.6)	0
Sinusitis	4 (6.6)	0	4 (6.6)	0	0
Viral infection	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Viral upper respiratory tract infection	3 (4.9)	1 (1.6)	1 (1.6)	1 (1.6)	0
Cytomegalovirus infection	2 (3.3)	2 (3.3)	0	0	0
Ear infection	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Otitis media acute	2 (3.3)	0	2 (3.3)	0	0
Parainfluenzae virus infection	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Skin infection	2 (3.3)	0	2 (3.3)	0	0
Staphylococcal infection	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Vulvovaginal candidiasis	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Bacterial sepsis	1 (1.6)	0	0	0	1 (1.6)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Body tinea	1 (1.6)	1 (1.6)	0	0	0
Campylobacter infection	1 (1.6)	0	0	1 (1.6)	0
Catheter site cellulitis	1 (1.6)	1 (1.6)	0	0	0
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cellulitis of male external genital organ	1 (1.6)	0	0	1 (1.6)	0
Cholecystitis infective	1 (1.6)	0	0	1 (1.6)	0
Corona virus infection	1 (1.6)	0	0	1 (1.6)	0
Enterococcal infection	1 (1.6)	1 (1.6)	0	0	0
Enterovirus infection	1 (1.6)	0	0	1 (1.6)	0
Escherichia urinary tract infection	1 (1.6)	0	0	1 (1.6)	0
Folliculitis	1 (1.6)	0	1 (1.6)	0	0
Fungal skin infection	1 (1.6)	1 (1.6)	0	0	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Gastroenteritis viral	1 (1.6)	1 (1.6)	0	0	0
Gingivitis	1 (1.6)	1 (1.6)	0	0	0
Haemophilus infection	1 (1.6)	0	1 (1.6)	0	0
Herpes simplex	1 (1.6)	1 (1.6)	0	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (1.6)	0	1 (1.6)	0	0
Hypopyon	1 (1.6)	0	1 (1.6)	0	0
Meningitis aseptic	1 (1.6)	0	1 (1.6)	0	0
Molluscum contagiosum	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	1 (1.6)	0	0	0
Oral herpes	1 (1.6)	0	1 (1.6)	0	0
Orchitis	1 (1.6)	1 (1.6)	0	0	0
Otitis externa	1 (1.6)	0	1 (1.6)	0	0
Paronychia	1 (1.6)	1 (1.6)	0	0	0
Pharyngitis	1 (1.6)	0	1 (1.6)	0	0
Rash pustular	1 (1.6)	0	1 (1.6)	0	0
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection	1 (1.6)	0	0	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	0	0	1 (1.6)	0
Rhinitis	1 (1.6)	1 (1.6)	0	0	0
Rotavirus infection	1 (1.6)	0	0	1 (1.6)	0
Sepsis	1 (1.6)	0	0	0	1 (1.6)
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Streptococcal infection	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Subcutaneous abscess	1 (1.6)	0	1 (1.6)	0	0
Tinea capitis	1 (1.6)	1 (1.6)	0	0	0
Urinary tract infection enterococcal	1 (1.6)	0	0	1 (1.6)	0
Vascular device infection	1 (1.6)	0	0	1 (1.6)	0
Vulvovaginal mycotic infection	1 (1.6)	0	1 (1.6)	0	0
Injury, poisoning and procedural complications					
-Total	20 (32.8)	10 (16.4)	8 (13.1)	1 (1.6)	1 (1.6)
Procedural pain	5 (8.2)	2 (3.3)	2 (3.3)	1 (1.6)	0
Infusion related reaction	4 (6.6)	1 (1.6)	3 (4.9)	0	0
Contusion	3 (4.9)	3 (4.9)	0	0	0
Transfusion reaction	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Skin abrasion	2 (3.3)	2 (3.3)	0	0	0
Arthropod bite	1 (1.6)	1 (1.6)	0	0	0
Foot fracture	1 (1.6)	0	1 (1.6)	0	0
Incision site pain	1 (1.6)	1 (1.6)	0	0	0
Limb injury	1 (1.6)	1 (1.6)	0	0	0
Mouth injury	1 (1.6)	1 (1.6)	0	0	0
Post procedural haemorrhage	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural headache	1 (1.6)	0	1 (1.6)	0	0
Procedural nausea	1 (1.6)	0	1 (1.6)	0	0
Procedural site reaction	1 (1.6)	1 (1.6)	0	0	0
Radius fracture	1 (1.6)	0	1 (1.6)	0	0
Skin laceration	1 (1.6)	0	1 (1.6)	0	0
Stoma site irritation	1 (1.6)	1 (1.6)	0	0	0
Subdural haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Sunburn	1 (1.6)	1 (1.6)	0	0	0
Tibia fracture	1 (1.6)	0	1 (1.6)	0	0
Tongue injury	1 (1.6)	1 (1.6)	0	0	0
Transfusion related complication	1 (1.6)	0	0	0	1 (1.6)
Investigations					
-Total	53 (86.9)	2 (3.3)	5 (8.2)	14 (23.0)	32 (52.5)
White blood cell count decreased	34 (55.7)	4 (6.6)	1 (1.6)	11 (18.0)	18 (29.5)
Neutrophil count decreased	27 (44.3)	1 (1.6)	2 (3.3)	3 (4.9)	21 (34.4)
Alanine aminotransferase increased	20 (32.8)	5 (8.2)	2 (3.3)	13 (21.3)	0
Platelet count decreased	19 (31.1)	3 (4.9)	2 (3.3)	2 (3.3)	12 (19.7)
Aspartate aminotransferase increased	18 (29.5)	4 (6.6)	4 (6.6)	8 (13.1)	2 (3.3)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	16 (26.2)	1 (1.6)	3 (4.9)	7 (11.5)	5 (8.2)
Blood bilirubin increased	8 (13.1)	2 (3.3)	3 (4.9)	3 (4.9)	0
Blood creatinine increased	8 (13.1)	5 (8.2)	2 (3.3)	1 (1.6)	0
International normalised ratio increased	8 (13.1)	7 (11.5)	0	1 (1.6)	0
Prothrombin time prolonged	8 (13.1)	5 (8.2)	2 (3.3)	1 (1.6)	0
Activated partial thromboplastin time prolonged	5 (8.2)	3 (4.9)	2 (3.3)	0	0
Blood immunoglobulin m decreased	4 (6.6)	4 (6.6)	0	0	0
Weight decreased	4 (6.6)	1 (1.6)	3 (4.9)	0	0
Blood immunoglobulin a decreased	3 (4.9)	3 (4.9)	0	0	0
Haemoglobin decreased	3 (4.9)	2 (3.3)	0	1 (1.6)	0
Transaminases increased	3 (4.9)	3 (4.9)	0	0	0
Blood fibrinogen decreased	2 (3.3)	0	0	2 (3.3)	0
Blood magnesium decreased	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Blood phosphorus increased	2 (3.3)	2 (3.3)	0	0	0
Blood urea increased	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Blood uric acid increased	2 (3.3)	2 (3.3)	0	0	0
C-reactive protein increased	2 (3.3)	1 (1.6)	0	1 (1.6)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lipase increased	2 (3.3)	0	0	0	2 (3.3)
Serum ferritin increased	2 (3.3)	0	2 (3.3)	0	0
Weight increased	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Blood alkaline phosphatase increased	1 (1.6)	1 (1.6)	0	0	0
Blood bicarbonate decreased	1 (1.6)	0	1 (1.6)	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Blood lactate dehydrogenase increased	1 (1.6)	1 (1.6)	0	0	0
Blood lactic acid increased	1 (1.6)	0	0	0	1 (1.6)
Blood sodium increased	1 (1.6)	0	1 (1.6)	0	0
Cardiac murmur	1 (1.6)	1 (1.6)	0	0	0
Culture stool positive	1 (1.6)	1 (1.6)	0	0	0
Fibrin d dimer increased	1 (1.6)	1 (1.6)	0	0	0
Hepatic enzyme increased	1 (1.6)	0	1 (1.6)	0	0
Norovirus test positive	1 (1.6)	1 (1.6)	0	0	0
Oxygen saturation decreased	1 (1.6)	1 (1.6)	0	0	0
Pulmonary function test decreased	1 (1.6)	0	1 (1.6)	0	0
Metabolism and nutrition disorders					

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	41 (67.2)	8 (13.1)	8 (13.1)	21 (34.4)	4 (6.6)
Decreased appetite	21 (34.4)	5 (8.2)	5 (8.2)	11 (18.0)	0
Hypokalaemia	17 (27.9)	3 (4.9)	6 (9.8)	7 (11.5)	1 (1.6)
Hyperphosphataemia	8 (13.1)	8 (13.1)	0	0	0
Hypophosphataemia	8 (13.1)	1 (1.6)	0	6 (9.8)	1 (1.6)
Dehydration	4 (6.6)	1 (1.6)	0	3 (4.9)	0
Hypoalbuminaemia	4 (6.6)	1 (1.6)	2 (3.3)	1 (1.6)	0
Fluid overload	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Hyperglycaemia	3 (4.9)	0	1 (1.6)	2 (3.3)	0
Hypernatraemia	3 (4.9)	1 (1.6)	1 (1.6)	0	1 (1.6)
Hyperuricaemia	3 (4.9)	2 (3.3)	0	0	1 (1.6)
Hypocalcaemia	3 (4.9)	1 (1.6)	1 (1.6)	1 (1.6)	0
Hypertriglyceridaemia	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Hyponatraemia	2 (3.3)	0	0	2 (3.3)	0
Tumour lysis syndrome	2 (3.3)	0	0	2 (3.3)	0
Vitamin d deficiency	2 (3.3)	2 (3.3)	0	0	0
Acidosis	1 (1.6)	1 (1.6)	0	0	0
Hypomagnesaemia	1 (1.6)	1 (1.6)	0	0	0
Iron overload	1 (1.6)	0	0	1 (1.6)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malnutrition	1 (1.6)	0	0	1 (1.6)	0
Metabolic acidosis	1 (1.6)	0	1 (1.6)	0	0
Musculoskeletal and connective tissue disorders					
-Total	25 (41.0)	14 (23.0)	10 (16.4)	1 (1.6)	0
Pain in extremity	11 (18.0)	7 (11.5)	4 (6.6)	0	0
Arthralgia	5 (8.2)	3 (4.9)	1 (1.6)	1 (1.6)	0
Myalgia	5 (8.2)	4 (6.6)	1 (1.6)	0	0
Muscular weakness	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Musculoskeletal pain	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Joint range of motion decreased	2 (3.3)	2 (3.3)	0	0	0
Muscle spasms	2 (3.3)	2 (3.3)	0	0	0
Musculoskeletal chest pain	2 (3.3)	2 (3.3)	0	0	0
Back pain	1 (1.6)	1 (1.6)	0	0	0
Coccydynia	1 (1.6)	1 (1.6)	0	0	0
Flank pain	1 (1.6)	0	1 (1.6)	0	0
Limb discomfort	1 (1.6)	1 (1.6)	0	0	0
Neck pain	1 (1.6)	0	1 (1.6)	0	0
Osteonecrosis	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Osteopenia	1 (1.6)	0	1 (1.6)	0	0
Pain in jaw	1 (1.6)	1 (1.6)	0	0	0
Toe walking	1 (1.6)	1 (1.6)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (4.9)	0	2 (3.3)	0	1 (1.6)
Glioblastoma multiforme	1 (1.6)	0	0	0	1 (1.6)
Myelodysplastic syndrome	1 (1.6)	0	1 (1.6)	0	0
Skin papilloma	1 (1.6)	0	1 (1.6)	0	0
Nervous system disorders					
-Total	34 (55.7)	16 (26.2)	12 (19.7)	5 (8.2)	1 (1.6)
Headache	24 (39.3)	15 (24.6)	7 (11.5)	2 (3.3)	0
Dizziness	5 (8.2)	5 (8.2)	0	0	0
Encephalopathy	4 (6.6)	1 (1.6)	1 (1.6)	2 (3.3)	0
Seizure	4 (6.6)	0	2 (3.3)	2 (3.3)	0
Dysarthria	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Peroneal nerve palsy	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Tremor	2 (3.3)	2 (3.3)	0	0	0
Asterixis	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ataxia	1 (1.6)	0	1 (1.6)	0	0
Depressed level of consciousness	1 (1.6)	1 (1.6)	0	0	0
Disturbance in attention	1 (1.6)	1 (1.6)	0	0	0
Embolic stroke	1 (1.6)	0	0	0	1 (1.6)
Idiopathic intracranial hypertension	1 (1.6)	0	1 (1.6)	0	0
Migraine	1 (1.6)	0	1 (1.6)	0	0
Myoclonus	1 (1.6)	1 (1.6)	0	0	0
Neuropathy peripheral	1 (1.6)	0	1 (1.6)	0	0
Pleocytosis	1 (1.6)	1 (1.6)	0	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0
Product issues					
-Total	1 (1.6)	1 (1.6)	0	0	0
Device occlusion	1 (1.6)	1 (1.6)	0	0	0
Psychiatric disorders					
-Total	15 (24.6)	7 (11.5)	7 (11.5)	1 (1.6)	0
Anxiety	7 (11.5)	3 (4.9)	3 (4.9)	1 (1.6)	0
Confusional state	5 (8.2)	2 (3.3)	3 (4.9)	0	0
Delirium	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Agitation	2 (3.3)	0	2 (3.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Depression	2 (3.3)	2 (3.3)	0	0	0
Hallucination	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Adjustment disorder	1 (1.6)	0	1 (1.6)	0	0
Irritability	1 (1.6)	1 (1.6)	0	0	0
Listless	1 (1.6)	1 (1.6)	0	0	0
Mental status changes	1 (1.6)	1 (1.6)	0	0	0
Panic attack	1 (1.6)	0	1 (1.6)	0	0
Sleep disorder	1 (1.6)	0	1 (1.6)	0	0
Suicidal ideation	1 (1.6)	1 (1.6)	0	0	0
Renal and urinary disorders					
-Total	13 (21.3)	3 (4.9)	2 (3.3)	5 (8.2)	3 (4.9)
Acute kidney injury	8 (13.1)	1 (1.6)	1 (1.6)	4 (6.6)	2 (3.3)
Haematuria	4 (6.6)	0	2 (3.3)	1 (1.6)	1 (1.6)
Dysuria	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Oliguria	2 (3.3)	0	0	2 (3.3)	0
Calculus urinary	1 (1.6)	0	1 (1.6)	0	0
Nephrolithiasis	1 (1.6)	0	0	1 (1.6)	0
Pollakiuria	1 (1.6)	1 (1.6)	0	0	0
Renal failure	1 (1.6)	0	0	0	1 (1.6)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary incontinence	1 (1.6)	1 (1.6)	0	0	0
Reproductive system and breast disorders					
-Total	6 (9.8)	2 (3.3)	2 (3.3)	2 (3.3)	0
Vulvovaginal adhesion	2 (3.3)	2 (3.3)	0	0	0
Oedema genital	1 (1.6)	0	1 (1.6)	0	0
Ovarian failure	1 (1.6)	0	0	1 (1.6)	0
Scrotal pain	1 (1.6)	0	1 (1.6)	0	0
Vaginal haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Respiratory, thoracic and mediastinal disorders					
-Total	36 (59.0)	14 (23.0)	9 (14.8)	7 (11.5)	6 (9.8)
Cough	13 (21.3)	11 (18.0)	2 (3.3)	0	0
Epistaxis	9 (14.8)	4 (6.6)	0	4 (6.6)	1 (1.6)
Hypoxia	9 (14.8)	0	3 (4.9)	4 (6.6)	2 (3.3)
Oropharyngeal pain	6 (9.8)	4 (6.6)	2 (3.3)	0	0
Pleural effusion	6 (9.8)	2 (3.3)	3 (4.9)	1 (1.6)	0
Rhinorrhoea	6 (9.8)	5 (8.2)	1 (1.6)	0	0
Nasal congestion	5 (8.2)	5 (8.2)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	5 (8.2)	1 (1.6)	0	3 (4.9)	1 (1.6)
Tachypnoea	5 (8.2)	3 (4.9)	1 (1.6)	1 (1.6)	0
Rhinitis allergic	4 (6.6)	3 (4.9)	1 (1.6)	0	0
Respiratory failure	3 (4.9)	0	0	0	3 (4.9)
Haemoptysis	2 (3.3)	1 (1.6)	0	0	1 (1.6)
Acute respiratory failure	1 (1.6)	0	0	0	1 (1.6)
Atelectasis	1 (1.6)	1 (1.6)	0	0	0
Dysphonia	1 (1.6)	1 (1.6)	0	0	0
Dyspnoea	1 (1.6)	0	0	1 (1.6)	0
Oropharyngeal plaque	1 (1.6)	1 (1.6)	0	0	0
Pharyngeal erythema	1 (1.6)	1 (1.6)	0	0	0
Pharyngeal lesion	1 (1.6)	0	0	1 (1.6)	0
Pharyngeal ulceration	1 (1.6)	0	1 (1.6)	0	0
Respiratory depression	1 (1.6)	0	1 (1.6)	0	0
Wheezing	1 (1.6)	0	1 (1.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	29 (47.5)	17 (27.9)	9 (14.8)	3 (4.9)	0
Rash	8 (13.1)	5 (8.2)	3 (4.9)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	5 (8.2)	5 (8.2)	0	0	0
Erythema	5 (8.2)	5 (8.2)	0	0	0
Rash maculo-papular	5 (8.2)	3 (4.9)	1 (1.6)	1 (1.6)	0
Petechiae	4 (6.6)	3 (4.9)	1 (1.6)	0	0
Pruritus	4 (6.6)	4 (6.6)	0	0	0
Hyperhidrosis	3 (4.9)	3 (4.9)	0	0	0
Ingrowing nail	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Macule	2 (3.3)	2 (3.3)	0	0	0
Rash erythematous	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Acne	1 (1.6)	1 (1.6)	0	0	0
Alopecia	1 (1.6)	0	1 (1.6)	0	0
Dermatitis	1 (1.6)	1 (1.6)	0	0	0
Dermatitis acneiform	1 (1.6)	0	0	1 (1.6)	0
Dermatitis atopic	1 (1.6)	1 (1.6)	0	0	0
Dermatitis diaper	1 (1.6)	1 (1.6)	0	0	0
Ecchymosis	1 (1.6)	0	0	1 (1.6)	0
Eczema	1 (1.6)	1 (1.6)	0	0	0
Keloid scar	1 (1.6)	0	1 (1.6)	0	0
Livedo reticularis	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Night sweats	1 (1.6)	0	1 (1.6)	0	0
Papule	1 (1.6)	1 (1.6)	0	0	0
Rash follicular	1 (1.6)	1 (1.6)	0	0	0
Rash macular	1 (1.6)	1 (1.6)	0	0	0
Rash papular	1 (1.6)	1 (1.6)	0	0	0
Rash pruritic	1 (1.6)	1 (1.6)	0	0	0
Rash vesicular	1 (1.6)	1 (1.6)	0	0	0
Skin exfoliation	1 (1.6)	1 (1.6)	0	0	0
Skin fissures	1 (1.6)	1 (1.6)	0	0	0
Skin irritation	1 (1.6)	1 (1.6)	0	0	0
Vascular disorders					
-Total	23 (37.7)	3 (4.9)	6 (9.8)	8 (13.1)	6 (9.8)
Hypotension	14 (23.0)	1 (1.6)	0	7 (11.5)	6 (9.8)
Hypertension	10 (16.4)	3 (4.9)	6 (9.8)	1 (1.6)	0
Orthostatic hypotension	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Embolism	1 (1.6)	0	0	1 (1.6)	0
Flushing	1 (1.6)	1 (1.6)	0	0	0
Haematoma	1 (1.6)	0	1 (1.6)	0	0
Hot flush	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Secondary hypertension	1 (1.6)	0	1 (1.6)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174h
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

			All patients N=1		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Blood and lymphatic system disorders					
-Total	1 (100)	0	0	1 (100)	0
Anaemia	1 (100)	0	0	1 (100)	0
Febrile neutropenia	1 (100)	0	0	1 (100)	0
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Haematemesis	1 (100)	1 (100)	0	0	0
Nausea	1 (100)	0	1 (100)	0	0
Vomiting	1 (100)	0	1 (100)	0	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0
Cytokine release syndrome	1 (100)	0	1 (100)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	1 (100)	0	0	1 (100)	0
Activated partial thromboplastin time prolonged	1 (100)	0	1 (100)	0	0
Aspartate aminotransferase increased	1 (100)	0	1 (100)	0	0
Blood phosphorus increased	1 (100)	1 (100)	0	0	0
International normalised ratio increased	1 (100)	1 (100)	0	0	0
Neutrophil count decreased	1 (100)	0	0	1 (100)	0
Platelet count decreased	1 (100)	0	0	1 (100)	0
White blood cell count decreased	1 (100)	1 (100)	0	0	0
Nervous system disorders					
-Total	1 (100)	0	1 (100)	0	0
Encephalopathy	1 (100)	0	1 (100)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174h
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: No

			All patients N=63		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	62 (98.4)	2 (3.2)	7 (11.1)	13 (20.6)	40 (63.5)
Blood and lymphatic system disorders					
-Total	42 (66.7)	2 (3.2)	3 (4.8)	26 (41.3)	11 (17.5)
Anaemia	26 (41.3)	3 (4.8)	5 (7.9)	17 (27.0)	1 (1.6)
Febrile neutropenia	21 (33.3)	0	0	21 (33.3)	0
Neutropenia	8 (12.7)	0	0	3 (4.8)	5 (7.9)
Thrombocytopenia	8 (12.7)	0	0	2 (3.2)	6 (9.5)
Disseminated intravascular coagulation	4 (6.3)	0	2 (3.2)	2 (3.2)	0
Lymphopenia	3 (4.8)	0	1 (1.6)	1 (1.6)	1 (1.6)
Coagulopathy	1 (1.6)	1 (1.6)	0	0	0
Pancytopenia	1 (1.6)	0	0	0	1 (1.6)
Cardiac disorders					
-Total	22 (34.9)	11 (17.5)	9 (14.3)	2 (3.2)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	15 (23.8)	8 (12.7)	5 (7.9)	2 (3.2)	0
Sinus tachycardia	5 (7.9)	3 (4.8)	2 (3.2)	0	0
Pericardial effusion	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Atrioventricular block second degree	1 (1.6)	1 (1.6)	0	0	0
Bradycardia	1 (1.6)	0	1 (1.6)	0	0
Cardiac dysfunction	1 (1.6)	1 (1.6)	0	0	0
Left ventricular dysfunction	1 (1.6)	0	0	1 (1.6)	0
Palpitations	1 (1.6)	1 (1.6)	0	0	0
Sinus bradycardia	1 (1.6)	1 (1.6)	0	0	0
Ventricular tachycardia	1 (1.6)	0	1 (1.6)	0	0
Ear and labyrinth disorders					
-Total	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Ear pain	2 (3.2)	2 (3.2)	0	0	0
Hypoacusis	1 (1.6)	0	1 (1.6)	0	0
Endocrine disorders					
-Total	1 (1.6)	0	1 (1.6)	0	0
Adrenal insufficiency	1 (1.6)	0	1 (1.6)	0	0
Eye disorders					
-Total	13 (20.6)	6 (9.5)	7 (11.1)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Periorbital oedema	4 (6.3)	3 (4.8)	1 (1.6)	0	0
Conjunctival haemorrhage	3 (4.8)	3 (4.8)	0	0	0
Eye pain	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Vision blurred	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Photophobia	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Retinal haemorrhage	2 (3.2)	2 (3.2)	0	0	0
Uveitis	2 (3.2)	0	2 (3.2)	0	0
Ocular hypertension	1 (1.6)	0	1 (1.6)	0	0
Papilloedema	1 (1.6)	0	1 (1.6)	0	0
Visual impairment	1 (1.6)	0	1 (1.6)	0	0
Gastrointestinal disorders					
-Total	35 (55.6)	11 (17.5)	13 (20.6)	11 (17.5)	0
Vomiting	21 (33.3)	13 (20.6)	5 (7.9)	3 (4.8)	0
Nausea	20 (31.7)	6 (9.5)	11 (17.5)	3 (4.8)	0
Diarrhoea	18 (28.6)	11 (17.5)	6 (9.5)	1 (1.6)	0
Abdominal pain	9 (14.3)	6 (9.5)	2 (3.2)	1 (1.6)	0
Constipation	7 (11.1)	6 (9.5)	1 (1.6)	0	0
Abdominal distension	2 (3.2)	0	2 (3.2)	0	0
Abdominal pain upper	2 (3.2)	0	2 (3.2)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphagia	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Pancreatitis	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Stomatitis	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Abdominal discomfort	1 (1.6)	1 (1.6)	0	0	0
Abdominal pain lower	1 (1.6)	0	1 (1.6)	0	0
Abdominal tenderness	1 (1.6)	1 (1.6)	0	0	0
Anal incontinence	1 (1.6)	1 (1.6)	0	0	0
Ascites	1 (1.6)	0	0	1 (1.6)	0
Dyspepsia	1 (1.6)	0	1 (1.6)	0	0
Flatulence	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Gastrooesophageal reflux disease	1 (1.6)	1 (1.6)	0	0	0
Glossodynia	1 (1.6)	1 (1.6)	0	0	0
Haematemesis	1 (1.6)	1 (1.6)	0	0	0
Ileus	1 (1.6)	0	0	1 (1.6)	0
Intestinal obstruction	1 (1.6)	0	0	1 (1.6)	0
Lip pain	1 (1.6)	0	1 (1.6)	0	0
Mouth haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Tooth socket haemorrhage	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	32 (50.8)	12 (19.0)	10 (15.9)	9 (14.3)	1 (1.6)
Pyrexia	16 (25.4)	3 (4.8)	7 (11.1)	5 (7.9)	1 (1.6)
Fatigue	13 (20.6)	10 (15.9)	2 (3.2)	1 (1.6)	0
Chills	8 (12.7)	8 (12.7)	0	0	0
Catheter site pain	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Malaise	3 (4.8)	0	3 (4.8)	0	0
Pain	3 (4.8)	0	1 (1.6)	2 (3.2)	0
Face oedema	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Generalised oedema	2 (3.2)	0	2 (3.2)	0	0
Oedema peripheral	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Asthenia	1 (1.6)	1 (1.6)	0	0	0
Catheter site extravasation	1 (1.6)	0	1 (1.6)	0	0
Catheter site haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Facial pain	1 (1.6)	0	1 (1.6)	0	0
Injection site haematoma	1 (1.6)	1 (1.6)	0	0	0
Localised oedema	1 (1.6)	0	0	1 (1.6)	0
Mucosal haemorrhage	1 (1.6)	0	1 (1.6)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	1 (1.6)	0	0	1 (1.6)	0
Non-cardiac chest pain	1 (1.6)	1 (1.6)	0	0	0
Peripheral swelling	1 (1.6)	0	1 (1.6)	0	0
Physical deconditioning	1 (1.6)	0	0	1 (1.6)	0
Hepatobiliary disorders					
-Total	7 (11.1)	3 (4.8)	2 (3.2)	2 (3.2)	0
Hepatomegaly	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Hyperbilirubinaemia	3 (4.8)	0	1 (1.6)	2 (3.2)	0
Gallbladder enlargement	1 (1.6)	1 (1.6)	0	0	0
Hepatosplenomegaly	1 (1.6)	1 (1.6)	0	0	0
Immune system disorders					
-Total	56 (88.9)	5 (7.9)	29 (46.0)	11 (17.5)	11 (17.5)
Cytokine release syndrome	49 (77.8)	6 (9.5)	24 (38.1)	8 (12.7)	11 (17.5)
Hypogammaglobulinaemia	25 (39.7)	3 (4.8)	18 (28.6)	4 (6.3)	0
Drug hypersensitivity	1 (1.6)	0	1 (1.6)	0	0
Graft versus host disease in skin	1 (1.6)	1 (1.6)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.6)	0	1 (1.6)	0	0
Infections and infestations					
-Total	26 (41.3)	5 (7.9)	14 (22.2)	6 (9.5)	1 (1.6)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	4 (6.3)	1 (1.6)	2 (3.2)	1 (1.6)	0
Clostridium difficile infection	4 (6.3)	0	4 (6.3)	0	0
Rhinovirus infection	3 (4.8)	3 (4.8)	0	0	0
Gastroenteritis	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Pneumonia	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Staphylococcal infection	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Body tinea	1 (1.6)	1 (1.6)	0	0	0
Catheter site cellulitis	1 (1.6)	1 (1.6)	0	0	0
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cytomegalovirus infection	1 (1.6)	1 (1.6)	0	0	0
Enterococcal infection	1 (1.6)	1 (1.6)	0	0	0
Folliculitis	1 (1.6)	0	1 (1.6)	0	0
Fungal skin infection	1 (1.6)	1 (1.6)	0	0	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Herpes simplex	1 (1.6)	1 (1.6)	0	0	0
Human herpesvirus 6 infection	1 (1.6)	0	1 (1.6)	0	0
Hypopyon	1 (1.6)	0	1 (1.6)	0	0
Influenza	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral candidiasis	1 (1.6)	1 (1.6)	0	0	0
Orchitis	1 (1.6)	1 (1.6)	0	0	0
Pharyngitis	1 (1.6)	0	1 (1.6)	0	0
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Skin infection	1 (1.6)	0	1 (1.6)	0	0
Streptococcal infection	1 (1.6)	0	1 (1.6)	0	0
Upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Urinary tract infection enterococcal	1 (1.6)	0	0	1 (1.6)	0
Viral infection	1 (1.6)	0	1 (1.6)	0	0
Viral upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Vulvovaginal candidiasis	1 (1.6)	1 (1.6)	0	0	0
Injury, poisoning and procedural complications					
-Total	15 (23.8)	8 (12.7)	5 (7.9)	1 (1.6)	1 (1.6)
Procedural pain	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Transfusion reaction	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Infusion related reaction	2 (3.2)	0	2 (3.2)	0	0
Contusion	1 (1.6)	1 (1.6)	0	0	0
Incision site pain	1 (1.6)	1 (1.6)	0	0	0
Limb injury	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mouth injury	1 (1.6)	1 (1.6)	0	0	0
Post procedural haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Procedural complication	1 (1.6)	1 (1.6)	0	0	0
Procedural headache	1 (1.6)	0	1 (1.6)	0	0
Procedural site reaction	1 (1.6)	1 (1.6)	0	0	0
Skin abrasion	1 (1.6)	1 (1.6)	0	0	0
Stoma site irritation	1 (1.6)	1 (1.6)	0	0	0
Subdural haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Tibia fracture	1 (1.6)	0	1 (1.6)	0	0
Tongue injury	1 (1.6)	1 (1.6)	0	0	0
Tracheal haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Transfusion related complication	1 (1.6)	0	0	0	1 (1.6)
Investigations					
-Total	51 (81.0)	4 (6.3)	4 (6.3)	12 (19.0)	31 (49.2)
White blood cell count decreased	29 (46.0)	2 (3.2)	1 (1.6)	10 (15.9)	16 (25.4)
Neutrophil count decreased	24 (38.1)	0	2 (3.2)	3 (4.8)	19 (30.2)
Alanine aminotransferase increased	19 (30.2)	5 (7.9)	3 (4.8)	11 (17.5)	0
Platelet count decreased	18 (28.6)	3 (4.8)	2 (3.2)	1 (1.6)	12 (19.0)
Aspartate aminotransferase increased	17 (27.0)	3 (4.8)	3 (4.8)	7 (11.1)	4 (6.3)

Timing: within 8 weeks post infusion, Hypodiploidy: No

			All patients N=63		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	14 (22.2)	1 (1.6)	2 (3.2)	6 (9.5)	5 (7.9)
Blood creatinine increased	9 (14.3)	5 (7.9)	2 (3.2)	2 (3.2)	0
Prothrombin time prolonged	9 (14.3)	5 (7.9)	3 (4.8)	1 (1.6)	0
International normalised ratio increased	8 (12.7)	7 (11.1)	0	1 (1.6)	0
Blood bilirubin increased	7 (11.1)	2 (3.2)	3 (4.8)	2 (3.2)	0
Activated partial thromboplastin time prolonged	4 (6.3)	3 (4.8)	1 (1.6)	0	0
Blood fibrinogen decreased	4 (6.3)	0	1 (1.6)	2 (3.2)	1 (1.6)
Blood immunoglobulin m decreased	4 (6.3)	4 (6.3)	0	0	0
Blood immunoglobulin a decreased	3 (4.8)	3 (4.8)	0	0	0
Blood urea increased	3 (4.8)	1 (1.6)	1 (1.6)	1 (1.6)	0
Lipase increased	2 (3.2)	0	0	0	2 (3.2)
Transaminases increased	2 (3.2)	2 (3.2)	0	0	0
Blood bicarbonate decreased	1 (1.6)	0	1 (1.6)	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Blood lactic acid increased	1 (1.6)	0	0	0	1 (1.6)
Blood magnesium decreased	1 (1.6)	0	0	1 (1.6)	0
Blood phosphorus decreased	1 (1.6)	1 (1.6)	0	0	0
Blood phosphorus increased	1 (1.6)	1 (1.6)	0	0	0
Blood sodium increased	1 (1.6)	0	1 (1.6)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	1 (1.6)	1 (1.6)	0	0	0
C-reactive protein increased	1 (1.6)	0	0	1 (1.6)	0
Cardiac murmur	1 (1.6)	1 (1.6)	0	0	0
Culture stool positive	1 (1.6)	1 (1.6)	0	0	0
Fibrin d dimer increased	1 (1.6)	1 (1.6)	0	0	0
Haemoglobin decreased	1 (1.6)	0	0	1 (1.6)	0
Hepatic enzyme increased	1 (1.6)	0	1 (1.6)	0	0
Norovirus test positive	1 (1.6)	1 (1.6)	0	0	0
Protein total decreased	1 (1.6)	0	0	1 (1.6)	0
Pulmonary function test decreased	1 (1.6)	0	1 (1.6)	0	0
Serum ferritin increased	1 (1.6)	0	1 (1.6)	0	0
Metabolism and nutrition disorders					
-Total	39 (61.9)	5 (7.9)	10 (15.9)	21 (33.3)	3 (4.8)
Decreased appetite	20 (31.7)	4 (6.3)	4 (6.3)	12 (19.0)	0
Hypokalaemia	16 (25.4)	3 (4.8)	6 (9.5)	7 (11.1)	0
Hypophosphataemia	9 (14.3)	2 (3.2)	0	6 (9.5)	1 (1.6)
Hyperphosphataemia	8 (12.7)	8 (12.7)	0	0	0
Hypoalbuminaemia	5 (7.9)	1 (1.6)	3 (4.8)	1 (1.6)	0
Hypernatraemia	4 (6.3)	1 (1.6)	2 (3.2)	0	1 (1.6)

Timing: within 8 weeks post infusion, Hypodiploidy: No

			All patients N=63		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	3 (4.8)	1 (1.6)	0	2 (3.2)	0
Fluid overload	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Hyperglycaemia	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Hyperuricaemia	3 (4.8)	2 (3.2)	0	0	1 (1.6)
Hypocalcaemia	3 (4.8)	1 (1.6)	1 (1.6)	1 (1.6)	0
Acidosis	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Hypertriglyceridaemia	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Hyponatraemia	2 (3.2)	0	0	2 (3.2)	0
Hyperalbuminaemia	1 (1.6)	1 (1.6)	0	0	0
Hypercalcaemia	1 (1.6)	1 (1.6)	0	0	0
Hyperchloraemia	1 (1.6)	1 (1.6)	0	0	0
Hypermagnesaemia	1 (1.6)	1 (1.6)	0	0	0
Hypomagnesaemia	1 (1.6)	1 (1.6)	0	0	0
Malnutrition	1 (1.6)	0	0	1 (1.6)	0
Metabolic acidosis	1 (1.6)	0	1 (1.6)	0	0
Metabolic alkalosis	1 (1.6)	1 (1.6)	0	0	0
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0
Musculoskeletal and connective tissue disorders					
-Total	15 (23.8)	8 (12.7)	6 (9.5)	1 (1.6)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	5 (7.9)	4 (6.3)	1 (1.6)	0	0
Arthralgia	4 (6.3)	3 (4.8)	0	1 (1.6)	0
Pain in extremity	4 (6.3)	2 (3.2)	2 (3.2)	0	0
Musculoskeletal pain	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Coccydynia	1 (1.6)	1 (1.6)	0	0	0
Limb discomfort	1 (1.6)	1 (1.6)	0	0	0
Muscle spasms	1 (1.6)	1 (1.6)	0	0	0
Muscular weakness	1 (1.6)	0	1 (1.6)	0	0
Musculoskeletal chest pain	1 (1.6)	1 (1.6)	0	0	0
Osteopenia	1 (1.6)	0	1 (1.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.6)	0	1 (1.6)	0	0
Skin papilloma	1 (1.6)	0	1 (1.6)	0	0
Nervous system disorders					
-Total	32 (50.8)	17 (27.0)	10 (15.9)	4 (6.3)	1 (1.6)
Headache	24 (38.1)	16 (25.4)	6 (9.5)	2 (3.2)	0
Dizziness	4 (6.3)	4 (6.3)	0	0	0
Encephalopathy	3 (4.8)	1 (1.6)	0	2 (3.2)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Dysarthria	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Tremor	2 (3.2)	2 (3.2)	0	0	0
Asterixis	1 (1.6)	1 (1.6)	0	0	0
Ataxia	1 (1.6)	0	1 (1.6)	0	0
Depressed level of consciousness	1 (1.6)	1 (1.6)	0	0	0
Embolic stroke	1 (1.6)	0	0	0	1 (1.6)
Idiopathic intracranial hypertension	1 (1.6)	0	1 (1.6)	0	0
Migraine	1 (1.6)	0	1 (1.6)	0	0
Myoclonus	1 (1.6)	1 (1.6)	0	0	0
Neuropathy peripheral	1 (1.6)	0	1 (1.6)	0	0
Pleocytosis	1 (1.6)	1 (1.6)	0	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0
Product issues					
-Total	1 (1.6)	1 (1.6)	0	0	0
Device occlusion	1 (1.6)	1 (1.6)	0	0	0
Psychiatric disorders					
-Total	16 (25.4)	8 (12.7)	7 (11.1)	1 (1.6)	0
Anxiety	6 (9.5)	2 (3.2)	3 (4.8)	1 (1.6)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	6 (9.5)	3 (4.8)	3 (4.8)	0	0
Delirium	4 (6.3)	2 (3.2)	2 (3.2)	0	0
Agitation	2 (3.2)	0	2 (3.2)	0	0
Hallucination	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Irritability	2 (3.2)	2 (3.2)	0	0	0
Adjustment disorder	1 (1.6)	0	1 (1.6)	0	0
Insomnia	1 (1.6)	0	1 (1.6)	0	0
Listless	1 (1.6)	1 (1.6)	0	0	0
Mental status changes	1 (1.6)	1 (1.6)	0	0	0
Panic attack	1 (1.6)	0	1 (1.6)	0	0
Suicidal ideation	1 (1.6)	1 (1.6)	0	0	0
Renal and urinary disorders					
-Total	11 (17.5)	2 (3.2)	2 (3.2)	3 (4.8)	4 (6.3)
Acute kidney injury	7 (11.1)	1 (1.6)	1 (1.6)	2 (3.2)	3 (4.8)
Haematuria	4 (6.3)	0	2 (3.2)	1 (1.6)	1 (1.6)
Dysuria	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Oliguria	2 (3.2)	0	0	2 (3.2)	0
Pollakiuria	1 (1.6)	1 (1.6)	0	0	0
Renal failure	1 (1.6)	0	0	0	1 (1.6)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal impairment	1 (1.6)	0	0	1 (1.6)	0
Reproductive system and breast disorders					
-Total	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Vulvovaginal adhesion	2 (3.2)	2 (3.2)	0	0	0
Oedema genital	1 (1.6)	0	1 (1.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	28 (44.4)	10 (15.9)	6 (9.5)	5 (7.9)	7 (11.1)
Hypoxia	10 (15.9)	0	3 (4.8)	4 (6.3)	3 (4.8)
Cough	8 (12.7)	8 (12.7)	0	0	0
Pleural effusion	8 (12.7)	2 (3.2)	4 (6.3)	2 (3.2)	0
Epistaxis	7 (11.1)	2 (3.2)	1 (1.6)	3 (4.8)	1 (1.6)
Pulmonary oedema	6 (9.5)	1 (1.6)	0	3 (4.8)	2 (3.2)
Tachypnoea	5 (7.9)	3 (4.8)	1 (1.6)	1 (1.6)	0
Respiratory failure	3 (4.8)	0	0	0	3 (4.8)
Dyspnoea	2 (3.2)	0	0	1 (1.6)	1 (1.6)
Haemoptysis	2 (3.2)	1 (1.6)	0	0	1 (1.6)
Oropharyngeal pain	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Atelectasis	1 (1.6)	1 (1.6)	0	0	0
Interstitial lung disease	1 (1.6)	0	0	0	1 (1.6)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	1 (1.6)	1 (1.6)	0	0	0
Oropharyngeal plaque	1 (1.6)	1 (1.6)	0	0	0
Pharyngeal ulceration	1 (1.6)	0	1 (1.6)	0	0
Respiratory depression	1 (1.6)	0	1 (1.6)	0	0
Respiratory distress	1 (1.6)	0	0	0	1 (1.6)
Rhinitis allergic	1 (1.6)	1 (1.6)	0	0	0
Rhinorrhoea	1 (1.6)	1 (1.6)	0	0	0
Wheezing	1 (1.6)	0	1 (1.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	21 (33.3)	15 (23.8)	4 (6.3)	2 (3.2)	0
Dry skin	4 (6.3)	4 (6.3)	0	0	0
Rash	4 (6.3)	4 (6.3)	0	0	0
Erythema	3 (4.8)	3 (4.8)	0	0	0
Hyperhidrosis	3 (4.8)	3 (4.8)	0	0	0
Petechiae	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Rash maculo-papular	3 (4.8)	1 (1.6)	1 (1.6)	1 (1.6)	0
Ingrowing nail	2 (3.2)	0	2 (3.2)	0	0
Pruritus	2 (3.2)	2 (3.2)	0	0	0
Rash papular	2 (3.2)	2 (3.2)	0	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dermatitis diaper	1 (1.6)	1 (1.6)	0	0	0
Ecchymosis	1 (1.6)	0	0	1 (1.6)	0
Livedo reticularis	1 (1.6)	1 (1.6)	0	0	0
Macule	1 (1.6)	1 (1.6)	0	0	0
Night sweats	1 (1.6)	0	1 (1.6)	0	0
Rash erythematous	1 (1.6)	1 (1.6)	0	0	0
Rash follicular	1 (1.6)	1 (1.6)	0	0	0
Rash macular	1 (1.6)	1 (1.6)	0	0	0
Rash vesicular	1 (1.6)	1 (1.6)	0	0	0
Skin exfoliation	1 (1.6)	1 (1.6)	0	0	0
Skin fissures	1 (1.6)	1 (1.6)	0	0	0
Skin irritation	1 (1.6)	1 (1.6)	0	0	0
Vascular disorders					
-Total	24 (38.1)	3 (4.8)	5 (7.9)	8 (12.7)	8 (12.7)
Hypotension	16 (25.4)	1 (1.6)	0	7 (11.1)	8 (12.7)
Hypertension	10 (15.9)	2 (3.2)	7 (11.1)	1 (1.6)	0
Flushing	2 (3.2)	2 (3.2)	0	0	0
Orthostatic hypotension	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Capillary leak syndrome	1 (1.6)	0	0	0	1 (1.6)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Embolism	1 (1.6)	0	0	1 (1.6)	0
Haematoma	1 (1.6)	0	1 (1.6)	0	0
Secondary hypertension	1 (1.6)	0	1 (1.6)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174h
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

			All patients N=55		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (83.6)	4 (7.3)	16 (29.1)	16 (29.1)	10 (18.2)
Blood and lymphatic system disorders					
-Total	11 (20.0)	1 (1.8)	3 (5.5)	3 (5.5)	4 (7.3)
Neutropenia	4 (7.3)	0	0	1 (1.8)	3 (5.5)
Febrile neutropenia	3 (5.5)	0	0	3 (5.5)	0
Anaemia	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Thrombocytopenia	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Eosinophilia	1 (1.8)	0	0	1 (1.8)	0
Leukopenia	1 (1.8)	0	0	0	1 (1.8)
Lymphadenopathy	1 (1.8)	0	1 (1.8)	0	0
Lymphopenia	1 (1.8)	0	1 (1.8)	0	0
Cardiac disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.8)	0	1 (1.8)	0	0
Sinus tachycardia	1 (1.8)	0	1 (1.8)	0	0
Endocrine disorders					
-Total	1 (1.8)	1 (1.8)	0	0	0
Adrenal insufficiency	1 (1.8)	1 (1.8)	0	0	0
Eye disorders					
-Total	5 (9.1)	4 (7.3)	1 (1.8)	0	0
Dry eye	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Conjunctivitis allergic	1 (1.8)	1 (1.8)	0	0	0
Ocular hyperaemia	1 (1.8)	1 (1.8)	0	0	0
Vision blurred	1 (1.8)	1 (1.8)	0	0	0
Gastrointestinal disorders					
-Total	16 (29.1)	9 (16.4)	3 (5.5)	4 (7.3)	0
Vomiting	9 (16.4)	5 (9.1)	2 (3.6)	2 (3.6)	0
Diarrhoea	8 (14.5)	6 (10.9)	1 (1.8)	1 (1.8)	0
Nausea	6 (10.9)	1 (1.8)	3 (5.5)	2 (3.6)	0
Abdominal pain	4 (7.3)	2 (3.6)	1 (1.8)	1 (1.8)	0
Oral pain	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Abdominal pain upper	1 (1.8)	1 (1.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterocolitis	1 (1.8)	0	0	1 (1.8)	0
Pigmentation lip	1 (1.8)	1 (1.8)	0	0	0
General disorders and administration site conditions					
-Total	17 (30.9)	13 (23.6)	3 (5.5)	1 (1.8)	0
Pyrexia	10 (18.2)	7 (12.7)	2 (3.6)	1 (1.8)	0
Fatigue	2 (3.6)	2 (3.6)	0	0	0
Influenza like illness	2 (3.6)	2 (3.6)	0	0	0
Acquired gene mutation	1 (1.8)	1 (1.8)	0	0	0
Catheter site pain	1 (1.8)	0	1 (1.8)	0	0
Chills	1 (1.8)	1 (1.8)	0	0	0
Crying	1 (1.8)	1 (1.8)	0	0	0
Generalised oedema	1 (1.8)	1 (1.8)	0	0	0
Malaise	1 (1.8)	1 (1.8)	0	0	0
Oedema peripheral	1 (1.8)	1 (1.8)	0	0	0
Pain	1 (1.8)	1 (1.8)	0	0	0
Immune system disorders					
-Total	14 (25.5)	3 (5.5)	10 (18.2)	1 (1.8)	0
Hypogammaglobulinaemia	8 (14.5)	0	7 (12.7)	1 (1.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Immunodeficiency common variable	2 (3.6)	0	2 (3.6)	0	0
Seasonal allergy	2 (3.6)	2 (3.6)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (1.8)	0	1 (1.8)	0	0
Infections and infestations					
-Total	33 (60.0)	6 (10.9)	15 (27.3)	10 (18.2)	2 (3.6)
Upper respiratory tract infection	7 (12.7)	3 (5.5)	3 (5.5)	1 (1.8)	0
Urinary tract infection	4 (7.3)	0	2 (3.6)	2 (3.6)	0
Gastroenteritis	3 (5.5)	1 (1.8)	2 (3.6)	0	0
Influenza	3 (5.5)	0	3 (5.5)	0	0
Ear infection	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Parainfluenzae virus infection	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Rhinovirus infection	2 (3.6)	2 (3.6)	0	0	0
Sinusitis	2 (3.6)	0	2 (3.6)	0	0
Viral upper respiratory tract infection	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Bacterial sepsis	1 (1.8)	0	0	0	1 (1.8)
Cellulitis of male external genital organ	1 (1.8)	0	0	1 (1.8)	0
Cholecystitis infective	1 (1.8)	0	0	1 (1.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	1 (1.8)	0	0	1 (1.8)	0
Cytomegalovirus infection	1 (1.8)	1 (1.8)	0	0	0
Enterovirus infection	1 (1.8)	0	0	1 (1.8)	0
Escherichia urinary tract infection	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	0	1 (1.8)	0	0
Gastroenteritis viral	1 (1.8)	1 (1.8)	0	0	0
Herpes zoster	1 (1.8)	0	0	1 (1.8)	0
Molluscum contagiosum	1 (1.8)	1 (1.8)	0	0	0
Oral herpes	1 (1.8)	0	1 (1.8)	0	0
Otitis externa	1 (1.8)	0	1 (1.8)	0	0
Otitis media	1 (1.8)	0	1 (1.8)	0	0
Otitis media acute	1 (1.8)	0	1 (1.8)	0	0
Paronychia	1 (1.8)	1 (1.8)	0	0	0
Rash pustular	1 (1.8)	0	1 (1.8)	0	0
Respiratory syncytial virus infection	1 (1.8)	0	0	1 (1.8)	0
Rhinitis	1 (1.8)	1 (1.8)	0	0	0
Rotavirus infection	1 (1.8)	0	0	1 (1.8)	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Subcutaneous abscess	1 (1.8)	0	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tinea capitis	1 (1.8)	1 (1.8)	0	0	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Viral infection	1 (1.8)	1 (1.8)	0	0	0
Vulvovaginal mycotic infection	1 (1.8)	0	1 (1.8)	0	0
Injury, poisoning and procedural complications					
-Total	8 (14.5)	3 (5.5)	5 (9.1)	0	0
Contusion	2 (3.6)	2 (3.6)	0	0	0
Infusion related reaction	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Procedural pain	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Arthropod bite	1 (1.8)	1 (1.8)	0	0	0
Foot fracture	1 (1.8)	0	1 (1.8)	0	0
Procedural nausea	1 (1.8)	0	1 (1.8)	0	0
Radius fracture	1 (1.8)	0	1 (1.8)	0	0
Skin abrasion	1 (1.8)	1 (1.8)	0	0	0
Skin laceration	1 (1.8)	0	1 (1.8)	0	0
Sunburn	1 (1.8)	1 (1.8)	0	0	0
Investigations					
-Total	23 (41.8)	6 (10.9)	5 (9.1)	8 (14.5)	4 (7.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	8 (14.5)	2 (3.6)	0	3 (5.5)	3 (5.5)
White blood cell count decreased	5 (9.1)	2 (3.6)	1 (1.8)	1 (1.8)	1 (1.8)
Weight decreased	4 (7.3)	1 (1.8)	3 (5.5)	0	0
Aspartate aminotransferase increased	3 (5.5)	1 (1.8)	0	2 (3.6)	0
Platelet count decreased	3 (5.5)	3 (5.5)	0	0	0
Alanine aminotransferase increased	2 (3.6)	0	0	2 (3.6)	0
Haemoglobin decreased	2 (3.6)	2 (3.6)	0	0	0
Lymphocyte count decreased	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Weight increased	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Blood bilirubin increased	1 (1.8)	0	0	1 (1.8)	0
Blood creatinine increased	1 (1.8)	1 (1.8)	0	0	0
Blood magnesium decreased	1 (1.8)	1 (1.8)	0	0	0
Blood urea increased	1 (1.8)	1 (1.8)	0	0	0
Blood uric acid increased	1 (1.8)	1 (1.8)	0	0	0
Oxygen saturation decreased	1 (1.8)	1 (1.8)	0	0	0
Serum ferritin increased	1 (1.8)	0	1 (1.8)	0	0
Transaminases increased	1 (1.8)	1 (1.8)	0	0	0
Metabolism and nutrition disorders					
-Total	10 (18.2)	5 (9.1)	1 (1.8)	3 (5.5)	1 (1.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Hyperphosphataemia	2 (3.6)	2 (3.6)	0	0	0
Hypokalaemia	2 (3.6)	1 (1.8)	0	0	1 (1.8)
Dehydration	1 (1.8)	0	0	1 (1.8)	0
Hyperalbuminaemia	1 (1.8)	1 (1.8)	0	0	0
Hypercalcaemia	1 (1.8)	1 (1.8)	0	0	0
Hyperglycaemia	1 (1.8)	0	0	1 (1.8)	0
Hypophosphataemia	1 (1.8)	0	0	1 (1.8)	0
Iron overload	1 (1.8)	0	0	1 (1.8)	0
Tumour lysis syndrome	1 (1.8)	0	0	1 (1.8)	0
Vitamin d deficiency	1 (1.8)	1 (1.8)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	16 (29.1)	11 (20.0)	5 (9.1)	0	0
Pain in extremity	8 (14.5)	6 (10.9)	2 (3.6)	0	0
Arthralgia	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Joint range of motion decreased	2 (3.6)	2 (3.6)	0	0	0
Muscular weakness	2 (3.6)	2 (3.6)	0	0	0
Back pain	1 (1.8)	1 (1.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flank pain	1 (1.8)	0	1 (1.8)	0	0
Muscle spasms	1 (1.8)	1 (1.8)	0	0	0
Musculoskeletal chest pain	1 (1.8)	1 (1.8)	0	0	0
Osteonecrosis	1 (1.8)	0	1 (1.8)	0	0
Pain in jaw	1 (1.8)	1 (1.8)	0	0	0
Toe walking	1 (1.8)	1 (1.8)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.8)	0	1 (1.8)	0	0
Myelodysplastic syndrome	1 (1.8)	0	1 (1.8)	0	0
Nervous system disorders					
-Total	8 (14.5)	6 (10.9)	2 (3.6)	0	0
Headache	5 (9.1)	4 (7.3)	1 (1.8)	0	0
Dizziness	3 (5.5)	3 (5.5)	0	0	0
Peroneal nerve palsy	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Psychiatric disorders					
-Total	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Depression	2 (3.6)	2 (3.6)	0	0	0
Anxiety	1 (1.8)	1 (1.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sleep disorder	1 (1.8)	0	1 (1.8)	0	0
Renal and urinary disorders					
-Total	3 (5.5)	1 (1.8)	0	2 (3.6)	0
Acute kidney injury	1 (1.8)	0	0	1 (1.8)	0
Calculus urinary	1 (1.8)	0	1 (1.8)	0	0
Haematuria	1 (1.8)	0	0	1 (1.8)	0
Nephrolithiasis	1 (1.8)	0	0	1 (1.8)	0
Urinary incontinence	1 (1.8)	1 (1.8)	0	0	0
Reproductive system and breast disorders					
-Total	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Scrotal pain	1 (1.8)	0	1 (1.8)	0	0
Vaginal haemorrhage	1 (1.8)	0	0	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders					
-Total	18 (32.7)	11 (20.0)	4 (7.3)	2 (3.6)	1 (1.8)
Cough	7 (12.7)	5 (9.1)	2 (3.6)	0	0
Nasal congestion	4 (7.3)	4 (7.3)	0	0	0
Rhinorrhoea	4 (7.3)	3 (5.5)	1 (1.8)	0	0
Oropharyngeal pain	3 (5.5)	2 (3.6)	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis allergic	3 (5.5)	2 (3.6)	1 (1.8)	0	0
Epistaxis	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Acute respiratory failure	1 (1.8)	0	0	0	1 (1.8)
Dysphonia	1 (1.8)	1 (1.8)	0	0	0
Pharyngeal erythema	1 (1.8)	1 (1.8)	0	0	0
Pharyngeal lesion	1 (1.8)	0	0	1 (1.8)	0
Pulmonary oedema	1 (1.8)	0	0	1 (1.8)	0
Skin and subcutaneous tissue disorders					
-Total	16 (29.1)	10 (18.2)	5 (9.1)	1 (1.8)	0
Rash	4 (7.3)	1 (1.8)	3 (5.5)	0	0
Erythema	2 (3.6)	2 (3.6)	0	0	0
Rash maculo-papular	2 (3.6)	2 (3.6)	0	0	0
Alopecia	1 (1.8)	0	1 (1.8)	0	0
Dermatitis	1 (1.8)	1 (1.8)	0	0	0
Dermatitis acneiform	1 (1.8)	0	0	1 (1.8)	0
Dermatitis atopic	1 (1.8)	1 (1.8)	0	0	0
Dry skin	1 (1.8)	1 (1.8)	0	0	0
Eczema	1 (1.8)	1 (1.8)	0	0	0
Hyperhidrosis	1 (1.8)	1 (1.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All patients N=55 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ingrowing nail	1 (1.8)	1 (1.8)	0	0	0
Keloid scar	1 (1.8)	0	1 (1.8)	0	0
Macule	1 (1.8)	1 (1.8)	0	0	0
Papule	1 (1.8)	1 (1.8)	0	0	0
Petechiae	1 (1.8)	1 (1.8)	0	0	0
Pruritus	1 (1.8)	1 (1.8)	0	0	0
Rash erythematous	1 (1.8)	0	1 (1.8)	0	0
Rash pruritic	1 (1.8)	1 (1.8)	0	0	0
Vascular disorders					
-Total	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Hypertension	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Hot flush	1 (1.8)	1 (1.8)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174h
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

			All patients N=33		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (66.7)	4 (12.1)	6 (18.2)	8 (24.2)	4 (12.1)
Blood and lymphatic system disorders					
-Total	2 (6.1)	1 (3.0)	0	0	1 (3.0)
Febrile neutropenia	1 (3.0)	0	0	0	1 (3.0)
Thrombocytopenia	1 (3.0)	1 (3.0)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Tympanic membrane perforation	1 (3.0)	0	1 (3.0)	0	0
Gastrointestinal disorders					
-Total	3 (9.1)	0	3 (9.1)	0	0
Diarrhoea	2 (6.1)	0	2 (6.1)	0	0
Abdominal pain	1 (3.0)	0	1 (3.0)	0	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (3.0)	0	1 (3.0)	0	0
General disorders and administration site conditions					
-Total	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Chills	1 (3.0)	0	1 (3.0)	0	0
Cyst	1 (3.0)	0	0	1 (3.0)	0
Pyrexia	1 (3.0)	0	1 (3.0)	0	0
Immune system disorders					
-Total	2 (6.1)	0	2 (6.1)	0	0
Chronic graft versus host disease	1 (3.0)	0	1 (3.0)	0	0
Immunodeficiency	1 (3.0)	0	1 (3.0)	0	0
Infections and infestations					
-Total	11 (33.3)	2 (6.1)	5 (15.2)	3 (9.1)	1 (3.0)
Otitis media	3 (9.1)	0	2 (6.1)	1 (3.0)	0
Sinusitis	3 (9.1)	0	3 (9.1)	0	0
Otitis media acute	2 (6.1)	0	2 (6.1)	0	0
Pneumonia	2 (6.1)	0	2 (6.1)	0	0
Upper respiratory tract infection	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Urinary tract infection	2 (6.1)	0	1 (3.0)	1 (3.0)	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (3.0)	0	0	1 (3.0)	0
Cellulitis of male external genital organ	1 (3.0)	0	0	1 (3.0)	0
Clostridium difficile infection	1 (3.0)	0	0	1 (3.0)	0
Gingivitis	1 (3.0)	1 (3.0)	0	0	0
Haemophilus infection	1 (3.0)	0	1 (3.0)	0	0
Meningitis aseptic	1 (3.0)	0	1 (3.0)	0	0
Respiratory tract infection	1 (3.0)	0	0	0	1 (3.0)
Respiratory tract infection viral	1 (3.0)	0	0	1 (3.0)	0
Skin infection	1 (3.0)	0	1 (3.0)	0	0
Viral infection	1 (3.0)	1 (3.0)	0	0	0
Vulvovaginal candidiasis	1 (3.0)	0	1 (3.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (3.0)	0	0	1 (3.0)	0
Procedural pain	1 (3.0)	0	0	1 (3.0)	0
Investigations					
-Total	8 (24.2)	1 (3.0)	2 (6.1)	4 (12.1)	1 (3.0)
White blood cell count decreased	4 (12.1)	1 (3.0)	0	2 (6.1)	1 (3.0)
Alanine aminotransferase increased	3 (9.1)	0	1 (3.0)	2 (6.1)	0
Lymphocyte count decreased	3 (9.1)	2 (6.1)	0	1 (3.0)	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Neutrophil count decreased	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Blood alkaline phosphatase increased	1 (3.0)	1 (3.0)	0	0	0
Blood lactate dehydrogenase increased	1 (3.0)	1 (3.0)	0	0	0
C-reactive protein increased	1 (3.0)	1 (3.0)	0	0	0
Platelet count decreased	1 (3.0)	0	0	1 (3.0)	0
Metabolism and nutrition disorders					
-Total	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Hypokalaemia	1 (3.0)	0	0	1 (3.0)	0
Vitamin d deficiency	1 (3.0)	1 (3.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Neck pain	1 (3.0)	0	1 (3.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.0)	0	0	0	1 (3.0)
Glioblastoma multiforme	1 (3.0)	0	0	0	1 (3.0)
Nervous system disorders					

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Disturbance in attention	1 (3.0)	1 (3.0)	0	0	0
Dizziness	1 (3.0)	1 (3.0)	0	0	0
Headache	1 (3.0)	0	1 (3.0)	0	0
Seizure	1 (3.0)	0	0	1 (3.0)	0
Renal and urinary disorders					
-Total	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Acute kidney injury	1 (3.0)	0	0	1 (3.0)	0
Haematuria	1 (3.0)	1 (3.0)	0	0	0
Reproductive system and breast disorders					
-Total	1 (3.0)	0	0	1 (3.0)	0
Ovarian failure	1 (3.0)	0	0	1 (3.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (12.1)	4 (12.1)	0	0	0
Cough	2 (6.1)	2 (6.1)	0	0	0
Epistaxis	1 (3.0)	1 (3.0)	0	0	0
Oropharyngeal pain	1 (3.0)	1 (3.0)	0	0	0
Rhinitis allergic	1 (3.0)	1 (3.0)	0	0	0
Rhinorrhoea	1 (3.0)	1 (3.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All patients N=33 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	3 (9.1)	3 (9.1)	0	0	0
Acne	1 (3.0)	1 (3.0)	0	0	0
Papule	1 (3.0)	1 (3.0)	0	0	0
Pruritus	1 (3.0)	1 (3.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174h
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

		All patients N=1			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Blood and lymphatic system disorders					
-Total	1 (100)	0	0	1 (100)	0
Anaemia	1 (100)	0	0	1 (100)	0
Febrile neutropenia	1 (100)	0	0	1 (100)	0
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Haematemesis	1 (100)	1 (100)	0	0	0
Nausea	1 (100)	0	1 (100)	0	0
Vomiting	1 (100)	0	1 (100)	0	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	0	0	1 (100)	0
Activated partial thromboplastin time prolonged	1 (100)	0	1 (100)	0	0
Aspartate aminotransferase increased	1 (100)	0	1 (100)	0	0
Blood phosphorus increased	1 (100)	1 (100)	0	0	0
International normalised ratio increased	1 (100)	1 (100)	0	0	0
Neutrophil count decreased	1 (100)	0	0	1 (100)	0
Platelet count decreased	1 (100)	0	0	1 (100)	0
White blood cell count decreased	1 (100)	1 (100)	0	0	0
Nervous system disorders					
-Total	1 (100)	0	1 (100)	0	0
Encephalopathy	1 (100)	0	1 (100)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174h
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: No

			All patients N=63		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	63 (100)	0	5 (7.9)	11 (17.5)	47 (74.6)
Blood and lymphatic system disorders					
-Total	47 (74.6)	2 (3.2)	3 (4.8)	26 (41.3)	16 (25.4)
Anaemia	26 (41.3)	3 (4.8)	4 (6.3)	18 (28.6)	1 (1.6)
Febrile neutropenia	23 (36.5)	0	0	22 (34.9)	1 (1.6)
Neutropenia	11 (17.5)	0	0	3 (4.8)	8 (12.7)
Thrombocytopenia	10 (15.9)	0	1 (1.6)	3 (4.8)	6 (9.5)
Disseminated intravascular coagulation	4 (6.3)	0	2 (3.2)	2 (3.2)	0
Lymphopenia	4 (6.3)	0	2 (3.2)	1 (1.6)	1 (1.6)
Coagulopathy	1 (1.6)	1 (1.6)	0	0	0
Eosinophilia	1 (1.6)	0	0	1 (1.6)	0
Leukopenia	1 (1.6)	0	0	0	1 (1.6)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphadenopathy	1 (1.6)	0	1 (1.6)	0	0
Pancytopenia	1 (1.6)	0	0	0	1 (1.6)
Cardiac disorders					
-Total	23 (36.5)	11 (17.5)	10 (15.9)	2 (3.2)	0
Tachycardia	15 (23.8)	8 (12.7)	5 (7.9)	2 (3.2)	0
Sinus tachycardia	6 (9.5)	3 (4.8)	3 (4.8)	0	0
Pericardial effusion	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Atrioventricular block second degree	1 (1.6)	1 (1.6)	0	0	0
Bradycardia	1 (1.6)	0	1 (1.6)	0	0
Cardiac dysfunction	1 (1.6)	1 (1.6)	0	0	0
Left ventricular dysfunction	1 (1.6)	0	0	1 (1.6)	0
Palpitations	1 (1.6)	1 (1.6)	0	0	0
Sinus bradycardia	1 (1.6)	1 (1.6)	0	0	0
Ventricular tachycardia	1 (1.6)	0	1 (1.6)	0	0
Ear and labyrinth disorders					
-Total	4 (6.3)	2 (3.2)	2 (3.2)	0	0
Ear pain	2 (3.2)	2 (3.2)	0	0	0
Hypoacusis	1 (1.6)	0	1 (1.6)	0	0
Tympanic membrane perforation	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Adrenal insufficiency	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Eye disorders					
-Total	18 (28.6)	10 (15.9)	8 (12.7)	0	0
Periorbital oedema	4 (6.3)	3 (4.8)	1 (1.6)	0	0
Vision blurred	4 (6.3)	2 (3.2)	2 (3.2)	0	0
Conjunctival haemorrhage	3 (4.8)	3 (4.8)	0	0	0
Eye pain	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Dry eye	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Photophobia	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Retinal haemorrhage	2 (3.2)	2 (3.2)	0	0	0
Uveitis	2 (3.2)	0	2 (3.2)	0	0
Conjunctivitis allergic	1 (1.6)	1 (1.6)	0	0	0
Ocular hyperaemia	1 (1.6)	1 (1.6)	0	0	0
Ocular hypertension	1 (1.6)	0	1 (1.6)	0	0
Papilloedema	1 (1.6)	0	1 (1.6)	0	0
Visual impairment	1 (1.6)	0	1 (1.6)	0	0
Gastrointestinal disorders					

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	42 (66.7)	13 (20.6)	16 (25.4)	13 (20.6)	0
Vomiting	26 (41.3)	16 (25.4)	7 (11.1)	3 (4.8)	0
Diarrhoea	24 (38.1)	13 (20.6)	9 (14.3)	2 (3.2)	0
Nausea	24 (38.1)	6 (9.5)	13 (20.6)	5 (7.9)	0
Abdominal pain	11 (17.5)	6 (9.5)	4 (6.3)	1 (1.6)	0
Constipation	7 (11.1)	6 (9.5)	1 (1.6)	0	0
Abdominal pain upper	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Abdominal distension	2 (3.2)	0	2 (3.2)	0	0
Dysphagia	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Oral pain	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Pancreatitis	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Stomatitis	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Abdominal discomfort	1 (1.6)	1 (1.6)	0	0	0
Abdominal pain lower	1 (1.6)	0	1 (1.6)	0	0
Abdominal tenderness	1 (1.6)	1 (1.6)	0	0	0
Anal incontinence	1 (1.6)	1 (1.6)	0	0	0
Ascites	1 (1.6)	0	0	1 (1.6)	0
Dyspepsia	1 (1.6)	0	1 (1.6)	0	0
Enterocolitis	1 (1.6)	0	0	1 (1.6)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flatulence	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Gastrooesophageal reflux disease	1 (1.6)	1 (1.6)	0	0	0
Glossodynia	1 (1.6)	1 (1.6)	0	0	0
Haematemesis	1 (1.6)	1 (1.6)	0	0	0
Ileus	1 (1.6)	0	0	1 (1.6)	0
Intestinal obstruction	1 (1.6)	0	0	1 (1.6)	0
Lip pain	1 (1.6)	0	1 (1.6)	0	0
Mouth haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Pigmentation lip	1 (1.6)	1 (1.6)	0	0	0
Tooth socket haemorrhage	1 (1.6)	1 (1.6)	0	0	0
General disorders and administration site conditions					
-Total	42 (66.7)	16 (25.4)	14 (22.2)	11 (17.5)	1 (1.6)
Pyrexia	25 (39.7)	8 (12.7)	10 (15.9)	6 (9.5)	1 (1.6)
Fatigue	15 (23.8)	12 (19.0)	2 (3.2)	1 (1.6)	0
Chills	10 (15.9)	9 (14.3)	1 (1.6)	0	0
Catheter site pain	4 (6.3)	1 (1.6)	3 (4.8)	0	0
Malaise	4 (6.3)	1 (1.6)	3 (4.8)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	4 (6.3)	1 (1.6)	1 (1.6)	2 (3.2)	0
Generalised oedema	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Oedema peripheral	3 (4.8)	2 (3.2)	0	1 (1.6)	0
Face oedema	2 (3.2)	0	1 (1.6)	1 (1.6)	0
Influenza like illness	2 (3.2)	2 (3.2)	0	0	0
Acquired gene mutation	1 (1.6)	1 (1.6)	0	0	0
Asthenia	1 (1.6)	1 (1.6)	0	0	0
Catheter site extravasation	1 (1.6)	0	1 (1.6)	0	0
Catheter site haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Crying	1 (1.6)	1 (1.6)	0	0	0
Cyst	1 (1.6)	0	0	1 (1.6)	0
Facial pain	1 (1.6)	0	1 (1.6)	0	0
Injection site haematoma	1 (1.6)	1 (1.6)	0	0	0
Localised oedema	1 (1.6)	0	0	1 (1.6)	0
Mucosal haemorrhage	1 (1.6)	0	1 (1.6)	0	0
Multiple organ dysfunction syndrome	1 (1.6)	0	0	1 (1.6)	0
Non-cardiac chest pain	1 (1.6)	1 (1.6)	0	0	0
Peripheral swelling	1 (1.6)	0	1 (1.6)	0	0
Physical deconditioning	1 (1.6)	0	0	1 (1.6)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	7 (11.1)	3 (4.8)	2 (3.2)	2 (3.2)	0
Hepatomegaly	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Hyperbilirubinaemia	3 (4.8)	0	1 (1.6)	2 (3.2)	0
Gallbladder enlargement	1 (1.6)	1 (1.6)	0	0	0
Hepatosplenomegaly	1 (1.6)	1 (1.6)	0	0	0
Immune system disorders					
-Total	57 (90.5)	5 (7.9)	30 (47.6)	11 (17.5)	11 (17.5)
Cytokine release syndrome	49 (77.8)	6 (9.5)	24 (38.1)	8 (12.7)	11 (17.5)
Hypogammaglobulinaemia	32 (50.8)	3 (4.8)	24 (38.1)	5 (7.9)	0
Graft versus host disease	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Immunodeficiency common variable	2 (3.2)	0	2 (3.2)	0	0
Seasonal allergy	2 (3.2)	2 (3.2)	0	0	0
Chronic graft versus host disease	1 (1.6)	0	1 (1.6)	0	0
Drug hypersensitivity	1 (1.6)	0	1 (1.6)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.6)	0	1 (1.6)	0	0
Graft versus host disease in skin	1 (1.6)	1 (1.6)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency	1 (1.6)	0	1 (1.6)	0	0
Infections and infestations					
-Total	46 (73.0)	7 (11.1)	21 (33.3)	14 (22.2)	4 (6.3)
Upper respiratory tract infection	9 (14.3)	4 (6.3)	4 (6.3)	1 (1.6)	0
Clostridium difficile infection	5 (7.9)	0	4 (6.3)	1 (1.6)	0
Gastroenteritis	5 (7.9)	1 (1.6)	3 (4.8)	1 (1.6)	0
Rhinovirus infection	5 (7.9)	5 (7.9)	0	0	0
Urinary tract infection	5 (7.9)	0	3 (4.8)	2 (3.2)	0
Clostridium difficile colitis	4 (6.3)	1 (1.6)	2 (3.2)	1 (1.6)	0
Influenza	4 (6.3)	1 (1.6)	3 (4.8)	0	0
Otitis media	4 (6.3)	0	3 (4.8)	1 (1.6)	0
Pneumonia	4 (6.3)	0	3 (4.8)	1 (1.6)	0
Sinusitis	4 (6.3)	0	4 (6.3)	0	0
Viral infection	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Viral upper respiratory tract infection	3 (4.8)	1 (1.6)	1 (1.6)	1 (1.6)	0
Cytomegalovirus infection	2 (3.2)	2 (3.2)	0	0	0
Ear infection	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Otitis media acute	2 (3.2)	0	2 (3.2)	0	0
Parainfluenzae virus infection	2 (3.2)	1 (1.6)	0	1 (1.6)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	2 (3.2)	0	2 (3.2)	0	0
Staphylococcal infection	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Vulvovaginal candidiasis	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Bacterial sepsis	1 (1.6)	0	0	0	1 (1.6)
Body tinea	1 (1.6)	1 (1.6)	0	0	0
Campylobacter infection	1 (1.6)	0	0	1 (1.6)	0
Catheter site cellulitis	1 (1.6)	1 (1.6)	0	0	0
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cellulitis of male external genital organ	1 (1.6)	0	0	1 (1.6)	0
Cholecystitis infective	1 (1.6)	0	0	1 (1.6)	0
Corona virus infection	1 (1.6)	0	0	1 (1.6)	0
Enterococcal infection	1 (1.6)	1 (1.6)	0	0	0
Enterovirus infection	1 (1.6)	0	0	1 (1.6)	0
Escherichia urinary tract infection	1 (1.6)	0	0	1 (1.6)	0
Folliculitis	1 (1.6)	0	1 (1.6)	0	0
Fungal skin infection	1 (1.6)	1 (1.6)	0	0	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Gastroenteritis viral	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingivitis	1 (1.6)	1 (1.6)	0	0	0
Haemophilus infection	1 (1.6)	0	1 (1.6)	0	0
Herpes simplex	1 (1.6)	1 (1.6)	0	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	0	1 (1.6)	0	0
Hypopyon	1 (1.6)	0	1 (1.6)	0	0
Meningitis aseptic	1 (1.6)	0	1 (1.6)	0	0
Molluscum contagiosum	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	1 (1.6)	0	0	0
Oral herpes	1 (1.6)	0	1 (1.6)	0	0
Orchitis	1 (1.6)	1 (1.6)	0	0	0
Otitis externa	1 (1.6)	0	1 (1.6)	0	0
Paronychia	1 (1.6)	1 (1.6)	0	0	0
Pharyngitis	1 (1.6)	0	1 (1.6)	0	0
Rash pustular	1 (1.6)	0	1 (1.6)	0	0
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection	1 (1.6)	0	0	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	0	0	1 (1.6)	0
Rhinitis	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rotavirus infection	1 (1.6)	0	0	1 (1.6)	0
Sepsis	1 (1.6)	0	0	0	1 (1.6)
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Streptococcal infection	1 (1.6)	0	1 (1.6)	0	0
Subcutaneous abscess	1 (1.6)	0	1 (1.6)	0	0
Tinea capitis	1 (1.6)	1 (1.6)	0	0	0
Urinary tract infection enterococcal	1 (1.6)	0	0	1 (1.6)	0
Vascular device infection	1 (1.6)	0	0	1 (1.6)	0
Vulvovaginal mycotic infection	1 (1.6)	0	1 (1.6)	0	0
Injury, poisoning and procedural complications					
-Total	22 (34.9)	11 (17.5)	8 (12.7)	2 (3.2)	1 (1.6)
Procedural pain	5 (7.9)	2 (3.2)	2 (3.2)	1 (1.6)	0
Infusion related reaction	4 (6.3)	1 (1.6)	3 (4.8)	0	0
Contusion	3 (4.8)	3 (4.8)	0	0	0
Transfusion reaction	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Skin abrasion	2 (3.2)	2 (3.2)	0	0	0
Arthropod bite	1 (1.6)	1 (1.6)	0	0	0
Foot fracture	1 (1.6)	0	1 (1.6)	0	0
Incision site pain	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Limb injury	1 (1.6)	1 (1.6)	0	0	0
Mouth injury	1 (1.6)	1 (1.6)	0	0	0
Post procedural haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Procedural complication	1 (1.6)	1 (1.6)	0	0	0
Procedural headache	1 (1.6)	0	1 (1.6)	0	0
Procedural nausea	1 (1.6)	0	1 (1.6)	0	0
Procedural site reaction	1 (1.6)	1 (1.6)	0	0	0
Radius fracture	1 (1.6)	0	1 (1.6)	0	0
Skin laceration	1 (1.6)	0	1 (1.6)	0	0
Stoma site irritation	1 (1.6)	1 (1.6)	0	0	0
Subdural haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Sunburn	1 (1.6)	1 (1.6)	0	0	0
Tibia fracture	1 (1.6)	0	1 (1.6)	0	0
Tongue injury	1 (1.6)	1 (1.6)	0	0	0
Tracheal haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Transfusion related complication	1 (1.6)	0	0	0	1 (1.6)
Investigations					
-Total	55 (87.3)	2 (3.2)	5 (7.9)	14 (22.2)	34 (54.0)
White blood cell count decreased	34 (54.0)	3 (4.8)	1 (1.6)	12 (19.0)	18 (28.6)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	27 (42.9)	1 (1.6)	2 (3.2)	3 (4.8)	21 (33.3)
Alanine aminotransferase increased	21 (33.3)	5 (7.9)	2 (3.2)	14 (22.2)	0
Aspartate aminotransferase increased	19 (30.2)	4 (6.3)	3 (4.8)	8 (12.7)	4 (6.3)
Platelet count decreased	19 (30.2)	3 (4.8)	2 (3.2)	2 (3.2)	12 (19.0)
Lymphocyte count decreased	16 (25.4)	1 (1.6)	3 (4.8)	7 (11.1)	5 (7.9)
Blood creatinine increased	9 (14.3)	5 (7.9)	2 (3.2)	2 (3.2)	0
Prothrombin time prolonged	9 (14.3)	5 (7.9)	3 (4.8)	1 (1.6)	0
Blood bilirubin increased	8 (12.7)	2 (3.2)	3 (4.8)	3 (4.8)	0
International normalised ratio increased	8 (12.7)	7 (11.1)	0	1 (1.6)	0
Activated partial thromboplastin time prolonged	4 (6.3)	3 (4.8)	1 (1.6)	0	0
Blood fibrinogen decreased	4 (6.3)	0	1 (1.6)	2 (3.2)	1 (1.6)
Blood immunoglobulin m decreased	4 (6.3)	4 (6.3)	0	0	0
Weight decreased	4 (6.3)	1 (1.6)	3 (4.8)	0	0
Blood immunoglobulin a decreased	3 (4.8)	3 (4.8)	0	0	0
Blood urea increased	3 (4.8)	1 (1.6)	1 (1.6)	1 (1.6)	0
Haemoglobin decreased	3 (4.8)	2 (3.2)	0	1 (1.6)	0
Transaminases increased	3 (4.8)	3 (4.8)	0	0	0
Blood magnesium decreased	2 (3.2)	1 (1.6)	0	1 (1.6)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	2 (3.2)	2 (3.2)	0	0	0
C-reactive protein increased	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Lipase increased	2 (3.2)	0	0	0	2 (3.2)
Serum ferritin increased	2 (3.2)	0	2 (3.2)	0	0
Weight increased	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Blood alkaline phosphatase increased	1 (1.6)	1 (1.6)	0	0	0
Blood bicarbonate decreased	1 (1.6)	0	1 (1.6)	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Blood lactate dehydrogenase increased	1 (1.6)	1 (1.6)	0	0	0
Blood lactic acid increased	1 (1.6)	0	0	0	1 (1.6)
Blood phosphorus decreased	1 (1.6)	1 (1.6)	0	0	0
Blood phosphorus increased	1 (1.6)	1 (1.6)	0	0	0
Blood sodium increased	1 (1.6)	0	1 (1.6)	0	0
Cardiac murmur	1 (1.6)	1 (1.6)	0	0	0
Culture stool positive	1 (1.6)	1 (1.6)	0	0	0
Fibrin d dimer increased	1 (1.6)	1 (1.6)	0	0	0
Hepatic enzyme increased	1 (1.6)	0	1 (1.6)	0	0
Norovirus test positive	1 (1.6)	1 (1.6)	0	0	0
Oxygen saturation decreased	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Protein total decreased	1 (1.6)	0	0	1 (1.6)	0
Pulmonary function test decreased	1 (1.6)	0	1 (1.6)	0	0
Metabolism and nutrition disorders					
-Total	43 (68.3)	8 (12.7)	8 (12.7)	23 (36.5)	4 (6.3)
Decreased appetite	22 (34.9)	5 (7.9)	5 (7.9)	12 (19.0)	0
Hypokalaemia	19 (30.2)	4 (6.3)	6 (9.5)	8 (12.7)	1 (1.6)
Hypophosphataemia	10 (15.9)	2 (3.2)	0	7 (11.1)	1 (1.6)
Hyperphosphataemia	8 (12.7)	8 (12.7)	0	0	0
Hypoalbuminaemia	5 (7.9)	1 (1.6)	3 (4.8)	1 (1.6)	0
Dehydration	4 (6.3)	1 (1.6)	0	3 (4.8)	0
Hypernatraemia	4 (6.3)	1 (1.6)	2 (3.2)	0	1 (1.6)
Fluid overload	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Hyperglycaemia	3 (4.8)	0	1 (1.6)	2 (3.2)	0
Hyperuricaemia	3 (4.8)	2 (3.2)	0	0	1 (1.6)
Hypocalcaemia	3 (4.8)	1 (1.6)	1 (1.6)	1 (1.6)	0
Acidosis	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Hypertriglyceridaemia	2 (3.2)	1 (1.6)	0	1 (1.6)	0
Hyponatraemia	2 (3.2)	0	0	2 (3.2)	0
Tumour lysis syndrome	2 (3.2)	0	0	2 (3.2)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vitamin d deficiency	2 (3.2)	2 (3.2)	0	0	0
Hyperalbuminaemia	1 (1.6)	1 (1.6)	0	0	0
Hypercalcaemia	1 (1.6)	1 (1.6)	0	0	0
Hyperchloraemia	1 (1.6)	1 (1.6)	0	0	0
Hypermagnesaemia	1 (1.6)	1 (1.6)	0	0	0
Hypomagnesaemia	1 (1.6)	1 (1.6)	0	0	0
Iron overload	1 (1.6)	0	0	1 (1.6)	0
Malnutrition	1 (1.6)	0	0	1 (1.6)	0
Metabolic acidosis	1 (1.6)	0	1 (1.6)	0	0
Metabolic alkalosis	1 (1.6)	1 (1.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	25 (39.7)	14 (22.2)	10 (15.9)	1 (1.6)	0
Pain in extremity	11 (17.5)	7 (11.1)	4 (6.3)	0	0
Arthralgia	5 (7.9)	3 (4.8)	1 (1.6)	1 (1.6)	0
Myalgia	5 (7.9)	4 (6.3)	1 (1.6)	0	0
Muscular weakness	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Musculoskeletal pain	3 (4.8)	2 (3.2)	1 (1.6)	0	0
Joint range of motion decreased	2 (3.2)	2 (3.2)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscle spasms	2 (3.2)	2 (3.2)	0	0	0
Musculoskeletal chest pain	2 (3.2)	2 (3.2)	0	0	0
Back pain	1 (1.6)	1 (1.6)	0	0	0
Coccydynia	1 (1.6)	1 (1.6)	0	0	0
Flank pain	1 (1.6)	0	1 (1.6)	0	0
Limb discomfort	1 (1.6)	1 (1.6)	0	0	0
Neck pain	1 (1.6)	0	1 (1.6)	0	0
Osteonecrosis	1 (1.6)	0	1 (1.6)	0	0
Osteopenia	1 (1.6)	0	1 (1.6)	0	0
Pain in jaw	1 (1.6)	1 (1.6)	0	0	0
Toe walking	1 (1.6)	1 (1.6)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (4.8)	0	2 (3.2)	0	1 (1.6)
Glioblastoma multiforme	1 (1.6)	0	0	0	1 (1.6)
Myelodysplastic syndrome	1 (1.6)	0	1 (1.6)	0	0
Skin papilloma	1 (1.6)	0	1 (1.6)	0	0
Nervous system disorders					
-Total	34 (54.0)	17 (27.0)	11 (17.5)	5 (7.9)	1 (1.6)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	24 (38.1)	15 (23.8)	7 (11.1)	2 (3.2)	0
Dizziness	6 (9.5)	6 (9.5)	0	0	0
Seizure	4 (6.3)	0	2 (3.2)	2 (3.2)	0
Encephalopathy	3 (4.8)	1 (1.6)	0	2 (3.2)	0
Dysarthria	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Peroneal nerve palsy	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Tremor	2 (3.2)	2 (3.2)	0	0	0
Asterixis	1 (1.6)	1 (1.6)	0	0	0
Ataxia	1 (1.6)	0	1 (1.6)	0	0
Depressed level of consciousness	1 (1.6)	1 (1.6)	0	0	0
Disturbance in attention	1 (1.6)	1 (1.6)	0	0	0
Embolic stroke	1 (1.6)	0	0	0	1 (1.6)
Idiopathic intracranial hypertension	1 (1.6)	0	1 (1.6)	0	0
Migraine	1 (1.6)	0	1 (1.6)	0	0
Myoclonus	1 (1.6)	1 (1.6)	0	0	0
Neuropathy peripheral	1 (1.6)	0	1 (1.6)	0	0
Pleocytosis	1 (1.6)	1 (1.6)	0	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0
Product issues					

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.6)	1 (1.6)	0	0	0
Device occlusion	1 (1.6)	1 (1.6)	0	0	0
Psychiatric disorders					
-Total	17 (27.0)	8 (12.7)	8 (12.7)	1 (1.6)	0
Anxiety	7 (11.1)	3 (4.8)	3 (4.8)	1 (1.6)	0
Confusional state	6 (9.5)	3 (4.8)	3 (4.8)	0	0
Delirium	4 (6.3)	2 (3.2)	2 (3.2)	0	0
Agitation	2 (3.2)	0	2 (3.2)	0	0
Depression	2 (3.2)	2 (3.2)	0	0	0
Hallucination	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Irritability	2 (3.2)	2 (3.2)	0	0	0
Adjustment disorder	1 (1.6)	0	1 (1.6)	0	0
Insomnia	1 (1.6)	0	1 (1.6)	0	0
Listless	1 (1.6)	1 (1.6)	0	0	0
Mental status changes	1 (1.6)	1 (1.6)	0	0	0
Panic attack	1 (1.6)	0	1 (1.6)	0	0
Sleep disorder	1 (1.6)	0	1 (1.6)	0	0
Suicidal ideation	1 (1.6)	1 (1.6)	0	0	0
Renal and urinary disorders					

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (23.8)	3 (4.8)	2 (3.2)	6 (9.5)	4 (6.3)
Acute kidney injury	9 (14.3)	1 (1.6)	1 (1.6)	4 (6.3)	3 (4.8)
Haematuria	5 (7.9)	0	2 (3.2)	2 (3.2)	1 (1.6)
Dysuria	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Oliguria	2 (3.2)	0	0	2 (3.2)	0
Calculus urinary	1 (1.6)	0	1 (1.6)	0	0
Nephrolithiasis	1 (1.6)	0	0	1 (1.6)	0
Pollakiuria	1 (1.6)	1 (1.6)	0	0	0
Renal failure	1 (1.6)	0	0	0	1 (1.6)
Renal impairment	1 (1.6)	0	0	1 (1.6)	0
Urinary incontinence	1 (1.6)	1 (1.6)	0	0	0
Reproductive system and breast disorders					
-Total	6 (9.5)	2 (3.2)	2 (3.2)	2 (3.2)	0
Vulvovaginal adhesion	2 (3.2)	2 (3.2)	0	0	0
Oedema genital	1 (1.6)	0	1 (1.6)	0	0
Ovarian failure	1 (1.6)	0	0	1 (1.6)	0
Scrotal pain	1 (1.6)	0	1 (1.6)	0	0
Vaginal haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Respiratory, thoracic and mediastinal disorders					

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	38 (60.3)	14 (22.2)	9 (14.3)	7 (11.1)	8 (12.7)
Cough	14 (22.2)	12 (19.0)	2 (3.2)	0	0
Epistaxis	10 (15.9)	4 (6.3)	1 (1.6)	4 (6.3)	1 (1.6)
Hypoxia	10 (15.9)	0	3 (4.8)	4 (6.3)	3 (4.8)
Pleural effusion	8 (12.7)	2 (3.2)	4 (6.3)	2 (3.2)	0
Pulmonary oedema	7 (11.1)	1 (1.6)	0	4 (6.3)	2 (3.2)
Oropharyngeal pain	6 (9.5)	4 (6.3)	2 (3.2)	0	0
Rhinorrhoea	6 (9.5)	5 (7.9)	1 (1.6)	0	0
Nasal congestion	5 (7.9)	5 (7.9)	0	0	0
Tachypnoea	5 (7.9)	3 (4.8)	1 (1.6)	1 (1.6)	0
Rhinitis allergic	4 (6.3)	3 (4.8)	1 (1.6)	0	0
Respiratory failure	3 (4.8)	0	0	0	3 (4.8)
Dyspnoea	2 (3.2)	0	0	1 (1.6)	1 (1.6)
Haemoptysis	2 (3.2)	1 (1.6)	0	0	1 (1.6)
Acute respiratory failure	1 (1.6)	0	0	0	1 (1.6)
Atelectasis	1 (1.6)	1 (1.6)	0	0	0
Dysphonia	1 (1.6)	1 (1.6)	0	0	0
Interstitial lung disease	1 (1.6)	0	0	0	1 (1.6)
Oropharyngeal plaque	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngeal erythema	1 (1.6)	1 (1.6)	0	0	0
Pharyngeal lesion	1 (1.6)	0	0	1 (1.6)	0
Pharyngeal ulceration	1 (1.6)	0	1 (1.6)	0	0
Respiratory depression	1 (1.6)	0	1 (1.6)	0	0
Respiratory distress	1 (1.6)	0	0	0	1 (1.6)
Wheezing	1 (1.6)	0	1 (1.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	30 (47.6)	18 (28.6)	9 (14.3)	3 (4.8)	0
Rash	8 (12.7)	5 (7.9)	3 (4.8)	0	0
Dry skin	5 (7.9)	5 (7.9)	0	0	0
Erythema	5 (7.9)	5 (7.9)	0	0	0
Rash maculo-papular	5 (7.9)	3 (4.8)	1 (1.6)	1 (1.6)	0
Hyperhidrosis	4 (6.3)	4 (6.3)	0	0	0
Petechiae	4 (6.3)	3 (4.8)	1 (1.6)	0	0
Pruritus	4 (6.3)	4 (6.3)	0	0	0
Ingrowing nail	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Macule	2 (3.2)	2 (3.2)	0	0	0
Papule	2 (3.2)	2 (3.2)	0	0	0
Rash erythematous	2 (3.2)	1 (1.6)	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash papular	2 (3.2)	2 (3.2)	0	0	0
Acne	1 (1.6)	1 (1.6)	0	0	0
Alopecia	1 (1.6)	0	1 (1.6)	0	0
Dermatitis	1 (1.6)	1 (1.6)	0	0	0
Dermatitis acneiform	1 (1.6)	0	0	1 (1.6)	0
Dermatitis atopic	1 (1.6)	1 (1.6)	0	0	0
Dermatitis diaper	1 (1.6)	1 (1.6)	0	0	0
Ecchymosis	1 (1.6)	0	0	1 (1.6)	0
Eczema	1 (1.6)	1 (1.6)	0	0	0
Keloid scar	1 (1.6)	0	1 (1.6)	0	0
Livedo reticularis	1 (1.6)	1 (1.6)	0	0	0
Night sweats	1 (1.6)	0	1 (1.6)	0	0
Rash follicular	1 (1.6)	1 (1.6)	0	0	0
Rash macular	1 (1.6)	1 (1.6)	0	0	0
Rash pruritic	1 (1.6)	1 (1.6)	0	0	0
Rash vesicular	1 (1.6)	1 (1.6)	0	0	0
Skin exfoliation	1 (1.6)	1 (1.6)	0	0	0
Skin fissures	1 (1.6)	1 (1.6)	0	0	0
Skin irritation	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

Primary system organ class Preferred term	All patients N=63 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	25 (39.7)	3 (4.8)	6 (9.5)	8 (12.7)	8 (12.7)
Hypotension	16 (25.4)	1 (1.6)	0	7 (11.1)	8 (12.7)
Hypertension	12 (19.0)	3 (4.8)	8 (12.7)	1 (1.6)	0
Flushing	2 (3.2)	2 (3.2)	0	0	0
Orthostatic hypotension	2 (3.2)	1 (1.6)	1 (1.6)	0	0
Capillary leak syndrome	1 (1.6)	0	0	0	1 (1.6)
Embolism	1 (1.6)	0	0	1 (1.6)	0
Haematoma	1 (1.6)	0	1 (1.6)	0	0
Hot flush	1 (1.6)	1 (1.6)	0	0	0
Secondary hypertension	1 (1.6)	0	1 (1.6)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174i
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

			All patients N=4		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	2 (50.0)	1 (25.0)	1 (25.0)
Blood and lymphatic system disorders					
-Total	3 (75.0)	0	1 (25.0)	2 (50.0)	0
Anaemia	3 (75.0)	0	2 (50.0)	1 (25.0)	0
Febrile neutropenia	2 (50.0)	0	0	2 (50.0)	0
Cardiac disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Cardiac dysfunction	1 (25.0)	1 (25.0)	0	0	0
Sinus tachycardia	1 (25.0)	0	1 (25.0)	0	0
Tachycardia	1 (25.0)	1 (25.0)	0	0	0
Gastrointestinal disorders					
-Total	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Diarrhoea	3 (75.0)	2 (50.0)	1 (25.0)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	2 (50.0)	2 (50.0)	0	0	0
Nausea	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Abdominal distension	1 (25.0)	0	1 (25.0)	0	0
Abdominal tenderness	1 (25.0)	1 (25.0)	0	0	0
Constipation	1 (25.0)	1 (25.0)	0	0	0
Gastrooesophageal reflux disease	1 (25.0)	1 (25.0)	0	0	0
Vomiting	1 (25.0)	1 (25.0)	0	0	0
General disorders and administration site conditions					
-Total	3 (75.0)	2 (50.0)	1 (25.0)	0	0
Fatigue	3 (75.0)	3 (75.0)	0	0	0
Pain	1 (25.0)	0	1 (25.0)	0	0
Immune system disorders					
-Total	4 (100)	0	3 (75.0)	1 (25.0)	0
Hypogammaglobulinaemia	4 (100)	0	4 (100)	0	0
Cytokine release syndrome	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Infections and infestations					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Clostridium difficile infection	1 (25.0)	0	1 (25.0)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (25.0)	0	0	1 (25.0)	0
Pharyngitis	1 (25.0)	0	1 (25.0)	0	0
Streptococcal infection	1 (25.0)	0	1 (25.0)	0	0
Injury, poisoning and procedural complications					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Contusion	1 (25.0)	1 (25.0)	0	0	0
Infusion related reaction	1 (25.0)	0	1 (25.0)	0	0
Procedural pain	1 (25.0)	0	1 (25.0)	0	0
Procedural site reaction	1 (25.0)	1 (25.0)	0	0	0
Investigations					
-Total	3 (75.0)	0	2 (50.0)	0	1 (25.0)
International normalised ratio increased	2 (50.0)	2 (50.0)	0	0	0
Lymphocyte count decreased	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Neutrophil count decreased	2 (50.0)	0	1 (25.0)	0	1 (25.0)
White blood cell count decreased	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Activated partial thromboplastin time prolonged	1 (25.0)	1 (25.0)	0	0	0
Alanine aminotransferase increased	1 (25.0)	0	0	1 (25.0)	0
Aspartate aminotransferase increased	1 (25.0)	0	0	1 (25.0)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (25.0)	0	1 (25.0)	0	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0
Platelet count decreased	1 (25.0)	0	1 (25.0)	0	0
Pulmonary function test decreased	1 (25.0)	0	1 (25.0)	0	0
Metabolism and nutrition disorders					
-Total	4 (100)	1 (25.0)	1 (25.0)	2 (50.0)	0
Hyperphosphataemia	2 (50.0)	2 (50.0)	0	0	0
Decreased appetite	1 (25.0)	0	0	1 (25.0)	0
Dehydration	1 (25.0)	0	0	1 (25.0)	0
Hyperuricaemia	1 (25.0)	1 (25.0)	0	0	0
Hypokalaemia	1 (25.0)	0	1 (25.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Arthralgia	2 (50.0)	2 (50.0)	0	0	0
Musculoskeletal chest pain	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal pain	1 (25.0)	0	1 (25.0)	0	0
Myalgia	1 (25.0)	1 (25.0)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	1 (25.0)	1 (25.0)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (25.0)	0	1 (25.0)	0	0
Skin papilloma	1 (25.0)	0	1 (25.0)	0	0
Nervous system disorders					
-Total	3 (75.0)	3 (75.0)	0	0	0
Headache	3 (75.0)	3 (75.0)	0	0	0
Dizziness	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Rhinorrhoea	1 (25.0)	1 (25.0)	0	0	0
Tachypnoea	1 (25.0)	1 (25.0)	0	0	0
Wheezing	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (50.0)	2 (50.0)	0	0	0
Petechiae	1 (25.0)	1 (25.0)	0	0	0
Rash follicular	1 (25.0)	1 (25.0)	0	0	0
Rash papular	1 (25.0)	1 (25.0)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Hypotension	1 (25.0)	0	0	0	1 (25.0)

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174i
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (98.3)	2 (3.3)	5 (8.3)	13 (21.7)	39 (65.0)
Blood and lymphatic system disorders					
-Total	40 (66.7)	2 (3.3)	2 (3.3)	25 (41.7)	11 (18.3)
Anaemia	24 (40.0)	3 (5.0)	3 (5.0)	17 (28.3)	1 (1.7)
Febrile neutropenia	20 (33.3)	0	0	20 (33.3)	0
Neutropenia	8 (13.3)	0	0	3 (5.0)	5 (8.3)
Thrombocytopenia	8 (13.3)	0	0	2 (3.3)	6 (10.0)
Disseminated intravascular coagulation	4 (6.7)	0	2 (3.3)	2 (3.3)	0
Lymphopenia	3 (5.0)	0	1 (1.7)	1 (1.7)	1 (1.7)
Coagulopathy	1 (1.7)	1 (1.7)	0	0	0
Pancytopenia	1 (1.7)	0	0	0	1 (1.7)
Cardiac disorders					
-Total	20 (33.3)	10 (16.7)	8 (13.3)	2 (3.3)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	14 (23.3)	7 (11.7)	5 (8.3)	2 (3.3)	0
Sinus tachycardia	4 (6.7)	3 (5.0)	1 (1.7)	0	0
Pericardial effusion	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Atrioventricular block second degree	1 (1.7)	1 (1.7)	0	0	0
Bradycardia	1 (1.7)	0	1 (1.7)	0	0
Left ventricular dysfunction	1 (1.7)	0	0	1 (1.7)	0
Palpitations	1 (1.7)	1 (1.7)	0	0	0
Sinus bradycardia	1 (1.7)	1 (1.7)	0	0	0
Ventricular tachycardia	1 (1.7)	0	1 (1.7)	0	0
Ear and labyrinth disorders					
-Total	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Ear pain	2 (3.3)	2 (3.3)	0	0	0
Hypoacusis	1 (1.7)	0	1 (1.7)	0	0
Endocrine disorders					
-Total	1 (1.7)	0	1 (1.7)	0	0
Adrenal insufficiency	1 (1.7)	0	1 (1.7)	0	0
Eye disorders					
-Total	13 (21.7)	6 (10.0)	7 (11.7)	0	0
Periorbital oedema	4 (6.7)	3 (5.0)	1 (1.7)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctival haemorrhage	3 (5.0)	3 (5.0)	0	0	0
Eye pain	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Vision blurred	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Photophobia	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Retinal haemorrhage	2 (3.3)	2 (3.3)	0	0	0
Uveitis	2 (3.3)	0	2 (3.3)	0	0
Ocular hypertension	1 (1.7)	0	1 (1.7)	0	0
Papilloedema	1 (1.7)	0	1 (1.7)	0	0
Visual impairment	1 (1.7)	0	1 (1.7)	0	0
Gastrointestinal disorders					
-Total	33 (55.0)	10 (16.7)	12 (20.0)	11 (18.3)	0
Vomiting	21 (35.0)	12 (20.0)	6 (10.0)	3 (5.0)	0
Nausea	19 (31.7)	5 (8.3)	11 (18.3)	3 (5.0)	0
Diarrhoea	15 (25.0)	9 (15.0)	5 (8.3)	1 (1.7)	0
Abdominal pain	7 (11.7)	4 (6.7)	2 (3.3)	1 (1.7)	0
Constipation	6 (10.0)	5 (8.3)	1 (1.7)	0	0
Abdominal pain upper	2 (3.3)	0	2 (3.3)	0	0
Dysphagia	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Haematemesis	2 (3.3)	2 (3.3)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Stomatitis	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Abdominal discomfort	1 (1.7)	1 (1.7)	0	0	0
Abdominal distension	1 (1.7)	0	1 (1.7)	0	0
Abdominal pain lower	1 (1.7)	0	1 (1.7)	0	0
Anal incontinence	1 (1.7)	1 (1.7)	0	0	0
Ascites	1 (1.7)	0	0	1 (1.7)	0
Dyspepsia	1 (1.7)	0	1 (1.7)	0	0
Flatulence	1 (1.7)	1 (1.7)	0	0	0
Gastrointestinal haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Glossodynia	1 (1.7)	1 (1.7)	0	0	0
Ileus	1 (1.7)	0	0	1 (1.7)	0
Intestinal obstruction	1 (1.7)	0	0	1 (1.7)	0
Lip pain	1 (1.7)	0	1 (1.7)	0	0
Mouth haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Tooth socket haemorrhage	1 (1.7)	1 (1.7)	0	0	0
General disorders and administration site conditions					
-Total	29 (48.3)	10 (16.7)	9 (15.0)	9 (15.0)	1 (1.7)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	16 (26.7)	3 (5.0)	7 (11.7)	5 (8.3)	1 (1.7)
Fatigue	10 (16.7)	7 (11.7)	2 (3.3)	1 (1.7)	0
Chills	8 (13.3)	8 (13.3)	0	0	0
Catheter site pain	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Malaise	3 (5.0)	0	3 (5.0)	0	0
Face oedema	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Generalised oedema	2 (3.3)	0	2 (3.3)	0	0
Oedema peripheral	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Pain	2 (3.3)	0	0	2 (3.3)	0
Asthenia	1 (1.7)	1 (1.7)	0	0	0
Catheter site extravasation	1 (1.7)	0	1 (1.7)	0	0
Catheter site haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Facial pain	1 (1.7)	0	1 (1.7)	0	0
Injection site haematoma	1 (1.7)	1 (1.7)	0	0	0
Localised oedema	1 (1.7)	0	0	1 (1.7)	0
Mucosal haemorrhage	1 (1.7)	0	1 (1.7)	0	0
Multiple organ dysfunction syndrome	1 (1.7)	0	0	1 (1.7)	0
Non-cardiac chest pain	1 (1.7)	1 (1.7)	0	0	0
Peripheral swelling	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Physical deconditioning	1 (1.7)	0	0	1 (1.7)	0
Hepatobiliary disorders					
-Total	7 (11.7)	3 (5.0)	2 (3.3)	2 (3.3)	0
Hepatomegaly	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Hyperbilirubinaemia	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Gallbladder enlargement	1 (1.7)	1 (1.7)	0	0	0
Hepatosplenomegaly	1 (1.7)	1 (1.7)	0	0	0
Immune system disorders					
-Total	53 (88.3)	5 (8.3)	27 (45.0)	10 (16.7)	11 (18.3)
Cytokine release syndrome	48 (80.0)	6 (10.0)	24 (40.0)	7 (11.7)	11 (18.3)
Hypogammaglobulinaemia	21 (35.0)	3 (5.0)	14 (23.3)	4 (6.7)	0
Drug hypersensitivity	1 (1.7)	0	1 (1.7)	0	0
Graft versus host disease in skin	1 (1.7)	1 (1.7)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	1 (1.7)	0	0
Infections and infestations					
-Total	24 (40.0)	5 (8.3)	13 (21.7)	5 (8.3)	1 (1.7)
Clostridium difficile colitis	4 (6.7)	1 (1.7)	2 (3.3)	1 (1.7)	0
Clostridium difficile infection	3 (5.0)	0	3 (5.0)	0	0
Rhinovirus infection	3 (5.0)	3 (5.0)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Staphylococcal infection	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Acute sinusitis	1 (1.7)	0	1 (1.7)	0	0
Body tinea	1 (1.7)	1 (1.7)	0	0	0
Catheter site cellulitis	1 (1.7)	1 (1.7)	0	0	0
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cytomegalovirus infection	1 (1.7)	1 (1.7)	0	0	0
Enterococcal infection	1 (1.7)	1 (1.7)	0	0	0
Folliculitis	1 (1.7)	0	1 (1.7)	0	0
Fungal skin infection	1 (1.7)	1 (1.7)	0	0	0
Gastroenteritis	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Herpes simplex	1 (1.7)	1 (1.7)	0	0	0
Human herpesvirus 6 infection	1 (1.7)	0	1 (1.7)	0	0
Hypopyon	1 (1.7)	0	1 (1.7)	0	0
Influenza	1 (1.7)	1 (1.7)	0	0	0
Oral candidiasis	1 (1.7)	1 (1.7)	0	0	0
Orchitis	1 (1.7)	1 (1.7)	0	0	0
Septic embolus	1 (1.7)	0	0	0	1 (1.7)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	1 (1.7)	0	1 (1.7)	0	0
Upper respiratory tract infection	1 (1.7)	0	1 (1.7)	0	0
Urinary tract infection enterococcal	1 (1.7)	0	0	1 (1.7)	0
Viral infection	1 (1.7)	0	1 (1.7)	0	0
Viral upper respiratory tract infection	1 (1.7)	0	1 (1.7)	0	0
Vulvovaginal candidiasis	1 (1.7)	1 (1.7)	0	0	0
Injury, poisoning and procedural complications					
-Total	13 (21.7)	7 (11.7)	4 (6.7)	1 (1.7)	1 (1.7)
Transfusion reaction	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Procedural pain	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Incision site pain	1 (1.7)	1 (1.7)	0	0	0
Infusion related reaction	1 (1.7)	0	1 (1.7)	0	0
Limb injury	1 (1.7)	1 (1.7)	0	0	0
Mouth injury	1 (1.7)	1 (1.7)	0	0	0
Post procedural haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Procedural complication	1 (1.7)	1 (1.7)	0	0	0
Procedural headache	1 (1.7)	0	1 (1.7)	0	0
Skin abrasion	1 (1.7)	1 (1.7)	0	0	0
Stoma site irritation	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Subdural haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Tibia fracture	1 (1.7)	0	1 (1.7)	0	0
Tongue injury	1 (1.7)	1 (1.7)	0	0	0
Tracheal haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Transfusion related complication	1 (1.7)	0	0	0	1 (1.7)
Investigations					
-Total	49 (81.7)	4 (6.7)	2 (3.3)	13 (21.7)	30 (50.0)
White blood cell count decreased	28 (46.7)	3 (5.0)	0	9 (15.0)	16 (26.7)
Neutrophil count decreased	23 (38.3)	0	1 (1.7)	4 (6.7)	18 (30.0)
Alanine aminotransferase increased	18 (30.0)	5 (8.3)	3 (5.0)	10 (16.7)	0
Platelet count decreased	18 (30.0)	3 (5.0)	1 (1.7)	2 (3.3)	12 (20.0)
Aspartate aminotransferase increased	17 (28.3)	3 (5.0)	4 (6.7)	6 (10.0)	4 (6.7)
Lymphocyte count decreased	12 (20.0)	1 (1.7)	1 (1.7)	5 (8.3)	5 (8.3)
Prothrombin time prolonged	9 (15.0)	5 (8.3)	3 (5.0)	1 (1.7)	0
Blood creatinine increased	8 (13.3)	4 (6.7)	2 (3.3)	2 (3.3)	0
International normalised ratio increased	7 (11.7)	6 (10.0)	0	1 (1.7)	0
Blood bilirubin increased	6 (10.0)	2 (3.3)	2 (3.3)	2 (3.3)	0
Activated partial thromboplastin time prolonged	4 (6.7)	2 (3.3)	2 (3.3)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	4 (6.7)	0	1 (1.7)	2 (3.3)	1 (1.7)
Blood immunoglobulin m decreased	4 (6.7)	4 (6.7)	0	0	0
Blood urea increased	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Blood immunoglobulin a decreased	2 (3.3)	2 (3.3)	0	0	0
Blood phosphorus increased	2 (3.3)	2 (3.3)	0	0	0
Lipase increased	2 (3.3)	0	0	0	2 (3.3)
Transaminases increased	2 (3.3)	2 (3.3)	0	0	0
Blood bicarbonate decreased	1 (1.7)	0	1 (1.7)	0	0
Blood immunoglobulin g decreased	1 (1.7)	0	1 (1.7)	0	0
Blood lactic acid increased	1 (1.7)	0	0	0	1 (1.7)
Blood magnesium decreased	1 (1.7)	0	0	1 (1.7)	0
Blood phosphorus decreased	1 (1.7)	1 (1.7)	0	0	0
Blood sodium increased	1 (1.7)	0	1 (1.7)	0	0
Blood uric acid increased	1 (1.7)	1 (1.7)	0	0	0
C-reactive protein increased	1 (1.7)	0	0	1 (1.7)	0
Cardiac murmur	1 (1.7)	1 (1.7)	0	0	0
Culture stool positive	1 (1.7)	1 (1.7)	0	0	0
Fibrin d dimer increased	1 (1.7)	1 (1.7)	0	0	0
Haemoglobin decreased	1 (1.7)	0	0	1 (1.7)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic enzyme increased	1 (1.7)	0	1 (1.7)	0	0
Norovirus test positive	1 (1.7)	1 (1.7)	0	0	0
Protein total decreased	1 (1.7)	0	0	1 (1.7)	0
Serum ferritin increased	1 (1.7)	0	1 (1.7)	0	0
Metabolism and nutrition disorders					
-Total	35 (58.3)	4 (6.7)	9 (15.0)	19 (31.7)	3 (5.0)
Decreased appetite	19 (31.7)	4 (6.7)	4 (6.7)	11 (18.3)	0
Hypokalaemia	15 (25.0)	3 (5.0)	5 (8.3)	7 (11.7)	0
Hypophosphataemia	9 (15.0)	2 (3.3)	0	6 (10.0)	1 (1.7)
Hyperphosphataemia	6 (10.0)	6 (10.0)	0	0	0
Hypoalbuminaemia	5 (8.3)	1 (1.7)	3 (5.0)	1 (1.7)	0
Hypernatraemia	4 (6.7)	1 (1.7)	2 (3.3)	0	1 (1.7)
Fluid overload	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Hyperglycaemia	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Hypocalcaemia	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Acidosis	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Dehydration	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Hypertriglyceridaemia	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Hyperuricaemia	2 (3.3)	1 (1.7)	0	0	1 (1.7)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyponatraemia	2 (3.3)	0	0	2 (3.3)	0
Hyperalbuminaemia	1 (1.7)	1 (1.7)	0	0	0
Hypercalcaemia	1 (1.7)	1 (1.7)	0	0	0
Hyperchloraemia	1 (1.7)	1 (1.7)	0	0	0
Hypermagnesaemia	1 (1.7)	1 (1.7)	0	0	0
Hypomagnesaemia	1 (1.7)	1 (1.7)	0	0	0
Malnutrition	1 (1.7)	0	0	1 (1.7)	0
Metabolic acidosis	1 (1.7)	0	1 (1.7)	0	0
Metabolic alkalosis	1 (1.7)	1 (1.7)	0	0	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0
Musculoskeletal and connective tissue disorders					
-Total	13 (21.7)	7 (11.7)	5 (8.3)	1 (1.7)	0
Myalgia	4 (6.7)	3 (5.0)	1 (1.7)	0	0
Pain in extremity	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Arthralgia	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Musculoskeletal pain	2 (3.3)	2 (3.3)	0	0	0
Coccydynia	1 (1.7)	1 (1.7)	0	0	0
Limb discomfort	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscle spasms	1 (1.7)	1 (1.7)	0	0	0
Muscular weakness	1 (1.7)	0	1 (1.7)	0	0
Osteopenia	1 (1.7)	0	1 (1.7)	0	0
Nervous system disorders					
-Total	30 (50.0)	14 (23.3)	11 (18.3)	4 (6.7)	1 (1.7)
Headache	21 (35.0)	13 (21.7)	6 (10.0)	2 (3.3)	0
Encephalopathy	4 (6.7)	1 (1.7)	1 (1.7)	2 (3.3)	0
Dizziness	3 (5.0)	3 (5.0)	0	0	0
Seizure	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Dysarthria	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Tremor	2 (3.3)	2 (3.3)	0	0	0
Asterixis	1 (1.7)	1 (1.7)	0	0	0
Ataxia	1 (1.7)	0	1 (1.7)	0	0
Depressed level of consciousness	1 (1.7)	1 (1.7)	0	0	0
Embolic stroke	1 (1.7)	0	0	0	1 (1.7)
Idiopathic intracranial hypertension	1 (1.7)	0	1 (1.7)	0	0
Migraine	1 (1.7)	0	1 (1.7)	0	0
Myoclonus	1 (1.7)	1 (1.7)	0	0	0
Neuropathy peripheral	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleocytosis	1 (1.7)	1 (1.7)	0	0	0
Somnolence	1 (1.7)	1 (1.7)	0	0	0
Product issues					
-Total	1 (1.7)	1 (1.7)	0	0	0
Device occlusion	1 (1.7)	1 (1.7)	0	0	0
Psychiatric disorders					
-Total	16 (26.7)	8 (13.3)	7 (11.7)	1 (1.7)	0
Anxiety	6 (10.0)	2 (3.3)	3 (5.0)	1 (1.7)	0
Confusional state	6 (10.0)	3 (5.0)	3 (5.0)	0	0
Delirium	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Agitation	2 (3.3)	0	2 (3.3)	0	0
Hallucination	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Irritability	2 (3.3)	2 (3.3)	0	0	0
Adjustment disorder	1 (1.7)	0	1 (1.7)	0	0
Insomnia	1 (1.7)	0	1 (1.7)	0	0
Listless	1 (1.7)	1 (1.7)	0	0	0
Mental status changes	1 (1.7)	1 (1.7)	0	0	0
Panic attack	1 (1.7)	0	1 (1.7)	0	0
Suicidal ideation	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	11 (18.3)	2 (3.3)	2 (3.3)	3 (5.0)	4 (6.7)
Acute kidney injury	7 (11.7)	1 (1.7)	1 (1.7)	2 (3.3)	3 (5.0)
Haematuria	4 (6.7)	0	2 (3.3)	1 (1.7)	1 (1.7)
Dysuria	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Oliguria	2 (3.3)	0	0	2 (3.3)	0
Pollakiuria	1 (1.7)	1 (1.7)	0	0	0
Renal failure	1 (1.7)	0	0	0	1 (1.7)
Renal impairment	1 (1.7)	0	0	1 (1.7)	0
Reproductive system and breast disorders					
-Total	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Vulvovaginal adhesion	2 (3.3)	2 (3.3)	0	0	0
Oedema genital	1 (1.7)	0	1 (1.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	26 (43.3)	9 (15.0)	5 (8.3)	5 (8.3)	7 (11.7)
Hypoxia	10 (16.7)	0	3 (5.0)	4 (6.7)	3 (5.0)
Cough	8 (13.3)	8 (13.3)	0	0	0
Pleural effusion	8 (13.3)	2 (3.3)	4 (6.7)	2 (3.3)	0
Epistaxis	7 (11.7)	2 (3.3)	1 (1.7)	3 (5.0)	1 (1.7)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	6 (10.0)	1 (1.7)	0	3 (5.0)	2 (3.3)
Tachypnoea	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Respiratory failure	3 (5.0)	0	0	0	3 (5.0)
Dyspnoea	2 (3.3)	0	0	1 (1.7)	1 (1.7)
Haemoptysis	2 (3.3)	1 (1.7)	0	0	1 (1.7)
Oropharyngeal pain	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Atelectasis	1 (1.7)	1 (1.7)	0	0	0
Interstitial lung disease	1 (1.7)	0	0	0	1 (1.7)
Nasal congestion	1 (1.7)	1 (1.7)	0	0	0
Oropharyngeal plaque	1 (1.7)	1 (1.7)	0	0	0
Pharyngeal ulceration	1 (1.7)	0	1 (1.7)	0	0
Respiratory depression	1 (1.7)	0	1 (1.7)	0	0
Respiratory distress	1 (1.7)	0	0	0	1 (1.7)
Rhinitis allergic	1 (1.7)	1 (1.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	19 (31.7)	13 (21.7)	4 (6.7)	2 (3.3)	0
Dry skin	4 (6.7)	4 (6.7)	0	0	0
Rash	4 (6.7)	4 (6.7)	0	0	0
Erythema	3 (5.0)	3 (5.0)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperhidrosis	3 (5.0)	3 (5.0)	0	0	0
Rash maculo-papular	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Ingrowing nail	2 (3.3)	0	2 (3.3)	0	0
Petechiae	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Pruritus	2 (3.3)	2 (3.3)	0	0	0
Dermatitis diaper	1 (1.7)	1 (1.7)	0	0	0
Ecchymosis	1 (1.7)	0	0	1 (1.7)	0
Livedo reticularis	1 (1.7)	1 (1.7)	0	0	0
Macule	1 (1.7)	1 (1.7)	0	0	0
Night sweats	1 (1.7)	0	1 (1.7)	0	0
Rash erythematous	1 (1.7)	1 (1.7)	0	0	0
Rash macular	1 (1.7)	1 (1.7)	0	0	0
Rash papular	1 (1.7)	1 (1.7)	0	0	0
Rash vesicular	1 (1.7)	1 (1.7)	0	0	0
Skin exfoliation	1 (1.7)	1 (1.7)	0	0	0
Skin fissures	1 (1.7)	1 (1.7)	0	0	0
Skin irritation	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					
-Total	23 (38.3)	3 (5.0)	5 (8.3)	8 (13.3)	7 (11.7)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	15 (25.0)	1 (1.7)	0	7 (11.7)	7 (11.7)
Hypertension	10 (16.7)	2 (3.3)	7 (11.7)	1 (1.7)	0
Flushing	2 (3.3)	2 (3.3)	0	0	0
Orthostatic hypotension	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Capillary leak syndrome	1 (1.7)	0	0	0	1 (1.7)
Embolism	1 (1.7)	0	0	1 (1.7)	0
Haematoma	1 (1.7)	0	1 (1.7)	0	0
Secondary hypertension	1 (1.7)	0	1 (1.7)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174i
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

			All patients N=4		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	2 (50.0)	1 (25.0)	1 (25.0)
Blood and lymphatic system disorders					
-Total	2 (50.0)	0	1 (25.0)	0	1 (25.0)
Febrile neutropenia	1 (25.0)	0	0	1 (25.0)	0
Lymphopenia	1 (25.0)	0	1 (25.0)	0	0
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
Eye disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Dry eye	1 (25.0)	0	1 (25.0)	0	0
Gastrointestinal disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Vomiting	1 (25.0)	0	1 (25.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	1 (25.0)	1 (25.0)	0	0	0
Fatigue	1 (25.0)	1 (25.0)	0	0	0
Pyrexia	1 (25.0)	1 (25.0)	0	0	0
Infections and infestations					
-Total	3 (75.0)	1 (25.0)	1 (25.0)	1 (25.0)	0
Cytomegalovirus infection	1 (25.0)	1 (25.0)	0	0	0
Herpes zoster	1 (25.0)	0	0	1 (25.0)	0
Otitis media acute	1 (25.0)	0	1 (25.0)	0	0
Parainfluenzae virus infection	1 (25.0)	1 (25.0)	0	0	0
Sinusitis	1 (25.0)	0	1 (25.0)	0	0
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0
Investigations					
-Total	3 (75.0)	1 (25.0)	0	1 (25.0)	1 (25.0)
Neutrophil count decreased	3 (75.0)	1 (25.0)	0	1 (25.0)	1 (25.0)
Aspartate aminotransferase increased	1 (25.0)	0	0	1 (25.0)	0
Blood uric acid increased	1 (25.0)	1 (25.0)	0	0	0
Platelet count decreased	1 (25.0)	1 (25.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (25.0)	0	1 (25.0)	0	0
Metabolism and nutrition disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Decreased appetite	1 (25.0)	0	1 (25.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Joint range of motion decreased	1 (25.0)	1 (25.0)	0	0	0
Osteonecrosis	1 (25.0)	0	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Pulmonary oedema	1 (25.0)	0	0	1 (25.0)	0
Skin and subcutaneous tissue disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Rash	1 (25.0)	0	1 (25.0)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174i
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (80.8)	4 (7.7)	14 (26.9)	15 (28.8)	9 (17.3)
Blood and lymphatic system disorders					
-Total	9 (17.3)	1 (1.9)	2 (3.8)	3 (5.8)	3 (5.8)
Neutropenia	3 (5.8)	0	0	1 (1.9)	2 (3.8)
Anaemia	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Febrile neutropenia	2 (3.8)	0	0	2 (3.8)	0
Thrombocytopenia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Eosinophilia	1 (1.9)	0	0	1 (1.9)	0
Leukopenia	1 (1.9)	0	0	0	1 (1.9)
Lymphadenopathy	1 (1.9)	0	1 (1.9)	0	0
Cardiac disorders					
-Total	1 (1.9)	0	1 (1.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	1 (1.9)	0	1 (1.9)	0	0
Endocrine disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Adrenal insufficiency	1 (1.9)	1 (1.9)	0	0	0
Eye disorders					
-Total	4 (7.7)	4 (7.7)	0	0	0
Conjunctivitis allergic	1 (1.9)	1 (1.9)	0	0	0
Dry eye	1 (1.9)	1 (1.9)	0	0	0
Ocular hyperaemia	1 (1.9)	1 (1.9)	0	0	0
Vision blurred	1 (1.9)	1 (1.9)	0	0	0
Gastrointestinal disorders					
-Total	15 (28.8)	9 (17.3)	2 (3.8)	4 (7.7)	0
Diarrhoea	8 (15.4)	6 (11.5)	1 (1.9)	1 (1.9)	0
Vomiting	8 (15.4)	5 (9.6)	1 (1.9)	2 (3.8)	0
Nausea	6 (11.5)	1 (1.9)	3 (5.8)	2 (3.8)	0
Abdominal pain	4 (7.7)	2 (3.8)	1 (1.9)	1 (1.9)	0
Oral pain	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Abdominal pain upper	1 (1.9)	1 (1.9)	0	0	0
Enterocolitis	1 (1.9)	0	0	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pigmentation lip	1 (1.9)	1 (1.9)	0	0	0
General disorders and administration site conditions					
-Total	16 (30.8)	12 (23.1)	3 (5.8)	1 (1.9)	0
Pyrexia	9 (17.3)	6 (11.5)	2 (3.8)	1 (1.9)	0
Influenza like illness	2 (3.8)	2 (3.8)	0	0	0
Acquired gene mutation	1 (1.9)	1 (1.9)	0	0	0
Catheter site pain	1 (1.9)	0	1 (1.9)	0	0
Chills	1 (1.9)	1 (1.9)	0	0	0
Crying	1 (1.9)	1 (1.9)	0	0	0
Fatigue	1 (1.9)	1 (1.9)	0	0	0
Generalised oedema	1 (1.9)	1 (1.9)	0	0	0
Malaise	1 (1.9)	1 (1.9)	0	0	0
Oedema peripheral	1 (1.9)	1 (1.9)	0	0	0
Pain	1 (1.9)	1 (1.9)	0	0	0
Immune system disorders					
-Total	14 (26.9)	3 (5.8)	10 (19.2)	1 (1.9)	0
Hypogammaglobulinaemia	8 (15.4)	0	7 (13.5)	1 (1.9)	0
Graft versus host disease	2 (3.8)	1 (1.9)	1 (1.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency common variable	2 (3.8)	0	2 (3.8)	0	0
Seasonal allergy	2 (3.8)	2 (3.8)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (1.9)	0	1 (1.9)	0	0
Infections and infestations					
-Total	30 (57.7)	5 (9.6)	14 (26.9)	9 (17.3)	2 (3.8)
Upper respiratory tract infection	6 (11.5)	2 (3.8)	3 (5.8)	1 (1.9)	0
Urinary tract infection	4 (7.7)	0	2 (3.8)	2 (3.8)	0
Gastroenteritis	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Influenza	3 (5.8)	0	3 (5.8)	0	0
Ear infection	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Rhinovirus infection	2 (3.8)	2 (3.8)	0	0	0
Viral upper respiratory tract infection	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Bacterial sepsis	1 (1.9)	0	0	0	1 (1.9)
Cellulitis of male external genital organ	1 (1.9)	0	0	1 (1.9)	0
Cholecystitis infective	1 (1.9)	0	0	1 (1.9)	0
Corona virus infection	1 (1.9)	0	0	1 (1.9)	0
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis viral	1 (1.9)	1 (1.9)	0	0	0
Molluscum contagiosum	1 (1.9)	1 (1.9)	0	0	0
Oral herpes	1 (1.9)	0	1 (1.9)	0	0
Otitis externa	1 (1.9)	0	1 (1.9)	0	0
Otitis media	1 (1.9)	0	1 (1.9)	0	0
Parainfluenzae virus infection	1 (1.9)	0	0	1 (1.9)	0
Paronychia	1 (1.9)	1 (1.9)	0	0	0
Rash pustular	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus infection	1 (1.9)	0	0	1 (1.9)	0
Rhinitis	1 (1.9)	1 (1.9)	0	0	0
Rotavirus infection	1 (1.9)	0	0	1 (1.9)	0
Sepsis	1 (1.9)	0	0	0	1 (1.9)
Sinusitis	1 (1.9)	0	1 (1.9)	0	0
Subcutaneous abscess	1 (1.9)	0	1 (1.9)	0	0
Tinea capitis	1 (1.9)	1 (1.9)	0	0	0
Vascular device infection	1 (1.9)	0	0	1 (1.9)	0
Viral infection	1 (1.9)	1 (1.9)	0	0	0
Vulvovaginal mycotic infection	1 (1.9)	0	1 (1.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

		All patients N=52			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	8 (15.4)	3 (5.8)	5 (9.6)	0	0
Contusion	2 (3.8)	2 (3.8)	0	0	0
Infusion related reaction	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Procedural pain	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Arthropod bite	1 (1.9)	1 (1.9)	0	0	0
Foot fracture	1 (1.9)	0	1 (1.9)	0	0
Procedural nausea	1 (1.9)	0	1 (1.9)	0	0
Radius fracture	1 (1.9)	0	1 (1.9)	0	0
Skin abrasion	1 (1.9)	1 (1.9)	0	0	0
Skin laceration	1 (1.9)	0	1 (1.9)	0	0
Sunburn	1 (1.9)	1 (1.9)	0	0	0
Investigations					
-Total	20 (38.5)	5 (9.6)	5 (9.6)	7 (13.5)	3 (5.8)
Neutrophil count decreased	5 (9.6)	1 (1.9)	0	2 (3.8)	2 (3.8)
Weight decreased	4 (7.7)	1 (1.9)	3 (5.8)	0	0
White blood cell count decreased	4 (7.7)	2 (3.8)	0	1 (1.9)	1 (1.9)
Alanine aminotransferase increased	2 (3.8)	0	0	2 (3.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Haemoglobin decreased	2 (3.8)	2 (3.8)	0	0	0
Lymphocyte count decreased	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Platelet count decreased	2 (3.8)	2 (3.8)	0	0	0
Weight increased	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Blood bilirubin increased	1 (1.9)	0	0	1 (1.9)	0
Blood creatinine increased	1 (1.9)	1 (1.9)	0	0	0
Blood magnesium decreased	1 (1.9)	1 (1.9)	0	0	0
Blood urea increased	1 (1.9)	1 (1.9)	0	0	0
Oxygen saturation decreased	1 (1.9)	1 (1.9)	0	0	0
Serum ferritin increased	1 (1.9)	0	1 (1.9)	0	0
Transaminases increased	1 (1.9)	1 (1.9)	0	0	0
Metabolism and nutrition disorders					
-Total	9 (17.3)	5 (9.6)	0	3 (5.8)	1 (1.9)
Hyperphosphataemia	2 (3.8)	2 (3.8)	0	0	0
Hypokalaemia	2 (3.8)	1 (1.9)	0	0	1 (1.9)
Decreased appetite	1 (1.9)	1 (1.9)	0	0	0
Dehydration	1 (1.9)	0	0	1 (1.9)	0
Hyperalbuminaemia	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypercalcaemia	1 (1.9)	1 (1.9)	0	0	0
Hyperglycaemia	1 (1.9)	0	0	1 (1.9)	0
Hypophosphataemia	1 (1.9)	0	0	1 (1.9)	0
Iron overload	1 (1.9)	0	0	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0
Vitamin d deficiency	1 (1.9)	1 (1.9)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	14 (26.9)	10 (19.2)	4 (7.7)	0	0
Pain in extremity	8 (15.4)	6 (11.5)	2 (3.8)	0	0
Arthralgia	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Muscular weakness	2 (3.8)	2 (3.8)	0	0	0
Back pain	1 (1.9)	1 (1.9)	0	0	0
Flank pain	1 (1.9)	0	1 (1.9)	0	0
Joint range of motion decreased	1 (1.9)	1 (1.9)	0	0	0
Muscle spasms	1 (1.9)	1 (1.9)	0	0	0
Musculoskeletal chest pain	1 (1.9)	1 (1.9)	0	0	0
Pain in jaw	1 (1.9)	1 (1.9)	0	0	0
Toe walking	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.9)	0	1 (1.9)	0	0
Myelodysplastic syndrome	1 (1.9)	0	1 (1.9)	0	0
Nervous system disorders					
-Total	8 (15.4)	6 (11.5)	2 (3.8)	0	0
Headache	5 (9.6)	4 (7.7)	1 (1.9)	0	0
Dizziness	3 (5.8)	3 (5.8)	0	0	0
Peroneal nerve palsy	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Psychiatric disorders					
-Total	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Depression	2 (3.8)	2 (3.8)	0	0	0
Anxiety	1 (1.9)	1 (1.9)	0	0	0
Sleep disorder	1 (1.9)	0	1 (1.9)	0	0
Renal and urinary disorders					
-Total	3 (5.8)	1 (1.9)	0	2 (3.8)	0
Acute kidney injury	1 (1.9)	0	0	1 (1.9)	0
Calculus urinary	1 (1.9)	0	1 (1.9)	0	0
Haematuria	1 (1.9)	0	0	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nephrolithiasis	1 (1.9)	0	0	1 (1.9)	0
Urinary incontinence	1 (1.9)	1 (1.9)	0	0	0
Reproductive system and breast disorders					
-Total	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Scrotal pain	1 (1.9)	0	1 (1.9)	0	0
Vaginal haemorrhage	1 (1.9)	0	0	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	17 (32.7)	11 (21.2)	4 (7.7)	1 (1.9)	1 (1.9)
Cough	7 (13.5)	5 (9.6)	2 (3.8)	0	0
Nasal congestion	4 (7.7)	4 (7.7)	0	0	0
Rhinorrhoea	4 (7.7)	3 (5.8)	1 (1.9)	0	0
Oropharyngeal pain	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Rhinitis allergic	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Epistaxis	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Acute respiratory failure	1 (1.9)	0	0	0	1 (1.9)
Dysphonia	1 (1.9)	1 (1.9)	0	0	0
Pharyngeal erythema	1 (1.9)	1 (1.9)	0	0	0
Pharyngeal lesion	1 (1.9)	0	0	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	15 (28.8)	10 (19.2)	4 (7.7)	1 (1.9)	0
Rash	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Erythema	2 (3.8)	2 (3.8)	0	0	0
Rash maculo-papular	2 (3.8)	2 (3.8)	0	0	0
Alopecia	1 (1.9)	0	1 (1.9)	0	0
Dermatitis	1 (1.9)	1 (1.9)	0	0	0
Dermatitis acneiform	1 (1.9)	0	0	1 (1.9)	0
Dermatitis atopic	1 (1.9)	1 (1.9)	0	0	0
Dry skin	1 (1.9)	1 (1.9)	0	0	0
Eczema	1 (1.9)	1 (1.9)	0	0	0
Hyperhidrosis	1 (1.9)	1 (1.9)	0	0	0
Ingrowing nail	1 (1.9)	1 (1.9)	0	0	0
Keloid scar	1 (1.9)	0	1 (1.9)	0	0
Macule	1 (1.9)	1 (1.9)	0	0	0
Papule	1 (1.9)	1 (1.9)	0	0	0
Petechiae	1 (1.9)	1 (1.9)	0	0	0
Pruritus	1 (1.9)	1 (1.9)	0	0	0
Rash erythematous	1 (1.9)	0	1 (1.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash pruritic	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					
-Total	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Hypertension	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Hot flush	1 (1.9)	1 (1.9)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174i
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	0	2 (66.7)	0
General disorders and administration site conditions					
-Total	1 (33.3)	0	0	1 (33.3)	0
Cyst	1 (33.3)	0	0	1 (33.3)	0
Infections and infestations					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Gingivitis	1 (33.3)	1 (33.3)	0	0	0
Otitis media acute	1 (33.3)	0	1 (33.3)	0	0
Viral infection	1 (33.3)	1 (33.3)	0	0	0
Investigations					
-Total	1 (33.3)	0	0	1 (33.3)	0
White blood cell count decreased	1 (33.3)	0	0	1 (33.3)	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174i
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (64.5)	4 (12.9)	6 (19.4)	6 (19.4)	4 (12.9)
Blood and lymphatic system disorders					
-Total	2 (6.5)	1 (3.2)	0	0	1 (3.2)
Febrile neutropenia	1 (3.2)	0	0	0	1 (3.2)
Thrombocytopenia	1 (3.2)	1 (3.2)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.2)	0	1 (3.2)	0	0
Tympanic membrane perforation	1 (3.2)	0	1 (3.2)	0	0
Gastrointestinal disorders					
-Total	3 (9.7)	0	3 (9.7)	0	0
Diarrhoea	2 (6.5)	0	2 (6.5)	0	0
Abdominal pain	1 (3.2)	0	1 (3.2)	0	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (3.2)	0	1 (3.2)	0	0
General disorders and administration site conditions					
-Total	1 (3.2)	0	1 (3.2)	0	0
Chills	1 (3.2)	0	1 (3.2)	0	0
Pyrexia	1 (3.2)	0	1 (3.2)	0	0
Immune system disorders					
-Total	2 (6.5)	0	2 (6.5)	0	0
Chronic graft versus host disease	1 (3.2)	0	1 (3.2)	0	0
Immunodeficiency	1 (3.2)	0	1 (3.2)	0	0
Infections and infestations					
-Total	9 (29.0)	1 (3.2)	4 (12.9)	3 (9.7)	1 (3.2)
Otitis media	3 (9.7)	0	2 (6.5)	1 (3.2)	0
Sinusitis	3 (9.7)	0	3 (9.7)	0	0
Pneumonia	2 (6.5)	0	2 (6.5)	0	0
Upper respiratory tract infection	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Urinary tract infection	2 (6.5)	0	1 (3.2)	1 (3.2)	0
Campylobacter infection	1 (3.2)	0	0	1 (3.2)	0
Cellulitis of male external genital organ	1 (3.2)	0	0	1 (3.2)	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (3.2)	0	0	1 (3.2)	0
Haemophilus infection	1 (3.2)	0	1 (3.2)	0	0
Meningitis aseptic	1 (3.2)	0	1 (3.2)	0	0
Otitis media acute	1 (3.2)	0	1 (3.2)	0	0
Respiratory tract infection	1 (3.2)	0	0	0	1 (3.2)
Respiratory tract infection viral	1 (3.2)	0	0	1 (3.2)	0
Skin infection	1 (3.2)	0	1 (3.2)	0	0
Vulvovaginal candidiasis	1 (3.2)	0	1 (3.2)	0	0
Injury, poisoning and procedural complications					
-Total	1 (3.2)	0	0	1 (3.2)	0
Procedural pain	1 (3.2)	0	0	1 (3.2)	0
Investigations					
-Total	7 (22.6)	1 (3.2)	2 (6.5)	3 (9.7)	1 (3.2)
Alanine aminotransferase increased	3 (9.7)	0	1 (3.2)	2 (6.5)	0
Lymphocyte count decreased	3 (9.7)	2 (6.5)	0	1 (3.2)	0
White blood cell count decreased	3 (9.7)	1 (3.2)	0	1 (3.2)	1 (3.2)
Aspartate aminotransferase increased	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Neutrophil count decreased	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Blood alkaline phosphatase increased	1 (3.2)	1 (3.2)	0	0	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

		All patients N=31			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	1 (3.2)	1 (3.2)	0	0	0
C-reactive protein increased	1 (3.2)	1 (3.2)	0	0	0
Platelet count decreased	1 (3.2)	0	0	1 (3.2)	0
Metabolism and nutrition disorders					
-Total	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Hypokalaemia	1 (3.2)	0	0	1 (3.2)	0
Vitamin d deficiency	1 (3.2)	1 (3.2)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (3.2)	0	1 (3.2)	0	0
Neck pain	1 (3.2)	0	1 (3.2)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.2)	0	0	0	1 (3.2)
Glioblastoma multiforme	1 (3.2)	0	0	0	1 (3.2)
Nervous system disorders					
-Total	3 (9.7)	1 (3.2)	1 (3.2)	1 (3.2)	0
Disturbance in attention	1 (3.2)	1 (3.2)	0	0	0
Dizziness	1 (3.2)	1 (3.2)	0	0	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (3.2)	0	1 (3.2)	0	0
Seizure	1 (3.2)	0	0	1 (3.2)	0
Renal and urinary disorders					
-Total	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Acute kidney injury	1 (3.2)	0	0	1 (3.2)	0
Haematuria	1 (3.2)	1 (3.2)	0	0	0
Reproductive system and breast disorders					
-Total	1 (3.2)	0	0	1 (3.2)	0
Ovarian failure	1 (3.2)	0	0	1 (3.2)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (12.9)	4 (12.9)	0	0	0
Cough	2 (6.5)	2 (6.5)	0	0	0
Epistaxis	1 (3.2)	1 (3.2)	0	0	0
Oropharyngeal pain	1 (3.2)	1 (3.2)	0	0	0
Rhinitis allergic	1 (3.2)	1 (3.2)	0	0	0
Rhinorrhoea	1 (3.2)	1 (3.2)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (9.7)	3 (9.7)	0	0	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=31 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acne	1 (3.2)	1 (3.2)	0	0	0
Papule	1 (3.2)	1 (3.2)	0	0	0
Pruritus	1 (3.2)	1 (3.2)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174i
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

			All patients N=4		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	1 (25.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders					
-Total	3 (75.0)	0	1 (25.0)	1 (25.0)	1 (25.0)
Anaemia	3 (75.0)	0	2 (50.0)	1 (25.0)	0
Febrile neutropenia	2 (50.0)	0	0	2 (50.0)	0
Lymphopenia	1 (25.0)	0	1 (25.0)	0	0
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
Cardiac disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Cardiac dysfunction	1 (25.0)	1 (25.0)	0	0	0
Sinus tachycardia	1 (25.0)	0	1 (25.0)	0	0
Tachycardia	1 (25.0)	1 (25.0)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Dry eye	1 (25.0)	0	1 (25.0)	0	0
Gastrointestinal disorders					
-Total	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Diarrhoea	3 (75.0)	2 (50.0)	1 (25.0)	0	0
Abdominal pain	2 (50.0)	2 (50.0)	0	0	0
Nausea	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Vomiting	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Abdominal distension	1 (25.0)	0	1 (25.0)	0	0
Abdominal tenderness	1 (25.0)	1 (25.0)	0	0	0
Constipation	1 (25.0)	1 (25.0)	0	0	0
Gastrooesophageal reflux disease	1 (25.0)	1 (25.0)	0	0	0
General disorders and administration site conditions					
-Total	4 (100)	2 (50.0)	1 (25.0)	1 (25.0)	0
Fatigue	4 (100)	4 (100)	0	0	0
Cyst	1 (25.0)	0	0	1 (25.0)	0
Pain	1 (25.0)	0	1 (25.0)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (25.0)	1 (25.0)	0	0	0
Immune system disorders					
-Total	4 (100)	0	3 (75.0)	1 (25.0)	0
Hypogammaglobulinaemia	4 (100)	0	4 (100)	0	0
Cytokine release syndrome	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Infections and infestations					
-Total	3 (75.0)	1 (25.0)	1 (25.0)	1 (25.0)	0
Clostridium difficile infection	1 (25.0)	0	1 (25.0)	0	0
Cytomegalovirus infection	1 (25.0)	1 (25.0)	0	0	0
Gastroenteritis	1 (25.0)	0	0	1 (25.0)	0
Gingivitis	1 (25.0)	1 (25.0)	0	0	0
Herpes zoster	1 (25.0)	0	0	1 (25.0)	0
Otitis media acute	1 (25.0)	0	1 (25.0)	0	0
Parainfluenzae virus infection	1 (25.0)	1 (25.0)	0	0	0
Pharyngitis	1 (25.0)	0	1 (25.0)	0	0
Sinusitis	1 (25.0)	0	1 (25.0)	0	0
Streptococcal infection	1 (25.0)	0	1 (25.0)	0	0
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0
Viral infection	1 (25.0)	1 (25.0)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Contusion	1 (25.0)	1 (25.0)	0	0	0
Infusion related reaction	1 (25.0)	0	1 (25.0)	0	0
Procedural pain	1 (25.0)	0	1 (25.0)	0	0
Procedural site reaction	1 (25.0)	1 (25.0)	0	0	0
Investigations					
-Total	4 (100)	0	2 (50.0)	0	2 (50.0)
Neutrophil count decreased	3 (75.0)	0	1 (25.0)	0	2 (50.0)
White blood cell count decreased	3 (75.0)	0	1 (25.0)	2 (50.0)	0
International normalised ratio increased	2 (50.0)	2 (50.0)	0	0	0
Lymphocyte count decreased	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Activated partial thromboplastin time prolonged	1 (25.0)	1 (25.0)	0	0	0
Alanine aminotransferase increased	1 (25.0)	0	0	1 (25.0)	0
Aspartate aminotransferase increased	1 (25.0)	0	0	1 (25.0)	0
Blood bilirubin increased	1 (25.0)	0	1 (25.0)	0	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0
Blood uric acid increased	1 (25.0)	1 (25.0)	0	0	0
Platelet count decreased	1 (25.0)	0	1 (25.0)	0	0
Pulmonary function test decreased	1 (25.0)	0	1 (25.0)	0	0
Metabolism and nutrition disorders					
-Total	4 (100)	1 (25.0)	1 (25.0)	2 (50.0)	0
Decreased appetite	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Hyperphosphataemia	2 (50.0)	2 (50.0)	0	0	0
Dehydration	1 (25.0)	0	0	1 (25.0)	0
Hyperuricaemia	1 (25.0)	1 (25.0)	0	0	0
Hypokalaemia	1 (25.0)	0	1 (25.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Arthralgia	2 (50.0)	2 (50.0)	0	0	0
Joint range of motion decreased	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal chest pain	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal pain	1 (25.0)	0	1 (25.0)	0	0
Myalgia	1 (25.0)	1 (25.0)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Osteonecrosis	1 (25.0)	0	1 (25.0)	0	0
Pain in extremity	1 (25.0)	1 (25.0)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (25.0)	0	1 (25.0)	0	0
Skin papilloma	1 (25.0)	0	1 (25.0)	0	0
Nervous system disorders					
-Total	3 (75.0)	3 (75.0)	0	0	0
Headache	3 (75.0)	3 (75.0)	0	0	0
Dizziness	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (75.0)	1 (25.0)	1 (25.0)	1 (25.0)	0
Pulmonary oedema	1 (25.0)	0	0	1 (25.0)	0
Rhinorrhoea	1 (25.0)	1 (25.0)	0	0	0
Tachypnoea	1 (25.0)	1 (25.0)	0	0	0
Wheezing	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (75.0)	2 (50.0)	1 (25.0)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Petechiae	1 (25.0)	1 (25.0)	0	0	0
Rash	1 (25.0)	0	1 (25.0)	0	0
Rash follicular	1 (25.0)	1 (25.0)	0	0	0
Rash papular	1 (25.0)	1 (25.0)	0	0	0
Vascular disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Hypotension	1 (25.0)	0	0	0	1 (25.0)

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174i
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

			All patients N=60		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	60 (100)	0	4 (6.7)	11 (18.3)	45 (75.0)
Blood and lymphatic system disorders					
-Total	45 (75.0)	2 (3.3)	2 (3.3)	26 (43.3)	15 (25.0)
Anaemia	24 (40.0)	3 (5.0)	2 (3.3)	18 (30.0)	1 (1.7)
Febrile neutropenia	22 (36.7)	0	0	21 (35.0)	1 (1.7)
Neutropenia	10 (16.7)	0	0	3 (5.0)	7 (11.7)
Thrombocytopenia	10 (16.7)	0	1 (1.7)	3 (5.0)	6 (10.0)
Disseminated intravascular coagulation	4 (6.7)	0	2 (3.3)	2 (3.3)	0
Lymphopenia	3 (5.0)	0	1 (1.7)	1 (1.7)	1 (1.7)
Coagulopathy	1 (1.7)	1 (1.7)	0	0	0
Eosinophilia	1 (1.7)	0	0	1 (1.7)	0
Leukopenia	1 (1.7)	0	0	0	1 (1.7)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphadenopathy	1 (1.7)	0	1 (1.7)	0	0
Pancytopenia	1 (1.7)	0	0	0	1 (1.7)
Cardiac disorders					
-Total	21 (35.0)	10 (16.7)	9 (15.0)	2 (3.3)	0
Tachycardia	14 (23.3)	7 (11.7)	5 (8.3)	2 (3.3)	0
Sinus tachycardia	5 (8.3)	3 (5.0)	2 (3.3)	0	0
Pericardial effusion	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Atrioventricular block second degree	1 (1.7)	1 (1.7)	0	0	0
Bradycardia	1 (1.7)	0	1 (1.7)	0	0
Left ventricular dysfunction	1 (1.7)	0	0	1 (1.7)	0
Palpitations	1 (1.7)	1 (1.7)	0	0	0
Sinus bradycardia	1 (1.7)	1 (1.7)	0	0	0
Ventricular tachycardia	1 (1.7)	0	1 (1.7)	0	0
Ear and labyrinth disorders					
-Total	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Ear pain	2 (3.3)	2 (3.3)	0	0	0
Hypoacusis	1 (1.7)	0	1 (1.7)	0	0
Tympanic membrane perforation	1 (1.7)	0	1 (1.7)	0	0
Endocrine disorders					

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Adrenal insufficiency	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Eye disorders					
-Total	17 (28.3)	10 (16.7)	7 (11.7)	0	0
Periorbital oedema	4 (6.7)	3 (5.0)	1 (1.7)	0	0
Vision blurred	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Conjunctival haemorrhage	3 (5.0)	3 (5.0)	0	0	0
Eye pain	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Photophobia	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Retinal haemorrhage	2 (3.3)	2 (3.3)	0	0	0
Uveitis	2 (3.3)	0	2 (3.3)	0	0
Conjunctivitis allergic	1 (1.7)	1 (1.7)	0	0	0
Dry eye	1 (1.7)	1 (1.7)	0	0	0
Ocular hyperaemia	1 (1.7)	1 (1.7)	0	0	0
Ocular hypertension	1 (1.7)	0	1 (1.7)	0	0
Papilloedema	1 (1.7)	0	1 (1.7)	0	0
Visual impairment	1 (1.7)	0	1 (1.7)	0	0
Gastrointestinal disorders					
-Total	40 (66.7)	12 (20.0)	15 (25.0)	13 (21.7)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	25 (41.7)	15 (25.0)	7 (11.7)	3 (5.0)	0
Nausea	23 (38.3)	5 (8.3)	13 (21.7)	5 (8.3)	0
Diarrhoea	21 (35.0)	11 (18.3)	8 (13.3)	2 (3.3)	0
Abdominal pain	9 (15.0)	4 (6.7)	4 (6.7)	1 (1.7)	0
Constipation	6 (10.0)	5 (8.3)	1 (1.7)	0	0
Abdominal pain upper	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Dysphagia	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Haematemesis	2 (3.3)	2 (3.3)	0	0	0
Oral pain	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Pancreatitis	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Stomatitis	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Abdominal discomfort	1 (1.7)	1 (1.7)	0	0	0
Abdominal distension	1 (1.7)	0	1 (1.7)	0	0
Abdominal pain lower	1 (1.7)	0	1 (1.7)	0	0
Anal incontinence	1 (1.7)	1 (1.7)	0	0	0
Ascites	1 (1.7)	0	0	1 (1.7)	0
Dyspepsia	1 (1.7)	0	1 (1.7)	0	0
Enterocolitis	1 (1.7)	0	0	1 (1.7)	0
Flatulence	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Glossodynia	1 (1.7)	1 (1.7)	0	0	0
Ileus	1 (1.7)	0	0	1 (1.7)	0
Intestinal obstruction	1 (1.7)	0	0	1 (1.7)	0
Lip pain	1 (1.7)	0	1 (1.7)	0	0
Mouth haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Pigmentation lip	1 (1.7)	1 (1.7)	0	0	0
Tooth socket haemorrhage	1 (1.7)	1 (1.7)	0	0	0
General disorders and administration site conditions					
-Total	38 (63.3)	14 (23.3)	13 (21.7)	10 (16.7)	1 (1.7)
Pyrexia	24 (40.0)	7 (11.7)	10 (16.7)	6 (10.0)	1 (1.7)
Fatigue	11 (18.3)	8 (13.3)	2 (3.3)	1 (1.7)	0
Chills	10 (16.7)	9 (15.0)	1 (1.7)	0	0
Catheter site pain	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Malaise	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Generalised oedema	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Oedema peripheral	3 (5.0)	2 (3.3)	0	1 (1.7)	0
Pain	3 (5.0)	1 (1.7)	0	2 (3.3)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Face oedema	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Influenza like illness	2 (3.3)	2 (3.3)	0	0	0
Acquired gene mutation	1 (1.7)	1 (1.7)	0	0	0
Asthenia	1 (1.7)	1 (1.7)	0	0	0
Catheter site extravasation	1 (1.7)	0	1 (1.7)	0	0
Catheter site haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Crying	1 (1.7)	1 (1.7)	0	0	0
Facial pain	1 (1.7)	0	1 (1.7)	0	0
Injection site haematoma	1 (1.7)	1 (1.7)	0	0	0
Localised oedema	1 (1.7)	0	0	1 (1.7)	0
Mucosal haemorrhage	1 (1.7)	0	1 (1.7)	0	0
Multiple organ dysfunction syndrome	1 (1.7)	0	0	1 (1.7)	0
Non-cardiac chest pain	1 (1.7)	1 (1.7)	0	0	0
Peripheral swelling	1 (1.7)	0	1 (1.7)	0	0
Physical deconditioning	1 (1.7)	0	0	1 (1.7)	0
Hepatobiliary disorders					
-Total	7 (11.7)	3 (5.0)	2 (3.3)	2 (3.3)	0
Hepatomegaly	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Hyperbilirubinaemia	3 (5.0)	0	1 (1.7)	2 (3.3)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gallbladder enlargement	1 (1.7)	1 (1.7)	0	0	0
Hepatosplenomegaly	1 (1.7)	1 (1.7)	0	0	0
Immune system disorders					
-Total	54 (90.0)	5 (8.3)	28 (46.7)	10 (16.7)	11 (18.3)
Cytokine release syndrome	48 (80.0)	6 (10.0)	24 (40.0)	7 (11.7)	11 (18.3)
Hypogammaglobulinaemia	28 (46.7)	3 (5.0)	20 (33.3)	5 (8.3)	0
Graft versus host disease	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Immunodeficiency common variable	2 (3.3)	0	2 (3.3)	0	0
Seasonal allergy	2 (3.3)	2 (3.3)	0	0	0
Chronic graft versus host disease	1 (1.7)	0	1 (1.7)	0	0
Drug hypersensitivity	1 (1.7)	0	1 (1.7)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.7)	0	1 (1.7)	0	0
Graft versus host disease in skin	1 (1.7)	1 (1.7)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	1 (1.7)	0	0
Immunodeficiency	1 (1.7)	0	1 (1.7)	0	0
Infections and infestations					
-Total	43 (71.7)	6 (10.0)	20 (33.3)	13 (21.7)	4 (6.7)
Upper respiratory tract infection	8 (13.3)	3 (5.0)	4 (6.7)	1 (1.7)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinovirus infection	5 (8.3)	5 (8.3)	0	0	0
Urinary tract infection	5 (8.3)	0	3 (5.0)	2 (3.3)	0
Clostridium difficile colitis	4 (6.7)	1 (1.7)	2 (3.3)	1 (1.7)	0
Clostridium difficile infection	4 (6.7)	0	3 (5.0)	1 (1.7)	0
Gastroenteritis	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Influenza	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Otitis media	4 (6.7)	0	3 (5.0)	1 (1.7)	0
Pneumonia	4 (6.7)	0	3 (5.0)	1 (1.7)	0
Sinusitis	3 (5.0)	0	3 (5.0)	0	0
Viral upper respiratory tract infection	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Ear infection	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Skin infection	2 (3.3)	0	2 (3.3)	0	0
Staphylococcal infection	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Viral infection	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Vulvovaginal candidiasis	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Acute sinusitis	1 (1.7)	0	1 (1.7)	0	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Body tinea	1 (1.7)	1 (1.7)	0	0	0
Campylobacter infection	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site cellulitis	1 (1.7)	1 (1.7)	0	0	0
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Cholecystitis infective	1 (1.7)	0	0	1 (1.7)	0
Corona virus infection	1 (1.7)	0	0	1 (1.7)	0
Cytomegalovirus infection	1 (1.7)	1 (1.7)	0	0	0
Enterococcal infection	1 (1.7)	1 (1.7)	0	0	0
Enterovirus infection	1 (1.7)	0	0	1 (1.7)	0
Escherichia urinary tract infection	1 (1.7)	0	0	1 (1.7)	0
Folliculitis	1 (1.7)	0	1 (1.7)	0	0
Fungal skin infection	1 (1.7)	1 (1.7)	0	0	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis viral	1 (1.7)	1 (1.7)	0	0	0
Haemophilus infection	1 (1.7)	0	1 (1.7)	0	0
Herpes simplex	1 (1.7)	1 (1.7)	0	0	0
Human herpesvirus 6 infection	1 (1.7)	0	1 (1.7)	0	0
Hypopyon	1 (1.7)	0	1 (1.7)	0	0
Meningitis aseptic	1 (1.7)	0	1 (1.7)	0	0
Molluscum contagiosum	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral candidiasis	1 (1.7)	1 (1.7)	0	0	0
Oral herpes	1 (1.7)	0	1 (1.7)	0	0
Orchitis	1 (1.7)	1 (1.7)	0	0	0
Otitis externa	1 (1.7)	0	1 (1.7)	0	0
Otitis media acute	1 (1.7)	0	1 (1.7)	0	0
Parainfluenzae virus infection	1 (1.7)	0	0	1 (1.7)	0
Paronychia	1 (1.7)	1 (1.7)	0	0	0
Rash pustular	1 (1.7)	0	1 (1.7)	0	0
Respiratory syncytial virus infection	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection	1 (1.7)	0	0	0	1 (1.7)
Respiratory tract infection viral	1 (1.7)	0	0	1 (1.7)	0
Rhinitis	1 (1.7)	1 (1.7)	0	0	0
Rotavirus infection	1 (1.7)	0	0	1 (1.7)	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Subcutaneous abscess	1 (1.7)	0	1 (1.7)	0	0
Tinea capitis	1 (1.7)	1 (1.7)	0	0	0
Urinary tract infection enterococcal	1 (1.7)	0	0	1 (1.7)	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal mycotic infection	1 (1.7)	0	1 (1.7)	0	0
Injury, poisoning and procedural complications					
-Total	20 (33.3)	10 (16.7)	7 (11.7)	2 (3.3)	1 (1.7)
Procedural pain	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Infusion related reaction	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Transfusion reaction	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Contusion	2 (3.3)	2 (3.3)	0	0	0
Skin abrasion	2 (3.3)	2 (3.3)	0	0	0
Arthropod bite	1 (1.7)	1 (1.7)	0	0	0
Foot fracture	1 (1.7)	0	1 (1.7)	0	0
Incision site pain	1 (1.7)	1 (1.7)	0	0	0
Limb injury	1 (1.7)	1 (1.7)	0	0	0
Mouth injury	1 (1.7)	1 (1.7)	0	0	0
Post procedural haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Procedural complication	1 (1.7)	1 (1.7)	0	0	0
Procedural headache	1 (1.7)	0	1 (1.7)	0	0
Procedural nausea	1 (1.7)	0	1 (1.7)	0	0
Radius fracture	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin laceration	1 (1.7)	0	1 (1.7)	0	0
Stoma site irritation	1 (1.7)	1 (1.7)	0	0	0
Subdural haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Sunburn	1 (1.7)	1 (1.7)	0	0	0
Tibia fracture	1 (1.7)	0	1 (1.7)	0	0
Tongue injury	1 (1.7)	1 (1.7)	0	0	0
Tracheal haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Transfusion related complication	1 (1.7)	0	0	0	1 (1.7)
Investigations					
-Total	52 (86.7)	2 (3.3)	3 (5.0)	15 (25.0)	32 (53.3)
White blood cell count decreased	32 (53.3)	4 (6.7)	0	10 (16.7)	18 (30.0)
Neutrophil count decreased	25 (41.7)	1 (1.7)	1 (1.7)	4 (6.7)	19 (31.7)
Alanine aminotransferase increased	20 (33.3)	5 (8.3)	2 (3.3)	13 (21.7)	0
Aspartate aminotransferase increased	19 (31.7)	4 (6.7)	4 (6.7)	7 (11.7)	4 (6.7)
Platelet count decreased	19 (31.7)	3 (5.0)	1 (1.7)	3 (5.0)	12 (20.0)
Lymphocyte count decreased	14 (23.3)	1 (1.7)	2 (3.3)	6 (10.0)	5 (8.3)
Prothrombin time prolonged	9 (15.0)	5 (8.3)	3 (5.0)	1 (1.7)	0
Blood creatinine increased	8 (13.3)	4 (6.7)	2 (3.3)	2 (3.3)	0
Blood bilirubin increased	7 (11.7)	2 (3.3)	2 (3.3)	3 (5.0)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	7 (11.7)	6 (10.0)	0	1 (1.7)	0
Activated partial thromboplastin time prolonged	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Blood fibrinogen decreased	4 (6.7)	0	1 (1.7)	2 (3.3)	1 (1.7)
Blood immunoglobulin m decreased	4 (6.7)	4 (6.7)	0	0	0
Weight decreased	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Blood urea increased	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Haemoglobin decreased	3 (5.0)	2 (3.3)	0	1 (1.7)	0
Transaminases increased	3 (5.0)	3 (5.0)	0	0	0
Blood immunoglobulin a decreased	2 (3.3)	2 (3.3)	0	0	0
Blood magnesium decreased	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Blood phosphorus increased	2 (3.3)	2 (3.3)	0	0	0
C-reactive protein increased	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Lipase increased	2 (3.3)	0	0	0	2 (3.3)
Serum ferritin increased	2 (3.3)	0	2 (3.3)	0	0
Weight increased	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Blood alkaline phosphatase increased	1 (1.7)	1 (1.7)	0	0	0
Blood bicarbonate decreased	1 (1.7)	0	1 (1.7)	0	0
Blood immunoglobulin g decreased	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	1 (1.7)	1 (1.7)	0	0	0
Blood lactic acid increased	1 (1.7)	0	0	0	1 (1.7)
Blood phosphorus decreased	1 (1.7)	1 (1.7)	0	0	0
Blood sodium increased	1 (1.7)	0	1 (1.7)	0	0
Blood uric acid increased	1 (1.7)	1 (1.7)	0	0	0
Cardiac murmur	1 (1.7)	1 (1.7)	0	0	0
Culture stool positive	1 (1.7)	1 (1.7)	0	0	0
Fibrin d dimer increased	1 (1.7)	1 (1.7)	0	0	0
Hepatic enzyme increased	1 (1.7)	0	1 (1.7)	0	0
Norovirus test positive	1 (1.7)	1 (1.7)	0	0	0
Oxygen saturation decreased	1 (1.7)	1 (1.7)	0	0	0
Protein total decreased	1 (1.7)	0	0	1 (1.7)	0
Metabolism and nutrition disorders					
-Total	39 (65.0)	7 (11.7)	7 (11.7)	21 (35.0)	4 (6.7)
Decreased appetite	20 (33.3)	5 (8.3)	4 (6.7)	11 (18.3)	0
Hypokalaemia	18 (30.0)	4 (6.7)	5 (8.3)	8 (13.3)	1 (1.7)
Hypophosphataemia	10 (16.7)	2 (3.3)	0	7 (11.7)	1 (1.7)
Hyperphosphataemia	6 (10.0)	6 (10.0)	0	0	0
Hypoalbuminaemia	5 (8.3)	1 (1.7)	3 (5.0)	1 (1.7)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypernatraemia	4 (6.7)	1 (1.7)	2 (3.3)	0	1 (1.7)
Dehydration	3 (5.0)	1 (1.7)	0	2 (3.3)	0
Fluid overload	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Hyperglycaemia	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Hypocalcaemia	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Acidosis	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Hypertriglyceridaemia	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Hyperuricaemia	2 (3.3)	1 (1.7)	0	0	1 (1.7)
Hyponatraemia	2 (3.3)	0	0	2 (3.3)	0
Tumour lysis syndrome	2 (3.3)	0	0	2 (3.3)	0
Vitamin d deficiency	2 (3.3)	2 (3.3)	0	0	0
Hyperalbuminaemia	1 (1.7)	1 (1.7)	0	0	0
Hypercalcaemia	1 (1.7)	1 (1.7)	0	0	0
Hyperchloraemia	1 (1.7)	1 (1.7)	0	0	0
Hypermagnesaemia	1 (1.7)	1 (1.7)	0	0	0
Hypomagnesaemia	1 (1.7)	1 (1.7)	0	0	0
Iron overload	1 (1.7)	0	0	1 (1.7)	0
Malnutrition	1 (1.7)	0	0	1 (1.7)	0
Metabolic acidosis	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic alkalosis	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	22 (36.7)	13 (21.7)	8 (13.3)	1 (1.7)	0
Pain in extremity	10 (16.7)	6 (10.0)	4 (6.7)	0	0
Myalgia	4 (6.7)	3 (5.0)	1 (1.7)	0	0
Arthralgia	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Muscular weakness	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Muscle spasms	2 (3.3)	2 (3.3)	0	0	0
Musculoskeletal pain	2 (3.3)	2 (3.3)	0	0	0
Back pain	1 (1.7)	1 (1.7)	0	0	0
Coccydynia	1 (1.7)	1 (1.7)	0	0	0
Flank pain	1 (1.7)	0	1 (1.7)	0	0
Joint range of motion decreased	1 (1.7)	1 (1.7)	0	0	0
Limb discomfort	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal chest pain	1 (1.7)	1 (1.7)	0	0	0
Neck pain	1 (1.7)	0	1 (1.7)	0	0
Osteopenia	1 (1.7)	0	1 (1.7)	0	0
Pain in jaw	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Toe walking	1 (1.7)	1 (1.7)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (3.3)	0	1 (1.7)	0	1 (1.7)
Glioblastoma multiforme	1 (1.7)	0	0	0	1 (1.7)
Myelodysplastic syndrome	1 (1.7)	0	1 (1.7)	0	0
Nervous system disorders					
-Total	32 (53.3)	14 (23.3)	12 (20.0)	5 (8.3)	1 (1.7)
Headache	21 (35.0)	12 (20.0)	7 (11.7)	2 (3.3)	0
Dizziness	5 (8.3)	5 (8.3)	0	0	0
Encephalopathy	4 (6.7)	1 (1.7)	1 (1.7)	2 (3.3)	0
Seizure	4 (6.7)	0	2 (3.3)	2 (3.3)	0
Dysarthria	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Peroneal nerve palsy	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Tremor	2 (3.3)	2 (3.3)	0	0	0
Asterixis	1 (1.7)	1 (1.7)	0	0	0
Ataxia	1 (1.7)	0	1 (1.7)	0	0
Depressed level of consciousness	1 (1.7)	1 (1.7)	0	0	0
Disturbance in attention	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Embolic stroke	1 (1.7)	0	0	0	1 (1.7)
Idiopathic intracranial hypertension	1 (1.7)	0	1 (1.7)	0	0
Migraine	1 (1.7)	0	1 (1.7)	0	0
Myoclonus	1 (1.7)	1 (1.7)	0	0	0
Neuropathy peripheral	1 (1.7)	0	1 (1.7)	0	0
Pleocytosis	1 (1.7)	1 (1.7)	0	0	0
Somnolence	1 (1.7)	1 (1.7)	0	0	0
Product issues					
-Total	1 (1.7)	1 (1.7)	0	0	0
Device occlusion	1 (1.7)	1 (1.7)	0	0	0
Psychiatric disorders					
-Total	17 (28.3)	8 (13.3)	8 (13.3)	1 (1.7)	0
Anxiety	7 (11.7)	3 (5.0)	3 (5.0)	1 (1.7)	0
Confusional state	6 (10.0)	3 (5.0)	3 (5.0)	0	0
Delirium	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Agitation	2 (3.3)	0	2 (3.3)	0	0
Depression	2 (3.3)	2 (3.3)	0	0	0
Hallucination	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Irritability	2 (3.3)	2 (3.3)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adjustment disorder	1 (1.7)	0	1 (1.7)	0	0
Insomnia	1 (1.7)	0	1 (1.7)	0	0
Listless	1 (1.7)	1 (1.7)	0	0	0
Mental status changes	1 (1.7)	1 (1.7)	0	0	0
Panic attack	1 (1.7)	0	1 (1.7)	0	0
Sleep disorder	1 (1.7)	0	1 (1.7)	0	0
Suicidal ideation	1 (1.7)	1 (1.7)	0	0	0
Renal and urinary disorders					
-Total	15 (25.0)	3 (5.0)	2 (3.3)	6 (10.0)	4 (6.7)
Acute kidney injury	9 (15.0)	1 (1.7)	1 (1.7)	4 (6.7)	3 (5.0)
Haematuria	5 (8.3)	0	2 (3.3)	2 (3.3)	1 (1.7)
Dysuria	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Oliguria	2 (3.3)	0	0	2 (3.3)	0
Calculus urinary	1 (1.7)	0	1 (1.7)	0	0
Nephrolithiasis	1 (1.7)	0	0	1 (1.7)	0
Pollakiuria	1 (1.7)	1 (1.7)	0	0	0
Renal failure	1 (1.7)	0	0	0	1 (1.7)
Renal impairment	1 (1.7)	0	0	1 (1.7)	0
Urinary incontinence	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	6 (10.0)	2 (3.3)	2 (3.3)	2 (3.3)	0
Vulvovaginal adhesion	2 (3.3)	2 (3.3)	0	0	0
Oedema genital	1 (1.7)	0	1 (1.7)	0	0
Ovarian failure	1 (1.7)	0	0	1 (1.7)	0
Scrotal pain	1 (1.7)	0	1 (1.7)	0	0
Vaginal haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	35 (58.3)	13 (21.7)	8 (13.3)	6 (10.0)	8 (13.3)
Cough	14 (23.3)	12 (20.0)	2 (3.3)	0	0
Epistaxis	10 (16.7)	4 (6.7)	1 (1.7)	4 (6.7)	1 (1.7)
Hypoxia	10 (16.7)	0	3 (5.0)	4 (6.7)	3 (5.0)
Pleural effusion	8 (13.3)	2 (3.3)	4 (6.7)	2 (3.3)	0
Oropharyngeal pain	6 (10.0)	4 (6.7)	2 (3.3)	0	0
Pulmonary oedema	6 (10.0)	1 (1.7)	0	3 (5.0)	2 (3.3)
Nasal congestion	5 (8.3)	5 (8.3)	0	0	0
Rhinorrhoea	5 (8.3)	4 (6.7)	1 (1.7)	0	0
Rhinitis allergic	4 (6.7)	3 (5.0)	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Respiratory failure	3 (5.0)	0	0	0	3 (5.0)
Dyspnoea	2 (3.3)	0	0	1 (1.7)	1 (1.7)
Haemoptysis	2 (3.3)	1 (1.7)	0	0	1 (1.7)
Acute respiratory failure	1 (1.7)	0	0	0	1 (1.7)
Atelectasis	1 (1.7)	1 (1.7)	0	0	0
Dysphonia	1 (1.7)	1 (1.7)	0	0	0
Interstitial lung disease	1 (1.7)	0	0	0	1 (1.7)
Oropharyngeal plaque	1 (1.7)	1 (1.7)	0	0	0
Pharyngeal erythema	1 (1.7)	1 (1.7)	0	0	0
Pharyngeal lesion	1 (1.7)	0	0	1 (1.7)	0
Pharyngeal ulceration	1 (1.7)	0	1 (1.7)	0	0
Respiratory depression	1 (1.7)	0	1 (1.7)	0	0
Respiratory distress	1 (1.7)	0	0	0	1 (1.7)
Skin and subcutaneous tissue disorders					
-Total	27 (45.0)	16 (26.7)	8 (13.3)	3 (5.0)	0
Rash	7 (11.7)	5 (8.3)	2 (3.3)	0	0
Dry skin	5 (8.3)	5 (8.3)	0	0	0
Erythema	5 (8.3)	5 (8.3)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash maculo-papular	5 (8.3)	3 (5.0)	1 (1.7)	1 (1.7)	0
Hyperhidrosis	4 (6.7)	4 (6.7)	0	0	0
Pruritus	4 (6.7)	4 (6.7)	0	0	0
Ingrowing nail	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Petechiae	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Macule	2 (3.3)	2 (3.3)	0	0	0
Papule	2 (3.3)	2 (3.3)	0	0	0
Rash erythematous	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Acne	1 (1.7)	1 (1.7)	0	0	0
Alopecia	1 (1.7)	0	1 (1.7)	0	0
Dermatitis	1 (1.7)	1 (1.7)	0	0	0
Dermatitis acneiform	1 (1.7)	0	0	1 (1.7)	0
Dermatitis atopic	1 (1.7)	1 (1.7)	0	0	0
Dermatitis diaper	1 (1.7)	1 (1.7)	0	0	0
Ecchymosis	1 (1.7)	0	0	1 (1.7)	0
Eczema	1 (1.7)	1 (1.7)	0	0	0
Keloid scar	1 (1.7)	0	1 (1.7)	0	0
Livedo reticularis	1 (1.7)	1 (1.7)	0	0	0
Night sweats	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash macular	1 (1.7)	1 (1.7)	0	0	0
Rash papular	1 (1.7)	1 (1.7)	0	0	0
Rash pruritic	1 (1.7)	1 (1.7)	0	0	0
Rash vesicular	1 (1.7)	1 (1.7)	0	0	0
Skin exfoliation	1 (1.7)	1 (1.7)	0	0	0
Skin fissures	1 (1.7)	1 (1.7)	0	0	0
Skin irritation	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					
-Total	24 (40.0)	3 (5.0)	6 (10.0)	8 (13.3)	7 (11.7)
Hypotension	15 (25.0)	1 (1.7)	0	7 (11.7)	7 (11.7)
Hypertension	12 (20.0)	3 (5.0)	8 (13.3)	1 (1.7)	0
Flushing	2 (3.3)	2 (3.3)	0	0	0
Orthostatic hypotension	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Capillary leak syndrome	1 (1.7)	0	0	0	1 (1.7)
Embolism	1 (1.7)	0	0	1 (1.7)	0
Haematoma	1 (1.7)	0	1 (1.7)	0	0
Hot flush	1 (1.7)	1 (1.7)	0	0	0
Secondary hypertension	1 (1.7)	0	1 (1.7)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174j
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (100)	1 (5.3)	2 (10.5)	3 (15.8)	13 (68.4)
Blood and lymphatic system disorders					
-Total	13 (68.4)	1 (5.3)	0	8 (42.1)	4 (21.1)
Febrile neutropenia	8 (42.1)	0	0	8 (42.1)	0
Anaemia	7 (36.8)	1 (5.3)	0	6 (31.6)	0
Thrombocytopenia	2 (10.5)	0	0	0	2 (10.5)
Coagulopathy	1 (5.3)	1 (5.3)	0	0	0
Disseminated intravascular coagulation	1 (5.3)	0	0	1 (5.3)	0
Lymphopenia	1 (5.3)	0	0	0	1 (5.3)
Neutropenia	1 (5.3)	0	0	1 (5.3)	0
Pancytopenia	1 (5.3)	0	0	0	1 (5.3)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	8 (42.1)	4 (21.1)	3 (15.8)	1 (5.3)	0
Tachycardia	4 (21.1)	2 (10.5)	1 (5.3)	1 (5.3)	0
Sinus tachycardia	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Atrioventricular block second degree	1 (5.3)	1 (5.3)	0	0	0
Bradycardia	1 (5.3)	0	1 (5.3)	0	0
Pericardial effusion	1 (5.3)	0	1 (5.3)	0	0
Ear and labyrinth disorders					
-Total	1 (5.3)	1 (5.3)	0	0	0
Ear pain	1 (5.3)	1 (5.3)	0	0	0
Eye disorders					
-Total	6 (31.6)	4 (21.1)	2 (10.5)	0	0
Periorbital oedema	3 (15.8)	2 (10.5)	1 (5.3)	0	0
Conjunctival haemorrhage	2 (10.5)	2 (10.5)	0	0	0
Photophobia	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Vision blurred	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Eye pain	1 (5.3)	0	1 (5.3)	0	0
Retinal haemorrhage	1 (5.3)	1 (5.3)	0	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	13 (68.4)	3 (15.8)	4 (21.1)	6 (31.6)	0
Vomiting	10 (52.6)	6 (31.6)	2 (10.5)	2 (10.5)	0
Diarrhoea	8 (42.1)	4 (21.1)	3 (15.8)	1 (5.3)	0
Nausea	7 (36.8)	2 (10.5)	4 (21.1)	1 (5.3)	0
Abdominal pain	5 (26.3)	3 (15.8)	1 (5.3)	1 (5.3)	0
Constipation	3 (15.8)	2 (10.5)	1 (5.3)	0	0
Abdominal discomfort	1 (5.3)	1 (5.3)	0	0	0
Abdominal distension	1 (5.3)	0	1 (5.3)	0	0
Abdominal pain upper	1 (5.3)	0	1 (5.3)	0	0
Dyspepsia	1 (5.3)	0	1 (5.3)	0	0
Dysphagia	1 (5.3)	0	0	1 (5.3)	0
Haematemesis	1 (5.3)	1 (5.3)	0	0	0
Intestinal obstruction	1 (5.3)	0	0	1 (5.3)	0
Lip pain	1 (5.3)	0	1 (5.3)	0	0
Mouth haemorrhage	1 (5.3)	0	0	1 (5.3)	0
General disorders and administration site conditions					
-Total	11 (57.9)	2 (10.5)	5 (26.3)	4 (21.1)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	7 (36.8)	1 (5.3)	4 (21.1)	2 (10.5)	0
Fatigue	5 (26.3)	3 (15.8)	1 (5.3)	1 (5.3)	0
Chills	2 (10.5)	2 (10.5)	0	0	0
Face oedema	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Malaise	2 (10.5)	0	2 (10.5)	0	0
Oedema peripheral	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Pain	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Catheter site extravasation	1 (5.3)	0	1 (5.3)	0	0
Catheter site haemorrhage	1 (5.3)	1 (5.3)	0	0	0
Catheter site pain	1 (5.3)	1 (5.3)	0	0	0
Generalised oedema	1 (5.3)	0	1 (5.3)	0	0
Injection site haematoma	1 (5.3)	1 (5.3)	0	0	0
Localised oedema	1 (5.3)	0	0	1 (5.3)	0
Mucosal haemorrhage	1 (5.3)	0	1 (5.3)	0	0
Multiple organ dysfunction syndrome	1 (5.3)	0	0	1 (5.3)	0
Peripheral swelling	1 (5.3)	0	1 (5.3)	0	0
Hepatobiliary disorders					
-Total	3 (15.8)	0	1 (5.3)	2 (10.5)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	3 (15.8)	0	1 (5.3)	2 (10.5)	0
Hepatomegaly	1 (5.3)	0	1 (5.3)	0	0
Immune system disorders					
-Total	19 (100)	1 (5.3)	9 (47.4)	4 (21.1)	5 (26.3)
Cytokine release syndrome	18 (94.7)	1 (5.3)	9 (47.4)	3 (15.8)	5 (26.3)
Hypogammaglobulinaemia	9 (47.4)	2 (10.5)	5 (26.3)	2 (10.5)	0
Graft versus host disease in skin	1 (5.3)	1 (5.3)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (5.3)	0	1 (5.3)	0	0
Infections and infestations					
-Total	11 (57.9)	3 (15.8)	4 (21.1)	3 (15.8)	1 (5.3)
Clostridium difficile colitis	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Gastroenteritis	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Rhinovirus infection	2 (10.5)	2 (10.5)	0	0	0
Catheter site cellulitis	1 (5.3)	1 (5.3)	0	0	0
Clostridium difficile infection	1 (5.3)	0	1 (5.3)	0	0
Folliculitis	1 (5.3)	0	1 (5.3)	0	0
Fungal skin infection	1 (5.3)	1 (5.3)	0	0	0
Herpes simplex	1 (5.3)	1 (5.3)	0	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Orchitis	1 (5.3)	1 (5.3)	0	0	0
Pharyngitis	1 (5.3)	0	1 (5.3)	0	0
Pneumonia	1 (5.3)	0	1 (5.3)	0	0
Septic embolus	1 (5.3)	0	0	0	1 (5.3)
Staphylococcal infection	1 (5.3)	0	0	1 (5.3)	0
Streptococcal infection	1 (5.3)	0	1 (5.3)	0	0
Upper respiratory tract infection	1 (5.3)	0	1 (5.3)	0	0
Urinary tract infection enterococcal	1 (5.3)	0	0	1 (5.3)	0
Injury, poisoning and procedural complications					
-Total	9 (47.4)	5 (26.3)	3 (15.8)	0	1 (5.3)
Transfusion reaction	2 (10.5)	2 (10.5)	0	0	0
Incision site pain	1 (5.3)	1 (5.3)	0	0	0
Infusion related reaction	1 (5.3)	0	1 (5.3)	0	0
Mouth injury	1 (5.3)	1 (5.3)	0	0	0
Procedural complication	1 (5.3)	1 (5.3)	0	0	0
Procedural headache	1 (5.3)	0	1 (5.3)	0	0
Procedural pain	1 (5.3)	0	1 (5.3)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin abrasion	1 (5.3)	1 (5.3)	0	0	0
Stoma site irritation	1 (5.3)	1 (5.3)	0	0	0
Subdural haemorrhage	1 (5.3)	1 (5.3)	0	0	0
Tibia fracture	1 (5.3)	0	1 (5.3)	0	0
Tongue injury	1 (5.3)	1 (5.3)	0	0	0
Transfusion related complication	1 (5.3)	0	0	0	1 (5.3)
Investigations					
-Total	14 (73.7)	1 (5.3)	0	3 (15.8)	10 (52.6)
Alanine aminotransferase increased	8 (42.1)	2 (10.5)	1 (5.3)	5 (26.3)	0
White blood cell count decreased	7 (36.8)	0	0	0	7 (36.8)
Aspartate aminotransferase increased	6 (31.6)	2 (10.5)	1 (5.3)	1 (5.3)	2 (10.5)
Neutrophil count decreased	6 (31.6)	0	0	1 (5.3)	5 (26.3)
Platelet count decreased	6 (31.6)	1 (5.3)	0	0	5 (26.3)
Blood creatinine increased	5 (26.3)	2 (10.5)	1 (5.3)	2 (10.5)	0
Prothrombin time prolonged	4 (21.1)	2 (10.5)	1 (5.3)	1 (5.3)	0
Blood bilirubin increased	3 (15.8)	1 (5.3)	1 (5.3)	1 (5.3)	0
International normalised ratio increased	3 (15.8)	2 (10.5)	0	1 (5.3)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	2 (10.5)	0	0	1 (5.3)	1 (5.3)
Blood immunoglobulin a decreased	2 (10.5)	2 (10.5)	0	0	0
Blood immunoglobulin m decreased	2 (10.5)	2 (10.5)	0	0	0
Blood urea increased	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Lymphocyte count decreased	2 (10.5)	0	0	2 (10.5)	0
Activated partial thromboplastin time prolonged	1 (5.3)	0	1 (5.3)	0	0
Blood bicarbonate decreased	1 (5.3)	0	1 (5.3)	0	0
Blood phosphorus decreased	1 (5.3)	1 (5.3)	0	0	0
Culture stool positive	1 (5.3)	1 (5.3)	0	0	0
Haemoglobin decreased	1 (5.3)	0	0	1 (5.3)	0
Protein total decreased	1 (5.3)	0	0	1 (5.3)	0
Transaminases increased	1 (5.3)	1 (5.3)	0	0	0
Metabolism and nutrition disorders					
-Total	16 (84.2)	2 (10.5)	4 (21.1)	9 (47.4)	1 (5.3)
Decreased appetite	7 (36.8)	1 (5.3)	2 (10.5)	4 (21.1)	0
Hypokalaemia	4 (21.1)	1 (5.3)	1 (5.3)	2 (10.5)	0
Hypophosphataemia	4 (21.1)	2 (10.5)	0	2 (10.5)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	2 (10.5)	0	0	2 (10.5)	0
Fluid overload	2 (10.5)	0	2 (10.5)	0	0
Hypernatraemia	2 (10.5)	0	1 (5.3)	0	1 (5.3)
Hyperphosphataemia	2 (10.5)	2 (10.5)	0	0	0
Hypoalbuminaemia	2 (10.5)	0	2 (10.5)	0	0
Hypocalcaemia	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Acidosis	1 (5.3)	0	0	1 (5.3)	0
Hyperalbuminaemia	1 (5.3)	1 (5.3)	0	0	0
Hypercalcaemia	1 (5.3)	1 (5.3)	0	0	0
Hyperchloraemia	1 (5.3)	1 (5.3)	0	0	0
Hyperglycaemia	1 (5.3)	0	0	1 (5.3)	0
Hypermagnesaemia	1 (5.3)	1 (5.3)	0	0	0
Hyponatraemia	1 (5.3)	0	0	1 (5.3)	0
Malnutrition	1 (5.3)	0	0	1 (5.3)	0
Metabolic acidosis	1 (5.3)	0	1 (5.3)	0	0
Metabolic alkalosis	1 (5.3)	1 (5.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (36.8)	4 (21.1)	3 (15.8)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Pain in extremity	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Coccydynia	1 (5.3)	1 (5.3)	0	0	0
Limb discomfort	1 (5.3)	1 (5.3)	0	0	0
Muscle spasms	1 (5.3)	1 (5.3)	0	0	0
Musculoskeletal pain	1 (5.3)	1 (5.3)	0	0	0
Osteopenia	1 (5.3)	0	1 (5.3)	0	0
Nervous system disorders					
-Total	10 (52.6)	5 (26.3)	1 (5.3)	3 (15.8)	1 (5.3)
Headache	7 (36.8)	5 (26.3)	1 (5.3)	1 (5.3)	0
Encephalopathy	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Dizziness	1 (5.3)	1 (5.3)	0	0	0
Embolic stroke	1 (5.3)	0	0	0	1 (5.3)
Myoclonus	1 (5.3)	1 (5.3)	0	0	0
Seizure	1 (5.3)	0	0	1 (5.3)	0
Psychiatric disorders					
-Total	8 (42.1)	3 (15.8)	5 (26.3)	0	0
Anxiety	3 (15.8)	1 (5.3)	2 (10.5)	0	0
Confusional state	2 (10.5)	0	2 (10.5)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Hallucination	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Irritability	2 (10.5)	2 (10.5)	0	0	0
Agitation	1 (5.3)	0	1 (5.3)	0	0
Insomnia	1 (5.3)	0	1 (5.3)	0	0
Listless	1 (5.3)	1 (5.3)	0	0	0
Mental status changes	1 (5.3)	1 (5.3)	0	0	0
Panic attack	1 (5.3)	0	1 (5.3)	0	0
Renal and urinary disorders					
-Total	4 (21.1)	1 (5.3)	0	1 (5.3)	2 (10.5)
Acute kidney injury	3 (15.8)	1 (5.3)	0	0	2 (10.5)
Haematuria	2 (10.5)	0	2 (10.5)	0	0
Oliguria	1 (5.3)	0	0	1 (5.3)	0
Renal impairment	1 (5.3)	0	0	1 (5.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (57.9)	4 (21.1)	2 (10.5)	2 (10.5)	3 (15.8)
Cough	4 (21.1)	4 (21.1)	0	0	0
Epistaxis	4 (21.1)	1 (5.3)	1 (5.3)	2 (10.5)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	4 (21.1)	0	1 (5.3)	1 (5.3)	2 (10.5)
Pulmonary oedema	3 (15.8)	1 (5.3)	0	2 (10.5)	0
Pleural effusion	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Dyspnoea	1 (5.3)	0	0	1 (5.3)	0
Pharyngeal ulceration	1 (5.3)	0	1 (5.3)	0	0
Respiratory depression	1 (5.3)	0	1 (5.3)	0	0
Respiratory distress	1 (5.3)	0	0	0	1 (5.3)
Tachypnoea	1 (5.3)	1 (5.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (31.6)	4 (21.1)	2 (10.5)	0	0
Erythema	2 (10.5)	2 (10.5)	0	0	0
Hyperhidrosis	2 (10.5)	2 (10.5)	0	0	0
Dry skin	1 (5.3)	1 (5.3)	0	0	0
Night sweats	1 (5.3)	0	1 (5.3)	0	0
Pruritus	1 (5.3)	1 (5.3)	0	0	0
Rash	1 (5.3)	1 (5.3)	0	0	0
Rash maculo-papular	1 (5.3)	0	1 (5.3)	0	0
Rash papular	1 (5.3)	1 (5.3)	0	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash vesicular	1 (5.3)	1 (5.3)	0	0	0
Skin irritation	1 (5.3)	1 (5.3)	0	0	0
Vascular disorders					
-Total	8 (42.1)	2 (10.5)	0	2 (10.5)	4 (21.1)
Hypotension	7 (36.8)	1 (5.3)	0	2 (10.5)	4 (21.1)
Hypertension	3 (15.8)	1 (5.3)	1 (5.3)	1 (5.3)	0
Flushing	2 (10.5)	2 (10.5)	0	0	0
Capillary leak syndrome	1 (5.3)	0	0	0	1 (5.3)

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174j
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	44 (97.8)	1 (2.2)	5 (11.1)	11 (24.4)	27 (60.0)
Blood and lymphatic system disorders					
-Total	30 (66.7)	1 (2.2)	3 (6.7)	19 (42.2)	7 (15.6)
Anaemia	20 (44.4)	2 (4.4)	5 (11.1)	12 (26.7)	1 (2.2)
Febrile neutropenia	14 (31.1)	0	0	14 (31.1)	0
Neutropenia	7 (15.6)	0	0	2 (4.4)	5 (11.1)
Thrombocytopenia	6 (13.3)	0	0	2 (4.4)	4 (8.9)
Disseminated intravascular coagulation	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Lymphopenia	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Cardiac disorders					
-Total	14 (31.1)	7 (15.6)	6 (13.3)	1 (2.2)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	11 (24.4)	6 (13.3)	4 (8.9)	1 (2.2)	0
Sinus tachycardia	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Cardiac dysfunction	1 (2.2)	1 (2.2)	0	0	0
Left ventricular dysfunction	1 (2.2)	0	0	1 (2.2)	0
Palpitations	1 (2.2)	1 (2.2)	0	0	0
Pericardial effusion	1 (2.2)	1 (2.2)	0	0	0
Sinus bradycardia	1 (2.2)	1 (2.2)	0	0	0
Ventricular tachycardia	1 (2.2)	0	1 (2.2)	0	0
Ear and labyrinth disorders					
-Total	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Ear pain	1 (2.2)	1 (2.2)	0	0	0
Hypoacusis	1 (2.2)	0	1 (2.2)	0	0
Endocrine disorders					
-Total	1 (2.2)	0	1 (2.2)	0	0
Adrenal insufficiency	1 (2.2)	0	1 (2.2)	0	0
Eye disorders					
-Total	7 (15.6)	2 (4.4)	5 (11.1)	0	0
Eye pain	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Uveitis	2 (4.4)	0	2 (4.4)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctival haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Ocular hypertension	1 (2.2)	0	1 (2.2)	0	0
Papilloedema	1 (2.2)	0	1 (2.2)	0	0
Periorbital oedema	1 (2.2)	1 (2.2)	0	0	0
Retinal haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Vision blurred	1 (2.2)	0	1 (2.2)	0	0
Visual impairment	1 (2.2)	0	1 (2.2)	0	0
Gastrointestinal disorders					
-Total	23 (51.1)	8 (17.8)	10 (22.2)	5 (11.1)	0
Nausea	14 (31.1)	4 (8.9)	8 (17.8)	2 (4.4)	0
Vomiting	12 (26.7)	7 (15.6)	4 (8.9)	1 (2.2)	0
Diarrhoea	10 (22.2)	7 (15.6)	3 (6.7)	0	0
Abdominal pain	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Constipation	4 (8.9)	4 (8.9)	0	0	0
Pancreatitis	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Stomatitis	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Abdominal distension	1 (2.2)	0	1 (2.2)	0	0
Abdominal pain lower	1 (2.2)	0	1 (2.2)	0	0
Abdominal pain upper	1 (2.2)	0	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal tenderness	1 (2.2)	1 (2.2)	0	0	0
Anal incontinence	1 (2.2)	1 (2.2)	0	0	0
Ascites	1 (2.2)	0	0	1 (2.2)	0
Dysphagia	1 (2.2)	0	1 (2.2)	0	0
Flatulence	1 (2.2)	1 (2.2)	0	0	0
Gastrointestinal haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Gastrooesophageal reflux disease	1 (2.2)	1 (2.2)	0	0	0
Glossodynia	1 (2.2)	1 (2.2)	0	0	0
Haematemesis	1 (2.2)	1 (2.2)	0	0	0
Ileus	1 (2.2)	0	0	1 (2.2)	0
Tooth socket haemorrhage	1 (2.2)	1 (2.2)	0	0	0
General disorders and administration site conditions					
-Total	21 (46.7)	10 (22.2)	5 (11.1)	5 (11.1)	1 (2.2)
Pyrexia	9 (20.0)	2 (4.4)	3 (6.7)	3 (6.7)	1 (2.2)
Fatigue	8 (17.8)	7 (15.6)	1 (2.2)	0	0
Chills	6 (13.3)	6 (13.3)	0	0	0
Catheter site pain	2 (4.4)	0	2 (4.4)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Asthenia	1 (2.2)	1 (2.2)	0	0	0
Facial pain	1 (2.2)	0	1 (2.2)	0	0
Generalised oedema	1 (2.2)	0	1 (2.2)	0	0
Malaise	1 (2.2)	0	1 (2.2)	0	0
Non-cardiac chest pain	1 (2.2)	1 (2.2)	0	0	0
Pain	1 (2.2)	0	0	1 (2.2)	0
Physical deconditioning	1 (2.2)	0	0	1 (2.2)	0
Hepatobiliary disorders					
-Total	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Hepatomegaly	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Gallbladder enlargement	1 (2.2)	1 (2.2)	0	0	0
Hepatosplenomegaly	1 (2.2)	1 (2.2)	0	0	0
Immune system disorders					
-Total	38 (84.4)	4 (8.9)	21 (46.7)	7 (15.6)	6 (13.3)
Cytokine release syndrome	32 (71.1)	5 (11.1)	16 (35.6)	5 (11.1)	6 (13.3)
Hypogammaglobulinaemia	16 (35.6)	1 (2.2)	13 (28.9)	2 (4.4)	0
Drug hypersensitivity	1 (2.2)	0	1 (2.2)	0	0
Infections and infestations					
-Total	15 (33.3)	2 (4.4)	10 (22.2)	3 (6.7)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	3 (6.7)	0	3 (6.7)	0	0
Clostridium difficile colitis	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Acute sinusitis	1 (2.2)	0	1 (2.2)	0	0
Body tinea	1 (2.2)	1 (2.2)	0	0	0
Catheter site infection	1 (2.2)	0	0	1 (2.2)	0
Cytomegalovirus infection	1 (2.2)	1 (2.2)	0	0	0
Enterococcal infection	1 (2.2)	1 (2.2)	0	0	0
Gastroenteritis norovirus	1 (2.2)	0	1 (2.2)	0	0
Human herpesvirus 6 infection	1 (2.2)	0	1 (2.2)	0	0
Hypopyon	1 (2.2)	0	1 (2.2)	0	0
Influenza	1 (2.2)	1 (2.2)	0	0	0
Oral candidiasis	1 (2.2)	1 (2.2)	0	0	0
Pneumonia	1 (2.2)	0	0	1 (2.2)	0
Rhinovirus infection	1 (2.2)	1 (2.2)	0	0	0
Skin infection	1 (2.2)	0	1 (2.2)	0	0
Staphylococcal infection	1 (2.2)	1 (2.2)	0	0	0
Viral infection	1 (2.2)	0	1 (2.2)	0	0
Viral upper respiratory tract infection	1 (2.2)	0	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal candidiasis	1 (2.2)	1 (2.2)	0	0	0
Injury, poisoning and procedural complications					
-Total	6 (13.3)	3 (6.7)	2 (4.4)	1 (2.2)	0
Procedural pain	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Contusion	1 (2.2)	1 (2.2)	0	0	0
Infusion related reaction	1 (2.2)	0	1 (2.2)	0	0
Limb injury	1 (2.2)	1 (2.2)	0	0	0
Post procedural haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Procedural site reaction	1 (2.2)	1 (2.2)	0	0	0
Tracheal haemorrhage	1 (2.2)	0	0	1 (2.2)	0
Transfusion reaction	1 (2.2)	0	1 (2.2)	0	0
Investigations					
-Total	38 (84.4)	3 (6.7)	4 (8.9)	10 (22.2)	21 (46.7)
White blood cell count decreased	23 (51.1)	3 (6.7)	1 (2.2)	10 (22.2)	9 (20.0)
Neutrophil count decreased	19 (42.2)	0	2 (4.4)	3 (6.7)	14 (31.1)
Platelet count decreased	13 (28.9)	2 (4.4)	2 (4.4)	2 (4.4)	7 (15.6)
Aspartate aminotransferase increased	12 (26.7)	1 (2.2)	3 (6.7)	6 (13.3)	2 (4.4)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	12 (26.7)	1 (2.2)	2 (4.4)	4 (8.9)	5 (11.1)
Alanine aminotransferase increased	11 (24.4)	3 (6.7)	2 (4.4)	6 (13.3)	0
International normalised ratio increased	6 (13.3)	6 (13.3)	0	0	0
Prothrombin time prolonged	5 (11.1)	3 (6.7)	2 (4.4)	0	0
Activated partial thromboplastin time prolonged	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Blood bilirubin increased	4 (8.9)	1 (2.2)	2 (4.4)	1 (2.2)	0
Blood creatinine increased	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Blood fibrinogen decreased	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Blood immunoglobulin m decreased	2 (4.4)	2 (4.4)	0	0	0
Blood phosphorus increased	2 (4.4)	2 (4.4)	0	0	0
Lipase increased	2 (4.4)	0	0	0	2 (4.4)
Blood immunoglobulin a decreased	1 (2.2)	1 (2.2)	0	0	0
Blood immunoglobulin g decreased	1 (2.2)	0	1 (2.2)	0	0
Blood lactic acid increased	1 (2.2)	0	0	0	1 (2.2)
Blood magnesium decreased	1 (2.2)	0	0	1 (2.2)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood sodium increased	1 (2.2)	0	1 (2.2)	0	0
Blood urea increased	1 (2.2)	1 (2.2)	0	0	0
Blood uric acid increased	1 (2.2)	1 (2.2)	0	0	0
C-reactive protein increased	1 (2.2)	0	0	1 (2.2)	0
Cardiac murmur	1 (2.2)	1 (2.2)	0	0	0
Fibrin d dimer increased	1 (2.2)	1 (2.2)	0	0	0
Hepatic enzyme increased	1 (2.2)	0	1 (2.2)	0	0
Norovirus test positive	1 (2.2)	1 (2.2)	0	0	0
Pulmonary function test decreased	1 (2.2)	0	1 (2.2)	0	0
Serum ferritin increased	1 (2.2)	0	1 (2.2)	0	0
Transaminases increased	1 (2.2)	1 (2.2)	0	0	0
Metabolism and nutrition disorders					
-Total	23 (51.1)	3 (6.7)	6 (13.3)	12 (26.7)	2 (4.4)
Decreased appetite	13 (28.9)	3 (6.7)	2 (4.4)	8 (17.8)	0
Hypokalaemia	12 (26.7)	2 (4.4)	5 (11.1)	5 (11.1)	0
Hyperphosphataemia	6 (13.3)	6 (13.3)	0	0	0
Hypophosphataemia	5 (11.1)	0	0	4 (8.9)	1 (2.2)
Hyperuricaemia	3 (6.7)	2 (4.4)	0	0	1 (2.2)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Hyperglycaemia	2 (4.4)	0	2 (4.4)	0	0
Hypernatraemia	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Hypertriglyceridaemia	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Acidosis	1 (2.2)	1 (2.2)	0	0	0
Dehydration	1 (2.2)	1 (2.2)	0	0	0
Fluid overload	1 (2.2)	1 (2.2)	0	0	0
Hypocalcaemia	1 (2.2)	1 (2.2)	0	0	0
Hypomagnesaemia	1 (2.2)	1 (2.2)	0	0	0
Hyponatraemia	1 (2.2)	0	0	1 (2.2)	0
Tumour lysis syndrome	1 (2.2)	0	0	1 (2.2)	0
Musculoskeletal and connective tissue disorders					
-Total	8 (17.8)	4 (8.9)	3 (6.7)	1 (2.2)	0
Arthralgia	4 (8.9)	3 (6.7)	0	1 (2.2)	0
Myalgia	3 (6.7)	3 (6.7)	0	0	0
Musculoskeletal pain	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Pain in extremity	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Muscular weakness	1 (2.2)	0	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal chest pain	1 (2.2)	1 (2.2)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.2)	0	1 (2.2)	0	0
Skin papilloma	1 (2.2)	0	1 (2.2)	0	0
Nervous system disorders					
-Total	23 (51.1)	12 (26.7)	10 (22.2)	1 (2.2)	0
Headache	17 (37.8)	11 (24.4)	5 (11.1)	1 (2.2)	0
Dizziness	3 (6.7)	3 (6.7)	0	0	0
Dysarthria	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Encephalopathy	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Seizure	2 (4.4)	0	2 (4.4)	0	0
Tremor	2 (4.4)	2 (4.4)	0	0	0
Asterixis	1 (2.2)	1 (2.2)	0	0	0
Ataxia	1 (2.2)	0	1 (2.2)	0	0
Depressed level of consciousness	1 (2.2)	1 (2.2)	0	0	0
Idiopathic intracranial hypertension	1 (2.2)	0	1 (2.2)	0	0
Migraine	1 (2.2)	0	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neuropathy peripheral	1 (2.2)	0	1 (2.2)	0	0
Pleocytosis	1 (2.2)	1 (2.2)	0	0	0
Somnolence	1 (2.2)	1 (2.2)	0	0	0
Product issues					
-Total	1 (2.2)	1 (2.2)	0	0	0
Device occlusion	1 (2.2)	1 (2.2)	0	0	0
Psychiatric disorders					
-Total	8 (17.8)	5 (11.1)	2 (4.4)	1 (2.2)	0
Confusional state	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Anxiety	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Delirium	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Adjustment disorder	1 (2.2)	0	1 (2.2)	0	0
Agitation	1 (2.2)	0	1 (2.2)	0	0
Suicidal ideation	1 (2.2)	1 (2.2)	0	0	0
Renal and urinary disorders					
-Total	7 (15.6)	1 (2.2)	2 (4.4)	2 (4.4)	2 (4.4)
Acute kidney injury	4 (8.9)	0	1 (2.2)	2 (4.4)	1 (2.2)
Dysuria	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Haematuria	2 (4.4)	0	0	1 (2.2)	1 (2.2)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oliguria	1 (2.2)	0	0	1 (2.2)	0
Pollakiuria	1 (2.2)	1 (2.2)	0	0	0
Renal failure	1 (2.2)	0	0	0	1 (2.2)
Reproductive system and breast disorders					
-Total	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Vulvovaginal adhesion	2 (4.4)	2 (4.4)	0	0	0
Oedema genital	1 (2.2)	0	1 (2.2)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	17 (37.8)	6 (13.3)	4 (8.9)	3 (6.7)	4 (8.9)
Hypoxia	6 (13.3)	0	2 (4.4)	3 (6.7)	1 (2.2)
Pleural effusion	6 (13.3)	2 (4.4)	3 (6.7)	1 (2.2)	0
Cough	4 (8.9)	4 (8.9)	0	0	0
Tachypnoea	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Epistaxis	3 (6.7)	1 (2.2)	0	1 (2.2)	1 (2.2)
Pulmonary oedema	3 (6.7)	0	0	1 (2.2)	2 (4.4)
Respiratory failure	3 (6.7)	0	0	0	3 (6.7)
Haemoptysis	2 (4.4)	1 (2.2)	0	0	1 (2.2)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Atelectasis	1 (2.2)	1 (2.2)	0	0	0
Dyspnoea	1 (2.2)	0	0	0	1 (2.2)
Interstitial lung disease	1 (2.2)	0	0	0	1 (2.2)
Nasal congestion	1 (2.2)	1 (2.2)	0	0	0
Oropharyngeal plaque	1 (2.2)	1 (2.2)	0	0	0
Rhinitis allergic	1 (2.2)	1 (2.2)	0	0	0
Rhinorrhoea	1 (2.2)	1 (2.2)	0	0	0
Wheezing	1 (2.2)	0	1 (2.2)	0	0
Skin and subcutaneous tissue disorders					
-Total	15 (33.3)	11 (24.4)	2 (4.4)	2 (4.4)	0
Dry skin	3 (6.7)	3 (6.7)	0	0	0
Petechiae	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Rash	3 (6.7)	3 (6.7)	0	0	0
Ingrowing nail	2 (4.4)	0	2 (4.4)	0	0
Rash maculo-papular	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Dermatitis diaper	1 (2.2)	1 (2.2)	0	0	0
Ecchymosis	1 (2.2)	0	0	1 (2.2)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	1 (2.2)	1 (2.2)	0	0	0
Hyperhidrosis	1 (2.2)	1 (2.2)	0	0	0
Livedo reticularis	1 (2.2)	1 (2.2)	0	0	0
Macule	1 (2.2)	1 (2.2)	0	0	0
Pruritus	1 (2.2)	1 (2.2)	0	0	0
Rash erythematous	1 (2.2)	1 (2.2)	0	0	0
Rash follicular	1 (2.2)	1 (2.2)	0	0	0
Rash macular	1 (2.2)	1 (2.2)	0	0	0
Rash papular	1 (2.2)	1 (2.2)	0	0	0
Skin exfoliation	1 (2.2)	1 (2.2)	0	0	0
Skin fissures	1 (2.2)	1 (2.2)	0	0	0
Vascular disorders					
-Total	16 (35.6)	1 (2.2)	5 (11.1)	6 (13.3)	4 (8.9)
Hypotension	9 (20.0)	0	0	5 (11.1)	4 (8.9)
Hypertension	7 (15.6)	1 (2.2)	6 (13.3)	0	0
Orthostatic hypotension	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Embolism	1 (2.2)	0	0	1 (2.2)	0
Haematoma	1 (2.2)	0	1 (2.2)	0	0
Secondary hypertension	1 (2.2)	0	1 (2.2)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174j
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=18		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (88.9)	1 (5.6)	6 (33.3)	2 (11.1)	7 (38.9)
Blood and lymphatic system disorders					
-Total	5 (27.8)	1 (5.6)	0	0	4 (22.2)
Neutropenia	3 (16.7)	0	0	0	3 (16.7)
Anaemia	1 (5.6)	1 (5.6)	0	0	0
Eosinophilia	1 (5.6)	0	0	1 (5.6)	0
Febrile neutropenia	1 (5.6)	0	0	1 (5.6)	0
Leukopenia	1 (5.6)	0	0	0	1 (5.6)
Cardiac disorders					
-Total	1 (5.6)	0	1 (5.6)	0	0
Sinus tachycardia	1 (5.6)	0	1 (5.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	3 (16.7)	3 (16.7)	0	0	0
Conjunctivitis allergic	1 (5.6)	1 (5.6)	0	0	0
Ocular hyperaemia	1 (5.6)	1 (5.6)	0	0	0
Vision blurred	1 (5.6)	1 (5.6)	0	0	0
Gastrointestinal disorders					
-Total	7 (38.9)	5 (27.8)	1 (5.6)	1 (5.6)	0
Diarrhoea	4 (22.2)	3 (16.7)	0	1 (5.6)	0
Vomiting	4 (22.2)	2 (11.1)	1 (5.6)	1 (5.6)	0
Nausea	3 (16.7)	1 (5.6)	1 (5.6)	1 (5.6)	0
Abdominal pain	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Pigmentation lip	1 (5.6)	1 (5.6)	0	0	0
General disorders and administration site conditions					
-Total	7 (38.9)	5 (27.8)	2 (11.1)	0	0
Pyrexia	6 (33.3)	4 (22.2)	2 (11.1)	0	0
Chills	1 (5.6)	1 (5.6)	0	0	0
Crying	1 (5.6)	1 (5.6)	0	0	0
Influenza like illness	1 (5.6)	1 (5.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	1 (5.6)	1 (5.6)	0	0	0
Immune system disorders					
-Total	5 (27.8)	2 (11.1)	2 (11.1)	1 (5.6)	0
Hypogammaglobulinaemia	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Graft versus host disease	1 (5.6)	1 (5.6)	0	0	0
Seasonal allergy	1 (5.6)	1 (5.6)	0	0	0
Infections and infestations					
-Total	13 (72.2)	4 (22.2)	4 (22.2)	4 (22.2)	1 (5.6)
Upper respiratory tract infection	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Ear infection	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Gastroenteritis	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Bacterial sepsis	1 (5.6)	0	0	0	1 (5.6)
Cellulitis of male external genital organ	1 (5.6)	0	0	1 (5.6)	0
Enterovirus infection	1 (5.6)	0	0	1 (5.6)	0
Herpes zoster	1 (5.6)	0	0	1 (5.6)	0
Molluscum contagiosum	1 (5.6)	1 (5.6)	0	0	0
Oral herpes	1 (5.6)	0	1 (5.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis	1 (5.6)	1 (5.6)	0	0	0
Rhinovirus infection	1 (5.6)	1 (5.6)	0	0	0
Rotavirus infection	1 (5.6)	0	0	1 (5.6)	0
Tinea capitis	1 (5.6)	1 (5.6)	0	0	0
Urinary tract infection	1 (5.6)	0	0	1 (5.6)	0
Vascular device infection	1 (5.6)	0	0	1 (5.6)	0
Injury, poisoning and procedural complications					
-Total	4 (22.2)	2 (11.1)	2 (11.1)	0	0
Contusion	1 (5.6)	1 (5.6)	0	0	0
Radius fracture	1 (5.6)	0	1 (5.6)	0	0
Skin abrasion	1 (5.6)	1 (5.6)	0	0	0
Skin laceration	1 (5.6)	0	1 (5.6)	0	0
Investigations					
-Total	10 (55.6)	2 (11.1)	4 (22.2)	1 (5.6)	3 (16.7)
Neutrophil count decreased	4 (22.2)	1 (5.6)	0	1 (5.6)	2 (11.1)
Lymphocyte count decreased	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Weight decreased	2 (11.1)	0	2 (11.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	2 (11.1)	1 (5.6)	0	0	1 (5.6)
Blood creatinine increased	1 (5.6)	1 (5.6)	0	0	0
Blood urea increased	1 (5.6)	1 (5.6)	0	0	0
Haemoglobin decreased	1 (5.6)	1 (5.6)	0	0	0
Platelet count decreased	1 (5.6)	1 (5.6)	0	0	0
Weight increased	1 (5.6)	0	1 (5.6)	0	0
Metabolism and nutrition disorders					
-Total	5 (27.8)	4 (22.2)	0	1 (5.6)	0
Decreased appetite	1 (5.6)	1 (5.6)	0	0	0
Dehydration	1 (5.6)	0	0	1 (5.6)	0
Hyperalbuminaemia	1 (5.6)	1 (5.6)	0	0	0
Hypercalcaemia	1 (5.6)	1 (5.6)	0	0	0
Hyperphosphataemia	1 (5.6)	1 (5.6)	0	0	0
Vitamin d deficiency	1 (5.6)	1 (5.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	10 (55.6)	6 (33.3)	4 (22.2)	0	0
Pain in extremity	6 (33.3)	4 (22.2)	2 (11.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	1 (5.6)	0	1 (5.6)	0	0
Back pain	1 (5.6)	1 (5.6)	0	0	0
Joint range of motion decreased	1 (5.6)	1 (5.6)	0	0	0
Muscle spasms	1 (5.6)	1 (5.6)	0	0	0
Musculoskeletal chest pain	1 (5.6)	1 (5.6)	0	0	0
Osteonecrosis	1 (5.6)	0	1 (5.6)	0	0
Toe walking	1 (5.6)	1 (5.6)	0	0	0
Nervous system disorders					
-Total	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Headache	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Dizziness	1 (5.6)	1 (5.6)	0	0	0
Renal and urinary disorders					
-Total	1 (5.6)	0	0	1 (5.6)	0
Acute kidney injury	1 (5.6)	0	0	1 (5.6)	0
Reproductive system and breast disorders					
-Total	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Scrotal pain	1 (5.6)	0	1 (5.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal haemorrhage	1 (5.6)	0	0	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (50.0)	5 (27.8)	2 (11.1)	1 (5.6)	1 (5.6)
Cough	5 (27.8)	4 (22.2)	1 (5.6)	0	0
Rhinitis allergic	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Acute respiratory failure	1 (5.6)	0	0	0	1 (5.6)
Dysphonia	1 (5.6)	1 (5.6)	0	0	0
Nasal congestion	1 (5.6)	1 (5.6)	0	0	0
Pulmonary oedema	1 (5.6)	0	0	1 (5.6)	0
Rhinorrhoea	1 (5.6)	1 (5.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (38.9)	5 (27.8)	2 (11.1)	0	0
Rash	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Rash maculo-papular	2 (11.1)	2 (11.1)	0	0	0
Dermatitis atopic	1 (5.6)	1 (5.6)	0	0	0
Macule	1 (5.6)	1 (5.6)	0	0	0
Papule	1 (5.6)	1 (5.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=18		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	1 (5.6)	1 (5.6)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174j
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=38		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (78.9)	3 (7.9)	10 (26.3)	14 (36.8)	3 (7.9)
Blood and lymphatic system disorders					
-Total	6 (15.8)	0	3 (7.9)	3 (7.9)	0
Febrile neutropenia	2 (5.3)	0	0	2 (5.3)	0
Thrombocytopenia	2 (5.3)	0	1 (2.6)	1 (2.6)	0
Anaemia	1 (2.6)	0	0	1 (2.6)	0
Lymphadenopathy	1 (2.6)	0	1 (2.6)	0	0
Lymphopenia	1 (2.6)	0	1 (2.6)	0	0
Neutropenia	1 (2.6)	0	0	1 (2.6)	0
Endocrine disorders					
-Total	1 (2.6)	1 (2.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=38		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	1 (2.6)	1 (2.6)	0	0	0
Eye disorders					
-Total	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Dry eye	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Gastrointestinal disorders					
-Total	9 (23.7)	4 (10.5)	2 (5.3)	3 (7.9)	0
Vomiting	5 (13.2)	3 (7.9)	1 (2.6)	1 (2.6)	0
Diarrhoea	4 (10.5)	3 (7.9)	1 (2.6)	0	0
Nausea	3 (7.9)	0	2 (5.3)	1 (2.6)	0
Abdominal pain	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Oral pain	2 (5.3)	1 (2.6)	0	1 (2.6)	0
Abdominal pain upper	1 (2.6)	1 (2.6)	0	0	0
Enterocolitis	1 (2.6)	0	0	1 (2.6)	0
General disorders and administration site conditions					
-Total	10 (26.3)	8 (21.1)	1 (2.6)	1 (2.6)	0
Pyrexia	4 (10.5)	3 (7.9)	0	1 (2.6)	0
Fatigue	2 (5.3)	2 (5.3)	0	0	0
Acquired gene mutation	1 (2.6)	1 (2.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=38				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site pain	1 (2.6)	0	1 (2.6)	0	0
Generalised oedema	1 (2.6)	1 (2.6)	0	0	0
Influenza like illness	1 (2.6)	1 (2.6)	0	0	0
Malaise	1 (2.6)	1 (2.6)	0	0	0
Oedema peripheral	1 (2.6)	1 (2.6)	0	0	0
Immune system disorders					
-Total	9 (23.7)	1 (2.6)	8 (21.1)	0	0
Hypogammaglobulinaemia	5 (13.2)	0	5 (13.2)	0	0
Immunodeficiency common variable	2 (5.3)	0	2 (5.3)	0	0
Graft versus host disease	1 (2.6)	0	1 (2.6)	0	0
Graft versus host disease in gastrointestinal tract	1 (2.6)	0	1 (2.6)	0	0
Seasonal allergy	1 (2.6)	1 (2.6)	0	0	0
Infections and infestations					
-Total	20 (52.6)	2 (5.3)	11 (28.9)	6 (15.8)	1 (2.6)
Upper respiratory tract infection	4 (10.5)	2 (5.3)	1 (2.6)	1 (2.6)	0
Influenza	3 (7.9)	0	3 (7.9)	0	0
Urinary tract infection	3 (7.9)	0	2 (5.3)	1 (2.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=38				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	2 (5.3)	1 (2.6)	0	1 (2.6)	0
Sinusitis	2 (5.3)	0	2 (5.3)	0	0
Viral upper respiratory tract infection	2 (5.3)	1 (2.6)	0	1 (2.6)	0
Cholecystitis infective	1 (2.6)	0	0	1 (2.6)	0
Corona virus infection	1 (2.6)	0	0	1 (2.6)	0
Cytomegalovirus infection	1 (2.6)	1 (2.6)	0	0	0
Escherichia urinary tract infection	1 (2.6)	0	0	1 (2.6)	0
Gastroenteritis	1 (2.6)	0	1 (2.6)	0	0
Gastroenteritis norovirus	1 (2.6)	0	1 (2.6)	0	0
Gastroenteritis viral	1 (2.6)	1 (2.6)	0	0	0
Otitis externa	1 (2.6)	0	1 (2.6)	0	0
Otitis media	1 (2.6)	0	1 (2.6)	0	0
Otitis media acute	1 (2.6)	0	1 (2.6)	0	0
Paronychia	1 (2.6)	1 (2.6)	0	0	0
Rash pustular	1 (2.6)	0	1 (2.6)	0	0
Respiratory syncytial virus infection	1 (2.6)	0	0	1 (2.6)	0
Rhinovirus infection	1 (2.6)	1 (2.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=38				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (2.6)	0	0	0	1 (2.6)
Subcutaneous abscess	1 (2.6)	0	1 (2.6)	0	0
Viral infection	1 (2.6)	1 (2.6)	0	0	0
Vulvovaginal mycotic infection	1 (2.6)	0	1 (2.6)	0	0
Injury, poisoning and procedural complications					
-Total	4 (10.5)	1 (2.6)	3 (7.9)	0	0
Infusion related reaction	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Procedural pain	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Arthropod bite	1 (2.6)	1 (2.6)	0	0	0
Contusion	1 (2.6)	1 (2.6)	0	0	0
Foot fracture	1 (2.6)	0	1 (2.6)	0	0
Procedural nausea	1 (2.6)	0	1 (2.6)	0	0
Sunburn	1 (2.6)	1 (2.6)	0	0	0
Investigations					
-Total	13 (34.2)	4 (10.5)	1 (2.6)	7 (18.4)	1 (2.6)
Neutrophil count decreased	4 (10.5)	1 (2.6)	0	2 (5.3)	1 (2.6)
Aspartate aminotransferase increased	3 (7.9)	1 (2.6)	0	2 (5.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=38				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	3 (7.9)	1 (2.6)	1 (2.6)	1 (2.6)	0
Alanine aminotransferase increased	2 (5.3)	0	0	2 (5.3)	0
Platelet count decreased	2 (5.3)	2 (5.3)	0	0	0
Weight decreased	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Blood bilirubin increased	1 (2.6)	0	0	1 (2.6)	0
Blood magnesium decreased	1 (2.6)	1 (2.6)	0	0	0
Blood uric acid increased	1 (2.6)	1 (2.6)	0	0	0
Haemoglobin decreased	1 (2.6)	1 (2.6)	0	0	0
Oxygen saturation decreased	1 (2.6)	1 (2.6)	0	0	0
Serum ferritin increased	1 (2.6)	0	1 (2.6)	0	0
Transaminases increased	1 (2.6)	1 (2.6)	0	0	0
Weight increased	1 (2.6)	1 (2.6)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (13.2)	1 (2.6)	1 (2.6)	2 (5.3)	1 (2.6)
Hypokalaemia	2 (5.3)	1 (2.6)	0	0	1 (2.6)
Decreased appetite	1 (2.6)	0	1 (2.6)	0	0
Hyperglycaemia	1 (2.6)	0	0	1 (2.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=38		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	1 (2.6)	1 (2.6)	0	0	0
Hypophosphataemia	1 (2.6)	0	0	1 (2.6)	0
Iron overload	1 (2.6)	0	0	1 (2.6)	0
Tumour lysis syndrome	1 (2.6)	0	0	1 (2.6)	0
Musculoskeletal and connective tissue disorders					
-Total	6 (15.8)	5 (13.2)	1 (2.6)	0	0
Muscular weakness	2 (5.3)	2 (5.3)	0	0	0
Pain in extremity	2 (5.3)	2 (5.3)	0	0	0
Arthralgia	1 (2.6)	1 (2.6)	0	0	0
Flank pain	1 (2.6)	0	1 (2.6)	0	0
Joint range of motion decreased	1 (2.6)	1 (2.6)	0	0	0
Pain in jaw	1 (2.6)	1 (2.6)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.6)	0	1 (2.6)	0	0
Myelodysplastic syndrome	1 (2.6)	0	1 (2.6)	0	0
Nervous system disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=38		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (13.2)	4 (10.5)	1 (2.6)	0	0
Dizziness	2 (5.3)	2 (5.3)	0	0	0
Headache	2 (5.3)	2 (5.3)	0	0	0
Peroneal nerve palsy	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Psychiatric disorders					
-Total	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Depression	2 (5.3)	2 (5.3)	0	0	0
Anxiety	1 (2.6)	1 (2.6)	0	0	0
Sleep disorder	1 (2.6)	0	1 (2.6)	0	0
Renal and urinary disorders					
-Total	2 (5.3)	1 (2.6)	0	1 (2.6)	0
Calculus urinary	1 (2.6)	0	1 (2.6)	0	0
Haematuria	1 (2.6)	0	0	1 (2.6)	0
Nephrolithiasis	1 (2.6)	0	0	1 (2.6)	0
Urinary incontinence	1 (2.6)	1 (2.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (23.7)	6 (15.8)	2 (5.3)	1 (2.6)	0
Nasal congestion	3 (7.9)	3 (7.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=38				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	3 (7.9)	2 (5.3)	1 (2.6)	0	0
Rhinorrhoea	3 (7.9)	2 (5.3)	1 (2.6)	0	0
Cough	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Epistaxis	2 (5.3)	1 (2.6)	0	1 (2.6)	0
Pharyngeal erythema	1 (2.6)	1 (2.6)	0	0	0
Pharyngeal lesion	1 (2.6)	0	0	1 (2.6)	0
Rhinitis allergic	1 (2.6)	1 (2.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (23.7)	5 (13.2)	3 (7.9)	1 (2.6)	0
Erythema	2 (5.3)	2 (5.3)	0	0	0
Alopecia	1 (2.6)	0	1 (2.6)	0	0
Dermatitis	1 (2.6)	1 (2.6)	0	0	0
Dermatitis acneiform	1 (2.6)	0	0	1 (2.6)	0
Dry skin	1 (2.6)	1 (2.6)	0	0	0
Eczema	1 (2.6)	1 (2.6)	0	0	0
Hyperhidrosis	1 (2.6)	1 (2.6)	0	0	0
Ingrowing nail	1 (2.6)	1 (2.6)	0	0	0
Keloid scar	1 (2.6)	0	1 (2.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=38				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Petechiae	1 (2.6)	1 (2.6)	0	0	0
Rash	1 (2.6)	0	1 (2.6)	0	0
Rash erythematous	1 (2.6)	0	1 (2.6)	0	0
Rash pruritic	1 (2.6)	1 (2.6)	0	0	0
Vascular disorders					
-Total	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Hypertension	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Hot flush	1 (2.6)	1 (2.6)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174j
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (90.9)	1 (9.1)	4 (36.4)	4 (36.4)	1 (9.1)
Gastrointestinal disorders					
-Total	2 (18.2)	0	2 (18.2)	0	0
Diarrhoea	2 (18.2)	0	2 (18.2)	0	0
Abdominal pain	1 (9.1)	0	1 (9.1)	0	0
Immune system disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Chronic graft versus host disease	1 (9.1)	0	1 (9.1)	0	0
Infections and infestations					
-Total	6 (54.5)	2 (18.2)	1 (9.1)	2 (18.2)	1 (9.1)
Urinary tract infection	2 (18.2)	0	1 (9.1)	1 (9.1)	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (9.1)	0	0	1 (9.1)	0
Cellulitis of male external genital organ	1 (9.1)	0	0	1 (9.1)	0
Clostridium difficile infection	1 (9.1)	0	0	1 (9.1)	0
Gingivitis	1 (9.1)	1 (9.1)	0	0	0
Otitis media	1 (9.1)	0	1 (9.1)	0	0
Respiratory tract infection	1 (9.1)	0	0	0	1 (9.1)
Respiratory tract infection viral	1 (9.1)	0	0	1 (9.1)	0
Skin infection	1 (9.1)	0	1 (9.1)	0	0
Upper respiratory tract infection	1 (9.1)	1 (9.1)	0	0	0
Viral infection	1 (9.1)	1 (9.1)	0	0	0
Vulvovaginal candidiasis	1 (9.1)	0	1 (9.1)	0	0
Investigations					
-Total	4 (36.4)	1 (9.1)	1 (9.1)	2 (18.2)	0
Lymphocyte count decreased	3 (27.3)	2 (18.2)	0	1 (9.1)	0
Neutrophil count decreased	2 (18.2)	1 (9.1)	1 (9.1)	0	0
White blood cell count decreased	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Metabolism and nutrition disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vitamin d deficiency	1 (9.1)	1 (9.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Neck pain	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	2 (18.2)	1 (9.1)	1 (9.1)	0	0
Disturbance in attention	1 (9.1)	1 (9.1)	0	0	0
Dizziness	1 (9.1)	1 (9.1)	0	0	0
Headache	1 (9.1)	0	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (18.2)	2 (18.2)	0	0	0
Cough	1 (9.1)	1 (9.1)	0	0	0
Oropharyngeal pain	1 (9.1)	1 (9.1)	0	0	0
Rhinitis allergic	1 (9.1)	1 (9.1)	0	0	0
Rhinorrhoea	1 (9.1)	1 (9.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acne	1 (9.1)	1 (9.1)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174j
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=23		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (52.2)	3 (13.0)	2 (8.7)	4 (17.4)	3 (13.0)
Blood and lymphatic system disorders					
-Total	2 (8.7)	1 (4.3)	0	0	1 (4.3)
Febrile neutropenia	1 (4.3)	0	0	0	1 (4.3)
Thrombocytopenia	1 (4.3)	1 (4.3)	0	0	0
Ear and labyrinth disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Tympanic membrane perforation	1 (4.3)	0	1 (4.3)	0	0
Gastrointestinal disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Nausea	1 (4.3)	0	1 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=23		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Chills	1 (4.3)	0	1 (4.3)	0	0
Cyst	1 (4.3)	0	0	1 (4.3)	0
Pyrexia	1 (4.3)	0	1 (4.3)	0	0
Immune system disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Immunodeficiency	1 (4.3)	0	1 (4.3)	0	0
Infections and infestations					
-Total	5 (21.7)	0	4 (17.4)	1 (4.3)	0
Sinusitis	3 (13.0)	0	3 (13.0)	0	0
Otitis media	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Otitis media acute	2 (8.7)	0	2 (8.7)	0	0
Pneumonia	2 (8.7)	0	2 (8.7)	0	0
Haemophilus infection	1 (4.3)	0	1 (4.3)	0	0
Meningitis aseptic	1 (4.3)	0	1 (4.3)	0	0
Upper respiratory tract infection	1 (4.3)	0	1 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=23		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	1 (4.3)	0	0	1 (4.3)	0
Procedural pain	1 (4.3)	0	0	1 (4.3)	0
Investigations					
-Total	4 (17.4)	0	1 (4.3)	2 (8.7)	1 (4.3)
Alanine aminotransferase increased	3 (13.0)	0	1 (4.3)	2 (8.7)	0
Aspartate aminotransferase increased	2 (8.7)	1 (4.3)	0	1 (4.3)	0
White blood cell count decreased	2 (8.7)	0	0	1 (4.3)	1 (4.3)
Blood alkaline phosphatase increased	1 (4.3)	1 (4.3)	0	0	0
Blood lactate dehydrogenase increased	1 (4.3)	1 (4.3)	0	0	0
C-reactive protein increased	1 (4.3)	1 (4.3)	0	0	0
Platelet count decreased	1 (4.3)	0	0	1 (4.3)	0
Metabolism and nutrition disorders					
-Total	1 (4.3)	0	0	1 (4.3)	0
Hypokalaemia	1 (4.3)	0	0	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=23		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (4.3)	0	0	0	1 (4.3)
Glioblastoma multiforme	1 (4.3)	0	0	0	1 (4.3)
Nervous system disorders					
-Total	1 (4.3)	0	0	1 (4.3)	0
Seizure	1 (4.3)	0	0	1 (4.3)	0
Renal and urinary disorders					
-Total	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Acute kidney injury	1 (4.3)	0	0	1 (4.3)	0
Haematuria	1 (4.3)	1 (4.3)	0	0	0
Reproductive system and breast disorders					
-Total	1 (4.3)	0	0	1 (4.3)	0
Ovarian failure	1 (4.3)	0	0	1 (4.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (8.7)	2 (8.7)	0	0	0
Cough	1 (4.3)	1 (4.3)	0	0	0
Epistaxis	1 (4.3)	1 (4.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=23		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	2 (8.7)	2 (8.7)	0	0	0
Papule	1 (4.3)	1 (4.3)	0	0	0
Pruritus	1 (4.3)	1 (4.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174j
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (100)	0	1 (5.3)	1 (5.3)	17 (89.5)
Blood and lymphatic system disorders					
-Total	16 (84.2)	1 (5.3)	0	7 (36.8)	8 (42.1)
Febrile neutropenia	8 (42.1)	0	0	8 (42.1)	0
Anaemia	7 (36.8)	1 (5.3)	0	6 (31.6)	0
Neutropenia	4 (21.1)	0	0	1 (5.3)	3 (15.8)
Thrombocytopenia	2 (10.5)	0	0	0	2 (10.5)
Coagulopathy	1 (5.3)	1 (5.3)	0	0	0
Disseminated intravascular coagulation	1 (5.3)	0	0	1 (5.3)	0
Eosinophilia	1 (5.3)	0	0	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (5.3)	0	0	0	1 (5.3)
Lymphopenia	1 (5.3)	0	0	0	1 (5.3)
Pancytopenia	1 (5.3)	0	0	0	1 (5.3)
Cardiac disorders					
-Total	9 (47.4)	4 (21.1)	4 (21.1)	1 (5.3)	0
Tachycardia	4 (21.1)	2 (10.5)	1 (5.3)	1 (5.3)	0
Sinus tachycardia	3 (15.8)	1 (5.3)	2 (10.5)	0	0
Atrioventricular block second degree	1 (5.3)	1 (5.3)	0	0	0
Bradycardia	1 (5.3)	0	1 (5.3)	0	0
Pericardial effusion	1 (5.3)	0	1 (5.3)	0	0
Ear and labyrinth disorders					
-Total	1 (5.3)	1 (5.3)	0	0	0
Ear pain	1 (5.3)	1 (5.3)	0	0	0
Eye disorders					
-Total	9 (47.4)	7 (36.8)	2 (10.5)	0	0
Periorbital oedema	3 (15.8)	2 (10.5)	1 (5.3)	0	0
Vision blurred	3 (15.8)	2 (10.5)	1 (5.3)	0	0
Conjunctival haemorrhage	2 (10.5)	2 (10.5)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Photophobia	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Conjunctivitis allergic	1 (5.3)	1 (5.3)	0	0	0
Eye pain	1 (5.3)	0	1 (5.3)	0	0
Ocular hyperaemia	1 (5.3)	1 (5.3)	0	0	0
Retinal haemorrhage	1 (5.3)	1 (5.3)	0	0	0
Gastrointestinal disorders					
-Total	15 (78.9)	3 (15.8)	6 (31.6)	6 (31.6)	0
Diarrhoea	12 (63.2)	5 (26.3)	5 (26.3)	2 (10.5)	0
Vomiting	11 (57.9)	6 (31.6)	3 (15.8)	2 (10.5)	0
Nausea	8 (42.1)	2 (10.5)	4 (21.1)	2 (10.5)	0
Abdominal pain	5 (26.3)	2 (10.5)	2 (10.5)	1 (5.3)	0
Constipation	3 (15.8)	2 (10.5)	1 (5.3)	0	0
Abdominal discomfort	1 (5.3)	1 (5.3)	0	0	0
Abdominal distension	1 (5.3)	0	1 (5.3)	0	0
Abdominal pain upper	1 (5.3)	0	1 (5.3)	0	0
Dyspepsia	1 (5.3)	0	1 (5.3)	0	0
Dysphagia	1 (5.3)	0	0	1 (5.3)	0
Haematemesis	1 (5.3)	1 (5.3)	0	0	0
Intestinal obstruction	1 (5.3)	0	0	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lip pain	1 (5.3)	0	1 (5.3)	0	0
Mouth haemorrhage	1 (5.3)	0	0	1 (5.3)	0
Pigmentation lip	1 (5.3)	1 (5.3)	0	0	0
General disorders and administration site conditions					
-Total	15 (78.9)	4 (21.1)	7 (36.8)	4 (21.1)	0
Pyrexia	11 (57.9)	3 (15.8)	6 (31.6)	2 (10.5)	0
Fatigue	5 (26.3)	3 (15.8)	1 (5.3)	1 (5.3)	0
Chills	3 (15.8)	3 (15.8)	0	0	0
Pain	3 (15.8)	1 (5.3)	1 (5.3)	1 (5.3)	0
Face oedema	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Malaise	2 (10.5)	0	2 (10.5)	0	0
Oedema peripheral	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Catheter site extravasation	1 (5.3)	0	1 (5.3)	0	0
Catheter site haemorrhage	1 (5.3)	1 (5.3)	0	0	0
Catheter site pain	1 (5.3)	1 (5.3)	0	0	0
Crying	1 (5.3)	1 (5.3)	0	0	0
Generalised oedema	1 (5.3)	0	1 (5.3)	0	0
Influenza like illness	1 (5.3)	1 (5.3)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injection site haematoma	1 (5.3)	1 (5.3)	0	0	0
Localised oedema	1 (5.3)	0	0	1 (5.3)	0
Mucosal haemorrhage	1 (5.3)	0	1 (5.3)	0	0
Multiple organ dysfunction syndrome	1 (5.3)	0	0	1 (5.3)	0
Peripheral swelling	1 (5.3)	0	1 (5.3)	0	0
Hepatobiliary disorders					
-Total	3 (15.8)	0	1 (5.3)	2 (10.5)	0
Hyperbilirubinaemia	3 (15.8)	0	1 (5.3)	2 (10.5)	0
Hepatomegaly	1 (5.3)	0	1 (5.3)	0	0
Immune system disorders					
-Total	19 (100)	1 (5.3)	9 (47.4)	4 (21.1)	5 (26.3)
Cytokine release syndrome	18 (94.7)	1 (5.3)	9 (47.4)	3 (15.8)	5 (26.3)
Hypogammaglobulinaemia	12 (63.2)	2 (10.5)	7 (36.8)	3 (15.8)	0
Chronic graft versus host disease	1 (5.3)	0	1 (5.3)	0	0
Graft versus host disease	1 (5.3)	1 (5.3)	0	0	0
Graft versus host disease in skin	1 (5.3)	1 (5.3)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (5.3)	0	1 (5.3)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seasonal allergy	1 (5.3)	1 (5.3)	0	0	0
Infections and infestations					
-Total	16 (84.2)	3 (15.8)	5 (26.3)	5 (26.3)	3 (15.8)
Gastroenteritis	4 (21.1)	1 (5.3)	2 (10.5)	1 (5.3)	0
Upper respiratory tract infection	4 (21.1)	2 (10.5)	2 (10.5)	0	0
Rhinovirus infection	3 (15.8)	3 (15.8)	0	0	0
Clostridium difficile colitis	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Clostridium difficile infection	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Ear infection	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Urinary tract infection	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Bacterial sepsis	1 (5.3)	0	0	0	1 (5.3)
Campylobacter infection	1 (5.3)	0	0	1 (5.3)	0
Catheter site cellulitis	1 (5.3)	1 (5.3)	0	0	0
Cellulitis of male external genital organ	1 (5.3)	0	0	1 (5.3)	0
Enterovirus infection	1 (5.3)	0	0	1 (5.3)	0
Folliculitis	1 (5.3)	0	1 (5.3)	0	0
Fungal skin infection	1 (5.3)	1 (5.3)	0	0	0
Gingivitis	1 (5.3)	1 (5.3)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes simplex	1 (5.3)	1 (5.3)	0	0	0
Herpes zoster	1 (5.3)	0	0	1 (5.3)	0
Molluscum contagiosum	1 (5.3)	1 (5.3)	0	0	0
Oral herpes	1 (5.3)	0	1 (5.3)	0	0
Orchitis	1 (5.3)	1 (5.3)	0	0	0
Otitis media	1 (5.3)	0	1 (5.3)	0	0
Pharyngitis	1 (5.3)	0	1 (5.3)	0	0
Pneumonia	1 (5.3)	0	1 (5.3)	0	0
Respiratory tract infection	1 (5.3)	0	0	0	1 (5.3)
Respiratory tract infection viral	1 (5.3)	0	0	1 (5.3)	0
Rhinitis	1 (5.3)	1 (5.3)	0	0	0
Rotavirus infection	1 (5.3)	0	0	1 (5.3)	0
Septic embolus	1 (5.3)	0	0	0	1 (5.3)
Skin infection	1 (5.3)	0	1 (5.3)	0	0
Staphylococcal infection	1 (5.3)	0	0	1 (5.3)	0
Streptococcal infection	1 (5.3)	0	1 (5.3)	0	0
Tinea capitis	1 (5.3)	1 (5.3)	0	0	0
Urinary tract infection enterococcal	1 (5.3)	0	0	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (5.3)	0	0	1 (5.3)	0
Viral infection	1 (5.3)	1 (5.3)	0	0	0
Vulvovaginal candidiasis	1 (5.3)	0	1 (5.3)	0	0
Injury, poisoning and procedural complications					
-Total	12 (63.2)	7 (36.8)	4 (21.1)	0	1 (5.3)
Skin abrasion	2 (10.5)	2 (10.5)	0	0	0
Transfusion reaction	2 (10.5)	2 (10.5)	0	0	0
Contusion	1 (5.3)	1 (5.3)	0	0	0
Incision site pain	1 (5.3)	1 (5.3)	0	0	0
Infusion related reaction	1 (5.3)	0	1 (5.3)	0	0
Mouth injury	1 (5.3)	1 (5.3)	0	0	0
Procedural complication	1 (5.3)	1 (5.3)	0	0	0
Procedural headache	1 (5.3)	0	1 (5.3)	0	0
Procedural pain	1 (5.3)	0	1 (5.3)	0	0
Radius fracture	1 (5.3)	0	1 (5.3)	0	0
Skin laceration	1 (5.3)	0	1 (5.3)	0	0
Stoma site irritation	1 (5.3)	1 (5.3)	0	0	0
Subdural haemorrhage	1 (5.3)	1 (5.3)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tibia fracture	1 (5.3)	0	1 (5.3)	0	0
Tongue injury	1 (5.3)	1 (5.3)	0	0	0
Transfusion related complication	1 (5.3)	0	0	0	1 (5.3)
Investigations					
-Total	16 (84.2)	0	1 (5.3)	3 (15.8)	12 (63.2)
White blood cell count decreased	10 (52.6)	1 (5.3)	0	1 (5.3)	8 (42.1)
Alanine aminotransferase increased	8 (42.1)	2 (10.5)	1 (5.3)	5 (26.3)	0
Neutrophil count decreased	8 (42.1)	1 (5.3)	0	1 (5.3)	6 (31.6)
Aspartate aminotransferase increased	6 (31.6)	2 (10.5)	1 (5.3)	1 (5.3)	2 (10.5)
Platelet count decreased	6 (31.6)	1 (5.3)	0	0	5 (26.3)
Blood creatinine increased	5 (26.3)	2 (10.5)	1 (5.3)	2 (10.5)	0
Lymphocyte count decreased	4 (21.1)	0	1 (5.3)	3 (15.8)	0
Prothrombin time prolonged	4 (21.1)	2 (10.5)	1 (5.3)	1 (5.3)	0
Blood bilirubin increased	3 (15.8)	1 (5.3)	1 (5.3)	1 (5.3)	0
International normalised ratio increased	3 (15.8)	2 (10.5)	0	1 (5.3)	0
Blood fibrinogen decreased	2 (10.5)	0	0	1 (5.3)	1 (5.3)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	2 (10.5)	2 (10.5)	0	0	0
Blood immunoglobulin m decreased	2 (10.5)	2 (10.5)	0	0	0
Blood urea increased	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Haemoglobin decreased	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Weight decreased	2 (10.5)	0	2 (10.5)	0	0
Activated partial thromboplastin time prolonged	1 (5.3)	0	1 (5.3)	0	0
Blood bicarbonate decreased	1 (5.3)	0	1 (5.3)	0	0
Blood phosphorus decreased	1 (5.3)	1 (5.3)	0	0	0
Culture stool positive	1 (5.3)	1 (5.3)	0	0	0
Protein total decreased	1 (5.3)	0	0	1 (5.3)	0
Transaminases increased	1 (5.3)	1 (5.3)	0	0	0
Weight increased	1 (5.3)	0	1 (5.3)	0	0
Metabolism and nutrition disorders					
-Total	18 (94.7)	4 (21.1)	3 (15.8)	10 (52.6)	1 (5.3)
Decreased appetite	8 (42.1)	2 (10.5)	2 (10.5)	4 (21.1)	0
Hypokalaemia	4 (21.1)	1 (5.3)	1 (5.3)	2 (10.5)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	4 (21.1)	2 (10.5)	0	2 (10.5)	0
Dehydration	3 (15.8)	0	0	3 (15.8)	0
Fluid overload	2 (10.5)	0	2 (10.5)	0	0
Hypernatraemia	2 (10.5)	0	1 (5.3)	0	1 (5.3)
Hyperphosphataemia	2 (10.5)	2 (10.5)	0	0	0
Hypoalbuminaemia	2 (10.5)	0	2 (10.5)	0	0
Hypocalcaemia	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Vitamin d deficiency	2 (10.5)	2 (10.5)	0	0	0
Acidosis	1 (5.3)	0	0	1 (5.3)	0
Hyperalbuminaemia	1 (5.3)	1 (5.3)	0	0	0
Hypercalcaemia	1 (5.3)	1 (5.3)	0	0	0
Hyperchloraemia	1 (5.3)	1 (5.3)	0	0	0
Hyperglycaemia	1 (5.3)	0	0	1 (5.3)	0
Hypermagnesaemia	1 (5.3)	1 (5.3)	0	0	0
Hyponatraemia	1 (5.3)	0	0	1 (5.3)	0
Malnutrition	1 (5.3)	0	0	1 (5.3)	0
Metabolic acidosis	1 (5.3)	0	1 (5.3)	0	0
Metabolic alkalosis	1 (5.3)	1 (5.3)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	13 (68.4)	7 (36.8)	6 (31.6)	0	0
Pain in extremity	7 (36.8)	4 (21.1)	3 (15.8)	0	0
Muscle spasms	2 (10.5)	2 (10.5)	0	0	0
Myalgia	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Arthralgia	1 (5.3)	0	1 (5.3)	0	0
Back pain	1 (5.3)	1 (5.3)	0	0	0
Coccydynia	1 (5.3)	1 (5.3)	0	0	0
Joint range of motion decreased	1 (5.3)	1 (5.3)	0	0	0
Limb discomfort	1 (5.3)	1 (5.3)	0	0	0
Musculoskeletal chest pain	1 (5.3)	1 (5.3)	0	0	0
Musculoskeletal pain	1 (5.3)	1 (5.3)	0	0	0
Neck pain	1 (5.3)	0	1 (5.3)	0	0
Osteonecrosis	1 (5.3)	0	1 (5.3)	0	0
Osteopenia	1 (5.3)	0	1 (5.3)	0	0
Toe walking	1 (5.3)	1 (5.3)	0	0	0
Nervous system disorders					
-Total	10 (52.6)	5 (26.3)	1 (5.3)	3 (15.8)	1 (5.3)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	7 (36.8)	4 (21.1)	2 (10.5)	1 (5.3)	0
Encephalopathy	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Disturbance in attention	1 (5.3)	1 (5.3)	0	0	0
Dizziness	1 (5.3)	1 (5.3)	0	0	0
Embolic stroke	1 (5.3)	0	0	0	1 (5.3)
Myoclonus	1 (5.3)	1 (5.3)	0	0	0
Seizure	1 (5.3)	0	0	1 (5.3)	0
Psychiatric disorders					
-Total	8 (42.1)	3 (15.8)	5 (26.3)	0	0
Anxiety	3 (15.8)	1 (5.3)	2 (10.5)	0	0
Confusional state	2 (10.5)	0	2 (10.5)	0	0
Delirium	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Hallucination	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Irritability	2 (10.5)	2 (10.5)	0	0	0
Agitation	1 (5.3)	0	1 (5.3)	0	0
Insomnia	1 (5.3)	0	1 (5.3)	0	0
Listless	1 (5.3)	1 (5.3)	0	0	0
Mental status changes	1 (5.3)	1 (5.3)	0	0	0
Panic attack	1 (5.3)	0	1 (5.3)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	5 (26.3)	1 (5.3)	0	2 (10.5)	2 (10.5)
Acute kidney injury	4 (21.1)	1 (5.3)	0	1 (5.3)	2 (10.5)
Haematuria	2 (10.5)	0	2 (10.5)	0	0
Oliguria	1 (5.3)	0	0	1 (5.3)	0
Renal impairment	1 (5.3)	0	0	1 (5.3)	0
Reproductive system and breast disorders					
-Total	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Scrotal pain	1 (5.3)	0	1 (5.3)	0	0
Vaginal haemorrhage	1 (5.3)	0	0	1 (5.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	15 (78.9)	5 (26.3)	3 (15.8)	3 (15.8)	4 (21.1)
Cough	8 (42.1)	7 (36.8)	1 (5.3)	0	0
Epistaxis	4 (21.1)	1 (5.3)	1 (5.3)	2 (10.5)	0
Hypoxia	4 (21.1)	0	1 (5.3)	1 (5.3)	2 (10.5)
Pulmonary oedema	4 (21.1)	1 (5.3)	0	3 (15.8)	0
Pleural effusion	2 (10.5)	0	1 (5.3)	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis allergic	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Rhinorrhoea	2 (10.5)	2 (10.5)	0	0	0
Acute respiratory failure	1 (5.3)	0	0	0	1 (5.3)
Dysphonia	1 (5.3)	1 (5.3)	0	0	0
Dyspnoea	1 (5.3)	0	0	1 (5.3)	0
Nasal congestion	1 (5.3)	1 (5.3)	0	0	0
Oropharyngeal pain	1 (5.3)	1 (5.3)	0	0	0
Pharyngeal ulceration	1 (5.3)	0	1 (5.3)	0	0
Respiratory depression	1 (5.3)	0	1 (5.3)	0	0
Respiratory distress	1 (5.3)	0	0	0	1 (5.3)
Tachypnoea	1 (5.3)	1 (5.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	10 (52.6)	6 (31.6)	4 (21.1)	0	0
Rash	4 (21.1)	2 (10.5)	2 (10.5)	0	0
Rash maculo-papular	3 (15.8)	2 (10.5)	1 (5.3)	0	0
Erythema	2 (10.5)	2 (10.5)	0	0	0
Hyperhidrosis	2 (10.5)	2 (10.5)	0	0	0
Pruritus	2 (10.5)	2 (10.5)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acne	1 (5.3)	1 (5.3)	0	0	0
Dermatitis atopic	1 (5.3)	1 (5.3)	0	0	0
Dry skin	1 (5.3)	1 (5.3)	0	0	0
Macule	1 (5.3)	1 (5.3)	0	0	0
Night sweats	1 (5.3)	0	1 (5.3)	0	0
Papule	1 (5.3)	1 (5.3)	0	0	0
Rash papular	1 (5.3)	1 (5.3)	0	0	0
Rash vesicular	1 (5.3)	1 (5.3)	0	0	0
Skin irritation	1 (5.3)	1 (5.3)	0	0	0
Vascular disorders					
-Total	8 (42.1)	2 (10.5)	0	2 (10.5)	4 (21.1)
Hypotension	7 (36.8)	1 (5.3)	0	2 (10.5)	4 (21.1)
Hypertension	3 (15.8)	1 (5.3)	1 (5.3)	1 (5.3)	0
Flushing	2 (10.5)	2 (10.5)	0	0	0
Capillary leak syndrome	1 (5.3)	0	0	0	1 (5.3)

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174j
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (100)	0	4 (8.9)	11 (24.4)	30 (66.7)
Blood and lymphatic system disorders					
-Total	32 (71.1)	1 (2.2)	3 (6.7)	20 (44.4)	8 (17.8)
Anaemia	20 (44.4)	2 (4.4)	4 (8.9)	13 (28.9)	1 (2.2)
Febrile neutropenia	16 (35.6)	0	0	15 (33.3)	1 (2.2)
Thrombocytopenia	8 (17.8)	0	1 (2.2)	3 (6.7)	4 (8.9)
Neutropenia	7 (15.6)	0	0	2 (4.4)	5 (11.1)
Disseminated intravascular coagulation	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Lymphopenia	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Lymphadenopathy	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	14 (31.1)	7 (15.6)	6 (13.3)	1 (2.2)	0
Tachycardia	11 (24.4)	6 (13.3)	4 (8.9)	1 (2.2)	0
Sinus tachycardia	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Cardiac dysfunction	1 (2.2)	1 (2.2)	0	0	0
Left ventricular dysfunction	1 (2.2)	0	0	1 (2.2)	0
Palpitations	1 (2.2)	1 (2.2)	0	0	0
Pericardial effusion	1 (2.2)	1 (2.2)	0	0	0
Sinus bradycardia	1 (2.2)	1 (2.2)	0	0	0
Ventricular tachycardia	1 (2.2)	0	1 (2.2)	0	0
Ear and labyrinth disorders					
-Total	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Ear pain	1 (2.2)	1 (2.2)	0	0	0
Hypoacusis	1 (2.2)	0	1 (2.2)	0	0
Tympanic membrane perforation	1 (2.2)	0	1 (2.2)	0	0
Endocrine disorders					
-Total	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Adrenal insufficiency	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Eye disorders					

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (20.0)	3 (6.7)	6 (13.3)	0	0
Dry eye	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Eye pain	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Uveitis	2 (4.4)	0	2 (4.4)	0	0
Conjunctival haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Ocular hypertension	1 (2.2)	0	1 (2.2)	0	0
Papilloedema	1 (2.2)	0	1 (2.2)	0	0
Periorbital oedema	1 (2.2)	1 (2.2)	0	0	0
Retinal haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Vision blurred	1 (2.2)	0	1 (2.2)	0	0
Visual impairment	1 (2.2)	0	1 (2.2)	0	0
Gastrointestinal disorders					
-Total	28 (62.2)	10 (22.2)	11 (24.4)	7 (15.6)	0
Nausea	17 (37.8)	4 (8.9)	10 (22.2)	3 (6.7)	0
Vomiting	16 (35.6)	10 (22.2)	5 (11.1)	1 (2.2)	0
Diarrhoea	12 (26.7)	8 (17.8)	4 (8.9)	0	0
Abdominal pain	6 (13.3)	4 (8.9)	2 (4.4)	0	0
Constipation	4 (8.9)	4 (8.9)	0	0	0
Abdominal pain upper	2 (4.4)	1 (2.2)	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral pain	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Pancreatitis	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Stomatitis	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Abdominal distension	1 (2.2)	0	1 (2.2)	0	0
Abdominal pain lower	1 (2.2)	0	1 (2.2)	0	0
Abdominal tenderness	1 (2.2)	1 (2.2)	0	0	0
Anal incontinence	1 (2.2)	1 (2.2)	0	0	0
Ascites	1 (2.2)	0	0	1 (2.2)	0
Dysphagia	1 (2.2)	0	1 (2.2)	0	0
Enterocolitis	1 (2.2)	0	0	1 (2.2)	0
Flatulence	1 (2.2)	1 (2.2)	0	0	0
Gastrointestinal haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Gastrooesophageal reflux disease	1 (2.2)	1 (2.2)	0	0	0
Glossodynia	1 (2.2)	1 (2.2)	0	0	0
Haematemesis	1 (2.2)	1 (2.2)	0	0	0
Ileus	1 (2.2)	0	0	1 (2.2)	0
Tooth socket haemorrhage	1 (2.2)	1 (2.2)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	27 (60.0)	12 (26.7)	7 (15.6)	7 (15.6)	1 (2.2)
Pyrexia	14 (31.1)	5 (11.1)	4 (8.9)	4 (8.9)	1 (2.2)
Fatigue	10 (22.2)	9 (20.0)	1 (2.2)	0	0
Chills	7 (15.6)	6 (13.3)	1 (2.2)	0	0
Catheter site pain	3 (6.7)	0	3 (6.7)	0	0
Generalised oedema	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Malaise	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Acquired gene mutation	1 (2.2)	1 (2.2)	0	0	0
Asthenia	1 (2.2)	1 (2.2)	0	0	0
Cyst	1 (2.2)	0	0	1 (2.2)	0
Facial pain	1 (2.2)	0	1 (2.2)	0	0
Influenza like illness	1 (2.2)	1 (2.2)	0	0	0
Non-cardiac chest pain	1 (2.2)	1 (2.2)	0	0	0
Oedema peripheral	1 (2.2)	1 (2.2)	0	0	0
Pain	1 (2.2)	0	0	1 (2.2)	0
Physical deconditioning	1 (2.2)	0	0	1 (2.2)	0
Hepatobiliary disorders					

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Hepatomegaly	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Gallbladder enlargement	1 (2.2)	1 (2.2)	0	0	0
Hepatosplenomegaly	1 (2.2)	1 (2.2)	0	0	0
Immune system disorders					
-Total	39 (86.7)	4 (8.9)	22 (48.9)	7 (15.6)	6 (13.3)
Cytokine release syndrome	32 (71.1)	5 (11.1)	16 (35.6)	5 (11.1)	6 (13.3)
Hypogammaglobulinaemia	20 (44.4)	1 (2.2)	17 (37.8)	2 (4.4)	0
Immunodeficiency common variable	2 (4.4)	0	2 (4.4)	0	0
Drug hypersensitivity	1 (2.2)	0	1 (2.2)	0	0
Graft versus host disease	1 (2.2)	0	1 (2.2)	0	0
Graft versus host disease in gastrointestinal tract	1 (2.2)	0	1 (2.2)	0	0
Immunodeficiency	1 (2.2)	0	1 (2.2)	0	0
Seasonal allergy	1 (2.2)	1 (2.2)	0	0	0
Infections and infestations					
-Total	30 (66.7)	4 (8.9)	16 (35.6)	9 (20.0)	1 (2.2)
Upper respiratory tract infection	5 (11.1)	2 (4.4)	2 (4.4)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	4 (8.9)	1 (2.2)	3 (6.7)	0	0
Sinusitis	4 (8.9)	0	4 (8.9)	0	0
Clostridium difficile infection	3 (6.7)	0	3 (6.7)	0	0
Otitis media	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Pneumonia	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Urinary tract infection	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Viral upper respiratory tract infection	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Clostridium difficile colitis	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Cytomegalovirus infection	2 (4.4)	2 (4.4)	0	0	0
Otitis media acute	2 (4.4)	0	2 (4.4)	0	0
Parainfluenzae virus infection	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Rhinovirus infection	2 (4.4)	2 (4.4)	0	0	0
Viral infection	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Acute sinusitis	1 (2.2)	0	1 (2.2)	0	0
Body tinea	1 (2.2)	1 (2.2)	0	0	0
Catheter site infection	1 (2.2)	0	0	1 (2.2)	0
Cholecystitis infective	1 (2.2)	0	0	1 (2.2)	0
Corona virus infection	1 (2.2)	0	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterococcal infection	1 (2.2)	1 (2.2)	0	0	0
Escherichia urinary tract infection	1 (2.2)	0	0	1 (2.2)	0
Gastroenteritis	1 (2.2)	0	1 (2.2)	0	0
Gastroenteritis norovirus	1 (2.2)	0	1 (2.2)	0	0
Gastroenteritis viral	1 (2.2)	1 (2.2)	0	0	0
Haemophilus infection	1 (2.2)	0	1 (2.2)	0	0
Human herpesvirus 6 infection	1 (2.2)	0	1 (2.2)	0	0
Hypopyon	1 (2.2)	0	1 (2.2)	0	0
Meningitis aseptic	1 (2.2)	0	1 (2.2)	0	0
Oral candidiasis	1 (2.2)	1 (2.2)	0	0	0
Otitis externa	1 (2.2)	0	1 (2.2)	0	0
Paronychia	1 (2.2)	1 (2.2)	0	0	0
Rash pustular	1 (2.2)	0	1 (2.2)	0	0
Respiratory syncytial virus infection	1 (2.2)	0	0	1 (2.2)	0
Sepsis	1 (2.2)	0	0	0	1 (2.2)
Skin infection	1 (2.2)	0	1 (2.2)	0	0
Staphylococcal infection	1 (2.2)	1 (2.2)	0	0	0
Subcutaneous abscess	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal candidiasis	1 (2.2)	1 (2.2)	0	0	0
Vulvovaginal mycotic infection	1 (2.2)	0	1 (2.2)	0	0
Injury, poisoning and procedural complications					
-Total	10 (22.2)	4 (8.9)	4 (8.9)	2 (4.4)	0
Procedural pain	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Infusion related reaction	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Contusion	2 (4.4)	2 (4.4)	0	0	0
Arthropod bite	1 (2.2)	1 (2.2)	0	0	0
Foot fracture	1 (2.2)	0	1 (2.2)	0	0
Limb injury	1 (2.2)	1 (2.2)	0	0	0
Post procedural haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Procedural nausea	1 (2.2)	0	1 (2.2)	0	0
Procedural site reaction	1 (2.2)	1 (2.2)	0	0	0
Sunburn	1 (2.2)	1 (2.2)	0	0	0
Tracheal haemorrhage	1 (2.2)	0	0	1 (2.2)	0
Transfusion reaction	1 (2.2)	0	1 (2.2)	0	0
Investigations					
-Total	40 (88.9)	2 (4.4)	4 (8.9)	12 (26.7)	22 (48.9)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	25 (55.6)	3 (6.7)	1 (2.2)	11 (24.4)	10 (22.2)
Neutrophil count decreased	20 (44.4)	0	2 (4.4)	3 (6.7)	15 (33.3)
Aspartate aminotransferase increased	14 (31.1)	2 (4.4)	3 (6.7)	7 (15.6)	2 (4.4)
Platelet count decreased	14 (31.1)	2 (4.4)	2 (4.4)	3 (6.7)	7 (15.6)
Alanine aminotransferase increased	13 (28.9)	3 (6.7)	1 (2.2)	9 (20.0)	0
Lymphocyte count decreased	12 (26.7)	1 (2.2)	2 (4.4)	4 (8.9)	5 (11.1)
International normalised ratio increased	6 (13.3)	6 (13.3)	0	0	0
Blood bilirubin increased	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Prothrombin time prolonged	5 (11.1)	3 (6.7)	2 (4.4)	0	0
Activated partial thromboplastin time prolonged	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Blood creatinine increased	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Blood fibrinogen decreased	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Blood immunoglobulin m decreased	2 (4.4)	2 (4.4)	0	0	0
Blood magnesium decreased	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Blood phosphorus increased	2 (4.4)	2 (4.4)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	2 (4.4)	2 (4.4)	0	0	0
C-reactive protein increased	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Lipase increased	2 (4.4)	0	0	0	2 (4.4)
Serum ferritin increased	2 (4.4)	0	2 (4.4)	0	0
Transaminases increased	2 (4.4)	2 (4.4)	0	0	0
Weight decreased	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Blood alkaline phosphatase increased	1 (2.2)	1 (2.2)	0	0	0
Blood immunoglobulin a decreased	1 (2.2)	1 (2.2)	0	0	0
Blood immunoglobulin g decreased	1 (2.2)	0	1 (2.2)	0	0
Blood lactate dehydrogenase increased	1 (2.2)	1 (2.2)	0	0	0
Blood lactic acid increased	1 (2.2)	0	0	0	1 (2.2)
Blood sodium increased	1 (2.2)	0	1 (2.2)	0	0
Blood urea increased	1 (2.2)	1 (2.2)	0	0	0
Cardiac murmur	1 (2.2)	1 (2.2)	0	0	0
Fibrin d dimer increased	1 (2.2)	1 (2.2)	0	0	0
Haemoglobin decreased	1 (2.2)	1 (2.2)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic enzyme increased	1 (2.2)	0	1 (2.2)	0	0
Norovirus test positive	1 (2.2)	1 (2.2)	0	0	0
Oxygen saturation decreased	1 (2.2)	1 (2.2)	0	0	0
Pulmonary function test decreased	1 (2.2)	0	1 (2.2)	0	0
Weight increased	1 (2.2)	1 (2.2)	0	0	0
Metabolism and nutrition disorders					
-Total	25 (55.6)	4 (8.9)	5 (11.1)	13 (28.9)	3 (6.7)
Hypokalaemia	15 (33.3)	3 (6.7)	5 (11.1)	6 (13.3)	1 (2.2)
Decreased appetite	14 (31.1)	3 (6.7)	3 (6.7)	8 (17.8)	0
Hyperphosphataemia	6 (13.3)	6 (13.3)	0	0	0
Hypophosphataemia	6 (13.3)	0	0	5 (11.1)	1 (2.2)
Hyperuricaemia	3 (6.7)	2 (4.4)	0	0	1 (2.2)
Hypoalbuminaemia	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Hyperglycaemia	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Hypernatraemia	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Hypertriglyceridaemia	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Tumour lysis syndrome	2 (4.4)	0	0	2 (4.4)	0
Acidosis	1 (2.2)	1 (2.2)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (2.2)	1 (2.2)	0	0	0
Fluid overload	1 (2.2)	1 (2.2)	0	0	0
Hypocalcaemia	1 (2.2)	1 (2.2)	0	0	0
Hypomagnesaemia	1 (2.2)	1 (2.2)	0	0	0
Hyponatraemia	1 (2.2)	0	0	1 (2.2)	0
Iron overload	1 (2.2)	0	0	1 (2.2)	0
Musculoskeletal and connective tissue disorders					
-Total	12 (26.7)	7 (15.6)	4 (8.9)	1 (2.2)	0
Arthralgia	4 (8.9)	3 (6.7)	0	1 (2.2)	0
Pain in extremity	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Muscular weakness	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Myalgia	3 (6.7)	3 (6.7)	0	0	0
Musculoskeletal pain	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Flank pain	1 (2.2)	0	1 (2.2)	0	0
Joint range of motion decreased	1 (2.2)	1 (2.2)	0	0	0
Musculoskeletal chest pain	1 (2.2)	1 (2.2)	0	0	0
Pain in jaw	1 (2.2)	1 (2.2)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (6.7)	0	2 (4.4)	0	1 (2.2)
Glioblastoma multiforme	1 (2.2)	0	0	0	1 (2.2)
Myelodysplastic syndrome	1 (2.2)	0	1 (2.2)	0	0
Skin papilloma	1 (2.2)	0	1 (2.2)	0	0
Nervous system disorders					
-Total	25 (55.6)	12 (26.7)	11 (24.4)	2 (4.4)	0
Headache	17 (37.8)	11 (24.4)	5 (11.1)	1 (2.2)	0
Dizziness	5 (11.1)	5 (11.1)	0	0	0
Seizure	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Dysarthria	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Encephalopathy	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Peroneal nerve palsy	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Tremor	2 (4.4)	2 (4.4)	0	0	0
Asterixis	1 (2.2)	1 (2.2)	0	0	0
Ataxia	1 (2.2)	0	1 (2.2)	0	0
Depressed level of consciousness	1 (2.2)	1 (2.2)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Idiopathic intracranial hypertension	1 (2.2)	0	1 (2.2)	0	0
Migraine	1 (2.2)	0	1 (2.2)	0	0
Neuropathy peripheral	1 (2.2)	0	1 (2.2)	0	0
Pleocytosis	1 (2.2)	1 (2.2)	0	0	0
Somnolence	1 (2.2)	1 (2.2)	0	0	0
Product issues					
-Total	1 (2.2)	1 (2.2)	0	0	0
Device occlusion	1 (2.2)	1 (2.2)	0	0	0
Psychiatric disorders					
-Total	9 (20.0)	5 (11.1)	3 (6.7)	1 (2.2)	0
Anxiety	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Confusional state	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Delirium	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Depression	2 (4.4)	2 (4.4)	0	0	0
Adjustment disorder	1 (2.2)	0	1 (2.2)	0	0
Agitation	1 (2.2)	0	1 (2.2)	0	0
Sleep disorder	1 (2.2)	0	1 (2.2)	0	0
Suicidal ideation	1 (2.2)	1 (2.2)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	10 (22.2)	2 (4.4)	2 (4.4)	4 (8.9)	2 (4.4)
Acute kidney injury	5 (11.1)	0	1 (2.2)	3 (6.7)	1 (2.2)
Haematuria	3 (6.7)	0	0	2 (4.4)	1 (2.2)
Dysuria	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Calculus urinary	1 (2.2)	0	1 (2.2)	0	0
Nephrolithiasis	1 (2.2)	0	0	1 (2.2)	0
Oliguria	1 (2.2)	0	0	1 (2.2)	0
Pollakiuria	1 (2.2)	1 (2.2)	0	0	0
Renal failure	1 (2.2)	0	0	0	1 (2.2)
Urinary incontinence	1 (2.2)	1 (2.2)	0	0	0
Reproductive system and breast disorders					
-Total	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Vulvovaginal adhesion	2 (4.4)	2 (4.4)	0	0	0
Oedema genital	1 (2.2)	0	1 (2.2)	0	0
Ovarian failure	1 (2.2)	0	0	1 (2.2)	0
Respiratory, thoracic and mediastinal disorders					

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	23 (51.1)	9 (20.0)	6 (13.3)	4 (8.9)	4 (8.9)
Cough	6 (13.3)	5 (11.1)	1 (2.2)	0	0
Epistaxis	6 (13.3)	3 (6.7)	0	2 (4.4)	1 (2.2)
Hypoxia	6 (13.3)	0	2 (4.4)	3 (6.7)	1 (2.2)
Pleural effusion	6 (13.3)	2 (4.4)	3 (6.7)	1 (2.2)	0
Oropharyngeal pain	5 (11.1)	3 (6.7)	2 (4.4)	0	0
Nasal congestion	4 (8.9)	4 (8.9)	0	0	0
Rhinorrhoea	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Tachypnoea	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Pulmonary oedema	3 (6.7)	0	0	1 (2.2)	2 (4.4)
Respiratory failure	3 (6.7)	0	0	0	3 (6.7)
Haemoptysis	2 (4.4)	1 (2.2)	0	0	1 (2.2)
Rhinitis allergic	2 (4.4)	2 (4.4)	0	0	0
Atelectasis	1 (2.2)	1 (2.2)	0	0	0
Dyspnoea	1 (2.2)	0	0	0	1 (2.2)
Interstitial lung disease	1 (2.2)	0	0	0	1 (2.2)
Oropharyngeal plaque	1 (2.2)	1 (2.2)	0	0	0
Pharyngeal erythema	1 (2.2)	1 (2.2)	0	0	0
Pharyngeal lesion	1 (2.2)	0	0	1 (2.2)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wheezing	1 (2.2)	0	1 (2.2)	0	0
Skin and subcutaneous tissue disorders					
-Total	20 (44.4)	12 (26.7)	5 (11.1)	3 (6.7)	0
Dry skin	4 (8.9)	4 (8.9)	0	0	0
Petechiae	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Rash	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Erythema	3 (6.7)	3 (6.7)	0	0	0
Ingrowing nail	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Hyperhidrosis	2 (4.4)	2 (4.4)	0	0	0
Pruritus	2 (4.4)	2 (4.4)	0	0	0
Rash erythematous	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Rash maculo-papular	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Alopecia	1 (2.2)	0	1 (2.2)	0	0
Dermatitis	1 (2.2)	1 (2.2)	0	0	0
Dermatitis acneiform	1 (2.2)	0	0	1 (2.2)	0
Dermatitis diaper	1 (2.2)	1 (2.2)	0	0	0
Ecchymosis	1 (2.2)	0	0	1 (2.2)	0
Eczema	1 (2.2)	1 (2.2)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Keloid scar	1 (2.2)	0	1 (2.2)	0	0
Livedo reticularis	1 (2.2)	1 (2.2)	0	0	0
Macule	1 (2.2)	1 (2.2)	0	0	0
Papule	1 (2.2)	1 (2.2)	0	0	0
Rash follicular	1 (2.2)	1 (2.2)	0	0	0
Rash macular	1 (2.2)	1 (2.2)	0	0	0
Rash papular	1 (2.2)	1 (2.2)	0	0	0
Rash pruritic	1 (2.2)	1 (2.2)	0	0	0
Skin exfoliation	1 (2.2)	1 (2.2)	0	0	0
Skin fissures	1 (2.2)	1 (2.2)	0	0	0
Vascular disorders					
-Total	17 (37.8)	1 (2.2)	6 (13.3)	6 (13.3)	4 (8.9)
Hypertension	9 (20.0)	2 (4.4)	7 (15.6)	0	0
Hypotension	9 (20.0)	0	0	5 (11.1)	4 (8.9)
Orthostatic hypotension	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Embolism	1 (2.2)	0	0	1 (2.2)	0
Haematoma	1 (2.2)	0	1 (2.2)	0	0
Hot flush	1 (2.2)	1 (2.2)	0	0	0
Secondary hypertension	1 (2.2)	0	1 (2.2)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174k
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: US

			All patients N=64		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	63 (98.4)	2 (3.1)	7 (10.9)	14 (21.9)	40 (62.5)
Blood and lymphatic system disorders					
-Total	43 (67.2)	2 (3.1)	3 (4.7)	27 (42.2)	11 (17.2)
Anaemia	27 (42.2)	3 (4.7)	5 (7.8)	18 (28.1)	1 (1.6)
Febrile neutropenia	22 (34.4)	0	0	22 (34.4)	0
Neutropenia	8 (12.5)	0	0	3 (4.7)	5 (7.8)
Thrombocytopenia	8 (12.5)	0	0	2 (3.1)	6 (9.4)
Disseminated intravascular coagulation	4 (6.3)	0	2 (3.1)	2 (3.1)	0
Lymphopenia	3 (4.7)	0	1 (1.6)	1 (1.6)	1 (1.6)
Coagulopathy	1 (1.6)	1 (1.6)	0	0	0
Pancytopenia	1 (1.6)	0	0	0	1 (1.6)
Cardiac disorders					
-Total	22 (34.4)	11 (17.2)	9 (14.1)	2 (3.1)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	15 (23.4)	8 (12.5)	5 (7.8)	2 (3.1)	0
Sinus tachycardia	5 (7.8)	3 (4.7)	2 (3.1)	0	0
Pericardial effusion	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Atrioventricular block second degree	1 (1.6)	1 (1.6)	0	0	0
Bradycardia	1 (1.6)	0	1 (1.6)	0	0
Cardiac dysfunction	1 (1.6)	1 (1.6)	0	0	0
Left ventricular dysfunction	1 (1.6)	0	0	1 (1.6)	0
Palpitations	1 (1.6)	1 (1.6)	0	0	0
Sinus bradycardia	1 (1.6)	1 (1.6)	0	0	0
Ventricular tachycardia	1 (1.6)	0	1 (1.6)	0	0
Ear and labyrinth disorders					
-Total	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Ear pain	2 (3.1)	2 (3.1)	0	0	0
Hypoacusis	1 (1.6)	0	1 (1.6)	0	0
Endocrine disorders					
-Total	1 (1.6)	0	1 (1.6)	0	0
Adrenal insufficiency	1 (1.6)	0	1 (1.6)	0	0
Eye disorders					
-Total	13 (20.3)	6 (9.4)	7 (10.9)	0	0

Timing: within 8 weeks post infusion, Region: US

Primary system organ class Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Periorbital oedema	4 (6.3)	3 (4.7)	1 (1.6)	0	0
Conjunctival haemorrhage	3 (4.7)	3 (4.7)	0	0	0
Eye pain	3 (4.7)	1 (1.6)	2 (3.1)	0	0
Vision blurred	3 (4.7)	1 (1.6)	2 (3.1)	0	0
Photophobia	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Retinal haemorrhage	2 (3.1)	2 (3.1)	0	0	0
Uveitis	2 (3.1)	0	2 (3.1)	0	0
Ocular hypertension	1 (1.6)	0	1 (1.6)	0	0
Papilloedema	1 (1.6)	0	1 (1.6)	0	0
Visual impairment	1 (1.6)	0	1 (1.6)	0	0
Gastrointestinal disorders					
-Total	36 (56.3)	11 (17.2)	14 (21.9)	11 (17.2)	0
Vomiting	22 (34.4)	13 (20.3)	6 (9.4)	3 (4.7)	0
Nausea	21 (32.8)	6 (9.4)	12 (18.8)	3 (4.7)	0
Diarrhoea	18 (28.1)	11 (17.2)	6 (9.4)	1 (1.6)	0
Abdominal pain	9 (14.1)	6 (9.4)	2 (3.1)	1 (1.6)	0
Constipation	7 (10.9)	6 (9.4)	1 (1.6)	0	0
Abdominal distension	2 (3.1)	0	2 (3.1)	0	0
Abdominal pain upper	2 (3.1)	0	2 (3.1)	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphagia	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Haematemesis	2 (3.1)	2 (3.1)	0	0	0
Pancreatitis	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Stomatitis	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Abdominal discomfort	1 (1.6)	1 (1.6)	0	0	0
Abdominal pain lower	1 (1.6)	0	1 (1.6)	0	0
Abdominal tenderness	1 (1.6)	1 (1.6)	0	0	0
Anal incontinence	1 (1.6)	1 (1.6)	0	0	0
Ascites	1 (1.6)	0	0	1 (1.6)	0
Dyspepsia	1 (1.6)	0	1 (1.6)	0	0
Flatulence	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Gastrooesophageal reflux disease	1 (1.6)	1 (1.6)	0	0	0
Glossodynia	1 (1.6)	1 (1.6)	0	0	0
Ileus	1 (1.6)	0	0	1 (1.6)	0
Intestinal obstruction	1 (1.6)	0	0	1 (1.6)	0
Lip pain	1 (1.6)	0	1 (1.6)	0	0
Mouth haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Tooth socket haemorrhage	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	32 (50.0)	12 (18.8)	10 (15.6)	9 (14.1)	1 (1.6)
Pyrexia	16 (25.0)	3 (4.7)	7 (10.9)	5 (7.8)	1 (1.6)
Fatigue	13 (20.3)	10 (15.6)	2 (3.1)	1 (1.6)	0
Chills	8 (12.5)	8 (12.5)	0	0	0
Catheter site pain	3 (4.7)	1 (1.6)	2 (3.1)	0	0
Malaise	3 (4.7)	0	3 (4.7)	0	0
Pain	3 (4.7)	0	1 (1.6)	2 (3.1)	0
Face oedema	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Generalised oedema	2 (3.1)	0	2 (3.1)	0	0
Oedema peripheral	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Asthenia	1 (1.6)	1 (1.6)	0	0	0
Catheter site extravasation	1 (1.6)	0	1 (1.6)	0	0
Catheter site haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Facial pain	1 (1.6)	0	1 (1.6)	0	0
Injection site haematoma	1 (1.6)	1 (1.6)	0	0	0
Localised oedema	1 (1.6)	0	0	1 (1.6)	0
Mucosal haemorrhage	1 (1.6)	0	1 (1.6)	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	1 (1.6)	0	0	1 (1.6)	0
Non-cardiac chest pain	1 (1.6)	1 (1.6)	0	0	0
Peripheral swelling	1 (1.6)	0	1 (1.6)	0	0
Physical deconditioning	1 (1.6)	0	0	1 (1.6)	0
Hepatobiliary disorders					
-Total	7 (10.9)	3 (4.7)	2 (3.1)	2 (3.1)	0
Hepatomegaly	3 (4.7)	1 (1.6)	2 (3.1)	0	0
Hyperbilirubinaemia	3 (4.7)	0	1 (1.6)	2 (3.1)	0
Gallbladder enlargement	1 (1.6)	1 (1.6)	0	0	0
Hepatosplenomegaly	1 (1.6)	1 (1.6)	0	0	0
Immune system disorders					
-Total	57 (89.1)	5 (7.8)	30 (46.9)	11 (17.2)	11 (17.2)
Cytokine release syndrome	50 (78.1)	6 (9.4)	25 (39.1)	8 (12.5)	11 (17.2)
Hypogammaglobulinaemia	25 (39.1)	3 (4.7)	18 (28.1)	4 (6.3)	0
Drug hypersensitivity	1 (1.6)	0	1 (1.6)	0	0
Graft versus host disease in skin	1 (1.6)	1 (1.6)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.6)	0	1 (1.6)	0	0
Infections and infestations					
-Total	26 (40.6)	5 (7.8)	14 (21.9)	6 (9.4)	1 (1.6)

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	4 (6.3)	1 (1.6)	2 (3.1)	1 (1.6)	0
Clostridium difficile infection	4 (6.3)	0	4 (6.3)	0	0
Rhinovirus infection	3 (4.7)	3 (4.7)	0	0	0
Gastroenteritis	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Pneumonia	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Staphylococcal infection	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Body tinea	1 (1.6)	1 (1.6)	0	0	0
Catheter site cellulitis	1 (1.6)	1 (1.6)	0	0	0
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cytomegalovirus infection	1 (1.6)	1 (1.6)	0	0	0
Enterococcal infection	1 (1.6)	1 (1.6)	0	0	0
Folliculitis	1 (1.6)	0	1 (1.6)	0	0
Fungal skin infection	1 (1.6)	1 (1.6)	0	0	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Herpes simplex	1 (1.6)	1 (1.6)	0	0	0
Human herpesvirus 6 infection	1 (1.6)	0	1 (1.6)	0	0
Hypopyon	1 (1.6)	0	1 (1.6)	0	0
Influenza	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral candidiasis	1 (1.6)	1 (1.6)	0	0	0
Orchitis	1 (1.6)	1 (1.6)	0	0	0
Pharyngitis	1 (1.6)	0	1 (1.6)	0	0
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Skin infection	1 (1.6)	0	1 (1.6)	0	0
Streptococcal infection	1 (1.6)	0	1 (1.6)	0	0
Upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Urinary tract infection enterococcal	1 (1.6)	0	0	1 (1.6)	0
Viral infection	1 (1.6)	0	1 (1.6)	0	0
Viral upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Vulvovaginal candidiasis	1 (1.6)	1 (1.6)	0	0	0
Injury, poisoning and procedural complications					
-Total	15 (23.4)	8 (12.5)	5 (7.8)	1 (1.6)	1 (1.6)
Procedural pain	3 (4.7)	1 (1.6)	2 (3.1)	0	0
Transfusion reaction	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Infusion related reaction	2 (3.1)	0	2 (3.1)	0	0
Contusion	1 (1.6)	1 (1.6)	0	0	0
Incision site pain	1 (1.6)	1 (1.6)	0	0	0
Limb injury	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mouth injury	1 (1.6)	1 (1.6)	0	0	0
Post procedural haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Procedural complication	1 (1.6)	1 (1.6)	0	0	0
Procedural headache	1 (1.6)	0	1 (1.6)	0	0
Procedural site reaction	1 (1.6)	1 (1.6)	0	0	0
Skin abrasion	1 (1.6)	1 (1.6)	0	0	0
Stoma site irritation	1 (1.6)	1 (1.6)	0	0	0
Subdural haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Tibia fracture	1 (1.6)	0	1 (1.6)	0	0
Tongue injury	1 (1.6)	1 (1.6)	0	0	0
Tracheal haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Transfusion related complication	1 (1.6)	0	0	0	1 (1.6)
Investigations					
-Total	52 (81.3)	4 (6.3)	4 (6.3)	13 (20.3)	31 (48.4)
White blood cell count decreased	30 (46.9)	3 (4.7)	1 (1.6)	10 (15.6)	16 (25.0)
Neutrophil count decreased	25 (39.1)	0	2 (3.1)	4 (6.3)	19 (29.7)
Alanine aminotransferase increased	19 (29.7)	5 (7.8)	3 (4.7)	11 (17.2)	0
Platelet count decreased	19 (29.7)	3 (4.7)	2 (3.1)	2 (3.1)	12 (18.8)
Aspartate aminotransferase increased	18 (28.1)	3 (4.7)	4 (6.3)	7 (10.9)	4 (6.3)

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	14 (21.9)	1 (1.6)	2 (3.1)	6 (9.4)	5 (7.8)
Blood creatinine increased	9 (14.1)	5 (7.8)	2 (3.1)	2 (3.1)	0
International normalised ratio increased	9 (14.1)	8 (12.5)	0	1 (1.6)	0
Prothrombin time prolonged	9 (14.1)	5 (7.8)	3 (4.7)	1 (1.6)	0
Blood bilirubin increased	7 (10.9)	2 (3.1)	3 (4.7)	2 (3.1)	0
Activated partial thromboplastin time prolonged	5 (7.8)	3 (4.7)	2 (3.1)	0	0
Blood fibrinogen decreased	4 (6.3)	0	1 (1.6)	2 (3.1)	1 (1.6)
Blood immunoglobulin m decreased	4 (6.3)	4 (6.3)	0	0	0
Blood immunoglobulin a decreased	3 (4.7)	3 (4.7)	0	0	0
Blood urea increased	3 (4.7)	1 (1.6)	1 (1.6)	1 (1.6)	0
Blood phosphorus increased	2 (3.1)	2 (3.1)	0	0	0
Lipase increased	2 (3.1)	0	0	0	2 (3.1)
Transaminases increased	2 (3.1)	2 (3.1)	0	0	0
Blood bicarbonate decreased	1 (1.6)	0	1 (1.6)	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Blood lactic acid increased	1 (1.6)	0	0	0	1 (1.6)
Blood magnesium decreased	1 (1.6)	0	0	1 (1.6)	0
Blood phosphorus decreased	1 (1.6)	1 (1.6)	0	0	0
Blood sodium increased	1 (1.6)	0	1 (1.6)	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	1 (1.6)	1 (1.6)	0	0	0
C-reactive protein increased	1 (1.6)	0	0	1 (1.6)	0
Cardiac murmur	1 (1.6)	1 (1.6)	0	0	0
Culture stool positive	1 (1.6)	1 (1.6)	0	0	0
Fibrin d dimer increased	1 (1.6)	1 (1.6)	0	0	0
Haemoglobin decreased	1 (1.6)	0	0	1 (1.6)	0
Hepatic enzyme increased	1 (1.6)	0	1 (1.6)	0	0
Norovirus test positive	1 (1.6)	1 (1.6)	0	0	0
Protein total decreased	1 (1.6)	0	0	1 (1.6)	0
Pulmonary function test decreased	1 (1.6)	0	1 (1.6)	0	0
Serum ferritin increased	1 (1.6)	0	1 (1.6)	0	0
Metabolism and nutrition disorders					
-Total	39 (60.9)	5 (7.8)	10 (15.6)	21 (32.8)	3 (4.7)
Decreased appetite	20 (31.3)	4 (6.3)	4 (6.3)	12 (18.8)	0
Hypokalaemia	16 (25.0)	3 (4.7)	6 (9.4)	7 (10.9)	0
Hypophosphataemia	9 (14.1)	2 (3.1)	0	6 (9.4)	1 (1.6)
Hyperphosphataemia	8 (12.5)	8 (12.5)	0	0	0
Hypoalbuminaemia	5 (7.8)	1 (1.6)	3 (4.7)	1 (1.6)	0
Hypernatraemia	4 (6.3)	1 (1.6)	2 (3.1)	0	1 (1.6)

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	3 (4.7)	1 (1.6)	0	2 (3.1)	0
Fluid overload	3 (4.7)	1 (1.6)	2 (3.1)	0	0
Hyperglycaemia	3 (4.7)	0	2 (3.1)	1 (1.6)	0
Hyperuricaemia	3 (4.7)	2 (3.1)	0	0	1 (1.6)
Hypocalcaemia	3 (4.7)	1 (1.6)	1 (1.6)	1 (1.6)	0
Acidosis	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Hypertriglyceridaemia	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Hyponatraemia	2 (3.1)	0	0	2 (3.1)	0
Hyperalbuminaemia	1 (1.6)	1 (1.6)	0	0	0
Hypercalcaemia	1 (1.6)	1 (1.6)	0	0	0
Hyperchloraemia	1 (1.6)	1 (1.6)	0	0	0
Hypermagnesaemia	1 (1.6)	1 (1.6)	0	0	0
Hypomagnesaemia	1 (1.6)	1 (1.6)	0	0	0
Malnutrition	1 (1.6)	0	0	1 (1.6)	0
Metabolic acidosis	1 (1.6)	0	1 (1.6)	0	0
Metabolic alkalosis	1 (1.6)	1 (1.6)	0	0	0
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0
Musculoskeletal and connective tissue disorders					
-Total	15 (23.4)	8 (12.5)	6 (9.4)	1 (1.6)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	5 (7.8)	4 (6.3)	1 (1.6)	0	0
Arthralgia	4 (6.3)	3 (4.7)	0	1 (1.6)	0
Pain in extremity	4 (6.3)	2 (3.1)	2 (3.1)	0	0
Musculoskeletal pain	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Coccydynia	1 (1.6)	1 (1.6)	0	0	0
Limb discomfort	1 (1.6)	1 (1.6)	0	0	0
Muscle spasms	1 (1.6)	1 (1.6)	0	0	0
Muscular weakness	1 (1.6)	0	1 (1.6)	0	0
Musculoskeletal chest pain	1 (1.6)	1 (1.6)	0	0	0
Osteopenia	1 (1.6)	0	1 (1.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.6)	0	1 (1.6)	0	0
Skin papilloma	1 (1.6)	0	1 (1.6)	0	0
Nervous system disorders					
-Total	33 (51.6)	17 (26.6)	11 (17.2)	4 (6.3)	1 (1.6)
Headache	24 (37.5)	16 (25.0)	6 (9.4)	2 (3.1)	0
Dizziness	4 (6.3)	4 (6.3)	0	0	0
Encephalopathy	4 (6.3)	1 (1.6)	1 (1.6)	2 (3.1)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	3 (4.7)	0	2 (3.1)	1 (1.6)	0
Dysarthria	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Tremor	2 (3.1)	2 (3.1)	0	0	0
Asterixis	1 (1.6)	1 (1.6)	0	0	0
Ataxia	1 (1.6)	0	1 (1.6)	0	0
Depressed level of consciousness	1 (1.6)	1 (1.6)	0	0	0
Embolic stroke	1 (1.6)	0	0	0	1 (1.6)
Idiopathic intracranial hypertension	1 (1.6)	0	1 (1.6)	0	0
Migraine	1 (1.6)	0	1 (1.6)	0	0
Myoclonus	1 (1.6)	1 (1.6)	0	0	0
Neuropathy peripheral	1 (1.6)	0	1 (1.6)	0	0
Pleocytosis	1 (1.6)	1 (1.6)	0	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0
Product issues					
-Total	1 (1.6)	1 (1.6)	0	0	0
Device occlusion	1 (1.6)	1 (1.6)	0	0	0
Psychiatric disorders					
-Total	16 (25.0)	8 (12.5)	7 (10.9)	1 (1.6)	0
Anxiety	6 (9.4)	2 (3.1)	3 (4.7)	1 (1.6)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	6 (9.4)	3 (4.7)	3 (4.7)	0	0
Delirium	4 (6.3)	2 (3.1)	2 (3.1)	0	0
Agitation	2 (3.1)	0	2 (3.1)	0	0
Hallucination	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Irritability	2 (3.1)	2 (3.1)	0	0	0
Adjustment disorder	1 (1.6)	0	1 (1.6)	0	0
Insomnia	1 (1.6)	0	1 (1.6)	0	0
Listless	1 (1.6)	1 (1.6)	0	0	0
Mental status changes	1 (1.6)	1 (1.6)	0	0	0
Panic attack	1 (1.6)	0	1 (1.6)	0	0
Suicidal ideation	1 (1.6)	1 (1.6)	0	0	0
Renal and urinary disorders					
-Total	11 (17.2)	2 (3.1)	2 (3.1)	3 (4.7)	4 (6.3)
Acute kidney injury	7 (10.9)	1 (1.6)	1 (1.6)	2 (3.1)	3 (4.7)
Haematuria	4 (6.3)	0	2 (3.1)	1 (1.6)	1 (1.6)
Dysuria	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Oliguria	2 (3.1)	0	0	2 (3.1)	0
Pollakiuria	1 (1.6)	1 (1.6)	0	0	0
Renal failure	1 (1.6)	0	0	0	1 (1.6)

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal impairment	1 (1.6)	0	0	1 (1.6)	0
Reproductive system and breast disorders					
-Total	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Vulvovaginal adhesion	2 (3.1)	2 (3.1)	0	0	0
Oedema genital	1 (1.6)	0	1 (1.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	28 (43.8)	10 (15.6)	6 (9.4)	5 (7.8)	7 (10.9)
Hypoxia	10 (15.6)	0	3 (4.7)	4 (6.3)	3 (4.7)
Cough	8 (12.5)	8 (12.5)	0	0	0
Pleural effusion	8 (12.5)	2 (3.1)	4 (6.3)	2 (3.1)	0
Epistaxis	7 (10.9)	2 (3.1)	1 (1.6)	3 (4.7)	1 (1.6)
Pulmonary oedema	6 (9.4)	1 (1.6)	0	3 (4.7)	2 (3.1)
Tachypnoea	5 (7.8)	3 (4.7)	1 (1.6)	1 (1.6)	0
Respiratory failure	3 (4.7)	0	0	0	3 (4.7)
Dyspnoea	2 (3.1)	0	0	1 (1.6)	1 (1.6)
Haemoptysis	2 (3.1)	1 (1.6)	0	0	1 (1.6)
Oropharyngeal pain	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Atelectasis	1 (1.6)	1 (1.6)	0	0	0
Interstitial lung disease	1 (1.6)	0	0	0	1 (1.6)

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	1 (1.6)	1 (1.6)	0	0	0
Oropharyngeal plaque	1 (1.6)	1 (1.6)	0	0	0
Pharyngeal ulceration	1 (1.6)	0	1 (1.6)	0	0
Respiratory depression	1 (1.6)	0	1 (1.6)	0	0
Respiratory distress	1 (1.6)	0	0	0	1 (1.6)
Rhinitis allergic	1 (1.6)	1 (1.6)	0	0	0
Rhinorrhoea	1 (1.6)	1 (1.6)	0	0	0
Wheezing	1 (1.6)	0	1 (1.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	21 (32.8)	15 (23.4)	4 (6.3)	2 (3.1)	0
Dry skin	4 (6.3)	4 (6.3)	0	0	0
Rash	4 (6.3)	4 (6.3)	0	0	0
Erythema	3 (4.7)	3 (4.7)	0	0	0
Hyperhidrosis	3 (4.7)	3 (4.7)	0	0	0
Petechiae	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Rash maculo-papular	3 (4.7)	1 (1.6)	1 (1.6)	1 (1.6)	0
Ingrowing nail	2 (3.1)	0	2 (3.1)	0	0
Pruritus	2 (3.1)	2 (3.1)	0	0	0
Rash papular	2 (3.1)	2 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dermatitis diaper	1 (1.6)	1 (1.6)	0	0	0
Ecchymosis	1 (1.6)	0	0	1 (1.6)	0
Livedo reticularis	1 (1.6)	1 (1.6)	0	0	0
Macule	1 (1.6)	1 (1.6)	0	0	0
Night sweats	1 (1.6)	0	1 (1.6)	0	0
Rash erythematous	1 (1.6)	1 (1.6)	0	0	0
Rash follicular	1 (1.6)	1 (1.6)	0	0	0
Rash macular	1 (1.6)	1 (1.6)	0	0	0
Rash vesicular	1 (1.6)	1 (1.6)	0	0	0
Skin exfoliation	1 (1.6)	1 (1.6)	0	0	0
Skin fissures	1 (1.6)	1 (1.6)	0	0	0
Skin irritation	1 (1.6)	1 (1.6)	0	0	0
Vascular disorders					
-Total	24 (37.5)	3 (4.7)	5 (7.8)	8 (12.5)	8 (12.5)
Hypotension	16 (25.0)	1 (1.6)	0	7 (10.9)	8 (12.5)
Hypertension	10 (15.6)	2 (3.1)	7 (10.9)	1 (1.6)	0
Flushing	2 (3.1)	2 (3.1)	0	0	0
Orthostatic hypotension	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Capillary leak syndrome	1 (1.6)	0	0	0	1 (1.6)

Timing: within 8 weeks post infusion, Region: US

		All patients N=64			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Embolism	1 (1.6)	0	0	1 (1.6)	0
Haematoma	1 (1.6)	0	1 (1.6)	0	0
Secondary hypertension	1 (1.6)	0	1 (1.6)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174k
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

			All patients N=56		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (82.1)	4 (7.1)	16 (28.6)	16 (28.6)	10 (17.9)
Blood and lymphatic system disorders					
-Total	11 (19.6)	1 (1.8)	3 (5.4)	3 (5.4)	4 (7.1)
Neutropenia	4 (7.1)	0	0	1 (1.8)	3 (5.4)
Febrile neutropenia	3 (5.4)	0	0	3 (5.4)	0
Anaemia	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Thrombocytopenia	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Eosinophilia	1 (1.8)	0	0	1 (1.8)	0
Leukopenia	1 (1.8)	0	0	0	1 (1.8)
Lymphadenopathy	1 (1.8)	0	1 (1.8)	0	0
Lymphopenia	1 (1.8)	0	1 (1.8)	0	0
Cardiac disorders					
-Total	1 (1.8)	0	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	1 (1.8)	0	1 (1.8)	0	0
Endocrine disorders					
-Total	1 (1.8)	1 (1.8)	0	0	0
Adrenal insufficiency	1 (1.8)	1 (1.8)	0	0	0
Eye disorders					
-Total	5 (8.9)	4 (7.1)	1 (1.8)	0	0
Dry eye	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Conjunctivitis allergic	1 (1.8)	1 (1.8)	0	0	0
Ocular hyperaemia	1 (1.8)	1 (1.8)	0	0	0
Vision blurred	1 (1.8)	1 (1.8)	0	0	0
Gastrointestinal disorders					
-Total	16 (28.6)	9 (16.1)	3 (5.4)	4 (7.1)	0
Vomiting	9 (16.1)	5 (8.9)	2 (3.6)	2 (3.6)	0
Diarrhoea	8 (14.3)	6 (10.7)	1 (1.8)	1 (1.8)	0
Nausea	6 (10.7)	1 (1.8)	3 (5.4)	2 (3.6)	0
Abdominal pain	4 (7.1)	2 (3.6)	1 (1.8)	1 (1.8)	0
Oral pain	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Abdominal pain upper	1 (1.8)	1 (1.8)	0	0	0
Enterocolitis	1 (1.8)	0	0	1 (1.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pigmentation lip	1 (1.8)	1 (1.8)	0	0	0
General disorders and administration site conditions					
-Total	17 (30.4)	13 (23.2)	3 (5.4)	1 (1.8)	0
Pyrexia	10 (17.9)	7 (12.5)	2 (3.6)	1 (1.8)	0
Fatigue	2 (3.6)	2 (3.6)	0	0	0
Influenza like illness	2 (3.6)	2 (3.6)	0	0	0
Acquired gene mutation	1 (1.8)	1 (1.8)	0	0	0
Catheter site pain	1 (1.8)	0	1 (1.8)	0	0
Chills	1 (1.8)	1 (1.8)	0	0	0
Crying	1 (1.8)	1 (1.8)	0	0	0
Generalised oedema	1 (1.8)	1 (1.8)	0	0	0
Malaise	1 (1.8)	1 (1.8)	0	0	0
Oedema peripheral	1 (1.8)	1 (1.8)	0	0	0
Pain	1 (1.8)	1 (1.8)	0	0	0
Immune system disorders					
-Total	14 (25.0)	3 (5.4)	10 (17.9)	1 (1.8)	0
Hypogammaglobulinaemia	8 (14.3)	0	7 (12.5)	1 (1.8)	0
Graft versus host disease	2 (3.6)	1 (1.8)	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency common variable	2 (3.6)	0	2 (3.6)	0	0
Seasonal allergy	2 (3.6)	2 (3.6)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (1.8)	0	1 (1.8)	0	0
Infections and infestations					
-Total	33 (58.9)	6 (10.7)	15 (26.8)	10 (17.9)	2 (3.6)
Upper respiratory tract infection	7 (12.5)	3 (5.4)	3 (5.4)	1 (1.8)	0
Urinary tract infection	4 (7.1)	0	2 (3.6)	2 (3.6)	0
Gastroenteritis	3 (5.4)	1 (1.8)	2 (3.6)	0	0
Influenza	3 (5.4)	0	3 (5.4)	0	0
Ear infection	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Parainfluenzae virus infection	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Rhinovirus infection	2 (3.6)	2 (3.6)	0	0	0
Sinusitis	2 (3.6)	0	2 (3.6)	0	0
Viral upper respiratory tract infection	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Bacterial sepsis	1 (1.8)	0	0	0	1 (1.8)
Cellulitis of male external genital organ	1 (1.8)	0	0	1 (1.8)	0
Cholecystitis infective	1 (1.8)	0	0	1 (1.8)	0
Corona virus infection	1 (1.8)	0	0	1 (1.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection	1 (1.8)	1 (1.8)	0	0	0
Enterovirus infection	1 (1.8)	0	0	1 (1.8)	0
Escherichia urinary tract infection	1 (1.8)	0	0	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	0	1 (1.8)	0	0
Gastroenteritis viral	1 (1.8)	1 (1.8)	0	0	0
Herpes zoster	1 (1.8)	0	0	1 (1.8)	0
Molluscum contagiosum	1 (1.8)	1 (1.8)	0	0	0
Oral herpes	1 (1.8)	0	1 (1.8)	0	0
Otitis externa	1 (1.8)	0	1 (1.8)	0	0
Otitis media	1 (1.8)	0	1 (1.8)	0	0
Otitis media acute	1 (1.8)	0	1 (1.8)	0	0
Paronychia	1 (1.8)	1 (1.8)	0	0	0
Rash pustular	1 (1.8)	0	1 (1.8)	0	0
Respiratory syncytial virus infection	1 (1.8)	0	0	1 (1.8)	0
Rhinitis	1 (1.8)	1 (1.8)	0	0	0
Rotavirus infection	1 (1.8)	0	0	1 (1.8)	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Subcutaneous abscess	1 (1.8)	0	1 (1.8)	0	0
Tinea capitis	1 (1.8)	1 (1.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Viral infection	1 (1.8)	1 (1.8)	0	0	0
Vulvovaginal mycotic infection	1 (1.8)	0	1 (1.8)	0	0
Injury, poisoning and procedural complications					
-Total	8 (14.3)	3 (5.4)	5 (8.9)	0	0
Contusion	2 (3.6)	2 (3.6)	0	0	0
Infusion related reaction	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Procedural pain	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Arthropod bite	1 (1.8)	1 (1.8)	0	0	0
Foot fracture	1 (1.8)	0	1 (1.8)	0	0
Procedural nausea	1 (1.8)	0	1 (1.8)	0	0
Radius fracture	1 (1.8)	0	1 (1.8)	0	0
Skin abrasion	1 (1.8)	1 (1.8)	0	0	0
Skin laceration	1 (1.8)	0	1 (1.8)	0	0
Sunburn	1 (1.8)	1 (1.8)	0	0	0
Investigations					
-Total	23 (41.1)	6 (10.7)	5 (8.9)	8 (14.3)	4 (7.1)
Neutrophil count decreased	8 (14.3)	2 (3.6)	0	3 (5.4)	3 (5.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All patients N=56 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	5 (8.9)	2 (3.6)	1 (1.8)	1 (1.8)	1 (1.8)
Weight decreased	4 (7.1)	1 (1.8)	3 (5.4)	0	0
Aspartate aminotransferase increased	3 (5.4)	1 (1.8)	0	2 (3.6)	0
Platelet count decreased	3 (5.4)	3 (5.4)	0	0	0
Alanine aminotransferase increased	2 (3.6)	0	0	2 (3.6)	0
Haemoglobin decreased	2 (3.6)	2 (3.6)	0	0	0
Lymphocyte count decreased	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Weight increased	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Blood bilirubin increased	1 (1.8)	0	0	1 (1.8)	0
Blood creatinine increased	1 (1.8)	1 (1.8)	0	0	0
Blood magnesium decreased	1 (1.8)	1 (1.8)	0	0	0
Blood urea increased	1 (1.8)	1 (1.8)	0	0	0
Blood uric acid increased	1 (1.8)	1 (1.8)	0	0	0
Oxygen saturation decreased	1 (1.8)	1 (1.8)	0	0	0
Serum ferritin increased	1 (1.8)	0	1 (1.8)	0	0
Transaminases increased	1 (1.8)	1 (1.8)	0	0	0
Metabolism and nutrition disorders					
-Total	10 (17.9)	5 (8.9)	1 (1.8)	3 (5.4)	1 (1.8)
Decreased appetite	2 (3.6)	1 (1.8)	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	2 (3.6)	2 (3.6)	0	0	0
Hypokalaemia	2 (3.6)	1 (1.8)	0	0	1 (1.8)
Dehydration	1 (1.8)	0	0	1 (1.8)	0
Hyperalbuminaemia	1 (1.8)	1 (1.8)	0	0	0
Hypercalcaemia	1 (1.8)	1 (1.8)	0	0	0
Hyperglycaemia	1 (1.8)	0	0	1 (1.8)	0
Hypophosphataemia	1 (1.8)	0	0	1 (1.8)	0
Iron overload	1 (1.8)	0	0	1 (1.8)	0
Tumour lysis syndrome	1 (1.8)	0	0	1 (1.8)	0
Vitamin d deficiency	1 (1.8)	1 (1.8)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	16 (28.6)	11 (19.6)	5 (8.9)	0	0
Pain in extremity	8 (14.3)	6 (10.7)	2 (3.6)	0	0
Arthralgia	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Joint range of motion decreased	2 (3.6)	2 (3.6)	0	0	0
Muscular weakness	2 (3.6)	2 (3.6)	0	0	0
Back pain	1 (1.8)	1 (1.8)	0	0	0
Flank pain	1 (1.8)	0	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscle spasms	1 (1.8)	1 (1.8)	0	0	0
Musculoskeletal chest pain	1 (1.8)	1 (1.8)	0	0	0
Osteonecrosis	1 (1.8)	0	1 (1.8)	0	0
Pain in jaw	1 (1.8)	1 (1.8)	0	0	0
Toe walking	1 (1.8)	1 (1.8)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.8)	0	1 (1.8)	0	0
Myelodysplastic syndrome	1 (1.8)	0	1 (1.8)	0	0
Nervous system disorders					
-Total	8 (14.3)	6 (10.7)	2 (3.6)	0	0
Headache	5 (8.9)	4 (7.1)	1 (1.8)	0	0
Dizziness	3 (5.4)	3 (5.4)	0	0	0
Peroneal nerve palsy	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Psychiatric disorders					
-Total	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Depression	2 (3.6)	2 (3.6)	0	0	0
Anxiety	1 (1.8)	1 (1.8)	0	0	0
Sleep disorder	1 (1.8)	0	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	3 (5.4)	1 (1.8)	0	2 (3.6)	0
Acute kidney injury	1 (1.8)	0	0	1 (1.8)	0
Calculus urinary	1 (1.8)	0	1 (1.8)	0	0
Haematuria	1 (1.8)	0	0	1 (1.8)	0
Nephrolithiasis	1 (1.8)	0	0	1 (1.8)	0
Urinary incontinence	1 (1.8)	1 (1.8)	0	0	0
Reproductive system and breast disorders					
-Total	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Scrotal pain	1 (1.8)	0	1 (1.8)	0	0
Vaginal haemorrhage	1 (1.8)	0	0	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders					
-Total	18 (32.1)	11 (19.6)	4 (7.1)	2 (3.6)	1 (1.8)
Cough	7 (12.5)	5 (8.9)	2 (3.6)	0	0
Nasal congestion	4 (7.1)	4 (7.1)	0	0	0
Rhinorrhoea	4 (7.1)	3 (5.4)	1 (1.8)	0	0
Oropharyngeal pain	3 (5.4)	2 (3.6)	1 (1.8)	0	0
Rhinitis allergic	3 (5.4)	2 (3.6)	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Acute respiratory failure	1 (1.8)	0	0	0	1 (1.8)
Dysphonia	1 (1.8)	1 (1.8)	0	0	0
Pharyngeal erythema	1 (1.8)	1 (1.8)	0	0	0
Pharyngeal lesion	1 (1.8)	0	0	1 (1.8)	0
Pulmonary oedema	1 (1.8)	0	0	1 (1.8)	0
Skin and subcutaneous tissue disorders					
-Total	16 (28.6)	10 (17.9)	5 (8.9)	1 (1.8)	0
Rash	4 (7.1)	1 (1.8)	3 (5.4)	0	0
Erythema	2 (3.6)	2 (3.6)	0	0	0
Rash maculo-papular	2 (3.6)	2 (3.6)	0	0	0
Alopecia	1 (1.8)	0	1 (1.8)	0	0
Dermatitis	1 (1.8)	1 (1.8)	0	0	0
Dermatitis acneiform	1 (1.8)	0	0	1 (1.8)	0
Dermatitis atopic	1 (1.8)	1 (1.8)	0	0	0
Dry skin	1 (1.8)	1 (1.8)	0	0	0
Eczema	1 (1.8)	1 (1.8)	0	0	0
Hyperhidrosis	1 (1.8)	1 (1.8)	0	0	0
Ingrowing nail	1 (1.8)	1 (1.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

Primary system organ class Preferred term	All patients N=56 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Keloid scar	1 (1.8)	0	1 (1.8)	0	0
Macule	1 (1.8)	1 (1.8)	0	0	0
Papule	1 (1.8)	1 (1.8)	0	0	0
Petechiae	1 (1.8)	1 (1.8)	0	0	0
Pruritus	1 (1.8)	1 (1.8)	0	0	0
Rash erythematous	1 (1.8)	0	1 (1.8)	0	0
Rash pruritic	1 (1.8)	1 (1.8)	0	0	0
Vascular disorders					
-Total	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Hypertension	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Hot flush	1 (1.8)	1 (1.8)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174k
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: US

			All patients N=34		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (64.7)	4 (11.8)	6 (17.6)	8 (23.5)	4 (11.8)
Blood and lymphatic system disorders					
-Total	2 (5.9)	1 (2.9)	0	0	1 (2.9)
Febrile neutropenia	1 (2.9)	0	0	0	1 (2.9)
Thrombocytopenia	1 (2.9)	1 (2.9)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Tympanic membrane perforation	1 (2.9)	0	1 (2.9)	0	0
Gastrointestinal disorders					
-Total	3 (8.8)	0	3 (8.8)	0	0
Diarrhoea	2 (5.9)	0	2 (5.9)	0	0
Abdominal pain	1 (2.9)	0	1 (2.9)	0	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (2.9)	0	1 (2.9)	0	0
General disorders and administration site conditions					
-Total	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Chills	1 (2.9)	0	1 (2.9)	0	0
Cyst	1 (2.9)	0	0	1 (2.9)	0
Pyrexia	1 (2.9)	0	1 (2.9)	0	0
Immune system disorders					
-Total	2 (5.9)	0	2 (5.9)	0	0
Chronic graft versus host disease	1 (2.9)	0	1 (2.9)	0	0
Immunodeficiency	1 (2.9)	0	1 (2.9)	0	0
Infections and infestations					
-Total	11 (32.4)	2 (5.9)	5 (14.7)	3 (8.8)	1 (2.9)
Otitis media	3 (8.8)	0	2 (5.9)	1 (2.9)	0
Sinusitis	3 (8.8)	0	3 (8.8)	0	0
Otitis media acute	2 (5.9)	0	2 (5.9)	0	0
Pneumonia	2 (5.9)	0	2 (5.9)	0	0
Upper respiratory tract infection	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Urinary tract infection	2 (5.9)	0	1 (2.9)	1 (2.9)	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (2.9)	0	0	1 (2.9)	0
Cellulitis of male external genital organ	1 (2.9)	0	0	1 (2.9)	0
Clostridium difficile infection	1 (2.9)	0	0	1 (2.9)	0
Gingivitis	1 (2.9)	1 (2.9)	0	0	0
Haemophilus infection	1 (2.9)	0	1 (2.9)	0	0
Meningitis aseptic	1 (2.9)	0	1 (2.9)	0	0
Respiratory tract infection	1 (2.9)	0	0	0	1 (2.9)
Respiratory tract infection viral	1 (2.9)	0	0	1 (2.9)	0
Skin infection	1 (2.9)	0	1 (2.9)	0	0
Viral infection	1 (2.9)	1 (2.9)	0	0	0
Vulvovaginal candidiasis	1 (2.9)	0	1 (2.9)	0	0
Injury, poisoning and procedural complications					
-Total	1 (2.9)	0	0	1 (2.9)	0
Procedural pain	1 (2.9)	0	0	1 (2.9)	0
Investigations					
-Total	8 (23.5)	1 (2.9)	2 (5.9)	4 (11.8)	1 (2.9)
White blood cell count decreased	4 (11.8)	1 (2.9)	0	2 (5.9)	1 (2.9)
Alanine aminotransferase increased	3 (8.8)	0	1 (2.9)	2 (5.9)	0
Lymphocyte count decreased	3 (8.8)	2 (5.9)	0	1 (2.9)	0

Timing: >1 year post-CTL019 infusion, Region: US

			All patients N=34		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Neutrophil count decreased	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Blood alkaline phosphatase increased	1 (2.9)	1 (2.9)	0	0	0
Blood lactate dehydrogenase increased	1 (2.9)	1 (2.9)	0	0	0
C-reactive protein increased	1 (2.9)	1 (2.9)	0	0	0
Platelet count decreased	1 (2.9)	0	0	1 (2.9)	0
Metabolism and nutrition disorders					
-Total	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Hypokalaemia	1 (2.9)	0	0	1 (2.9)	0
Vitamin d deficiency	1 (2.9)	1 (2.9)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Neck pain	1 (2.9)	0	1 (2.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.9)	0	0	0	1 (2.9)
Glioblastoma multiforme	1 (2.9)	0	0	0	1 (2.9)
Nervous system disorders					
-Total	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Disturbance in attention	1 (2.9)	1 (2.9)	0	0	0
Dizziness	1 (2.9)	1 (2.9)	0	0	0
Headache	1 (2.9)	0	1 (2.9)	0	0
Seizure	1 (2.9)	0	0	1 (2.9)	0
Renal and urinary disorders					
-Total	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Acute kidney injury	1 (2.9)	0	0	1 (2.9)	0
Haematuria	1 (2.9)	1 (2.9)	0	0	0
Reproductive system and breast disorders					
-Total	1 (2.9)	0	0	1 (2.9)	0
Ovarian failure	1 (2.9)	0	0	1 (2.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (11.8)	4 (11.8)	0	0	0
Cough	2 (5.9)	2 (5.9)	0	0	0
Epistaxis	1 (2.9)	1 (2.9)	0	0	0
Oropharyngeal pain	1 (2.9)	1 (2.9)	0	0	0
Rhinitis allergic	1 (2.9)	1 (2.9)	0	0	0
Rhinorrhoea	1 (2.9)	1 (2.9)	0	0	0
Skin and subcutaneous tissue disorders					

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=34				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (8.8)	3 (8.8)	0	0	0
Acne	1 (2.9)	1 (2.9)	0	0	0
Papule	1 (2.9)	1 (2.9)	0	0	0
Pruritus	1 (2.9)	1 (2.9)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174k
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: US

			All patients N=64		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	64 (100)	0	5 (7.8)	12 (18.8)	47 (73.4)
Blood and lymphatic system disorders					
-Total	48 (75.0)	2 (3.1)	3 (4.7)	27 (42.2)	16 (25.0)
Anaemia	27 (42.2)	3 (4.7)	4 (6.3)	19 (29.7)	1 (1.6)
Febrile neutropenia	24 (37.5)	0	0	23 (35.9)	1 (1.6)
Neutropenia	11 (17.2)	0	0	3 (4.7)	8 (12.5)
Thrombocytopenia	10 (15.6)	0	1 (1.6)	3 (4.7)	6 (9.4)
Disseminated intravascular coagulation	4 (6.3)	0	2 (3.1)	2 (3.1)	0
Lymphopenia	4 (6.3)	0	2 (3.1)	1 (1.6)	1 (1.6)
Coagulopathy	1 (1.6)	1 (1.6)	0	0	0
Eosinophilia	1 (1.6)	0	0	1 (1.6)	0
Leukopenia	1 (1.6)	0	0	0	1 (1.6)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphadenopathy	1 (1.6)	0	1 (1.6)	0	0
Pancytopenia	1 (1.6)	0	0	0	1 (1.6)
Cardiac disorders					
-Total	23 (35.9)	11 (17.2)	10 (15.6)	2 (3.1)	0
Tachycardia	15 (23.4)	8 (12.5)	5 (7.8)	2 (3.1)	0
Sinus tachycardia	6 (9.4)	3 (4.7)	3 (4.7)	0	0
Pericardial effusion	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Atrioventricular block second degree	1 (1.6)	1 (1.6)	0	0	0
Bradycardia	1 (1.6)	0	1 (1.6)	0	0
Cardiac dysfunction	1 (1.6)	1 (1.6)	0	0	0
Left ventricular dysfunction	1 (1.6)	0	0	1 (1.6)	0
Palpitations	1 (1.6)	1 (1.6)	0	0	0
Sinus bradycardia	1 (1.6)	1 (1.6)	0	0	0
Ventricular tachycardia	1 (1.6)	0	1 (1.6)	0	0
Ear and labyrinth disorders					
-Total	4 (6.3)	2 (3.1)	2 (3.1)	0	0
Ear pain	2 (3.1)	2 (3.1)	0	0	0
Hypoacusis	1 (1.6)	0	1 (1.6)	0	0
Tympanic membrane perforation	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Region: US

Primary system organ class Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Endocrine disorders					
-Total	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Adrenal insufficiency	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Eye disorders					
-Total	18 (28.1)	10 (15.6)	8 (12.5)	0	0
Periorbital oedema	4 (6.3)	3 (4.7)	1 (1.6)	0	0
Vision blurred	4 (6.3)	2 (3.1)	2 (3.1)	0	0
Conjunctival haemorrhage	3 (4.7)	3 (4.7)	0	0	0
Eye pain	3 (4.7)	1 (1.6)	2 (3.1)	0	0
Dry eye	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Photophobia	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Retinal haemorrhage	2 (3.1)	2 (3.1)	0	0	0
Uveitis	2 (3.1)	0	2 (3.1)	0	0
Conjunctivitis allergic	1 (1.6)	1 (1.6)	0	0	0
Ocular hyperaemia	1 (1.6)	1 (1.6)	0	0	0
Ocular hypertension	1 (1.6)	0	1 (1.6)	0	0
Papilloedema	1 (1.6)	0	1 (1.6)	0	0
Visual impairment	1 (1.6)	0	1 (1.6)	0	0
Gastrointestinal disorders					

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	43 (67.2)	13 (20.3)	17 (26.6)	13 (20.3)	0
Vomiting	27 (42.2)	16 (25.0)	8 (12.5)	3 (4.7)	0
Nausea	25 (39.1)	6 (9.4)	14 (21.9)	5 (7.8)	0
Diarrhoea	24 (37.5)	13 (20.3)	9 (14.1)	2 (3.1)	0
Abdominal pain	11 (17.2)	6 (9.4)	4 (6.3)	1 (1.6)	0
Constipation	7 (10.9)	6 (9.4)	1 (1.6)	0	0
Abdominal pain upper	3 (4.7)	1 (1.6)	2 (3.1)	0	0
Abdominal distension	2 (3.1)	0	2 (3.1)	0	0
Dysphagia	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Haematemesis	2 (3.1)	2 (3.1)	0	0	0
Oral pain	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Pancreatitis	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Stomatitis	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Abdominal discomfort	1 (1.6)	1 (1.6)	0	0	0
Abdominal pain lower	1 (1.6)	0	1 (1.6)	0	0
Abdominal tenderness	1 (1.6)	1 (1.6)	0	0	0
Anal incontinence	1 (1.6)	1 (1.6)	0	0	0
Ascites	1 (1.6)	0	0	1 (1.6)	0
Dyspepsia	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterocolitis	1 (1.6)	0	0	1 (1.6)	0
Flatulence	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Gastrooesophageal reflux disease	1 (1.6)	1 (1.6)	0	0	0
Glossodynia	1 (1.6)	1 (1.6)	0	0	0
Ileus	1 (1.6)	0	0	1 (1.6)	0
Intestinal obstruction	1 (1.6)	0	0	1 (1.6)	0
Lip pain	1 (1.6)	0	1 (1.6)	0	0
Mouth haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Pigmentation lip	1 (1.6)	1 (1.6)	0	0	0
Tooth socket haemorrhage	1 (1.6)	1 (1.6)	0	0	0
General disorders and administration site conditions					
-Total	42 (65.6)	16 (25.0)	14 (21.9)	11 (17.2)	1 (1.6)
Pyrexia	25 (39.1)	8 (12.5)	10 (15.6)	6 (9.4)	1 (1.6)
Fatigue	15 (23.4)	12 (18.8)	2 (3.1)	1 (1.6)	0
Chills	10 (15.6)	9 (14.1)	1 (1.6)	0	0
Catheter site pain	4 (6.3)	1 (1.6)	3 (4.7)	0	0
Malaise	4 (6.3)	1 (1.6)	3 (4.7)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	4 (6.3)	1 (1.6)	1 (1.6)	2 (3.1)	0
Generalised oedema	3 (4.7)	1 (1.6)	2 (3.1)	0	0
Oedema peripheral	3 (4.7)	2 (3.1)	0	1 (1.6)	0
Face oedema	2 (3.1)	0	1 (1.6)	1 (1.6)	0
Influenza like illness	2 (3.1)	2 (3.1)	0	0	0
Acquired gene mutation	1 (1.6)	1 (1.6)	0	0	0
Asthenia	1 (1.6)	1 (1.6)	0	0	0
Catheter site extravasation	1 (1.6)	0	1 (1.6)	0	0
Catheter site haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Crying	1 (1.6)	1 (1.6)	0	0	0
Cyst	1 (1.6)	0	0	1 (1.6)	0
Facial pain	1 (1.6)	0	1 (1.6)	0	0
Injection site haematoma	1 (1.6)	1 (1.6)	0	0	0
Localised oedema	1 (1.6)	0	0	1 (1.6)	0
Mucosal haemorrhage	1 (1.6)	0	1 (1.6)	0	0
Multiple organ dysfunction syndrome	1 (1.6)	0	0	1 (1.6)	0
Non-cardiac chest pain	1 (1.6)	1 (1.6)	0	0	0
Peripheral swelling	1 (1.6)	0	1 (1.6)	0	0
Physical deconditioning	1 (1.6)	0	0	1 (1.6)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	7 (10.9)	3 (4.7)	2 (3.1)	2 (3.1)	0
Hepatomegaly	3 (4.7)	1 (1.6)	2 (3.1)	0	0
Hyperbilirubinaemia	3 (4.7)	0	1 (1.6)	2 (3.1)	0
Gallbladder enlargement	1 (1.6)	1 (1.6)	0	0	0
Hepatosplenomegaly	1 (1.6)	1 (1.6)	0	0	0
Immune system disorders					
-Total	58 (90.6)	5 (7.8)	31 (48.4)	11 (17.2)	11 (17.2)
Cytokine release syndrome	50 (78.1)	6 (9.4)	25 (39.1)	8 (12.5)	11 (17.2)
Hypogammaglobulinaemia	32 (50.0)	3 (4.7)	24 (37.5)	5 (7.8)	0
Graft versus host disease	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Immunodeficiency common variable	2 (3.1)	0	2 (3.1)	0	0
Seasonal allergy	2 (3.1)	2 (3.1)	0	0	0
Chronic graft versus host disease	1 (1.6)	0	1 (1.6)	0	0
Drug hypersensitivity	1 (1.6)	0	1 (1.6)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.6)	0	1 (1.6)	0	0
Graft versus host disease in skin	1 (1.6)	1 (1.6)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.6)	0	1 (1.6)	0	0
Immunodeficiency	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	46 (71.9)	7 (10.9)	21 (32.8)	14 (21.9)	4 (6.3)
Upper respiratory tract infection	9 (14.1)	4 (6.3)	4 (6.3)	1 (1.6)	0
Clostridium difficile infection	5 (7.8)	0	4 (6.3)	1 (1.6)	0
Gastroenteritis	5 (7.8)	1 (1.6)	3 (4.7)	1 (1.6)	0
Rhinovirus infection	5 (7.8)	5 (7.8)	0	0	0
Urinary tract infection	5 (7.8)	0	3 (4.7)	2 (3.1)	0
Clostridium difficile colitis	4 (6.3)	1 (1.6)	2 (3.1)	1 (1.6)	0
Influenza	4 (6.3)	1 (1.6)	3 (4.7)	0	0
Otitis media	4 (6.3)	0	3 (4.7)	1 (1.6)	0
Pneumonia	4 (6.3)	0	3 (4.7)	1 (1.6)	0
Sinusitis	4 (6.3)	0	4 (6.3)	0	0
Viral infection	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Viral upper respiratory tract infection	3 (4.7)	1 (1.6)	1 (1.6)	1 (1.6)	0
Cytomegalovirus infection	2 (3.1)	2 (3.1)	0	0	0
Ear infection	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Otitis media acute	2 (3.1)	0	2 (3.1)	0	0
Parainfluenzae virus infection	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Skin infection	2 (3.1)	0	2 (3.1)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Vulvovaginal candidiasis	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Acute sinusitis	1 (1.6)	0	1 (1.6)	0	0
Bacterial sepsis	1 (1.6)	0	0	0	1 (1.6)
Body tinea	1 (1.6)	1 (1.6)	0	0	0
Campylobacter infection	1 (1.6)	0	0	1 (1.6)	0
Catheter site cellulitis	1 (1.6)	1 (1.6)	0	0	0
Catheter site infection	1 (1.6)	0	0	1 (1.6)	0
Cellulitis of male external genital organ	1 (1.6)	0	0	1 (1.6)	0
Cholecystitis infective	1 (1.6)	0	0	1 (1.6)	0
Corona virus infection	1 (1.6)	0	0	1 (1.6)	0
Enterococcal infection	1 (1.6)	1 (1.6)	0	0	0
Enterovirus infection	1 (1.6)	0	0	1 (1.6)	0
Escherichia urinary tract infection	1 (1.6)	0	0	1 (1.6)	0
Folliculitis	1 (1.6)	0	1 (1.6)	0	0
Fungal skin infection	1 (1.6)	1 (1.6)	0	0	0
Gastroenteritis norovirus	1 (1.6)	0	1 (1.6)	0	0
Gastroenteritis viral	1 (1.6)	1 (1.6)	0	0	0
Gingivitis	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Region: US

Primary system organ class Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemophilus infection	1 (1.6)	0	1 (1.6)	0	0
Herpes simplex	1 (1.6)	1 (1.6)	0	0	0
Herpes zoster	1 (1.6)	0	0	1 (1.6)	0
Human herpesvirus 6 infection	1 (1.6)	0	1 (1.6)	0	0
Hypopyon	1 (1.6)	0	1 (1.6)	0	0
Meningitis aseptic	1 (1.6)	0	1 (1.6)	0	0
Molluscum contagiosum	1 (1.6)	1 (1.6)	0	0	0
Oral candidiasis	1 (1.6)	1 (1.6)	0	0	0
Oral herpes	1 (1.6)	0	1 (1.6)	0	0
Orchitis	1 (1.6)	1 (1.6)	0	0	0
Otitis externa	1 (1.6)	0	1 (1.6)	0	0
Paronychia	1 (1.6)	1 (1.6)	0	0	0
Pharyngitis	1 (1.6)	0	1 (1.6)	0	0
Rash pustular	1 (1.6)	0	1 (1.6)	0	0
Respiratory syncytial virus infection	1 (1.6)	0	0	1 (1.6)	0
Respiratory tract infection	1 (1.6)	0	0	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	0	0	1 (1.6)	0
Rhinitis	1 (1.6)	1 (1.6)	0	0	0
Rotavirus infection	1 (1.6)	0	0	1 (1.6)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (1.6)	0	0	0	1 (1.6)
Septic embolus	1 (1.6)	0	0	0	1 (1.6)
Streptococcal infection	1 (1.6)	0	1 (1.6)	0	0
Subcutaneous abscess	1 (1.6)	0	1 (1.6)	0	0
Tinea capitis	1 (1.6)	1 (1.6)	0	0	0
Urinary tract infection enterococcal	1 (1.6)	0	0	1 (1.6)	0
Vascular device infection	1 (1.6)	0	0	1 (1.6)	0
Vulvovaginal mycotic infection	1 (1.6)	0	1 (1.6)	0	0
Injury, poisoning and procedural complications					
-Total	22 (34.4)	11 (17.2)	8 (12.5)	2 (3.1)	1 (1.6)
Procedural pain	5 (7.8)	2 (3.1)	2 (3.1)	1 (1.6)	0
Infusion related reaction	4 (6.3)	1 (1.6)	3 (4.7)	0	0
Contusion	3 (4.7)	3 (4.7)	0	0	0
Transfusion reaction	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Skin abrasion	2 (3.1)	2 (3.1)	0	0	0
Arthropod bite	1 (1.6)	1 (1.6)	0	0	0
Foot fracture	1 (1.6)	0	1 (1.6)	0	0
Incision site pain	1 (1.6)	1 (1.6)	0	0	0
Limb injury	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mouth injury	1 (1.6)	1 (1.6)	0	0	0
Post procedural haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Procedural complication	1 (1.6)	1 (1.6)	0	0	0
Procedural headache	1 (1.6)	0	1 (1.6)	0	0
Procedural nausea	1 (1.6)	0	1 (1.6)	0	0
Procedural site reaction	1 (1.6)	1 (1.6)	0	0	0
Radius fracture	1 (1.6)	0	1 (1.6)	0	0
Skin laceration	1 (1.6)	0	1 (1.6)	0	0
Stoma site irritation	1 (1.6)	1 (1.6)	0	0	0
Subdural haemorrhage	1 (1.6)	1 (1.6)	0	0	0
Sunburn	1 (1.6)	1 (1.6)	0	0	0
Tibia fracture	1 (1.6)	0	1 (1.6)	0	0
Tongue injury	1 (1.6)	1 (1.6)	0	0	0
Tracheal haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Transfusion related complication	1 (1.6)	0	0	0	1 (1.6)
Investigations					
-Total	56 (87.5)	2 (3.1)	5 (7.8)	15 (23.4)	34 (53.1)
White blood cell count decreased	35 (54.7)	4 (6.3)	1 (1.6)	12 (18.8)	18 (28.1)
Neutrophil count decreased	28 (43.8)	1 (1.6)	2 (3.1)	4 (6.3)	21 (32.8)

Timing: Any time post CTL019 infusion, Region: US

		All patients N=64			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	21 (32.8)	5 (7.8)	2 (3.1)	14 (21.9)	0
Aspartate aminotransferase increased	20 (31.3)	4 (6.3)	4 (6.3)	8 (12.5)	4 (6.3)
Platelet count decreased	20 (31.3)	3 (4.7)	2 (3.1)	3 (4.7)	12 (18.8)
Lymphocyte count decreased	16 (25.0)	1 (1.6)	3 (4.7)	7 (10.9)	5 (7.8)
Blood creatinine increased	9 (14.1)	5 (7.8)	2 (3.1)	2 (3.1)	0
International normalised ratio increased	9 (14.1)	8 (12.5)	0	1 (1.6)	0
Prothrombin time prolonged	9 (14.1)	5 (7.8)	3 (4.7)	1 (1.6)	0
Blood bilirubin increased	8 (12.5)	2 (3.1)	3 (4.7)	3 (4.7)	0
Activated partial thromboplastin time prolonged	5 (7.8)	3 (4.7)	2 (3.1)	0	0
Blood fibrinogen decreased	4 (6.3)	0	1 (1.6)	2 (3.1)	1 (1.6)
Blood immunoglobulin m decreased	4 (6.3)	4 (6.3)	0	0	0
Weight decreased	4 (6.3)	1 (1.6)	3 (4.7)	0	0
Blood immunoglobulin a decreased	3 (4.7)	3 (4.7)	0	0	0
Blood urea increased	3 (4.7)	1 (1.6)	1 (1.6)	1 (1.6)	0
Haemoglobin decreased	3 (4.7)	2 (3.1)	0	1 (1.6)	0
Transaminases increased	3 (4.7)	3 (4.7)	0	0	0
Blood magnesium decreased	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Blood phosphorus increased	2 (3.1)	2 (3.1)	0	0	0
Blood uric acid increased	2 (3.1)	2 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Region: US

		All patients N=64			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Lipase increased	2 (3.1)	0	0	0	2 (3.1)
Serum ferritin increased	2 (3.1)	0	2 (3.1)	0	0
Weight increased	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Blood alkaline phosphatase increased	1 (1.6)	1 (1.6)	0	0	0
Blood bicarbonate decreased	1 (1.6)	0	1 (1.6)	0	0
Blood immunoglobulin g decreased	1 (1.6)	0	1 (1.6)	0	0
Blood lactate dehydrogenase increased	1 (1.6)	1 (1.6)	0	0	0
Blood lactic acid increased	1 (1.6)	0	0	0	1 (1.6)
Blood phosphorus decreased	1 (1.6)	1 (1.6)	0	0	0
Blood sodium increased	1 (1.6)	0	1 (1.6)	0	0
Cardiac murmur	1 (1.6)	1 (1.6)	0	0	0
Culture stool positive	1 (1.6)	1 (1.6)	0	0	0
Fibrin d dimer increased	1 (1.6)	1 (1.6)	0	0	0
Hepatic enzyme increased	1 (1.6)	0	1 (1.6)	0	0
Norovirus test positive	1 (1.6)	1 (1.6)	0	0	0
Oxygen saturation decreased	1 (1.6)	1 (1.6)	0	0	0
Protein total decreased	1 (1.6)	0	0	1 (1.6)	0
Pulmonary function test decreased	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	43 (67.2)	8 (12.5)	8 (12.5)	23 (35.9)	4 (6.3)
Decreased appetite	22 (34.4)	5 (7.8)	5 (7.8)	12 (18.8)	0
Hypokalaemia	19 (29.7)	4 (6.3)	6 (9.4)	8 (12.5)	1 (1.6)
Hypophosphataemia	10 (15.6)	2 (3.1)	0	7 (10.9)	1 (1.6)
Hyperphosphataemia	8 (12.5)	8 (12.5)	0	0	0
Hypoalbuminaemia	5 (7.8)	1 (1.6)	3 (4.7)	1 (1.6)	0
Dehydration	4 (6.3)	1 (1.6)	0	3 (4.7)	0
Hypernatraemia	4 (6.3)	1 (1.6)	2 (3.1)	0	1 (1.6)
Fluid overload	3 (4.7)	1 (1.6)	2 (3.1)	0	0
Hyperglycaemia	3 (4.7)	0	1 (1.6)	2 (3.1)	0
Hyperuricaemia	3 (4.7)	2 (3.1)	0	0	1 (1.6)
Hypocalcaemia	3 (4.7)	1 (1.6)	1 (1.6)	1 (1.6)	0
Acidosis	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Hypertriglyceridaemia	2 (3.1)	1 (1.6)	0	1 (1.6)	0
Hyponatraemia	2 (3.1)	0	0	2 (3.1)	0
Tumour lysis syndrome	2 (3.1)	0	0	2 (3.1)	0
Vitamin d deficiency	2 (3.1)	2 (3.1)	0	0	0
Hyperalbuminaemia	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Region: US

Primary system organ class Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypercalcaemia	1 (1.6)	1 (1.6)	0	0	0
Hyperchloraemia	1 (1.6)	1 (1.6)	0	0	0
Hypermagnesaemia	1 (1.6)	1 (1.6)	0	0	0
Hypomagnesaemia	1 (1.6)	1 (1.6)	0	0	0
Iron overload	1 (1.6)	0	0	1 (1.6)	0
Malnutrition	1 (1.6)	0	0	1 (1.6)	0
Metabolic acidosis	1 (1.6)	0	1 (1.6)	0	0
Metabolic alkalosis	1 (1.6)	1 (1.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	25 (39.1)	14 (21.9)	10 (15.6)	1 (1.6)	0
Pain in extremity	11 (17.2)	7 (10.9)	4 (6.3)	0	0
Arthralgia	5 (7.8)	3 (4.7)	1 (1.6)	1 (1.6)	0
Myalgia	5 (7.8)	4 (6.3)	1 (1.6)	0	0
Muscular weakness	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Musculoskeletal pain	3 (4.7)	2 (3.1)	1 (1.6)	0	0
Joint range of motion decreased	2 (3.1)	2 (3.1)	0	0	0
Muscle spasms	2 (3.1)	2 (3.1)	0	0	0
Musculoskeletal chest pain	2 (3.1)	2 (3.1)	0	0	0
Back pain	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Region: US

Primary system organ class Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Coccydynia	1 (1.6)	1 (1.6)	0	0	0
Flank pain	1 (1.6)	0	1 (1.6)	0	0
Limb discomfort	1 (1.6)	1 (1.6)	0	0	0
Neck pain	1 (1.6)	0	1 (1.6)	0	0
Osteonecrosis	1 (1.6)	0	1 (1.6)	0	0
Osteopenia	1 (1.6)	0	1 (1.6)	0	0
Pain in jaw	1 (1.6)	1 (1.6)	0	0	0
Toe walking	1 (1.6)	1 (1.6)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (4.7)	0	2 (3.1)	0	1 (1.6)
Glioblastoma multiforme	1 (1.6)	0	0	0	1 (1.6)
Myelodysplastic syndrome	1 (1.6)	0	1 (1.6)	0	0
Skin papilloma	1 (1.6)	0	1 (1.6)	0	0
Nervous system disorders					
-Total	35 (54.7)	17 (26.6)	12 (18.8)	5 (7.8)	1 (1.6)
Headache	24 (37.5)	15 (23.4)	7 (10.9)	2 (3.1)	0
Dizziness	6 (9.4)	6 (9.4)	0	0	0
Encephalopathy	4 (6.3)	1 (1.6)	1 (1.6)	2 (3.1)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	4 (6.3)	0	2 (3.1)	2 (3.1)	0
Dysarthria	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Peroneal nerve palsy	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Tremor	2 (3.1)	2 (3.1)	0	0	0
Asterixis	1 (1.6)	1 (1.6)	0	0	0
Ataxia	1 (1.6)	0	1 (1.6)	0	0
Depressed level of consciousness	1 (1.6)	1 (1.6)	0	0	0
Disturbance in attention	1 (1.6)	1 (1.6)	0	0	0
Embolic stroke	1 (1.6)	0	0	0	1 (1.6)
Idiopathic intracranial hypertension	1 (1.6)	0	1 (1.6)	0	0
Migraine	1 (1.6)	0	1 (1.6)	0	0
Myoclonus	1 (1.6)	1 (1.6)	0	0	0
Neuropathy peripheral	1 (1.6)	0	1 (1.6)	0	0
Pleocytosis	1 (1.6)	1 (1.6)	0	0	0
Somnolence	1 (1.6)	1 (1.6)	0	0	0
Product issues					
-Total	1 (1.6)	1 (1.6)	0	0	0
Device occlusion	1 (1.6)	1 (1.6)	0	0	0
Psychiatric disorders					

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	17 (26.6)	8 (12.5)	8 (12.5)	1 (1.6)	0
Anxiety	7 (10.9)	3 (4.7)	3 (4.7)	1 (1.6)	0
Confusional state	6 (9.4)	3 (4.7)	3 (4.7)	0	0
Delirium	4 (6.3)	2 (3.1)	2 (3.1)	0	0
Agitation	2 (3.1)	0	2 (3.1)	0	0
Depression	2 (3.1)	2 (3.1)	0	0	0
Hallucination	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Irritability	2 (3.1)	2 (3.1)	0	0	0
Adjustment disorder	1 (1.6)	0	1 (1.6)	0	0
Insomnia	1 (1.6)	0	1 (1.6)	0	0
Listless	1 (1.6)	1 (1.6)	0	0	0
Mental status changes	1 (1.6)	1 (1.6)	0	0	0
Panic attack	1 (1.6)	0	1 (1.6)	0	0
Sleep disorder	1 (1.6)	0	1 (1.6)	0	0
Suicidal ideation	1 (1.6)	1 (1.6)	0	0	0
Renal and urinary disorders					
-Total	15 (23.4)	3 (4.7)	2 (3.1)	6 (9.4)	4 (6.3)
Acute kidney injury	9 (14.1)	1 (1.6)	1 (1.6)	4 (6.3)	3 (4.7)
Haematuria	5 (7.8)	0	2 (3.1)	2 (3.1)	1 (1.6)

Timing: Any time post CTL019 infusion, Region: US

Primary system organ class Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysuria	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Oliguria	2 (3.1)	0	0	2 (3.1)	0
Calculus urinary	1 (1.6)	0	1 (1.6)	0	0
Nephrolithiasis	1 (1.6)	0	0	1 (1.6)	0
Pollakiuria	1 (1.6)	1 (1.6)	0	0	0
Renal failure	1 (1.6)	0	0	0	1 (1.6)
Renal impairment	1 (1.6)	0	0	1 (1.6)	0
Urinary incontinence	1 (1.6)	1 (1.6)	0	0	0
Reproductive system and breast disorders					
-Total	6 (9.4)	2 (3.1)	2 (3.1)	2 (3.1)	0
Vulvovaginal adhesion	2 (3.1)	2 (3.1)	0	0	0
Oedema genital	1 (1.6)	0	1 (1.6)	0	0
Ovarian failure	1 (1.6)	0	0	1 (1.6)	0
Scrotal pain	1 (1.6)	0	1 (1.6)	0	0
Vaginal haemorrhage	1 (1.6)	0	0	1 (1.6)	0
Respiratory, thoracic and mediastinal disorders					
-Total	38 (59.4)	14 (21.9)	9 (14.1)	7 (10.9)	8 (12.5)
Cough	14 (21.9)	12 (18.8)	2 (3.1)	0	0
Epistaxis	10 (15.6)	4 (6.3)	1 (1.6)	4 (6.3)	1 (1.6)

Timing: Any time post CTL019 infusion, Region: US

		All patients N=64			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	10 (15.6)	0	3 (4.7)	4 (6.3)	3 (4.7)
Pleural effusion	8 (12.5)	2 (3.1)	4 (6.3)	2 (3.1)	0
Pulmonary oedema	7 (10.9)	1 (1.6)	0	4 (6.3)	2 (3.1)
Oropharyngeal pain	6 (9.4)	4 (6.3)	2 (3.1)	0	0
Rhinorrhoea	6 (9.4)	5 (7.8)	1 (1.6)	0	0
Nasal congestion	5 (7.8)	5 (7.8)	0	0	0
Tachypnoea	5 (7.8)	3 (4.7)	1 (1.6)	1 (1.6)	0
Rhinitis allergic	4 (6.3)	3 (4.7)	1 (1.6)	0	0
Respiratory failure	3 (4.7)	0	0	0	3 (4.7)
Dyspnoea	2 (3.1)	0	0	1 (1.6)	1 (1.6)
Haemoptysis	2 (3.1)	1 (1.6)	0	0	1 (1.6)
Acute respiratory failure	1 (1.6)	0	0	0	1 (1.6)
Atelectasis	1 (1.6)	1 (1.6)	0	0	0
Dysphonia	1 (1.6)	1 (1.6)	0	0	0
Interstitial lung disease	1 (1.6)	0	0	0	1 (1.6)
Oropharyngeal plaque	1 (1.6)	1 (1.6)	0	0	0
Pharyngeal erythema	1 (1.6)	1 (1.6)	0	0	0
Pharyngeal lesion	1 (1.6)	0	0	1 (1.6)	0
Pharyngeal ulceration	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Region: US

		All patients N=64			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory depression	1 (1.6)	0	1 (1.6)	0	0
Respiratory distress	1 (1.6)	0	0	0	1 (1.6)
Wheezing	1 (1.6)	0	1 (1.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	30 (46.9)	18 (28.1)	9 (14.1)	3 (4.7)	0
Rash	8 (12.5)	5 (7.8)	3 (4.7)	0	0
Dry skin	5 (7.8)	5 (7.8)	0	0	0
Erythema	5 (7.8)	5 (7.8)	0	0	0
Rash maculo-papular	5 (7.8)	3 (4.7)	1 (1.6)	1 (1.6)	0
Hyperhidrosis	4 (6.3)	4 (6.3)	0	0	0
Petechiae	4 (6.3)	3 (4.7)	1 (1.6)	0	0
Pruritus	4 (6.3)	4 (6.3)	0	0	0
Ingrowing nail	3 (4.7)	1 (1.6)	2 (3.1)	0	0
Macule	2 (3.1)	2 (3.1)	0	0	0
Papule	2 (3.1)	2 (3.1)	0	0	0
Rash erythematous	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Rash papular	2 (3.1)	2 (3.1)	0	0	0
Acne	1 (1.6)	1 (1.6)	0	0	0
Alopecia	1 (1.6)	0	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dermatitis	1 (1.6)	1 (1.6)	0	0	0
Dermatitis acneiform	1 (1.6)	0	0	1 (1.6)	0
Dermatitis atopic	1 (1.6)	1 (1.6)	0	0	0
Dermatitis diaper	1 (1.6)	1 (1.6)	0	0	0
Ecchymosis	1 (1.6)	0	0	1 (1.6)	0
Eczema	1 (1.6)	1 (1.6)	0	0	0
Keloid scar	1 (1.6)	0	1 (1.6)	0	0
Livedo reticularis	1 (1.6)	1 (1.6)	0	0	0
Night sweats	1 (1.6)	0	1 (1.6)	0	0
Rash follicular	1 (1.6)	1 (1.6)	0	0	0
Rash macular	1 (1.6)	1 (1.6)	0	0	0
Rash pruritic	1 (1.6)	1 (1.6)	0	0	0
Rash vesicular	1 (1.6)	1 (1.6)	0	0	0
Skin exfoliation	1 (1.6)	1 (1.6)	0	0	0
Skin fissures	1 (1.6)	1 (1.6)	0	0	0
Skin irritation	1 (1.6)	1 (1.6)	0	0	0
Vascular disorders					
-Total	25 (39.1)	3 (4.7)	6 (9.4)	8 (12.5)	8 (12.5)
Hypotension	16 (25.0)	1 (1.6)	0	7 (10.9)	8 (12.5)

Timing: Any time post CTL019 infusion, Region: US

Primary system organ class Preferred term	All patients N=64 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	12 (18.8)	3 (4.7)	8 (12.5)	1 (1.6)	0
Flushing	2 (3.1)	2 (3.1)	0	0	0
Orthostatic hypotension	2 (3.1)	1 (1.6)	1 (1.6)	0	0
Capillary leak syndrome	1 (1.6)	0	0	0	1 (1.6)
Embolism	1 (1.6)	0	0	1 (1.6)	0
Haematoma	1 (1.6)	0	1 (1.6)	0	0
Hot flush	1 (1.6)	1 (1.6)	0	0	0
Secondary hypertension	1 (1.6)	0	1 (1.6)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174l
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

			All patients N=28		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (96.4)	1 (3.6)	4 (14.3)	7 (25.0)	15 (53.6)
Blood and lymphatic system disorders					
-Total	18 (64.3)	0	2 (7.1)	13 (46.4)	3 (10.7)
Anaemia	14 (50.0)	1 (3.6)	4 (14.3)	9 (32.1)	0
Febrile neutropenia	9 (32.1)	0	0	9 (32.1)	0
Lymphopenia	2 (7.1)	0	1 (3.6)	0	1 (3.6)
Thrombocytopenia	2 (7.1)	0	0	1 (3.6)	1 (3.6)
Disseminated intravascular coagulation	1 (3.6)	0	1 (3.6)	0	0
Neutropenia	1 (3.6)	0	0	0	1 (3.6)
Cardiac disorders					
-Total	10 (35.7)	4 (14.3)	5 (17.9)	1 (3.6)	0
Tachycardia	7 (25.0)	3 (10.7)	3 (10.7)	1 (3.6)	0
Sinus tachycardia	4 (14.3)	2 (7.1)	2 (7.1)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac dysfunction	1 (3.6)	1 (3.6)	0	0	0
Sinus bradycardia	1 (3.6)	1 (3.6)	0	0	0
Ear and labyrinth disorders					
-Total	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Ear pain	2 (7.1)	2 (7.1)	0	0	0
Hypoacusis	1 (3.6)	0	1 (3.6)	0	0
Eye disorders					
-Total	7 (25.0)	1 (3.6)	6 (21.4)	0	0
Eye pain	2 (7.1)	0	2 (7.1)	0	0
Photophobia	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Uveitis	2 (7.1)	0	2 (7.1)	0	0
Ocular hypertension	1 (3.6)	0	1 (3.6)	0	0
Papilloedema	1 (3.6)	0	1 (3.6)	0	0
Periorbital oedema	1 (3.6)	0	1 (3.6)	0	0
Vision blurred	1 (3.6)	0	1 (3.6)	0	0
Visual impairment	1 (3.6)	0	1 (3.6)	0	0
Gastrointestinal disorders					
-Total	17 (60.7)	5 (17.9)	8 (28.6)	4 (14.3)	0
Nausea	12 (42.9)	5 (17.9)	6 (21.4)	1 (3.6)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	10 (35.7)	7 (25.0)	3 (10.7)	0	0
Vomiting	10 (35.7)	8 (28.6)	0	2 (7.1)	0
Abdominal pain	7 (25.0)	5 (17.9)	2 (7.1)	0	0
Abdominal distension	2 (7.1)	0	2 (7.1)	0	0
Constipation	2 (7.1)	2 (7.1)	0	0	0
Stomatitis	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Abdominal pain lower	1 (3.6)	0	1 (3.6)	0	0
Abdominal tenderness	1 (3.6)	1 (3.6)	0	0	0
Anal incontinence	1 (3.6)	1 (3.6)	0	0	0
Gastrointestinal haemorrhage	1 (3.6)	1 (3.6)	0	0	0
Gastrooesophageal reflux disease	1 (3.6)	1 (3.6)	0	0	0
Glossodynia	1 (3.6)	1 (3.6)	0	0	0
Haematemesis	1 (3.6)	1 (3.6)	0	0	0
Lip pain	1 (3.6)	0	1 (3.6)	0	0
Mouth haemorrhage	1 (3.6)	0	0	1 (3.6)	0
General disorders and administration site conditions					
-Total	14 (50.0)	8 (28.6)	4 (14.3)	2 (7.1)	0
Fatigue	8 (28.6)	6 (21.4)	1 (3.6)	1 (3.6)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	6 (21.4)	3 (10.7)	2 (7.1)	1 (3.6)	0
Chills	3 (10.7)	3 (10.7)	0	0	0
Malaise	2 (7.1)	0	2 (7.1)	0	0
Catheter site extravasation	1 (3.6)	0	1 (3.6)	0	0
Catheter site haemorrhage	1 (3.6)	1 (3.6)	0	0	0
Catheter site pain	1 (3.6)	1 (3.6)	0	0	0
Face oedema	1 (3.6)	0	1 (3.6)	0	0
Facial pain	1 (3.6)	0	1 (3.6)	0	0
Generalised oedema	1 (3.6)	0	1 (3.6)	0	0
Injection site haematoma	1 (3.6)	1 (3.6)	0	0	0
Non-cardiac chest pain	1 (3.6)	1 (3.6)	0	0	0
Oedema peripheral	1 (3.6)	1 (3.6)	0	0	0
Pain	1 (3.6)	0	0	1 (3.6)	0
Peripheral swelling	1 (3.6)	0	1 (3.6)	0	0
Hepatobiliary disorders					
-Total	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Hepatomegaly	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Hyperbilirubinaemia	1 (3.6)	0	0	1 (3.6)	0
Immune system disorders					

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	23 (82.1)	4 (14.3)	12 (42.9)	5 (17.9)	2 (7.1)
Cytokine release syndrome	20 (71.4)	3 (10.7)	11 (39.3)	4 (14.3)	2 (7.1)
Hypogammaglobulinaemia	9 (32.1)	2 (7.1)	6 (21.4)	1 (3.6)	0
Graft versus host disease in skin	1 (3.6)	1 (3.6)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (3.6)	0	1 (3.6)	0	0
Infections and infestations					
-Total	13 (46.4)	4 (14.3)	8 (28.6)	0	1 (3.6)
Clostridium difficile infection	3 (10.7)	0	3 (10.7)	0	0
Acute sinusitis	1 (3.6)	0	1 (3.6)	0	0
Body tinea	1 (3.6)	1 (3.6)	0	0	0
Catheter site cellulitis	1 (3.6)	1 (3.6)	0	0	0
Clostridium difficile colitis	1 (3.6)	0	1 (3.6)	0	0
Cytomegalovirus infection	1 (3.6)	1 (3.6)	0	0	0
Enterococcal infection	1 (3.6)	1 (3.6)	0	0	0
Fungal skin infection	1 (3.6)	1 (3.6)	0	0	0
Gastroenteritis norovirus	1 (3.6)	0	1 (3.6)	0	0
Herpes simplex	1 (3.6)	1 (3.6)	0	0	0
Human herpesvirus 6 infection	1 (3.6)	0	1 (3.6)	0	0
Hypopyon	1 (3.6)	0	1 (3.6)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	1 (3.6)	1 (3.6)	0	0	0
Oral candidiasis	1 (3.6)	1 (3.6)	0	0	0
Rhinovirus infection	1 (3.6)	1 (3.6)	0	0	0
Septic embolus	1 (3.6)	0	0	0	1 (3.6)
Skin infection	1 (3.6)	0	1 (3.6)	0	0
Vulvovaginal candidiasis	1 (3.6)	1 (3.6)	0	0	0
Injury, poisoning and procedural complications					
-Total	8 (28.6)	3 (10.7)	4 (14.3)	0	1 (3.6)
Transfusion reaction	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Infusion related reaction	2 (7.1)	0	2 (7.1)	0	0
Procedural pain	2 (7.1)	0	2 (7.1)	0	0
Contusion	1 (3.6)	1 (3.6)	0	0	0
Limb injury	1 (3.6)	1 (3.6)	0	0	0
Mouth injury	1 (3.6)	1 (3.6)	0	0	0
Procedural headache	1 (3.6)	0	1 (3.6)	0	0
Procedural site reaction	1 (3.6)	1 (3.6)	0	0	0
Skin abrasion	1 (3.6)	1 (3.6)	0	0	0
Tongue injury	1 (3.6)	1 (3.6)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion related complication	1 (3.6)	0	0	0	1 (3.6)
Investigations					
-Total	23 (82.1)	2 (7.1)	3 (10.7)	5 (17.9)	13 (46.4)
White blood cell count decreased	15 (53.6)	0	1 (3.6)	7 (25.0)	7 (25.0)
Alanine aminotransferase increased	12 (42.9)	4 (14.3)	2 (7.1)	6 (21.4)	0
Aspartate aminotransferase increased	12 (42.9)	3 (10.7)	2 (7.1)	5 (17.9)	2 (7.1)
Neutrophil count decreased	12 (42.9)	0	1 (3.6)	1 (3.6)	10 (35.7)
Platelet count decreased	11 (39.3)	2 (7.1)	1 (3.6)	1 (3.6)	7 (25.0)
Blood bilirubin increased	6 (21.4)	2 (7.1)	2 (7.1)	2 (7.1)	0
Blood creatinine increased	6 (21.4)	4 (14.3)	1 (3.6)	1 (3.6)	0
Lymphocyte count decreased	6 (21.4)	0	1 (3.6)	4 (14.3)	1 (3.6)
Prothrombin time prolonged	6 (21.4)	4 (14.3)	2 (7.1)	0	0
International normalised ratio increased	5 (17.9)	5 (17.9)	0	0	0
Blood immunoglobulin a decreased	3 (10.7)	3 (10.7)	0	0	0
Blood immunoglobulin m decreased	3 (10.7)	3 (10.7)	0	0	0
Activated partial thromboplastin time prolonged	2 (7.1)	2 (7.1)	0	0	0
Blood bicarbonate decreased	1 (3.6)	0	1 (3.6)	0	0
Blood lactic acid increased	1 (3.6)	0	0	0	1 (3.6)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood urea increased	1 (3.6)	0	1 (3.6)	0	0
Culture stool positive	1 (3.6)	1 (3.6)	0	0	0
Haemoglobin decreased	1 (3.6)	0	0	1 (3.6)	0
Hepatic enzyme increased	1 (3.6)	0	1 (3.6)	0	0
Norovirus test positive	1 (3.6)	1 (3.6)	0	0	0
Pulmonary function test decreased	1 (3.6)	0	1 (3.6)	0	0
Serum ferritin increased	1 (3.6)	0	1 (3.6)	0	0
Metabolism and nutrition disorders					
-Total	17 (60.7)	3 (10.7)	7 (25.0)	7 (25.0)	0
Decreased appetite	9 (32.1)	2 (7.1)	2 (7.1)	5 (17.9)	0
Hyperphosphataemia	7 (25.0)	7 (25.0)	0	0	0
Hypokalaemia	7 (25.0)	1 (3.6)	3 (10.7)	3 (10.7)	0
Hypophosphataemia	4 (14.3)	1 (3.6)	0	3 (10.7)	0
Fluid overload	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Hyperuricaemia	2 (7.1)	2 (7.1)	0	0	0
Hypoalbuminaemia	2 (7.1)	0	2 (7.1)	0	0
Hypocalcaemia	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Hyponatraemia	2 (7.1)	0	0	2 (7.1)	0
Dehydration	1 (3.6)	1 (3.6)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	1 (3.6)	0	1 (3.6)	0	0
Musculoskeletal and connective tissue disorders					
-Total	10 (35.7)	7 (25.0)	3 (10.7)	0	0
Myalgia	5 (17.9)	4 (14.3)	1 (3.6)	0	0
Pain in extremity	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Arthralgia	2 (7.1)	2 (7.1)	0	0	0
Musculoskeletal pain	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Coccydynia	1 (3.6)	1 (3.6)	0	0	0
Muscle spasms	1 (3.6)	1 (3.6)	0	0	0
Musculoskeletal chest pain	1 (3.6)	1 (3.6)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.6)	0	1 (3.6)	0	0
Skin papilloma	1 (3.6)	0	1 (3.6)	0	0
Nervous system disorders					
-Total	15 (53.6)	6 (21.4)	5 (17.9)	3 (10.7)	1 (3.6)
Headache	12 (42.9)	6 (21.4)	4 (14.3)	2 (7.1)	0
Dizziness	3 (10.7)	3 (10.7)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Embolic stroke	1 (3.6)	0	0	0	1 (3.6)
Idiopathic intracranial hypertension	1 (3.6)	0	1 (3.6)	0	0
Myoclonus	1 (3.6)	1 (3.6)	0	0	0
Seizure	1 (3.6)	0	0	1 (3.6)	0
Product issues					
-Total	1 (3.6)	1 (3.6)	0	0	0
Device occlusion	1 (3.6)	1 (3.6)	0	0	0
Psychiatric disorders					
-Total	4 (14.3)	1 (3.6)	2 (7.1)	1 (3.6)	0
Anxiety	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Confusional state	2 (7.1)	0	2 (7.1)	0	0
Agitation	1 (3.6)	0	1 (3.6)	0	0
Hallucination	1 (3.6)	0	1 (3.6)	0	0
Irritability	1 (3.6)	1 (3.6)	0	0	0
Listless	1 (3.6)	1 (3.6)	0	0	0
Renal and urinary disorders					
-Total	2 (7.1)	1 (3.6)	0	0	1 (3.6)
Acute kidney injury	2 (7.1)	1 (3.6)	0	0	1 (3.6)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	1 (3.6)	0	1 (3.6)	0	0
Oliguria	1 (3.6)	0	0	1 (3.6)	0
Reproductive system and breast disorders					
-Total	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Oedema genital	1 (3.6)	0	1 (3.6)	0	0
Vulvovaginal adhesion	1 (3.6)	1 (3.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	13 (46.4)	4 (14.3)	5 (17.9)	3 (10.7)	1 (3.6)
Hypoxia	5 (17.9)	0	3 (10.7)	1 (3.6)	1 (3.6)
Cough	4 (14.3)	4 (14.3)	0	0	0
Epistaxis	3 (10.7)	1 (3.6)	0	2 (7.1)	0
Pleural effusion	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Tachypnoea	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Atelectasis	1 (3.6)	1 (3.6)	0	0	0
Dyspnoea	1 (3.6)	0	0	1 (3.6)	0
Oropharyngeal pain	1 (3.6)	1 (3.6)	0	0	0
Pulmonary oedema	1 (3.6)	0	0	1 (3.6)	0
Rhinitis allergic	1 (3.6)	1 (3.6)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	1 (3.6)	1 (3.6)	0	0	0
Wheezing	1 (3.6)	0	1 (3.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (28.6)	4 (14.3)	3 (10.7)	1 (3.6)	0
Ingrowing nail	2 (7.1)	0	2 (7.1)	0	0
Petechiae	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Rash	2 (7.1)	2 (7.1)	0	0	0
Dry skin	1 (3.6)	1 (3.6)	0	0	0
Erythema	1 (3.6)	1 (3.6)	0	0	0
Hyperhidrosis	1 (3.6)	1 (3.6)	0	0	0
Night sweats	1 (3.6)	0	1 (3.6)	0	0
Pruritus	1 (3.6)	1 (3.6)	0	0	0
Rash follicular	1 (3.6)	1 (3.6)	0	0	0
Rash maculo-papular	1 (3.6)	0	0	1 (3.6)	0
Rash papular	1 (3.6)	1 (3.6)	0	0	0
Rash vesicular	1 (3.6)	1 (3.6)	0	0	0
Skin irritation	1 (3.6)	1 (3.6)	0	0	0
Vascular disorders					
-Total	11 (39.3)	3 (10.7)	2 (7.1)	3 (10.7)	3 (10.7)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	6 (21.4)	1 (3.6)	0	2 (7.1)	3 (10.7)
Hypertension	5 (17.9)	1 (3.6)	3 (10.7)	1 (3.6)	0
Orthostatic hypotension	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Embolism	1 (3.6)	0	0	1 (3.6)	0
Flushing	1 (3.6)	1 (3.6)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174l
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: No

			All patients N=36		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (100)	1 (2.8)	3 (8.3)	7 (19.4)	25 (69.4)
Blood and lymphatic system disorders					
-Total	25 (69.4)	2 (5.6)	1 (2.8)	14 (38.9)	8 (22.2)
Anaemia	13 (36.1)	2 (5.6)	1 (2.8)	9 (25.0)	1 (2.8)
Febrile neutropenia	13 (36.1)	0	0	13 (36.1)	0
Neutropenia	7 (19.4)	0	0	3 (8.3)	4 (11.1)
Thrombocytopenia	6 (16.7)	0	0	1 (2.8)	5 (13.9)
Disseminated intravascular coagulation	3 (8.3)	0	1 (2.8)	2 (5.6)	0
Coagulopathy	1 (2.8)	1 (2.8)	0	0	0
Lymphopenia	1 (2.8)	0	0	1 (2.8)	0
Pancytopenia	1 (2.8)	0	0	0	1 (2.8)
Cardiac disorders					
-Total	12 (33.3)	7 (19.4)	4 (11.1)	1 (2.8)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	8 (22.2)	5 (13.9)	2 (5.6)	1 (2.8)	0
Pericardial effusion	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Atrioventricular block second degree	1 (2.8)	1 (2.8)	0	0	0
Bradycardia	1 (2.8)	0	1 (2.8)	0	0
Left ventricular dysfunction	1 (2.8)	0	0	1 (2.8)	0
Palpitations	1 (2.8)	1 (2.8)	0	0	0
Sinus tachycardia	1 (2.8)	1 (2.8)	0	0	0
Ventricular tachycardia	1 (2.8)	0	1 (2.8)	0	0
Endocrine disorders					
-Total	1 (2.8)	0	1 (2.8)	0	0
Adrenal insufficiency	1 (2.8)	0	1 (2.8)	0	0
Eye disorders					
-Total	6 (16.7)	5 (13.9)	1 (2.8)	0	0
Conjunctival haemorrhage	3 (8.3)	3 (8.3)	0	0	0
Periorbital oedema	3 (8.3)	3 (8.3)	0	0	0
Retinal haemorrhage	2 (5.6)	2 (5.6)	0	0	0
Vision blurred	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Eye pain	1 (2.8)	1 (2.8)	0	0	0
Gastrointestinal disorders					

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	19 (52.8)	6 (16.7)	6 (16.7)	7 (19.4)	0
Vomiting	12 (33.3)	5 (13.9)	6 (16.7)	1 (2.8)	0
Nausea	9 (25.0)	1 (2.8)	6 (16.7)	2 (5.6)	0
Diarrhoea	8 (22.2)	4 (11.1)	3 (8.3)	1 (2.8)	0
Constipation	5 (13.9)	4 (11.1)	1 (2.8)	0	0
Abdominal pain	2 (5.6)	1 (2.8)	0	1 (2.8)	0
Abdominal pain upper	2 (5.6)	0	2 (5.6)	0	0
Dysphagia	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Pancreatitis	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Abdominal discomfort	1 (2.8)	1 (2.8)	0	0	0
Ascites	1 (2.8)	0	0	1 (2.8)	0
Dyspepsia	1 (2.8)	0	1 (2.8)	0	0
Flatulence	1 (2.8)	1 (2.8)	0	0	0
Haematemesis	1 (2.8)	1 (2.8)	0	0	0
Ileus	1 (2.8)	0	0	1 (2.8)	0
Intestinal obstruction	1 (2.8)	0	0	1 (2.8)	0
Tooth socket haemorrhage	1 (2.8)	1 (2.8)	0	0	0
General disorders and administration site conditions					

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	18 (50.0)	4 (11.1)	6 (16.7)	7 (19.4)	1 (2.8)
Pyrexia	10 (27.8)	0	5 (13.9)	4 (11.1)	1 (2.8)
Chills	5 (13.9)	5 (13.9)	0	0	0
Fatigue	5 (13.9)	4 (11.1)	1 (2.8)	0	0
Catheter site pain	2 (5.6)	0	2 (5.6)	0	0
Pain	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Asthenia	1 (2.8)	1 (2.8)	0	0	0
Face oedema	1 (2.8)	0	0	1 (2.8)	0
Generalised oedema	1 (2.8)	0	1 (2.8)	0	0
Localised oedema	1 (2.8)	0	0	1 (2.8)	0
Malaise	1 (2.8)	0	1 (2.8)	0	0
Mucosal haemorrhage	1 (2.8)	0	1 (2.8)	0	0
Multiple organ dysfunction syndrome	1 (2.8)	0	0	1 (2.8)	0
Oedema peripheral	1 (2.8)	0	0	1 (2.8)	0
Physical deconditioning	1 (2.8)	0	0	1 (2.8)	0
Hepatobiliary disorders					
-Total	5 (13.9)	2 (5.6)	2 (5.6)	1 (2.8)	0
Hyperbilirubinaemia	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Gallbladder enlargement	1 (2.8)	1 (2.8)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	1 (2.8)	0	1 (2.8)	0	0
Hepatosplenomegaly	1 (2.8)	1 (2.8)	0	0	0
Immune system disorders					
-Total	34 (94.4)	1 (2.8)	18 (50.0)	6 (16.7)	9 (25.0)
Cytokine release syndrome	30 (83.3)	3 (8.3)	14 (38.9)	4 (11.1)	9 (25.0)
Hypogammaglobulinaemia	16 (44.4)	1 (2.8)	12 (33.3)	3 (8.3)	0
Drug hypersensitivity	1 (2.8)	0	1 (2.8)	0	0
Infections and infestations					
-Total	13 (36.1)	1 (2.8)	6 (16.7)	6 (16.7)	0
Clostridium difficile colitis	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Gastroenteritis	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Pneumonia	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Rhinovirus infection	2 (5.6)	2 (5.6)	0	0	0
Staphylococcal infection	2 (5.6)	1 (2.8)	0	1 (2.8)	0
Catheter site infection	1 (2.8)	0	0	1 (2.8)	0
Clostridium difficile infection	1 (2.8)	0	1 (2.8)	0	0
Folliculitis	1 (2.8)	0	1 (2.8)	0	0
Orchitis	1 (2.8)	1 (2.8)	0	0	0
Pharyngitis	1 (2.8)	0	1 (2.8)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal infection	1 (2.8)	0	1 (2.8)	0	0
Upper respiratory tract infection	1 (2.8)	0	1 (2.8)	0	0
Urinary tract infection enterococcal	1 (2.8)	0	0	1 (2.8)	0
Viral infection	1 (2.8)	0	1 (2.8)	0	0
Viral upper respiratory tract infection	1 (2.8)	0	1 (2.8)	0	0
Injury, poisoning and procedural complications					
-Total	7 (19.4)	5 (13.9)	1 (2.8)	1 (2.8)	0
Incision site pain	1 (2.8)	1 (2.8)	0	0	0
Post procedural haemorrhage	1 (2.8)	1 (2.8)	0	0	0
Procedural complication	1 (2.8)	1 (2.8)	0	0	0
Procedural pain	1 (2.8)	1 (2.8)	0	0	0
Stoma site irritation	1 (2.8)	1 (2.8)	0	0	0
Subdural haemorrhage	1 (2.8)	1 (2.8)	0	0	0
Tibia fracture	1 (2.8)	0	1 (2.8)	0	0
Tracheal haemorrhage	1 (2.8)	0	0	1 (2.8)	0
Investigations					
-Total	29 (80.6)	2 (5.6)	1 (2.8)	8 (22.2)	18 (50.0)
White blood cell count decreased	15 (41.7)	3 (8.3)	0	3 (8.3)	9 (25.0)
Neutrophil count decreased	13 (36.1)	0	1 (2.8)	3 (8.3)	9 (25.0)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	8 (22.2)	1 (2.8)	1 (2.8)	2 (5.6)	4 (11.1)
Platelet count decreased	8 (22.2)	1 (2.8)	1 (2.8)	1 (2.8)	5 (13.9)
Alanine aminotransferase increased	7 (19.4)	1 (2.8)	1 (2.8)	5 (13.9)	0
Aspartate aminotransferase increased	6 (16.7)	0	2 (5.6)	2 (5.6)	2 (5.6)
Blood fibrinogen decreased	4 (11.1)	0	1 (2.8)	2 (5.6)	1 (2.8)
International normalised ratio increased	4 (11.1)	3 (8.3)	0	1 (2.8)	0
Activated partial thromboplastin time prolonged	3 (8.3)	1 (2.8)	2 (5.6)	0	0
Blood creatinine increased	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Prothrombin time prolonged	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Blood phosphorus increased	2 (5.6)	2 (5.6)	0	0	0
Blood urea increased	2 (5.6)	1 (2.8)	0	1 (2.8)	0
Lipase increased	2 (5.6)	0	0	0	2 (5.6)
Transaminases increased	2 (5.6)	2 (5.6)	0	0	0
Blood bilirubin increased	1 (2.8)	0	1 (2.8)	0	0
Blood immunoglobulin g decreased	1 (2.8)	0	1 (2.8)	0	0
Blood immunoglobulin m decreased	1 (2.8)	1 (2.8)	0	0	0
Blood magnesium decreased	1 (2.8)	0	0	1 (2.8)	0
Blood phosphorus decreased	1 (2.8)	1 (2.8)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood sodium increased	1 (2.8)	0	1 (2.8)	0	0
Blood uric acid increased	1 (2.8)	1 (2.8)	0	0	0
C-reactive protein increased	1 (2.8)	0	0	1 (2.8)	0
Cardiac murmur	1 (2.8)	1 (2.8)	0	0	0
Fibrin d dimer increased	1 (2.8)	1 (2.8)	0	0	0
Protein total decreased	1 (2.8)	0	0	1 (2.8)	0
Metabolism and nutrition disorders					
-Total	22 (61.1)	2 (5.6)	3 (8.3)	14 (38.9)	3 (8.3)
Decreased appetite	11 (30.6)	2 (5.6)	2 (5.6)	7 (19.4)	0
Hypokalaemia	9 (25.0)	2 (5.6)	3 (8.3)	4 (11.1)	0
Hypophosphataemia	5 (13.9)	1 (2.8)	0	3 (8.3)	1 (2.8)
Hypernatraemia	4 (11.1)	1 (2.8)	2 (5.6)	0	1 (2.8)
Hypoalbuminaemia	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Acidosis	2 (5.6)	1 (2.8)	0	1 (2.8)	0
Dehydration	2 (5.6)	0	0	2 (5.6)	0
Hyperglycaemia	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Hypertriglyceridaemia	2 (5.6)	1 (2.8)	0	1 (2.8)	0
Fluid overload	1 (2.8)	0	1 (2.8)	0	0
Hyperalbuminaemia	1 (2.8)	1 (2.8)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypercalcaemia	1 (2.8)	1 (2.8)	0	0	0
Hyperchloraemia	1 (2.8)	1 (2.8)	0	0	0
Hypermagnesaemia	1 (2.8)	1 (2.8)	0	0	0
Hyperphosphataemia	1 (2.8)	1 (2.8)	0	0	0
Hyperuricaemia	1 (2.8)	0	0	0	1 (2.8)
Hypocalcaemia	1 (2.8)	1 (2.8)	0	0	0
Hypomagnesaemia	1 (2.8)	1 (2.8)	0	0	0
Malnutrition	1 (2.8)	0	0	1 (2.8)	0
Metabolic acidosis	1 (2.8)	0	1 (2.8)	0	0
Metabolic alkalosis	1 (2.8)	1 (2.8)	0	0	0
Tumour lysis syndrome	1 (2.8)	0	0	1 (2.8)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (13.9)	1 (2.8)	3 (8.3)	1 (2.8)	0
Arthralgia	2 (5.6)	1 (2.8)	0	1 (2.8)	0
Limb discomfort	1 (2.8)	1 (2.8)	0	0	0
Muscular weakness	1 (2.8)	0	1 (2.8)	0	0
Musculoskeletal pain	1 (2.8)	1 (2.8)	0	0	0
Osteopenia	1 (2.8)	0	1 (2.8)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	1 (2.8)	0	1 (2.8)	0	0
Nervous system disorders					
-Total	18 (50.0)	11 (30.6)	6 (16.7)	1 (2.8)	0
Headache	12 (33.3)	10 (27.8)	2 (5.6)	0	0
Dysarthria	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Encephalopathy	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Seizure	2 (5.6)	0	2 (5.6)	0	0
Tremor	2 (5.6)	2 (5.6)	0	0	0
Asterixis	1 (2.8)	1 (2.8)	0	0	0
Ataxia	1 (2.8)	0	1 (2.8)	0	0
Depressed level of consciousness	1 (2.8)	1 (2.8)	0	0	0
Dizziness	1 (2.8)	1 (2.8)	0	0	0
Migraine	1 (2.8)	0	1 (2.8)	0	0
Neuropathy peripheral	1 (2.8)	0	1 (2.8)	0	0
Pleocytosis	1 (2.8)	1 (2.8)	0	0	0
Somnolence	1 (2.8)	1 (2.8)	0	0	0
Psychiatric disorders					
-Total	12 (33.3)	7 (19.4)	5 (13.9)	0	0
Confusional state	4 (11.1)	3 (8.3)	1 (2.8)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	4 (11.1)	2 (5.6)	2 (5.6)	0	0
Anxiety	3 (8.3)	1 (2.8)	2 (5.6)	0	0
Adjustment disorder	1 (2.8)	0	1 (2.8)	0	0
Agitation	1 (2.8)	0	1 (2.8)	0	0
Hallucination	1 (2.8)	1 (2.8)	0	0	0
Insomnia	1 (2.8)	0	1 (2.8)	0	0
Irritability	1 (2.8)	1 (2.8)	0	0	0
Mental status changes	1 (2.8)	1 (2.8)	0	0	0
Panic attack	1 (2.8)	0	1 (2.8)	0	0
Suicidal ideation	1 (2.8)	1 (2.8)	0	0	0
Renal and urinary disorders					
-Total	9 (25.0)	1 (2.8)	2 (5.6)	3 (8.3)	3 (8.3)
Acute kidney injury	5 (13.9)	0	1 (2.8)	2 (5.6)	2 (5.6)
Haematuria	3 (8.3)	0	1 (2.8)	1 (2.8)	1 (2.8)
Dysuria	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Oliguria	1 (2.8)	0	0	1 (2.8)	0
Pollakiuria	1 (2.8)	1 (2.8)	0	0	0
Renal failure	1 (2.8)	0	0	0	1 (2.8)
Renal impairment	1 (2.8)	0	0	1 (2.8)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	1 (2.8)	1 (2.8)	0	0	0
Vulvovaginal adhesion	1 (2.8)	1 (2.8)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	15 (41.7)	6 (16.7)	1 (2.8)	2 (5.6)	6 (16.7)
Hypoxia	5 (13.9)	0	0	3 (8.3)	2 (5.6)
Pleural effusion	5 (13.9)	1 (2.8)	2 (5.6)	2 (5.6)	0
Pulmonary oedema	5 (13.9)	1 (2.8)	0	2 (5.6)	2 (5.6)
Cough	4 (11.1)	4 (11.1)	0	0	0
Epistaxis	4 (11.1)	1 (2.8)	1 (2.8)	1 (2.8)	1 (2.8)
Respiratory failure	3 (8.3)	0	0	0	3 (8.3)
Tachypnoea	3 (8.3)	2 (5.6)	1 (2.8)	0	0
Haemoptysis	2 (5.6)	1 (2.8)	0	0	1 (2.8)
Dyspnoea	1 (2.8)	0	0	0	1 (2.8)
Interstitial lung disease	1 (2.8)	0	0	0	1 (2.8)
Nasal congestion	1 (2.8)	1 (2.8)	0	0	0
Oropharyngeal pain	1 (2.8)	0	1 (2.8)	0	0
Oropharyngeal plaque	1 (2.8)	1 (2.8)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngeal ulceration	1 (2.8)	0	1 (2.8)	0	0
Respiratory depression	1 (2.8)	0	1 (2.8)	0	0
Respiratory distress	1 (2.8)	0	0	0	1 (2.8)
Skin and subcutaneous tissue disorders					
-Total	13 (36.1)	11 (30.6)	1 (2.8)	1 (2.8)	0
Dry skin	3 (8.3)	3 (8.3)	0	0	0
Erythema	2 (5.6)	2 (5.6)	0	0	0
Hyperhidrosis	2 (5.6)	2 (5.6)	0	0	0
Rash	2 (5.6)	2 (5.6)	0	0	0
Rash maculo-papular	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Dermatitis diaper	1 (2.8)	1 (2.8)	0	0	0
Ecchymosis	1 (2.8)	0	0	1 (2.8)	0
Livedo reticularis	1 (2.8)	1 (2.8)	0	0	0
Macule	1 (2.8)	1 (2.8)	0	0	0
Petechiae	1 (2.8)	1 (2.8)	0	0	0
Pruritus	1 (2.8)	1 (2.8)	0	0	0
Rash erythematous	1 (2.8)	1 (2.8)	0	0	0
Rash macular	1 (2.8)	1 (2.8)	0	0	0
Rash papular	1 (2.8)	1 (2.8)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=36 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin exfoliation	1 (2.8)	1 (2.8)	0	0	0
Skin fissures	1 (2.8)	1 (2.8)	0	0	0
Vascular disorders					
-Total	13 (36.1)	0	3 (8.3)	5 (13.9)	5 (13.9)
Hypotension	10 (27.8)	0	0	5 (13.9)	5 (13.9)
Hypertension	5 (13.9)	1 (2.8)	4 (11.1)	0	0
Capillary leak syndrome	1 (2.8)	0	0	0	1 (2.8)
Flushing	1 (2.8)	1 (2.8)	0	0	0
Haematoma	1 (2.8)	0	1 (2.8)	0	0
Secondary hypertension	1 (2.8)	0	1 (2.8)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174l
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

			All patients N=25		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (76.0)	2 (8.0)	6 (24.0)	6 (24.0)	5 (20.0)
Blood and lymphatic system disorders					
-Total	5 (20.0)	1 (4.0)	1 (4.0)	2 (8.0)	1 (4.0)
Anaemia	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Eosinophilia	1 (4.0)	0	0	1 (4.0)	0
Febrile neutropenia	1 (4.0)	0	0	1 (4.0)	0
Lymphopenia	1 (4.0)	0	1 (4.0)	0	0
Neutropenia	1 (4.0)	0	0	0	1 (4.0)
Thrombocytopenia	1 (4.0)	0	0	1 (4.0)	0
Cardiac disorders					
-Total	1 (4.0)	0	1 (4.0)	0	0
Sinus tachycardia	1 (4.0)	0	1 (4.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Dry eye	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Ocular hyperaemia	1 (4.0)	1 (4.0)	0	0	0
Gastrointestinal disorders					
-Total	9 (36.0)	5 (20.0)	3 (12.0)	1 (4.0)	0
Vomiting	5 (20.0)	2 (8.0)	2 (8.0)	1 (4.0)	0
Nausea	4 (16.0)	1 (4.0)	2 (8.0)	1 (4.0)	0
Diarrhoea	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Abdominal pain	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Abdominal pain upper	1 (4.0)	1 (4.0)	0	0	0
Pigmentation lip	1 (4.0)	1 (4.0)	0	0	0
General disorders and administration site conditions					
-Total	10 (40.0)	9 (36.0)	1 (4.0)	0	0
Pyrexia	6 (24.0)	5 (20.0)	1 (4.0)	0	0
Influenza like illness	2 (8.0)	2 (8.0)	0	0	0
Acquired gene mutation	1 (4.0)	1 (4.0)	0	0	0
Chills	1 (4.0)	1 (4.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Crying	1 (4.0)	1 (4.0)	0	0	0
Fatigue	1 (4.0)	1 (4.0)	0	0	0
Generalised oedema	1 (4.0)	1 (4.0)	0	0	0
Oedema peripheral	1 (4.0)	1 (4.0)	0	0	0
Pain	1 (4.0)	1 (4.0)	0	0	0
Immune system disorders					
-Total	7 (28.0)	1 (4.0)	6 (24.0)	0	0
Hypogammaglobulinaemia	5 (20.0)	0	5 (20.0)	0	0
Graft versus host disease	1 (4.0)	1 (4.0)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (4.0)	0	1 (4.0)	0	0
Immunodeficiency common variable	1 (4.0)	0	1 (4.0)	0	0
Infections and infestations					
-Total	13 (52.0)	1 (4.0)	5 (20.0)	6 (24.0)	1 (4.0)
Upper respiratory tract infection	3 (12.0)	2 (8.0)	0	1 (4.0)	0
Urinary tract infection	3 (12.0)	0	1 (4.0)	2 (8.0)	0
Cellulitis of male external genital organ	1 (4.0)	0	0	1 (4.0)	0
Cholecystitis infective	1 (4.0)	0	0	1 (4.0)	0
Cytomegalovirus infection	1 (4.0)	1 (4.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	1 (4.0)	0	1 (4.0)	0	0
Enterovirus infection	1 (4.0)	0	0	1 (4.0)	0
Escherichia urinary tract infection	1 (4.0)	0	0	1 (4.0)	0
Gastroenteritis norovirus	1 (4.0)	0	1 (4.0)	0	0
Influenza	1 (4.0)	0	1 (4.0)	0	0
Oral herpes	1 (4.0)	0	1 (4.0)	0	0
Otitis media	1 (4.0)	0	1 (4.0)	0	0
Otitis media acute	1 (4.0)	0	1 (4.0)	0	0
Parainfluenzae virus infection	1 (4.0)	1 (4.0)	0	0	0
Rhinitis	1 (4.0)	1 (4.0)	0	0	0
Rotavirus infection	1 (4.0)	0	0	1 (4.0)	0
Sepsis	1 (4.0)	0	0	0	1 (4.0)
Sinusitis	1 (4.0)	0	1 (4.0)	0	0
Vascular device infection	1 (4.0)	0	0	1 (4.0)	0
Injury, poisoning and procedural complications					
-Total	3 (12.0)	1 (4.0)	2 (8.0)	0	0
Contusion	1 (4.0)	1 (4.0)	0	0	0
Foot fracture	1 (4.0)	0	1 (4.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin laceration	1 (4.0)	0	1 (4.0)	0	0
Investigations					
-Total	10 (40.0)	3 (12.0)	2 (8.0)	3 (12.0)	2 (8.0)
Neutrophil count decreased	5 (20.0)	2 (8.0)	0	1 (4.0)	2 (8.0)
Aspartate aminotransferase increased	3 (12.0)	1 (4.0)	0	2 (8.0)	0
Platelet count decreased	3 (12.0)	3 (12.0)	0	0	0
Haemoglobin decreased	2 (8.0)	2 (8.0)	0	0	0
Lymphocyte count decreased	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Weight increased	2 (8.0)	1 (4.0)	1 (4.0)	0	0
White blood cell count decreased	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Alanine aminotransferase increased	1 (4.0)	0	0	1 (4.0)	0
Blood creatinine increased	1 (4.0)	1 (4.0)	0	0	0
Blood uric acid increased	1 (4.0)	1 (4.0)	0	0	0
Transaminases increased	1 (4.0)	1 (4.0)	0	0	0
Weight decreased	1 (4.0)	0	1 (4.0)	0	0
Metabolism and nutrition disorders					
-Total	7 (28.0)	4 (16.0)	1 (4.0)	1 (4.0)	1 (4.0)
Decreased appetite	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Hyperphosphataemia	2 (8.0)	2 (8.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	2 (8.0)	1 (4.0)	0	0	1 (4.0)
Dehydration	1 (4.0)	0	0	1 (4.0)	0
Hyperglycaemia	1 (4.0)	0	0	1 (4.0)	0
Hypophosphataemia	1 (4.0)	0	0	1 (4.0)	0
Vitamin d deficiency	1 (4.0)	1 (4.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (28.0)	5 (20.0)	2 (8.0)	0	0
Pain in extremity	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Joint range of motion decreased	2 (8.0)	2 (8.0)	0	0	0
Back pain	1 (4.0)	1 (4.0)	0	0	0
Flank pain	1 (4.0)	0	1 (4.0)	0	0
Muscle spasms	1 (4.0)	1 (4.0)	0	0	0
Muscular weakness	1 (4.0)	1 (4.0)	0	0	0
Musculoskeletal chest pain	1 (4.0)	1 (4.0)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (4.0)	0	1 (4.0)	0	0
Myelodysplastic syndrome	1 (4.0)	0	1 (4.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	4 (16.0)	2 (8.0)	2 (8.0)	0	0
Headache	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Dizziness	2 (8.0)	2 (8.0)	0	0	0
Peroneal nerve palsy	1 (4.0)	0	1 (4.0)	0	0
Renal and urinary disorders					
-Total	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Calculus urinary	1 (4.0)	0	1 (4.0)	0	0
Haematuria	1 (4.0)	0	0	1 (4.0)	0
Nephrolithiasis	1 (4.0)	0	0	1 (4.0)	0
Urinary incontinence	1 (4.0)	1 (4.0)	0	0	0
Reproductive system and breast disorders					
-Total	1 (4.0)	0	1 (4.0)	0	0
Scrotal pain	1 (4.0)	0	1 (4.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (24.0)	5 (20.0)	1 (4.0)	0	0
Cough	4 (16.0)	3 (12.0)	1 (4.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis allergic	2 (8.0)	2 (8.0)	0	0	0
Epistaxis	1 (4.0)	1 (4.0)	0	0	0
Nasal congestion	1 (4.0)	1 (4.0)	0	0	0
Oropharyngeal pain	1 (4.0)	1 (4.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (32.0)	7 (28.0)	1 (4.0)	0	0
Rash	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Rash maculo-papular	2 (8.0)	2 (8.0)	0	0	0
Dermatitis atopic	1 (4.0)	1 (4.0)	0	0	0
Dry skin	1 (4.0)	1 (4.0)	0	0	0
Erythema	1 (4.0)	1 (4.0)	0	0	0
Hyperhidrosis	1 (4.0)	1 (4.0)	0	0	0
Macule	1 (4.0)	1 (4.0)	0	0	0
Petechiae	1 (4.0)	1 (4.0)	0	0	0
Pruritus	1 (4.0)	1 (4.0)	0	0	0
Rash pruritic	1 (4.0)	1 (4.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174l
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (87.1)	2 (6.5)	10 (32.3)	10 (32.3)	5 (16.1)
Blood and lymphatic system disorders					
-Total	6 (19.4)	0	2 (6.5)	1 (3.2)	3 (9.7)
Neutropenia	3 (9.7)	0	0	1 (3.2)	2 (6.5)
Febrile neutropenia	2 (6.5)	0	0	2 (6.5)	0
Leukopenia	1 (3.2)	0	0	0	1 (3.2)
Lymphadenopathy	1 (3.2)	0	1 (3.2)	0	0
Thrombocytopenia	1 (3.2)	0	1 (3.2)	0	0
Endocrine disorders					
-Total	1 (3.2)	1 (3.2)	0	0	0
Adrenal insufficiency	1 (3.2)	1 (3.2)	0	0	0
Eye disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (6.5)	2 (6.5)	0	0	0
Conjunctivitis allergic	1 (3.2)	1 (3.2)	0	0	0
Vision blurred	1 (3.2)	1 (3.2)	0	0	0
Gastrointestinal disorders					
-Total	7 (22.6)	4 (12.9)	0	3 (9.7)	0
Diarrhoea	5 (16.1)	4 (12.9)	0	1 (3.2)	0
Vomiting	4 (12.9)	3 (9.7)	0	1 (3.2)	0
Abdominal pain	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Nausea	2 (6.5)	0	1 (3.2)	1 (3.2)	0
Oral pain	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Enterocolitis	1 (3.2)	0	0	1 (3.2)	0
General disorders and administration site conditions					
-Total	7 (22.6)	4 (12.9)	2 (6.5)	1 (3.2)	0
Pyrexia	4 (12.9)	2 (6.5)	1 (3.2)	1 (3.2)	0
Catheter site pain	1 (3.2)	0	1 (3.2)	0	0
Fatigue	1 (3.2)	1 (3.2)	0	0	0
Malaise	1 (3.2)	1 (3.2)	0	0	0
Immune system disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (22.6)	2 (6.5)	4 (12.9)	1 (3.2)	0
Hypogammaglobulinaemia	3 (9.7)	0	2 (6.5)	1 (3.2)	0
Seasonal allergy	2 (6.5)	2 (6.5)	0	0	0
Graft versus host disease	1 (3.2)	0	1 (3.2)	0	0
Immunodeficiency common variable	1 (3.2)	0	1 (3.2)	0	0
Infections and infestations					
-Total	20 (64.5)	5 (16.1)	10 (32.3)	4 (12.9)	1 (3.2)
Upper respiratory tract infection	4 (12.9)	1 (3.2)	3 (9.7)	0	0
Gastroenteritis	3 (9.7)	1 (3.2)	2 (6.5)	0	0
Influenza	2 (6.5)	0	2 (6.5)	0	0
Rhinovirus infection	2 (6.5)	2 (6.5)	0	0	0
Viral upper respiratory tract infection	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Bacterial sepsis	1 (3.2)	0	0	0	1 (3.2)
Corona virus infection	1 (3.2)	0	0	1 (3.2)	0
Ear infection	1 (3.2)	1 (3.2)	0	0	0
Gastroenteritis viral	1 (3.2)	1 (3.2)	0	0	0
Herpes zoster	1 (3.2)	0	0	1 (3.2)	0
Molluscum contagiosum	1 (3.2)	1 (3.2)	0	0	0
Otitis externa	1 (3.2)	0	1 (3.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (3.2)	0	0	1 (3.2)	0
Paronychia	1 (3.2)	1 (3.2)	0	0	0
Rash pustular	1 (3.2)	0	1 (3.2)	0	0
Respiratory syncytial virus infection	1 (3.2)	0	0	1 (3.2)	0
Sinusitis	1 (3.2)	0	1 (3.2)	0	0
Subcutaneous abscess	1 (3.2)	0	1 (3.2)	0	0
Tinea capitis	1 (3.2)	1 (3.2)	0	0	0
Urinary tract infection	1 (3.2)	0	1 (3.2)	0	0
Viral infection	1 (3.2)	1 (3.2)	0	0	0
Vulvovaginal mycotic infection	1 (3.2)	0	1 (3.2)	0	0
Injury, poisoning and procedural complications					
-Total	5 (16.1)	2 (6.5)	3 (9.7)	0	0
Infusion related reaction	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Procedural pain	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Arthropod bite	1 (3.2)	1 (3.2)	0	0	0
Contusion	1 (3.2)	1 (3.2)	0	0	0
Procedural nausea	1 (3.2)	0	1 (3.2)	0	0
Radius fracture	1 (3.2)	0	1 (3.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin abrasion	1 (3.2)	1 (3.2)	0	0	0
Sunburn	1 (3.2)	1 (3.2)	0	0	0
Investigations					
-Total	13 (41.9)	3 (9.7)	3 (9.7)	5 (16.1)	2 (6.5)
Neutrophil count decreased	3 (9.7)	0	0	2 (6.5)	1 (3.2)
Weight decreased	3 (9.7)	1 (3.2)	2 (6.5)	0	0
White blood cell count decreased	3 (9.7)	1 (3.2)	0	1 (3.2)	1 (3.2)
Alanine aminotransferase increased	1 (3.2)	0	0	1 (3.2)	0
Blood bilirubin increased	1 (3.2)	0	0	1 (3.2)	0
Blood magnesium decreased	1 (3.2)	1 (3.2)	0	0	0
Blood urea increased	1 (3.2)	1 (3.2)	0	0	0
Oxygen saturation decreased	1 (3.2)	1 (3.2)	0	0	0
Serum ferritin increased	1 (3.2)	0	1 (3.2)	0	0
Metabolism and nutrition disorders					
-Total	3 (9.7)	1 (3.2)	0	2 (6.5)	0
Hyperalbuminaemia	1 (3.2)	1 (3.2)	0	0	0
Hypercalcaemia	1 (3.2)	1 (3.2)	0	0	0
Iron overload	1 (3.2)	0	0	1 (3.2)	0
Tumour lysis syndrome	1 (3.2)	0	0	1 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	9 (29.0)	6 (19.4)	3 (9.7)	0	0
Pain in extremity	5 (16.1)	4 (12.9)	1 (3.2)	0	0
Arthralgia	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Muscular weakness	1 (3.2)	1 (3.2)	0	0	0
Osteonecrosis	1 (3.2)	0	1 (3.2)	0	0
Pain in jaw	1 (3.2)	1 (3.2)	0	0	0
Toe walking	1 (3.2)	1 (3.2)	0	0	0
Nervous system disorders					
-Total	4 (12.9)	4 (12.9)	0	0	0
Headache	2 (6.5)	2 (6.5)	0	0	0
Dizziness	1 (3.2)	1 (3.2)	0	0	0
Peroneal nerve palsy	1 (3.2)	1 (3.2)	0	0	0
Psychiatric disorders					
-Total	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Depression	2 (6.5)	2 (6.5)	0	0	0
Anxiety	1 (3.2)	1 (3.2)	0	0	0
Sleep disorder	1 (3.2)	0	1 (3.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	1 (3.2)	0	0	1 (3.2)	0
Acute kidney injury	1 (3.2)	0	0	1 (3.2)	0
Reproductive system and breast disorders					
-Total	1 (3.2)	0	0	1 (3.2)	0
Vaginal haemorrhage	1 (3.2)	0	0	1 (3.2)	0
Respiratory, thoracic and mediastinal disorders					
-Total	12 (38.7)	6 (19.4)	3 (9.7)	2 (6.5)	1 (3.2)
Rhinorrhoea	4 (12.9)	3 (9.7)	1 (3.2)	0	0
Cough	3 (9.7)	2 (6.5)	1 (3.2)	0	0
Nasal congestion	3 (9.7)	3 (9.7)	0	0	0
Oropharyngeal pain	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Acute respiratory failure	1 (3.2)	0	0	0	1 (3.2)
Dysphonia	1 (3.2)	1 (3.2)	0	0	0
Epistaxis	1 (3.2)	0	0	1 (3.2)	0
Pharyngeal erythema	1 (3.2)	1 (3.2)	0	0	0
Pharyngeal lesion	1 (3.2)	0	0	1 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	1 (3.2)	0	0	1 (3.2)	0
Rhinitis allergic	1 (3.2)	0	1 (3.2)	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (25.8)	3 (9.7)	4 (12.9)	1 (3.2)	0
Rash	2 (6.5)	0	2 (6.5)	0	0
Alopecia	1 (3.2)	0	1 (3.2)	0	0
Dermatitis	1 (3.2)	1 (3.2)	0	0	0
Dermatitis acneiform	1 (3.2)	0	0	1 (3.2)	0
Eczema	1 (3.2)	1 (3.2)	0	0	0
Erythema	1 (3.2)	1 (3.2)	0	0	0
Ingrowing nail	1 (3.2)	1 (3.2)	0	0	0
Keloid scar	1 (3.2)	0	1 (3.2)	0	0
Papule	1 (3.2)	1 (3.2)	0	0	0
Rash erythematous	1 (3.2)	0	1 (3.2)	0	0
Vascular disorders					
-Total	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Hypertension	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Hot flush	1 (3.2)	1 (3.2)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174l
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (78.6)	3 (21.4)	2 (14.3)	5 (35.7)	1 (7.1)
Blood and lymphatic system disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Thrombocytopenia	1 (7.1)	1 (7.1)	0	0	0
Ear and labyrinth disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0
Tympanic membrane perforation	1 (7.1)	0	1 (7.1)	0	0
Gastrointestinal disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Diarrhoea	2 (14.3)	0	2 (14.3)	0	0
Abdominal pain	1 (7.1)	0	1 (7.1)	0	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (7.1)	0	0	1 (7.1)	0
Cyst	1 (7.1)	0	0	1 (7.1)	0
Infections and infestations					
-Total	6 (42.9)	1 (7.1)	2 (14.3)	3 (21.4)	0
Otitis media	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Otitis media acute	2 (14.3)	0	2 (14.3)	0	0
Sinusitis	2 (14.3)	0	2 (14.3)	0	0
Upper respiratory tract infection	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Urinary tract infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Campylobacter infection	1 (7.1)	0	0	1 (7.1)	0
Cellulitis of male external genital organ	1 (7.1)	0	0	1 (7.1)	0
Clostridium difficile infection	1 (7.1)	0	0	1 (7.1)	0
Haemophilus infection	1 (7.1)	0	1 (7.1)	0	0
Pneumonia	1 (7.1)	0	1 (7.1)	0	0
Respiratory tract infection viral	1 (7.1)	0	0	1 (7.1)	0
Vulvovaginal candidiasis	1 (7.1)	0	1 (7.1)	0	0
Investigations					
-Total	3 (21.4)	1 (7.1)	1 (7.1)	1 (7.1)	0
Lymphocyte count decreased	2 (14.3)	2 (14.3)	0	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Alanine aminotransferase increased	1 (7.1)	0	0	1 (7.1)	0
Aspartate aminotransferase increased	1 (7.1)	0	0	1 (7.1)	0
White blood cell count decreased	1 (7.1)	1 (7.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0
Neck pain	1 (7.1)	0	1 (7.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (7.1)	0	0	0	1 (7.1)
Glioblastoma multiforme	1 (7.1)	0	0	0	1 (7.1)
Nervous system disorders					
-Total	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Dizziness	1 (7.1)	1 (7.1)	0	0	0
Headache	1 (7.1)	0	1 (7.1)	0	0
Seizure	1 (7.1)	0	0	1 (7.1)	0
Renal and urinary disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	1 (7.1)	1 (7.1)	0	0	0
Reproductive system and breast disorders					
-Total	1 (7.1)	0	0	1 (7.1)	0
Ovarian failure	1 (7.1)	0	0	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (21.4)	3 (21.4)	0	0	0
Cough	1 (7.1)	1 (7.1)	0	0	0
Epistaxis	1 (7.1)	1 (7.1)	0	0	0
Oropharyngeal pain	1 (7.1)	1 (7.1)	0	0	0
Rhinitis allergic	1 (7.1)	1 (7.1)	0	0	0
Rhinorrhoea	1 (7.1)	1 (7.1)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174l
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (55.0)	1 (5.0)	4 (20.0)	3 (15.0)	3 (15.0)
Blood and lymphatic system disorders					
-Total	1 (5.0)	0	0	0	1 (5.0)
Febrile neutropenia	1 (5.0)	0	0	0	1 (5.0)
Gastrointestinal disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Nausea	1 (5.0)	0	1 (5.0)	0	0
General disorders and administration site conditions					
-Total	1 (5.0)	0	1 (5.0)	0	0
Chills	1 (5.0)	0	1 (5.0)	0	0
Pyrexia	1 (5.0)	0	1 (5.0)	0	0
Immune system disorders					

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (10.0)	0	2 (10.0)	0	0
Chronic graft versus host disease	1 (5.0)	0	1 (5.0)	0	0
Immunodeficiency	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	5 (25.0)	1 (5.0)	3 (15.0)	0	1 (5.0)
Gingivitis	1 (5.0)	1 (5.0)	0	0	0
Meningitis aseptic	1 (5.0)	0	1 (5.0)	0	0
Otitis media	1 (5.0)	0	1 (5.0)	0	0
Pneumonia	1 (5.0)	0	1 (5.0)	0	0
Respiratory tract infection	1 (5.0)	0	0	0	1 (5.0)
Sinusitis	1 (5.0)	0	1 (5.0)	0	0
Skin infection	1 (5.0)	0	1 (5.0)	0	0
Viral infection	1 (5.0)	1 (5.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (5.0)	0	0	1 (5.0)	0
Procedural pain	1 (5.0)	0	0	1 (5.0)	0
Investigations					
-Total	5 (25.0)	0	1 (5.0)	3 (15.0)	1 (5.0)

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

		All patients N=20			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	3 (15.0)	0	0	2 (10.0)	1 (5.0)
Alanine aminotransferase increased	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Aspartate aminotransferase increased	1 (5.0)	1 (5.0)	0	0	0
Blood alkaline phosphatase increased	1 (5.0)	1 (5.0)	0	0	0
Blood lactate dehydrogenase increased	1 (5.0)	1 (5.0)	0	0	0
C-reactive protein increased	1 (5.0)	1 (5.0)	0	0	0
Lymphocyte count decreased	1 (5.0)	0	0	1 (5.0)	0
Platelet count decreased	1 (5.0)	0	0	1 (5.0)	0
Metabolism and nutrition disorders					
-Total	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Hypokalaemia	1 (5.0)	0	0	1 (5.0)	0
Vitamin d deficiency	1 (5.0)	1 (5.0)	0	0	0
Nervous system disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Disturbance in attention	1 (5.0)	1 (5.0)	0	0	0
Renal and urinary disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Acute kidney injury	1 (5.0)	0	0	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Cough	1 (5.0)	1 (5.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (15.0)	3 (15.0)	0	0	0
Acne	1 (5.0)	1 (5.0)	0	0	0
Papule	1 (5.0)	1 (5.0)	0	0	0
Pruritus	1 (5.0)	1 (5.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174l
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

			All patients N=28		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (100)	0	2 (7.1)	7 (25.0)	19 (67.9)
Blood and lymphatic system disorders					
-Total	20 (71.4)	0	1 (3.6)	15 (53.6)	4 (14.3)
Anaemia	14 (50.0)	1 (3.6)	3 (10.7)	10 (35.7)	0
Febrile neutropenia	10 (35.7)	0	0	10 (35.7)	0
Lymphopenia	3 (10.7)	0	2 (7.1)	0	1 (3.6)
Thrombocytopenia	3 (10.7)	0	0	2 (7.1)	1 (3.6)
Neutropenia	2 (7.1)	0	0	0	2 (7.1)
Disseminated intravascular coagulation	1 (3.6)	0	1 (3.6)	0	0
Eosinophilia	1 (3.6)	0	0	1 (3.6)	0
Cardiac disorders					
-Total	11 (39.3)	4 (14.3)	6 (21.4)	1 (3.6)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	7 (25.0)	3 (10.7)	3 (10.7)	1 (3.6)	0
Sinus tachycardia	5 (17.9)	2 (7.1)	3 (10.7)	0	0
Cardiac dysfunction	1 (3.6)	1 (3.6)	0	0	0
Sinus bradycardia	1 (3.6)	1 (3.6)	0	0	0
Ear and labyrinth disorders					
-Total	4 (14.3)	2 (7.1)	2 (7.1)	0	0
Ear pain	2 (7.1)	2 (7.1)	0	0	0
Hypoacusis	1 (3.6)	0	1 (3.6)	0	0
Tympanic membrane perforation	1 (3.6)	0	1 (3.6)	0	0
Eye disorders					
-Total	10 (35.7)	3 (10.7)	7 (25.0)	0	0
Dry eye	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Eye pain	2 (7.1)	0	2 (7.1)	0	0
Photophobia	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Uveitis	2 (7.1)	0	2 (7.1)	0	0
Ocular hyperaemia	1 (3.6)	1 (3.6)	0	0	0
Ocular hypertension	1 (3.6)	0	1 (3.6)	0	0
Papilloedema	1 (3.6)	0	1 (3.6)	0	0
Periorbital oedema	1 (3.6)	0	1 (3.6)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vision blurred	1 (3.6)	0	1 (3.6)	0	0
Visual impairment	1 (3.6)	0	1 (3.6)	0	0
Gastrointestinal disorders					
-Total	20 (71.4)	6 (21.4)	10 (35.7)	4 (14.3)	0
Nausea	14 (50.0)	5 (17.9)	7 (25.0)	2 (7.1)	0
Vomiting	13 (46.4)	9 (32.1)	2 (7.1)	2 (7.1)	0
Diarrhoea	12 (42.9)	6 (21.4)	6 (21.4)	0	0
Abdominal pain	8 (28.6)	4 (14.3)	4 (14.3)	0	0
Abdominal distension	2 (7.1)	0	2 (7.1)	0	0
Constipation	2 (7.1)	2 (7.1)	0	0	0
Stomatitis	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Abdominal pain lower	1 (3.6)	0	1 (3.6)	0	0
Abdominal pain upper	1 (3.6)	1 (3.6)	0	0	0
Abdominal tenderness	1 (3.6)	1 (3.6)	0	0	0
Anal incontinence	1 (3.6)	1 (3.6)	0	0	0
Gastrointestinal haemorrhage	1 (3.6)	1 (3.6)	0	0	0
Gastrooesophageal reflux disease	1 (3.6)	1 (3.6)	0	0	0
Glossodynia	1 (3.6)	1 (3.6)	0	0	0
Haematemesis	1 (3.6)	1 (3.6)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lip pain	1 (3.6)	0	1 (3.6)	0	0
Mouth haemorrhage	1 (3.6)	0	0	1 (3.6)	0
Pigmentation lip	1 (3.6)	1 (3.6)	0	0	0
General disorders and administration site conditions					
-Total	20 (71.4)	12 (42.9)	5 (17.9)	3 (10.7)	0
Pyrexia	11 (39.3)	7 (25.0)	3 (10.7)	1 (3.6)	0
Fatigue	9 (32.1)	7 (25.0)	1 (3.6)	1 (3.6)	0
Chills	4 (14.3)	4 (14.3)	0	0	0
Generalised oedema	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Influenza like illness	2 (7.1)	2 (7.1)	0	0	0
Malaise	2 (7.1)	0	2 (7.1)	0	0
Oedema peripheral	2 (7.1)	2 (7.1)	0	0	0
Pain	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Acquired gene mutation	1 (3.6)	1 (3.6)	0	0	0
Catheter site extravasation	1 (3.6)	0	1 (3.6)	0	0
Catheter site haemorrhage	1 (3.6)	1 (3.6)	0	0	0
Catheter site pain	1 (3.6)	1 (3.6)	0	0	0
Crying	1 (3.6)	1 (3.6)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cyst	1 (3.6)	0	0	1 (3.6)	0
Face oedema	1 (3.6)	0	1 (3.6)	0	0
Facial pain	1 (3.6)	0	1 (3.6)	0	0
Injection site haematoma	1 (3.6)	1 (3.6)	0	0	0
Non-cardiac chest pain	1 (3.6)	1 (3.6)	0	0	0
Peripheral swelling	1 (3.6)	0	1 (3.6)	0	0
Hepatobiliary disorders					
-Total	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Hepatomegaly	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Hyperbilirubinaemia	1 (3.6)	0	0	1 (3.6)	0
Immune system disorders					
-Total	24 (85.7)	4 (14.3)	13 (46.4)	5 (17.9)	2 (7.1)
Cytokine release syndrome	20 (71.4)	3 (10.7)	11 (39.3)	4 (14.3)	2 (7.1)
Hypogammaglobulinaemia	13 (46.4)	2 (7.1)	10 (35.7)	1 (3.6)	0
Graft versus host disease	1 (3.6)	1 (3.6)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (3.6)	0	1 (3.6)	0	0
Graft versus host disease in skin	1 (3.6)	1 (3.6)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (3.6)	0	1 (3.6)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency common variable	1 (3.6)	0	1 (3.6)	0	0
Infections and infestations					
-Total	21 (75.0)	4 (14.3)	8 (28.6)	7 (25.0)	2 (7.1)
Upper respiratory tract infection	5 (17.9)	3 (10.7)	1 (3.6)	1 (3.6)	0
Clostridium difficile infection	4 (14.3)	0	3 (10.7)	1 (3.6)	0
Urinary tract infection	4 (14.3)	0	2 (7.1)	2 (7.1)	0
Otitis media	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Sinusitis	3 (10.7)	0	3 (10.7)	0	0
Cytomegalovirus infection	2 (7.1)	2 (7.1)	0	0	0
Influenza	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Otitis media acute	2 (7.1)	0	2 (7.1)	0	0
Vulvovaginal candidiasis	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Acute sinusitis	1 (3.6)	0	1 (3.6)	0	0
Body tinea	1 (3.6)	1 (3.6)	0	0	0
Campylobacter infection	1 (3.6)	0	0	1 (3.6)	0
Catheter site cellulitis	1 (3.6)	1 (3.6)	0	0	0
Cellulitis of male external genital organ	1 (3.6)	0	0	1 (3.6)	0
Cholecystitis infective	1 (3.6)	0	0	1 (3.6)	0
Clostridium difficile colitis	1 (3.6)	0	1 (3.6)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	1 (3.6)	0	1 (3.6)	0	0
Enterococcal infection	1 (3.6)	1 (3.6)	0	0	0
Enterovirus infection	1 (3.6)	0	0	1 (3.6)	0
Escherichia urinary tract infection	1 (3.6)	0	0	1 (3.6)	0
Fungal skin infection	1 (3.6)	1 (3.6)	0	0	0
Gastroenteritis norovirus	1 (3.6)	0	1 (3.6)	0	0
Haemophilus infection	1 (3.6)	0	1 (3.6)	0	0
Herpes simplex	1 (3.6)	1 (3.6)	0	0	0
Human herpesvirus 6 infection	1 (3.6)	0	1 (3.6)	0	0
Hypopyon	1 (3.6)	0	1 (3.6)	0	0
Oral candidiasis	1 (3.6)	1 (3.6)	0	0	0
Oral herpes	1 (3.6)	0	1 (3.6)	0	0
Parainfluenzae virus infection	1 (3.6)	1 (3.6)	0	0	0
Pneumonia	1 (3.6)	0	1 (3.6)	0	0
Respiratory tract infection viral	1 (3.6)	0	0	1 (3.6)	0
Rhinitis	1 (3.6)	1 (3.6)	0	0	0
Rhinovirus infection	1 (3.6)	1 (3.6)	0	0	0
Rotavirus infection	1 (3.6)	0	0	1 (3.6)	0
Sepsis	1 (3.6)	0	0	0	1 (3.6)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic embolus	1 (3.6)	0	0	0	1 (3.6)
Skin infection	1 (3.6)	0	1 (3.6)	0	0
Vascular device infection	1 (3.6)	0	0	1 (3.6)	0
Injury, poisoning and procedural complications					
-Total	11 (39.3)	4 (14.3)	6 (21.4)	0	1 (3.6)
Transfusion reaction	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Contusion	2 (7.1)	2 (7.1)	0	0	0
Infusion related reaction	2 (7.1)	0	2 (7.1)	0	0
Procedural pain	2 (7.1)	0	2 (7.1)	0	0
Foot fracture	1 (3.6)	0	1 (3.6)	0	0
Limb injury	1 (3.6)	1 (3.6)	0	0	0
Mouth injury	1 (3.6)	1 (3.6)	0	0	0
Procedural headache	1 (3.6)	0	1 (3.6)	0	0
Procedural site reaction	1 (3.6)	1 (3.6)	0	0	0
Skin abrasion	1 (3.6)	1 (3.6)	0	0	0
Skin laceration	1 (3.6)	0	1 (3.6)	0	0
Tongue injury	1 (3.6)	1 (3.6)	0	0	0
Transfusion related complication	1 (3.6)	0	0	0	1 (3.6)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	24 (85.7)	1 (3.6)	4 (14.3)	5 (17.9)	14 (50.0)
White blood cell count decreased	16 (57.1)	1 (3.6)	1 (3.6)	7 (25.0)	7 (25.0)
Neutrophil count decreased	14 (50.0)	1 (3.6)	1 (3.6)	1 (3.6)	11 (39.3)
Alanine aminotransferase increased	13 (46.4)	4 (14.3)	1 (3.6)	8 (28.6)	0
Aspartate aminotransferase increased	13 (46.4)	3 (10.7)	2 (7.1)	6 (21.4)	2 (7.1)
Platelet count decreased	11 (39.3)	2 (7.1)	1 (3.6)	1 (3.6)	7 (25.0)
Lymphocyte count decreased	7 (25.0)	0	2 (7.1)	4 (14.3)	1 (3.6)
Blood bilirubin increased	6 (21.4)	2 (7.1)	2 (7.1)	2 (7.1)	0
Blood creatinine increased	6 (21.4)	4 (14.3)	1 (3.6)	1 (3.6)	0
Prothrombin time prolonged	6 (21.4)	4 (14.3)	2 (7.1)	0	0
International normalised ratio increased	5 (17.9)	5 (17.9)	0	0	0
Blood immunoglobulin a decreased	3 (10.7)	3 (10.7)	0	0	0
Blood immunoglobulin m decreased	3 (10.7)	3 (10.7)	0	0	0
Haemoglobin decreased	3 (10.7)	2 (7.1)	0	1 (3.6)	0
Activated partial thromboplastin time prolonged	2 (7.1)	2 (7.1)	0	0	0
Weight increased	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Blood bicarbonate decreased	1 (3.6)	0	1 (3.6)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactic acid increased	1 (3.6)	0	0	0	1 (3.6)
Blood urea increased	1 (3.6)	0	1 (3.6)	0	0
Blood uric acid increased	1 (3.6)	1 (3.6)	0	0	0
Culture stool positive	1 (3.6)	1 (3.6)	0	0	0
Hepatic enzyme increased	1 (3.6)	0	1 (3.6)	0	0
Norovirus test positive	1 (3.6)	1 (3.6)	0	0	0
Pulmonary function test decreased	1 (3.6)	0	1 (3.6)	0	0
Serum ferritin increased	1 (3.6)	0	1 (3.6)	0	0
Transaminases increased	1 (3.6)	1 (3.6)	0	0	0
Weight decreased	1 (3.6)	0	1 (3.6)	0	0
Metabolism and nutrition disorders					
-Total	19 (67.9)	5 (17.9)	5 (17.9)	8 (28.6)	1 (3.6)
Decreased appetite	11 (39.3)	3 (10.7)	3 (10.7)	5 (17.9)	0
Hypokalaemia	9 (32.1)	2 (7.1)	3 (10.7)	3 (10.7)	1 (3.6)
Hyperphosphataemia	7 (25.0)	7 (25.0)	0	0	0
Hypophosphataemia	5 (17.9)	1 (3.6)	0	4 (14.3)	0
Dehydration	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Fluid overload	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Hyperuricaemia	2 (7.1)	2 (7.1)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	2 (7.1)	0	2 (7.1)	0	0
Hypocalcaemia	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Hyponatraemia	2 (7.1)	0	0	2 (7.1)	0
Hyperglycaemia	1 (3.6)	0	0	1 (3.6)	0
Vitamin d deficiency	1 (3.6)	1 (3.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	13 (46.4)	8 (28.6)	5 (17.9)	0	0
Myalgia	5 (17.9)	4 (14.3)	1 (3.6)	0	0
Pain in extremity	5 (17.9)	3 (10.7)	2 (7.1)	0	0
Arthralgia	2 (7.1)	2 (7.1)	0	0	0
Joint range of motion decreased	2 (7.1)	2 (7.1)	0	0	0
Muscle spasms	2 (7.1)	2 (7.1)	0	0	0
Musculoskeletal chest pain	2 (7.1)	2 (7.1)	0	0	0
Musculoskeletal pain	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Back pain	1 (3.6)	1 (3.6)	0	0	0
Coccydynia	1 (3.6)	1 (3.6)	0	0	0
Flank pain	1 (3.6)	0	1 (3.6)	0	0
Muscular weakness	1 (3.6)	1 (3.6)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neck pain	1 (3.6)	0	1 (3.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (10.7)	0	2 (7.1)	0	1 (3.6)
Glioblastoma multiforme	1 (3.6)	0	0	0	1 (3.6)
Myelodysplastic syndrome	1 (3.6)	0	1 (3.6)	0	0
Skin papilloma	1 (3.6)	0	1 (3.6)	0	0
Nervous system disorders					
-Total	17 (60.7)	6 (21.4)	6 (21.4)	4 (14.3)	1 (3.6)
Headache	12 (42.9)	5 (17.9)	5 (17.9)	2 (7.1)	0
Dizziness	4 (14.3)	4 (14.3)	0	0	0
Encephalopathy	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Seizure	2 (7.1)	0	0	2 (7.1)	0
Embolic stroke	1 (3.6)	0	0	0	1 (3.6)
Idiopathic intracranial hypertension	1 (3.6)	0	1 (3.6)	0	0
Myoclonus	1 (3.6)	1 (3.6)	0	0	0
Peroneal nerve palsy	1 (3.6)	0	1 (3.6)	0	0
Product issues					
-Total	1 (3.6)	1 (3.6)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device occlusion	1 (3.6)	1 (3.6)	0	0	0
Psychiatric disorders					
-Total	4 (14.3)	1 (3.6)	2 (7.1)	1 (3.6)	0
Anxiety	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Confusional state	2 (7.1)	0	2 (7.1)	0	0
Agitation	1 (3.6)	0	1 (3.6)	0	0
Hallucination	1 (3.6)	0	1 (3.6)	0	0
Irritability	1 (3.6)	1 (3.6)	0	0	0
Listless	1 (3.6)	1 (3.6)	0	0	0
Renal and urinary disorders					
-Total	4 (14.3)	2 (7.1)	0	1 (3.6)	1 (3.6)
Acute kidney injury	2 (7.1)	1 (3.6)	0	0	1 (3.6)
Haematuria	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Calculus urinary	1 (3.6)	0	1 (3.6)	0	0
Nephrolithiasis	1 (3.6)	0	0	1 (3.6)	0
Oliguria	1 (3.6)	0	0	1 (3.6)	0
Urinary incontinence	1 (3.6)	1 (3.6)	0	0	0
Reproductive system and breast disorders					
-Total	4 (14.3)	1 (3.6)	2 (7.1)	1 (3.6)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema genital	1 (3.6)	0	1 (3.6)	0	0
Ovarian failure	1 (3.6)	0	0	1 (3.6)	0
Scrotal pain	1 (3.6)	0	1 (3.6)	0	0
Vulvovaginal adhesion	1 (3.6)	1 (3.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	17 (60.7)	8 (28.6)	5 (17.9)	3 (10.7)	1 (3.6)
Cough	7 (25.0)	6 (21.4)	1 (3.6)	0	0
Epistaxis	5 (17.9)	3 (10.7)	0	2 (7.1)	0
Hypoxia	5 (17.9)	0	3 (10.7)	1 (3.6)	1 (3.6)
Oropharyngeal pain	3 (10.7)	3 (10.7)	0	0	0
Pleural effusion	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Rhinitis allergic	3 (10.7)	3 (10.7)	0	0	0
Rhinorrhoea	2 (7.1)	2 (7.1)	0	0	0
Tachypnoea	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Atelectasis	1 (3.6)	1 (3.6)	0	0	0
Dyspnoea	1 (3.6)	0	0	1 (3.6)	0
Nasal congestion	1 (3.6)	1 (3.6)	0	0	0
Pulmonary oedema	1 (3.6)	0	0	1 (3.6)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wheezing	1 (3.6)	0	1 (3.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	12 (42.9)	7 (25.0)	4 (14.3)	1 (3.6)	0
Rash	4 (14.3)	3 (10.7)	1 (3.6)	0	0
Petechiae	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Rash maculo-papular	3 (10.7)	2 (7.1)	0	1 (3.6)	0
Dry skin	2 (7.1)	2 (7.1)	0	0	0
Erythema	2 (7.1)	2 (7.1)	0	0	0
Hyperhidrosis	2 (7.1)	2 (7.1)	0	0	0
Ingrowing nail	2 (7.1)	0	2 (7.1)	0	0
Pruritus	2 (7.1)	2 (7.1)	0	0	0
Dermatitis atopic	1 (3.6)	1 (3.6)	0	0	0
Macule	1 (3.6)	1 (3.6)	0	0	0
Night sweats	1 (3.6)	0	1 (3.6)	0	0
Rash follicular	1 (3.6)	1 (3.6)	0	0	0
Rash papular	1 (3.6)	1 (3.6)	0	0	0
Rash pruritic	1 (3.6)	1 (3.6)	0	0	0
Rash vesicular	1 (3.6)	1 (3.6)	0	0	0
Skin irritation	1 (3.6)	1 (3.6)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	11 (39.3)	3 (10.7)	2 (7.1)	3 (10.7)	3 (10.7)
Hypotension	6 (21.4)	1 (3.6)	0	2 (7.1)	3 (10.7)
Hypertension	5 (17.9)	1 (3.6)	3 (10.7)	1 (3.6)	0
Orthostatic hypotension	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Embolism	1 (3.6)	0	0	1 (3.6)	0
Flushing	1 (3.6)	1 (3.6)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174l
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

			All patients N=36		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (100)	0	3 (8.3)	5 (13.9)	28 (77.8)
Blood and lymphatic system disorders					
-Total	28 (77.8)	2 (5.6)	2 (5.6)	12 (33.3)	12 (33.3)
Febrile neutropenia	14 (38.9)	0	0	13 (36.1)	1 (2.8)
Anaemia	13 (36.1)	2 (5.6)	1 (2.8)	9 (25.0)	1 (2.8)
Neutropenia	9 (25.0)	0	0	3 (8.3)	6 (16.7)
Thrombocytopenia	7 (19.4)	0	1 (2.8)	1 (2.8)	5 (13.9)
Disseminated intravascular coagulation	3 (8.3)	0	1 (2.8)	2 (5.6)	0
Coagulopathy	1 (2.8)	1 (2.8)	0	0	0
Leukopenia	1 (2.8)	0	0	0	1 (2.8)
Lymphadenopathy	1 (2.8)	0	1 (2.8)	0	0
Lymphopenia	1 (2.8)	0	0	1 (2.8)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	1 (2.8)	0	0	0	1 (2.8)
Cardiac disorders					
-Total	12 (33.3)	7 (19.4)	4 (11.1)	1 (2.8)	0
Tachycardia	8 (22.2)	5 (13.9)	2 (5.6)	1 (2.8)	0
Pericardial effusion	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Atrioventricular block second degree	1 (2.8)	1 (2.8)	0	0	0
Bradycardia	1 (2.8)	0	1 (2.8)	0	0
Left ventricular dysfunction	1 (2.8)	0	0	1 (2.8)	0
Palpitations	1 (2.8)	1 (2.8)	0	0	0
Sinus tachycardia	1 (2.8)	1 (2.8)	0	0	0
Ventricular tachycardia	1 (2.8)	0	1 (2.8)	0	0
Endocrine disorders					
-Total	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Adrenal insufficiency	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Eye disorders					
-Total	8 (22.2)	7 (19.4)	1 (2.8)	0	0
Conjunctival haemorrhage	3 (8.3)	3 (8.3)	0	0	0
Periorbital oedema	3 (8.3)	3 (8.3)	0	0	0
Vision blurred	3 (8.3)	2 (5.6)	1 (2.8)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

			All patients N=36		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Retinal haemorrhage	2 (5.6)	2 (5.6)	0	0	0
Conjunctivitis allergic	1 (2.8)	1 (2.8)	0	0	0
Eye pain	1 (2.8)	1 (2.8)	0	0	0
Gastrointestinal disorders					
-Total	23 (63.9)	7 (19.4)	7 (19.4)	9 (25.0)	0
Vomiting	14 (38.9)	7 (19.4)	6 (16.7)	1 (2.8)	0
Diarrhoea	12 (33.3)	7 (19.4)	3 (8.3)	2 (5.6)	0
Nausea	11 (30.6)	1 (2.8)	7 (19.4)	3 (8.3)	0
Constipation	5 (13.9)	4 (11.1)	1 (2.8)	0	0
Abdominal pain	3 (8.3)	2 (5.6)	0	1 (2.8)	0
Abdominal pain upper	2 (5.6)	0	2 (5.6)	0	0
Dysphagia	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Oral pain	2 (5.6)	1 (2.8)	0	1 (2.8)	0
Pancreatitis	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Abdominal discomfort	1 (2.8)	1 (2.8)	0	0	0
Ascites	1 (2.8)	0	0	1 (2.8)	0
Dyspepsia	1 (2.8)	0	1 (2.8)	0	0
Enterocolitis	1 (2.8)	0	0	1 (2.8)	0
Flatulence	1 (2.8)	1 (2.8)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematemesis	1 (2.8)	1 (2.8)	0	0	0
Ileus	1 (2.8)	0	0	1 (2.8)	0
Intestinal obstruction	1 (2.8)	0	0	1 (2.8)	0
Tooth socket haemorrhage	1 (2.8)	1 (2.8)	0	0	0
General disorders and administration site conditions					
-Total	22 (61.1)	4 (11.1)	9 (25.0)	8 (22.2)	1 (2.8)
Pyrexia	14 (38.9)	1 (2.8)	7 (19.4)	5 (13.9)	1 (2.8)
Chills	6 (16.7)	5 (13.9)	1 (2.8)	0	0
Fatigue	6 (16.7)	5 (13.9)	1 (2.8)	0	0
Catheter site pain	3 (8.3)	0	3 (8.3)	0	0
Malaise	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Pain	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Asthenia	1 (2.8)	1 (2.8)	0	0	0
Face oedema	1 (2.8)	0	0	1 (2.8)	0
Generalised oedema	1 (2.8)	0	1 (2.8)	0	0
Localised oedema	1 (2.8)	0	0	1 (2.8)	0
Mucosal haemorrhage	1 (2.8)	0	1 (2.8)	0	0
Multiple organ dysfunction syndrome	1 (2.8)	0	0	1 (2.8)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	1 (2.8)	0	0	1 (2.8)	0
Physical deconditioning	1 (2.8)	0	0	1 (2.8)	0
Hepatobiliary disorders					
-Total	5 (13.9)	2 (5.6)	2 (5.6)	1 (2.8)	0
Hyperbilirubinaemia	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Gallbladder enlargement	1 (2.8)	1 (2.8)	0	0	0
Hepatomegaly	1 (2.8)	0	1 (2.8)	0	0
Hepatosplenomegaly	1 (2.8)	1 (2.8)	0	0	0
Immune system disorders					
-Total	34 (94.4)	1 (2.8)	18 (50.0)	6 (16.7)	9 (25.0)
Cytokine release syndrome	30 (83.3)	3 (8.3)	14 (38.9)	4 (11.1)	9 (25.0)
Hypogammaglobulinaemia	19 (52.8)	1 (2.8)	14 (38.9)	4 (11.1)	0
Seasonal allergy	2 (5.6)	2 (5.6)	0	0	0
Chronic graft versus host disease	1 (2.8)	0	1 (2.8)	0	0
Drug hypersensitivity	1 (2.8)	0	1 (2.8)	0	0
Graft versus host disease	1 (2.8)	0	1 (2.8)	0	0
Immunodeficiency	1 (2.8)	0	1 (2.8)	0	0
Immunodeficiency common variable	1 (2.8)	0	1 (2.8)	0	0
Infections and infestations					

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	25 (69.4)	3 (8.3)	13 (36.1)	7 (19.4)	2 (5.6)
Gastroenteritis	5 (13.9)	1 (2.8)	3 (8.3)	1 (2.8)	0
Rhinovirus infection	4 (11.1)	4 (11.1)	0	0	0
Upper respiratory tract infection	4 (11.1)	1 (2.8)	3 (8.3)	0	0
Clostridium difficile colitis	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Pneumonia	3 (8.3)	0	2 (5.6)	1 (2.8)	0
Viral infection	3 (8.3)	2 (5.6)	1 (2.8)	0	0
Viral upper respiratory tract infection	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Influenza	2 (5.6)	0	2 (5.6)	0	0
Staphylococcal infection	2 (5.6)	1 (2.8)	0	1 (2.8)	0
Bacterial sepsis	1 (2.8)	0	0	0	1 (2.8)
Catheter site infection	1 (2.8)	0	0	1 (2.8)	0
Clostridium difficile infection	1 (2.8)	0	1 (2.8)	0	0
Corona virus infection	1 (2.8)	0	0	1 (2.8)	0
Ear infection	1 (2.8)	1 (2.8)	0	0	0
Folliculitis	1 (2.8)	0	1 (2.8)	0	0
Gastroenteritis viral	1 (2.8)	1 (2.8)	0	0	0
Gingivitis	1 (2.8)	1 (2.8)	0	0	0
Herpes zoster	1 (2.8)	0	0	1 (2.8)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis aseptic	1 (2.8)	0	1 (2.8)	0	0
Molluscum contagiosum	1 (2.8)	1 (2.8)	0	0	0
Orchitis	1 (2.8)	1 (2.8)	0	0	0
Otitis externa	1 (2.8)	0	1 (2.8)	0	0
Otitis media	1 (2.8)	0	1 (2.8)	0	0
Parainfluenzae virus infection	1 (2.8)	0	0	1 (2.8)	0
Paronychia	1 (2.8)	1 (2.8)	0	0	0
Pharyngitis	1 (2.8)	0	1 (2.8)	0	0
Rash pustular	1 (2.8)	0	1 (2.8)	0	0
Respiratory syncytial virus infection	1 (2.8)	0	0	1 (2.8)	0
Respiratory tract infection	1 (2.8)	0	0	0	1 (2.8)
Sinusitis	1 (2.8)	0	1 (2.8)	0	0
Skin infection	1 (2.8)	0	1 (2.8)	0	0
Streptococcal infection	1 (2.8)	0	1 (2.8)	0	0
Subcutaneous abscess	1 (2.8)	0	1 (2.8)	0	0
Tinea capitis	1 (2.8)	1 (2.8)	0	0	0
Urinary tract infection	1 (2.8)	0	1 (2.8)	0	0
Urinary tract infection enterococcal	1 (2.8)	0	0	1 (2.8)	0
Vulvovaginal mycotic infection	1 (2.8)	0	1 (2.8)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	11 (30.6)	7 (19.4)	2 (5.6)	2 (5.6)	0
Procedural pain	3 (8.3)	2 (5.6)	0	1 (2.8)	0
Infusion related reaction	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Arthropod bite	1 (2.8)	1 (2.8)	0	0	0
Contusion	1 (2.8)	1 (2.8)	0	0	0
Incision site pain	1 (2.8)	1 (2.8)	0	0	0
Post procedural haemorrhage	1 (2.8)	1 (2.8)	0	0	0
Procedural complication	1 (2.8)	1 (2.8)	0	0	0
Procedural nausea	1 (2.8)	0	1 (2.8)	0	0
Radius fracture	1 (2.8)	0	1 (2.8)	0	0
Skin abrasion	1 (2.8)	1 (2.8)	0	0	0
Stoma site irritation	1 (2.8)	1 (2.8)	0	0	0
Subdural haemorrhage	1 (2.8)	1 (2.8)	0	0	0
Sunburn	1 (2.8)	1 (2.8)	0	0	0
Tibia fracture	1 (2.8)	0	1 (2.8)	0	0
Tracheal haemorrhage	1 (2.8)	0	0	1 (2.8)	0
Investigations					

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	32 (88.9)	1 (2.8)	1 (2.8)	10 (27.8)	20 (55.6)
White blood cell count decreased	19 (52.8)	3 (8.3)	0	5 (13.9)	11 (30.6)
Neutrophil count decreased	14 (38.9)	0	1 (2.8)	3 (8.3)	10 (27.8)
Lymphocyte count decreased	9 (25.0)	1 (2.8)	1 (2.8)	3 (8.3)	4 (11.1)
Platelet count decreased	9 (25.0)	1 (2.8)	1 (2.8)	2 (5.6)	5 (13.9)
Alanine aminotransferase increased	8 (22.2)	1 (2.8)	1 (2.8)	6 (16.7)	0
Aspartate aminotransferase increased	7 (19.4)	1 (2.8)	2 (5.6)	2 (5.6)	2 (5.6)
Blood fibrinogen decreased	4 (11.1)	0	1 (2.8)	2 (5.6)	1 (2.8)
International normalised ratio increased	4 (11.1)	3 (8.3)	0	1 (2.8)	0
Activated partial thromboplastin time prolonged	3 (8.3)	1 (2.8)	2 (5.6)	0	0
Blood creatinine increased	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Prothrombin time prolonged	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Weight decreased	3 (8.3)	1 (2.8)	2 (5.6)	0	0
Blood bilirubin increased	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Blood magnesium decreased	2 (5.6)	1 (2.8)	0	1 (2.8)	0
Blood phosphorus increased	2 (5.6)	2 (5.6)	0	0	0
Blood urea increased	2 (5.6)	1 (2.8)	0	1 (2.8)	0
C-reactive protein increased	2 (5.6)	1 (2.8)	0	1 (2.8)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lipase increased	2 (5.6)	0	0	0	2 (5.6)
Transaminases increased	2 (5.6)	2 (5.6)	0	0	0
Blood alkaline phosphatase increased	1 (2.8)	1 (2.8)	0	0	0
Blood immunoglobulin g decreased	1 (2.8)	0	1 (2.8)	0	0
Blood immunoglobulin m decreased	1 (2.8)	1 (2.8)	0	0	0
Blood lactate dehydrogenase increased	1 (2.8)	1 (2.8)	0	0	0
Blood phosphorus decreased	1 (2.8)	1 (2.8)	0	0	0
Blood sodium increased	1 (2.8)	0	1 (2.8)	0	0
Blood uric acid increased	1 (2.8)	1 (2.8)	0	0	0
Cardiac murmur	1 (2.8)	1 (2.8)	0	0	0
Fibrin d dimer increased	1 (2.8)	1 (2.8)	0	0	0
Oxygen saturation decreased	1 (2.8)	1 (2.8)	0	0	0
Protein total decreased	1 (2.8)	0	0	1 (2.8)	0
Serum ferritin increased	1 (2.8)	0	1 (2.8)	0	0
Metabolism and nutrition disorders					
-Total	24 (66.7)	3 (8.3)	3 (8.3)	15 (41.7)	3 (8.3)
Decreased appetite	11 (30.6)	2 (5.6)	2 (5.6)	7 (19.4)	0
Hypokalaemia	10 (27.8)	2 (5.6)	3 (8.3)	5 (13.9)	0
Hypophosphataemia	5 (13.9)	1 (2.8)	0	3 (8.3)	1 (2.8)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	4 (11.1)	1 (2.8)	2 (5.6)	0	1 (2.8)
Hypoalbuminaemia	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Acidosis	2 (5.6)	1 (2.8)	0	1 (2.8)	0
Dehydration	2 (5.6)	0	0	2 (5.6)	0
Hyperglycaemia	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Hypertriglyceridaemia	2 (5.6)	1 (2.8)	0	1 (2.8)	0
Tumour lysis syndrome	2 (5.6)	0	0	2 (5.6)	0
Fluid overload	1 (2.8)	0	1 (2.8)	0	0
Hyperalbuminaemia	1 (2.8)	1 (2.8)	0	0	0
Hypercalcaemia	1 (2.8)	1 (2.8)	0	0	0
Hyperchloraemia	1 (2.8)	1 (2.8)	0	0	0
Hypermagnesaemia	1 (2.8)	1 (2.8)	0	0	0
Hyperphosphataemia	1 (2.8)	1 (2.8)	0	0	0
Hyperuricaemia	1 (2.8)	0	0	0	1 (2.8)
Hypocalcaemia	1 (2.8)	1 (2.8)	0	0	0
Hypomagnesaemia	1 (2.8)	1 (2.8)	0	0	0
Iron overload	1 (2.8)	0	0	1 (2.8)	0
Malnutrition	1 (2.8)	0	0	1 (2.8)	0
Metabolic acidosis	1 (2.8)	0	1 (2.8)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic alkalosis	1 (2.8)	1 (2.8)	0	0	0
Vitamin d deficiency	1 (2.8)	1 (2.8)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	12 (33.3)	6 (16.7)	5 (13.9)	1 (2.8)	0
Pain in extremity	6 (16.7)	4 (11.1)	2 (5.6)	0	0
Arthralgia	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Muscular weakness	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Limb discomfort	1 (2.8)	1 (2.8)	0	0	0
Musculoskeletal pain	1 (2.8)	1 (2.8)	0	0	0
Osteonecrosis	1 (2.8)	0	1 (2.8)	0	0
Osteopenia	1 (2.8)	0	1 (2.8)	0	0
Pain in jaw	1 (2.8)	1 (2.8)	0	0	0
Toe walking	1 (2.8)	1 (2.8)	0	0	0
Nervous system disorders					
-Total	18 (50.0)	11 (30.6)	6 (16.7)	1 (2.8)	0
Headache	12 (33.3)	10 (27.8)	2 (5.6)	0	0
Dizziness	2 (5.6)	2 (5.6)	0	0	0
Dysarthria	2 (5.6)	1 (2.8)	1 (2.8)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=36 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Seizure	2 (5.6)	0	2 (5.6)	0	0
Tremor	2 (5.6)	2 (5.6)	0	0	0
Asterixis	1 (2.8)	1 (2.8)	0	0	0
Ataxia	1 (2.8)	0	1 (2.8)	0	0
Depressed level of consciousness	1 (2.8)	1 (2.8)	0	0	0
Disturbance in attention	1 (2.8)	1 (2.8)	0	0	0
Migraine	1 (2.8)	0	1 (2.8)	0	0
Neuropathy peripheral	1 (2.8)	0	1 (2.8)	0	0
Peroneal nerve palsy	1 (2.8)	1 (2.8)	0	0	0
Pleocytosis	1 (2.8)	1 (2.8)	0	0	0
Somnolence	1 (2.8)	1 (2.8)	0	0	0
Psychiatric disorders					
-Total	13 (36.1)	7 (19.4)	6 (16.7)	0	0
Anxiety	4 (11.1)	2 (5.6)	2 (5.6)	0	0
Confusional state	4 (11.1)	3 (8.3)	1 (2.8)	0	0
Delirium	4 (11.1)	2 (5.6)	2 (5.6)	0	0
Depression	2 (5.6)	2 (5.6)	0	0	0
Adjustment disorder	1 (2.8)	0	1 (2.8)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	1 (2.8)	0	1 (2.8)	0	0
Hallucination	1 (2.8)	1 (2.8)	0	0	0
Insomnia	1 (2.8)	0	1 (2.8)	0	0
Irritability	1 (2.8)	1 (2.8)	0	0	0
Mental status changes	1 (2.8)	1 (2.8)	0	0	0
Panic attack	1 (2.8)	0	1 (2.8)	0	0
Sleep disorder	1 (2.8)	0	1 (2.8)	0	0
Suicidal ideation	1 (2.8)	1 (2.8)	0	0	0
Renal and urinary disorders					
-Total	11 (30.6)	1 (2.8)	2 (5.6)	5 (13.9)	3 (8.3)
Acute kidney injury	7 (19.4)	0	1 (2.8)	4 (11.1)	2 (5.6)
Haematuria	3 (8.3)	0	1 (2.8)	1 (2.8)	1 (2.8)
Dysuria	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Oliguria	1 (2.8)	0	0	1 (2.8)	0
Pollakiuria	1 (2.8)	1 (2.8)	0	0	0
Renal failure	1 (2.8)	0	0	0	1 (2.8)
Renal impairment	1 (2.8)	0	0	1 (2.8)	0
Reproductive system and breast disorders					
-Total	2 (5.6)	1 (2.8)	0	1 (2.8)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal haemorrhage	1 (2.8)	0	0	1 (2.8)	0
Vulvovaginal adhesion	1 (2.8)	1 (2.8)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	21 (58.3)	6 (16.7)	4 (11.1)	4 (11.1)	7 (19.4)
Cough	7 (19.4)	6 (16.7)	1 (2.8)	0	0
Pulmonary oedema	6 (16.7)	1 (2.8)	0	3 (8.3)	2 (5.6)
Epistaxis	5 (13.9)	1 (2.8)	1 (2.8)	2 (5.6)	1 (2.8)
Hypoxia	5 (13.9)	0	0	3 (8.3)	2 (5.6)
Pleural effusion	5 (13.9)	1 (2.8)	2 (5.6)	2 (5.6)	0
Nasal congestion	4 (11.1)	4 (11.1)	0	0	0
Rhinorrhoea	4 (11.1)	3 (8.3)	1 (2.8)	0	0
Oropharyngeal pain	3 (8.3)	1 (2.8)	2 (5.6)	0	0
Respiratory failure	3 (8.3)	0	0	0	3 (8.3)
Tachypnoea	3 (8.3)	2 (5.6)	1 (2.8)	0	0
Haemoptysis	2 (5.6)	1 (2.8)	0	0	1 (2.8)
Acute respiratory failure	1 (2.8)	0	0	0	1 (2.8)
Dysphonia	1 (2.8)	1 (2.8)	0	0	0
Dyspnoea	1 (2.8)	0	0	0	1 (2.8)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Interstitial lung disease	1 (2.8)	0	0	0	1 (2.8)
Oropharyngeal plaque	1 (2.8)	1 (2.8)	0	0	0
Pharyngeal erythema	1 (2.8)	1 (2.8)	0	0	0
Pharyngeal lesion	1 (2.8)	0	0	1 (2.8)	0
Pharyngeal ulceration	1 (2.8)	0	1 (2.8)	0	0
Respiratory depression	1 (2.8)	0	1 (2.8)	0	0
Respiratory distress	1 (2.8)	0	0	0	1 (2.8)
Rhinitis allergic	1 (2.8)	0	1 (2.8)	0	0
Skin and subcutaneous tissue disorders					
-Total	18 (50.0)	11 (30.6)	5 (13.9)	2 (5.6)	0
Rash	4 (11.1)	2 (5.6)	2 (5.6)	0	0
Dry skin	3 (8.3)	3 (8.3)	0	0	0
Erythema	3 (8.3)	3 (8.3)	0	0	0
Hyperhidrosis	2 (5.6)	2 (5.6)	0	0	0
Papule	2 (5.6)	2 (5.6)	0	0	0
Pruritus	2 (5.6)	2 (5.6)	0	0	0
Rash erythematous	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Rash maculo-papular	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Acne	1 (2.8)	1 (2.8)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alopecia	1 (2.8)	0	1 (2.8)	0	0
Dermatitis	1 (2.8)	1 (2.8)	0	0	0
Dermatitis acneiform	1 (2.8)	0	0	1 (2.8)	0
Dermatitis diaper	1 (2.8)	1 (2.8)	0	0	0
Ecchymosis	1 (2.8)	0	0	1 (2.8)	0
Eczema	1 (2.8)	1 (2.8)	0	0	0
Ingrowing nail	1 (2.8)	1 (2.8)	0	0	0
Keloid scar	1 (2.8)	0	1 (2.8)	0	0
Livedo reticularis	1 (2.8)	1 (2.8)	0	0	0
Macule	1 (2.8)	1 (2.8)	0	0	0
Petechiae	1 (2.8)	1 (2.8)	0	0	0
Rash macular	1 (2.8)	1 (2.8)	0	0	0
Rash papular	1 (2.8)	1 (2.8)	0	0	0
Skin exfoliation	1 (2.8)	1 (2.8)	0	0	0
Skin fissures	1 (2.8)	1 (2.8)	0	0	0
Vascular disorders					
-Total	14 (38.9)	0	4 (11.1)	5 (13.9)	5 (13.9)
Hypotension	10 (27.8)	0	0	5 (13.9)	5 (13.9)
Hypertension	7 (19.4)	2 (5.6)	5 (13.9)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Capillary leak syndrome	1 (2.8)	0	0	0	1 (2.8)
Flushing	1 (2.8)	1 (2.8)	0	0	0
Haematoma	1 (2.8)	0	1 (2.8)	0	0
Hot flush	1 (2.8)	1 (2.8)	0	0	0
Secondary hypertension	1 (2.8)	0	1 (2.8)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174m
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (100)	0	1 (7.1)	4 (28.6)	9 (64.3)
Blood and lymphatic system disorders					
-Total	12 (85.7)	0	1 (7.1)	8 (57.1)	3 (21.4)
Febrile neutropenia	9 (64.3)	0	0	9 (64.3)	0
Anaemia	5 (35.7)	2 (14.3)	1 (7.1)	2 (14.3)	0
Thrombocytopenia	2 (14.3)	0	0	0	2 (14.3)
Neutropenia	1 (7.1)	0	0	1 (7.1)	0
Pancytopenia	1 (7.1)	0	0	0	1 (7.1)
Cardiac disorders					
-Total	4 (28.6)	4 (28.6)	0	0	0
Tachycardia	2 (14.3)	2 (14.3)	0	0	0
Atrioventricular block second degree	1 (7.1)	1 (7.1)	0	0	0
Sinus tachycardia	1 (7.1)	1 (7.1)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Retinal haemorrhage	1 (7.1)	1 (7.1)	0	0	0
Gastrointestinal disorders					
-Total	5 (35.7)	1 (7.1)	1 (7.1)	3 (21.4)	0
Nausea	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Abdominal pain	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Constipation	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Vomiting	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Abdominal pain upper	1 (7.1)	0	1 (7.1)	0	0
Ascites	1 (7.1)	0	0	1 (7.1)	0
Diarrhoea	1 (7.1)	1 (7.1)	0	0	0
Dyspepsia	1 (7.1)	0	1 (7.1)	0	0
Intestinal obstruction	1 (7.1)	0	0	1 (7.1)	0
Pancreatitis	1 (7.1)	0	0	1 (7.1)	0
Tooth socket haemorrhage	1 (7.1)	1 (7.1)	0	0	0
General disorders and administration site conditions					
-Total	4 (28.6)	1 (7.1)	2 (14.3)	1 (7.1)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Catheter site pain	1 (7.1)	0	1 (7.1)	0	0
Chills	1 (7.1)	1 (7.1)	0	0	0
Fatigue	1 (7.1)	1 (7.1)	0	0	0
Hepatobiliary disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Hepatosplenomegaly	1 (7.1)	1 (7.1)	0	0	0
Immune system disorders					
-Total	14 (100)	0	10 (71.4)	3 (21.4)	1 (7.1)
Cytokine release syndrome	13 (92.9)	0	10 (71.4)	2 (14.3)	1 (7.1)
Hypogammaglobulinaemia	8 (57.1)	1 (7.1)	6 (42.9)	1 (7.1)	0
Infections and infestations					
-Total	6 (42.9)	1 (7.1)	2 (14.3)	3 (21.4)	0
Catheter site infection	1 (7.1)	0	0	1 (7.1)	0
Clostridium difficile infection	1 (7.1)	0	1 (7.1)	0	0
Cytomegalovirus infection	1 (7.1)	1 (7.1)	0	0	0
Folliculitis	1 (7.1)	0	1 (7.1)	0	0
Fungal skin infection	1 (7.1)	1 (7.1)	0	0	0
Pneumonia	1 (7.1)	0	0	1 (7.1)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (7.1)	1 (7.1)	0	0	0
Staphylococcal infection	1 (7.1)	1 (7.1)	0	0	0
Urinary tract infection enterococcal	1 (7.1)	0	0	1 (7.1)	0
Viral infection	1 (7.1)	0	1 (7.1)	0	0
Injury, poisoning and procedural complications					
-Total	1 (7.1)	1 (7.1)	0	0	0
Procedural pain	1 (7.1)	1 (7.1)	0	0	0
Investigations					
-Total	12 (85.7)	1 (7.1)	0	3 (21.4)	8 (57.1)
White blood cell count decreased	8 (57.1)	1 (7.1)	0	1 (7.1)	6 (42.9)
Neutrophil count decreased	7 (50.0)	0	0	2 (14.3)	5 (35.7)
Lymphocyte count decreased	5 (35.7)	1 (7.1)	0	2 (14.3)	2 (14.3)
Platelet count decreased	4 (28.6)	1 (7.1)	0	0	3 (21.4)
Alanine aminotransferase increased	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Blood bilirubin increased	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Aspartate aminotransferase increased	1 (7.1)	0	1 (7.1)	0	0
Blood creatinine increased	1 (7.1)	1 (7.1)	0	0	0
Blood fibrinogen decreased	1 (7.1)	0	0	1 (7.1)	0
Blood immunoglobulin a decreased	1 (7.1)	1 (7.1)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin g decreased	1 (7.1)	0	1 (7.1)	0	0
Blood immunoglobulin m decreased	1 (7.1)	1 (7.1)	0	0	0
Blood sodium increased	1 (7.1)	0	1 (7.1)	0	0
Blood urea increased	1 (7.1)	1 (7.1)	0	0	0
C-reactive protein increased	1 (7.1)	0	0	1 (7.1)	0
Fibrin d dimer increased	1 (7.1)	1 (7.1)	0	0	0
International normalised ratio increased	1 (7.1)	1 (7.1)	0	0	0
Lipase increased	1 (7.1)	0	0	0	1 (7.1)
Prothrombin time prolonged	1 (7.1)	1 (7.1)	0	0	0
Metabolism and nutrition disorders					
-Total	8 (57.1)	1 (7.1)	1 (7.1)	4 (28.6)	2 (14.3)
Decreased appetite	4 (28.6)	1 (7.1)	1 (7.1)	2 (14.3)	0
Hypokalaemia	4 (28.6)	1 (7.1)	1 (7.1)	2 (14.3)	0
Hyperphosphataemia	2 (14.3)	2 (14.3)	0	0	0
Dehydration	1 (7.1)	0	0	1 (7.1)	0
Hypertriglyceridaemia	1 (7.1)	1 (7.1)	0	0	0
Hyperuricaemia	1 (7.1)	0	0	0	1 (7.1)
Hypoalbuminaemia	1 (7.1)	0	0	1 (7.1)	0
Hypomagnesaemia	1 (7.1)	1 (7.1)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	1 (7.1)	0	0	0	1 (7.1)
Musculoskeletal and connective tissue disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Arthralgia	1 (7.1)	1 (7.1)	0	0	0
Muscular weakness	1 (7.1)	0	1 (7.1)	0	0
Pain in extremity	1 (7.1)	0	1 (7.1)	0	0
Nervous system disorders					
-Total	5 (35.7)	2 (14.3)	3 (21.4)	0	0
Headache	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Depressed level of consciousness	1 (7.1)	1 (7.1)	0	0	0
Dysarthria	1 (7.1)	0	1 (7.1)	0	0
Migraine	1 (7.1)	0	1 (7.1)	0	0
Somnolence	1 (7.1)	1 (7.1)	0	0	0
Psychiatric disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0
Panic attack	1 (7.1)	0	1 (7.1)	0	0
Renal and urinary disorders					
-Total	2 (14.3)	1 (7.1)	0	1 (7.1)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (7.1)	0	0	1 (7.1)	0
Dysuria	1 (7.1)	1 (7.1)	0	0	0
Reproductive system and breast disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Vulvovaginal adhesion	1 (7.1)	1 (7.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (42.9)	3 (21.4)	1 (7.1)	1 (7.1)	1 (7.1)
Hypoxia	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Pleural effusion	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Cough	1 (7.1)	1 (7.1)	0	0	0
Nasal congestion	1 (7.1)	1 (7.1)	0	0	0
Oropharyngeal plaque	1 (7.1)	1 (7.1)	0	0	0
Pulmonary oedema	1 (7.1)	0	0	1 (7.1)	0
Respiratory failure	1 (7.1)	0	0	0	1 (7.1)
Tachypnoea	1 (7.1)	1 (7.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (28.6)	4 (28.6)	0	0	0
Dermatitis diaper	1 (7.1)	1 (7.1)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	1 (7.1)	1 (7.1)	0	0	0
Hyperhidrosis	1 (7.1)	1 (7.1)	0	0	0
Macule	1 (7.1)	1 (7.1)	0	0	0
Petechiae	1 (7.1)	1 (7.1)	0	0	0
Pruritus	1 (7.1)	1 (7.1)	0	0	0
Rash	1 (7.1)	1 (7.1)	0	0	0
Rash erythematous	1 (7.1)	1 (7.1)	0	0	0
Rash macular	1 (7.1)	1 (7.1)	0	0	0
Vascular disorders					
-Total	5 (35.7)	0	3 (21.4)	2 (14.3)	0
Hypertension	2 (14.3)	0	2 (14.3)	0	0
Hypotension	2 (14.3)	0	0	2 (14.3)	0
Orthostatic hypotension	1 (7.1)	0	1 (7.1)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174m
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: No

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	49 (98.0)	2 (4.0)	6 (12.0)	10 (20.0)	31 (62.0)
Blood and lymphatic system disorders					
-Total	31 (62.0)	2 (4.0)	2 (4.0)	19 (38.0)	8 (16.0)
Anaemia	22 (44.0)	1 (2.0)	4 (8.0)	16 (32.0)	1 (2.0)
Febrile neutropenia	13 (26.0)	0	0	13 (26.0)	0
Neutropenia	7 (14.0)	0	0	2 (4.0)	5 (10.0)
Thrombocytopenia	6 (12.0)	0	0	2 (4.0)	4 (8.0)
Disseminated intravascular coagulation	4 (8.0)	0	2 (4.0)	2 (4.0)	0
Lymphopenia	3 (6.0)	0	1 (2.0)	1 (2.0)	1 (2.0)
Coagulopathy	1 (2.0)	1 (2.0)	0	0	0
Cardiac disorders					
-Total	18 (36.0)	7 (14.0)	9 (18.0)	2 (4.0)	0
Tachycardia	13 (26.0)	6 (12.0)	5 (10.0)	2 (4.0)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Pericardial effusion	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Bradycardia	1 (2.0)	0	1 (2.0)	0	0
Cardiac dysfunction	1 (2.0)	1 (2.0)	0	0	0
Left ventricular dysfunction	1 (2.0)	0	0	1 (2.0)	0
Palpitations	1 (2.0)	1 (2.0)	0	0	0
Sinus bradycardia	1 (2.0)	1 (2.0)	0	0	0
Ventricular tachycardia	1 (2.0)	0	1 (2.0)	0	0
Ear and labyrinth disorders					
-Total	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Ear pain	2 (4.0)	2 (4.0)	0	0	0
Hypoacusis	1 (2.0)	0	1 (2.0)	0	0
Endocrine disorders					
-Total	1 (2.0)	0	1 (2.0)	0	0
Adrenal insufficiency	1 (2.0)	0	1 (2.0)	0	0
Eye disorders					
-Total	12 (24.0)	5 (10.0)	7 (14.0)	0	0
Periorbital oedema	4 (8.0)	3 (6.0)	1 (2.0)	0	0
Conjunctival haemorrhage	3 (6.0)	3 (6.0)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye pain	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Vision blurred	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Photophobia	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Uveitis	2 (4.0)	0	2 (4.0)	0	0
Ocular hypertension	1 (2.0)	0	1 (2.0)	0	0
Papilloedema	1 (2.0)	0	1 (2.0)	0	0
Retinal haemorrhage	1 (2.0)	1 (2.0)	0	0	0
Visual impairment	1 (2.0)	0	1 (2.0)	0	0
Gastrointestinal disorders					
-Total	31 (62.0)	10 (20.0)	13 (26.0)	8 (16.0)	0
Vomiting	20 (40.0)	13 (26.0)	5 (10.0)	2 (4.0)	0
Nausea	18 (36.0)	6 (12.0)	10 (20.0)	2 (4.0)	0
Diarrhoea	17 (34.0)	10 (20.0)	6 (12.0)	1 (2.0)	0
Abdominal pain	7 (14.0)	5 (10.0)	2 (4.0)	0	0
Constipation	5 (10.0)	5 (10.0)	0	0	0
Abdominal distension	2 (4.0)	0	2 (4.0)	0	0
Dysphagia	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Haematemesis	2 (4.0)	2 (4.0)	0	0	0
Stomatitis	2 (4.0)	1 (2.0)	1 (2.0)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal discomfort	1 (2.0)	1 (2.0)	0	0	0
Abdominal pain lower	1 (2.0)	0	1 (2.0)	0	0
Abdominal pain upper	1 (2.0)	0	1 (2.0)	0	0
Abdominal tenderness	1 (2.0)	1 (2.0)	0	0	0
Anal incontinence	1 (2.0)	1 (2.0)	0	0	0
Flatulence	1 (2.0)	1 (2.0)	0	0	0
Gastrointestinal haemorrhage	1 (2.0)	1 (2.0)	0	0	0
Gastrooesophageal reflux disease	1 (2.0)	1 (2.0)	0	0	0
Glossodynia	1 (2.0)	1 (2.0)	0	0	0
Ileus	1 (2.0)	0	0	1 (2.0)	0
Lip pain	1 (2.0)	0	1 (2.0)	0	0
Mouth haemorrhage	1 (2.0)	0	0	1 (2.0)	0
Pancreatitis	1 (2.0)	0	1 (2.0)	0	0
General disorders and administration site conditions					
-Total	28 (56.0)	11 (22.0)	8 (16.0)	8 (16.0)	1 (2.0)
Pyrexia	14 (28.0)	3 (6.0)	6 (12.0)	4 (8.0)	1 (2.0)
Fatigue	12 (24.0)	9 (18.0)	2 (4.0)	1 (2.0)	0
Chills	7 (14.0)	7 (14.0)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	3 (6.0)	0	3 (6.0)	0	0
Pain	3 (6.0)	0	1 (2.0)	2 (4.0)	0
Catheter site pain	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Face oedema	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Generalised oedema	2 (4.0)	0	2 (4.0)	0	0
Oedema peripheral	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Asthenia	1 (2.0)	1 (2.0)	0	0	0
Catheter site extravasation	1 (2.0)	0	1 (2.0)	0	0
Catheter site haemorrhage	1 (2.0)	1 (2.0)	0	0	0
Facial pain	1 (2.0)	0	1 (2.0)	0	0
Injection site haematoma	1 (2.0)	1 (2.0)	0	0	0
Localised oedema	1 (2.0)	0	0	1 (2.0)	0
Mucosal haemorrhage	1 (2.0)	0	1 (2.0)	0	0
Multiple organ dysfunction syndrome	1 (2.0)	0	0	1 (2.0)	0
Non-cardiac chest pain	1 (2.0)	1 (2.0)	0	0	0
Peripheral swelling	1 (2.0)	0	1 (2.0)	0	0
Physical deconditioning	1 (2.0)	0	0	1 (2.0)	0
Hepatobiliary disorders					
-Total	6 (12.0)	2 (4.0)	2 (4.0)	2 (4.0)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Hyperbilirubinaemia	3 (6.0)	0	1 (2.0)	2 (4.0)	0
Gallbladder enlargement	1 (2.0)	1 (2.0)	0	0	0
Immune system disorders					
-Total	43 (86.0)	5 (10.0)	20 (40.0)	8 (16.0)	10 (20.0)
Cytokine release syndrome	37 (74.0)	6 (12.0)	15 (30.0)	6 (12.0)	10 (20.0)
Hypogammaglobulinaemia	17 (34.0)	2 (4.0)	12 (24.0)	3 (6.0)	0
Drug hypersensitivity	1 (2.0)	0	1 (2.0)	0	0
Graft versus host disease in skin	1 (2.0)	1 (2.0)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	1 (2.0)	0	0
Infections and infestations					
-Total	20 (40.0)	4 (8.0)	12 (24.0)	3 (6.0)	1 (2.0)
Clostridium difficile colitis	4 (8.0)	1 (2.0)	2 (4.0)	1 (2.0)	0
Clostridium difficile infection	3 (6.0)	0	3 (6.0)	0	0
Gastroenteritis	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Rhinovirus infection	2 (4.0)	2 (4.0)	0	0	0
Acute sinusitis	1 (2.0)	0	1 (2.0)	0	0
Body tinea	1 (2.0)	1 (2.0)	0	0	0
Catheter site cellulitis	1 (2.0)	1 (2.0)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterococcal infection	1 (2.0)	1 (2.0)	0	0	0
Gastroenteritis norovirus	1 (2.0)	0	1 (2.0)	0	0
Herpes simplex	1 (2.0)	1 (2.0)	0	0	0
Human herpesvirus 6 infection	1 (2.0)	0	1 (2.0)	0	0
Hypopyon	1 (2.0)	0	1 (2.0)	0	0
Influenza	1 (2.0)	1 (2.0)	0	0	0
Oral candidiasis	1 (2.0)	1 (2.0)	0	0	0
Orchitis	1 (2.0)	1 (2.0)	0	0	0
Pharyngitis	1 (2.0)	0	1 (2.0)	0	0
Pneumonia	1 (2.0)	0	1 (2.0)	0	0
Septic embolus	1 (2.0)	0	0	0	1 (2.0)
Skin infection	1 (2.0)	0	1 (2.0)	0	0
Staphylococcal infection	1 (2.0)	0	0	1 (2.0)	0
Streptococcal infection	1 (2.0)	0	1 (2.0)	0	0
Upper respiratory tract infection	1 (2.0)	0	1 (2.0)	0	0
Viral upper respiratory tract infection	1 (2.0)	0	1 (2.0)	0	0
Vulvovaginal candidiasis	1 (2.0)	1 (2.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	14 (28.0)	7 (14.0)	5 (10.0)	1 (2.0)	1 (2.0)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion reaction	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Infusion related reaction	2 (4.0)	0	2 (4.0)	0	0
Procedural pain	2 (4.0)	0	2 (4.0)	0	0
Contusion	1 (2.0)	1 (2.0)	0	0	0
Incision site pain	1 (2.0)	1 (2.0)	0	0	0
Limb injury	1 (2.0)	1 (2.0)	0	0	0
Mouth injury	1 (2.0)	1 (2.0)	0	0	0
Post procedural haemorrhage	1 (2.0)	1 (2.0)	0	0	0
Procedural complication	1 (2.0)	1 (2.0)	0	0	0
Procedural headache	1 (2.0)	0	1 (2.0)	0	0
Procedural site reaction	1 (2.0)	1 (2.0)	0	0	0
Skin abrasion	1 (2.0)	1 (2.0)	0	0	0
Stoma site irritation	1 (2.0)	1 (2.0)	0	0	0
Subdural haemorrhage	1 (2.0)	1 (2.0)	0	0	0
Tibia fracture	1 (2.0)	0	1 (2.0)	0	0
Tongue injury	1 (2.0)	1 (2.0)	0	0	0
Tracheal haemorrhage	1 (2.0)	0	0	1 (2.0)	0
Transfusion related complication	1 (2.0)	0	0	0	1 (2.0)
Investigations					

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	40 (80.0)	3 (6.0)	4 (8.0)	10 (20.0)	23 (46.0)
White blood cell count decreased	22 (44.0)	2 (4.0)	1 (2.0)	9 (18.0)	10 (20.0)
Neutrophil count decreased	18 (36.0)	0	2 (4.0)	2 (4.0)	14 (28.0)
Alanine aminotransferase increased	17 (34.0)	5 (10.0)	2 (4.0)	10 (20.0)	0
Aspartate aminotransferase increased	17 (34.0)	3 (6.0)	3 (6.0)	7 (14.0)	4 (8.0)
Platelet count decreased	15 (30.0)	2 (4.0)	2 (4.0)	2 (4.0)	9 (18.0)
Lymphocyte count decreased	9 (18.0)	0	2 (4.0)	4 (8.0)	3 (6.0)
Blood creatinine increased	8 (16.0)	4 (8.0)	2 (4.0)	2 (4.0)	0
International normalised ratio increased	8 (16.0)	7 (14.0)	0	1 (2.0)	0
Prothrombin time prolonged	8 (16.0)	4 (8.0)	3 (6.0)	1 (2.0)	0
Activated partial thromboplastin time prolonged	5 (10.0)	3 (6.0)	2 (4.0)	0	0
Blood bilirubin increased	5 (10.0)	1 (2.0)	2 (4.0)	2 (4.0)	0
Blood fibrinogen decreased	3 (6.0)	0	1 (2.0)	1 (2.0)	1 (2.0)
Blood immunoglobulin m decreased	3 (6.0)	3 (6.0)	0	0	0
Blood immunoglobulin a decreased	2 (4.0)	2 (4.0)	0	0	0
Blood phosphorus increased	2 (4.0)	2 (4.0)	0	0	0
Blood urea increased	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Transaminases increased	2 (4.0)	2 (4.0)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bicarbonate decreased	1 (2.0)	0	1 (2.0)	0	0
Blood lactic acid increased	1 (2.0)	0	0	0	1 (2.0)
Blood magnesium decreased	1 (2.0)	0	0	1 (2.0)	0
Blood phosphorus decreased	1 (2.0)	1 (2.0)	0	0	0
Blood uric acid increased	1 (2.0)	1 (2.0)	0	0	0
Cardiac murmur	1 (2.0)	1 (2.0)	0	0	0
Culture stool positive	1 (2.0)	1 (2.0)	0	0	0
Haemoglobin decreased	1 (2.0)	0	0	1 (2.0)	0
Hepatic enzyme increased	1 (2.0)	0	1 (2.0)	0	0
Lipase increased	1 (2.0)	0	0	0	1 (2.0)
Norovirus test positive	1 (2.0)	1 (2.0)	0	0	0
Protein total decreased	1 (2.0)	0	0	1 (2.0)	0
Pulmonary function test decreased	1 (2.0)	0	1 (2.0)	0	0
Serum ferritin increased	1 (2.0)	0	1 (2.0)	0	0
Metabolism and nutrition disorders					
-Total	31 (62.0)	4 (8.0)	9 (18.0)	17 (34.0)	1 (2.0)
Decreased appetite	16 (32.0)	3 (6.0)	3 (6.0)	10 (20.0)	0
Hypokalaemia	12 (24.0)	2 (4.0)	5 (10.0)	5 (10.0)	0
Hypophosphataemia	8 (16.0)	2 (4.0)	0	6 (12.0)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	6 (12.0)	6 (12.0)	0	0	0
Hypernatraemia	4 (8.0)	1 (2.0)	2 (4.0)	0	1 (2.0)
Hypoalbuminaemia	4 (8.0)	1 (2.0)	3 (6.0)	0	0
Fluid overload	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Hyperglycaemia	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Hypocalcaemia	3 (6.0)	1 (2.0)	1 (2.0)	1 (2.0)	0
Acidosis	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Dehydration	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Hyperuricaemia	2 (4.0)	2 (4.0)	0	0	0
Hyponatraemia	2 (4.0)	0	0	2 (4.0)	0
Hyperalbuminaemia	1 (2.0)	1 (2.0)	0	0	0
Hypercalcaemia	1 (2.0)	1 (2.0)	0	0	0
Hyperchloraemia	1 (2.0)	1 (2.0)	0	0	0
Hypermagnesaemia	1 (2.0)	1 (2.0)	0	0	0
Hypertriglyceridaemia	1 (2.0)	0	0	1 (2.0)	0
Malnutrition	1 (2.0)	0	0	1 (2.0)	0
Metabolic acidosis	1 (2.0)	0	1 (2.0)	0	0
Metabolic alkalosis	1 (2.0)	1 (2.0)	0	0	0
Tumour lysis syndrome	1 (2.0)	0	0	1 (2.0)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	13 (26.0)	8 (16.0)	4 (8.0)	1 (2.0)	0
Myalgia	5 (10.0)	4 (8.0)	1 (2.0)	0	0
Arthralgia	3 (6.0)	2 (4.0)	0	1 (2.0)	0
Musculoskeletal pain	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Pain in extremity	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Coccydynia	1 (2.0)	1 (2.0)	0	0	0
Limb discomfort	1 (2.0)	1 (2.0)	0	0	0
Muscle spasms	1 (2.0)	1 (2.0)	0	0	0
Musculoskeletal chest pain	1 (2.0)	1 (2.0)	0	0	0
Osteopenia	1 (2.0)	0	1 (2.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.0)	0	1 (2.0)	0	0
Skin papilloma	1 (2.0)	0	1 (2.0)	0	0
Nervous system disorders					
-Total	28 (56.0)	15 (30.0)	8 (16.0)	4 (8.0)	1 (2.0)
Headache	21 (42.0)	14 (28.0)	5 (10.0)	2 (4.0)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dizziness	4 (8.0)	4 (8.0)	0	0	0
Encephalopathy	4 (8.0)	1 (2.0)	1 (2.0)	2 (4.0)	0
Seizure	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Tremor	2 (4.0)	2 (4.0)	0	0	0
Asterixis	1 (2.0)	1 (2.0)	0	0	0
Ataxia	1 (2.0)	0	1 (2.0)	0	0
Dysarthria	1 (2.0)	1 (2.0)	0	0	0
Embolic stroke	1 (2.0)	0	0	0	1 (2.0)
Idiopathic intracranial hypertension	1 (2.0)	0	1 (2.0)	0	0
Myoclonus	1 (2.0)	1 (2.0)	0	0	0
Neuropathy peripheral	1 (2.0)	0	1 (2.0)	0	0
Pleocytosis	1 (2.0)	1 (2.0)	0	0	0
Product issues					
-Total	1 (2.0)	1 (2.0)	0	0	0
Device occlusion	1 (2.0)	1 (2.0)	0	0	0
Psychiatric disorders					
-Total	15 (30.0)	8 (16.0)	6 (12.0)	1 (2.0)	0
Anxiety	6 (12.0)	2 (4.0)	3 (6.0)	1 (2.0)	0
Confusional state	6 (12.0)	3 (6.0)	3 (6.0)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Agitation	2 (4.0)	0	2 (4.0)	0	0
Hallucination	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Irritability	2 (4.0)	2 (4.0)	0	0	0
Adjustment disorder	1 (2.0)	0	1 (2.0)	0	0
Insomnia	1 (2.0)	0	1 (2.0)	0	0
Listless	1 (2.0)	1 (2.0)	0	0	0
Mental status changes	1 (2.0)	1 (2.0)	0	0	0
Suicidal ideation	1 (2.0)	1 (2.0)	0	0	0
Renal and urinary disorders					
-Total	9 (18.0)	1 (2.0)	2 (4.0)	2 (4.0)	4 (8.0)
Acute kidney injury	6 (12.0)	1 (2.0)	1 (2.0)	1 (2.0)	3 (6.0)
Haematuria	4 (8.0)	0	2 (4.0)	1 (2.0)	1 (2.0)
Oliguria	2 (4.0)	0	0	2 (4.0)	0
Dysuria	1 (2.0)	0	1 (2.0)	0	0
Pollakiuria	1 (2.0)	1 (2.0)	0	0	0
Renal failure	1 (2.0)	0	0	0	1 (2.0)
Renal impairment	1 (2.0)	0	0	1 (2.0)	0
Reproductive system and breast disorders					

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Oedema genital	1 (2.0)	0	1 (2.0)	0	0
Vulvovaginal adhesion	1 (2.0)	1 (2.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	22 (44.0)	7 (14.0)	5 (10.0)	4 (8.0)	6 (12.0)
Hypoxia	8 (16.0)	0	2 (4.0)	3 (6.0)	3 (6.0)
Cough	7 (14.0)	7 (14.0)	0	0	0
Epistaxis	7 (14.0)	2 (4.0)	1 (2.0)	3 (6.0)	1 (2.0)
Pleural effusion	6 (12.0)	1 (2.0)	4 (8.0)	1 (2.0)	0
Pulmonary oedema	5 (10.0)	1 (2.0)	0	2 (4.0)	2 (4.0)
Tachypnoea	4 (8.0)	2 (4.0)	1 (2.0)	1 (2.0)	0
Dyspnoea	2 (4.0)	0	0	1 (2.0)	1 (2.0)
Haemoptysis	2 (4.0)	1 (2.0)	0	0	1 (2.0)
Oropharyngeal pain	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Respiratory failure	2 (4.0)	0	0	0	2 (4.0)
Atelectasis	1 (2.0)	1 (2.0)	0	0	0
Interstitial lung disease	1 (2.0)	0	0	0	1 (2.0)
Pharyngeal ulceration	1 (2.0)	0	1 (2.0)	0	0
Respiratory depression	1 (2.0)	0	1 (2.0)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	1 (2.0)	0	0	0	1 (2.0)
Rhinitis allergic	1 (2.0)	1 (2.0)	0	0	0
Rhinorrhoea	1 (2.0)	1 (2.0)	0	0	0
Wheezing	1 (2.0)	0	1 (2.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	17 (34.0)	11 (22.0)	4 (8.0)	2 (4.0)	0
Dry skin	4 (8.0)	4 (8.0)	0	0	0
Rash	3 (6.0)	3 (6.0)	0	0	0
Rash maculo-papular	3 (6.0)	1 (2.0)	1 (2.0)	1 (2.0)	0
Erythema	2 (4.0)	2 (4.0)	0	0	0
Hyperhidrosis	2 (4.0)	2 (4.0)	0	0	0
Ingrowing nail	2 (4.0)	0	2 (4.0)	0	0
Petechiae	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Rash papular	2 (4.0)	2 (4.0)	0	0	0
Ecchymosis	1 (2.0)	0	0	1 (2.0)	0
Livedo reticularis	1 (2.0)	1 (2.0)	0	0	0
Night sweats	1 (2.0)	0	1 (2.0)	0	0
Pruritus	1 (2.0)	1 (2.0)	0	0	0
Rash follicular	1 (2.0)	1 (2.0)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash vesicular	1 (2.0)	1 (2.0)	0	0	0
Skin exfoliation	1 (2.0)	1 (2.0)	0	0	0
Skin fissures	1 (2.0)	1 (2.0)	0	0	0
Skin irritation	1 (2.0)	1 (2.0)	0	0	0
Vascular disorders					
-Total	19 (38.0)	3 (6.0)	2 (4.0)	6 (12.0)	8 (16.0)
Hypotension	14 (28.0)	1 (2.0)	0	5 (10.0)	8 (16.0)
Hypertension	8 (16.0)	2 (4.0)	5 (10.0)	1 (2.0)	0
Flushing	2 (4.0)	2 (4.0)	0	0	0
Capillary leak syndrome	1 (2.0)	0	0	0	1 (2.0)
Embolism	1 (2.0)	0	0	1 (2.0)	0
Haematoma	1 (2.0)	0	1 (2.0)	0	0
Orthostatic hypotension	1 (2.0)	1 (2.0)	0	0	0
Secondary hypertension	1 (2.0)	0	1 (2.0)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174m
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

			All patients N=12		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (100)	1 (8.3)	2 (16.7)	8 (66.7)	1 (8.3)
Blood and lymphatic system disorders					
-Total	3 (25.0)	1 (8.3)	1 (8.3)	1 (8.3)	0
Anaemia	2 (16.7)	1 (8.3)	0	1 (8.3)	0
Febrile neutropenia	1 (8.3)	0	0	1 (8.3)	0
Thrombocytopenia	1 (8.3)	0	1 (8.3)	0	0
Eye disorders					
-Total	3 (25.0)	3 (25.0)	0	0	0
Conjunctivitis allergic	1 (8.3)	1 (8.3)	0	0	0
Dry eye	1 (8.3)	1 (8.3)	0	0	0
Ocular hyperaemia	1 (8.3)	1 (8.3)	0	0	0
Gastrointestinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=12				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (33.3)	2 (16.7)	0	2 (16.7)	0
Vomiting	3 (25.0)	2 (16.7)	0	1 (8.3)	0
Diarrhoea	2 (16.7)	1 (8.3)	0	1 (8.3)	0
Nausea	2 (16.7)	0	1 (8.3)	1 (8.3)	0
Abdominal pain	1 (8.3)	0	0	1 (8.3)	0
Enterocolitis	1 (8.3)	0	0	1 (8.3)	0
General disorders and administration site conditions					
-Total	4 (33.3)	3 (25.0)	1 (8.3)	0	0
Pyrexia	2 (16.7)	1 (8.3)	1 (8.3)	0	0
Influenza like illness	1 (8.3)	1 (8.3)	0	0	0
Malaise	1 (8.3)	1 (8.3)	0	0	0
Immune system disorders					
-Total	1 (8.3)	0	1 (8.3)	0	0
Immunodeficiency common variable	1 (8.3)	0	1 (8.3)	0	0
Infections and infestations					
-Total	9 (75.0)	1 (8.3)	4 (33.3)	3 (25.0)	1 (8.3)
Influenza	2 (16.7)	0	2 (16.7)	0	0
Urinary tract infection	2 (16.7)	0	2 (16.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=12				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	2 (16.7)	1 (8.3)	0	1 (8.3)	0
Bacterial sepsis	1 (8.3)	0	0	0	1 (8.3)
Corona virus infection	1 (8.3)	0	0	1 (8.3)	0
Gastroenteritis	1 (8.3)	0	1 (8.3)	0	0
Gastroenteritis viral	1 (8.3)	1 (8.3)	0	0	0
Molluscum contagiosum	1 (8.3)	1 (8.3)	0	0	0
Otitis externa	1 (8.3)	0	1 (8.3)	0	0
Parainfluenzae virus infection	1 (8.3)	0	0	1 (8.3)	0
Paronychia	1 (8.3)	1 (8.3)	0	0	0
Respiratory syncytial virus infection	1 (8.3)	0	0	1 (8.3)	0
Subcutaneous abscess	1 (8.3)	0	1 (8.3)	0	0
Injury, poisoning and procedural complications					
-Total	3 (25.0)	2 (16.7)	1 (8.3)	0	0
Infusion related reaction	1 (8.3)	1 (8.3)	0	0	0
Procedural pain	1 (8.3)	1 (8.3)	0	0	0
Skin abrasion	1 (8.3)	1 (8.3)	0	0	0
Skin laceration	1 (8.3)	0	1 (8.3)	0	0
Investigations					

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=12				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (41.7)	0	2 (16.7)	3 (25.0)	0
Neutrophil count decreased	3 (25.0)	1 (8.3)	0	2 (16.7)	0
White blood cell count decreased	2 (16.7)	1 (8.3)	0	1 (8.3)	0
Lymphocyte count decreased	1 (8.3)	0	1 (8.3)	0	0
Oxygen saturation decreased	1 (8.3)	1 (8.3)	0	0	0
Platelet count decreased	1 (8.3)	1 (8.3)	0	0	0
Serum ferritin increased	1 (8.3)	0	1 (8.3)	0	0
Metabolism and nutrition disorders					
-Total	4 (33.3)	2 (16.7)	0	2 (16.7)	0
Hyperphosphataemia	1 (8.3)	1 (8.3)	0	0	0
Hypokalaemia	1 (8.3)	1 (8.3)	0	0	0
Iron overload	1 (8.3)	0	0	1 (8.3)	0
Tumour lysis syndrome	1 (8.3)	0	0	1 (8.3)	0
Musculoskeletal and connective tissue disorders					
-Total	6 (50.0)	5 (41.7)	1 (8.3)	0	0
Pain in extremity	3 (25.0)	3 (25.0)	0	0	0
Arthralgia	1 (8.3)	0	1 (8.3)	0	0
Muscular weakness	1 (8.3)	1 (8.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=12				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Toe walking	1 (8.3)	1 (8.3)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (8.3)	0	1 (8.3)	0	0
Myelodysplastic syndrome	1 (8.3)	0	1 (8.3)	0	0
Nervous system disorders					
-Total	1 (8.3)	1 (8.3)	0	0	0
Dizziness	1 (8.3)	1 (8.3)	0	0	0
Psychiatric disorders					
-Total	1 (8.3)	1 (8.3)	0	0	0
Depression	1 (8.3)	1 (8.3)	0	0	0
Reproductive system and breast disorders					
-Total	1 (8.3)	0	0	1 (8.3)	0
Vaginal haemorrhage	1 (8.3)	0	0	1 (8.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (41.7)	1 (8.3)	4 (33.3)	0	0
Cough	2 (16.7)	0	2 (16.7)	0	0
Nasal congestion	2 (16.7)	2 (16.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=12				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	2 (16.7)	1 (8.3)	1 (8.3)	0	0
Oropharyngeal pain	1 (8.3)	1 (8.3)	0	0	0
Rhinitis allergic	1 (8.3)	0	1 (8.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (33.3)	2 (16.7)	1 (8.3)	1 (8.3)	0
Dermatitis acneiform	1 (8.3)	0	0	1 (8.3)	0
Dry skin	1 (8.3)	1 (8.3)	0	0	0
Keloid scar	1 (8.3)	0	1 (8.3)	0	0
Rash maculo-papular	1 (8.3)	1 (8.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174m
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=44		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (77.3)	3 (6.8)	14 (31.8)	8 (18.2)	9 (20.5)
Blood and lymphatic system disorders					
-Total	8 (18.2)	0	2 (4.5)	2 (4.5)	4 (9.1)
Neutropenia	4 (9.1)	0	0	1 (2.3)	3 (6.8)
Febrile neutropenia	2 (4.5)	0	0	2 (4.5)	0
Eosinophilia	1 (2.3)	0	0	1 (2.3)	0
Leukopenia	1 (2.3)	0	0	0	1 (2.3)
Lymphadenopathy	1 (2.3)	0	1 (2.3)	0	0
Lymphopenia	1 (2.3)	0	1 (2.3)	0	0
Thrombocytopenia	1 (2.3)	0	0	1 (2.3)	0
Cardiac disorders					
-Total	1 (2.3)	0	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	1 (2.3)	0	1 (2.3)	0	0
Endocrine disorders					
-Total	1 (2.3)	1 (2.3)	0	0	0
Adrenal insufficiency	1 (2.3)	1 (2.3)	0	0	0
Eye disorders					
-Total	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Dry eye	1 (2.3)	0	1 (2.3)	0	0
Vision blurred	1 (2.3)	1 (2.3)	0	0	0
Gastrointestinal disorders					
-Total	12 (27.3)	7 (15.9)	3 (6.8)	2 (4.5)	0
Diarrhoea	6 (13.6)	5 (11.4)	1 (2.3)	0	0
Vomiting	6 (13.6)	3 (6.8)	2 (4.5)	1 (2.3)	0
Nausea	4 (9.1)	1 (2.3)	2 (4.5)	1 (2.3)	0
Abdominal pain	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Oral pain	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Abdominal pain upper	1 (2.3)	1 (2.3)	0	0	0
Pigmentation lip	1 (2.3)	1 (2.3)	0	0	0
General disorders and administration site conditions					

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (29.5)	10 (22.7)	2 (4.5)	1 (2.3)	0
Pyrexia	8 (18.2)	6 (13.6)	1 (2.3)	1 (2.3)	0
Fatigue	2 (4.5)	2 (4.5)	0	0	0
Acquired gene mutation	1 (2.3)	1 (2.3)	0	0	0
Catheter site pain	1 (2.3)	0	1 (2.3)	0	0
Chills	1 (2.3)	1 (2.3)	0	0	0
Crying	1 (2.3)	1 (2.3)	0	0	0
Generalised oedema	1 (2.3)	1 (2.3)	0	0	0
Influenza like illness	1 (2.3)	1 (2.3)	0	0	0
Oedema peripheral	1 (2.3)	1 (2.3)	0	0	0
Pain	1 (2.3)	1 (2.3)	0	0	0
Immune system disorders					
-Total	13 (29.5)	3 (6.8)	9 (20.5)	1 (2.3)	0
Hypogammaglobulinaemia	8 (18.2)	0	7 (15.9)	1 (2.3)	0
Graft versus host disease	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Seasonal allergy	2 (4.5)	2 (4.5)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (2.3)	0	1 (2.3)	0	0
Immunodeficiency common variable	1 (2.3)	0	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	24 (54.5)	5 (11.4)	11 (25.0)	7 (15.9)	1 (2.3)
Upper respiratory tract infection	7 (15.9)	3 (6.8)	3 (6.8)	1 (2.3)	0
Ear infection	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Gastroenteritis	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Rhinovirus infection	2 (4.5)	2 (4.5)	0	0	0
Sinusitis	2 (4.5)	0	2 (4.5)	0	0
Urinary tract infection	2 (4.5)	0	0	2 (4.5)	0
Cellulitis of male external genital organ	1 (2.3)	0	0	1 (2.3)	0
Cholecystitis infective	1 (2.3)	0	0	1 (2.3)	0
Cytomegalovirus infection	1 (2.3)	1 (2.3)	0	0	0
Enterovirus infection	1 (2.3)	0	0	1 (2.3)	0
Escherichia urinary tract infection	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis norovirus	1 (2.3)	0	1 (2.3)	0	0
Herpes zoster	1 (2.3)	0	0	1 (2.3)	0
Influenza	1 (2.3)	0	1 (2.3)	0	0
Oral herpes	1 (2.3)	0	1 (2.3)	0	0
Otitis media	1 (2.3)	0	1 (2.3)	0	0
Otitis media acute	1 (2.3)	0	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (2.3)	1 (2.3)	0	0	0
Rash pustular	1 (2.3)	0	1 (2.3)	0	0
Rhinitis	1 (2.3)	1 (2.3)	0	0	0
Rotavirus infection	1 (2.3)	0	0	1 (2.3)	0
Sepsis	1 (2.3)	0	0	0	1 (2.3)
Tinea capitis	1 (2.3)	1 (2.3)	0	0	0
Vascular device infection	1 (2.3)	0	0	1 (2.3)	0
Viral infection	1 (2.3)	1 (2.3)	0	0	0
Vulvovaginal mycotic infection	1 (2.3)	0	1 (2.3)	0	0
Injury, poisoning and procedural complications					
-Total	5 (11.4)	1 (2.3)	4 (9.1)	0	0
Contusion	2 (4.5)	2 (4.5)	0	0	0
Arthropod bite	1 (2.3)	1 (2.3)	0	0	0
Foot fracture	1 (2.3)	0	1 (2.3)	0	0
Infusion related reaction	1 (2.3)	0	1 (2.3)	0	0
Procedural nausea	1 (2.3)	0	1 (2.3)	0	0
Procedural pain	1 (2.3)	0	1 (2.3)	0	0
Radius fracture	1 (2.3)	0	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=44		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sunburn	1 (2.3)	1 (2.3)	0	0	0
Investigations					
-Total	18 (40.9)	6 (13.6)	3 (6.8)	5 (11.4)	4 (9.1)
Neutrophil count decreased	5 (11.4)	1 (2.3)	0	1 (2.3)	3 (6.8)
Weight decreased	4 (9.1)	1 (2.3)	3 (6.8)	0	0
Aspartate aminotransferase increased	3 (6.8)	1 (2.3)	0	2 (4.5)	0
White blood cell count decreased	3 (6.8)	1 (2.3)	1 (2.3)	0	1 (2.3)
Alanine aminotransferase increased	2 (4.5)	0	0	2 (4.5)	0
Haemoglobin decreased	2 (4.5)	2 (4.5)	0	0	0
Platelet count decreased	2 (4.5)	2 (4.5)	0	0	0
Weight increased	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Blood bilirubin increased	1 (2.3)	0	0	1 (2.3)	0
Blood creatinine increased	1 (2.3)	1 (2.3)	0	0	0
Blood magnesium decreased	1 (2.3)	1 (2.3)	0	0	0
Blood urea increased	1 (2.3)	1 (2.3)	0	0	0
Blood uric acid increased	1 (2.3)	1 (2.3)	0	0	0
Lymphocyte count decreased	1 (2.3)	1 (2.3)	0	0	0
Transaminases increased	1 (2.3)	1 (2.3)	0	0	0
Metabolism and nutrition disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (13.6)	3 (6.8)	1 (2.3)	1 (2.3)	1 (2.3)
Decreased appetite	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Dehydration	1 (2.3)	0	0	1 (2.3)	0
Hyperalbuminaemia	1 (2.3)	1 (2.3)	0	0	0
Hypercalcaemia	1 (2.3)	1 (2.3)	0	0	0
Hyperglycaemia	1 (2.3)	0	0	1 (2.3)	0
Hyperphosphataemia	1 (2.3)	1 (2.3)	0	0	0
Hypokalaemia	1 (2.3)	0	0	0	1 (2.3)
Hypophosphataemia	1 (2.3)	0	0	1 (2.3)	0
Vitamin d deficiency	1 (2.3)	1 (2.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	10 (22.7)	6 (13.6)	4 (9.1)	0	0
Pain in extremity	5 (11.4)	3 (6.8)	2 (4.5)	0	0
Joint range of motion decreased	2 (4.5)	2 (4.5)	0	0	0
Arthralgia	1 (2.3)	1 (2.3)	0	0	0
Back pain	1 (2.3)	1 (2.3)	0	0	0
Flank pain	1 (2.3)	0	1 (2.3)	0	0
Muscle spasms	1 (2.3)	1 (2.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	1 (2.3)	1 (2.3)	0	0	0
Musculoskeletal chest pain	1 (2.3)	1 (2.3)	0	0	0
Osteonecrosis	1 (2.3)	0	1 (2.3)	0	0
Pain in jaw	1 (2.3)	1 (2.3)	0	0	0
Nervous system disorders					
-Total	7 (15.9)	5 (11.4)	2 (4.5)	0	0
Headache	5 (11.4)	4 (9.1)	1 (2.3)	0	0
Dizziness	2 (4.5)	2 (4.5)	0	0	0
Peroneal nerve palsy	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Psychiatric disorders					
-Total	1 (2.3)	0	1 (2.3)	0	0
Anxiety	1 (2.3)	1 (2.3)	0	0	0
Depression	1 (2.3)	1 (2.3)	0	0	0
Sleep disorder	1 (2.3)	0	1 (2.3)	0	0
Renal and urinary disorders					
-Total	3 (6.8)	1 (2.3)	0	2 (4.5)	0
Acute kidney injury	1 (2.3)	0	0	1 (2.3)	0
Calculus urinary	1 (2.3)	0	1 (2.3)	0	0
Haematuria	1 (2.3)	0	0	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nephrolithiasis	1 (2.3)	0	0	1 (2.3)	0
Urinary incontinence	1 (2.3)	1 (2.3)	0	0	0
Reproductive system and breast disorders					
-Total	1 (2.3)	0	1 (2.3)	0	0
Scrotal pain	1 (2.3)	0	1 (2.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	13 (29.5)	10 (22.7)	0	2 (4.5)	1 (2.3)
Cough	5 (11.4)	5 (11.4)	0	0	0
Epistaxis	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Nasal congestion	2 (4.5)	2 (4.5)	0	0	0
Oropharyngeal pain	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Rhinitis allergic	2 (4.5)	2 (4.5)	0	0	0
Rhinorrhoea	2 (4.5)	2 (4.5)	0	0	0
Acute respiratory failure	1 (2.3)	0	0	0	1 (2.3)
Dysphonia	1 (2.3)	1 (2.3)	0	0	0
Pharyngeal erythema	1 (2.3)	1 (2.3)	0	0	0
Pharyngeal lesion	1 (2.3)	0	0	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=44		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	1 (2.3)	0	0	1 (2.3)	0
Skin and subcutaneous tissue disorders					
-Total	12 (27.3)	8 (18.2)	4 (9.1)	0	0
Rash	4 (9.1)	1 (2.3)	3 (6.8)	0	0
Erythema	2 (4.5)	2 (4.5)	0	0	0
Alopecia	1 (2.3)	0	1 (2.3)	0	0
Dermatitis	1 (2.3)	1 (2.3)	0	0	0
Dermatitis atopic	1 (2.3)	1 (2.3)	0	0	0
Eczema	1 (2.3)	1 (2.3)	0	0	0
Hyperhidrosis	1 (2.3)	1 (2.3)	0	0	0
Ingrowing nail	1 (2.3)	1 (2.3)	0	0	0
Macule	1 (2.3)	1 (2.3)	0	0	0
Papule	1 (2.3)	1 (2.3)	0	0	0
Petechiae	1 (2.3)	1 (2.3)	0	0	0
Pruritus	1 (2.3)	1 (2.3)	0	0	0
Rash erythematous	1 (2.3)	0	1 (2.3)	0	0
Rash maculo-papular	1 (2.3)	1 (2.3)	0	0	0
Rash pruritic	1 (2.3)	1 (2.3)	0	0	0
Vascular disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Hypertension	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Hot flush	1 (2.3)	1 (2.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174m
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

			All patients N=9		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (44.4)	2 (22.2)	0	1 (11.1)	1 (11.1)
Infections and infestations					
-Total	1 (11.1)	0	0	0	1 (11.1)
Respiratory tract infection	1 (11.1)	0	0	0	1 (11.1)
Investigations					
-Total	1 (11.1)	1 (11.1)	0	0	0
Lymphocyte count decreased	1 (11.1)	1 (11.1)	0	0	0
Neutrophil count decreased	1 (11.1)	1 (11.1)	0	0	0
Reproductive system and breast disorders					
-Total	1 (11.1)	0	0	1 (11.1)	0
Ovarian failure	1 (11.1)	0	0	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders					

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (11.1)	1 (11.1)	0	0	0
Epistaxis	1 (11.1)	1 (11.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (11.1)	1 (11.1)	0	0	0
Papule	1 (11.1)	1 (11.1)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174m
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

			All patients N=25		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (72.0)	2 (8.0)	6 (24.0)	7 (28.0)	3 (12.0)
Blood and lymphatic system disorders					
-Total	2 (8.0)	1 (4.0)	0	0	1 (4.0)
Febrile neutropenia	1 (4.0)	0	0	0	1 (4.0)
Thrombocytopenia	1 (4.0)	1 (4.0)	0	0	0
Ear and labyrinth disorders					
-Total	1 (4.0)	0	1 (4.0)	0	0
Tympanic membrane perforation	1 (4.0)	0	1 (4.0)	0	0
Gastrointestinal disorders					
-Total	3 (12.0)	0	3 (12.0)	0	0
Diarrhoea	2 (8.0)	0	2 (8.0)	0	0
Abdominal pain	1 (4.0)	0	1 (4.0)	0	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (4.0)	0	1 (4.0)	0	0
General disorders and administration site conditions					
-Total	2 (8.0)	0	1 (4.0)	1 (4.0)	0
Chills	1 (4.0)	0	1 (4.0)	0	0
Cyst	1 (4.0)	0	0	1 (4.0)	0
Pyrexia	1 (4.0)	0	1 (4.0)	0	0
Immune system disorders					
-Total	2 (8.0)	0	2 (8.0)	0	0
Chronic graft versus host disease	1 (4.0)	0	1 (4.0)	0	0
Immunodeficiency	1 (4.0)	0	1 (4.0)	0	0
Infections and infestations					
-Total	10 (40.0)	2 (8.0)	5 (20.0)	3 (12.0)	0
Otitis media	3 (12.0)	0	2 (8.0)	1 (4.0)	0
Sinusitis	3 (12.0)	0	3 (12.0)	0	0
Otitis media acute	2 (8.0)	0	2 (8.0)	0	0
Pneumonia	2 (8.0)	0	2 (8.0)	0	0
Upper respiratory tract infection	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Urinary tract infection	2 (8.0)	0	1 (4.0)	1 (4.0)	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (4.0)	0	0	1 (4.0)	0
Cellulitis of male external genital organ	1 (4.0)	0	0	1 (4.0)	0
Clostridium difficile infection	1 (4.0)	0	0	1 (4.0)	0
Gingivitis	1 (4.0)	1 (4.0)	0	0	0
Haemophilus infection	1 (4.0)	0	1 (4.0)	0	0
Meningitis aseptic	1 (4.0)	0	1 (4.0)	0	0
Respiratory tract infection viral	1 (4.0)	0	0	1 (4.0)	0
Skin infection	1 (4.0)	0	1 (4.0)	0	0
Viral infection	1 (4.0)	1 (4.0)	0	0	0
Vulvovaginal candidiasis	1 (4.0)	0	1 (4.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (4.0)	0	0	1 (4.0)	0
Procedural pain	1 (4.0)	0	0	1 (4.0)	0
Investigations					
-Total	7 (28.0)	0	2 (8.0)	4 (16.0)	1 (4.0)
White blood cell count decreased	4 (16.0)	1 (4.0)	0	2 (8.0)	1 (4.0)
Alanine aminotransferase increased	3 (12.0)	0	1 (4.0)	2 (8.0)	0
Aspartate aminotransferase increased	2 (8.0)	1 (4.0)	0	1 (4.0)	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Blood alkaline phosphatase increased	1 (4.0)	1 (4.0)	0	0	0
Blood lactate dehydrogenase increased	1 (4.0)	1 (4.0)	0	0	0
C-reactive protein increased	1 (4.0)	1 (4.0)	0	0	0
Neutrophil count decreased	1 (4.0)	0	1 (4.0)	0	0
Platelet count decreased	1 (4.0)	0	0	1 (4.0)	0
Metabolism and nutrition disorders					
-Total	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Hypokalaemia	1 (4.0)	0	0	1 (4.0)	0
Vitamin d deficiency	1 (4.0)	1 (4.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (4.0)	0	1 (4.0)	0	0
Neck pain	1 (4.0)	0	1 (4.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (4.0)	0	0	0	1 (4.0)
Glioblastoma multiforme	1 (4.0)	0	0	0	1 (4.0)
Nervous system disorders					

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (12.0)	1 (4.0)	1 (4.0)	1 (4.0)	0
Disturbance in attention	1 (4.0)	1 (4.0)	0	0	0
Dizziness	1 (4.0)	1 (4.0)	0	0	0
Headache	1 (4.0)	0	1 (4.0)	0	0
Seizure	1 (4.0)	0	0	1 (4.0)	0
Renal and urinary disorders					
-Total	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Acute kidney injury	1 (4.0)	0	0	1 (4.0)	0
Haematuria	1 (4.0)	1 (4.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (12.0)	3 (12.0)	0	0	0
Cough	2 (8.0)	2 (8.0)	0	0	0
Oropharyngeal pain	1 (4.0)	1 (4.0)	0	0	0
Rhinitis allergic	1 (4.0)	1 (4.0)	0	0	0
Rhinorrhoea	1 (4.0)	1 (4.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (8.0)	2 (8.0)	0	0	0
Acne	1 (4.0)	1 (4.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=25				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	1 (4.0)	1 (4.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174m
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (100)	0	0	4 (28.6)	10 (71.4)
Blood and lymphatic system disorders					
-Total	13 (92.9)	0	1 (7.1)	9 (64.3)	3 (21.4)
Febrile neutropenia	10 (71.4)	0	0	10 (71.4)	0
Anaemia	5 (35.7)	2 (14.3)	0	3 (21.4)	0
Thrombocytopenia	3 (21.4)	0	1 (7.1)	0	2 (14.3)
Neutropenia	1 (7.1)	0	0	1 (7.1)	0
Pancytopenia	1 (7.1)	0	0	0	1 (7.1)
Cardiac disorders					
-Total	4 (28.6)	4 (28.6)	0	0	0
Tachycardia	2 (14.3)	2 (14.3)	0	0	0
Atrioventricular block second degree	1 (7.1)	1 (7.1)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	1 (7.1)	1 (7.1)	0	0	0
Eye disorders					
-Total	4 (28.6)	4 (28.6)	0	0	0
Conjunctivitis allergic	1 (7.1)	1 (7.1)	0	0	0
Dry eye	1 (7.1)	1 (7.1)	0	0	0
Ocular hyperaemia	1 (7.1)	1 (7.1)	0	0	0
Retinal haemorrhage	1 (7.1)	1 (7.1)	0	0	0
Gastrointestinal disorders					
-Total	7 (50.0)	2 (14.3)	1 (7.1)	4 (28.6)	0
Nausea	4 (28.6)	0	2 (14.3)	2 (14.3)	0
Vomiting	4 (28.6)	2 (14.3)	1 (7.1)	1 (7.1)	0
Diarrhoea	3 (21.4)	2 (14.3)	0	1 (7.1)	0
Abdominal pain	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Constipation	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Abdominal pain upper	1 (7.1)	0	1 (7.1)	0	0
Ascites	1 (7.1)	0	0	1 (7.1)	0
Dyspepsia	1 (7.1)	0	1 (7.1)	0	0
Enterocolitis	1 (7.1)	0	0	1 (7.1)	0
Intestinal obstruction	1 (7.1)	0	0	1 (7.1)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	1 (7.1)	0	0	1 (7.1)	0
Tooth socket haemorrhage	1 (7.1)	1 (7.1)	0	0	0
General disorders and administration site conditions					
-Total	6 (42.9)	2 (14.3)	3 (21.4)	1 (7.1)	0
Pyrexia	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Catheter site pain	1 (7.1)	0	1 (7.1)	0	0
Chills	1 (7.1)	1 (7.1)	0	0	0
Fatigue	1 (7.1)	1 (7.1)	0	0	0
Influenza like illness	1 (7.1)	1 (7.1)	0	0	0
Malaise	1 (7.1)	1 (7.1)	0	0	0
Hepatobiliary disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Hepatosplenomegaly	1 (7.1)	1 (7.1)	0	0	0
Immune system disorders					
-Total	14 (100)	0	10 (71.4)	3 (21.4)	1 (7.1)
Cytokine release syndrome	13 (92.9)	0	10 (71.4)	2 (14.3)	1 (7.1)
Hypogammaglobulinaemia	8 (57.1)	1 (7.1)	6 (42.9)	1 (7.1)	0
Immunodeficiency common variable	1 (7.1)	0	1 (7.1)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	11 (78.6)	1 (7.1)	4 (28.6)	4 (28.6)	2 (14.3)
Influenza	2 (14.3)	0	2 (14.3)	0	0
Urinary tract infection	2 (14.3)	0	2 (14.3)	0	0
Viral upper respiratory tract infection	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Bacterial sepsis	1 (7.1)	0	0	0	1 (7.1)
Catheter site infection	1 (7.1)	0	0	1 (7.1)	0
Clostridium difficile infection	1 (7.1)	0	1 (7.1)	0	0
Corona virus infection	1 (7.1)	0	0	1 (7.1)	0
Cytomegalovirus infection	1 (7.1)	1 (7.1)	0	0	0
Folliculitis	1 (7.1)	0	1 (7.1)	0	0
Fungal skin infection	1 (7.1)	1 (7.1)	0	0	0
Gastroenteritis	1 (7.1)	0	1 (7.1)	0	0
Gastroenteritis viral	1 (7.1)	1 (7.1)	0	0	0
Molluscum contagiosum	1 (7.1)	1 (7.1)	0	0	0
Otitis externa	1 (7.1)	0	1 (7.1)	0	0
Parainfluenzae virus infection	1 (7.1)	0	0	1 (7.1)	0
Paronychia	1 (7.1)	1 (7.1)	0	0	0
Pneumonia	1 (7.1)	0	0	1 (7.1)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (7.1)	0	0	1 (7.1)	0
Respiratory tract infection	1 (7.1)	0	0	0	1 (7.1)
Rhinovirus infection	1 (7.1)	1 (7.1)	0	0	0
Staphylococcal infection	1 (7.1)	1 (7.1)	0	0	0
Subcutaneous abscess	1 (7.1)	0	1 (7.1)	0	0
Urinary tract infection enterococcal	1 (7.1)	0	0	1 (7.1)	0
Viral infection	1 (7.1)	0	1 (7.1)	0	0
Injury, poisoning and procedural complications					
-Total	4 (28.6)	3 (21.4)	1 (7.1)	0	0
Procedural pain	2 (14.3)	2 (14.3)	0	0	0
Infusion related reaction	1 (7.1)	1 (7.1)	0	0	0
Skin abrasion	1 (7.1)	1 (7.1)	0	0	0
Skin laceration	1 (7.1)	0	1 (7.1)	0	0
Investigations					
-Total	13 (92.9)	0	1 (7.1)	4 (28.6)	8 (57.1)
White blood cell count decreased	10 (71.4)	2 (14.3)	0	2 (14.3)	6 (42.9)
Neutrophil count decreased	8 (57.1)	1 (7.1)	0	2 (14.3)	5 (35.7)
Lymphocyte count decreased	6 (42.9)	1 (7.1)	1 (7.1)	2 (14.3)	2 (14.3)

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

		All patients N=14			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	4 (28.6)	1 (7.1)	0	0	3 (21.4)
Alanine aminotransferase increased	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Blood bilirubin increased	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Aspartate aminotransferase increased	1 (7.1)	0	1 (7.1)	0	0
Blood creatinine increased	1 (7.1)	1 (7.1)	0	0	0
Blood fibrinogen decreased	1 (7.1)	0	0	1 (7.1)	0
Blood immunoglobulin a decreased	1 (7.1)	1 (7.1)	0	0	0
Blood immunoglobulin g decreased	1 (7.1)	0	1 (7.1)	0	0
Blood immunoglobulin m decreased	1 (7.1)	1 (7.1)	0	0	0
Blood sodium increased	1 (7.1)	0	1 (7.1)	0	0
Blood urea increased	1 (7.1)	1 (7.1)	0	0	0
C-reactive protein increased	1 (7.1)	0	0	1 (7.1)	0
Fibrin d dimer increased	1 (7.1)	1 (7.1)	0	0	0
International normalised ratio increased	1 (7.1)	1 (7.1)	0	0	0
Lipase increased	1 (7.1)	0	0	0	1 (7.1)
Oxygen saturation decreased	1 (7.1)	1 (7.1)	0	0	0
Prothrombin time prolonged	1 (7.1)	1 (7.1)	0	0	0
Serum ferritin increased	1 (7.1)	0	1 (7.1)	0	0
Metabolism and nutrition disorders					

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (64.3)	2 (14.3)	1 (7.1)	4 (28.6)	2 (14.3)
Hypokalaemia	5 (35.7)	2 (14.3)	1 (7.1)	2 (14.3)	0
Decreased appetite	4 (28.6)	1 (7.1)	1 (7.1)	2 (14.3)	0
Hyperphosphataemia	2 (14.3)	2 (14.3)	0	0	0
Dehydration	1 (7.1)	0	0	1 (7.1)	0
Hypertriglyceridaemia	1 (7.1)	1 (7.1)	0	0	0
Hyperuricaemia	1 (7.1)	0	0	0	1 (7.1)
Hypoalbuminaemia	1 (7.1)	0	0	1 (7.1)	0
Hypomagnesaemia	1 (7.1)	1 (7.1)	0	0	0
Hypophosphataemia	1 (7.1)	0	0	0	1 (7.1)
Iron overload	1 (7.1)	0	0	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	0	0	1 (7.1)	0
Musculoskeletal and connective tissue disorders					
-Total	7 (50.0)	5 (35.7)	2 (14.3)	0	0
Pain in extremity	4 (28.6)	3 (21.4)	1 (7.1)	0	0
Arthralgia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Muscular weakness	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Toe walking	1 (7.1)	1 (7.1)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (7.1)	0	1 (7.1)	0	0
Myelodysplastic syndrome	1 (7.1)	0	1 (7.1)	0	0
Nervous system disorders					
-Total	5 (35.7)	2 (14.3)	3 (21.4)	0	0
Headache	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Depressed level of consciousness	1 (7.1)	1 (7.1)	0	0	0
Dizziness	1 (7.1)	1 (7.1)	0	0	0
Dysarthria	1 (7.1)	0	1 (7.1)	0	0
Migraine	1 (7.1)	0	1 (7.1)	0	0
Somnolence	1 (7.1)	1 (7.1)	0	0	0
Psychiatric disorders					
-Total	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Depression	1 (7.1)	1 (7.1)	0	0	0
Panic attack	1 (7.1)	0	1 (7.1)	0	0
Renal and urinary disorders					
-Total	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Acute kidney injury	1 (7.1)	0	0	1 (7.1)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysuria	1 (7.1)	1 (7.1)	0	0	0
Reproductive system and breast disorders					
-Total	3 (21.4)	1 (7.1)	0	2 (14.3)	0
Ovarian failure	1 (7.1)	0	0	1 (7.1)	0
Vaginal haemorrhage	1 (7.1)	0	0	1 (7.1)	0
Vulvovaginal adhesion	1 (7.1)	1 (7.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (64.3)	3 (21.4)	4 (28.6)	1 (7.1)	1 (7.1)
Cough	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Nasal congestion	3 (21.4)	3 (21.4)	0	0	0
Hypoxia	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Pleural effusion	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Rhinorrhoea	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Epistaxis	1 (7.1)	1 (7.1)	0	0	0
Oropharyngeal pain	1 (7.1)	1 (7.1)	0	0	0
Oropharyngeal plaque	1 (7.1)	1 (7.1)	0	0	0
Pulmonary oedema	1 (7.1)	0	0	1 (7.1)	0
Respiratory failure	1 (7.1)	0	0	0	1 (7.1)

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis allergic	1 (7.1)	0	1 (7.1)	0	0
Tachypnoea	1 (7.1)	1 (7.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (57.1)	6 (42.9)	1 (7.1)	1 (7.1)	0
Dermatitis acneiform	1 (7.1)	0	0	1 (7.1)	0
Dermatitis diaper	1 (7.1)	1 (7.1)	0	0	0
Dry skin	1 (7.1)	1 (7.1)	0	0	0
Erythema	1 (7.1)	1 (7.1)	0	0	0
Hyperhidrosis	1 (7.1)	1 (7.1)	0	0	0
Keloid scar	1 (7.1)	0	1 (7.1)	0	0
Macule	1 (7.1)	1 (7.1)	0	0	0
Papule	1 (7.1)	1 (7.1)	0	0	0
Petechiae	1 (7.1)	1 (7.1)	0	0	0
Pruritus	1 (7.1)	1 (7.1)	0	0	0
Rash	1 (7.1)	1 (7.1)	0	0	0
Rash erythematous	1 (7.1)	1 (7.1)	0	0	0
Rash macular	1 (7.1)	1 (7.1)	0	0	0
Rash maculo-papular	1 (7.1)	1 (7.1)	0	0	0
Vascular disorders					

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

		All patients N=14			
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (35.7)	0	3 (21.4)	2 (14.3)	0
Hypertension	2 (14.3)	0	2 (14.3)	0	0
Hypotension	2 (14.3)	0	0	2 (14.3)	0
Orthostatic hypotension	1 (7.1)	0	1 (7.1)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174m
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

			All patients N=50		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (100)	0	5 (10.0)	8 (16.0)	37 (74.0)
Blood and lymphatic system disorders					
-Total	35 (70.0)	2 (4.0)	2 (4.0)	18 (36.0)	13 (26.0)
Anaemia	22 (44.0)	1 (2.0)	4 (8.0)	16 (32.0)	1 (2.0)
Febrile neutropenia	14 (28.0)	0	0	13 (26.0)	1 (2.0)
Neutropenia	10 (20.0)	0	0	2 (4.0)	8 (16.0)
Thrombocytopenia	7 (14.0)	0	0	3 (6.0)	4 (8.0)
Disseminated intravascular coagulation	4 (8.0)	0	2 (4.0)	2 (4.0)	0
Lymphopenia	4 (8.0)	0	2 (4.0)	1 (2.0)	1 (2.0)
Coagulopathy	1 (2.0)	1 (2.0)	0	0	0
Eosinophilia	1 (2.0)	0	0	1 (2.0)	0
Leukopenia	1 (2.0)	0	0	0	1 (2.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphadenopathy	1 (2.0)	0	1 (2.0)	0	0
Cardiac disorders					
-Total	19 (38.0)	7 (14.0)	10 (20.0)	2 (4.0)	0
Tachycardia	13 (26.0)	6 (12.0)	5 (10.0)	2 (4.0)	0
Sinus tachycardia	5 (10.0)	2 (4.0)	3 (6.0)	0	0
Pericardial effusion	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Bradycardia	1 (2.0)	0	1 (2.0)	0	0
Cardiac dysfunction	1 (2.0)	1 (2.0)	0	0	0
Left ventricular dysfunction	1 (2.0)	0	0	1 (2.0)	0
Palpitations	1 (2.0)	1 (2.0)	0	0	0
Sinus bradycardia	1 (2.0)	1 (2.0)	0	0	0
Ventricular tachycardia	1 (2.0)	0	1 (2.0)	0	0
Ear and labyrinth disorders					
-Total	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Ear pain	2 (4.0)	2 (4.0)	0	0	0
Hypoacusis	1 (2.0)	0	1 (2.0)	0	0
Tympanic membrane perforation	1 (2.0)	0	1 (2.0)	0	0
Endocrine disorders					
-Total	2 (4.0)	1 (2.0)	1 (2.0)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Eye disorders					
-Total	14 (28.0)	6 (12.0)	8 (16.0)	0	0
Periorbital oedema	4 (8.0)	3 (6.0)	1 (2.0)	0	0
Vision blurred	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Conjunctival haemorrhage	3 (6.0)	3 (6.0)	0	0	0
Eye pain	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Photophobia	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Uveitis	2 (4.0)	0	2 (4.0)	0	0
Dry eye	1 (2.0)	0	1 (2.0)	0	0
Ocular hypertension	1 (2.0)	0	1 (2.0)	0	0
Papilloedema	1 (2.0)	0	1 (2.0)	0	0
Retinal haemorrhage	1 (2.0)	1 (2.0)	0	0	0
Visual impairment	1 (2.0)	0	1 (2.0)	0	0
Gastrointestinal disorders					
-Total	36 (72.0)	11 (22.0)	16 (32.0)	9 (18.0)	0
Vomiting	23 (46.0)	14 (28.0)	7 (14.0)	2 (4.0)	0
Diarrhoea	21 (42.0)	11 (22.0)	9 (18.0)	1 (2.0)	0
Nausea	21 (42.0)	6 (12.0)	12 (24.0)	3 (6.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	9 (18.0)	5 (10.0)	4 (8.0)	0	0
Constipation	5 (10.0)	5 (10.0)	0	0	0
Abdominal distension	2 (4.0)	0	2 (4.0)	0	0
Abdominal pain upper	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Dysphagia	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Haematemesis	2 (4.0)	2 (4.0)	0	0	0
Oral pain	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Stomatitis	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Abdominal discomfort	1 (2.0)	1 (2.0)	0	0	0
Abdominal pain lower	1 (2.0)	0	1 (2.0)	0	0
Abdominal tenderness	1 (2.0)	1 (2.0)	0	0	0
Anal incontinence	1 (2.0)	1 (2.0)	0	0	0
Flatulence	1 (2.0)	1 (2.0)	0	0	0
Gastrointestinal haemorrhage	1 (2.0)	1 (2.0)	0	0	0
Gastrooesophageal reflux disease	1 (2.0)	1 (2.0)	0	0	0
Glossodynia	1 (2.0)	1 (2.0)	0	0	0
Ileus	1 (2.0)	0	0	1 (2.0)	0
Lip pain	1 (2.0)	0	1 (2.0)	0	0
Mouth haemorrhage	1 (2.0)	0	0	1 (2.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	1 (2.0)	0	1 (2.0)	0	0
Pigmentation lip	1 (2.0)	1 (2.0)	0	0	0
General disorders and administration site conditions					
-Total	36 (72.0)	14 (28.0)	11 (22.0)	10 (20.0)	1 (2.0)
Pyrexia	22 (44.0)	8 (16.0)	8 (16.0)	5 (10.0)	1 (2.0)
Fatigue	14 (28.0)	11 (22.0)	2 (4.0)	1 (2.0)	0
Chills	9 (18.0)	8 (16.0)	1 (2.0)	0	0
Pain	4 (8.0)	1 (2.0)	1 (2.0)	2 (4.0)	0
Catheter site pain	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Generalised oedema	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Malaise	3 (6.0)	0	3 (6.0)	0	0
Oedema peripheral	3 (6.0)	2 (4.0)	0	1 (2.0)	0
Face oedema	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Acquired gene mutation	1 (2.0)	1 (2.0)	0	0	0
Asthenia	1 (2.0)	1 (2.0)	0	0	0
Catheter site extravasation	1 (2.0)	0	1 (2.0)	0	0
Catheter site haemorrhage	1 (2.0)	1 (2.0)	0	0	0
Crying	1 (2.0)	1 (2.0)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cyst	1 (2.0)	0	0	1 (2.0)	0
Facial pain	1 (2.0)	0	1 (2.0)	0	0
Influenza like illness	1 (2.0)	1 (2.0)	0	0	0
Injection site haematoma	1 (2.0)	1 (2.0)	0	0	0
Localised oedema	1 (2.0)	0	0	1 (2.0)	0
Mucosal haemorrhage	1 (2.0)	0	1 (2.0)	0	0
Multiple organ dysfunction syndrome	1 (2.0)	0	0	1 (2.0)	0
Non-cardiac chest pain	1 (2.0)	1 (2.0)	0	0	0
Peripheral swelling	1 (2.0)	0	1 (2.0)	0	0
Physical deconditioning	1 (2.0)	0	0	1 (2.0)	0
Hepatobiliary disorders					
-Total	6 (12.0)	2 (4.0)	2 (4.0)	2 (4.0)	0
Hepatomegaly	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Hyperbilirubinaemia	3 (6.0)	0	1 (2.0)	2 (4.0)	0
Gallbladder enlargement	1 (2.0)	1 (2.0)	0	0	0
Immune system disorders					
-Total	44 (88.0)	5 (10.0)	21 (42.0)	8 (16.0)	10 (20.0)
Cytokine release syndrome	37 (74.0)	6 (12.0)	15 (30.0)	6 (12.0)	10 (20.0)
Hypogammaglobulinaemia	24 (48.0)	2 (4.0)	18 (36.0)	4 (8.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Seasonal allergy	2 (4.0)	2 (4.0)	0	0	0
Chronic graft versus host disease	1 (2.0)	0	1 (2.0)	0	0
Drug hypersensitivity	1 (2.0)	0	1 (2.0)	0	0
Graft versus host disease in gastrointestinal tract	1 (2.0)	0	1 (2.0)	0	0
Graft versus host disease in skin	1 (2.0)	1 (2.0)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (2.0)	0	1 (2.0)	0	0
Immunodeficiency	1 (2.0)	0	1 (2.0)	0	0
Immunodeficiency common variable	1 (2.0)	0	1 (2.0)	0	0
Infections and infestations					
-Total	35 (70.0)	6 (12.0)	17 (34.0)	10 (20.0)	2 (4.0)
Upper respiratory tract infection	9 (18.0)	4 (8.0)	4 (8.0)	1 (2.0)	0
Clostridium difficile colitis	4 (8.0)	1 (2.0)	2 (4.0)	1 (2.0)	0
Clostridium difficile infection	4 (8.0)	0	3 (6.0)	1 (2.0)	0
Gastroenteritis	4 (8.0)	1 (2.0)	2 (4.0)	1 (2.0)	0
Otitis media	4 (8.0)	0	3 (6.0)	1 (2.0)	0
Rhinovirus infection	4 (8.0)	4 (8.0)	0	0	0
Sinusitis	4 (8.0)	0	4 (8.0)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	3 (6.0)	0	3 (6.0)	0	0
Urinary tract infection	3 (6.0)	0	1 (2.0)	2 (4.0)	0
Ear infection	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Influenza	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Otitis media acute	2 (4.0)	0	2 (4.0)	0	0
Skin infection	2 (4.0)	0	2 (4.0)	0	0
Viral infection	2 (4.0)	2 (4.0)	0	0	0
Vulvovaginal candidiasis	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Acute sinusitis	1 (2.0)	0	1 (2.0)	0	0
Body tinea	1 (2.0)	1 (2.0)	0	0	0
Campylobacter infection	1 (2.0)	0	0	1 (2.0)	0
Catheter site cellulitis	1 (2.0)	1 (2.0)	0	0	0
Cellulitis of male external genital organ	1 (2.0)	0	0	1 (2.0)	0
Cholecystitis infective	1 (2.0)	0	0	1 (2.0)	0
Cytomegalovirus infection	1 (2.0)	1 (2.0)	0	0	0
Enterococcal infection	1 (2.0)	1 (2.0)	0	0	0
Enterovirus infection	1 (2.0)	0	0	1 (2.0)	0
Escherichia urinary tract infection	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis norovirus	1 (2.0)	0	1 (2.0)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingivitis	1 (2.0)	1 (2.0)	0	0	0
Haemophilus infection	1 (2.0)	0	1 (2.0)	0	0
Herpes simplex	1 (2.0)	1 (2.0)	0	0	0
Herpes zoster	1 (2.0)	0	0	1 (2.0)	0
Human herpesvirus 6 infection	1 (2.0)	0	1 (2.0)	0	0
Hypopyon	1 (2.0)	0	1 (2.0)	0	0
Meningitis aseptic	1 (2.0)	0	1 (2.0)	0	0
Oral candidiasis	1 (2.0)	1 (2.0)	0	0	0
Oral herpes	1 (2.0)	0	1 (2.0)	0	0
Orchitis	1 (2.0)	1 (2.0)	0	0	0
Parainfluenzae virus infection	1 (2.0)	1 (2.0)	0	0	0
Pharyngitis	1 (2.0)	0	1 (2.0)	0	0
Rash pustular	1 (2.0)	0	1 (2.0)	0	0
Respiratory tract infection viral	1 (2.0)	0	0	1 (2.0)	0
Rhinitis	1 (2.0)	1 (2.0)	0	0	0
Rotavirus infection	1 (2.0)	0	0	1 (2.0)	0
Sepsis	1 (2.0)	0	0	0	1 (2.0)
Septic embolus	1 (2.0)	0	0	0	1 (2.0)
Staphylococcal infection	1 (2.0)	0	0	1 (2.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal infection	1 (2.0)	0	1 (2.0)	0	0
Tinea capitis	1 (2.0)	1 (2.0)	0	0	0
Vascular device infection	1 (2.0)	0	0	1 (2.0)	0
Viral upper respiratory tract infection	1 (2.0)	0	1 (2.0)	0	0
Vulvovaginal mycotic infection	1 (2.0)	0	1 (2.0)	0	0
Injury, poisoning and procedural complications					
-Total	18 (36.0)	8 (16.0)	7 (14.0)	2 (4.0)	1 (2.0)
Contusion	3 (6.0)	3 (6.0)	0	0	0
Infusion related reaction	3 (6.0)	0	3 (6.0)	0	0
Procedural pain	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Transfusion reaction	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Arthropod bite	1 (2.0)	1 (2.0)	0	0	0
Foot fracture	1 (2.0)	0	1 (2.0)	0	0
Incision site pain	1 (2.0)	1 (2.0)	0	0	0
Limb injury	1 (2.0)	1 (2.0)	0	0	0
Mouth injury	1 (2.0)	1 (2.0)	0	0	0
Post procedural haemorrhage	1 (2.0)	1 (2.0)	0	0	0
Procedural complication	1 (2.0)	1 (2.0)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural headache	1 (2.0)	0	1 (2.0)	0	0
Procedural nausea	1 (2.0)	0	1 (2.0)	0	0
Procedural site reaction	1 (2.0)	1 (2.0)	0	0	0
Radius fracture	1 (2.0)	0	1 (2.0)	0	0
Skin abrasion	1 (2.0)	1 (2.0)	0	0	0
Stoma site irritation	1 (2.0)	1 (2.0)	0	0	0
Subdural haemorrhage	1 (2.0)	1 (2.0)	0	0	0
Sunburn	1 (2.0)	1 (2.0)	0	0	0
Tibia fracture	1 (2.0)	0	1 (2.0)	0	0
Tongue injury	1 (2.0)	1 (2.0)	0	0	0
Tracheal haemorrhage	1 (2.0)	0	0	1 (2.0)	0
Transfusion related complication	1 (2.0)	0	0	0	1 (2.0)
Investigations					
-Total	43 (86.0)	2 (4.0)	4 (8.0)	11 (22.0)	26 (52.0)
White blood cell count decreased	25 (50.0)	2 (4.0)	1 (2.0)	10 (20.0)	12 (24.0)
Neutrophil count decreased	20 (40.0)	0	2 (4.0)	2 (4.0)	16 (32.0)
Alanine aminotransferase increased	19 (38.0)	5 (10.0)	1 (2.0)	13 (26.0)	0
Aspartate aminotransferase increased	19 (38.0)	4 (8.0)	3 (6.0)	8 (16.0)	4 (8.0)
Platelet count decreased	16 (32.0)	2 (4.0)	2 (4.0)	3 (6.0)	9 (18.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	10 (20.0)	0	2 (4.0)	5 (10.0)	3 (6.0)
Blood creatinine increased	8 (16.0)	4 (8.0)	2 (4.0)	2 (4.0)	0
International normalised ratio increased	8 (16.0)	7 (14.0)	0	1 (2.0)	0
Prothrombin time prolonged	8 (16.0)	4 (8.0)	3 (6.0)	1 (2.0)	0
Blood bilirubin increased	6 (12.0)	1 (2.0)	2 (4.0)	3 (6.0)	0
Activated partial thromboplastin time prolonged	5 (10.0)	3 (6.0)	2 (4.0)	0	0
Weight decreased	4 (8.0)	1 (2.0)	3 (6.0)	0	0
Blood fibrinogen decreased	3 (6.0)	0	1 (2.0)	1 (2.0)	1 (2.0)
Blood immunoglobulin m decreased	3 (6.0)	3 (6.0)	0	0	0
Haemoglobin decreased	3 (6.0)	2 (4.0)	0	1 (2.0)	0
Transaminases increased	3 (6.0)	3 (6.0)	0	0	0
Blood immunoglobulin a decreased	2 (4.0)	2 (4.0)	0	0	0
Blood magnesium decreased	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Blood phosphorus increased	2 (4.0)	2 (4.0)	0	0	0
Blood urea increased	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Blood uric acid increased	2 (4.0)	2 (4.0)	0	0	0
Weight increased	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Blood alkaline phosphatase increased	1 (2.0)	1 (2.0)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bicarbonate decreased	1 (2.0)	0	1 (2.0)	0	0
Blood lactate dehydrogenase increased	1 (2.0)	1 (2.0)	0	0	0
Blood lactic acid increased	1 (2.0)	0	0	0	1 (2.0)
Blood phosphorus decreased	1 (2.0)	1 (2.0)	0	0	0
C-reactive protein increased	1 (2.0)	1 (2.0)	0	0	0
Cardiac murmur	1 (2.0)	1 (2.0)	0	0	0
Culture stool positive	1 (2.0)	1 (2.0)	0	0	0
Hepatic enzyme increased	1 (2.0)	0	1 (2.0)	0	0
Lipase increased	1 (2.0)	0	0	0	1 (2.0)
Norovirus test positive	1 (2.0)	1 (2.0)	0	0	0
Protein total decreased	1 (2.0)	0	0	1 (2.0)	0
Pulmonary function test decreased	1 (2.0)	0	1 (2.0)	0	0
Serum ferritin increased	1 (2.0)	0	1 (2.0)	0	0
Metabolism and nutrition disorders					
-Total	34 (68.0)	6 (12.0)	7 (14.0)	19 (38.0)	2 (4.0)
Decreased appetite	18 (36.0)	4 (8.0)	4 (8.0)	10 (20.0)	0
Hypokalaemia	14 (28.0)	2 (4.0)	5 (10.0)	6 (12.0)	1 (2.0)
Hypophosphataemia	9 (18.0)	2 (4.0)	0	7 (14.0)	0
Hyperphosphataemia	6 (12.0)	6 (12.0)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	4 (8.0)	1 (2.0)	2 (4.0)	0	1 (2.0)
Hypoalbuminaemia	4 (8.0)	1 (2.0)	3 (6.0)	0	0
Dehydration	3 (6.0)	1 (2.0)	0	2 (4.0)	0
Fluid overload	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Hyperglycaemia	3 (6.0)	0	1 (2.0)	2 (4.0)	0
Hypocalcaemia	3 (6.0)	1 (2.0)	1 (2.0)	1 (2.0)	0
Acidosis	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Hyperuricaemia	2 (4.0)	2 (4.0)	0	0	0
Hyponatraemia	2 (4.0)	0	0	2 (4.0)	0
Vitamin d deficiency	2 (4.0)	2 (4.0)	0	0	0
Hyperalbuminaemia	1 (2.0)	1 (2.0)	0	0	0
Hypercalcaemia	1 (2.0)	1 (2.0)	0	0	0
Hyperchloraemia	1 (2.0)	1 (2.0)	0	0	0
Hypermagnesaemia	1 (2.0)	1 (2.0)	0	0	0
Hypertriglyceridaemia	1 (2.0)	0	0	1 (2.0)	0
Malnutrition	1 (2.0)	0	0	1 (2.0)	0
Metabolic acidosis	1 (2.0)	0	1 (2.0)	0	0
Metabolic alkalosis	1 (2.0)	1 (2.0)	0	0	0
Tumour lysis syndrome	1 (2.0)	0	0	1 (2.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	18 (36.0)	9 (18.0)	8 (16.0)	1 (2.0)	0
Pain in extremity	7 (14.0)	4 (8.0)	3 (6.0)	0	0
Myalgia	5 (10.0)	4 (8.0)	1 (2.0)	0	0
Arthralgia	3 (6.0)	2 (4.0)	0	1 (2.0)	0
Musculoskeletal pain	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Joint range of motion decreased	2 (4.0)	2 (4.0)	0	0	0
Muscle spasms	2 (4.0)	2 (4.0)	0	0	0
Musculoskeletal chest pain	2 (4.0)	2 (4.0)	0	0	0
Back pain	1 (2.0)	1 (2.0)	0	0	0
Coccydynia	1 (2.0)	1 (2.0)	0	0	0
Flank pain	1 (2.0)	0	1 (2.0)	0	0
Limb discomfort	1 (2.0)	1 (2.0)	0	0	0
Muscular weakness	1 (2.0)	1 (2.0)	0	0	0
Neck pain	1 (2.0)	0	1 (2.0)	0	0
Osteonecrosis	1 (2.0)	0	1 (2.0)	0	0
Osteopenia	1 (2.0)	0	1 (2.0)	0	0
Pain in jaw	1 (2.0)	1 (2.0)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (4.0)	0	1 (2.0)	0	1 (2.0)
Glioblastoma multiforme	1 (2.0)	0	0	0	1 (2.0)
Skin papilloma	1 (2.0)	0	1 (2.0)	0	0
Nervous system disorders					
-Total	30 (60.0)	15 (30.0)	9 (18.0)	5 (10.0)	1 (2.0)
Headache	21 (42.0)	13 (26.0)	6 (12.0)	2 (4.0)	0
Dizziness	5 (10.0)	5 (10.0)	0	0	0
Encephalopathy	4 (8.0)	1 (2.0)	1 (2.0)	2 (4.0)	0
Seizure	4 (8.0)	0	2 (4.0)	2 (4.0)	0
Peroneal nerve palsy	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Tremor	2 (4.0)	2 (4.0)	0	0	0
Asterixis	1 (2.0)	1 (2.0)	0	0	0
Ataxia	1 (2.0)	0	1 (2.0)	0	0
Disturbance in attention	1 (2.0)	1 (2.0)	0	0	0
Dysarthria	1 (2.0)	1 (2.0)	0	0	0
Embolic stroke	1 (2.0)	0	0	0	1 (2.0)
Idiopathic intracranial hypertension	1 (2.0)	0	1 (2.0)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myoclonus	1 (2.0)	1 (2.0)	0	0	0
Neuropathy peripheral	1 (2.0)	0	1 (2.0)	0	0
Pleocytosis	1 (2.0)	1 (2.0)	0	0	0
Product issues					
-Total	1 (2.0)	1 (2.0)	0	0	0
Device occlusion	1 (2.0)	1 (2.0)	0	0	0
Psychiatric disorders					
-Total	15 (30.0)	7 (14.0)	7 (14.0)	1 (2.0)	0
Anxiety	7 (14.0)	3 (6.0)	3 (6.0)	1 (2.0)	0
Confusional state	6 (12.0)	3 (6.0)	3 (6.0)	0	0
Delirium	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Agitation	2 (4.0)	0	2 (4.0)	0	0
Hallucination	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Irritability	2 (4.0)	2 (4.0)	0	0	0
Adjustment disorder	1 (2.0)	0	1 (2.0)	0	0
Depression	1 (2.0)	1 (2.0)	0	0	0
Insomnia	1 (2.0)	0	1 (2.0)	0	0
Listless	1 (2.0)	1 (2.0)	0	0	0
Mental status changes	1 (2.0)	1 (2.0)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sleep disorder	1 (2.0)	0	1 (2.0)	0	0
Suicidal ideation	1 (2.0)	1 (2.0)	0	0	0
Renal and urinary disorders					
-Total	13 (26.0)	2 (4.0)	2 (4.0)	5 (10.0)	4 (8.0)
Acute kidney injury	8 (16.0)	1 (2.0)	1 (2.0)	3 (6.0)	3 (6.0)
Haematuria	5 (10.0)	0	2 (4.0)	2 (4.0)	1 (2.0)
Oliguria	2 (4.0)	0	0	2 (4.0)	0
Calculus urinary	1 (2.0)	0	1 (2.0)	0	0
Dysuria	1 (2.0)	0	1 (2.0)	0	0
Nephrolithiasis	1 (2.0)	0	0	1 (2.0)	0
Pollakiuria	1 (2.0)	1 (2.0)	0	0	0
Renal failure	1 (2.0)	0	0	0	1 (2.0)
Renal impairment	1 (2.0)	0	0	1 (2.0)	0
Urinary incontinence	1 (2.0)	1 (2.0)	0	0	0
Reproductive system and breast disorders					
-Total	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Oedema genital	1 (2.0)	0	1 (2.0)	0	0
Scrotal pain	1 (2.0)	0	1 (2.0)	0	0
Vulvovaginal adhesion	1 (2.0)	1 (2.0)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	29 (58.0)	11 (22.0)	5 (10.0)	6 (12.0)	7 (14.0)
Cough	11 (22.0)	11 (22.0)	0	0	0
Epistaxis	9 (18.0)	3 (6.0)	1 (2.0)	4 (8.0)	1 (2.0)
Hypoxia	8 (16.0)	0	2 (4.0)	3 (6.0)	3 (6.0)
Pleural effusion	6 (12.0)	1 (2.0)	4 (8.0)	1 (2.0)	0
Pulmonary oedema	6 (12.0)	1 (2.0)	0	3 (6.0)	2 (4.0)
Oropharyngeal pain	5 (10.0)	3 (6.0)	2 (4.0)	0	0
Rhinorrhoea	4 (8.0)	4 (8.0)	0	0	0
Tachypnoea	4 (8.0)	2 (4.0)	1 (2.0)	1 (2.0)	0
Rhinitis allergic	3 (6.0)	3 (6.0)	0	0	0
Dyspnoea	2 (4.0)	0	0	1 (2.0)	1 (2.0)
Haemoptysis	2 (4.0)	1 (2.0)	0	0	1 (2.0)
Nasal congestion	2 (4.0)	2 (4.0)	0	0	0
Respiratory failure	2 (4.0)	0	0	0	2 (4.0)
Acute respiratory failure	1 (2.0)	0	0	0	1 (2.0)
Atelectasis	1 (2.0)	1 (2.0)	0	0	0
Dysphonia	1 (2.0)	1 (2.0)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Interstitial lung disease	1 (2.0)	0	0	0	1 (2.0)
Pharyngeal erythema	1 (2.0)	1 (2.0)	0	0	0
Pharyngeal lesion	1 (2.0)	0	0	1 (2.0)	0
Pharyngeal ulceration	1 (2.0)	0	1 (2.0)	0	0
Respiratory depression	1 (2.0)	0	1 (2.0)	0	0
Respiratory distress	1 (2.0)	0	0	0	1 (2.0)
Wheezing	1 (2.0)	0	1 (2.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	22 (44.0)	12 (24.0)	8 (16.0)	2 (4.0)	0
Rash	7 (14.0)	4 (8.0)	3 (6.0)	0	0
Dry skin	4 (8.0)	4 (8.0)	0	0	0
Erythema	4 (8.0)	4 (8.0)	0	0	0
Rash maculo-papular	4 (8.0)	2 (4.0)	1 (2.0)	1 (2.0)	0
Hyperhidrosis	3 (6.0)	3 (6.0)	0	0	0
Ingrowing nail	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Petechiae	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Pruritus	3 (6.0)	3 (6.0)	0	0	0
Rash papular	2 (4.0)	2 (4.0)	0	0	0
Acne	1 (2.0)	1 (2.0)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alopecia	1 (2.0)	0	1 (2.0)	0	0
Dermatitis	1 (2.0)	1 (2.0)	0	0	0
Dermatitis atopic	1 (2.0)	1 (2.0)	0	0	0
Ecchymosis	1 (2.0)	0	0	1 (2.0)	0
Eczema	1 (2.0)	1 (2.0)	0	0	0
Livedo reticularis	1 (2.0)	1 (2.0)	0	0	0
Macule	1 (2.0)	1 (2.0)	0	0	0
Night sweats	1 (2.0)	0	1 (2.0)	0	0
Papule	1 (2.0)	1 (2.0)	0	0	0
Rash erythematous	1 (2.0)	0	1 (2.0)	0	0
Rash follicular	1 (2.0)	1 (2.0)	0	0	0
Rash pruritic	1 (2.0)	1 (2.0)	0	0	0
Rash vesicular	1 (2.0)	1 (2.0)	0	0	0
Skin exfoliation	1 (2.0)	1 (2.0)	0	0	0
Skin fissures	1 (2.0)	1 (2.0)	0	0	0
Skin irritation	1 (2.0)	1 (2.0)	0	0	0
Vascular disorders					
-Total	20 (40.0)	3 (6.0)	3 (6.0)	6 (12.0)	8 (16.0)
Hypotension	14 (28.0)	1 (2.0)	0	5 (10.0)	8 (16.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=50 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	10 (20.0)	3 (6.0)	6 (12.0)	1 (2.0)	0
Flushing	2 (4.0)	2 (4.0)	0	0	0
Capillary leak syndrome	1 (2.0)	0	0	0	1 (2.0)
Embolism	1 (2.0)	0	0	1 (2.0)	0
Haematoma	1 (2.0)	0	1 (2.0)	0	0
Hot flush	1 (2.0)	1 (2.0)	0	0	0
Orthostatic hypotension	1 (2.0)	1 (2.0)	0	0	0
Secondary hypertension	1 (2.0)	0	1 (2.0)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174n
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (95.0)	0	1 (5.0)	7 (35.0)	11 (55.0)
Blood and lymphatic system disorders					
-Total	14 (70.0)	0	0	12 (60.0)	2 (10.0)
Anaemia	9 (45.0)	2 (10.0)	2 (10.0)	5 (25.0)	0
Febrile neutropenia	9 (45.0)	0	0	9 (45.0)	0
Neutropenia	3 (15.0)	0	0	2 (10.0)	1 (5.0)
Disseminated intravascular coagulation	1 (5.0)	0	1 (5.0)	0	0
Lymphopenia	1 (5.0)	0	0	1 (5.0)	0
Pancytopenia	1 (5.0)	0	0	0	1 (5.0)
Cardiac disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Tachycardia	2 (10.0)	1 (5.0)	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus bradycardia	1 (5.0)	1 (5.0)	0	0	0
Ear and labyrinth disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Hypoacusis	1 (5.0)	0	1 (5.0)	0	0
Eye disorders					
-Total	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Eye pain	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Retinal haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Vision blurred	1 (5.0)	1 (5.0)	0	0	0
Gastrointestinal disorders					
-Total	11 (55.0)	4 (20.0)	6 (30.0)	1 (5.0)	0
Nausea	7 (35.0)	3 (15.0)	4 (20.0)	0	0
Vomiting	7 (35.0)	4 (20.0)	2 (10.0)	1 (5.0)	0
Abdominal pain	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Constipation	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Diarrhoea	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Abdominal pain upper	1 (5.0)	0	1 (5.0)	0	0
Anal incontinence	1 (5.0)	1 (5.0)	0	0	0
Dyspepsia	1 (5.0)	0	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Haematemesis	1 (5.0)	1 (5.0)	0	0	0
Intestinal obstruction	1 (5.0)	0	0	1 (5.0)	0
Lip pain	1 (5.0)	0	1 (5.0)	0	0
Stomatitis	1 (5.0)	0	1 (5.0)	0	0
General disorders and administration site conditions					
-Total	7 (35.0)	4 (20.0)	1 (5.0)	2 (10.0)	0
Fatigue	4 (20.0)	4 (20.0)	0	0	0
Chills	2 (10.0)	2 (10.0)	0	0	0
Pain	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Pyrexia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Catheter site pain	1 (5.0)	1 (5.0)	0	0	0
Non-cardiac chest pain	1 (5.0)	1 (5.0)	0	0	0
Hepatobiliary disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Hepatomegaly	1 (5.0)	1 (5.0)	0	0	0
Hyperbilirubinaemia	1 (5.0)	0	1 (5.0)	0	0
Immune system disorders					

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	17 (85.0)	0	11 (55.0)	4 (20.0)	2 (10.0)
Cytokine release syndrome	16 (80.0)	0	11 (55.0)	3 (15.0)	2 (10.0)
Hypogammaglobulinaemia	9 (45.0)	1 (5.0)	7 (35.0)	1 (5.0)	0
Drug hypersensitivity	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	9 (45.0)	2 (10.0)	5 (25.0)	2 (10.0)	0
Gastroenteritis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Acute sinusitis	1 (5.0)	0	1 (5.0)	0	0
Clostridium difficile colitis	1 (5.0)	0	1 (5.0)	0	0
Folliculitis	1 (5.0)	0	1 (5.0)	0	0
Fungal skin infection	1 (5.0)	1 (5.0)	0	0	0
Herpes simplex	1 (5.0)	1 (5.0)	0	0	0
Oral candidiasis	1 (5.0)	1 (5.0)	0	0	0
Orchitis	1 (5.0)	1 (5.0)	0	0	0
Pharyngitis	1 (5.0)	0	1 (5.0)	0	0
Streptococcal infection	1 (5.0)	0	1 (5.0)	0	0
Upper respiratory tract infection	1 (5.0)	0	1 (5.0)	0	0
Urinary tract infection enterococcal	1 (5.0)	0	0	1 (5.0)	0
Viral infection	1 (5.0)	0	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal candidiasis	1 (5.0)	1 (5.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (5.0)	0	1 (5.0)	0	0
Procedural pain	1 (5.0)	0	1 (5.0)	0	0
Investigations					
-Total	16 (80.0)	2 (10.0)	1 (5.0)	3 (15.0)	10 (50.0)
White blood cell count decreased	9 (45.0)	1 (5.0)	0	3 (15.0)	5 (25.0)
Neutrophil count decreased	8 (40.0)	0	0	2 (10.0)	6 (30.0)
Lymphocyte count decreased	6 (30.0)	1 (5.0)	0	2 (10.0)	3 (15.0)
Platelet count decreased	6 (30.0)	2 (10.0)	0	1 (5.0)	3 (15.0)
Aspartate aminotransferase increased	5 (25.0)	0	3 (15.0)	1 (5.0)	1 (5.0)
Alanine aminotransferase increased	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0
Blood bilirubin increased	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Blood creatinine increased	3 (15.0)	3 (15.0)	0	0	0
International normalised ratio increased	3 (15.0)	3 (15.0)	0	0	0
Prothrombin time prolonged	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Activated partial thromboplastin time prolonged	1 (5.0)	0	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (5.0)	1 (5.0)	0	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Blood lactic acid increased	1 (5.0)	0	0	0	1 (5.0)
Blood phosphorus increased	1 (5.0)	1 (5.0)	0	0	0
Cardiac murmur	1 (5.0)	1 (5.0)	0	0	0
Culture stool positive	1 (5.0)	1 (5.0)	0	0	0
Fibrin d dimer increased	1 (5.0)	1 (5.0)	0	0	0
Serum ferritin increased	1 (5.0)	0	1 (5.0)	0	0
Metabolism and nutrition disorders					
-Total	10 (50.0)	1 (5.0)	1 (5.0)	7 (35.0)	1 (5.0)
Decreased appetite	5 (25.0)	1 (5.0)	1 (5.0)	3 (15.0)	0
Dehydration	2 (10.0)	0	0	2 (10.0)	0
Hyperphosphataemia	2 (10.0)	2 (10.0)	0	0	0
Hypophosphataemia	2 (10.0)	0	0	2 (10.0)	0
Fluid overload	1 (5.0)	1 (5.0)	0	0	0
Hyperuricaemia	1 (5.0)	0	0	0	1 (5.0)
Hypokalaemia	1 (5.0)	0	0	1 (5.0)	0
Hyponatraemia	1 (5.0)	0	0	1 (5.0)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	5 (25.0)	2 (10.0)	2 (10.0)	1 (5.0)	0
Myalgia	2 (10.0)	2 (10.0)	0	0	0
Pain in extremity	2 (10.0)	0	2 (10.0)	0	0
Arthralgia	1 (5.0)	0	0	1 (5.0)	0
Nervous system disorders					
-Total	9 (45.0)	5 (25.0)	3 (15.0)	1 (5.0)	0
Headache	6 (30.0)	4 (20.0)	1 (5.0)	1 (5.0)	0
Encephalopathy	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Myoclonus	1 (5.0)	1 (5.0)	0	0	0
Seizure	1 (5.0)	0	1 (5.0)	0	0
Tremor	1 (5.0)	1 (5.0)	0	0	0
Psychiatric disorders					
-Total	4 (20.0)	2 (10.0)	2 (10.0)	0	0
Anxiety	1 (5.0)	0	1 (5.0)	0	0
Confusional state	1 (5.0)	1 (5.0)	0	0	0
Delirium	1 (5.0)	1 (5.0)	0	0	0
Mental status changes	1 (5.0)	1 (5.0)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Panic attack	1 (5.0)	0	1 (5.0)	0	0
Reproductive system and breast disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Vulvovaginal adhesion	1 (5.0)	1 (5.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (30.0)	2 (10.0)	4 (20.0)	0	0
Hypoxia	3 (15.0)	0	3 (15.0)	0	0
Cough	2 (10.0)	2 (10.0)	0	0	0
Atelectasis	1 (5.0)	1 (5.0)	0	0	0
Nasal congestion	1 (5.0)	1 (5.0)	0	0	0
Pharyngeal ulceration	1 (5.0)	0	1 (5.0)	0	0
Pleural effusion	1 (5.0)	1 (5.0)	0	0	0
Respiratory depression	1 (5.0)	0	1 (5.0)	0	0
Rhinitis allergic	1 (5.0)	1 (5.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (30.0)	5 (25.0)	0	1 (5.0)	0
Dry skin	2 (10.0)	2 (10.0)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	2 (10.0)	2 (10.0)	0	0	0
Dermatitis diaper	1 (5.0)	1 (5.0)	0	0	0
Ingrowing nail	1 (5.0)	0	1 (5.0)	0	0
Livedo reticularis	1 (5.0)	1 (5.0)	0	0	0
Rash maculo-papular	1 (5.0)	0	0	1 (5.0)	0
Vascular disorders					
-Total	5 (25.0)	0	0	4 (20.0)	1 (5.0)
Hypotension	4 (20.0)	0	0	3 (15.0)	1 (5.0)
Hypertension	2 (10.0)	0	2 (10.0)	0	0
Embolism	1 (5.0)	0	0	1 (5.0)	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174n
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=44		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	44 (100)	2 (4.5)	6 (13.6)	7 (15.9)	29 (65.9)
Blood and lymphatic system disorders					
-Total	29 (65.9)	2 (4.5)	3 (6.8)	15 (34.1)	9 (20.5)
Anaemia	18 (40.9)	1 (2.3)	3 (6.8)	13 (29.5)	1 (2.3)
Febrile neutropenia	13 (29.5)	0	0	13 (29.5)	0
Thrombocytopenia	8 (18.2)	0	0	2 (4.5)	6 (13.6)
Neutropenia	5 (11.4)	0	0	1 (2.3)	4 (9.1)
Disseminated intravascular coagulation	3 (6.8)	0	1 (2.3)	2 (4.5)	0
Lymphopenia	2 (4.5)	0	1 (2.3)	0	1 (2.3)
Coagulopathy	1 (2.3)	1 (2.3)	0	0	0
Cardiac disorders					
-Total	20 (45.5)	10 (22.7)	8 (18.2)	2 (4.5)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	13 (29.5)	7 (15.9)	4 (9.1)	2 (4.5)	0
Sinus tachycardia	5 (11.4)	3 (6.8)	2 (4.5)	0	0
Pericardial effusion	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Atrioventricular block second degree	1 (2.3)	1 (2.3)	0	0	0
Bradycardia	1 (2.3)	0	1 (2.3)	0	0
Cardiac dysfunction	1 (2.3)	1 (2.3)	0	0	0
Left ventricular dysfunction	1 (2.3)	0	0	1 (2.3)	0
Palpitations	1 (2.3)	1 (2.3)	0	0	0
Ventricular tachycardia	1 (2.3)	0	1 (2.3)	0	0
Ear and labyrinth disorders					
-Total	2 (4.5)	2 (4.5)	0	0	0
Ear pain	2 (4.5)	2 (4.5)	0	0	0
Endocrine disorders					
-Total	1 (2.3)	0	1 (2.3)	0	0
Adrenal insufficiency	1 (2.3)	0	1 (2.3)	0	0
Eye disorders					
-Total	10 (22.7)	4 (9.1)	6 (13.6)	0	0
Periorbital oedema	4 (9.1)	3 (6.8)	1 (2.3)	0	0
Conjunctival haemorrhage	3 (6.8)	3 (6.8)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Photophobia	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Uveitis	2 (4.5)	0	2 (4.5)	0	0
Vision blurred	2 (4.5)	0	2 (4.5)	0	0
Eye pain	1 (2.3)	0	1 (2.3)	0	0
Ocular hypertension	1 (2.3)	0	1 (2.3)	0	0
Papilloedema	1 (2.3)	0	1 (2.3)	0	0
Retinal haemorrhage	1 (2.3)	1 (2.3)	0	0	0
Visual impairment	1 (2.3)	0	1 (2.3)	0	0
Gastrointestinal disorders					
-Total	25 (56.8)	7 (15.9)	8 (18.2)	10 (22.7)	0
Diarrhoea	15 (34.1)	10 (22.7)	4 (9.1)	1 (2.3)	0
Vomiting	15 (34.1)	9 (20.5)	4 (9.1)	2 (4.5)	0
Nausea	14 (31.8)	3 (6.8)	8 (18.2)	3 (6.8)	0
Abdominal pain	6 (13.6)	5 (11.4)	1 (2.3)	0	0
Constipation	4 (9.1)	4 (9.1)	0	0	0
Abdominal distension	2 (4.5)	0	2 (4.5)	0	0
Dysphagia	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Pancreatitis	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Abdominal discomfort	1 (2.3)	1 (2.3)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain lower	1 (2.3)	0	1 (2.3)	0	0
Abdominal pain upper	1 (2.3)	0	1 (2.3)	0	0
Abdominal tenderness	1 (2.3)	1 (2.3)	0	0	0
Ascites	1 (2.3)	0	0	1 (2.3)	0
Flatulence	1 (2.3)	1 (2.3)	0	0	0
Gastrooesophageal reflux disease	1 (2.3)	1 (2.3)	0	0	0
Glossodynia	1 (2.3)	1 (2.3)	0	0	0
Haematemesis	1 (2.3)	1 (2.3)	0	0	0
Ileus	1 (2.3)	0	0	1 (2.3)	0
Mouth haemorrhage	1 (2.3)	0	0	1 (2.3)	0
Stomatitis	1 (2.3)	1 (2.3)	0	0	0
Tooth socket haemorrhage	1 (2.3)	1 (2.3)	0	0	0
General disorders and administration site conditions					
-Total	25 (56.8)	8 (18.2)	9 (20.5)	7 (15.9)	1 (2.3)
Pyrexia	14 (31.8)	3 (6.8)	6 (13.6)	4 (9.1)	1 (2.3)
Fatigue	9 (20.5)	6 (13.6)	2 (4.5)	1 (2.3)	0
Chills	6 (13.6)	6 (13.6)	0	0	0
Malaise	3 (6.8)	0	3 (6.8)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site pain	2 (4.5)	0	2 (4.5)	0	0
Face oedema	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Generalised oedema	2 (4.5)	0	2 (4.5)	0	0
Oedema peripheral	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Asthenia	1 (2.3)	1 (2.3)	0	0	0
Catheter site extravasation	1 (2.3)	0	1 (2.3)	0	0
Catheter site haemorrhage	1 (2.3)	1 (2.3)	0	0	0
Facial pain	1 (2.3)	0	1 (2.3)	0	0
Injection site haematoma	1 (2.3)	1 (2.3)	0	0	0
Localised oedema	1 (2.3)	0	0	1 (2.3)	0
Mucosal haemorrhage	1 (2.3)	0	1 (2.3)	0	0
Multiple organ dysfunction syndrome	1 (2.3)	0	0	1 (2.3)	0
Pain	1 (2.3)	0	0	1 (2.3)	0
Peripheral swelling	1 (2.3)	0	1 (2.3)	0	0
Physical deconditioning	1 (2.3)	0	0	1 (2.3)	0
Hepatobiliary disorders					
-Total	5 (11.4)	2 (4.5)	1 (2.3)	2 (4.5)	0
Hepatomegaly	2 (4.5)	0	2 (4.5)	0	0
Hyperbilirubinaemia	2 (4.5)	0	0	2 (4.5)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=44		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gallbladder enlargement	1 (2.3)	1 (2.3)	0	0	0
Hepatosplenomegaly	1 (2.3)	1 (2.3)	0	0	0
Immune system disorders					
-Total	40 (90.9)	5 (11.4)	19 (43.2)	7 (15.9)	9 (20.5)
Cytokine release syndrome	34 (77.3)	6 (13.6)	14 (31.8)	5 (11.4)	9 (20.5)
Hypogammaglobulinaemia	16 (36.4)	2 (4.5)	11 (25.0)	3 (6.8)	0
Graft versus host disease in skin	1 (2.3)	1 (2.3)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (2.3)	0	1 (2.3)	0	0
Infections and infestations					
-Total	17 (38.6)	3 (6.8)	9 (20.5)	4 (9.1)	1 (2.3)
Clostridium difficile infection	4 (9.1)	0	4 (9.1)	0	0
Clostridium difficile colitis	3 (6.8)	1 (2.3)	1 (2.3)	1 (2.3)	0
Rhinovirus infection	3 (6.8)	3 (6.8)	0	0	0
Pneumonia	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Staphylococcal infection	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Body tinea	1 (2.3)	1 (2.3)	0	0	0
Catheter site cellulitis	1 (2.3)	1 (2.3)	0	0	0
Catheter site infection	1 (2.3)	0	0	1 (2.3)	0
Cytomegalovirus infection	1 (2.3)	1 (2.3)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterococcal infection	1 (2.3)	1 (2.3)	0	0	0
Gastroenteritis norovirus	1 (2.3)	0	1 (2.3)	0	0
Human herpesvirus 6 infection	1 (2.3)	0	1 (2.3)	0	0
Hypopyon	1 (2.3)	0	1 (2.3)	0	0
Influenza	1 (2.3)	1 (2.3)	0	0	0
Septic embolus	1 (2.3)	0	0	0	1 (2.3)
Skin infection	1 (2.3)	0	1 (2.3)	0	0
Viral upper respiratory tract infection	1 (2.3)	0	1 (2.3)	0	0
Injury, poisoning and procedural complications					
-Total	14 (31.8)	8 (18.2)	4 (9.1)	1 (2.3)	1 (2.3)
Transfusion reaction	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Infusion related reaction	2 (4.5)	0	2 (4.5)	0	0
Procedural pain	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Contusion	1 (2.3)	1 (2.3)	0	0	0
Incision site pain	1 (2.3)	1 (2.3)	0	0	0
Limb injury	1 (2.3)	1 (2.3)	0	0	0
Mouth injury	1 (2.3)	1 (2.3)	0	0	0
Post procedural haemorrhage	1 (2.3)	1 (2.3)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural complication	1 (2.3)	1 (2.3)	0	0	0
Procedural headache	1 (2.3)	0	1 (2.3)	0	0
Procedural site reaction	1 (2.3)	1 (2.3)	0	0	0
Skin abrasion	1 (2.3)	1 (2.3)	0	0	0
Stoma site irritation	1 (2.3)	1 (2.3)	0	0	0
Subdural haemorrhage	1 (2.3)	1 (2.3)	0	0	0
Tibia fracture	1 (2.3)	0	1 (2.3)	0	0
Tongue injury	1 (2.3)	1 (2.3)	0	0	0
Tracheal haemorrhage	1 (2.3)	0	0	1 (2.3)	0
Transfusion related complication	1 (2.3)	0	0	0	1 (2.3)
Investigations					
-Total	36 (81.8)	2 (4.5)	3 (6.8)	10 (22.7)	21 (47.7)
White blood cell count decreased	21 (47.7)	2 (4.5)	1 (2.3)	7 (15.9)	11 (25.0)
Neutrophil count decreased	17 (38.6)	0	2 (4.5)	2 (4.5)	13 (29.5)
Alanine aminotransferase increased	15 (34.1)	4 (9.1)	2 (4.5)	9 (20.5)	0
Aspartate aminotransferase increased	13 (29.5)	3 (6.8)	1 (2.3)	6 (13.6)	3 (6.8)
Platelet count decreased	13 (29.5)	1 (2.3)	2 (4.5)	1 (2.3)	9 (20.5)
Lymphocyte count decreased	8 (18.2)	0	2 (4.5)	4 (9.1)	2 (4.5)
Prothrombin time prolonged	7 (15.9)	4 (9.1)	2 (4.5)	1 (2.3)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	6 (13.6)	2 (4.5)	2 (4.5)	2 (4.5)	0
International normalised ratio increased	6 (13.6)	5 (11.4)	0	1 (2.3)	0
Activated partial thromboplastin time prolonged	4 (9.1)	3 (6.8)	1 (2.3)	0	0
Blood bilirubin increased	4 (9.1)	0	3 (6.8)	1 (2.3)	0
Blood fibrinogen decreased	4 (9.1)	0	1 (2.3)	2 (4.5)	1 (2.3)
Blood immunoglobulin m decreased	3 (6.8)	3 (6.8)	0	0	0
Blood urea increased	3 (6.8)	1 (2.3)	1 (2.3)	1 (2.3)	0
Blood immunoglobulin a decreased	2 (4.5)	2 (4.5)	0	0	0
Lipase increased	2 (4.5)	0	0	0	2 (4.5)
Transaminases increased	2 (4.5)	2 (4.5)	0	0	0
Blood bicarbonate decreased	1 (2.3)	0	1 (2.3)	0	0
Blood immunoglobulin g decreased	1 (2.3)	0	1 (2.3)	0	0
Blood magnesium decreased	1 (2.3)	0	0	1 (2.3)	0
Blood phosphorus decreased	1 (2.3)	1 (2.3)	0	0	0
Blood phosphorus increased	1 (2.3)	1 (2.3)	0	0	0
Blood sodium increased	1 (2.3)	0	1 (2.3)	0	0
Blood uric acid increased	1 (2.3)	1 (2.3)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	1 (2.3)	0	0	1 (2.3)	0
Haemoglobin decreased	1 (2.3)	0	0	1 (2.3)	0
Hepatic enzyme increased	1 (2.3)	0	1 (2.3)	0	0
Norovirus test positive	1 (2.3)	1 (2.3)	0	0	0
Protein total decreased	1 (2.3)	0	0	1 (2.3)	0
Pulmonary function test decreased	1 (2.3)	0	1 (2.3)	0	0
Metabolism and nutrition disorders					
-Total	29 (65.9)	4 (9.1)	9 (20.5)	14 (31.8)	2 (4.5)
Decreased appetite	15 (34.1)	3 (6.8)	3 (6.8)	9 (20.5)	0
Hypokalaemia	15 (34.1)	3 (6.8)	6 (13.6)	6 (13.6)	0
Hypophosphataemia	7 (15.9)	2 (4.5)	0	4 (9.1)	1 (2.3)
Hyperphosphataemia	6 (13.6)	6 (13.6)	0	0	0
Hypoalbuminaemia	5 (11.4)	1 (2.3)	3 (6.8)	1 (2.3)	0
Hypernatraemia	4 (9.1)	1 (2.3)	2 (4.5)	0	1 (2.3)
Hyperglycaemia	3 (6.8)	0	2 (4.5)	1 (2.3)	0
Hypocalcaemia	3 (6.8)	1 (2.3)	1 (2.3)	1 (2.3)	0
Acidosis	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Fluid overload	2 (4.5)	0	2 (4.5)	0	0
Hypertriglyceridaemia	2 (4.5)	1 (2.3)	0	1 (2.3)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=44		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	2 (4.5)	2 (4.5)	0	0	0
Dehydration	1 (2.3)	1 (2.3)	0	0	0
Hyperalbuminaemia	1 (2.3)	1 (2.3)	0	0	0
Hypercalcaemia	1 (2.3)	1 (2.3)	0	0	0
Hyperchloraemia	1 (2.3)	1 (2.3)	0	0	0
Hypermagnesaemia	1 (2.3)	1 (2.3)	0	0	0
Hypomagnesaemia	1 (2.3)	1 (2.3)	0	0	0
Hyponatraemia	1 (2.3)	0	0	1 (2.3)	0
Malnutrition	1 (2.3)	0	0	1 (2.3)	0
Metabolic acidosis	1 (2.3)	0	1 (2.3)	0	0
Metabolic alkalosis	1 (2.3)	1 (2.3)	0	0	0
Tumour lysis syndrome	1 (2.3)	0	0	1 (2.3)	0
Musculoskeletal and connective tissue disorders					
-Total	10 (22.7)	6 (13.6)	4 (9.1)	0	0
Arthralgia	3 (6.8)	3 (6.8)	0	0	0
Musculoskeletal pain	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Myalgia	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Pain in extremity	2 (4.5)	2 (4.5)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Coccydynia	1 (2.3)	1 (2.3)	0	0	0
Limb discomfort	1 (2.3)	1 (2.3)	0	0	0
Muscle spasms	1 (2.3)	1 (2.3)	0	0	0
Muscular weakness	1 (2.3)	0	1 (2.3)	0	0
Musculoskeletal chest pain	1 (2.3)	1 (2.3)	0	0	0
Osteopenia	1 (2.3)	0	1 (2.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.3)	0	1 (2.3)	0	0
Skin papilloma	1 (2.3)	0	1 (2.3)	0	0
Nervous system disorders					
-Total	24 (54.5)	12 (27.3)	8 (18.2)	3 (6.8)	1 (2.3)
Headache	18 (40.9)	12 (27.3)	5 (11.4)	1 (2.3)	0
Dizziness	4 (9.1)	4 (9.1)	0	0	0
Dysarthria	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Seizure	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Asterixis	1 (2.3)	1 (2.3)	0	0	0
Ataxia	1 (2.3)	0	1 (2.3)	0	0
Depressed level of consciousness	1 (2.3)	1 (2.3)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=44		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Embolic stroke	1 (2.3)	0	0	0	1 (2.3)
Encephalopathy	1 (2.3)	0	0	1 (2.3)	0
Idiopathic intracranial hypertension	1 (2.3)	0	1 (2.3)	0	0
Migraine	1 (2.3)	0	1 (2.3)	0	0
Neuropathy peripheral	1 (2.3)	0	1 (2.3)	0	0
Pleocytosis	1 (2.3)	1 (2.3)	0	0	0
Somnolence	1 (2.3)	1 (2.3)	0	0	0
Tremor	1 (2.3)	1 (2.3)	0	0	0
Product issues					
-Total	1 (2.3)	1 (2.3)	0	0	0
Device occlusion	1 (2.3)	1 (2.3)	0	0	0
Psychiatric disorders					
-Total	12 (27.3)	6 (13.6)	5 (11.4)	1 (2.3)	0
Anxiety	5 (11.4)	2 (4.5)	2 (4.5)	1 (2.3)	0
Confusional state	5 (11.4)	2 (4.5)	3 (6.8)	0	0
Delirium	3 (6.8)	1 (2.3)	2 (4.5)	0	0
Agitation	2 (4.5)	0	2 (4.5)	0	0
Hallucination	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Irritability	2 (4.5)	2 (4.5)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adjustment disorder	1 (2.3)	0	1 (2.3)	0	0
Insomnia	1 (2.3)	0	1 (2.3)	0	0
Listless	1 (2.3)	1 (2.3)	0	0	0
Suicidal ideation	1 (2.3)	1 (2.3)	0	0	0
Renal and urinary disorders					
-Total	11 (25.0)	2 (4.5)	2 (4.5)	3 (6.8)	4 (9.1)
Acute kidney injury	7 (15.9)	1 (2.3)	1 (2.3)	2 (4.5)	3 (6.8)
Haematuria	4 (9.1)	0	2 (4.5)	1 (2.3)	1 (2.3)
Dysuria	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Oliguria	2 (4.5)	0	0	2 (4.5)	0
Pollakiuria	1 (2.3)	1 (2.3)	0	0	0
Renal failure	1 (2.3)	0	0	0	1 (2.3)
Renal impairment	1 (2.3)	0	0	1 (2.3)	0
Reproductive system and breast disorders					
-Total	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Oedema genital	1 (2.3)	0	1 (2.3)	0	0
Vulvovaginal adhesion	1 (2.3)	1 (2.3)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	22 (50.0)	8 (18.2)	2 (4.5)	5 (11.4)	7 (15.9)
Epistaxis	7 (15.9)	2 (4.5)	1 (2.3)	3 (6.8)	1 (2.3)
Hypoxia	7 (15.9)	0	0	4 (9.1)	3 (6.8)
Pleural effusion	7 (15.9)	1 (2.3)	4 (9.1)	2 (4.5)	0
Cough	6 (13.6)	6 (13.6)	0	0	0
Pulmonary oedema	6 (13.6)	1 (2.3)	0	3 (6.8)	2 (4.5)
Tachypnoea	5 (11.4)	3 (6.8)	1 (2.3)	1 (2.3)	0
Respiratory failure	3 (6.8)	0	0	0	3 (6.8)
Dyspnoea	2 (4.5)	0	0	1 (2.3)	1 (2.3)
Haemoptysis	2 (4.5)	1 (2.3)	0	0	1 (2.3)
Oropharyngeal pain	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Interstitial lung disease	1 (2.3)	0	0	0	1 (2.3)
Oropharyngeal plaque	1 (2.3)	1 (2.3)	0	0	0
Respiratory distress	1 (2.3)	0	0	0	1 (2.3)
Rhinorrhoea	1 (2.3)	1 (2.3)	0	0	0
Wheezing	1 (2.3)	0	1 (2.3)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	15 (34.1)	10 (22.7)	4 (9.1)	1 (2.3)	0
Rash	4 (9.1)	4 (9.1)	0	0	0
Hyperhidrosis	3 (6.8)	3 (6.8)	0	0	0
Petechiae	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Dry skin	2 (4.5)	2 (4.5)	0	0	0
Pruritus	2 (4.5)	2 (4.5)	0	0	0
Rash maculo-papular	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Rash papular	2 (4.5)	2 (4.5)	0	0	0
Ecchymosis	1 (2.3)	0	0	1 (2.3)	0
Erythema	1 (2.3)	1 (2.3)	0	0	0
Ingrowing nail	1 (2.3)	0	1 (2.3)	0	0
Macule	1 (2.3)	1 (2.3)	0	0	0
Night sweats	1 (2.3)	0	1 (2.3)	0	0
Rash erythematous	1 (2.3)	1 (2.3)	0	0	0
Rash follicular	1 (2.3)	1 (2.3)	0	0	0
Rash macular	1 (2.3)	1 (2.3)	0	0	0
Rash vesicular	1 (2.3)	1 (2.3)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=44 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin exfoliation	1 (2.3)	1 (2.3)	0	0	0
Skin fissures	1 (2.3)	1 (2.3)	0	0	0
Skin irritation	1 (2.3)	1 (2.3)	0	0	0
Vascular disorders					
-Total	19 (43.2)	3 (6.8)	5 (11.4)	4 (9.1)	7 (15.9)
Hypotension	12 (27.3)	1 (2.3)	0	4 (9.1)	7 (15.9)
Hypertension	8 (18.2)	2 (4.5)	5 (11.4)	1 (2.3)	0
Flushing	2 (4.5)	2 (4.5)	0	0	0
Orthostatic hypotension	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Capillary leak syndrome	1 (2.3)	0	0	0	1 (2.3)
Haematoma	1 (2.3)	0	1 (2.3)	0	0
Secondary hypertension	1 (2.3)	0	1 (2.3)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174n
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (90.0)	2 (10.0)	5 (25.0)	7 (35.0)	4 (20.0)
Blood and lymphatic system disorders					
-Total	5 (25.0)	1 (5.0)	0	2 (10.0)	2 (10.0)
Neutropenia	3 (15.0)	0	0	1 (5.0)	2 (10.0)
Febrile neutropenia	2 (10.0)	0	0	2 (10.0)	0
Anaemia	1 (5.0)	1 (5.0)	0	0	0
Thrombocytopenia	1 (5.0)	0	0	1 (5.0)	0
Endocrine disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Adrenal insufficiency	1 (5.0)	1 (5.0)	0	0	0
Eye disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.0)	1 (5.0)	0	0	0
Ocular hyperaemia	1 (5.0)	1 (5.0)	0	0	0
Gastrointestinal disorders					
-Total	7 (35.0)	4 (20.0)	0	3 (15.0)	0
Vomiting	4 (20.0)	3 (15.0)	0	1 (5.0)	0
Diarrhoea	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Abdominal pain	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Nausea	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Oral pain	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Abdominal pain upper	1 (5.0)	1 (5.0)	0	0	0
Enterocolitis	1 (5.0)	0	0	1 (5.0)	0
General disorders and administration site conditions					
-Total	10 (50.0)	7 (35.0)	2 (10.0)	1 (5.0)	0
Pyrexia	6 (30.0)	4 (20.0)	1 (5.0)	1 (5.0)	0
Acquired gene mutation	1 (5.0)	1 (5.0)	0	0	0
Catheter site pain	1 (5.0)	0	1 (5.0)	0	0
Fatigue	1 (5.0)	1 (5.0)	0	0	0
Influenza like illness	1 (5.0)	1 (5.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	4 (20.0)	0	4 (20.0)	0	0
Hypogammaglobulinaemia	3 (15.0)	0	3 (15.0)	0	0
Graft versus host disease	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	11 (55.0)	1 (5.0)	5 (25.0)	4 (20.0)	1 (5.0)
Upper respiratory tract infection	3 (15.0)	0	3 (15.0)	0	0
Influenza	2 (10.0)	0	2 (10.0)	0	0
Bacterial sepsis	1 (5.0)	0	0	0	1 (5.0)
Cholecystitis infective	1 (5.0)	0	0	1 (5.0)	0
Corona virus infection	1 (5.0)	0	0	1 (5.0)	0
Ear infection	1 (5.0)	1 (5.0)	0	0	0
Herpes zoster	1 (5.0)	0	0	1 (5.0)	0
Respiratory syncytial virus infection	1 (5.0)	0	0	1 (5.0)	0
Rhinovirus infection	1 (5.0)	1 (5.0)	0	0	0
Tinea capitis	1 (5.0)	1 (5.0)	0	0	0
Vascular device infection	1 (5.0)	0	0	1 (5.0)	0
Viral infection	1 (5.0)	1 (5.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	3 (15.0)	0	3 (15.0)	0	0
Contusion	1 (5.0)	1 (5.0)	0	0	0
Foot fracture	1 (5.0)	0	1 (5.0)	0	0
Infusion related reaction	1 (5.0)	0	1 (5.0)	0	0
Procedural nausea	1 (5.0)	0	1 (5.0)	0	0
Skin laceration	1 (5.0)	0	1 (5.0)	0	0
Sunburn	1 (5.0)	1 (5.0)	0	0	0
Investigations					
-Total	9 (45.0)	2 (10.0)	1 (5.0)	3 (15.0)	3 (15.0)
Neutrophil count decreased	4 (20.0)	1 (5.0)	0	1 (5.0)	2 (10.0)
Lymphocyte count decreased	2 (10.0)	1 (5.0)	1 (5.0)	0	0
White blood cell count decreased	2 (10.0)	1 (5.0)	0	0	1 (5.0)
Alanine aminotransferase increased	1 (5.0)	0	0	1 (5.0)	0
Blood bilirubin increased	1 (5.0)	0	0	1 (5.0)	0
Blood magnesium decreased	1 (5.0)	1 (5.0)	0	0	0
Haemoglobin decreased	1 (5.0)	1 (5.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (5.0)	1 (5.0)	0	0	0
Transaminases increased	1 (5.0)	1 (5.0)	0	0	0
Weight decreased	1 (5.0)	1 (5.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Hyperphosphataemia	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	6 (30.0)	4 (20.0)	2 (10.0)	0	0
Pain in extremity	3 (15.0)	3 (15.0)	0	0	0
Arthralgia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Muscular weakness	1 (5.0)	1 (5.0)	0	0	0
Osteonecrosis	1 (5.0)	0	1 (5.0)	0	0
Pain in jaw	1 (5.0)	1 (5.0)	0	0	0
Nervous system disorders					
-Total	4 (20.0)	3 (15.0)	1 (5.0)	0	0
Headache	2 (10.0)	2 (10.0)	0	0	0
Peroneal nerve palsy	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Psychiatric disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Depression	2 (10.0)	2 (10.0)	0	0	0
Anxiety	1 (5.0)	1 (5.0)	0	0	0
Sleep disorder	1 (5.0)	0	1 (5.0)	0	0
Renal and urinary disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Urinary incontinence	1 (5.0)	1 (5.0)	0	0	0
Reproductive system and breast disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Vaginal haemorrhage	1 (5.0)	0	0	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (40.0)	4 (20.0)	2 (10.0)	2 (10.0)	0
Cough	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Nasal congestion	2 (10.0)	2 (10.0)	0	0	0
Rhinorrhoea	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Dysphonia	1 (5.0)	1 (5.0)	0	0	0
Epistaxis	1 (5.0)	0	0	1 (5.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	1 (5.0)	0	1 (5.0)	0	0
Pharyngeal erythema	1 (5.0)	1 (5.0)	0	0	0
Pharyngeal lesion	1 (5.0)	0	0	1 (5.0)	0
Pulmonary oedema	1 (5.0)	0	0	1 (5.0)	0
Rhinitis allergic	1 (5.0)	1 (5.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (35.0)	4 (20.0)	3 (15.0)	0	0
Erythema	2 (10.0)	2 (10.0)	0	0	0
Alopecia	1 (5.0)	0	1 (5.0)	0	0
Dermatitis atopic	1 (5.0)	1 (5.0)	0	0	0
Hyperhidrosis	1 (5.0)	1 (5.0)	0	0	0
Ingrowing nail	1 (5.0)	1 (5.0)	0	0	0
Keloid scar	1 (5.0)	0	1 (5.0)	0	0
Rash	1 (5.0)	0	1 (5.0)	0	0
Rash erythematous	1 (5.0)	0	1 (5.0)	0	0
Rash maculo-papular	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Hot flush	1 (5.0)	1 (5.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174n
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=36		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (77.8)	2 (5.6)	11 (30.6)	9 (25.0)	6 (16.7)
Blood and lymphatic system disorders					
-Total	6 (16.7)	0	3 (8.3)	1 (2.8)	2 (5.6)
Anaemia	1 (2.8)	0	0	1 (2.8)	0
Eosinophilia	1 (2.8)	0	0	1 (2.8)	0
Febrile neutropenia	1 (2.8)	0	0	1 (2.8)	0
Leukopenia	1 (2.8)	0	0	0	1 (2.8)
Lymphadenopathy	1 (2.8)	0	1 (2.8)	0	0
Lymphopenia	1 (2.8)	0	1 (2.8)	0	0
Neutropenia	1 (2.8)	0	0	0	1 (2.8)
Thrombocytopenia	1 (2.8)	0	1 (2.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=36		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	1 (2.8)	0	1 (2.8)	0	0
Sinus tachycardia	1 (2.8)	0	1 (2.8)	0	0
Eye disorders					
-Total	4 (11.1)	3 (8.3)	1 (2.8)	0	0
Dry eye	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Conjunctivitis allergic	1 (2.8)	1 (2.8)	0	0	0
Vision blurred	1 (2.8)	1 (2.8)	0	0	0
Gastrointestinal disorders					
-Total	9 (25.0)	5 (13.9)	3 (8.3)	1 (2.8)	0
Diarrhoea	5 (13.9)	4 (11.1)	1 (2.8)	0	0
Vomiting	5 (13.9)	2 (5.6)	2 (5.6)	1 (2.8)	0
Nausea	4 (11.1)	1 (2.8)	2 (5.6)	1 (2.8)	0
Abdominal pain	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Pigmentation lip	1 (2.8)	1 (2.8)	0	0	0
General disorders and administration site conditions					
-Total	7 (19.4)	6 (16.7)	1 (2.8)	0	0
Pyrexia	4 (11.1)	3 (8.3)	1 (2.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=36		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	1 (2.8)	1 (2.8)	0	0	0
Crying	1 (2.8)	1 (2.8)	0	0	0
Fatigue	1 (2.8)	1 (2.8)	0	0	0
Generalised oedema	1 (2.8)	1 (2.8)	0	0	0
Influenza like illness	1 (2.8)	1 (2.8)	0	0	0
Malaise	1 (2.8)	1 (2.8)	0	0	0
Oedema peripheral	1 (2.8)	1 (2.8)	0	0	0
Pain	1 (2.8)	1 (2.8)	0	0	0
Immune system disorders					
-Total	10 (27.8)	3 (8.3)	6 (16.7)	1 (2.8)	0
Hypogammaglobulinaemia	5 (13.9)	0	4 (11.1)	1 (2.8)	0
Immunodeficiency common variable	2 (5.6)	0	2 (5.6)	0	0
Seasonal allergy	2 (5.6)	2 (5.6)	0	0	0
Graft versus host disease	1 (2.8)	1 (2.8)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (2.8)	0	1 (2.8)	0	0
Infections and infestations					
-Total	22 (61.1)	5 (13.9)	10 (27.8)	6 (16.7)	1 (2.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	4 (11.1)	3 (8.3)	0	1 (2.8)	0
Urinary tract infection	4 (11.1)	0	2 (5.6)	2 (5.6)	0
Gastroenteritis	3 (8.3)	1 (2.8)	2 (5.6)	0	0
Parainfluenzae virus infection	2 (5.6)	1 (2.8)	0	1 (2.8)	0
Sinusitis	2 (5.6)	0	2 (5.6)	0	0
Viral upper respiratory tract infection	2 (5.6)	1 (2.8)	0	1 (2.8)	0
Cellulitis of male external genital organ	1 (2.8)	0	0	1 (2.8)	0
Cytomegalovirus infection	1 (2.8)	1 (2.8)	0	0	0
Ear infection	1 (2.8)	0	1 (2.8)	0	0
Enterovirus infection	1 (2.8)	0	0	1 (2.8)	0
Escherichia urinary tract infection	1 (2.8)	0	0	1 (2.8)	0
Gastroenteritis norovirus	1 (2.8)	0	1 (2.8)	0	0
Gastroenteritis viral	1 (2.8)	1 (2.8)	0	0	0
Influenza	1 (2.8)	0	1 (2.8)	0	0
Molluscum contagiosum	1 (2.8)	1 (2.8)	0	0	0
Oral herpes	1 (2.8)	0	1 (2.8)	0	0
Otitis externa	1 (2.8)	0	1 (2.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=36		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (2.8)	0	1 (2.8)	0	0
Otitis media acute	1 (2.8)	0	1 (2.8)	0	0
Paronychia	1 (2.8)	1 (2.8)	0	0	0
Rash pustular	1 (2.8)	0	1 (2.8)	0	0
Rhinitis	1 (2.8)	1 (2.8)	0	0	0
Rhinovirus infection	1 (2.8)	1 (2.8)	0	0	0
Rotavirus infection	1 (2.8)	0	0	1 (2.8)	0
Sepsis	1 (2.8)	0	0	0	1 (2.8)
Subcutaneous abscess	1 (2.8)	0	1 (2.8)	0	0
Vulvovaginal mycotic infection	1 (2.8)	0	1 (2.8)	0	0
Injury, poisoning and procedural complications					
-Total	5 (13.9)	3 (8.3)	2 (5.6)	0	0
Procedural pain	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Arthropod bite	1 (2.8)	1 (2.8)	0	0	0
Contusion	1 (2.8)	1 (2.8)	0	0	0
Infusion related reaction	1 (2.8)	1 (2.8)	0	0	0
Radius fracture	1 (2.8)	0	1 (2.8)	0	0
Skin abrasion	1 (2.8)	1 (2.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	14 (38.9)	4 (11.1)	4 (11.1)	5 (13.9)	1 (2.8)
Neutrophil count decreased	4 (11.1)	1 (2.8)	0	2 (5.6)	1 (2.8)
Aspartate aminotransferase increased	3 (8.3)	1 (2.8)	0	2 (5.6)	0
Weight decreased	3 (8.3)	0	3 (8.3)	0	0
White blood cell count decreased	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Platelet count decreased	2 (5.6)	2 (5.6)	0	0	0
Weight increased	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Alanine aminotransferase increased	1 (2.8)	0	0	1 (2.8)	0
Blood creatinine increased	1 (2.8)	1 (2.8)	0	0	0
Blood urea increased	1 (2.8)	1 (2.8)	0	0	0
Blood uric acid increased	1 (2.8)	1 (2.8)	0	0	0
Haemoglobin decreased	1 (2.8)	1 (2.8)	0	0	0
Oxygen saturation decreased	1 (2.8)	1 (2.8)	0	0	0
Serum ferritin increased	1 (2.8)	0	1 (2.8)	0	0
Metabolism and nutrition disorders					
-Total	9 (25.0)	4 (11.1)	1 (2.8)	3 (8.3)	1 (2.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=36		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Hypokalaemia	2 (5.6)	1 (2.8)	0	0	1 (2.8)
Dehydration	1 (2.8)	0	0	1 (2.8)	0
Hyperalbuminaemia	1 (2.8)	1 (2.8)	0	0	0
Hypercalcaemia	1 (2.8)	1 (2.8)	0	0	0
Hyperglycaemia	1 (2.8)	0	0	1 (2.8)	0
Hyperphosphataemia	1 (2.8)	1 (2.8)	0	0	0
Hypophosphataemia	1 (2.8)	0	0	1 (2.8)	0
Iron overload	1 (2.8)	0	0	1 (2.8)	0
Tumour lysis syndrome	1 (2.8)	0	0	1 (2.8)	0
Vitamin d deficiency	1 (2.8)	1 (2.8)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	10 (27.8)	7 (19.4)	3 (8.3)	0	0
Pain in extremity	5 (13.9)	3 (8.3)	2 (5.6)	0	0
Joint range of motion decreased	2 (5.6)	2 (5.6)	0	0	0
Back pain	1 (2.8)	1 (2.8)	0	0	0
Flank pain	1 (2.8)	0	1 (2.8)	0	0
Muscle spasms	1 (2.8)	1 (2.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=36		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	1 (2.8)	1 (2.8)	0	0	0
Musculoskeletal chest pain	1 (2.8)	1 (2.8)	0	0	0
Toe walking	1 (2.8)	1 (2.8)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.8)	0	1 (2.8)	0	0
Myelodysplastic syndrome	1 (2.8)	0	1 (2.8)	0	0
Nervous system disorders					
-Total	4 (11.1)	3 (8.3)	1 (2.8)	0	0
Dizziness	3 (8.3)	3 (8.3)	0	0	0
Headache	3 (8.3)	2 (5.6)	1 (2.8)	0	0
Renal and urinary disorders					
-Total	2 (5.6)	0	0	2 (5.6)	0
Acute kidney injury	1 (2.8)	0	0	1 (2.8)	0
Calculus urinary	1 (2.8)	0	1 (2.8)	0	0
Haematuria	1 (2.8)	0	0	1 (2.8)	0
Nephrolithiasis	1 (2.8)	0	0	1 (2.8)	0
Reproductive system and breast disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.8)	0	1 (2.8)	0	0
Scrotal pain	1 (2.8)	0	1 (2.8)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (27.8)	7 (19.4)	2 (5.6)	0	1 (2.8)
Cough	4 (11.1)	3 (8.3)	1 (2.8)	0	0
Nasal congestion	2 (5.6)	2 (5.6)	0	0	0
Oropharyngeal pain	2 (5.6)	2 (5.6)	0	0	0
Rhinitis allergic	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Rhinorrhoea	2 (5.6)	2 (5.6)	0	0	0
Acute respiratory failure	1 (2.8)	0	0	0	1 (2.8)
Epistaxis	1 (2.8)	1 (2.8)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (25.0)	6 (16.7)	2 (5.6)	1 (2.8)	0
Rash	3 (8.3)	1 (2.8)	2 (5.6)	0	0
Dermatitis	1 (2.8)	1 (2.8)	0	0	0
Dermatitis acneiform	1 (2.8)	0	0	1 (2.8)	0
Dry skin	1 (2.8)	1 (2.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=36		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eczema	1 (2.8)	1 (2.8)	0	0	0
Macule	1 (2.8)	1 (2.8)	0	0	0
Papule	1 (2.8)	1 (2.8)	0	0	0
Petechiae	1 (2.8)	1 (2.8)	0	0	0
Pruritus	1 (2.8)	1 (2.8)	0	0	0
Rash maculo-papular	1 (2.8)	1 (2.8)	0	0	0
Rash pruritic	1 (2.8)	1 (2.8)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174n
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (78.6)	3 (21.4)	3 (21.4)	3 (21.4)	2 (14.3)
Blood and lymphatic system disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Thrombocytopenia	1 (7.1)	1 (7.1)	0	0	0
Ear and labyrinth disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0
Tympanic membrane perforation	1 (7.1)	0	1 (7.1)	0	0
Infections and infestations					
-Total	5 (35.7)	2 (14.3)	2 (14.3)	1 (7.1)	0
Sinusitis	2 (14.3)	0	2 (14.3)	0	0
Upper respiratory tract infection	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Gingivitis	1 (7.1)	1 (7.1)	0	0	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophilus infection	1 (7.1)	0	1 (7.1)	0	0
Otitis media	1 (7.1)	0	0	1 (7.1)	0
Otitis media acute	1 (7.1)	0	1 (7.1)	0	0
Pneumonia	1 (7.1)	0	1 (7.1)	0	0
Skin infection	1 (7.1)	0	1 (7.1)	0	0
Viral infection	1 (7.1)	1 (7.1)	0	0	0
Investigations					
-Total	7 (50.0)	1 (7.1)	2 (14.3)	3 (21.4)	1 (7.1)
Lymphocyte count decreased	3 (21.4)	2 (14.3)	0	1 (7.1)	0
White blood cell count decreased	3 (21.4)	1 (7.1)	0	1 (7.1)	1 (7.1)
Alanine aminotransferase increased	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Neutrophil count decreased	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Aspartate aminotransferase increased	1 (7.1)	0	0	1 (7.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (7.1)	0	0	0	1 (7.1)
Glioblastoma multiforme	1 (7.1)	0	0	0	1 (7.1)
Nervous system disorders					

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Disturbance in attention	1 (7.1)	1 (7.1)	0	0	0
Seizure	1 (7.1)	0	0	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Cough	1 (7.1)	1 (7.1)	0	0	0
Rhinitis allergic	1 (7.1)	1 (7.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (14.3)	2 (14.3)	0	0	0
Acne	1 (7.1)	1 (7.1)	0	0	0
Papule	1 (7.1)	1 (7.1)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174n
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (55.0)	1 (5.0)	3 (15.0)	5 (25.0)	2 (10.0)
Blood and lymphatic system disorders					
-Total	1 (5.0)	0	0	0	1 (5.0)
Febrile neutropenia	1 (5.0)	0	0	0	1 (5.0)
Gastrointestinal disorders					
-Total	3 (15.0)	0	3 (15.0)	0	0
Diarrhoea	2 (10.0)	0	2 (10.0)	0	0
Abdominal pain	1 (5.0)	0	1 (5.0)	0	0
Nausea	1 (5.0)	0	1 (5.0)	0	0
General disorders and administration site conditions					
-Total	2 (10.0)	0	1 (5.0)	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	1 (5.0)	0	1 (5.0)	0	0
Cyst	1 (5.0)	0	0	1 (5.0)	0
Pyrexia	1 (5.0)	0	1 (5.0)	0	0
Immune system disorders					
-Total	2 (10.0)	0	2 (10.0)	0	0
Chronic graft versus host disease	1 (5.0)	0	1 (5.0)	0	0
Immunodeficiency	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	6 (30.0)	0	3 (15.0)	2 (10.0)	1 (5.0)
Otitis media	2 (10.0)	0	2 (10.0)	0	0
Urinary tract infection	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Campylobacter infection	1 (5.0)	0	0	1 (5.0)	0
Cellulitis of male external genital organ	1 (5.0)	0	0	1 (5.0)	0
Clostridium difficile infection	1 (5.0)	0	0	1 (5.0)	0
Meningitis aseptic	1 (5.0)	0	1 (5.0)	0	0
Otitis media acute	1 (5.0)	0	1 (5.0)	0	0
Pneumonia	1 (5.0)	0	1 (5.0)	0	0
Respiratory tract infection	1 (5.0)	0	0	0	1 (5.0)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (5.0)	0	0	1 (5.0)	0
Sinusitis	1 (5.0)	0	1 (5.0)	0	0
Vulvovaginal candidiasis	1 (5.0)	0	1 (5.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (5.0)	0	0	1 (5.0)	0
Procedural pain	1 (5.0)	0	0	1 (5.0)	0
Investigations					
-Total	1 (5.0)	0	0	1 (5.0)	0
Alanine aminotransferase increased	1 (5.0)	0	0	1 (5.0)	0
Aspartate aminotransferase increased	1 (5.0)	1 (5.0)	0	0	0
Blood alkaline phosphatase increased	1 (5.0)	1 (5.0)	0	0	0
Blood lactate dehydrogenase increased	1 (5.0)	1 (5.0)	0	0	0
C-reactive protein increased	1 (5.0)	1 (5.0)	0	0	0
Platelet count decreased	1 (5.0)	0	0	1 (5.0)	0
White blood cell count decreased	1 (5.0)	0	0	1 (5.0)	0
Metabolism and nutrition disorders					

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Hypokalaemia	1 (5.0)	0	0	1 (5.0)	0
Vitamin d deficiency	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Neck pain	1 (5.0)	0	1 (5.0)	0	0
Nervous system disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Dizziness	1 (5.0)	1 (5.0)	0	0	0
Headache	1 (5.0)	0	1 (5.0)	0	0
Renal and urinary disorders					
-Total	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Acute kidney injury	1 (5.0)	0	0	1 (5.0)	0
Haematuria	1 (5.0)	1 (5.0)	0	0	0
Reproductive system and breast disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Ovarian failure	1 (5.0)	0	0	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	3 (15.0)	3 (15.0)	0	0	0
Cough	1 (5.0)	1 (5.0)	0	0	0
Epistaxis	1 (5.0)	1 (5.0)	0	0	0
Oropharyngeal pain	1 (5.0)	1 (5.0)	0	0	0
Rhinorrhoea	1 (5.0)	1 (5.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Pruritus	1 (5.0)	1 (5.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174n
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (100)	0	0	6 (30.0)	14 (70.0)
Blood and lymphatic system disorders					
-Total	16 (80.0)	0	0	12 (60.0)	4 (20.0)
Anaemia	9 (45.0)	2 (10.0)	2 (10.0)	5 (25.0)	0
Febrile neutropenia	9 (45.0)	0	0	9 (45.0)	0
Neutropenia	5 (25.0)	0	0	2 (10.0)	3 (15.0)
Disseminated intravascular coagulation	1 (5.0)	0	1 (5.0)	0	0
Lymphopenia	1 (5.0)	0	0	1 (5.0)	0
Pancytopenia	1 (5.0)	0	0	0	1 (5.0)
Thrombocytopenia	1 (5.0)	0	0	1 (5.0)	0
Cardiac disorders					

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Tachycardia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Sinus bradycardia	1 (5.0)	1 (5.0)	0	0	0
Ear and labyrinth disorders					
-Total	2 (10.0)	0	2 (10.0)	0	0
Hypoacusis	1 (5.0)	0	1 (5.0)	0	0
Tympanic membrane perforation	1 (5.0)	0	1 (5.0)	0	0
Endocrine disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Adrenal insufficiency	1 (5.0)	1 (5.0)	0	0	0
Eye disorders					
-Total	4 (20.0)	3 (15.0)	1 (5.0)	0	0
Eye pain	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Ocular hyperaemia	1 (5.0)	1 (5.0)	0	0	0
Retinal haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Vision blurred	1 (5.0)	1 (5.0)	0	0	0
Gastrointestinal disorders					
-Total	15 (75.0)	6 (30.0)	6 (30.0)	3 (15.0)	0
Vomiting	10 (50.0)	7 (35.0)	2 (10.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	8 (40.0)	3 (15.0)	4 (20.0)	1 (5.0)	0
Diarrhoea	5 (25.0)	2 (10.0)	2 (10.0)	1 (5.0)	0
Abdominal pain	4 (20.0)	2 (10.0)	1 (5.0)	1 (5.0)	0
Constipation	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Abdominal pain upper	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Oral pain	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Anal incontinence	1 (5.0)	1 (5.0)	0	0	0
Dyspepsia	1 (5.0)	0	1 (5.0)	0	0
Enterocolitis	1 (5.0)	0	0	1 (5.0)	0
Gastrointestinal haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Haematemesis	1 (5.0)	1 (5.0)	0	0	0
Intestinal obstruction	1 (5.0)	0	0	1 (5.0)	0
Lip pain	1 (5.0)	0	1 (5.0)	0	0
Stomatitis	1 (5.0)	0	1 (5.0)	0	0
General disorders and administration site conditions					
-Total	14 (70.0)	8 (40.0)	3 (15.0)	3 (15.0)	0
Pyrexia	8 (40.0)	4 (20.0)	2 (10.0)	2 (10.0)	0
Fatigue	5 (25.0)	5 (25.0)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site pain	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Chills	2 (10.0)	2 (10.0)	0	0	0
Pain	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Acquired gene mutation	1 (5.0)	1 (5.0)	0	0	0
Influenza like illness	1 (5.0)	1 (5.0)	0	0	0
Non-cardiac chest pain	1 (5.0)	1 (5.0)	0	0	0
Hepatobiliary disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Hepatomegaly	1 (5.0)	1 (5.0)	0	0	0
Hyperbilirubinaemia	1 (5.0)	0	1 (5.0)	0	0
Immune system disorders					
-Total	17 (85.0)	0	11 (55.0)	4 (20.0)	2 (10.0)
Cytokine release syndrome	16 (80.0)	0	11 (55.0)	3 (15.0)	2 (10.0)
Hypogammaglobulinaemia	12 (60.0)	1 (5.0)	10 (50.0)	1 (5.0)	0
Drug hypersensitivity	1 (5.0)	0	1 (5.0)	0	0
Graft versus host disease	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	15 (75.0)	3 (15.0)	6 (30.0)	5 (25.0)	1 (5.0)
Upper respiratory tract infection	5 (25.0)	1 (5.0)	4 (20.0)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Gastroenteritis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Influenza	2 (10.0)	0	2 (10.0)	0	0
Sinusitis	2 (10.0)	0	2 (10.0)	0	0
Acute sinusitis	1 (5.0)	0	1 (5.0)	0	0
Bacterial sepsis	1 (5.0)	0	0	0	1 (5.0)
Cholecystitis infective	1 (5.0)	0	0	1 (5.0)	0
Clostridium difficile colitis	1 (5.0)	0	1 (5.0)	0	0
Corona virus infection	1 (5.0)	0	0	1 (5.0)	0
Ear infection	1 (5.0)	1 (5.0)	0	0	0
Folliculitis	1 (5.0)	0	1 (5.0)	0	0
Fungal skin infection	1 (5.0)	1 (5.0)	0	0	0
Gingivitis	1 (5.0)	1 (5.0)	0	0	0
Haemophilus infection	1 (5.0)	0	1 (5.0)	0	0
Herpes simplex	1 (5.0)	1 (5.0)	0	0	0
Herpes zoster	1 (5.0)	0	0	1 (5.0)	0
Oral candidiasis	1 (5.0)	1 (5.0)	0	0	0
Orchitis	1 (5.0)	1 (5.0)	0	0	0
Otitis media	1 (5.0)	0	0	1 (5.0)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media acute	1 (5.0)	0	1 (5.0)	0	0
Pharyngitis	1 (5.0)	0	1 (5.0)	0	0
Pneumonia	1 (5.0)	0	1 (5.0)	0	0
Respiratory syncytial virus infection	1 (5.0)	0	0	1 (5.0)	0
Rhinovirus infection	1 (5.0)	1 (5.0)	0	0	0
Skin infection	1 (5.0)	0	1 (5.0)	0	0
Streptococcal infection	1 (5.0)	0	1 (5.0)	0	0
Tinea capitis	1 (5.0)	1 (5.0)	0	0	0
Urinary tract infection enterococcal	1 (5.0)	0	0	1 (5.0)	0
Vascular device infection	1 (5.0)	0	0	1 (5.0)	0
Vulvovaginal candidiasis	1 (5.0)	1 (5.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	4 (20.0)	0	4 (20.0)	0	0
Contusion	1 (5.0)	1 (5.0)	0	0	0
Foot fracture	1 (5.0)	0	1 (5.0)	0	0
Infusion related reaction	1 (5.0)	0	1 (5.0)	0	0
Procedural nausea	1 (5.0)	0	1 (5.0)	0	0
Procedural pain	1 (5.0)	0	1 (5.0)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin laceration	1 (5.0)	0	1 (5.0)	0	0
Sunburn	1 (5.0)	1 (5.0)	0	0	0
Investigations					
-Total	19 (95.0)	0	2 (10.0)	5 (25.0)	12 (60.0)
White blood cell count decreased	12 (60.0)	2 (10.0)	0	3 (15.0)	7 (35.0)
Neutrophil count decreased	10 (50.0)	1 (5.0)	0	2 (10.0)	7 (35.0)
Lymphocyte count decreased	8 (40.0)	1 (5.0)	1 (5.0)	3 (15.0)	3 (15.0)
Aspartate aminotransferase increased	6 (30.0)	0	3 (15.0)	2 (10.0)	1 (5.0)
Platelet count decreased	6 (30.0)	2 (10.0)	0	1 (5.0)	3 (15.0)
Alanine aminotransferase increased	5 (25.0)	1 (5.0)	1 (5.0)	3 (15.0)	0
Blood bilirubin increased	4 (20.0)	2 (10.0)	0	2 (10.0)	0
Blood creatinine increased	3 (15.0)	3 (15.0)	0	0	0
International normalised ratio increased	3 (15.0)	3 (15.0)	0	0	0
Prothrombin time prolonged	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Activated partial thromboplastin time prolonged	1 (5.0)	0	1 (5.0)	0	0
Blood immunoglobulin a decreased	1 (5.0)	1 (5.0)	0	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactic acid increased	1 (5.0)	0	0	0	1 (5.0)
Blood magnesium decreased	1 (5.0)	1 (5.0)	0	0	0
Blood phosphorus increased	1 (5.0)	1 (5.0)	0	0	0
Cardiac murmur	1 (5.0)	1 (5.0)	0	0	0
Culture stool positive	1 (5.0)	1 (5.0)	0	0	0
Fibrin d dimer increased	1 (5.0)	1 (5.0)	0	0	0
Haemoglobin decreased	1 (5.0)	1 (5.0)	0	0	0
Serum ferritin increased	1 (5.0)	0	1 (5.0)	0	0
Transaminases increased	1 (5.0)	1 (5.0)	0	0	0
Weight decreased	1 (5.0)	1 (5.0)	0	0	0
Metabolism and nutrition disorders					
-Total	10 (50.0)	1 (5.0)	1 (5.0)	7 (35.0)	1 (5.0)
Decreased appetite	5 (25.0)	1 (5.0)	1 (5.0)	3 (15.0)	0
Dehydration	2 (10.0)	0	0	2 (10.0)	0
Hyperphosphataemia	2 (10.0)	2 (10.0)	0	0	0
Hypophosphataemia	2 (10.0)	0	0	2 (10.0)	0
Fluid overload	1 (5.0)	1 (5.0)	0	0	0
Hyperuricaemia	1 (5.0)	0	0	0	1 (5.0)
Hypokalaemia	1 (5.0)	0	0	1 (5.0)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyponatraemia	1 (5.0)	0	0	1 (5.0)	0
Musculoskeletal and connective tissue disorders					
-Total	8 (40.0)	4 (20.0)	3 (15.0)	1 (5.0)	0
Pain in extremity	5 (25.0)	3 (15.0)	2 (10.0)	0	0
Arthralgia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Myalgia	2 (10.0)	2 (10.0)	0	0	0
Muscular weakness	1 (5.0)	1 (5.0)	0	0	0
Osteonecrosis	1 (5.0)	0	1 (5.0)	0	0
Pain in jaw	1 (5.0)	1 (5.0)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (5.0)	0	0	0	1 (5.0)
Glioblastoma multiforme	1 (5.0)	0	0	0	1 (5.0)
Nervous system disorders					
-Total	11 (55.0)	5 (25.0)	4 (20.0)	2 (10.0)	0
Headache	6 (30.0)	4 (20.0)	1 (5.0)	1 (5.0)	0
Encephalopathy	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Peroneal nerve palsy	2 (10.0)	1 (5.0)	1 (5.0)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Disturbance in attention	1 (5.0)	1 (5.0)	0	0	0
Myoclonus	1 (5.0)	1 (5.0)	0	0	0
Tremor	1 (5.0)	1 (5.0)	0	0	0
Psychiatric disorders					
-Total	5 (25.0)	2 (10.0)	3 (15.0)	0	0
Anxiety	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Depression	2 (10.0)	2 (10.0)	0	0	0
Confusional state	1 (5.0)	1 (5.0)	0	0	0
Delirium	1 (5.0)	1 (5.0)	0	0	0
Mental status changes	1 (5.0)	1 (5.0)	0	0	0
Panic attack	1 (5.0)	0	1 (5.0)	0	0
Sleep disorder	1 (5.0)	0	1 (5.0)	0	0
Renal and urinary disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Urinary incontinence	1 (5.0)	1 (5.0)	0	0	0
Reproductive system and breast disorders					
-Total	2 (10.0)	1 (5.0)	0	1 (5.0)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal haemorrhage	1 (5.0)	0	0	1 (5.0)	0
Vulvovaginal adhesion	1 (5.0)	1 (5.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (55.0)	4 (20.0)	5 (25.0)	2 (10.0)	0
Cough	5 (25.0)	4 (20.0)	1 (5.0)	0	0
Hypoxia	3 (15.0)	0	3 (15.0)	0	0
Nasal congestion	3 (15.0)	3 (15.0)	0	0	0
Rhinitis allergic	2 (10.0)	2 (10.0)	0	0	0
Rhinorrhoea	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Atelectasis	1 (5.0)	1 (5.0)	0	0	0
Dysphonia	1 (5.0)	1 (5.0)	0	0	0
Epistaxis	1 (5.0)	0	0	1 (5.0)	0
Oropharyngeal pain	1 (5.0)	0	1 (5.0)	0	0
Pharyngeal erythema	1 (5.0)	1 (5.0)	0	0	0
Pharyngeal lesion	1 (5.0)	0	0	1 (5.0)	0
Pharyngeal ulceration	1 (5.0)	0	1 (5.0)	0	0
Pleural effusion	1 (5.0)	1 (5.0)	0	0	0
Pulmonary oedema	1 (5.0)	0	0	1 (5.0)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory depression	1 (5.0)	0	1 (5.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (55.0)	7 (35.0)	3 (15.0)	1 (5.0)	0
Erythema	4 (20.0)	4 (20.0)	0	0	0
Dry skin	2 (10.0)	2 (10.0)	0	0	0
Ingrowing nail	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Rash maculo-papular	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Acne	1 (5.0)	1 (5.0)	0	0	0
Alopecia	1 (5.0)	0	1 (5.0)	0	0
Dermatitis atopic	1 (5.0)	1 (5.0)	0	0	0
Dermatitis diaper	1 (5.0)	1 (5.0)	0	0	0
Hyperhidrosis	1 (5.0)	1 (5.0)	0	0	0
Keloid scar	1 (5.0)	0	1 (5.0)	0	0
Livedo reticularis	1 (5.0)	1 (5.0)	0	0	0
Papule	1 (5.0)	1 (5.0)	0	0	0
Rash	1 (5.0)	0	1 (5.0)	0	0
Rash erythematous	1 (5.0)	0	1 (5.0)	0	0
Vascular disorders					

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (30.0)	0	1 (5.0)	4 (20.0)	1 (5.0)
Hypertension	4 (20.0)	1 (5.0)	3 (15.0)	0	0
Hypotension	4 (20.0)	0	0	3 (15.0)	1 (5.0)
Embolism	1 (5.0)	0	0	1 (5.0)	0
Hot flush	1 (5.0)	1 (5.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174n
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=44		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	44 (100)	0	5 (11.4)	6 (13.6)	33 (75.0)
Blood and lymphatic system disorders					
-Total	32 (72.7)	2 (4.5)	3 (6.8)	15 (34.1)	12 (27.3)
Anaemia	18 (40.9)	1 (2.3)	2 (4.5)	14 (31.8)	1 (2.3)
Febrile neutropenia	15 (34.1)	0	0	14 (31.8)	1 (2.3)
Thrombocytopenia	9 (20.5)	0	1 (2.3)	2 (4.5)	6 (13.6)
Neutropenia	6 (13.6)	0	0	1 (2.3)	5 (11.4)
Disseminated intravascular coagulation	3 (6.8)	0	1 (2.3)	2 (4.5)	0
Lymphopenia	3 (6.8)	0	2 (4.5)	0	1 (2.3)
Coagulopathy	1 (2.3)	1 (2.3)	0	0	0
Eosinophilia	1 (2.3)	0	0	1 (2.3)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (2.3)	0	0	0	1 (2.3)
Lymphadenopathy	1 (2.3)	0	1 (2.3)	0	0
Cardiac disorders					
-Total	21 (47.7)	10 (22.7)	9 (20.5)	2 (4.5)	0
Tachycardia	13 (29.5)	7 (15.9)	4 (9.1)	2 (4.5)	0
Sinus tachycardia	6 (13.6)	3 (6.8)	3 (6.8)	0	0
Pericardial effusion	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Atrioventricular block second degree	1 (2.3)	1 (2.3)	0	0	0
Bradycardia	1 (2.3)	0	1 (2.3)	0	0
Cardiac dysfunction	1 (2.3)	1 (2.3)	0	0	0
Left ventricular dysfunction	1 (2.3)	0	0	1 (2.3)	0
Palpitations	1 (2.3)	1 (2.3)	0	0	0
Ventricular tachycardia	1 (2.3)	0	1 (2.3)	0	0
Ear and labyrinth disorders					
-Total	2 (4.5)	2 (4.5)	0	0	0
Ear pain	2 (4.5)	2 (4.5)	0	0	0
Endocrine disorders					
-Total	1 (2.3)	0	1 (2.3)	0	0
Adrenal insufficiency	1 (2.3)	0	1 (2.3)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	14 (31.8)	7 (15.9)	7 (15.9)	0	0
Periorbital oedema	4 (9.1)	3 (6.8)	1 (2.3)	0	0
Conjunctival haemorrhage	3 (6.8)	3 (6.8)	0	0	0
Vision blurred	3 (6.8)	1 (2.3)	2 (4.5)	0	0
Dry eye	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Photophobia	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Uveitis	2 (4.5)	0	2 (4.5)	0	0
Conjunctivitis allergic	1 (2.3)	1 (2.3)	0	0	0
Eye pain	1 (2.3)	0	1 (2.3)	0	0
Ocular hypertension	1 (2.3)	0	1 (2.3)	0	0
Papilloedema	1 (2.3)	0	1 (2.3)	0	0
Retinal haemorrhage	1 (2.3)	1 (2.3)	0	0	0
Visual impairment	1 (2.3)	0	1 (2.3)	0	0
Gastrointestinal disorders					
-Total	28 (63.6)	7 (15.9)	11 (25.0)	10 (22.7)	0
Diarrhoea	19 (43.2)	11 (25.0)	7 (15.9)	1 (2.3)	0
Nausea	17 (38.6)	3 (6.8)	10 (22.7)	4 (9.1)	0
Vomiting	17 (38.6)	9 (20.5)	6 (13.6)	2 (4.5)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	7 (15.9)	4 (9.1)	3 (6.8)	0	0
Constipation	4 (9.1)	4 (9.1)	0	0	0
Abdominal distension	2 (4.5)	0	2 (4.5)	0	0
Dysphagia	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Pancreatitis	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Abdominal discomfort	1 (2.3)	1 (2.3)	0	0	0
Abdominal pain lower	1 (2.3)	0	1 (2.3)	0	0
Abdominal pain upper	1 (2.3)	0	1 (2.3)	0	0
Abdominal tenderness	1 (2.3)	1 (2.3)	0	0	0
Ascites	1 (2.3)	0	0	1 (2.3)	0
Flatulence	1 (2.3)	1 (2.3)	0	0	0
Gastrooesophageal reflux disease	1 (2.3)	1 (2.3)	0	0	0
Glossodynia	1 (2.3)	1 (2.3)	0	0	0
Haematemesis	1 (2.3)	1 (2.3)	0	0	0
Ileus	1 (2.3)	0	0	1 (2.3)	0
Mouth haemorrhage	1 (2.3)	0	0	1 (2.3)	0
Pigmentation lip	1 (2.3)	1 (2.3)	0	0	0
Stomatitis	1 (2.3)	1 (2.3)	0	0	0
Tooth socket haemorrhage	1 (2.3)	1 (2.3)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	28 (63.6)	8 (18.2)	11 (25.0)	8 (18.2)	1 (2.3)
Pyrexia	17 (38.6)	4 (9.1)	8 (18.2)	4 (9.1)	1 (2.3)
Fatigue	10 (22.7)	7 (15.9)	2 (4.5)	1 (2.3)	0
Chills	8 (18.2)	7 (15.9)	1 (2.3)	0	0
Malaise	4 (9.1)	1 (2.3)	3 (6.8)	0	0
Generalised oedema	3 (6.8)	1 (2.3)	2 (4.5)	0	0
Oedema peripheral	3 (6.8)	2 (4.5)	0	1 (2.3)	0
Catheter site pain	2 (4.5)	0	2 (4.5)	0	0
Face oedema	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Pain	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Asthenia	1 (2.3)	1 (2.3)	0	0	0
Catheter site extravasation	1 (2.3)	0	1 (2.3)	0	0
Catheter site haemorrhage	1 (2.3)	1 (2.3)	0	0	0
Crying	1 (2.3)	1 (2.3)	0	0	0
Cyst	1 (2.3)	0	0	1 (2.3)	0
Facial pain	1 (2.3)	0	1 (2.3)	0	0
Influenza like illness	1 (2.3)	1 (2.3)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injection site haematoma	1 (2.3)	1 (2.3)	0	0	0
Localised oedema	1 (2.3)	0	0	1 (2.3)	0
Mucosal haemorrhage	1 (2.3)	0	1 (2.3)	0	0
Multiple organ dysfunction syndrome	1 (2.3)	0	0	1 (2.3)	0
Peripheral swelling	1 (2.3)	0	1 (2.3)	0	0
Physical deconditioning	1 (2.3)	0	0	1 (2.3)	0
Hepatobiliary disorders					
-Total	5 (11.4)	2 (4.5)	1 (2.3)	2 (4.5)	0
Hepatomegaly	2 (4.5)	0	2 (4.5)	0	0
Hyperbilirubinaemia	2 (4.5)	0	0	2 (4.5)	0
Gallbladder enlargement	1 (2.3)	1 (2.3)	0	0	0
Hepatosplenomegaly	1 (2.3)	1 (2.3)	0	0	0
Immune system disorders					
-Total	41 (93.2)	5 (11.4)	20 (45.5)	7 (15.9)	9 (20.5)
Cytokine release syndrome	34 (77.3)	6 (13.6)	14 (31.8)	5 (11.4)	9 (20.5)
Hypogammaglobulinaemia	20 (45.5)	2 (4.5)	14 (31.8)	4 (9.1)	0
Immunodeficiency common variable	2 (4.5)	0	2 (4.5)	0	0
Seasonal allergy	2 (4.5)	2 (4.5)	0	0	0
Chronic graft versus host disease	1 (2.3)	0	1 (2.3)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease	1 (2.3)	1 (2.3)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (2.3)	0	1 (2.3)	0	0
Graft versus host disease in skin	1 (2.3)	1 (2.3)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (2.3)	0	1 (2.3)	0	0
Immunodeficiency	1 (2.3)	0	1 (2.3)	0	0
Infections and infestations					
-Total	31 (70.5)	4 (9.1)	15 (34.1)	9 (20.5)	3 (6.8)
Clostridium difficile infection	5 (11.4)	0	4 (9.1)	1 (2.3)	0
Urinary tract infection	5 (11.4)	0	3 (6.8)	2 (4.5)	0
Rhinovirus infection	4 (9.1)	4 (9.1)	0	0	0
Upper respiratory tract infection	4 (9.1)	3 (6.8)	0	1 (2.3)	0
Clostridium difficile colitis	3 (6.8)	1 (2.3)	1 (2.3)	1 (2.3)	0
Gastroenteritis	3 (6.8)	1 (2.3)	2 (4.5)	0	0
Otitis media	3 (6.8)	0	3 (6.8)	0	0
Pneumonia	3 (6.8)	0	2 (4.5)	1 (2.3)	0
Viral upper respiratory tract infection	3 (6.8)	1 (2.3)	1 (2.3)	1 (2.3)	0
Cytomegalovirus infection	2 (4.5)	2 (4.5)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Parainfluenzae virus infection	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Sinusitis	2 (4.5)	0	2 (4.5)	0	0
Staphylococcal infection	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Body tinea	1 (2.3)	1 (2.3)	0	0	0
Campylobacter infection	1 (2.3)	0	0	1 (2.3)	0
Catheter site cellulitis	1 (2.3)	1 (2.3)	0	0	0
Catheter site infection	1 (2.3)	0	0	1 (2.3)	0
Cellulitis of male external genital organ	1 (2.3)	0	0	1 (2.3)	0
Ear infection	1 (2.3)	0	1 (2.3)	0	0
Enterococcal infection	1 (2.3)	1 (2.3)	0	0	0
Enterovirus infection	1 (2.3)	0	0	1 (2.3)	0
Escherichia urinary tract infection	1 (2.3)	0	0	1 (2.3)	0
Gastroenteritis norovirus	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis viral	1 (2.3)	1 (2.3)	0	0	0
Human herpesvirus 6 infection	1 (2.3)	0	1 (2.3)	0	0
Hypopyon	1 (2.3)	0	1 (2.3)	0	0
Meningitis aseptic	1 (2.3)	0	1 (2.3)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Molluscum contagiosum	1 (2.3)	1 (2.3)	0	0	0
Oral herpes	1 (2.3)	0	1 (2.3)	0	0
Otitis externa	1 (2.3)	0	1 (2.3)	0	0
Otitis media acute	1 (2.3)	0	1 (2.3)	0	0
Paronychia	1 (2.3)	1 (2.3)	0	0	0
Rash pustular	1 (2.3)	0	1 (2.3)	0	0
Respiratory tract infection	1 (2.3)	0	0	0	1 (2.3)
Respiratory tract infection viral	1 (2.3)	0	0	1 (2.3)	0
Rhinitis	1 (2.3)	1 (2.3)	0	0	0
Rotavirus infection	1 (2.3)	0	0	1 (2.3)	0
Sepsis	1 (2.3)	0	0	0	1 (2.3)
Septic embolus	1 (2.3)	0	0	0	1 (2.3)
Skin infection	1 (2.3)	0	1 (2.3)	0	0
Subcutaneous abscess	1 (2.3)	0	1 (2.3)	0	0
Vulvovaginal candidiasis	1 (2.3)	0	1 (2.3)	0	0
Vulvovaginal mycotic infection	1 (2.3)	0	1 (2.3)	0	0
Injury, poisoning and procedural complications					
-Total	18 (40.9)	11 (25.0)	4 (9.1)	2 (4.5)	1 (2.3)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural pain	4 (9.1)	2 (4.5)	1 (2.3)	1 (2.3)	0
Infusion related reaction	3 (6.8)	1 (2.3)	2 (4.5)	0	0
Transfusion reaction	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Contusion	2 (4.5)	2 (4.5)	0	0	0
Skin abrasion	2 (4.5)	2 (4.5)	0	0	0
Arthropod bite	1 (2.3)	1 (2.3)	0	0	0
Incision site pain	1 (2.3)	1 (2.3)	0	0	0
Limb injury	1 (2.3)	1 (2.3)	0	0	0
Mouth injury	1 (2.3)	1 (2.3)	0	0	0
Post procedural haemorrhage	1 (2.3)	1 (2.3)	0	0	0
Procedural complication	1 (2.3)	1 (2.3)	0	0	0
Procedural headache	1 (2.3)	0	1 (2.3)	0	0
Procedural site reaction	1 (2.3)	1 (2.3)	0	0	0
Radius fracture	1 (2.3)	0	1 (2.3)	0	0
Stoma site irritation	1 (2.3)	1 (2.3)	0	0	0
Subdural haemorrhage	1 (2.3)	1 (2.3)	0	0	0
Tibia fracture	1 (2.3)	0	1 (2.3)	0	0
Tongue injury	1 (2.3)	1 (2.3)	0	0	0
Tracheal haemorrhage	1 (2.3)	0	0	1 (2.3)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion related complication	1 (2.3)	0	0	0	1 (2.3)
Investigations					
-Total	37 (84.1)	2 (4.5)	3 (6.8)	10 (22.7)	22 (50.0)
White blood cell count decreased	23 (52.3)	2 (4.5)	1 (2.3)	9 (20.5)	11 (25.0)
Neutrophil count decreased	18 (40.9)	0	2 (4.5)	2 (4.5)	14 (31.8)
Alanine aminotransferase increased	16 (36.4)	4 (9.1)	1 (2.3)	11 (25.0)	0
Aspartate aminotransferase increased	14 (31.8)	4 (9.1)	1 (2.3)	6 (13.6)	3 (6.8)
Platelet count decreased	14 (31.8)	1 (2.3)	2 (4.5)	2 (4.5)	9 (20.5)
Lymphocyte count decreased	8 (18.2)	0	2 (4.5)	4 (9.1)	2 (4.5)
Prothrombin time prolonged	7 (15.9)	4 (9.1)	2 (4.5)	1 (2.3)	0
Blood creatinine increased	6 (13.6)	2 (4.5)	2 (4.5)	2 (4.5)	0
International normalised ratio increased	6 (13.6)	5 (11.4)	0	1 (2.3)	0
Activated partial thromboplastin time prolonged	4 (9.1)	3 (6.8)	1 (2.3)	0	0
Blood bilirubin increased	4 (9.1)	0	3 (6.8)	1 (2.3)	0
Blood fibrinogen decreased	4 (9.1)	0	1 (2.3)	2 (4.5)	1 (2.3)
Blood immunoglobulin m decreased	3 (6.8)	3 (6.8)	0	0	0
Blood urea increased	3 (6.8)	1 (2.3)	1 (2.3)	1 (2.3)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight decreased	3 (6.8)	0	3 (6.8)	0	0
Blood immunoglobulin a decreased	2 (4.5)	2 (4.5)	0	0	0
Blood uric acid increased	2 (4.5)	2 (4.5)	0	0	0
C-reactive protein increased	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Haemoglobin decreased	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Lipase increased	2 (4.5)	0	0	0	2 (4.5)
Transaminases increased	2 (4.5)	2 (4.5)	0	0	0
Weight increased	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Blood alkaline phosphatase increased	1 (2.3)	1 (2.3)	0	0	0
Blood bicarbonate decreased	1 (2.3)	0	1 (2.3)	0	0
Blood immunoglobulin g decreased	1 (2.3)	0	1 (2.3)	0	0
Blood lactate dehydrogenase increased	1 (2.3)	1 (2.3)	0	0	0
Blood magnesium decreased	1 (2.3)	0	0	1 (2.3)	0
Blood phosphorus decreased	1 (2.3)	1 (2.3)	0	0	0
Blood phosphorus increased	1 (2.3)	1 (2.3)	0	0	0
Blood sodium increased	1 (2.3)	0	1 (2.3)	0	0
Hepatic enzyme increased	1 (2.3)	0	1 (2.3)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Norovirus test positive	1 (2.3)	1 (2.3)	0	0	0
Oxygen saturation decreased	1 (2.3)	1 (2.3)	0	0	0
Protein total decreased	1 (2.3)	0	0	1 (2.3)	0
Pulmonary function test decreased	1 (2.3)	0	1 (2.3)	0	0
Serum ferritin increased	1 (2.3)	0	1 (2.3)	0	0
Metabolism and nutrition disorders					
-Total	33 (75.0)	7 (15.9)	7 (15.9)	16 (36.4)	3 (6.8)
Hypokalaemia	18 (40.9)	4 (9.1)	6 (13.6)	7 (15.9)	1 (2.3)
Decreased appetite	17 (38.6)	4 (9.1)	4 (9.1)	9 (20.5)	0
Hypophosphataemia	8 (18.2)	2 (4.5)	0	5 (11.4)	1 (2.3)
Hyperphosphataemia	6 (13.6)	6 (13.6)	0	0	0
Hypoalbuminaemia	5 (11.4)	1 (2.3)	3 (6.8)	1 (2.3)	0
Hypernatraemia	4 (9.1)	1 (2.3)	2 (4.5)	0	1 (2.3)
Hyperglycaemia	3 (6.8)	0	1 (2.3)	2 (4.5)	0
Hypocalcaemia	3 (6.8)	1 (2.3)	1 (2.3)	1 (2.3)	0
Acidosis	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Dehydration	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Fluid overload	2 (4.5)	0	2 (4.5)	0	0
Hypertriglyceridaemia	2 (4.5)	1 (2.3)	0	1 (2.3)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	2 (4.5)	2 (4.5)	0	0	0
Tumour lysis syndrome	2 (4.5)	0	0	2 (4.5)	0
Vitamin d deficiency	2 (4.5)	2 (4.5)	0	0	0
Hyperalbuminaemia	1 (2.3)	1 (2.3)	0	0	0
Hypercalcaemia	1 (2.3)	1 (2.3)	0	0	0
Hyperchloraemia	1 (2.3)	1 (2.3)	0	0	0
Hypermagnesaemia	1 (2.3)	1 (2.3)	0	0	0
Hypomagnesaemia	1 (2.3)	1 (2.3)	0	0	0
Hyponatraemia	1 (2.3)	0	0	1 (2.3)	0
Iron overload	1 (2.3)	0	0	1 (2.3)	0
Malnutrition	1 (2.3)	0	0	1 (2.3)	0
Metabolic acidosis	1 (2.3)	0	1 (2.3)	0	0
Metabolic alkalosis	1 (2.3)	1 (2.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	17 (38.6)	10 (22.7)	7 (15.9)	0	0
Pain in extremity	6 (13.6)	4 (9.1)	2 (4.5)	0	0
Arthralgia	3 (6.8)	3 (6.8)	0	0	0
Musculoskeletal pain	3 (6.8)	2 (4.5)	1 (2.3)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=44		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Joint range of motion decreased	2 (4.5)	2 (4.5)	0	0	0
Muscle spasms	2 (4.5)	2 (4.5)	0	0	0
Muscular weakness	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Musculoskeletal chest pain	2 (4.5)	2 (4.5)	0	0	0
Back pain	1 (2.3)	1 (2.3)	0	0	0
Coccydynia	1 (2.3)	1 (2.3)	0	0	0
Flank pain	1 (2.3)	0	1 (2.3)	0	0
Limb discomfort	1 (2.3)	1 (2.3)	0	0	0
Neck pain	1 (2.3)	0	1 (2.3)	0	0
Osteopenia	1 (2.3)	0	1 (2.3)	0	0
Toe walking	1 (2.3)	1 (2.3)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (4.5)	0	2 (4.5)	0	0
Myelodysplastic syndrome	1 (2.3)	0	1 (2.3)	0	0
Skin papilloma	1 (2.3)	0	1 (2.3)	0	0
Nervous system disorders					
-Total	24 (54.5)	12 (27.3)	8 (18.2)	3 (6.8)	1 (2.3)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	18 (40.9)	11 (25.0)	6 (13.6)	1 (2.3)	0
Dizziness	6 (13.6)	6 (13.6)	0	0	0
Dysarthria	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Seizure	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Asterixis	1 (2.3)	1 (2.3)	0	0	0
Ataxia	1 (2.3)	0	1 (2.3)	0	0
Depressed level of consciousness	1 (2.3)	1 (2.3)	0	0	0
Embolic stroke	1 (2.3)	0	0	0	1 (2.3)
Encephalopathy	1 (2.3)	0	0	1 (2.3)	0
Idiopathic intracranial hypertension	1 (2.3)	0	1 (2.3)	0	0
Migraine	1 (2.3)	0	1 (2.3)	0	0
Neuropathy peripheral	1 (2.3)	0	1 (2.3)	0	0
Pleocytosis	1 (2.3)	1 (2.3)	0	0	0
Somnolence	1 (2.3)	1 (2.3)	0	0	0
Tremor	1 (2.3)	1 (2.3)	0	0	0
Product issues					
-Total	1 (2.3)	1 (2.3)	0	0	0
Device occlusion	1 (2.3)	1 (2.3)	0	0	0
Psychiatric disorders					

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (27.3)	6 (13.6)	5 (11.4)	1 (2.3)	0
Anxiety	5 (11.4)	2 (4.5)	2 (4.5)	1 (2.3)	0
Confusional state	5 (11.4)	2 (4.5)	3 (6.8)	0	0
Delirium	3 (6.8)	1 (2.3)	2 (4.5)	0	0
Agitation	2 (4.5)	0	2 (4.5)	0	0
Hallucination	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Irritability	2 (4.5)	2 (4.5)	0	0	0
Adjustment disorder	1 (2.3)	0	1 (2.3)	0	0
Insomnia	1 (2.3)	0	1 (2.3)	0	0
Listless	1 (2.3)	1 (2.3)	0	0	0
Suicidal ideation	1 (2.3)	1 (2.3)	0	0	0
Renal and urinary disorders					
-Total	14 (31.8)	2 (4.5)	2 (4.5)	6 (13.6)	4 (9.1)
Acute kidney injury	9 (20.5)	1 (2.3)	1 (2.3)	4 (9.1)	3 (6.8)
Haematuria	5 (11.4)	0	2 (4.5)	2 (4.5)	1 (2.3)
Dysuria	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Oliguria	2 (4.5)	0	0	2 (4.5)	0
Calculus urinary	1 (2.3)	0	1 (2.3)	0	0
Nephrolithiasis	1 (2.3)	0	0	1 (2.3)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pollakiuria	1 (2.3)	1 (2.3)	0	0	0
Renal failure	1 (2.3)	0	0	0	1 (2.3)
Renal impairment	1 (2.3)	0	0	1 (2.3)	0
Reproductive system and breast disorders					
-Total	4 (9.1)	1 (2.3)	2 (4.5)	1 (2.3)	0
Oedema genital	1 (2.3)	0	1 (2.3)	0	0
Ovarian failure	1 (2.3)	0	0	1 (2.3)	0
Scrotal pain	1 (2.3)	0	1 (2.3)	0	0
Vulvovaginal adhesion	1 (2.3)	1 (2.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	27 (61.4)	10 (22.7)	4 (9.1)	5 (11.4)	8 (18.2)
Cough	9 (20.5)	8 (18.2)	1 (2.3)	0	0
Epistaxis	9 (20.5)	4 (9.1)	1 (2.3)	3 (6.8)	1 (2.3)
Hypoxia	7 (15.9)	0	0	4 (9.1)	3 (6.8)
Pleural effusion	7 (15.9)	1 (2.3)	4 (9.1)	2 (4.5)	0
Pulmonary oedema	6 (13.6)	1 (2.3)	0	3 (6.8)	2 (4.5)
Oropharyngeal pain	5 (11.4)	4 (9.1)	1 (2.3)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	5 (11.4)	3 (6.8)	1 (2.3)	1 (2.3)	0
Rhinorrhoea	4 (9.1)	4 (9.1)	0	0	0
Respiratory failure	3 (6.8)	0	0	0	3 (6.8)
Dyspnoea	2 (4.5)	0	0	1 (2.3)	1 (2.3)
Haemoptysis	2 (4.5)	1 (2.3)	0	0	1 (2.3)
Nasal congestion	2 (4.5)	2 (4.5)	0	0	0
Rhinitis allergic	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Acute respiratory failure	1 (2.3)	0	0	0	1 (2.3)
Interstitial lung disease	1 (2.3)	0	0	0	1 (2.3)
Oropharyngeal plaque	1 (2.3)	1 (2.3)	0	0	0
Respiratory distress	1 (2.3)	0	0	0	1 (2.3)
Wheezing	1 (2.3)	0	1 (2.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	19 (43.2)	11 (25.0)	6 (13.6)	2 (4.5)	0
Rash	7 (15.9)	5 (11.4)	2 (4.5)	0	0
Petechiae	4 (9.1)	3 (6.8)	1 (2.3)	0	0
Pruritus	4 (9.1)	4 (9.1)	0	0	0
Dry skin	3 (6.8)	3 (6.8)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperhidrosis	3 (6.8)	3 (6.8)	0	0	0
Rash maculo-papular	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Macule	2 (4.5)	2 (4.5)	0	0	0
Rash papular	2 (4.5)	2 (4.5)	0	0	0
Dermatitis	1 (2.3)	1 (2.3)	0	0	0
Dermatitis acneiform	1 (2.3)	0	0	1 (2.3)	0
Ecchymosis	1 (2.3)	0	0	1 (2.3)	0
Eczema	1 (2.3)	1 (2.3)	0	0	0
Erythema	1 (2.3)	1 (2.3)	0	0	0
Ingrowing nail	1 (2.3)	0	1 (2.3)	0	0
Night sweats	1 (2.3)	0	1 (2.3)	0	0
Papule	1 (2.3)	1 (2.3)	0	0	0
Rash erythematous	1 (2.3)	1 (2.3)	0	0	0
Rash follicular	1 (2.3)	1 (2.3)	0	0	0
Rash macular	1 (2.3)	1 (2.3)	0	0	0
Rash pruritic	1 (2.3)	1 (2.3)	0	0	0
Rash vesicular	1 (2.3)	1 (2.3)	0	0	0
Skin exfoliation	1 (2.3)	1 (2.3)	0	0	0
Skin fissures	1 (2.3)	1 (2.3)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin irritation	1 (2.3)	1 (2.3)	0	0	0
Vascular disorders					
-Total	19 (43.2)	3 (6.8)	5 (11.4)	4 (9.1)	7 (15.9)
Hypotension	12 (27.3)	1 (2.3)	0	4 (9.1)	7 (15.9)
Hypertension	8 (18.2)	2 (4.5)	5 (11.4)	1 (2.3)	0
Flushing	2 (4.5)	2 (4.5)	0	0	0
Orthostatic hypotension	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Capillary leak syndrome	1 (2.3)	0	0	0	1 (2.3)
Haematoma	1 (2.3)	0	1 (2.3)	0	0
Secondary hypertension	1 (2.3)	0	1 (2.3)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174o
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	0	0	4 (80.0)
Blood and lymphatic system disorders					
-Total	2 (40.0)	0	0	2 (40.0)	0
Anaemia	2 (40.0)	0	0	2 (40.0)	0
Febrile neutropenia	1 (20.0)	0	0	1 (20.0)	0
Cardiac disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Bradycardia	1 (20.0)	0	1 (20.0)	0	0
Pericardial effusion	1 (20.0)	0	1 (20.0)	0	0
Tachycardia	1 (20.0)	1 (20.0)	0	0	0
Eye disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctival haemorrhage	1 (20.0)	1 (20.0)	0	0	0
Periorbital oedema	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal disorders					
-Total	3 (60.0)	1 (20.0)	1 (20.0)	1 (20.0)	0
Abdominal pain	1 (20.0)	1 (20.0)	0	0	0
Dysphagia	1 (20.0)	0	0	1 (20.0)	0
Nausea	1 (20.0)	0	1 (20.0)	0	0
Vomiting	1 (20.0)	1 (20.0)	0	0	0
General disorders and administration site conditions					
-Total	2 (40.0)	0	1 (20.0)	1 (20.0)	0
Face oedema	1 (20.0)	0	0	1 (20.0)	0
Localised oedema	1 (20.0)	0	0	1 (20.0)	0
Malaise	1 (20.0)	0	1 (20.0)	0	0
Mucosal haemorrhage	1 (20.0)	0	1 (20.0)	0	0
Multiple organ dysfunction syndrome	1 (20.0)	0	0	1 (20.0)	0
Oedema peripheral	1 (20.0)	0	0	1 (20.0)	0
Hepatobiliary disorders					

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (20.0)	0	0	1 (20.0)	0
Hyperbilirubinaemia	1 (20.0)	0	0	1 (20.0)	0
Immune system disorders					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	0	1 (20.0)
Cytokine release syndrome	4 (80.0)	2 (40.0)	1 (20.0)	0	1 (20.0)
Hypogammaglobulinaemia	2 (40.0)	0	2 (40.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (20.0)	1 (20.0)	0	0	0
Procedural complication	1 (20.0)	1 (20.0)	0	0	0
Investigations					
-Total	4 (80.0)	0	0	0	4 (80.0)
Alanine aminotransferase increased	2 (40.0)	0	0	2 (40.0)	0
Aspartate aminotransferase increased	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Neutrophil count decreased	2 (40.0)	0	0	0	2 (40.0)
White blood cell count decreased	2 (40.0)	0	0	0	2 (40.0)
Activated partial thromboplastin time prolonged	1 (20.0)	1 (20.0)	0	0	0
Blood creatinine increased	1 (20.0)	0	0	1 (20.0)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	1 (20.0)	0	0	0	1 (20.0)
Blood phosphorus decreased	1 (20.0)	1 (20.0)	0	0	0
Blood urea increased	1 (20.0)	0	0	1 (20.0)	0
Lymphocyte count decreased	1 (20.0)	0	0	0	1 (20.0)
Platelet count decreased	1 (20.0)	0	0	0	1 (20.0)
Protein total decreased	1 (20.0)	0	0	1 (20.0)	0
Metabolism and nutrition disorders					
-Total	2 (40.0)	0	0	2 (40.0)	0
Hypokalaemia	2 (40.0)	0	0	2 (40.0)	0
Acidosis	1 (20.0)	0	0	1 (20.0)	0
Decreased appetite	1 (20.0)	0	1 (20.0)	0	0
Hyperalbuminaemia	1 (20.0)	1 (20.0)	0	0	0
Hypercalcaemia	1 (20.0)	1 (20.0)	0	0	0
Hyperchloraemia	1 (20.0)	1 (20.0)	0	0	0
Hypermagnesaemia	1 (20.0)	1 (20.0)	0	0	0
Hypernatraemia	1 (20.0)	0	1 (20.0)	0	0
Hypoalbuminaemia	1 (20.0)	0	1 (20.0)	0	0
Hypophosphataemia	1 (20.0)	1 (20.0)	0	0	0
Metabolic alkalosis	1 (20.0)	1 (20.0)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Arthralgia	1 (20.0)	1 (20.0)	0	0	0
Muscular weakness	1 (20.0)	0	1 (20.0)	0	0
Nervous system disorders					
-Total	2 (40.0)	0	2 (40.0)	0	0
Dysarthria	1 (20.0)	0	1 (20.0)	0	0
Headache	1 (20.0)	0	1 (20.0)	0	0
Somnolence	1 (20.0)	1 (20.0)	0	0	0
Psychiatric disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Delirium	1 (20.0)	0	1 (20.0)	0	0
Insomnia	1 (20.0)	0	1 (20.0)	0	0
Irritability	1 (20.0)	1 (20.0)	0	0	0
Renal and urinary disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Renal impairment	1 (20.0)	0	0	1 (20.0)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	2 (40.0)	1 (20.0)	0	0	1 (20.0)
Epistaxis	1 (20.0)	0	1 (20.0)	0	0
Oropharyngeal plaque	1 (20.0)	1 (20.0)	0	0	0
Pleural effusion	1 (20.0)	0	0	1 (20.0)	0
Pulmonary oedema	1 (20.0)	0	0	1 (20.0)	0
Respiratory distress	1 (20.0)	0	0	0	1 (20.0)
Skin and subcutaneous tissue disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Hyperhidrosis	1 (20.0)	1 (20.0)	0	0	0
Rash papular	1 (20.0)	1 (20.0)	0	0	0
Vascular disorders					
-Total	1 (20.0)	0	0	0	1 (20.0)
Capillary leak syndrome	1 (20.0)	0	0	0	1 (20.0)
Flushing	1 (20.0)	1 (20.0)	0	0	0
Hypertension	1 (20.0)	0	1 (20.0)	0	0
Hypotension	1 (20.0)	0	0	0	1 (20.0)

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174o
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (100)	2 (3.4)	7 (11.9)	14 (23.7)	36 (61.0)
Blood and lymphatic system disorders					
-Total	41 (69.5)	2 (3.4)	3 (5.1)	25 (42.4)	11 (18.6)
Anaemia	25 (42.4)	3 (5.1)	5 (8.5)	16 (27.1)	1 (1.7)
Febrile neutropenia	21 (35.6)	0	0	21 (35.6)	0
Neutropenia	8 (13.6)	0	0	3 (5.1)	5 (8.5)
Thrombocytopenia	8 (13.6)	0	0	2 (3.4)	6 (10.2)
Disseminated intravascular coagulation	4 (6.8)	0	2 (3.4)	2 (3.4)	0
Lymphopenia	3 (5.1)	0	1 (1.7)	1 (1.7)	1 (1.7)
Coagulopathy	1 (1.7)	1 (1.7)	0	0	0
Pancytopenia	1 (1.7)	0	0	0	1 (1.7)
Cardiac disorders					

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	20 (33.9)	10 (16.9)	8 (13.6)	2 (3.4)	0
Tachycardia	14 (23.7)	7 (11.9)	5 (8.5)	2 (3.4)	0
Sinus tachycardia	5 (8.5)	3 (5.1)	2 (3.4)	0	0
Atrioventricular block second degree	1 (1.7)	1 (1.7)	0	0	0
Cardiac dysfunction	1 (1.7)	1 (1.7)	0	0	0
Left ventricular dysfunction	1 (1.7)	0	0	1 (1.7)	0
Palpitations	1 (1.7)	1 (1.7)	0	0	0
Pericardial effusion	1 (1.7)	1 (1.7)	0	0	0
Sinus bradycardia	1 (1.7)	1 (1.7)	0	0	0
Ventricular tachycardia	1 (1.7)	0	1 (1.7)	0	0
Ear and labyrinth disorders					
-Total	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Ear pain	2 (3.4)	2 (3.4)	0	0	0
Hypoacusis	1 (1.7)	0	1 (1.7)	0	0
Endocrine disorders					
-Total	1 (1.7)	0	1 (1.7)	0	0
Adrenal insufficiency	1 (1.7)	0	1 (1.7)	0	0
Eye disorders					
-Total	12 (20.3)	5 (8.5)	7 (11.9)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye pain	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Periorbital oedema	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Vision blurred	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Conjunctival haemorrhage	2 (3.4)	2 (3.4)	0	0	0
Photophobia	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Retinal haemorrhage	2 (3.4)	2 (3.4)	0	0	0
Uveitis	2 (3.4)	0	2 (3.4)	0	0
Ocular hypertension	1 (1.7)	0	1 (1.7)	0	0
Papilloedema	1 (1.7)	0	1 (1.7)	0	0
Visual impairment	1 (1.7)	0	1 (1.7)	0	0
Gastrointestinal disorders					
-Total	33 (55.9)	10 (16.9)	13 (22.0)	10 (16.9)	0
Vomiting	21 (35.6)	12 (20.3)	6 (10.2)	3 (5.1)	0
Nausea	20 (33.9)	6 (10.2)	11 (18.6)	3 (5.1)	0
Diarrhoea	18 (30.5)	11 (18.6)	6 (10.2)	1 (1.7)	0
Abdominal pain	8 (13.6)	5 (8.5)	2 (3.4)	1 (1.7)	0
Constipation	7 (11.9)	6 (10.2)	1 (1.7)	0	0
Abdominal distension	2 (3.4)	0	2 (3.4)	0	0
Abdominal pain upper	2 (3.4)	0	2 (3.4)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematemesis	2 (3.4)	2 (3.4)	0	0	0
Pancreatitis	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Stomatitis	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Abdominal discomfort	1 (1.7)	1 (1.7)	0	0	0
Abdominal pain lower	1 (1.7)	0	1 (1.7)	0	0
Abdominal tenderness	1 (1.7)	1 (1.7)	0	0	0
Anal incontinence	1 (1.7)	1 (1.7)	0	0	0
Ascites	1 (1.7)	0	0	1 (1.7)	0
Dyspepsia	1 (1.7)	0	1 (1.7)	0	0
Dysphagia	1 (1.7)	0	1 (1.7)	0	0
Flatulence	1 (1.7)	1 (1.7)	0	0	0
Gastrointestinal haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Gastrooesophageal reflux disease	1 (1.7)	1 (1.7)	0	0	0
Glossodynia	1 (1.7)	1 (1.7)	0	0	0
Ileus	1 (1.7)	0	0	1 (1.7)	0
Intestinal obstruction	1 (1.7)	0	0	1 (1.7)	0
Lip pain	1 (1.7)	0	1 (1.7)	0	0
Mouth haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Tooth socket haemorrhage	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	30 (50.8)	12 (20.3)	9 (15.3)	8 (13.6)	1 (1.7)
Pyrexia	16 (27.1)	3 (5.1)	7 (11.9)	5 (8.5)	1 (1.7)
Fatigue	13 (22.0)	10 (16.9)	2 (3.4)	1 (1.7)	0
Chills	8 (13.6)	8 (13.6)	0	0	0
Catheter site pain	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Pain	3 (5.1)	0	1 (1.7)	2 (3.4)	0
Generalised oedema	2 (3.4)	0	2 (3.4)	0	0
Malaise	2 (3.4)	0	2 (3.4)	0	0
Asthenia	1 (1.7)	1 (1.7)	0	0	0
Catheter site extravasation	1 (1.7)	0	1 (1.7)	0	0
Catheter site haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Face oedema	1 (1.7)	0	1 (1.7)	0	0
Facial pain	1 (1.7)	0	1 (1.7)	0	0
Injection site haematoma	1 (1.7)	1 (1.7)	0	0	0
Non-cardiac chest pain	1 (1.7)	1 (1.7)	0	0	0
Oedema peripheral	1 (1.7)	1 (1.7)	0	0	0
Peripheral swelling	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Physical deconditioning	1 (1.7)	0	0	1 (1.7)	0
Hepatobiliary disorders					
-Total	6 (10.2)	3 (5.1)	2 (3.4)	1 (1.7)	0
Hepatomegaly	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Hyperbilirubinaemia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Gallbladder enlargement	1 (1.7)	1 (1.7)	0	0	0
Hepatosplenomegaly	1 (1.7)	1 (1.7)	0	0	0
Immune system disorders					
-Total	53 (89.8)	4 (6.8)	28 (47.5)	11 (18.6)	10 (16.9)
Cytokine release syndrome	46 (78.0)	4 (6.8)	24 (40.7)	8 (13.6)	10 (16.9)
Hypogammaglobulinaemia	23 (39.0)	3 (5.1)	16 (27.1)	4 (6.8)	0
Drug hypersensitivity	1 (1.7)	0	1 (1.7)	0	0
Graft versus host disease in skin	1 (1.7)	1 (1.7)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	1 (1.7)	0	0
Infections and infestations					
-Total	26 (44.1)	5 (8.5)	14 (23.7)	6 (10.2)	1 (1.7)
Clostridium difficile colitis	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Clostridium difficile infection	4 (6.8)	0	4 (6.8)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	3 (5.1)	3 (5.1)	0	0	0
Gastroenteritis	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Pneumonia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Staphylococcal infection	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Acute sinusitis	1 (1.7)	0	1 (1.7)	0	0
Body tinea	1 (1.7)	1 (1.7)	0	0	0
Catheter site cellulitis	1 (1.7)	1 (1.7)	0	0	0
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cytomegalovirus infection	1 (1.7)	1 (1.7)	0	0	0
Enterococcal infection	1 (1.7)	1 (1.7)	0	0	0
Folliculitis	1 (1.7)	0	1 (1.7)	0	0
Fungal skin infection	1 (1.7)	1 (1.7)	0	0	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Herpes simplex	1 (1.7)	1 (1.7)	0	0	0
Human herpesvirus 6 infection	1 (1.7)	0	1 (1.7)	0	0
Hypopyon	1 (1.7)	0	1 (1.7)	0	0
Influenza	1 (1.7)	1 (1.7)	0	0	0
Oral candidiasis	1 (1.7)	1 (1.7)	0	0	0
Orchitis	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis	1 (1.7)	0	1 (1.7)	0	0
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Skin infection	1 (1.7)	0	1 (1.7)	0	0
Streptococcal infection	1 (1.7)	0	1 (1.7)	0	0
Upper respiratory tract infection	1 (1.7)	0	1 (1.7)	0	0
Urinary tract infection enterococcal	1 (1.7)	0	0	1 (1.7)	0
Viral infection	1 (1.7)	0	1 (1.7)	0	0
Viral upper respiratory tract infection	1 (1.7)	0	1 (1.7)	0	0
Vulvovaginal candidiasis	1 (1.7)	1 (1.7)	0	0	0
Injury, poisoning and procedural complications					
-Total	14 (23.7)	7 (11.9)	5 (8.5)	1 (1.7)	1 (1.7)
Procedural pain	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Transfusion reaction	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Infusion related reaction	2 (3.4)	0	2 (3.4)	0	0
Contusion	1 (1.7)	1 (1.7)	0	0	0
Incision site pain	1 (1.7)	1 (1.7)	0	0	0
Limb injury	1 (1.7)	1 (1.7)	0	0	0
Mouth injury	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Post procedural haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Procedural headache	1 (1.7)	0	1 (1.7)	0	0
Procedural site reaction	1 (1.7)	1 (1.7)	0	0	0
Skin abrasion	1 (1.7)	1 (1.7)	0	0	0
Stoma site irritation	1 (1.7)	1 (1.7)	0	0	0
Subdural haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Tibia fracture	1 (1.7)	0	1 (1.7)	0	0
Tongue injury	1 (1.7)	1 (1.7)	0	0	0
Tracheal haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Transfusion related complication	1 (1.7)	0	0	0	1 (1.7)
Investigations					
-Total	48 (81.4)	4 (6.8)	4 (6.8)	13 (22.0)	27 (45.8)
White blood cell count decreased	28 (47.5)	3 (5.1)	1 (1.7)	10 (16.9)	14 (23.7)
Neutrophil count decreased	23 (39.0)	0	2 (3.4)	4 (6.8)	17 (28.8)
Platelet count decreased	18 (30.5)	3 (5.1)	2 (3.4)	2 (3.4)	11 (18.6)
Alanine aminotransferase increased	17 (28.8)	5 (8.5)	3 (5.1)	9 (15.3)	0
Aspartate aminotransferase increased	16 (27.1)	3 (5.1)	4 (6.8)	6 (10.2)	3 (5.1)
Lymphocyte count decreased	13 (22.0)	1 (1.7)	2 (3.4)	6 (10.2)	4 (6.8)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	9 (15.3)	8 (13.6)	0	1 (1.7)	0
Prothrombin time prolonged	9 (15.3)	5 (8.5)	3 (5.1)	1 (1.7)	0
Blood creatinine increased	8 (13.6)	5 (8.5)	2 (3.4)	1 (1.7)	0
Blood bilirubin increased	7 (11.9)	2 (3.4)	3 (5.1)	2 (3.4)	0
Activated partial thromboplastin time prolonged	4 (6.8)	2 (3.4)	2 (3.4)	0	0
Blood immunoglobulin m decreased	4 (6.8)	4 (6.8)	0	0	0
Blood fibrinogen decreased	3 (5.1)	0	1 (1.7)	2 (3.4)	0
Blood immunoglobulin a decreased	3 (5.1)	3 (5.1)	0	0	0
Blood phosphorus increased	2 (3.4)	2 (3.4)	0	0	0
Blood urea increased	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Lipase increased	2 (3.4)	0	0	0	2 (3.4)
Transaminases increased	2 (3.4)	2 (3.4)	0	0	0
Blood bicarbonate decreased	1 (1.7)	0	1 (1.7)	0	0
Blood immunoglobulin g decreased	1 (1.7)	0	1 (1.7)	0	0
Blood lactic acid increased	1 (1.7)	0	0	0	1 (1.7)
Blood magnesium decreased	1 (1.7)	0	0	1 (1.7)	0
Blood sodium increased	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	1 (1.7)	1 (1.7)	0	0	0
C-reactive protein increased	1 (1.7)	0	0	1 (1.7)	0
Cardiac murmur	1 (1.7)	1 (1.7)	0	0	0
Culture stool positive	1 (1.7)	1 (1.7)	0	0	0
Fibrin d dimer increased	1 (1.7)	1 (1.7)	0	0	0
Haemoglobin decreased	1 (1.7)	0	0	1 (1.7)	0
Hepatic enzyme increased	1 (1.7)	0	1 (1.7)	0	0
Norovirus test positive	1 (1.7)	1 (1.7)	0	0	0
Pulmonary function test decreased	1 (1.7)	0	1 (1.7)	0	0
Serum ferritin increased	1 (1.7)	0	1 (1.7)	0	0
Metabolism and nutrition disorders					
-Total	37 (62.7)	5 (8.5)	10 (16.9)	19 (32.2)	3 (5.1)
Decreased appetite	19 (32.2)	4 (6.8)	3 (5.1)	12 (20.3)	0
Hypokalaemia	14 (23.7)	3 (5.1)	6 (10.2)	5 (8.5)	0
Hyperphosphataemia	8 (13.6)	8 (13.6)	0	0	0
Hypophosphataemia	8 (13.6)	1 (1.7)	0	6 (10.2)	1 (1.7)
Hypoalbuminaemia	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Dehydration	3 (5.1)	1 (1.7)	0	2 (3.4)	0
Fluid overload	3 (5.1)	1 (1.7)	2 (3.4)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	3 (5.1)	0	2 (3.4)	1 (1.7)	0
Hypernatraemia	3 (5.1)	1 (1.7)	1 (1.7)	0	1 (1.7)
Hyperuricaemia	3 (5.1)	2 (3.4)	0	0	1 (1.7)
Hypocalcaemia	3 (5.1)	1 (1.7)	1 (1.7)	1 (1.7)	0
Hypertriglyceridaemia	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Hyponatraemia	2 (3.4)	0	0	2 (3.4)	0
Acidosis	1 (1.7)	1 (1.7)	0	0	0
Hypomagnesaemia	1 (1.7)	1 (1.7)	0	0	0
Malnutrition	1 (1.7)	0	0	1 (1.7)	0
Metabolic acidosis	1 (1.7)	0	1 (1.7)	0	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0
Musculoskeletal and connective tissue disorders					
-Total	14 (23.7)	8 (13.6)	5 (8.5)	1 (1.7)	0
Myalgia	5 (8.5)	4 (6.8)	1 (1.7)	0	0
Pain in extremity	4 (6.8)	2 (3.4)	2 (3.4)	0	0
Arthralgia	3 (5.1)	2 (3.4)	0	1 (1.7)	0
Musculoskeletal pain	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Coccydynia	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Limb discomfort	1 (1.7)	1 (1.7)	0	0	0
Muscle spasms	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal chest pain	1 (1.7)	1 (1.7)	0	0	0
Osteopenia	1 (1.7)	0	1 (1.7)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.7)	0	1 (1.7)	0	0
Skin papilloma	1 (1.7)	0	1 (1.7)	0	0
Nervous system disorders					
-Total	31 (52.5)	17 (28.8)	9 (15.3)	4 (6.8)	1 (1.7)
Headache	23 (39.0)	16 (27.1)	5 (8.5)	2 (3.4)	0
Dizziness	4 (6.8)	4 (6.8)	0	0	0
Encephalopathy	4 (6.8)	1 (1.7)	1 (1.7)	2 (3.4)	0
Seizure	3 (5.1)	0	2 (3.4)	1 (1.7)	0
Tremor	2 (3.4)	2 (3.4)	0	0	0
Asterixis	1 (1.7)	1 (1.7)	0	0	0
Ataxia	1 (1.7)	0	1 (1.7)	0	0
Depressed level of consciousness	1 (1.7)	1 (1.7)	0	0	0
Dysarthria	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Embolic stroke	1 (1.7)	0	0	0	1 (1.7)
Idiopathic intracranial hypertension	1 (1.7)	0	1 (1.7)	0	0
Migraine	1 (1.7)	0	1 (1.7)	0	0
Myoclonus	1 (1.7)	1 (1.7)	0	0	0
Neuropathy peripheral	1 (1.7)	0	1 (1.7)	0	0
Pleocytosis	1 (1.7)	1 (1.7)	0	0	0
Product issues					
-Total	1 (1.7)	1 (1.7)	0	0	0
Device occlusion	1 (1.7)	1 (1.7)	0	0	0
Psychiatric disorders					
-Total	15 (25.4)	8 (13.6)	6 (10.2)	1 (1.7)	0
Anxiety	6 (10.2)	2 (3.4)	3 (5.1)	1 (1.7)	0
Confusional state	6 (10.2)	3 (5.1)	3 (5.1)	0	0
Delirium	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Agitation	2 (3.4)	0	2 (3.4)	0	0
Hallucination	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Adjustment disorder	1 (1.7)	0	1 (1.7)	0	0
Irritability	1 (1.7)	1 (1.7)	0	0	0
Listless	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (1.7)	1 (1.7)	0	0	0
Panic attack	1 (1.7)	0	1 (1.7)	0	0
Suicidal ideation	1 (1.7)	1 (1.7)	0	0	0
Renal and urinary disorders					
-Total	10 (16.9)	2 (3.4)	2 (3.4)	2 (3.4)	4 (6.8)
Acute kidney injury	7 (11.9)	1 (1.7)	1 (1.7)	2 (3.4)	3 (5.1)
Haematuria	4 (6.8)	0	2 (3.4)	1 (1.7)	1 (1.7)
Dysuria	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Oliguria	2 (3.4)	0	0	2 (3.4)	0
Pollakiuria	1 (1.7)	1 (1.7)	0	0	0
Renal failure	1 (1.7)	0	0	0	1 (1.7)
Reproductive system and breast disorders					
-Total	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Vulvovaginal adhesion	2 (3.4)	2 (3.4)	0	0	0
Oedema genital	1 (1.7)	0	1 (1.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	26 (44.1)	9 (15.3)	6 (10.2)	5 (8.5)	6 (10.2)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	10 (16.9)	0	3 (5.1)	4 (6.8)	3 (5.1)
Cough	8 (13.6)	8 (13.6)	0	0	0
Pleural effusion	7 (11.9)	2 (3.4)	4 (6.8)	1 (1.7)	0
Epistaxis	6 (10.2)	2 (3.4)	0	3 (5.1)	1 (1.7)
Pulmonary oedema	5 (8.5)	1 (1.7)	0	2 (3.4)	2 (3.4)
Tachypnoea	5 (8.5)	3 (5.1)	1 (1.7)	1 (1.7)	0
Respiratory failure	3 (5.1)	0	0	0	3 (5.1)
Dyspnoea	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Haemoptysis	2 (3.4)	1 (1.7)	0	0	1 (1.7)
Oropharyngeal pain	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Atelectasis	1 (1.7)	1 (1.7)	0	0	0
Interstitial lung disease	1 (1.7)	0	0	0	1 (1.7)
Nasal congestion	1 (1.7)	1 (1.7)	0	0	0
Pharyngeal ulceration	1 (1.7)	0	1 (1.7)	0	0
Respiratory depression	1 (1.7)	0	1 (1.7)	0	0
Rhinitis allergic	1 (1.7)	1 (1.7)	0	0	0
Rhinorrhoea	1 (1.7)	1 (1.7)	0	0	0
Wheezing	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	20 (33.9)	14 (23.7)	4 (6.8)	2 (3.4)	0
Dry skin	4 (6.8)	4 (6.8)	0	0	0
Rash	4 (6.8)	4 (6.8)	0	0	0
Erythema	3 (5.1)	3 (5.1)	0	0	0
Petechiae	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Rash maculo-papular	3 (5.1)	1 (1.7)	1 (1.7)	1 (1.7)	0
Hyperhidrosis	2 (3.4)	2 (3.4)	0	0	0
Ingrowing nail	2 (3.4)	0	2 (3.4)	0	0
Pruritus	2 (3.4)	2 (3.4)	0	0	0
Dermatitis diaper	1 (1.7)	1 (1.7)	0	0	0
Ecchymosis	1 (1.7)	0	0	1 (1.7)	0
Livedo reticularis	1 (1.7)	1 (1.7)	0	0	0
Macule	1 (1.7)	1 (1.7)	0	0	0
Night sweats	1 (1.7)	0	1 (1.7)	0	0
Rash erythematous	1 (1.7)	1 (1.7)	0	0	0
Rash follicular	1 (1.7)	1 (1.7)	0	0	0
Rash macular	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash papular	1 (1.7)	1 (1.7)	0	0	0
Rash vesicular	1 (1.7)	1 (1.7)	0	0	0
Skin exfoliation	1 (1.7)	1 (1.7)	0	0	0
Skin fissures	1 (1.7)	1 (1.7)	0	0	0
Skin irritation	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					
-Total	23 (39.0)	3 (5.1)	5 (8.5)	8 (13.6)	7 (11.9)
Hypotension	15 (25.4)	1 (1.7)	0	7 (11.9)	7 (11.9)
Hypertension	9 (15.3)	2 (3.4)	6 (10.2)	1 (1.7)	0
Orthostatic hypotension	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Embolism	1 (1.7)	0	0	1 (1.7)	0
Flushing	1 (1.7)	1 (1.7)	0	0	0
Haematoma	1 (1.7)	0	1 (1.7)	0	0
Secondary hypertension	1 (1.7)	0	1 (1.7)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174o
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	1 (20.0)	1 (20.0)	1 (20.0)	1 (20.0)
Blood and lymphatic system disorders					
-Total	2 (40.0)	0	1 (20.0)	0	1 (20.0)
Leukopenia	1 (20.0)	0	0	0	1 (20.0)
Lymphadenopathy	1 (20.0)	0	1 (20.0)	0	0
General disorders and administration site conditions					
-Total	1 (20.0)	1 (20.0)	0	0	0
Acquired gene mutation	1 (20.0)	1 (20.0)	0	0	0
Immune system disorders					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	1 (20.0)	0	0	1 (20.0)	0
Seasonal allergy	1 (20.0)	1 (20.0)	0	0	0
Infections and infestations					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Gastroenteritis	1 (20.0)	0	1 (20.0)	0	0
Subcutaneous abscess	1 (20.0)	0	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	1 (20.0)	0	0	0
Viral upper respiratory tract infection	1 (20.0)	0	0	1 (20.0)	0
Injury, poisoning and procedural complications					
-Total	1 (20.0)	0	1 (20.0)	0	0
Arthropod bite	1 (20.0)	1 (20.0)	0	0	0
Procedural pain	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Blood urea increased	1 (20.0)	1 (20.0)	0	0	0
Serum ferritin increased	1 (20.0)	0	1 (20.0)	0	0
Metabolism and nutrition disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Hyperalbuminaemia	1 (20.0)	1 (20.0)	0	0	0
Hypercalcaemia	1 (20.0)	1 (20.0)	0	0	0
Iron overload	1 (20.0)	0	0	1 (20.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Cough	1 (20.0)	1 (20.0)	0	0	0
Rhinorrhoea	1 (20.0)	1 (20.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Dermatitis	1 (20.0)	1 (20.0)	0	0	0
Papule	1 (20.0)	1 (20.0)	0	0	0
Rash	1 (20.0)	0	1 (20.0)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174o
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=51		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (82.4)	3 (5.9)	15 (29.4)	15 (29.4)	9 (17.6)
Blood and lymphatic system disorders					
-Total	9 (17.6)	1 (2.0)	2 (3.9)	3 (5.9)	3 (5.9)
Neutropenia	4 (7.8)	0	0	1 (2.0)	3 (5.9)
Febrile neutropenia	3 (5.9)	0	0	3 (5.9)	0
Anaemia	2 (3.9)	1 (2.0)	0	1 (2.0)	0
Thrombocytopenia	2 (3.9)	0	1 (2.0)	1 (2.0)	0
Eosinophilia	1 (2.0)	0	0	1 (2.0)	0
Lymphopenia	1 (2.0)	0	1 (2.0)	0	0
Cardiac disorders					
-Total	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=51		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	1 (2.0)	0	1 (2.0)	0	0
Endocrine disorders					
-Total	1 (2.0)	1 (2.0)	0	0	0
Adrenal insufficiency	1 (2.0)	1 (2.0)	0	0	0
Eye disorders					
-Total	5 (9.8)	4 (7.8)	1 (2.0)	0	0
Dry eye	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Conjunctivitis allergic	1 (2.0)	1 (2.0)	0	0	0
Ocular hyperaemia	1 (2.0)	1 (2.0)	0	0	0
Vision blurred	1 (2.0)	1 (2.0)	0	0	0
Gastrointestinal disorders					
-Total	16 (31.4)	9 (17.6)	3 (5.9)	4 (7.8)	0
Vomiting	9 (17.6)	5 (9.8)	2 (3.9)	2 (3.9)	0
Diarrhoea	8 (15.7)	6 (11.8)	1 (2.0)	1 (2.0)	0
Nausea	6 (11.8)	1 (2.0)	3 (5.9)	2 (3.9)	0
Abdominal pain	4 (7.8)	2 (3.9)	1 (2.0)	1 (2.0)	0
Oral pain	2 (3.9)	1 (2.0)	0	1 (2.0)	0
Abdominal pain upper	1 (2.0)	1 (2.0)	0	0	0
Enterocolitis	1 (2.0)	0	0	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=51		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pigmentation lip	1 (2.0)	1 (2.0)	0	0	0
General disorders and administration site conditions					
-Total	16 (31.4)	12 (23.5)	3 (5.9)	1 (2.0)	0
Pyrexia	10 (19.6)	7 (13.7)	2 (3.9)	1 (2.0)	0
Fatigue	2 (3.9)	2 (3.9)	0	0	0
Influenza like illness	2 (3.9)	2 (3.9)	0	0	0
Catheter site pain	1 (2.0)	0	1 (2.0)	0	0
Chills	1 (2.0)	1 (2.0)	0	0	0
Crying	1 (2.0)	1 (2.0)	0	0	0
Generalised oedema	1 (2.0)	1 (2.0)	0	0	0
Malaise	1 (2.0)	1 (2.0)	0	0	0
Oedema peripheral	1 (2.0)	1 (2.0)	0	0	0
Pain	1 (2.0)	1 (2.0)	0	0	0
Immune system disorders					
-Total	12 (23.5)	2 (3.9)	10 (19.6)	0	0
Hypogammaglobulinaemia	7 (13.7)	0	7 (13.7)	0	0
Graft versus host disease	2 (3.9)	1 (2.0)	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=51		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency common variable	2 (3.9)	0	2 (3.9)	0	0
Graft versus host disease in gastrointestinal tract	1 (2.0)	0	1 (2.0)	0	0
Seasonal allergy	1 (2.0)	1 (2.0)	0	0	0
Infections and infestations					
-Total	31 (60.8)	5 (9.8)	15 (29.4)	9 (17.6)	2 (3.9)
Upper respiratory tract infection	6 (11.8)	2 (3.9)	3 (5.9)	1 (2.0)	0
Urinary tract infection	4 (7.8)	0	2 (3.9)	2 (3.9)	0
Influenza	3 (5.9)	0	3 (5.9)	0	0
Ear infection	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Gastroenteritis	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Parainfluenzae virus infection	2 (3.9)	1 (2.0)	0	1 (2.0)	0
Rhinovirus infection	2 (3.9)	2 (3.9)	0	0	0
Sinusitis	2 (3.9)	0	2 (3.9)	0	0
Bacterial sepsis	1 (2.0)	0	0	0	1 (2.0)
Cellulitis of male external genital organ	1 (2.0)	0	0	1 (2.0)	0
Cholecystitis infective	1 (2.0)	0	0	1 (2.0)	0
Corona virus infection	1 (2.0)	0	0	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=51		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytomegalovirus infection	1 (2.0)	1 (2.0)	0	0	0
Enterovirus infection	1 (2.0)	0	0	1 (2.0)	0
Escherichia urinary tract infection	1 (2.0)	0	0	1 (2.0)	0
Gastroenteritis norovirus	1 (2.0)	0	1 (2.0)	0	0
Gastroenteritis viral	1 (2.0)	1 (2.0)	0	0	0
Herpes zoster	1 (2.0)	0	0	1 (2.0)	0
Molluscum contagiosum	1 (2.0)	1 (2.0)	0	0	0
Oral herpes	1 (2.0)	0	1 (2.0)	0	0
Otitis externa	1 (2.0)	0	1 (2.0)	0	0
Otitis media	1 (2.0)	0	1 (2.0)	0	0
Otitis media acute	1 (2.0)	0	1 (2.0)	0	0
Paronychia	1 (2.0)	1 (2.0)	0	0	0
Rash pustular	1 (2.0)	0	1 (2.0)	0	0
Respiratory syncytial virus infection	1 (2.0)	0	0	1 (2.0)	0
Rhinitis	1 (2.0)	1 (2.0)	0	0	0
Rotavirus infection	1 (2.0)	0	0	1 (2.0)	0
Sepsis	1 (2.0)	0	0	0	1 (2.0)
Tinea capitis	1 (2.0)	1 (2.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=51		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (2.0)	0	0	1 (2.0)	0
Viral infection	1 (2.0)	1 (2.0)	0	0	0
Viral upper respiratory tract infection	1 (2.0)	1 (2.0)	0	0	0
Vulvovaginal mycotic infection	1 (2.0)	0	1 (2.0)	0	0
Injury, poisoning and procedural complications					
-Total	7 (13.7)	3 (5.9)	4 (7.8)	0	0
Contusion	2 (3.9)	2 (3.9)	0	0	0
Infusion related reaction	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Foot fracture	1 (2.0)	0	1 (2.0)	0	0
Procedural nausea	1 (2.0)	0	1 (2.0)	0	0
Procedural pain	1 (2.0)	1 (2.0)	0	0	0
Radius fracture	1 (2.0)	0	1 (2.0)	0	0
Skin abrasion	1 (2.0)	1 (2.0)	0	0	0
Skin laceration	1 (2.0)	0	1 (2.0)	0	0
Sunburn	1 (2.0)	1 (2.0)	0	0	0
Investigations					
-Total	21 (41.2)	5 (9.8)	4 (7.8)	8 (15.7)	4 (7.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=51		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	8 (15.7)	2 (3.9)	0	3 (5.9)	3 (5.9)
White blood cell count decreased	5 (9.8)	2 (3.9)	1 (2.0)	1 (2.0)	1 (2.0)
Weight decreased	4 (7.8)	1 (2.0)	3 (5.9)	0	0
Aspartate aminotransferase increased	3 (5.9)	1 (2.0)	0	2 (3.9)	0
Platelet count decreased	3 (5.9)	3 (5.9)	0	0	0
Alanine aminotransferase increased	2 (3.9)	0	0	2 (3.9)	0
Haemoglobin decreased	2 (3.9)	2 (3.9)	0	0	0
Lymphocyte count decreased	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Weight increased	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Blood bilirubin increased	1 (2.0)	0	0	1 (2.0)	0
Blood creatinine increased	1 (2.0)	1 (2.0)	0	0	0
Blood magnesium decreased	1 (2.0)	1 (2.0)	0	0	0
Blood uric acid increased	1 (2.0)	1 (2.0)	0	0	0
Oxygen saturation decreased	1 (2.0)	1 (2.0)	0	0	0
Transaminases increased	1 (2.0)	1 (2.0)	0	0	0
Metabolism and nutrition disorders					
-Total	8 (15.7)	4 (7.8)	1 (2.0)	2 (3.9)	1 (2.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=51		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Hyperphosphataemia	2 (3.9)	2 (3.9)	0	0	0
Hypokalaemia	2 (3.9)	1 (2.0)	0	0	1 (2.0)
Dehydration	1 (2.0)	0	0	1 (2.0)	0
Hyperglycaemia	1 (2.0)	0	0	1 (2.0)	0
Hypophosphataemia	1 (2.0)	0	0	1 (2.0)	0
Tumour lysis syndrome	1 (2.0)	0	0	1 (2.0)	0
Vitamin d deficiency	1 (2.0)	1 (2.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	16 (31.4)	11 (21.6)	5 (9.8)	0	0
Pain in extremity	8 (15.7)	6 (11.8)	2 (3.9)	0	0
Arthralgia	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Joint range of motion decreased	2 (3.9)	2 (3.9)	0	0	0
Muscular weakness	2 (3.9)	2 (3.9)	0	0	0
Back pain	1 (2.0)	1 (2.0)	0	0	0
Flank pain	1 (2.0)	0	1 (2.0)	0	0
Muscle spasms	1 (2.0)	1 (2.0)	0	0	0
Musculoskeletal chest pain	1 (2.0)	1 (2.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=51		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Osteonecrosis	1 (2.0)	0	1 (2.0)	0	0
Pain in jaw	1 (2.0)	1 (2.0)	0	0	0
Toe walking	1 (2.0)	1 (2.0)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.0)	0	1 (2.0)	0	0
Myelodysplastic syndrome	1 (2.0)	0	1 (2.0)	0	0
Nervous system disorders					
-Total	8 (15.7)	6 (11.8)	2 (3.9)	0	0
Headache	5 (9.8)	4 (7.8)	1 (2.0)	0	0
Dizziness	3 (5.9)	3 (5.9)	0	0	0
Peroneal nerve palsy	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Psychiatric disorders					
-Total	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Depression	2 (3.9)	2 (3.9)	0	0	0
Anxiety	1 (2.0)	1 (2.0)	0	0	0
Sleep disorder	1 (2.0)	0	1 (2.0)	0	0
Renal and urinary disorders					
-Total	3 (5.9)	1 (2.0)	0	2 (3.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=51		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (2.0)	0	0	1 (2.0)	0
Calculus urinary	1 (2.0)	0	1 (2.0)	0	0
Haematuria	1 (2.0)	0	0	1 (2.0)	0
Nephrolithiasis	1 (2.0)	0	0	1 (2.0)	0
Urinary incontinence	1 (2.0)	1 (2.0)	0	0	0
Reproductive system and breast disorders					
-Total	2 (3.9)	0	1 (2.0)	1 (2.0)	0
Scrotal pain	1 (2.0)	0	1 (2.0)	0	0
Vaginal haemorrhage	1 (2.0)	0	0	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	17 (33.3)	10 (19.6)	4 (7.8)	2 (3.9)	1 (2.0)
Cough	6 (11.8)	4 (7.8)	2 (3.9)	0	0
Nasal congestion	4 (7.8)	4 (7.8)	0	0	0
Oropharyngeal pain	3 (5.9)	2 (3.9)	1 (2.0)	0	0
Rhinitis allergic	3 (5.9)	2 (3.9)	1 (2.0)	0	0
Rhinorrhoea	3 (5.9)	2 (3.9)	1 (2.0)	0	0
Epistaxis	2 (3.9)	1 (2.0)	0	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=51		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory failure	1 (2.0)	0	0	0	1 (2.0)
Dysphonia	1 (2.0)	1 (2.0)	0	0	0
Pharyngeal erythema	1 (2.0)	1 (2.0)	0	0	0
Pharyngeal lesion	1 (2.0)	0	0	1 (2.0)	0
Pulmonary oedema	1 (2.0)	0	0	1 (2.0)	0
Skin and subcutaneous tissue disorders					
-Total	14 (27.5)	9 (17.6)	4 (7.8)	1 (2.0)	0
Rash	3 (5.9)	1 (2.0)	2 (3.9)	0	0
Erythema	2 (3.9)	2 (3.9)	0	0	0
Rash maculo-papular	2 (3.9)	2 (3.9)	0	0	0
Alopecia	1 (2.0)	0	1 (2.0)	0	0
Dermatitis acneiform	1 (2.0)	0	0	1 (2.0)	0
Dermatitis atopic	1 (2.0)	1 (2.0)	0	0	0
Dry skin	1 (2.0)	1 (2.0)	0	0	0
Eczema	1 (2.0)	1 (2.0)	0	0	0
Hyperhidrosis	1 (2.0)	1 (2.0)	0	0	0
Ingrowing nail	1 (2.0)	1 (2.0)	0	0	0
Keloid scar	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=51		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Macule	1 (2.0)	1 (2.0)	0	0	0
Petechiae	1 (2.0)	1 (2.0)	0	0	0
Pruritus	1 (2.0)	1 (2.0)	0	0	0
Rash erythematous	1 (2.0)	0	1 (2.0)	0	0
Rash pruritic	1 (2.0)	1 (2.0)	0	0	0
Vascular disorders					
-Total	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Hypertension	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Hot flush	1 (2.0)	1 (2.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174o
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=3		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	0	0	2 (66.7)
Blood and lymphatic system disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Febrile neutropenia	1 (33.3)	0	0	0	1 (33.3)
Ear and labyrinth disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Tympanic membrane perforation	1 (33.3)	0	1 (33.3)	0	0
Gastrointestinal disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Nausea	1 (33.3)	0	1 (33.3)	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	1 (33.3)	0	1 (33.3)	0	0
Chills	1 (33.3)	0	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Immune system disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Immunodeficiency	1 (33.3)	0	1 (33.3)	0	0
Infections and infestations					
-Total	1 (33.3)	0	0	1 (33.3)	0
Haemophilus infection	1 (33.3)	0	1 (33.3)	0	0
Otitis media	1 (33.3)	0	0	1 (33.3)	0
Otitis media acute	1 (33.3)	0	1 (33.3)	0	0
Pneumonia	1 (33.3)	0	1 (33.3)	0	0
Sinusitis	1 (33.3)	0	1 (33.3)	0	0
Injury, poisoning and procedural complications					
-Total	1 (33.3)	0	0	1 (33.3)	0
Procedural pain	1 (33.3)	0	0	1 (33.3)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	1 (33.3)	0	0	1 (33.3)	0
Alanine aminotransferase increased	1 (33.3)	0	0	1 (33.3)	0
Aspartate aminotransferase increased	1 (33.3)	1 (33.3)	0	0	0
Blood alkaline phosphatase increased	1 (33.3)	1 (33.3)	0	0	0
Blood lactate dehydrogenase increased	1 (33.3)	1 (33.3)	0	0	0
C-reactive protein increased	1 (33.3)	1 (33.3)	0	0	0
Platelet count decreased	1 (33.3)	0	0	1 (33.3)	0
White blood cell count decreased	1 (33.3)	0	0	1 (33.3)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (33.3)	0	0	0	1 (33.3)
Glioblastoma multiforme	1 (33.3)	0	0	0	1 (33.3)
Nervous system disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Seizure	1 (33.3)	0	0	1 (33.3)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=3		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Cough	1 (33.3)	1 (33.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Pruritus	1 (33.3)	1 (33.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174o
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (64.5)	4 (12.9)	6 (19.4)	8 (25.8)	2 (6.5)
Blood and lymphatic system disorders					
-Total	1 (3.2)	1 (3.2)	0	0	0
Thrombocytopenia	1 (3.2)	1 (3.2)	0	0	0
Gastrointestinal disorders					
-Total	2 (6.5)	0	2 (6.5)	0	0
Diarrhoea	2 (6.5)	0	2 (6.5)	0	0
Abdominal pain	1 (3.2)	0	1 (3.2)	0	0
General disorders and administration site conditions					
-Total	1 (3.2)	0	0	1 (3.2)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cyst	1 (3.2)	0	0	1 (3.2)	0
Immune system disorders					
-Total	1 (3.2)	0	1 (3.2)	0	0
Chronic graft versus host disease	1 (3.2)	0	1 (3.2)	0	0
Infections and infestations					
-Total	10 (32.3)	2 (6.5)	5 (16.1)	2 (6.5)	1 (3.2)
Otitis media	2 (6.5)	0	2 (6.5)	0	0
Sinusitis	2 (6.5)	0	2 (6.5)	0	0
Upper respiratory tract infection	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Urinary tract infection	2 (6.5)	0	1 (3.2)	1 (3.2)	0
Campylobacter infection	1 (3.2)	0	0	1 (3.2)	0
Cellulitis of male external genital organ	1 (3.2)	0	0	1 (3.2)	0
Clostridium difficile infection	1 (3.2)	0	0	1 (3.2)	0
Gingivitis	1 (3.2)	1 (3.2)	0	0	0
Meningitis aseptic	1 (3.2)	0	1 (3.2)	0	0
Otitis media acute	1 (3.2)	0	1 (3.2)	0	0
Pneumonia	1 (3.2)	0	1 (3.2)	0	0
Respiratory tract infection	1 (3.2)	0	0	0	1 (3.2)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (3.2)	0	0	1 (3.2)	0
Skin infection	1 (3.2)	0	1 (3.2)	0	0
Viral infection	1 (3.2)	1 (3.2)	0	0	0
Vulvovaginal candidiasis	1 (3.2)	0	1 (3.2)	0	0
Investigations					
-Total	7 (22.6)	1 (3.2)	2 (6.5)	3 (9.7)	1 (3.2)
Lymphocyte count decreased	3 (9.7)	2 (6.5)	0	1 (3.2)	0
White blood cell count decreased	3 (9.7)	1 (3.2)	0	1 (3.2)	1 (3.2)
Alanine aminotransferase increased	2 (6.5)	0	1 (3.2)	1 (3.2)	0
Neutrophil count decreased	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Aspartate aminotransferase increased	1 (3.2)	0	0	1 (3.2)	0
Metabolism and nutrition disorders					
-Total	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Hypokalaemia	1 (3.2)	0	0	1 (3.2)	0
Vitamin d deficiency	1 (3.2)	1 (3.2)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (3.2)	0	1 (3.2)	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neck pain	1 (3.2)	0	1 (3.2)	0	0
Nervous system disorders					
-Total	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Disturbance in attention	1 (3.2)	1 (3.2)	0	0	0
Dizziness	1 (3.2)	1 (3.2)	0	0	0
Headache	1 (3.2)	0	1 (3.2)	0	0
Renal and urinary disorders					
-Total	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Acute kidney injury	1 (3.2)	0	0	1 (3.2)	0
Haematuria	1 (3.2)	1 (3.2)	0	0	0
Reproductive system and breast disorders					
-Total	1 (3.2)	0	0	1 (3.2)	0
Ovarian failure	1 (3.2)	0	0	1 (3.2)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (9.7)	3 (9.7)	0	0	0
Cough	1 (3.2)	1 (3.2)	0	0	0
Epistaxis	1 (3.2)	1 (3.2)	0	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=31		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	1 (3.2)	1 (3.2)	0	0	0
Rhinitis allergic	1 (3.2)	1 (3.2)	0	0	0
Rhinorrhoea	1 (3.2)	1 (3.2)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (6.5)	2 (6.5)	0	0	0
Acne	1 (3.2)	1 (3.2)	0	0	0
Papule	1 (3.2)	1 (3.2)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174o
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	0	0	0	5 (100)
Blood and lymphatic system disorders					
-Total	3 (60.0)	0	0	1 (20.0)	2 (40.0)
Anaemia	2 (40.0)	0	0	2 (40.0)	0
Febrile neutropenia	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Leukopenia	1 (20.0)	0	0	0	1 (20.0)
Lymphadenopathy	1 (20.0)	0	1 (20.0)	0	0
Cardiac disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Bradycardia	1 (20.0)	0	1 (20.0)	0	0
Pericardial effusion	1 (20.0)	0	1 (20.0)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (20.0)	1 (20.0)	0	0	0
Ear and labyrinth disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Tympanic membrane perforation	1 (20.0)	0	1 (20.0)	0	0
Eye disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Conjunctival haemorrhage	1 (20.0)	1 (20.0)	0	0	0
Periorbital oedema	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal disorders					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Nausea	2 (40.0)	0	2 (40.0)	0	0
Abdominal pain	1 (20.0)	1 (20.0)	0	0	0
Dysphagia	1 (20.0)	0	0	1 (20.0)	0
Vomiting	1 (20.0)	1 (20.0)	0	0	0
General disorders and administration site conditions					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Acquired gene mutation	1 (20.0)	1 (20.0)	0	0	0
Chills	1 (20.0)	0	1 (20.0)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	1 (20.0)	0	0	1 (20.0)	0
Localised oedema	1 (20.0)	0	0	1 (20.0)	0
Malaise	1 (20.0)	0	1 (20.0)	0	0
Mucosal haemorrhage	1 (20.0)	0	1 (20.0)	0	0
Multiple organ dysfunction syndrome	1 (20.0)	0	0	1 (20.0)	0
Oedema peripheral	1 (20.0)	0	0	1 (20.0)	0
Pyrexia	1 (20.0)	0	1 (20.0)	0	0
Hepatobiliary disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Hyperbilirubinaemia	1 (20.0)	0	0	1 (20.0)	0
Immune system disorders					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	0	1 (20.0)
Cytokine release syndrome	4 (80.0)	2 (40.0)	1 (20.0)	0	1 (20.0)
Hypogammaglobulinaemia	3 (60.0)	0	2 (40.0)	1 (20.0)	0
Immunodeficiency	1 (20.0)	0	1 (20.0)	0	0
Seasonal allergy	1 (20.0)	1 (20.0)	0	0	0
Infections and infestations					
-Total	3 (60.0)	1 (20.0)	0	2 (40.0)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (20.0)	0	1 (20.0)	0	0
Haemophilus infection	1 (20.0)	0	1 (20.0)	0	0
Otitis media	1 (20.0)	0	0	1 (20.0)	0
Otitis media acute	1 (20.0)	0	1 (20.0)	0	0
Pneumonia	1 (20.0)	0	1 (20.0)	0	0
Sinusitis	1 (20.0)	0	1 (20.0)	0	0
Subcutaneous abscess	1 (20.0)	0	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	1 (20.0)	0	0	0
Viral upper respiratory tract infection	1 (20.0)	0	0	1 (20.0)	0
Injury, poisoning and procedural complications					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Arthropod bite	1 (20.0)	1 (20.0)	0	0	0
Procedural complication	1 (20.0)	1 (20.0)	0	0	0
Procedural pain	1 (20.0)	0	0	1 (20.0)	0
Investigations					
-Total	4 (80.0)	0	0	0	4 (80.0)
Alanine aminotransferase increased	3 (60.0)	0	0	3 (60.0)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	3 (60.0)	1 (20.0)	0	1 (20.0)	1 (20.0)
White blood cell count decreased	3 (60.0)	0	0	1 (20.0)	2 (40.0)
Neutrophil count decreased	2 (40.0)	0	0	0	2 (40.0)
Platelet count decreased	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Activated partial thromboplastin time prolonged	1 (20.0)	1 (20.0)	0	0	0
Blood alkaline phosphatase increased	1 (20.0)	1 (20.0)	0	0	0
Blood creatinine increased	1 (20.0)	0	0	1 (20.0)	0
Blood fibrinogen decreased	1 (20.0)	0	0	0	1 (20.0)
Blood lactate dehydrogenase increased	1 (20.0)	1 (20.0)	0	0	0
Blood phosphorus decreased	1 (20.0)	1 (20.0)	0	0	0
Blood urea increased	1 (20.0)	0	0	1 (20.0)	0
C-reactive protein increased	1 (20.0)	1 (20.0)	0	0	0
Lymphocyte count decreased	1 (20.0)	0	0	0	1 (20.0)
Protein total decreased	1 (20.0)	0	0	1 (20.0)	0
Serum ferritin increased	1 (20.0)	0	1 (20.0)	0	0
Metabolism and nutrition disorders					

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (40.0)	0	0	2 (40.0)	0
Hypokalaemia	2 (40.0)	0	0	2 (40.0)	0
Acidosis	1 (20.0)	0	0	1 (20.0)	0
Decreased appetite	1 (20.0)	0	1 (20.0)	0	0
Hyperalbuminaemia	1 (20.0)	1 (20.0)	0	0	0
Hypercalcaemia	1 (20.0)	1 (20.0)	0	0	0
Hyperchloraemia	1 (20.0)	1 (20.0)	0	0	0
Hypermagnesaemia	1 (20.0)	1 (20.0)	0	0	0
Hypernatraemia	1 (20.0)	0	1 (20.0)	0	0
Hypoalbuminaemia	1 (20.0)	0	1 (20.0)	0	0
Hypophosphataemia	1 (20.0)	1 (20.0)	0	0	0
Iron overload	1 (20.0)	0	0	1 (20.0)	0
Metabolic alkalosis	1 (20.0)	1 (20.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Arthralgia	1 (20.0)	1 (20.0)	0	0	0
Muscular weakness	1 (20.0)	0	1 (20.0)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (20.0)	0	0	0	1 (20.0)
Glioblastoma multiforme	1 (20.0)	0	0	0	1 (20.0)
Nervous system disorders					
-Total	3 (60.0)	0	2 (40.0)	1 (20.0)	0
Dysarthria	1 (20.0)	0	1 (20.0)	0	0
Headache	1 (20.0)	0	1 (20.0)	0	0
Seizure	1 (20.0)	0	0	1 (20.0)	0
Somnolence	1 (20.0)	1 (20.0)	0	0	0
Psychiatric disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Delirium	1 (20.0)	0	1 (20.0)	0	0
Insomnia	1 (20.0)	0	1 (20.0)	0	0
Irritability	1 (20.0)	1 (20.0)	0	0	0
Renal and urinary disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Renal impairment	1 (20.0)	0	0	1 (20.0)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	3 (60.0)	2 (40.0)	0	0	1 (20.0)
Cough	1 (20.0)	1 (20.0)	0	0	0
Epistaxis	1 (20.0)	0	1 (20.0)	0	0
Oropharyngeal plaque	1 (20.0)	1 (20.0)	0	0	0
Pleural effusion	1 (20.0)	0	0	1 (20.0)	0
Pulmonary oedema	1 (20.0)	0	0	1 (20.0)	0
Respiratory distress	1 (20.0)	0	0	0	1 (20.0)
Rhinorrhoea	1 (20.0)	1 (20.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Dermatitis	1 (20.0)	1 (20.0)	0	0	0
Hyperhidrosis	1 (20.0)	1 (20.0)	0	0	0
Papule	1 (20.0)	1 (20.0)	0	0	0
Pruritus	1 (20.0)	1 (20.0)	0	0	0
Rash	1 (20.0)	0	1 (20.0)	0	0
Rash papular	1 (20.0)	1 (20.0)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	1 (20.0)	0	0	0	1 (20.0)
Capillary leak syndrome	1 (20.0)	0	0	0	1 (20.0)
Flushing	1 (20.0)	1 (20.0)	0	0	0
Hypertension	1 (20.0)	0	1 (20.0)	0	0
Hypotension	1 (20.0)	0	0	0	1 (20.0)

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174o
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (100)	0	5 (8.5)	12 (20.3)	42 (71.2)
Blood and lymphatic system disorders					
-Total	45 (76.3)	2 (3.4)	3 (5.1)	26 (44.1)	14 (23.7)
Anaemia	25 (42.4)	3 (5.1)	4 (6.8)	17 (28.8)	1 (1.7)
Febrile neutropenia	22 (37.3)	0	0	22 (37.3)	0
Neutropenia	11 (18.6)	0	0	3 (5.1)	8 (13.6)
Thrombocytopenia	10 (16.9)	0	1 (1.7)	3 (5.1)	6 (10.2)
Disseminated intravascular coagulation	4 (6.8)	0	2 (3.4)	2 (3.4)	0
Lymphopenia	4 (6.8)	0	2 (3.4)	1 (1.7)	1 (1.7)
Coagulopathy	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eosinophilia	1 (1.7)	0	0	1 (1.7)	0
Pancytopenia	1 (1.7)	0	0	0	1 (1.7)
Cardiac disorders					
-Total	21 (35.6)	10 (16.9)	9 (15.3)	2 (3.4)	0
Tachycardia	14 (23.7)	7 (11.9)	5 (8.5)	2 (3.4)	0
Sinus tachycardia	6 (10.2)	3 (5.1)	3 (5.1)	0	0
Atrioventricular block second degree	1 (1.7)	1 (1.7)	0	0	0
Cardiac dysfunction	1 (1.7)	1 (1.7)	0	0	0
Left ventricular dysfunction	1 (1.7)	0	0	1 (1.7)	0
Palpitations	1 (1.7)	1 (1.7)	0	0	0
Pericardial effusion	1 (1.7)	1 (1.7)	0	0	0
Sinus bradycardia	1 (1.7)	1 (1.7)	0	0	0
Ventricular tachycardia	1 (1.7)	0	1 (1.7)	0	0
Ear and labyrinth disorders					
-Total	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Ear pain	2 (3.4)	2 (3.4)	0	0	0
Hypoacusis	1 (1.7)	0	1 (1.7)	0	0
Endocrine disorders					

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Adrenal insufficiency	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Eye disorders					
-Total	17 (28.8)	9 (15.3)	8 (13.6)	0	0
Vision blurred	4 (6.8)	2 (3.4)	2 (3.4)	0	0
Eye pain	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Periorbital oedema	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Conjunctival haemorrhage	2 (3.4)	2 (3.4)	0	0	0
Dry eye	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Photophobia	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Retinal haemorrhage	2 (3.4)	2 (3.4)	0	0	0
Uveitis	2 (3.4)	0	2 (3.4)	0	0
Conjunctivitis allergic	1 (1.7)	1 (1.7)	0	0	0
Ocular hyperaemia	1 (1.7)	1 (1.7)	0	0	0
Ocular hypertension	1 (1.7)	0	1 (1.7)	0	0
Papilloedema	1 (1.7)	0	1 (1.7)	0	0
Visual impairment	1 (1.7)	0	1 (1.7)	0	0
Gastrointestinal disorders					
-Total	39 (66.1)	12 (20.3)	15 (25.4)	12 (20.3)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	26 (44.1)	15 (25.4)	8 (13.6)	3 (5.1)	0
Diarrhoea	24 (40.7)	13 (22.0)	9 (15.3)	2 (3.4)	0
Nausea	23 (39.0)	6 (10.2)	12 (20.3)	5 (8.5)	0
Abdominal pain	10 (16.9)	5 (8.5)	4 (6.8)	1 (1.7)	0
Constipation	7 (11.9)	6 (10.2)	1 (1.7)	0	0
Abdominal pain upper	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Abdominal distension	2 (3.4)	0	2 (3.4)	0	0
Haematemesis	2 (3.4)	2 (3.4)	0	0	0
Oral pain	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Pancreatitis	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Stomatitis	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Abdominal discomfort	1 (1.7)	1 (1.7)	0	0	0
Abdominal pain lower	1 (1.7)	0	1 (1.7)	0	0
Abdominal tenderness	1 (1.7)	1 (1.7)	0	0	0
Anal incontinence	1 (1.7)	1 (1.7)	0	0	0
Ascites	1 (1.7)	0	0	1 (1.7)	0
Dyspepsia	1 (1.7)	0	1 (1.7)	0	0
Dysphagia	1 (1.7)	0	1 (1.7)	0	0
Enterocolitis	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flatulence	1 (1.7)	1 (1.7)	0	0	0
Gastrointestinal haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Gastrooesophageal reflux disease	1 (1.7)	1 (1.7)	0	0	0
Glossodynia	1 (1.7)	1 (1.7)	0	0	0
Ileus	1 (1.7)	0	0	1 (1.7)	0
Intestinal obstruction	1 (1.7)	0	0	1 (1.7)	0
Lip pain	1 (1.7)	0	1 (1.7)	0	0
Mouth haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Pigmentation lip	1 (1.7)	1 (1.7)	0	0	0
Tooth socket haemorrhage	1 (1.7)	1 (1.7)	0	0	0
General disorders and administration site conditions					
-Total	38 (64.4)	15 (25.4)	12 (20.3)	10 (16.9)	1 (1.7)
Pyrexia	24 (40.7)	8 (13.6)	9 (15.3)	6 (10.2)	1 (1.7)
Fatigue	15 (25.4)	12 (20.3)	2 (3.4)	1 (1.7)	0
Chills	9 (15.3)	9 (15.3)	0	0	0
Catheter site pain	4 (6.8)	1 (1.7)	3 (5.1)	0	0
Pain	4 (6.8)	1 (1.7)	1 (1.7)	2 (3.4)	0
Generalised oedema	3 (5.1)	1 (1.7)	2 (3.4)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Influenza like illness	2 (3.4)	2 (3.4)	0	0	0
Oedema peripheral	2 (3.4)	2 (3.4)	0	0	0
Asthenia	1 (1.7)	1 (1.7)	0	0	0
Catheter site extravasation	1 (1.7)	0	1 (1.7)	0	0
Catheter site haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Crying	1 (1.7)	1 (1.7)	0	0	0
Cyst	1 (1.7)	0	0	1 (1.7)	0
Face oedema	1 (1.7)	0	1 (1.7)	0	0
Facial pain	1 (1.7)	0	1 (1.7)	0	0
Injection site haematoma	1 (1.7)	1 (1.7)	0	0	0
Non-cardiac chest pain	1 (1.7)	1 (1.7)	0	0	0
Peripheral swelling	1 (1.7)	0	1 (1.7)	0	0
Physical deconditioning	1 (1.7)	0	0	1 (1.7)	0
Hepatobiliary disorders					
-Total	6 (10.2)	3 (5.1)	2 (3.4)	1 (1.7)	0
Hepatomegaly	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Hyperbilirubinaemia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Gallbladder enlargement	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatosplenomegaly	1 (1.7)	1 (1.7)	0	0	0
Immune system disorders					
-Total	54 (91.5)	4 (6.8)	29 (49.2)	11 (18.6)	10 (16.9)
Cytokine release syndrome	46 (78.0)	4 (6.8)	24 (40.7)	8 (13.6)	10 (16.9)
Hypogammaglobulinaemia	29 (49.2)	3 (5.1)	22 (37.3)	4 (6.8)	0
Graft versus host disease	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Immunodeficiency common variable	2 (3.4)	0	2 (3.4)	0	0
Chronic graft versus host disease	1 (1.7)	0	1 (1.7)	0	0
Drug hypersensitivity	1 (1.7)	0	1 (1.7)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.7)	0	1 (1.7)	0	0
Graft versus host disease in skin	1 (1.7)	1 (1.7)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	1 (1.7)	0	0
Seasonal allergy	1 (1.7)	1 (1.7)	0	0	0
Infections and infestations					
-Total	43 (72.9)	6 (10.2)	21 (35.6)	12 (20.3)	4 (6.8)
Upper respiratory tract infection	8 (13.6)	3 (5.1)	4 (6.8)	1 (1.7)	0
Clostridium difficile infection	5 (8.5)	0	4 (6.8)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	5 (8.5)	5 (8.5)	0	0	0
Urinary tract infection	5 (8.5)	0	3 (5.1)	2 (3.4)	0
Clostridium difficile colitis	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Gastroenteritis	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Influenza	4 (6.8)	1 (1.7)	3 (5.1)	0	0
Otitis media	3 (5.1)	0	3 (5.1)	0	0
Pneumonia	3 (5.1)	0	2 (3.4)	1 (1.7)	0
Sinusitis	3 (5.1)	0	3 (5.1)	0	0
Viral infection	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Cytomegalovirus infection	2 (3.4)	2 (3.4)	0	0	0
Ear infection	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Parainfluenzae virus infection	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Skin infection	2 (3.4)	0	2 (3.4)	0	0
Staphylococcal infection	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Viral upper respiratory tract infection	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Vulvovaginal candidiasis	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Acute sinusitis	1 (1.7)	0	1 (1.7)	0	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Body tinea	1 (1.7)	1 (1.7)	0	0	0
Campylobacter infection	1 (1.7)	0	0	1 (1.7)	0
Catheter site cellulitis	1 (1.7)	1 (1.7)	0	0	0
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Cholecystitis infective	1 (1.7)	0	0	1 (1.7)	0
Corona virus infection	1 (1.7)	0	0	1 (1.7)	0
Enterococcal infection	1 (1.7)	1 (1.7)	0	0	0
Enterovirus infection	1 (1.7)	0	0	1 (1.7)	0
Escherichia urinary tract infection	1 (1.7)	0	0	1 (1.7)	0
Folliculitis	1 (1.7)	0	1 (1.7)	0	0
Fungal skin infection	1 (1.7)	1 (1.7)	0	0	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis viral	1 (1.7)	1 (1.7)	0	0	0
Gingivitis	1 (1.7)	1 (1.7)	0	0	0
Herpes simplex	1 (1.7)	1 (1.7)	0	0	0
Herpes zoster	1 (1.7)	0	0	1 (1.7)	0
Human herpesvirus 6 infection	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypopyon	1 (1.7)	0	1 (1.7)	0	0
Meningitis aseptic	1 (1.7)	0	1 (1.7)	0	0
Molluscum contagiosum	1 (1.7)	1 (1.7)	0	0	0
Oral candidiasis	1 (1.7)	1 (1.7)	0	0	0
Oral herpes	1 (1.7)	0	1 (1.7)	0	0
Orchitis	1 (1.7)	1 (1.7)	0	0	0
Otitis externa	1 (1.7)	0	1 (1.7)	0	0
Otitis media acute	1 (1.7)	0	1 (1.7)	0	0
Paronychia	1 (1.7)	1 (1.7)	0	0	0
Pharyngitis	1 (1.7)	0	1 (1.7)	0	0
Rash pustular	1 (1.7)	0	1 (1.7)	0	0
Respiratory syncytial virus infection	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection	1 (1.7)	0	0	0	1 (1.7)
Respiratory tract infection viral	1 (1.7)	0	0	1 (1.7)	0
Rhinitis	1 (1.7)	1 (1.7)	0	0	0
Rotavirus infection	1 (1.7)	0	0	1 (1.7)	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Streptococcal infection	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tinea capitis	1 (1.7)	1 (1.7)	0	0	0
Urinary tract infection enterococcal	1 (1.7)	0	0	1 (1.7)	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0
Vulvovaginal mycotic infection	1 (1.7)	0	1 (1.7)	0	0
Injury, poisoning and procedural complications					
-Total	20 (33.9)	10 (16.9)	8 (13.6)	1 (1.7)	1 (1.7)
Infusion related reaction	4 (6.8)	1 (1.7)	3 (5.1)	0	0
Procedural pain	4 (6.8)	2 (3.4)	2 (3.4)	0	0
Contusion	3 (5.1)	3 (5.1)	0	0	0
Transfusion reaction	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Skin abrasion	2 (3.4)	2 (3.4)	0	0	0
Foot fracture	1 (1.7)	0	1 (1.7)	0	0
Incision site pain	1 (1.7)	1 (1.7)	0	0	0
Limb injury	1 (1.7)	1 (1.7)	0	0	0
Mouth injury	1 (1.7)	1 (1.7)	0	0	0
Post procedural haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Procedural headache	1 (1.7)	0	1 (1.7)	0	0
Procedural nausea	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural site reaction	1 (1.7)	1 (1.7)	0	0	0
Radius fracture	1 (1.7)	0	1 (1.7)	0	0
Skin laceration	1 (1.7)	0	1 (1.7)	0	0
Stoma site irritation	1 (1.7)	1 (1.7)	0	0	0
Subdural haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Sunburn	1 (1.7)	1 (1.7)	0	0	0
Tibia fracture	1 (1.7)	0	1 (1.7)	0	0
Tongue injury	1 (1.7)	1 (1.7)	0	0	0
Tracheal haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Transfusion related complication	1 (1.7)	0	0	0	1 (1.7)
Investigations					
-Total	52 (88.1)	2 (3.4)	5 (8.5)	15 (25.4)	30 (50.8)
White blood cell count decreased	32 (54.2)	4 (6.8)	1 (1.7)	11 (18.6)	16 (27.1)
Neutrophil count decreased	26 (44.1)	1 (1.7)	2 (3.4)	4 (6.8)	19 (32.2)
Alanine aminotransferase increased	18 (30.5)	5 (8.5)	2 (3.4)	11 (18.6)	0
Platelet count decreased	18 (30.5)	3 (5.1)	2 (3.4)	2 (3.4)	11 (18.6)
Aspartate aminotransferase increased	17 (28.8)	3 (5.1)	4 (6.8)	7 (11.9)	3 (5.1)
Lymphocyte count decreased	15 (25.4)	1 (1.7)	3 (5.1)	7 (11.9)	4 (6.8)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	9 (15.3)	8 (13.6)	0	1 (1.7)	0
Prothrombin time prolonged	9 (15.3)	5 (8.5)	3 (5.1)	1 (1.7)	0
Blood bilirubin increased	8 (13.6)	2 (3.4)	3 (5.1)	3 (5.1)	0
Blood creatinine increased	8 (13.6)	5 (8.5)	2 (3.4)	1 (1.7)	0
Activated partial thromboplastin time prolonged	4 (6.8)	2 (3.4)	2 (3.4)	0	0
Blood immunoglobulin m decreased	4 (6.8)	4 (6.8)	0	0	0
Weight decreased	4 (6.8)	1 (1.7)	3 (5.1)	0	0
Blood fibrinogen decreased	3 (5.1)	0	1 (1.7)	2 (3.4)	0
Blood immunoglobulin a decreased	3 (5.1)	3 (5.1)	0	0	0
Haemoglobin decreased	3 (5.1)	2 (3.4)	0	1 (1.7)	0
Transaminases increased	3 (5.1)	3 (5.1)	0	0	0
Blood magnesium decreased	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Blood phosphorus increased	2 (3.4)	2 (3.4)	0	0	0
Blood urea increased	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Blood uric acid increased	2 (3.4)	2 (3.4)	0	0	0
Lipase increased	2 (3.4)	0	0	0	2 (3.4)
Weight increased	2 (3.4)	1 (1.7)	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bicarbonate decreased	1 (1.7)	0	1 (1.7)	0	0
Blood immunoglobulin g decreased	1 (1.7)	0	1 (1.7)	0	0
Blood lactic acid increased	1 (1.7)	0	0	0	1 (1.7)
Blood sodium increased	1 (1.7)	0	1 (1.7)	0	0
C-reactive protein increased	1 (1.7)	0	0	1 (1.7)	0
Cardiac murmur	1 (1.7)	1 (1.7)	0	0	0
Culture stool positive	1 (1.7)	1 (1.7)	0	0	0
Fibrin d dimer increased	1 (1.7)	1 (1.7)	0	0	0
Hepatic enzyme increased	1 (1.7)	0	1 (1.7)	0	0
Norovirus test positive	1 (1.7)	1 (1.7)	0	0	0
Oxygen saturation decreased	1 (1.7)	1 (1.7)	0	0	0
Pulmonary function test decreased	1 (1.7)	0	1 (1.7)	0	0
Serum ferritin increased	1 (1.7)	0	1 (1.7)	0	0
Metabolism and nutrition disorders					
-Total	41 (69.5)	8 (13.6)	8 (13.6)	21 (35.6)	4 (6.8)
Decreased appetite	21 (35.6)	5 (8.5)	4 (6.8)	12 (20.3)	0
Hypokalaemia	17 (28.8)	4 (6.8)	6 (10.2)	6 (10.2)	1 (1.7)
Hypophosphataemia	9 (15.3)	1 (1.7)	0	7 (11.9)	1 (1.7)
Hyperphosphataemia	8 (13.6)	8 (13.6)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	4 (6.8)	1 (1.7)	0	3 (5.1)	0
Hypoalbuminaemia	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Fluid overload	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Hyperglycaemia	3 (5.1)	0	1 (1.7)	2 (3.4)	0
Hypernatraemia	3 (5.1)	1 (1.7)	1 (1.7)	0	1 (1.7)
Hyperuricaemia	3 (5.1)	2 (3.4)	0	0	1 (1.7)
Hypocalcaemia	3 (5.1)	1 (1.7)	1 (1.7)	1 (1.7)	0
Hypertriglyceridaemia	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Hyponatraemia	2 (3.4)	0	0	2 (3.4)	0
Tumour lysis syndrome	2 (3.4)	0	0	2 (3.4)	0
Vitamin d deficiency	2 (3.4)	2 (3.4)	0	0	0
Acidosis	1 (1.7)	1 (1.7)	0	0	0
Hypomagnesaemia	1 (1.7)	1 (1.7)	0	0	0
Malnutrition	1 (1.7)	0	0	1 (1.7)	0
Metabolic acidosis	1 (1.7)	0	1 (1.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	24 (40.7)	14 (23.7)	9 (15.3)	1 (1.7)	0
Pain in extremity	11 (18.6)	7 (11.9)	4 (6.8)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	5 (8.5)	4 (6.8)	1 (1.7)	0	0
Arthralgia	4 (6.8)	2 (3.4)	1 (1.7)	1 (1.7)	0
Musculoskeletal pain	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Joint range of motion decreased	2 (3.4)	2 (3.4)	0	0	0
Muscle spasms	2 (3.4)	2 (3.4)	0	0	0
Muscular weakness	2 (3.4)	2 (3.4)	0	0	0
Musculoskeletal chest pain	2 (3.4)	2 (3.4)	0	0	0
Back pain	1 (1.7)	1 (1.7)	0	0	0
Coccydynia	1 (1.7)	1 (1.7)	0	0	0
Flank pain	1 (1.7)	0	1 (1.7)	0	0
Limb discomfort	1 (1.7)	1 (1.7)	0	0	0
Neck pain	1 (1.7)	0	1 (1.7)	0	0
Osteonecrosis	1 (1.7)	0	1 (1.7)	0	0
Osteopenia	1 (1.7)	0	1 (1.7)	0	0
Pain in jaw	1 (1.7)	1 (1.7)	0	0	0
Toe walking	1 (1.7)	1 (1.7)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (3.4)	0	2 (3.4)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myelodysplastic syndrome	1 (1.7)	0	1 (1.7)	0	0
Skin papilloma	1 (1.7)	0	1 (1.7)	0	0
Nervous system disorders					
-Total	32 (54.2)	17 (28.8)	10 (16.9)	4 (6.8)	1 (1.7)
Headache	23 (39.0)	15 (25.4)	6 (10.2)	2 (3.4)	0
Dizziness	6 (10.2)	6 (10.2)	0	0	0
Encephalopathy	4 (6.8)	1 (1.7)	1 (1.7)	2 (3.4)	0
Seizure	3 (5.1)	0	2 (3.4)	1 (1.7)	0
Peroneal nerve palsy	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Tremor	2 (3.4)	2 (3.4)	0	0	0
Asterixis	1 (1.7)	1 (1.7)	0	0	0
Ataxia	1 (1.7)	0	1 (1.7)	0	0
Depressed level of consciousness	1 (1.7)	1 (1.7)	0	0	0
Disturbance in attention	1 (1.7)	1 (1.7)	0	0	0
Dysarthria	1 (1.7)	1 (1.7)	0	0	0
Embolic stroke	1 (1.7)	0	0	0	1 (1.7)
Idiopathic intracranial hypertension	1 (1.7)	0	1 (1.7)	0	0
Migraine	1 (1.7)	0	1 (1.7)	0	0
Myoclonus	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neuropathy peripheral	1 (1.7)	0	1 (1.7)	0	0
Pleocytosis	1 (1.7)	1 (1.7)	0	0	0
Product issues					
-Total	1 (1.7)	1 (1.7)	0	0	0
Device occlusion	1 (1.7)	1 (1.7)	0	0	0
Psychiatric disorders					
-Total	16 (27.1)	8 (13.6)	7 (11.9)	1 (1.7)	0
Anxiety	7 (11.9)	3 (5.1)	3 (5.1)	1 (1.7)	0
Confusional state	6 (10.2)	3 (5.1)	3 (5.1)	0	0
Delirium	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Agitation	2 (3.4)	0	2 (3.4)	0	0
Depression	2 (3.4)	2 (3.4)	0	0	0
Hallucination	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Adjustment disorder	1 (1.7)	0	1 (1.7)	0	0
Irritability	1 (1.7)	1 (1.7)	0	0	0
Listless	1 (1.7)	1 (1.7)	0	0	0
Mental status changes	1 (1.7)	1 (1.7)	0	0	0
Panic attack	1 (1.7)	0	1 (1.7)	0	0
Sleep disorder	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Suicidal ideation	1 (1.7)	1 (1.7)	0	0	0
Renal and urinary disorders					
-Total	14 (23.7)	3 (5.1)	2 (3.4)	5 (8.5)	4 (6.8)
Acute kidney injury	9 (15.3)	1 (1.7)	1 (1.7)	4 (6.8)	3 (5.1)
Haematuria	5 (8.5)	0	2 (3.4)	2 (3.4)	1 (1.7)
Dysuria	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Oliguria	2 (3.4)	0	0	2 (3.4)	0
Calculus urinary	1 (1.7)	0	1 (1.7)	0	0
Nephrolithiasis	1 (1.7)	0	0	1 (1.7)	0
Pollakiuria	1 (1.7)	1 (1.7)	0	0	0
Renal failure	1 (1.7)	0	0	0	1 (1.7)
Urinary incontinence	1 (1.7)	1 (1.7)	0	0	0
Reproductive system and breast disorders					
-Total	6 (10.2)	2 (3.4)	2 (3.4)	2 (3.4)	0
Vulvovaginal adhesion	2 (3.4)	2 (3.4)	0	0	0
Oedema genital	1 (1.7)	0	1 (1.7)	0	0
Ovarian failure	1 (1.7)	0	0	1 (1.7)	0
Scrotal pain	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	35 (59.3)	12 (20.3)	9 (15.3)	7 (11.9)	7 (11.9)
Cough	13 (22.0)	11 (18.6)	2 (3.4)	0	0
Hypoxia	10 (16.9)	0	3 (5.1)	4 (6.8)	3 (5.1)
Epistaxis	9 (15.3)	4 (6.8)	0	4 (6.8)	1 (1.7)
Pleural effusion	7 (11.9)	2 (3.4)	4 (6.8)	1 (1.7)	0
Oropharyngeal pain	6 (10.2)	4 (6.8)	2 (3.4)	0	0
Pulmonary oedema	6 (10.2)	1 (1.7)	0	3 (5.1)	2 (3.4)
Nasal congestion	5 (8.5)	5 (8.5)	0	0	0
Rhinorrhoea	5 (8.5)	4 (6.8)	1 (1.7)	0	0
Tachypnoea	5 (8.5)	3 (5.1)	1 (1.7)	1 (1.7)	0
Rhinitis allergic	4 (6.8)	3 (5.1)	1 (1.7)	0	0
Respiratory failure	3 (5.1)	0	0	0	3 (5.1)
Dyspnoea	2 (3.4)	0	0	1 (1.7)	1 (1.7)
Haemoptysis	2 (3.4)	1 (1.7)	0	0	1 (1.7)
Acute respiratory failure	1 (1.7)	0	0	0	1 (1.7)
Atelectasis	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphonia	1 (1.7)	1 (1.7)	0	0	0
Interstitial lung disease	1 (1.7)	0	0	0	1 (1.7)
Pharyngeal erythema	1 (1.7)	1 (1.7)	0	0	0
Pharyngeal lesion	1 (1.7)	0	0	1 (1.7)	0
Pharyngeal ulceration	1 (1.7)	0	1 (1.7)	0	0
Respiratory depression	1 (1.7)	0	1 (1.7)	0	0
Wheezing	1 (1.7)	0	1 (1.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	28 (47.5)	17 (28.8)	8 (13.6)	3 (5.1)	0
Rash	7 (11.9)	5 (8.5)	2 (3.4)	0	0
Dry skin	5 (8.5)	5 (8.5)	0	0	0
Erythema	5 (8.5)	5 (8.5)	0	0	0
Rash maculo-papular	5 (8.5)	3 (5.1)	1 (1.7)	1 (1.7)	0
Petechiae	4 (6.8)	3 (5.1)	1 (1.7)	0	0
Hyperhidrosis	3 (5.1)	3 (5.1)	0	0	0
Ingrowing nail	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Pruritus	3 (5.1)	3 (5.1)	0	0	0
Macule	2 (3.4)	2 (3.4)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash erythematous	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Acne	1 (1.7)	1 (1.7)	0	0	0
Alopecia	1 (1.7)	0	1 (1.7)	0	0
Dermatitis acneiform	1 (1.7)	0	0	1 (1.7)	0
Dermatitis atopic	1 (1.7)	1 (1.7)	0	0	0
Dermatitis diaper	1 (1.7)	1 (1.7)	0	0	0
Ecchymosis	1 (1.7)	0	0	1 (1.7)	0
Eczema	1 (1.7)	1 (1.7)	0	0	0
Keloid scar	1 (1.7)	0	1 (1.7)	0	0
Livedo reticularis	1 (1.7)	1 (1.7)	0	0	0
Night sweats	1 (1.7)	0	1 (1.7)	0	0
Papule	1 (1.7)	1 (1.7)	0	0	0
Rash follicular	1 (1.7)	1 (1.7)	0	0	0
Rash macular	1 (1.7)	1 (1.7)	0	0	0
Rash papular	1 (1.7)	1 (1.7)	0	0	0
Rash pruritic	1 (1.7)	1 (1.7)	0	0	0
Rash vesicular	1 (1.7)	1 (1.7)	0	0	0
Skin exfoliation	1 (1.7)	1 (1.7)	0	0	0
Skin fissures	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin irritation	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					
-Total	24 (40.7)	3 (5.1)	6 (10.2)	8 (13.6)	7 (11.9)
Hypotension	15 (25.4)	1 (1.7)	0	7 (11.9)	7 (11.9)
Hypertension	11 (18.6)	3 (5.1)	7 (11.9)	1 (1.7)	0
Orthostatic hypotension	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Embolism	1 (1.7)	0	0	1 (1.7)	0
Flushing	1 (1.7)	1 (1.7)	0	0	0
Haematoma	1 (1.7)	0	1 (1.7)	0	0
Hot flush	1 (1.7)	1 (1.7)	0	0	0
Secondary hypertension	1 (1.7)	0	1 (1.7)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174p
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	1 (25.0)	0	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders					
-Total	3 (75.0)	0	0	2 (50.0)	1 (25.0)
Anaemia	2 (50.0)	2 (50.0)	0	0	0
Febrile neutropenia	2 (50.0)	0	0	2 (50.0)	0
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
Gastrointestinal disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Constipation	1 (25.0)	1 (25.0)	0	0	0
General disorders and administration site conditions					
-Total	1 (25.0)	1 (25.0)	0	0	0
Fatigue	1 (25.0)	1 (25.0)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Cytokine release syndrome	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Hypogammaglobulinaemia	1 (25.0)	0	1 (25.0)	0	0
Infections and infestations					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Fungal skin infection	1 (25.0)	1 (25.0)	0	0	0
Viral infection	1 (25.0)	0	1 (25.0)	0	0
Investigations					
-Total	3 (75.0)	1 (25.0)	0	0	2 (50.0)
Lymphocyte count decreased	2 (50.0)	1 (25.0)	0	0	1 (25.0)
Blood bilirubin increased	1 (25.0)	1 (25.0)	0	0	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0	0	0
Fibrin d dimer increased	1 (25.0)	1 (25.0)	0	0	0
Neutrophil count decreased	1 (25.0)	0	0	0	1 (25.0)
Platelet count decreased	1 (25.0)	1 (25.0)	0	0	0
White blood cell count decreased	1 (25.0)	0	0	0	1 (25.0)

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Decreased appetite	1 (25.0)	1 (25.0)	0	0	0
Hyperphosphataemia	1 (25.0)	1 (25.0)	0	0	0
Nervous system disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Headache	1 (25.0)	0	1 (25.0)	0	0
Tremor	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (50.0)	2 (50.0)	0	0	0
Dermatitis diaper	1 (25.0)	1 (25.0)	0	0	0
Dry skin	1 (25.0)	1 (25.0)	0	0	0
Erythema	1 (25.0)	1 (25.0)	0	0	0
Vascular disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Hypotension	1 (25.0)	0	0	1 (25.0)	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174p
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (98.3)	1 (1.7)	7 (11.7)	13 (21.7)	38 (63.3)
Blood and lymphatic system disorders					
-Total	40 (66.7)	2 (3.3)	3 (5.0)	25 (41.7)	10 (16.7)
Anaemia	25 (41.7)	1 (1.7)	5 (8.3)	18 (30.0)	1 (1.7)
Febrile neutropenia	20 (33.3)	0	0	20 (33.3)	0
Thrombocytopenia	8 (13.3)	0	0	2 (3.3)	6 (10.0)
Neutropenia	7 (11.7)	0	0	3 (5.0)	4 (6.7)
Disseminated intravascular coagulation	4 (6.7)	0	2 (3.3)	2 (3.3)	0
Lymphopenia	3 (5.0)	0	1 (1.7)	1 (1.7)	1 (1.7)
Coagulopathy	1 (1.7)	1 (1.7)	0	0	0
Pancytopenia	1 (1.7)	0	0	0	1 (1.7)
Cardiac disorders					
-Total	22 (36.7)	11 (18.3)	9 (15.0)	2 (3.3)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	15 (25.0)	8 (13.3)	5 (8.3)	2 (3.3)	0
Sinus tachycardia	5 (8.3)	3 (5.0)	2 (3.3)	0	0
Pericardial effusion	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Atrioventricular block second degree	1 (1.7)	1 (1.7)	0	0	0
Bradycardia	1 (1.7)	0	1 (1.7)	0	0
Cardiac dysfunction	1 (1.7)	1 (1.7)	0	0	0
Left ventricular dysfunction	1 (1.7)	0	0	1 (1.7)	0
Palpitations	1 (1.7)	1 (1.7)	0	0	0
Sinus bradycardia	1 (1.7)	1 (1.7)	0	0	0
Ventricular tachycardia	1 (1.7)	0	1 (1.7)	0	0
Ear and labyrinth disorders					
-Total	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Ear pain	2 (3.3)	2 (3.3)	0	0	0
Hypoacusis	1 (1.7)	0	1 (1.7)	0	0
Endocrine disorders					
-Total	1 (1.7)	0	1 (1.7)	0	0
Adrenal insufficiency	1 (1.7)	0	1 (1.7)	0	0
Eye disorders					
-Total	13 (21.7)	6 (10.0)	7 (11.7)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

			All patients N=60		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Periorbital oedema	4 (6.7)	3 (5.0)	1 (1.7)	0	0
Conjunctival haemorrhage	3 (5.0)	3 (5.0)	0	0	0
Eye pain	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Vision blurred	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Photophobia	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Retinal haemorrhage	2 (3.3)	2 (3.3)	0	0	0
Uveitis	2 (3.3)	0	2 (3.3)	0	0
Ocular hypertension	1 (1.7)	0	1 (1.7)	0	0
Papilloedema	1 (1.7)	0	1 (1.7)	0	0
Visual impairment	1 (1.7)	0	1 (1.7)	0	0
Gastrointestinal disorders					
-Total	35 (58.3)	10 (16.7)	14 (23.3)	11 (18.3)	0
Vomiting	22 (36.7)	13 (21.7)	6 (10.0)	3 (5.0)	0
Nausea	21 (35.0)	6 (10.0)	12 (20.0)	3 (5.0)	0
Diarrhoea	18 (30.0)	11 (18.3)	6 (10.0)	1 (1.7)	0
Abdominal pain	9 (15.0)	6 (10.0)	2 (3.3)	1 (1.7)	0
Constipation	6 (10.0)	5 (8.3)	1 (1.7)	0	0
Abdominal distension	2 (3.3)	0	2 (3.3)	0	0
Abdominal pain upper	2 (3.3)	0	2 (3.3)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphagia	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Haematemesis	2 (3.3)	2 (3.3)	0	0	0
Pancreatitis	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Stomatitis	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Abdominal discomfort	1 (1.7)	1 (1.7)	0	0	0
Abdominal pain lower	1 (1.7)	0	1 (1.7)	0	0
Abdominal tenderness	1 (1.7)	1 (1.7)	0	0	0
Anal incontinence	1 (1.7)	1 (1.7)	0	0	0
Ascites	1 (1.7)	0	0	1 (1.7)	0
Dyspepsia	1 (1.7)	0	1 (1.7)	0	0
Flatulence	1 (1.7)	1 (1.7)	0	0	0
Gastrointestinal haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Gastrooesophageal reflux disease	1 (1.7)	1 (1.7)	0	0	0
Glossodynia	1 (1.7)	1 (1.7)	0	0	0
Ileus	1 (1.7)	0	0	1 (1.7)	0
Intestinal obstruction	1 (1.7)	0	0	1 (1.7)	0
Lip pain	1 (1.7)	0	1 (1.7)	0	0
Mouth haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Tooth socket haemorrhage	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	31 (51.7)	11 (18.3)	10 (16.7)	9 (15.0)	1 (1.7)
Pyrexia	16 (26.7)	3 (5.0)	7 (11.7)	5 (8.3)	1 (1.7)
Fatigue	12 (20.0)	9 (15.0)	2 (3.3)	1 (1.7)	0
Chills	8 (13.3)	8 (13.3)	0	0	0
Catheter site pain	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Malaise	3 (5.0)	0	3 (5.0)	0	0
Pain	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Face oedema	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Generalised oedema	2 (3.3)	0	2 (3.3)	0	0
Oedema peripheral	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Asthenia	1 (1.7)	1 (1.7)	0	0	0
Catheter site extravasation	1 (1.7)	0	1 (1.7)	0	0
Catheter site haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Facial pain	1 (1.7)	0	1 (1.7)	0	0
Injection site haematoma	1 (1.7)	1 (1.7)	0	0	0
Localised oedema	1 (1.7)	0	0	1 (1.7)	0
Mucosal haemorrhage	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	1 (1.7)	0	0	1 (1.7)	0
Non-cardiac chest pain	1 (1.7)	1 (1.7)	0	0	0
Peripheral swelling	1 (1.7)	0	1 (1.7)	0	0
Physical deconditioning	1 (1.7)	0	0	1 (1.7)	0
Hepatobiliary disorders					
-Total	7 (11.7)	3 (5.0)	2 (3.3)	2 (3.3)	0
Hepatomegaly	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Hyperbilirubinaemia	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Gallbladder enlargement	1 (1.7)	1 (1.7)	0	0	0
Hepatosplenomegaly	1 (1.7)	1 (1.7)	0	0	0
Immune system disorders					
-Total	54 (90.0)	4 (6.7)	28 (46.7)	11 (18.3)	11 (18.3)
Cytokine release syndrome	47 (78.3)	5 (8.3)	23 (38.3)	8 (13.3)	11 (18.3)
Hypogammaglobulinaemia	24 (40.0)	3 (5.0)	17 (28.3)	4 (6.7)	0
Drug hypersensitivity	1 (1.7)	0	1 (1.7)	0	0
Graft versus host disease in skin	1 (1.7)	1 (1.7)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	1 (1.7)	0	0
Infections and infestations					
-Total	24 (40.0)	4 (6.7)	13 (21.7)	6 (10.0)	1 (1.7)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	4 (6.7)	1 (1.7)	2 (3.3)	1 (1.7)	0
Clostridium difficile infection	4 (6.7)	0	4 (6.7)	0	0
Rhinovirus infection	3 (5.0)	3 (5.0)	0	0	0
Gastroenteritis	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Pneumonia	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Staphylococcal infection	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Acute sinusitis	1 (1.7)	0	1 (1.7)	0	0
Body tinea	1 (1.7)	1 (1.7)	0	0	0
Catheter site cellulitis	1 (1.7)	1 (1.7)	0	0	0
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cytomegalovirus infection	1 (1.7)	1 (1.7)	0	0	0
Enterococcal infection	1 (1.7)	1 (1.7)	0	0	0
Folliculitis	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Herpes simplex	1 (1.7)	1 (1.7)	0	0	0
Human herpesvirus 6 infection	1 (1.7)	0	1 (1.7)	0	0
Hypopyon	1 (1.7)	0	1 (1.7)	0	0
Influenza	1 (1.7)	1 (1.7)	0	0	0
Oral candidiasis	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

			All patients N=60		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Orchitis	1 (1.7)	1 (1.7)	0	0	0
Pharyngitis	1 (1.7)	0	1 (1.7)	0	0
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Skin infection	1 (1.7)	0	1 (1.7)	0	0
Streptococcal infection	1 (1.7)	0	1 (1.7)	0	0
Upper respiratory tract infection	1 (1.7)	0	1 (1.7)	0	0
Urinary tract infection enterococcal	1 (1.7)	0	0	1 (1.7)	0
Viral upper respiratory tract infection	1 (1.7)	0	1 (1.7)	0	0
Vulvovaginal candidiasis	1 (1.7)	1 (1.7)	0	0	0
Injury, poisoning and procedural complications					
-Total	15 (25.0)	8 (13.3)	5 (8.3)	1 (1.7)	1 (1.7)
Procedural pain	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Transfusion reaction	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Infusion related reaction	2 (3.3)	0	2 (3.3)	0	0
Contusion	1 (1.7)	1 (1.7)	0	0	0
Incision site pain	1 (1.7)	1 (1.7)	0	0	0
Limb injury	1 (1.7)	1 (1.7)	0	0	0
Mouth injury	1 (1.7)	1 (1.7)	0	0	0
Post procedural haemorrhage	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural complication	1 (1.7)	1 (1.7)	0	0	0
Procedural headache	1 (1.7)	0	1 (1.7)	0	0
Procedural site reaction	1 (1.7)	1 (1.7)	0	0	0
Skin abrasion	1 (1.7)	1 (1.7)	0	0	0
Stoma site irritation	1 (1.7)	1 (1.7)	0	0	0
Subdural haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Tibia fracture	1 (1.7)	0	1 (1.7)	0	0
Tongue injury	1 (1.7)	1 (1.7)	0	0	0
Tracheal haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Transfusion related complication	1 (1.7)	0	0	0	1 (1.7)
Investigations					
-Total	49 (81.7)	3 (5.0)	4 (6.7)	13 (21.7)	29 (48.3)
White blood cell count decreased	29 (48.3)	3 (5.0)	1 (1.7)	10 (16.7)	15 (25.0)
Neutrophil count decreased	24 (40.0)	0	2 (3.3)	4 (6.7)	18 (30.0)
Alanine aminotransferase increased	19 (31.7)	5 (8.3)	3 (5.0)	11 (18.3)	0
Aspartate aminotransferase increased	18 (30.0)	3 (5.0)	4 (6.7)	7 (11.7)	4 (6.7)
Platelet count decreased	18 (30.0)	2 (3.3)	2 (3.3)	2 (3.3)	12 (20.0)
Lymphocyte count decreased	12 (20.0)	0	2 (3.3)	6 (10.0)	4 (6.7)
International normalised ratio increased	9 (15.0)	8 (13.3)	0	1 (1.7)	0

Timing: within 8 weeks post infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prothrombin time prolonged	9 (15.0)	5 (8.3)	3 (5.0)	1 (1.7)	0
Blood creatinine increased	8 (13.3)	4 (6.7)	2 (3.3)	2 (3.3)	0
Blood bilirubin increased	6 (10.0)	1 (1.7)	3 (5.0)	2 (3.3)	0
Activated partial thromboplastin time prolonged	5 (8.3)	3 (5.0)	2 (3.3)	0	0
Blood fibrinogen decreased	4 (6.7)	0	1 (1.7)	2 (3.3)	1 (1.7)
Blood immunoglobulin m decreased	3 (5.0)	3 (5.0)	0	0	0
Blood urea increased	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Blood immunoglobulin a decreased	2 (3.3)	2 (3.3)	0	0	0
Blood phosphorus increased	2 (3.3)	2 (3.3)	0	0	0
Lipase increased	2 (3.3)	0	0	0	2 (3.3)
Transaminases increased	2 (3.3)	2 (3.3)	0	0	0
Blood bicarbonate decreased	1 (1.7)	0	1 (1.7)	0	0
Blood immunoglobulin g decreased	1 (1.7)	0	1 (1.7)	0	0
Blood lactic acid increased	1 (1.7)	0	0	0	1 (1.7)
Blood magnesium decreased	1 (1.7)	0	0	1 (1.7)	0
Blood phosphorus decreased	1 (1.7)	1 (1.7)	0	0	0
Blood sodium increased	1 (1.7)	0	1 (1.7)	0	0
Blood uric acid increased	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	1 (1.7)	0	0	1 (1.7)	0
Cardiac murmur	1 (1.7)	1 (1.7)	0	0	0
Culture stool positive	1 (1.7)	1 (1.7)	0	0	0
Haemoglobin decreased	1 (1.7)	0	0	1 (1.7)	0
Hepatic enzyme increased	1 (1.7)	0	1 (1.7)	0	0
Norovirus test positive	1 (1.7)	1 (1.7)	0	0	0
Protein total decreased	1 (1.7)	0	0	1 (1.7)	0
Pulmonary function test decreased	1 (1.7)	0	1 (1.7)	0	0
Serum ferritin increased	1 (1.7)	0	1 (1.7)	0	0
Metabolism and nutrition disorders					
-Total	38 (63.3)	4 (6.7)	10 (16.7)	21 (35.0)	3 (5.0)
Decreased appetite	19 (31.7)	3 (5.0)	4 (6.7)	12 (20.0)	0
Hypokalaemia	16 (26.7)	3 (5.0)	6 (10.0)	7 (11.7)	0
Hypophosphataemia	9 (15.0)	2 (3.3)	0	6 (10.0)	1 (1.7)
Hyperphosphataemia	7 (11.7)	7 (11.7)	0	0	0
Hypoalbuminaemia	5 (8.3)	1 (1.7)	3 (5.0)	1 (1.7)	0
Hypernatraemia	4 (6.7)	1 (1.7)	2 (3.3)	0	1 (1.7)
Dehydration	3 (5.0)	1 (1.7)	0	2 (3.3)	0
Fluid overload	3 (5.0)	1 (1.7)	2 (3.3)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

			All patients N=60		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Hyperuricaemia	3 (5.0)	2 (3.3)	0	0	1 (1.7)
Hypocalcaemia	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Acidosis	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Hypertriglyceridaemia	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Hyponatraemia	2 (3.3)	0	0	2 (3.3)	0
Hyperalbuminaemia	1 (1.7)	1 (1.7)	0	0	0
Hypercalcaemia	1 (1.7)	1 (1.7)	0	0	0
Hyperchloraemia	1 (1.7)	1 (1.7)	0	0	0
Hypermagnesaemia	1 (1.7)	1 (1.7)	0	0	0
Hypomagnesaemia	1 (1.7)	1 (1.7)	0	0	0
Malnutrition	1 (1.7)	0	0	1 (1.7)	0
Metabolic acidosis	1 (1.7)	0	1 (1.7)	0	0
Metabolic alkalosis	1 (1.7)	1 (1.7)	0	0	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0
Musculoskeletal and connective tissue disorders					
-Total	15 (25.0)	8 (13.3)	6 (10.0)	1 (1.7)	0
Myalgia	5 (8.3)	4 (6.7)	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	4 (6.7)	3 (5.0)	0	1 (1.7)	0
Pain in extremity	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Musculoskeletal pain	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Coccydynia	1 (1.7)	1 (1.7)	0	0	0
Limb discomfort	1 (1.7)	1 (1.7)	0	0	0
Muscle spasms	1 (1.7)	1 (1.7)	0	0	0
Muscular weakness	1 (1.7)	0	1 (1.7)	0	0
Musculoskeletal chest pain	1 (1.7)	1 (1.7)	0	0	0
Osteopenia	1 (1.7)	0	1 (1.7)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.7)	0	1 (1.7)	0	0
Skin papilloma	1 (1.7)	0	1 (1.7)	0	0
Nervous system disorders					
-Total	32 (53.3)	17 (28.3)	10 (16.7)	4 (6.7)	1 (1.7)
Headache	23 (38.3)	16 (26.7)	5 (8.3)	2 (3.3)	0
Dizziness	4 (6.7)	4 (6.7)	0	0	0
Encephalopathy	4 (6.7)	1 (1.7)	1 (1.7)	2 (3.3)	0
Seizure	3 (5.0)	0	2 (3.3)	1 (1.7)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysarthria	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Asterixis	1 (1.7)	1 (1.7)	0	0	0
Ataxia	1 (1.7)	0	1 (1.7)	0	0
Depressed level of consciousness	1 (1.7)	1 (1.7)	0	0	0
Embolic stroke	1 (1.7)	0	0	0	1 (1.7)
Idiopathic intracranial hypertension	1 (1.7)	0	1 (1.7)	0	0
Migraine	1 (1.7)	0	1 (1.7)	0	0
Myoclonus	1 (1.7)	1 (1.7)	0	0	0
Neuropathy peripheral	1 (1.7)	0	1 (1.7)	0	0
Pleocytosis	1 (1.7)	1 (1.7)	0	0	0
Somnolence	1 (1.7)	1 (1.7)	0	0	0
Tremor	1 (1.7)	1 (1.7)	0	0	0
Product issues					
-Total	1 (1.7)	1 (1.7)	0	0	0
Device occlusion	1 (1.7)	1 (1.7)	0	0	0
Psychiatric disorders					
-Total	16 (26.7)	8 (13.3)	7 (11.7)	1 (1.7)	0
Anxiety	6 (10.0)	2 (3.3)	3 (5.0)	1 (1.7)	0
Confusional state	6 (10.0)	3 (5.0)	3 (5.0)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

			All patients N=60		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Agitation	2 (3.3)	0	2 (3.3)	0	0
Hallucination	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Irritability	2 (3.3)	2 (3.3)	0	0	0
Adjustment disorder	1 (1.7)	0	1 (1.7)	0	0
Insomnia	1 (1.7)	0	1 (1.7)	0	0
Listless	1 (1.7)	1 (1.7)	0	0	0
Mental status changes	1 (1.7)	1 (1.7)	0	0	0
Panic attack	1 (1.7)	0	1 (1.7)	0	0
Suicidal ideation	1 (1.7)	1 (1.7)	0	0	0
Renal and urinary disorders					
-Total	11 (18.3)	2 (3.3)	2 (3.3)	3 (5.0)	4 (6.7)
Acute kidney injury	7 (11.7)	1 (1.7)	1 (1.7)	2 (3.3)	3 (5.0)
Haematuria	4 (6.7)	0	2 (3.3)	1 (1.7)	1 (1.7)
Dysuria	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Oliguria	2 (3.3)	0	0	2 (3.3)	0
Pollakiuria	1 (1.7)	1 (1.7)	0	0	0
Renal failure	1 (1.7)	0	0	0	1 (1.7)
Renal impairment	1 (1.7)	0	0	1 (1.7)	0

Timing: within 8 weeks post infusion, Down syndrome: No

			All patients N=60		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Vulvovaginal adhesion	2 (3.3)	2 (3.3)	0	0	0
Oedema genital	1 (1.7)	0	1 (1.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	27 (45.0)	10 (16.7)	5 (8.3)	5 (8.3)	7 (11.7)
Hypoxia	9 (15.0)	0	2 (3.3)	4 (6.7)	3 (5.0)
Cough	8 (13.3)	8 (13.3)	0	0	0
Pleural effusion	8 (13.3)	2 (3.3)	4 (6.7)	2 (3.3)	0
Epistaxis	7 (11.7)	2 (3.3)	1 (1.7)	3 (5.0)	1 (1.7)
Pulmonary oedema	6 (10.0)	1 (1.7)	0	3 (5.0)	2 (3.3)
Tachypnoea	5 (8.3)	3 (5.0)	1 (1.7)	1 (1.7)	0
Respiratory failure	3 (5.0)	0	0	0	3 (5.0)
Dyspnoea	2 (3.3)	0	0	1 (1.7)	1 (1.7)
Haemoptysis	2 (3.3)	1 (1.7)	0	0	1 (1.7)
Oropharyngeal pain	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Atelectasis	1 (1.7)	1 (1.7)	0	0	0
Interstitial lung disease	1 (1.7)	0	0	0	1 (1.7)
Nasal congestion	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal plaque	1 (1.7)	1 (1.7)	0	0	0
Pharyngeal ulceration	1 (1.7)	0	1 (1.7)	0	0
Respiratory depression	1 (1.7)	0	1 (1.7)	0	0
Respiratory distress	1 (1.7)	0	0	0	1 (1.7)
Rhinitis allergic	1 (1.7)	1 (1.7)	0	0	0
Rhinorrhoea	1 (1.7)	1 (1.7)	0	0	0
Wheezing	1 (1.7)	0	1 (1.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	19 (31.7)	13 (21.7)	4 (6.7)	2 (3.3)	0
Rash	4 (6.7)	4 (6.7)	0	0	0
Dry skin	3 (5.0)	3 (5.0)	0	0	0
Hyperhidrosis	3 (5.0)	3 (5.0)	0	0	0
Petechiae	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Rash maculo-papular	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Erythema	2 (3.3)	2 (3.3)	0	0	0
Ingrowing nail	2 (3.3)	0	2 (3.3)	0	0
Pruritus	2 (3.3)	2 (3.3)	0	0	0
Rash papular	2 (3.3)	2 (3.3)	0	0	0
Ecchymosis	1 (1.7)	0	0	1 (1.7)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Livedo reticularis	1 (1.7)	1 (1.7)	0	0	0
Macule	1 (1.7)	1 (1.7)	0	0	0
Night sweats	1 (1.7)	0	1 (1.7)	0	0
Rash erythematous	1 (1.7)	1 (1.7)	0	0	0
Rash follicular	1 (1.7)	1 (1.7)	0	0	0
Rash macular	1 (1.7)	1 (1.7)	0	0	0
Rash vesicular	1 (1.7)	1 (1.7)	0	0	0
Skin exfoliation	1 (1.7)	1 (1.7)	0	0	0
Skin fissures	1 (1.7)	1 (1.7)	0	0	0
Skin irritation	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					
-Total	23 (38.3)	3 (5.0)	5 (8.3)	7 (11.7)	8 (13.3)
Hypotension	15 (25.0)	1 (1.7)	0	6 (10.0)	8 (13.3)
Hypertension	10 (16.7)	2 (3.3)	7 (11.7)	1 (1.7)	0
Flushing	2 (3.3)	2 (3.3)	0	0	0
Orthostatic hypotension	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Capillary leak syndrome	1 (1.7)	0	0	0	1 (1.7)
Embolism	1 (1.7)	0	0	1 (1.7)	0
Haematoma	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Secondary hypertension	1 (1.7)	0	1 (1.7)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174p
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

			All patients N=4		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	2 (50.0)	2 (50.0)	0
Blood and lymphatic system disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Anaemia	1 (25.0)	1 (25.0)	0	0	0
Eye disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Ocular hyperaemia	1 (25.0)	1 (25.0)	0	0	0
Gastrointestinal disorders					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Vomiting	2 (50.0)	2 (50.0)	0	0	0
Enterocolitis	1 (25.0)	0	0	1 (25.0)	0
Nausea	1 (25.0)	0	1 (25.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Influenza like illness	1 (25.0)	1 (25.0)	0	0	0
Pyrexia	1 (25.0)	0	0	1 (25.0)	0
Infections and infestations					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Corona virus infection	1 (25.0)	0	0	1 (25.0)	0
Rash pustular	1 (25.0)	0	1 (25.0)	0	0
Respiratory syncytial virus infection	1 (25.0)	0	0	1 (25.0)	0
Injury, poisoning and procedural complications					
-Total	1 (25.0)	0	1 (25.0)	0	0
Skin laceration	1 (25.0)	0	1 (25.0)	0	0
Investigations					
-Total	1 (25.0)	0	1 (25.0)	0	0
Lymphocyte count decreased	1 (25.0)	0	1 (25.0)	0	0
Neutrophil count decreased	1 (25.0)	1 (25.0)	0	0	0
Platelet count decreased	1 (25.0)	1 (25.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (25.0)	1 (25.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Hyperphosphataemia	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Pain in extremity	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (50.0)	0	2 (50.0)	0	0
Cough	1 (25.0)	0	1 (25.0)	0	0
Nasal congestion	1 (25.0)	1 (25.0)	0	0	0
Rhinorrhoea	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Rash maculo-papular	1 (25.0)	1 (25.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174p
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (80.8)	4 (7.7)	14 (26.9)	14 (26.9)	10 (19.2)
Blood and lymphatic system disorders					
-Total	10 (19.2)	0	3 (5.8)	3 (5.8)	4 (7.7)
Neutropenia	4 (7.7)	0	0	1 (1.9)	3 (5.8)
Febrile neutropenia	3 (5.8)	0	0	3 (5.8)	0
Thrombocytopenia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Anaemia	1 (1.9)	0	0	1 (1.9)	0
Eosinophilia	1 (1.9)	0	0	1 (1.9)	0
Leukopenia	1 (1.9)	0	0	0	1 (1.9)
Lymphadenopathy	1 (1.9)	0	1 (1.9)	0	0
Lymphopenia	1 (1.9)	0	1 (1.9)	0	0
Cardiac disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.9)	0	1 (1.9)	0	0
Sinus tachycardia	1 (1.9)	0	1 (1.9)	0	0
Endocrine disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Adrenal insufficiency	1 (1.9)	1 (1.9)	0	0	0
Eye disorders					
-Total	4 (7.7)	3 (5.8)	1 (1.9)	0	0
Dry eye	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Conjunctivitis allergic	1 (1.9)	1 (1.9)	0	0	0
Vision blurred	1 (1.9)	1 (1.9)	0	0	0
Gastrointestinal disorders					
-Total	14 (26.9)	8 (15.4)	3 (5.8)	3 (5.8)	0
Diarrhoea	8 (15.4)	6 (11.5)	1 (1.9)	1 (1.9)	0
Vomiting	7 (13.5)	3 (5.8)	2 (3.8)	2 (3.8)	0
Nausea	5 (9.6)	1 (1.9)	2 (3.8)	2 (3.8)	0
Abdominal pain	4 (7.7)	2 (3.8)	1 (1.9)	1 (1.9)	0
Oral pain	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Abdominal pain upper	1 (1.9)	1 (1.9)	0	0	0
Pigmentation lip	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	15 (28.8)	12 (23.1)	3 (5.8)	0	0
Pyrexia	9 (17.3)	7 (13.5)	2 (3.8)	0	0
Fatigue	2 (3.8)	2 (3.8)	0	0	0
Acquired gene mutation	1 (1.9)	1 (1.9)	0	0	0
Catheter site pain	1 (1.9)	0	1 (1.9)	0	0
Chills	1 (1.9)	1 (1.9)	0	0	0
Crying	1 (1.9)	1 (1.9)	0	0	0
Generalised oedema	1 (1.9)	1 (1.9)	0	0	0
Influenza like illness	1 (1.9)	1 (1.9)	0	0	0
Malaise	1 (1.9)	1 (1.9)	0	0	0
Oedema peripheral	1 (1.9)	1 (1.9)	0	0	0
Pain	1 (1.9)	1 (1.9)	0	0	0
Immune system disorders					
-Total	14 (26.9)	3 (5.8)	10 (19.2)	1 (1.9)	0
Hypogammaglobulinaemia	8 (15.4)	0	7 (13.5)	1 (1.9)	0
Graft versus host disease	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Immunodeficiency common variable	2 (3.8)	0	2 (3.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seasonal allergy	2 (3.8)	2 (3.8)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (1.9)	0	1 (1.9)	0	0
Infections and infestations					
-Total	31 (59.6)	6 (11.5)	14 (26.9)	9 (17.3)	2 (3.8)
Upper respiratory tract infection	7 (13.5)	3 (5.8)	3 (5.8)	1 (1.9)	0
Urinary tract infection	4 (7.7)	0	2 (3.8)	2 (3.8)	0
Gastroenteritis	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Influenza	3 (5.8)	0	3 (5.8)	0	0
Ear infection	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Parainfluenzae virus infection	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Rhinovirus infection	2 (3.8)	2 (3.8)	0	0	0
Sinusitis	2 (3.8)	0	2 (3.8)	0	0
Viral upper respiratory tract infection	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Bacterial sepsis	1 (1.9)	0	0	0	1 (1.9)
Cellulitis of male external genital organ	1 (1.9)	0	0	1 (1.9)	0
Cholecystitis infective	1 (1.9)	0	0	1 (1.9)	0
Cytomegalovirus infection	1 (1.9)	1 (1.9)	0	0	0
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis viral	1 (1.9)	1 (1.9)	0	0	0
Herpes zoster	1 (1.9)	0	0	1 (1.9)	0
Molluscum contagiosum	1 (1.9)	1 (1.9)	0	0	0
Oral herpes	1 (1.9)	0	1 (1.9)	0	0
Otitis externa	1 (1.9)	0	1 (1.9)	0	0
Otitis media	1 (1.9)	0	1 (1.9)	0	0
Otitis media acute	1 (1.9)	0	1 (1.9)	0	0
Paronychia	1 (1.9)	1 (1.9)	0	0	0
Rhinitis	1 (1.9)	1 (1.9)	0	0	0
Rotavirus infection	1 (1.9)	0	0	1 (1.9)	0
Sepsis	1 (1.9)	0	0	0	1 (1.9)
Subcutaneous abscess	1 (1.9)	0	1 (1.9)	0	0
Tinea capitis	1 (1.9)	1 (1.9)	0	0	0
Vascular device infection	1 (1.9)	0	0	1 (1.9)	0
Viral infection	1 (1.9)	1 (1.9)	0	0	0
Vulvovaginal mycotic infection	1 (1.9)	0	1 (1.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	7 (13.5)	3 (5.8)	4 (7.7)	0	0
Contusion	2 (3.8)	2 (3.8)	0	0	0
Infusion related reaction	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Procedural pain	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Arthropod bite	1 (1.9)	1 (1.9)	0	0	0
Foot fracture	1 (1.9)	0	1 (1.9)	0	0
Procedural nausea	1 (1.9)	0	1 (1.9)	0	0
Radius fracture	1 (1.9)	0	1 (1.9)	0	0
Skin abrasion	1 (1.9)	1 (1.9)	0	0	0
Sunburn	1 (1.9)	1 (1.9)	0	0	0
Investigations					
-Total	22 (42.3)	6 (11.5)	4 (7.7)	8 (15.4)	4 (7.7)
Neutrophil count decreased	7 (13.5)	1 (1.9)	0	3 (5.8)	3 (5.8)
Weight decreased	4 (7.7)	1 (1.9)	3 (5.8)	0	0
White blood cell count decreased	4 (7.7)	1 (1.9)	1 (1.9)	1 (1.9)	1 (1.9)
Aspartate aminotransferase increased	3 (5.8)	1 (1.9)	0	2 (3.8)	0
Alanine aminotransferase increased	2 (3.8)	0	0	2 (3.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoglobin decreased	2 (3.8)	2 (3.8)	0	0	0
Platelet count decreased	2 (3.8)	2 (3.8)	0	0	0
Weight increased	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Blood bilirubin increased	1 (1.9)	0	0	1 (1.9)	0
Blood creatinine increased	1 (1.9)	1 (1.9)	0	0	0
Blood magnesium decreased	1 (1.9)	1 (1.9)	0	0	0
Blood urea increased	1 (1.9)	1 (1.9)	0	0	0
Blood uric acid increased	1 (1.9)	1 (1.9)	0	0	0
Lymphocyte count decreased	1 (1.9)	1 (1.9)	0	0	0
Oxygen saturation decreased	1 (1.9)	1 (1.9)	0	0	0
Serum ferritin increased	1 (1.9)	0	1 (1.9)	0	0
Transaminases increased	1 (1.9)	1 (1.9)	0	0	0
Metabolism and nutrition disorders					
-Total	9 (17.3)	4 (7.7)	1 (1.9)	3 (5.8)	1 (1.9)
Decreased appetite	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Hypokalaemia	2 (3.8)	1 (1.9)	0	0	1 (1.9)
Dehydration	1 (1.9)	0	0	1 (1.9)	0
Hyperalbuminaemia	1 (1.9)	1 (1.9)	0	0	0
Hypercalcaemia	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	1 (1.9)	0	0	1 (1.9)	0
Hyperphosphataemia	1 (1.9)	1 (1.9)	0	0	0
Hypophosphataemia	1 (1.9)	0	0	1 (1.9)	0
Iron overload	1 (1.9)	0	0	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0
Vitamin d deficiency	1 (1.9)	1 (1.9)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	15 (28.8)	10 (19.2)	5 (9.6)	0	0
Pain in extremity	7 (13.5)	5 (9.6)	2 (3.8)	0	0
Arthralgia	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Joint range of motion decreased	2 (3.8)	2 (3.8)	0	0	0
Muscular weakness	2 (3.8)	2 (3.8)	0	0	0
Back pain	1 (1.9)	1 (1.9)	0	0	0
Flank pain	1 (1.9)	0	1 (1.9)	0	0
Muscle spasms	1 (1.9)	1 (1.9)	0	0	0
Musculoskeletal chest pain	1 (1.9)	1 (1.9)	0	0	0
Osteonecrosis	1 (1.9)	0	1 (1.9)	0	0
Pain in jaw	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Toe walking	1 (1.9)	1 (1.9)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (1.9)	0	1 (1.9)	0	0
Myelodysplastic syndrome	1 (1.9)	0	1 (1.9)	0	0
Nervous system disorders					
-Total	8 (15.4)	6 (11.5)	2 (3.8)	0	0
Headache	5 (9.6)	4 (7.7)	1 (1.9)	0	0
Dizziness	3 (5.8)	3 (5.8)	0	0	0
Peroneal nerve palsy	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Psychiatric disorders					
-Total	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Depression	2 (3.8)	2 (3.8)	0	0	0
Anxiety	1 (1.9)	1 (1.9)	0	0	0
Sleep disorder	1 (1.9)	0	1 (1.9)	0	0
Renal and urinary disorders					
-Total	3 (5.8)	1 (1.9)	0	2 (3.8)	0
Acute kidney injury	1 (1.9)	0	0	1 (1.9)	0
Calculus urinary	1 (1.9)	0	1 (1.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	1 (1.9)	0	0	1 (1.9)	0
Nephrolithiasis	1 (1.9)	0	0	1 (1.9)	0
Urinary incontinence	1 (1.9)	1 (1.9)	0	0	0
Reproductive system and breast disorders					
-Total	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Scrotal pain	1 (1.9)	0	1 (1.9)	0	0
Vaginal haemorrhage	1 (1.9)	0	0	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	16 (30.8)	11 (21.2)	2 (3.8)	2 (3.8)	1 (1.9)
Cough	6 (11.5)	5 (9.6)	1 (1.9)	0	0
Nasal congestion	3 (5.8)	3 (5.8)	0	0	0
Oropharyngeal pain	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Rhinitis allergic	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Rhinorrhoea	3 (5.8)	3 (5.8)	0	0	0
Epistaxis	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Acute respiratory failure	1 (1.9)	0	0	0	1 (1.9)
Dysphonia	1 (1.9)	1 (1.9)	0	0	0
Pharyngeal erythema	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

			All patients N=52		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngeal lesion	1 (1.9)	0	0	1 (1.9)	0
Pulmonary oedema	1 (1.9)	0	0	1 (1.9)	0
Skin and subcutaneous tissue disorders					
-Total	15 (28.8)	9 (17.3)	5 (9.6)	1 (1.9)	0
Rash	4 (7.7)	1 (1.9)	3 (5.8)	0	0
Erythema	2 (3.8)	2 (3.8)	0	0	0
Alopecia	1 (1.9)	0	1 (1.9)	0	0
Dermatitis	1 (1.9)	1 (1.9)	0	0	0
Dermatitis acneiform	1 (1.9)	0	0	1 (1.9)	0
Dermatitis atopic	1 (1.9)	1 (1.9)	0	0	0
Dry skin	1 (1.9)	1 (1.9)	0	0	0
Eczema	1 (1.9)	1 (1.9)	0	0	0
Hyperhidrosis	1 (1.9)	1 (1.9)	0	0	0
Ingrowing nail	1 (1.9)	1 (1.9)	0	0	0
Keloid scar	1 (1.9)	0	1 (1.9)	0	0
Macule	1 (1.9)	1 (1.9)	0	0	0
Papule	1 (1.9)	1 (1.9)	0	0	0
Petechiae	1 (1.9)	1 (1.9)	0	0	0
Pruritus	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash erythematous	1 (1.9)	0	1 (1.9)	0	0
Rash maculo-papular	1 (1.9)	1 (1.9)	0	0	0
Rash pruritic	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					
-Total	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Hypertension	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Hot flush	1 (1.9)	1 (1.9)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174p
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (33.3)	1 (33.3)	0	0	0
Investigations					
-Total	1 (33.3)	1 (33.3)	0	0	0
Lymphocyte count decreased	1 (33.3)	1 (33.3)	0	0	0
Neutrophil count decreased	1 (33.3)	1 (33.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174p
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (67.7)	3 (9.7)	6 (19.4)	8 (25.8)	4 (12.9)
Blood and lymphatic system disorders					
-Total	2 (6.5)	1 (3.2)	0	0	1 (3.2)
Febrile neutropenia	1 (3.2)	0	0	0	1 (3.2)
Thrombocytopenia	1 (3.2)	1 (3.2)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.2)	0	1 (3.2)	0	0
Tympanic membrane perforation	1 (3.2)	0	1 (3.2)	0	0
Gastrointestinal disorders					
-Total	3 (9.7)	0	3 (9.7)	0	0
Diarrhoea	2 (6.5)	0	2 (6.5)	0	0
Abdominal pain	1 (3.2)	0	1 (3.2)	0	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (3.2)	0	1 (3.2)	0	0
General disorders and administration site conditions					
-Total	2 (6.5)	0	1 (3.2)	1 (3.2)	0
Chills	1 (3.2)	0	1 (3.2)	0	0
Cyst	1 (3.2)	0	0	1 (3.2)	0
Pyrexia	1 (3.2)	0	1 (3.2)	0	0
Immune system disorders					
-Total	2 (6.5)	0	2 (6.5)	0	0
Chronic graft versus host disease	1 (3.2)	0	1 (3.2)	0	0
Immunodeficiency	1 (3.2)	0	1 (3.2)	0	0
Infections and infestations					
-Total	11 (35.5)	2 (6.5)	5 (16.1)	3 (9.7)	1 (3.2)
Otitis media	3 (9.7)	0	2 (6.5)	1 (3.2)	0
Sinusitis	3 (9.7)	0	3 (9.7)	0	0
Otitis media acute	2 (6.5)	0	2 (6.5)	0	0
Pneumonia	2 (6.5)	0	2 (6.5)	0	0
Upper respiratory tract infection	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Urinary tract infection	2 (6.5)	0	1 (3.2)	1 (3.2)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (3.2)	0	0	1 (3.2)	0
Cellulitis of male external genital organ	1 (3.2)	0	0	1 (3.2)	0
Clostridium difficile infection	1 (3.2)	0	0	1 (3.2)	0
Gingivitis	1 (3.2)	1 (3.2)	0	0	0
Haemophilus infection	1 (3.2)	0	1 (3.2)	0	0
Meningitis aseptic	1 (3.2)	0	1 (3.2)	0	0
Respiratory tract infection	1 (3.2)	0	0	0	1 (3.2)
Respiratory tract infection viral	1 (3.2)	0	0	1 (3.2)	0
Skin infection	1 (3.2)	0	1 (3.2)	0	0
Viral infection	1 (3.2)	1 (3.2)	0	0	0
Vulvovaginal candidiasis	1 (3.2)	0	1 (3.2)	0	0
Injury, poisoning and procedural complications					
-Total	1 (3.2)	0	0	1 (3.2)	0
Procedural pain	1 (3.2)	0	0	1 (3.2)	0
Investigations					
-Total	7 (22.6)	0	2 (6.5)	4 (12.9)	1 (3.2)
White blood cell count decreased	4 (12.9)	1 (3.2)	0	2 (6.5)	1 (3.2)
Alanine aminotransferase increased	3 (9.7)	0	1 (3.2)	2 (6.5)	0
Aspartate aminotransferase increased	2 (6.5)	1 (3.2)	0	1 (3.2)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Blood alkaline phosphatase increased	1 (3.2)	1 (3.2)	0	0	0
Blood lactate dehydrogenase increased	1 (3.2)	1 (3.2)	0	0	0
C-reactive protein increased	1 (3.2)	1 (3.2)	0	0	0
Neutrophil count decreased	1 (3.2)	0	1 (3.2)	0	0
Platelet count decreased	1 (3.2)	0	0	1 (3.2)	0
Metabolism and nutrition disorders					
-Total	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Hypokalaemia	1 (3.2)	0	0	1 (3.2)	0
Vitamin d deficiency	1 (3.2)	1 (3.2)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (3.2)	0	1 (3.2)	0	0
Neck pain	1 (3.2)	0	1 (3.2)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.2)	0	0	0	1 (3.2)
Glioblastoma multiforme	1 (3.2)	0	0	0	1 (3.2)
Nervous system disorders					

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (9.7)	1 (3.2)	1 (3.2)	1 (3.2)	0
Disturbance in attention	1 (3.2)	1 (3.2)	0	0	0
Dizziness	1 (3.2)	1 (3.2)	0	0	0
Headache	1 (3.2)	0	1 (3.2)	0	0
Seizure	1 (3.2)	0	0	1 (3.2)	0
Renal and urinary disorders					
-Total	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Acute kidney injury	1 (3.2)	0	0	1 (3.2)	0
Haematuria	1 (3.2)	1 (3.2)	0	0	0
Reproductive system and breast disorders					
-Total	1 (3.2)	0	0	1 (3.2)	0
Ovarian failure	1 (3.2)	0	0	1 (3.2)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (12.9)	4 (12.9)	0	0	0
Cough	2 (6.5)	2 (6.5)	0	0	0
Epistaxis	1 (3.2)	1 (3.2)	0	0	0
Oropharyngeal pain	1 (3.2)	1 (3.2)	0	0	0
Rhinitis allergic	1 (3.2)	1 (3.2)	0	0	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	1 (3.2)	1 (3.2)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (9.7)	3 (9.7)	0	0	0
Acne	1 (3.2)	1 (3.2)	0	0	0
Papule	1 (3.2)	1 (3.2)	0	0	0
Pruritus	1 (3.2)	1 (3.2)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174p
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	1 (25.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders					
-Total	3 (75.0)	0	0	2 (50.0)	1 (25.0)
Anaemia	2 (50.0)	2 (50.0)	0	0	0
Febrile neutropenia	2 (50.0)	0	0	2 (50.0)	0
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
Eye disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Ocular hyperaemia	1 (25.0)	1 (25.0)	0	0	0
Gastrointestinal disorders					
-Total	3 (75.0)	2 (50.0)	0	1 (25.0)	0
Vomiting	2 (50.0)	2 (50.0)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (25.0)	1 (25.0)	0	0	0
Enterocolitis	1 (25.0)	0	0	1 (25.0)	0
Nausea	1 (25.0)	0	1 (25.0)	0	0
General disorders and administration site conditions					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Fatigue	1 (25.0)	1 (25.0)	0	0	0
Influenza like illness	1 (25.0)	1 (25.0)	0	0	0
Pyrexia	1 (25.0)	0	0	1 (25.0)	0
Immune system disorders					
-Total	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Cytokine release syndrome	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Hypogammaglobulinaemia	1 (25.0)	0	1 (25.0)	0	0
Infections and infestations					
-Total	3 (75.0)	1 (25.0)	1 (25.0)	1 (25.0)	0
Corona virus infection	1 (25.0)	0	0	1 (25.0)	0
Fungal skin infection	1 (25.0)	1 (25.0)	0	0	0
Rash pustular	1 (25.0)	0	1 (25.0)	0	0
Respiratory syncytial virus infection	1 (25.0)	0	0	1 (25.0)	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	1 (25.0)	0	1 (25.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (25.0)	0	1 (25.0)	0	0
Skin laceration	1 (25.0)	0	1 (25.0)	0	0
Investigations					
-Total	3 (75.0)	0	1 (25.0)	0	2 (50.0)
Lymphocyte count decreased	3 (75.0)	1 (25.0)	1 (25.0)	0	1 (25.0)
Neutrophil count decreased	2 (50.0)	1 (25.0)	0	0	1 (25.0)
White blood cell count decreased	2 (50.0)	1 (25.0)	0	0	1 (25.0)
Blood bilirubin increased	1 (25.0)	1 (25.0)	0	0	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0	0	0
Fibrin d dimer increased	1 (25.0)	1 (25.0)	0	0	0
Platelet count decreased	1 (25.0)	1 (25.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Decreased appetite	1 (25.0)	1 (25.0)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Pain in extremity	1 (25.0)	1 (25.0)	0	0	0
Nervous system disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Headache	1 (25.0)	0	1 (25.0)	0	0
Tremor	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (50.0)	0	2 (50.0)	0	0
Cough	1 (25.0)	0	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	1 (25.0)	0	0
Nasal congestion	1 (25.0)	1 (25.0)	0	0	0
Rhinorrhoea	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (75.0)	3 (75.0)	0	0	0
Dermatitis diaper	1 (25.0)	1 (25.0)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	1 (25.0)	1 (25.0)	0	0	0
Erythema	1 (25.0)	1 (25.0)	0	0	0
Rash maculo-papular	1 (25.0)	1 (25.0)	0	0	0
Vascular disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Hypotension	1 (25.0)	0	0	1 (25.0)	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174p
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	60 (100)	0	4 (6.7)	11 (18.3)	45 (75.0)
Blood and lymphatic system disorders					
-Total	45 (75.0)	2 (3.3)	3 (5.0)	25 (41.7)	15 (25.0)
Anaemia	25 (41.7)	1 (1.7)	4 (6.7)	19 (31.7)	1 (1.7)
Febrile neutropenia	22 (36.7)	0	0	21 (35.0)	1 (1.7)
Neutropenia	10 (16.7)	0	0	3 (5.0)	7 (11.7)
Thrombocytopenia	10 (16.7)	0	1 (1.7)	3 (5.0)	6 (10.0)
Disseminated intravascular coagulation	4 (6.7)	0	2 (3.3)	2 (3.3)	0
Lymphopenia	4 (6.7)	0	2 (3.3)	1 (1.7)	1 (1.7)
Coagulopathy	1 (1.7)	1 (1.7)	0	0	0
Eosinophilia	1 (1.7)	0	0	1 (1.7)	0
Leukopenia	1 (1.7)	0	0	0	1 (1.7)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphadenopathy	1 (1.7)	0	1 (1.7)	0	0
Pancytopenia	1 (1.7)	0	0	0	1 (1.7)
Cardiac disorders					
-Total	23 (38.3)	11 (18.3)	10 (16.7)	2 (3.3)	0
Tachycardia	15 (25.0)	8 (13.3)	5 (8.3)	2 (3.3)	0
Sinus tachycardia	6 (10.0)	3 (5.0)	3 (5.0)	0	0
Pericardial effusion	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Atrioventricular block second degree	1 (1.7)	1 (1.7)	0	0	0
Bradycardia	1 (1.7)	0	1 (1.7)	0	0
Cardiac dysfunction	1 (1.7)	1 (1.7)	0	0	0
Left ventricular dysfunction	1 (1.7)	0	0	1 (1.7)	0
Palpitations	1 (1.7)	1 (1.7)	0	0	0
Sinus bradycardia	1 (1.7)	1 (1.7)	0	0	0
Ventricular tachycardia	1 (1.7)	0	1 (1.7)	0	0
Ear and labyrinth disorders					
-Total	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Ear pain	2 (3.3)	2 (3.3)	0	0	0
Hypoacusis	1 (1.7)	0	1 (1.7)	0	0
Tympanic membrane perforation	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Adrenal insufficiency	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Eye disorders					
-Total	17 (28.3)	9 (15.0)	8 (13.3)	0	0
Periorbital oedema	4 (6.7)	3 (5.0)	1 (1.7)	0	0
Vision blurred	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Conjunctival haemorrhage	3 (5.0)	3 (5.0)	0	0	0
Eye pain	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Dry eye	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Photophobia	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Retinal haemorrhage	2 (3.3)	2 (3.3)	0	0	0
Uveitis	2 (3.3)	0	2 (3.3)	0	0
Conjunctivitis allergic	1 (1.7)	1 (1.7)	0	0	0
Ocular hypertension	1 (1.7)	0	1 (1.7)	0	0
Papilloedema	1 (1.7)	0	1 (1.7)	0	0
Visual impairment	1 (1.7)	0	1 (1.7)	0	0
Gastrointestinal disorders					
-Total	40 (66.7)	11 (18.3)	17 (28.3)	12 (20.0)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	25 (41.7)	14 (23.3)	8 (13.3)	3 (5.0)	0
Diarrhoea	24 (40.0)	13 (21.7)	9 (15.0)	2 (3.3)	0
Nausea	24 (40.0)	6 (10.0)	13 (21.7)	5 (8.3)	0
Abdominal pain	11 (18.3)	6 (10.0)	4 (6.7)	1 (1.7)	0
Constipation	6 (10.0)	5 (8.3)	1 (1.7)	0	0
Abdominal pain upper	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Abdominal distension	2 (3.3)	0	2 (3.3)	0	0
Dysphagia	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Haematemesis	2 (3.3)	2 (3.3)	0	0	0
Oral pain	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Pancreatitis	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Stomatitis	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Abdominal discomfort	1 (1.7)	1 (1.7)	0	0	0
Abdominal pain lower	1 (1.7)	0	1 (1.7)	0	0
Abdominal tenderness	1 (1.7)	1 (1.7)	0	0	0
Anal incontinence	1 (1.7)	1 (1.7)	0	0	0
Ascites	1 (1.7)	0	0	1 (1.7)	0
Dyspepsia	1 (1.7)	0	1 (1.7)	0	0
Flatulence	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastrointestinal haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Gastrooesophageal reflux disease	1 (1.7)	1 (1.7)	0	0	0
Glossodynia	1 (1.7)	1 (1.7)	0	0	0
Ileus	1 (1.7)	0	0	1 (1.7)	0
Intestinal obstruction	1 (1.7)	0	0	1 (1.7)	0
Lip pain	1 (1.7)	0	1 (1.7)	0	0
Mouth haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Pigmentation lip	1 (1.7)	1 (1.7)	0	0	0
Tooth socket haemorrhage	1 (1.7)	1 (1.7)	0	0	0
General disorders and administration site conditions					
-Total	40 (66.7)	15 (25.0)	14 (23.3)	10 (16.7)	1 (1.7)
Pyrexia	24 (40.0)	8 (13.3)	10 (16.7)	5 (8.3)	1 (1.7)
Fatigue	14 (23.3)	11 (18.3)	2 (3.3)	1 (1.7)	0
Chills	10 (16.7)	9 (15.0)	1 (1.7)	0	0
Catheter site pain	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Malaise	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Pain	4 (6.7)	1 (1.7)	1 (1.7)	2 (3.3)	0
Generalised oedema	3 (5.0)	1 (1.7)	2 (3.3)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	3 (5.0)	2 (3.3)	0	1 (1.7)	0
Face oedema	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Acquired gene mutation	1 (1.7)	1 (1.7)	0	0	0
Asthenia	1 (1.7)	1 (1.7)	0	0	0
Catheter site extravasation	1 (1.7)	0	1 (1.7)	0	0
Catheter site haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Crying	1 (1.7)	1 (1.7)	0	0	0
Cyst	1 (1.7)	0	0	1 (1.7)	0
Facial pain	1 (1.7)	0	1 (1.7)	0	0
Influenza like illness	1 (1.7)	1 (1.7)	0	0	0
Injection site haematoma	1 (1.7)	1 (1.7)	0	0	0
Localised oedema	1 (1.7)	0	0	1 (1.7)	0
Mucosal haemorrhage	1 (1.7)	0	1 (1.7)	0	0
Multiple organ dysfunction syndrome	1 (1.7)	0	0	1 (1.7)	0
Non-cardiac chest pain	1 (1.7)	1 (1.7)	0	0	0
Peripheral swelling	1 (1.7)	0	1 (1.7)	0	0
Physical deconditioning	1 (1.7)	0	0	1 (1.7)	0
Hepatobiliary disorders					
-Total	7 (11.7)	3 (5.0)	2 (3.3)	2 (3.3)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatomegaly	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Hyperbilirubinaemia	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Gallbladder enlargement	1 (1.7)	1 (1.7)	0	0	0
Hepatosplenomegaly	1 (1.7)	1 (1.7)	0	0	0
Immune system disorders					
-Total	55 (91.7)	4 (6.7)	29 (48.3)	11 (18.3)	11 (18.3)
Cytokine release syndrome	47 (78.3)	5 (8.3)	23 (38.3)	8 (13.3)	11 (18.3)
Hypogammaglobulinaemia	31 (51.7)	3 (5.0)	23 (38.3)	5 (8.3)	0
Graft versus host disease	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Immunodeficiency common variable	2 (3.3)	0	2 (3.3)	0	0
Seasonal allergy	2 (3.3)	2 (3.3)	0	0	0
Chronic graft versus host disease	1 (1.7)	0	1 (1.7)	0	0
Drug hypersensitivity	1 (1.7)	0	1 (1.7)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.7)	0	1 (1.7)	0	0
Graft versus host disease in skin	1 (1.7)	1 (1.7)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	1 (1.7)	0	0
Immunodeficiency	1 (1.7)	0	1 (1.7)	0	0
Infections and infestations					

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	43 (71.7)	6 (10.0)	20 (33.3)	13 (21.7)	4 (6.7)
Upper respiratory tract infection	9 (15.0)	4 (6.7)	4 (6.7)	1 (1.7)	0
Clostridium difficile infection	5 (8.3)	0	4 (6.7)	1 (1.7)	0
Gastroenteritis	5 (8.3)	1 (1.7)	3 (5.0)	1 (1.7)	0
Rhinovirus infection	5 (8.3)	5 (8.3)	0	0	0
Urinary tract infection	5 (8.3)	0	3 (5.0)	2 (3.3)	0
Clostridium difficile colitis	4 (6.7)	1 (1.7)	2 (3.3)	1 (1.7)	0
Influenza	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Otitis media	4 (6.7)	0	3 (5.0)	1 (1.7)	0
Pneumonia	4 (6.7)	0	3 (5.0)	1 (1.7)	0
Sinusitis	4 (6.7)	0	4 (6.7)	0	0
Viral upper respiratory tract infection	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Cytomegalovirus infection	2 (3.3)	2 (3.3)	0	0	0
Ear infection	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Otitis media acute	2 (3.3)	0	2 (3.3)	0	0
Parainfluenzae virus infection	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Skin infection	2 (3.3)	0	2 (3.3)	0	0
Staphylococcal infection	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Viral infection	2 (3.3)	2 (3.3)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vulvovaginal candidiasis	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Acute sinusitis	1 (1.7)	0	1 (1.7)	0	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Body tinea	1 (1.7)	1 (1.7)	0	0	0
Campylobacter infection	1 (1.7)	0	0	1 (1.7)	0
Catheter site cellulitis	1 (1.7)	1 (1.7)	0	0	0
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Cholecystitis infective	1 (1.7)	0	0	1 (1.7)	0
Enterococcal infection	1 (1.7)	1 (1.7)	0	0	0
Enterovirus infection	1 (1.7)	0	0	1 (1.7)	0
Escherichia urinary tract infection	1 (1.7)	0	0	1 (1.7)	0
Folliculitis	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis viral	1 (1.7)	1 (1.7)	0	0	0
Gingivitis	1 (1.7)	1 (1.7)	0	0	0
Haemophilus infection	1 (1.7)	0	1 (1.7)	0	0
Herpes simplex	1 (1.7)	1 (1.7)	0	0	0
Herpes zoster	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Human herpesvirus 6 infection	1 (1.7)	0	1 (1.7)	0	0
Hypopyon	1 (1.7)	0	1 (1.7)	0	0
Meningitis aseptic	1 (1.7)	0	1 (1.7)	0	0
Molluscum contagiosum	1 (1.7)	1 (1.7)	0	0	0
Oral candidiasis	1 (1.7)	1 (1.7)	0	0	0
Oral herpes	1 (1.7)	0	1 (1.7)	0	0
Orchitis	1 (1.7)	1 (1.7)	0	0	0
Otitis externa	1 (1.7)	0	1 (1.7)	0	0
Paronychia	1 (1.7)	1 (1.7)	0	0	0
Pharyngitis	1 (1.7)	0	1 (1.7)	0	0
Respiratory tract infection	1 (1.7)	0	0	0	1 (1.7)
Respiratory tract infection viral	1 (1.7)	0	0	1 (1.7)	0
Rhinitis	1 (1.7)	1 (1.7)	0	0	0
Rotavirus infection	1 (1.7)	0	0	1 (1.7)	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Streptococcal infection	1 (1.7)	0	1 (1.7)	0	0
Subcutaneous abscess	1 (1.7)	0	1 (1.7)	0	0
Tinea capitis	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection enterococcal	1 (1.7)	0	0	1 (1.7)	0
Vascular device infection	1 (1.7)	0	0	1 (1.7)	0
Vulvovaginal mycotic infection	1 (1.7)	0	1 (1.7)	0	0
Injury, poisoning and procedural complications					
-Total	21 (35.0)	11 (18.3)	7 (11.7)	2 (3.3)	1 (1.7)
Procedural pain	5 (8.3)	2 (3.3)	2 (3.3)	1 (1.7)	0
Infusion related reaction	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Contusion	3 (5.0)	3 (5.0)	0	0	0
Transfusion reaction	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Skin abrasion	2 (3.3)	2 (3.3)	0	0	0
Arthropod bite	1 (1.7)	1 (1.7)	0	0	0
Foot fracture	1 (1.7)	0	1 (1.7)	0	0
Incision site pain	1 (1.7)	1 (1.7)	0	0	0
Limb injury	1 (1.7)	1 (1.7)	0	0	0
Mouth injury	1 (1.7)	1 (1.7)	0	0	0
Post procedural haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Procedural complication	1 (1.7)	1 (1.7)	0	0	0
Procedural headache	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural nausea	1 (1.7)	0	1 (1.7)	0	0
Procedural site reaction	1 (1.7)	1 (1.7)	0	0	0
Radius fracture	1 (1.7)	0	1 (1.7)	0	0
Stoma site irritation	1 (1.7)	1 (1.7)	0	0	0
Subdural haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Sunburn	1 (1.7)	1 (1.7)	0	0	0
Tibia fracture	1 (1.7)	0	1 (1.7)	0	0
Tongue injury	1 (1.7)	1 (1.7)	0	0	0
Tracheal haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Transfusion related complication	1 (1.7)	0	0	0	1 (1.7)
Investigations					
-Total	53 (88.3)	2 (3.3)	4 (6.7)	15 (25.0)	32 (53.3)
White blood cell count decreased	33 (55.0)	3 (5.0)	1 (1.7)	12 (20.0)	17 (28.3)
Neutrophil count decreased	26 (43.3)	0	2 (3.3)	4 (6.7)	20 (33.3)
Alanine aminotransferase increased	21 (35.0)	5 (8.3)	2 (3.3)	14 (23.3)	0
Aspartate aminotransferase increased	20 (33.3)	4 (6.7)	4 (6.7)	8 (13.3)	4 (6.7)
Platelet count decreased	19 (31.7)	2 (3.3)	2 (3.3)	3 (5.0)	12 (20.0)
Lymphocyte count decreased	13 (21.7)	0	2 (3.3)	7 (11.7)	4 (6.7)
International normalised ratio increased	9 (15.0)	8 (13.3)	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prothrombin time prolonged	9 (15.0)	5 (8.3)	3 (5.0)	1 (1.7)	0
Blood creatinine increased	8 (13.3)	4 (6.7)	2 (3.3)	2 (3.3)	0
Blood bilirubin increased	7 (11.7)	1 (1.7)	3 (5.0)	3 (5.0)	0
Activated partial thromboplastin time prolonged	5 (8.3)	3 (5.0)	2 (3.3)	0	0
Blood fibrinogen decreased	4 (6.7)	0	1 (1.7)	2 (3.3)	1 (1.7)
Weight decreased	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Blood immunoglobulin m decreased	3 (5.0)	3 (5.0)	0	0	0
Blood urea increased	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Haemoglobin decreased	3 (5.0)	2 (3.3)	0	1 (1.7)	0
Transaminases increased	3 (5.0)	3 (5.0)	0	0	0
Blood immunoglobulin a decreased	2 (3.3)	2 (3.3)	0	0	0
Blood magnesium decreased	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Blood phosphorus increased	2 (3.3)	2 (3.3)	0	0	0
Blood uric acid increased	2 (3.3)	2 (3.3)	0	0	0
C-reactive protein increased	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Lipase increased	2 (3.3)	0	0	0	2 (3.3)
Serum ferritin increased	2 (3.3)	0	2 (3.3)	0	0
Weight increased	2 (3.3)	1 (1.7)	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood alkaline phosphatase increased	1 (1.7)	1 (1.7)	0	0	0
Blood bicarbonate decreased	1 (1.7)	0	1 (1.7)	0	0
Blood immunoglobulin g decreased	1 (1.7)	0	1 (1.7)	0	0
Blood lactate dehydrogenase increased	1 (1.7)	1 (1.7)	0	0	0
Blood lactic acid increased	1 (1.7)	0	0	0	1 (1.7)
Blood phosphorus decreased	1 (1.7)	1 (1.7)	0	0	0
Blood sodium increased	1 (1.7)	0	1 (1.7)	0	0
Cardiac murmur	1 (1.7)	1 (1.7)	0	0	0
Culture stool positive	1 (1.7)	1 (1.7)	0	0	0
Hepatic enzyme increased	1 (1.7)	0	1 (1.7)	0	0
Norovirus test positive	1 (1.7)	1 (1.7)	0	0	0
Oxygen saturation decreased	1 (1.7)	1 (1.7)	0	0	0
Protein total decreased	1 (1.7)	0	0	1 (1.7)	0
Pulmonary function test decreased	1 (1.7)	0	1 (1.7)	0	0
Metabolism and nutrition disorders					
-Total	42 (70.0)	7 (11.7)	8 (13.3)	23 (38.3)	4 (6.7)
Decreased appetite	21 (35.0)	4 (6.7)	5 (8.3)	12 (20.0)	0
Hypokalaemia	19 (31.7)	4 (6.7)	6 (10.0)	8 (13.3)	1 (1.7)
Hypophosphataemia	10 (16.7)	2 (3.3)	0	7 (11.7)	1 (1.7)

Timing: Any time post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperphosphataemia	7 (11.7)	7 (11.7)	0	0	0
Hypoalbuminaemia	5 (8.3)	1 (1.7)	3 (5.0)	1 (1.7)	0
Dehydration	4 (6.7)	1 (1.7)	0	3 (5.0)	0
Hypernatraemia	4 (6.7)	1 (1.7)	2 (3.3)	0	1 (1.7)
Fluid overload	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Hyperglycaemia	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Hyperuricaemia	3 (5.0)	2 (3.3)	0	0	1 (1.7)
Hypocalcaemia	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Acidosis	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Hypertriglyceridaemia	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Hyponatraemia	2 (3.3)	0	0	2 (3.3)	0
Tumour lysis syndrome	2 (3.3)	0	0	2 (3.3)	0
Vitamin d deficiency	2 (3.3)	2 (3.3)	0	0	0
Hyperalbuminaemia	1 (1.7)	1 (1.7)	0	0	0
Hypercalcaemia	1 (1.7)	1 (1.7)	0	0	0
Hyperchloraemia	1 (1.7)	1 (1.7)	0	0	0
Hypermagnesaemia	1 (1.7)	1 (1.7)	0	0	0
Hypomagnesaemia	1 (1.7)	1 (1.7)	0	0	0
Iron overload	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Malnutrition	1 (1.7)	0	0	1 (1.7)	0
Metabolic acidosis	1 (1.7)	0	1 (1.7)	0	0
Metabolic alkalosis	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	24 (40.0)	13 (21.7)	10 (16.7)	1 (1.7)	0
Pain in extremity	10 (16.7)	6 (10.0)	4 (6.7)	0	0
Arthralgia	5 (8.3)	3 (5.0)	1 (1.7)	1 (1.7)	0
Myalgia	5 (8.3)	4 (6.7)	1 (1.7)	0	0
Muscular weakness	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Musculoskeletal pain	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Joint range of motion decreased	2 (3.3)	2 (3.3)	0	0	0
Muscle spasms	2 (3.3)	2 (3.3)	0	0	0
Musculoskeletal chest pain	2 (3.3)	2 (3.3)	0	0	0
Back pain	1 (1.7)	1 (1.7)	0	0	0
Coccydynia	1 (1.7)	1 (1.7)	0	0	0
Flank pain	1 (1.7)	0	1 (1.7)	0	0
Limb discomfort	1 (1.7)	1 (1.7)	0	0	0
Neck pain	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Osteonecrosis	1 (1.7)	0	1 (1.7)	0	0
Osteopenia	1 (1.7)	0	1 (1.7)	0	0
Pain in jaw	1 (1.7)	1 (1.7)	0	0	0
Toe walking	1 (1.7)	1 (1.7)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (5.0)	0	2 (3.3)	0	1 (1.7)
Glioblastoma multiforme	1 (1.7)	0	0	0	1 (1.7)
Myelodysplastic syndrome	1 (1.7)	0	1 (1.7)	0	0
Skin papilloma	1 (1.7)	0	1 (1.7)	0	0
Nervous system disorders					
-Total	34 (56.7)	17 (28.3)	11 (18.3)	5 (8.3)	1 (1.7)
Headache	23 (38.3)	15 (25.0)	6 (10.0)	2 (3.3)	0
Dizziness	6 (10.0)	6 (10.0)	0	0	0
Encephalopathy	4 (6.7)	1 (1.7)	1 (1.7)	2 (3.3)	0
Seizure	4 (6.7)	0	2 (3.3)	2 (3.3)	0
Dysarthria	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Peroneal nerve palsy	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Asterixis	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ataxia	1 (1.7)	0	1 (1.7)	0	0
Depressed level of consciousness	1 (1.7)	1 (1.7)	0	0	0
Disturbance in attention	1 (1.7)	1 (1.7)	0	0	0
Embolic stroke	1 (1.7)	0	0	0	1 (1.7)
Idiopathic intracranial hypertension	1 (1.7)	0	1 (1.7)	0	0
Migraine	1 (1.7)	0	1 (1.7)	0	0
Myoclonus	1 (1.7)	1 (1.7)	0	0	0
Neuropathy peripheral	1 (1.7)	0	1 (1.7)	0	0
Pleocytosis	1 (1.7)	1 (1.7)	0	0	0
Somnolence	1 (1.7)	1 (1.7)	0	0	0
Tremor	1 (1.7)	1 (1.7)	0	0	0
Product issues					
-Total	1 (1.7)	1 (1.7)	0	0	0
Device occlusion	1 (1.7)	1 (1.7)	0	0	0
Psychiatric disorders					
-Total	17 (28.3)	8 (13.3)	8 (13.3)	1 (1.7)	0
Anxiety	7 (11.7)	3 (5.0)	3 (5.0)	1 (1.7)	0
Confusional state	6 (10.0)	3 (5.0)	3 (5.0)	0	0
Delirium	4 (6.7)	2 (3.3)	2 (3.3)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Agitation	2 (3.3)	0	2 (3.3)	0	0
Depression	2 (3.3)	2 (3.3)	0	0	0
Hallucination	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Irritability	2 (3.3)	2 (3.3)	0	0	0
Adjustment disorder	1 (1.7)	0	1 (1.7)	0	0
Insomnia	1 (1.7)	0	1 (1.7)	0	0
Listless	1 (1.7)	1 (1.7)	0	0	0
Mental status changes	1 (1.7)	1 (1.7)	0	0	0
Panic attack	1 (1.7)	0	1 (1.7)	0	0
Sleep disorder	1 (1.7)	0	1 (1.7)	0	0
Suicidal ideation	1 (1.7)	1 (1.7)	0	0	0
Renal and urinary disorders					
-Total	15 (25.0)	3 (5.0)	2 (3.3)	6 (10.0)	4 (6.7)
Acute kidney injury	9 (15.0)	1 (1.7)	1 (1.7)	4 (6.7)	3 (5.0)
Haematuria	5 (8.3)	0	2 (3.3)	2 (3.3)	1 (1.7)
Dysuria	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Oliguria	2 (3.3)	0	0	2 (3.3)	0
Calculus urinary	1 (1.7)	0	1 (1.7)	0	0
Nephrolithiasis	1 (1.7)	0	0	1 (1.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pollakiuria	1 (1.7)	1 (1.7)	0	0	0
Renal failure	1 (1.7)	0	0	0	1 (1.7)
Renal impairment	1 (1.7)	0	0	1 (1.7)	0
Urinary incontinence	1 (1.7)	1 (1.7)	0	0	0
Reproductive system and breast disorders					
-Total	6 (10.0)	2 (3.3)	2 (3.3)	2 (3.3)	0
Vulvovaginal adhesion	2 (3.3)	2 (3.3)	0	0	0
Oedema genital	1 (1.7)	0	1 (1.7)	0	0
Ovarian failure	1 (1.7)	0	0	1 (1.7)	0
Scrotal pain	1 (1.7)	0	1 (1.7)	0	0
Vaginal haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	36 (60.0)	14 (23.3)	7 (11.7)	7 (11.7)	8 (13.3)
Cough	13 (21.7)	12 (20.0)	1 (1.7)	0	0
Epistaxis	10 (16.7)	4 (6.7)	1 (1.7)	4 (6.7)	1 (1.7)
Hypoxia	9 (15.0)	0	2 (3.3)	4 (6.7)	3 (5.0)
Pleural effusion	8 (13.3)	2 (3.3)	4 (6.7)	2 (3.3)	0
Pulmonary oedema	7 (11.7)	1 (1.7)	0	4 (6.7)	2 (3.3)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	6 (10.0)	4 (6.7)	2 (3.3)	0	0
Rhinorrhoea	5 (8.3)	5 (8.3)	0	0	0
Tachypnoea	5 (8.3)	3 (5.0)	1 (1.7)	1 (1.7)	0
Nasal congestion	4 (6.7)	4 (6.7)	0	0	0
Rhinitis allergic	4 (6.7)	3 (5.0)	1 (1.7)	0	0
Respiratory failure	3 (5.0)	0	0	0	3 (5.0)
Dyspnoea	2 (3.3)	0	0	1 (1.7)	1 (1.7)
Haemoptysis	2 (3.3)	1 (1.7)	0	0	1 (1.7)
Acute respiratory failure	1 (1.7)	0	0	0	1 (1.7)
Atelectasis	1 (1.7)	1 (1.7)	0	0	0
Dysphonia	1 (1.7)	1 (1.7)	0	0	0
Interstitial lung disease	1 (1.7)	0	0	0	1 (1.7)
Oropharyngeal plaque	1 (1.7)	1 (1.7)	0	0	0
Pharyngeal erythema	1 (1.7)	1 (1.7)	0	0	0
Pharyngeal lesion	1 (1.7)	0	0	1 (1.7)	0
Pharyngeal ulceration	1 (1.7)	0	1 (1.7)	0	0
Respiratory depression	1 (1.7)	0	1 (1.7)	0	0
Respiratory distress	1 (1.7)	0	0	0	1 (1.7)
Wheezing	1 (1.7)	0	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	27 (45.0)	15 (25.0)	9 (15.0)	3 (5.0)	0
Rash	8 (13.3)	5 (8.3)	3 (5.0)	0	0
Dry skin	4 (6.7)	4 (6.7)	0	0	0
Erythema	4 (6.7)	4 (6.7)	0	0	0
Hyperhidrosis	4 (6.7)	4 (6.7)	0	0	0
Petechiae	4 (6.7)	3 (5.0)	1 (1.7)	0	0
Pruritus	4 (6.7)	4 (6.7)	0	0	0
Rash maculo-papular	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Ingrowing nail	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Macule	2 (3.3)	2 (3.3)	0	0	0
Papule	2 (3.3)	2 (3.3)	0	0	0
Rash erythematous	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Rash papular	2 (3.3)	2 (3.3)	0	0	0
Acne	1 (1.7)	1 (1.7)	0	0	0
Alopecia	1 (1.7)	0	1 (1.7)	0	0
Dermatitis	1 (1.7)	1 (1.7)	0	0	0
Dermatitis acneiform	1 (1.7)	0	0	1 (1.7)	0
Dermatitis atopic	1 (1.7)	1 (1.7)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ecchymosis	1 (1.7)	0	0	1 (1.7)	0
Eczema	1 (1.7)	1 (1.7)	0	0	0
Keloid scar	1 (1.7)	0	1 (1.7)	0	0
Livedo reticularis	1 (1.7)	1 (1.7)	0	0	0
Night sweats	1 (1.7)	0	1 (1.7)	0	0
Rash follicular	1 (1.7)	1 (1.7)	0	0	0
Rash macular	1 (1.7)	1 (1.7)	0	0	0
Rash pruritic	1 (1.7)	1 (1.7)	0	0	0
Rash vesicular	1 (1.7)	1 (1.7)	0	0	0
Skin exfoliation	1 (1.7)	1 (1.7)	0	0	0
Skin fissures	1 (1.7)	1 (1.7)	0	0	0
Skin irritation	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					
-Total	24 (40.0)	3 (5.0)	6 (10.0)	7 (11.7)	8 (13.3)
Hypotension	15 (25.0)	1 (1.7)	0	6 (10.0)	8 (13.3)
Hypertension	12 (20.0)	3 (5.0)	8 (13.3)	1 (1.7)	0
Flushing	2 (3.3)	2 (3.3)	0	0	0
Orthostatic hypotension	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Capillary leak syndrome	1 (1.7)	0	0	0	1 (1.7)

Timing: Any time post CTL019 infusion, Down syndrome: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Embolism	1 (1.7)	0	0	1 (1.7)	0
Haematoma	1 (1.7)	0	1 (1.7)	0	0
Hot flush	1 (1.7)	1 (1.7)	0	0	0
Secondary hypertension	1 (1.7)	0	1 (1.7)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174q
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	3 (9.4)	7 (21.9)	22 (68.8)
Blood and lymphatic system disorders					
-Total	20 (62.5)	0	1 (3.1)	15 (46.9)	4 (12.5)
Anaemia	11 (34.4)	1 (3.1)	1 (3.1)	9 (28.1)	0
Febrile neutropenia	10 (31.3)	0	0	10 (31.3)	0
Disseminated intravascular coagulation	2 (6.3)	0	0	2 (6.3)	0
Neutropenia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Lymphopenia	1 (3.1)	0	0	0	1 (3.1)
Pancytopenia	1 (3.1)	0	0	0	1 (3.1)
Thrombocytopenia	1 (3.1)	0	0	0	1 (3.1)
Cardiac disorders					

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (25.0)	6 (18.8)	2 (6.3)	0	0
Tachycardia	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Sinus tachycardia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Atrioventricular block second degree	1 (3.1)	1 (3.1)	0	0	0
Cardiac dysfunction	1 (3.1)	1 (3.1)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.1)	1 (3.1)	0	0	0
Ear pain	1 (3.1)	1 (3.1)	0	0	0
Eye disorders					
-Total	5 (15.6)	3 (9.4)	2 (6.3)	0	0
Eye pain	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Photophobia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Vision blurred	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Retinal haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Uveitis	1 (3.1)	0	1 (3.1)	0	0
Gastrointestinal disorders					
-Total	17 (53.1)	6 (18.8)	5 (15.6)	6 (18.8)	0
Vomiting	11 (34.4)	7 (21.9)	1 (3.1)	3 (9.4)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	10 (31.3)	2 (6.3)	7 (21.9)	1 (3.1)	0
Diarrhoea	8 (25.0)	5 (15.6)	2 (6.3)	1 (3.1)	0
Abdominal pain	6 (18.8)	4 (12.5)	1 (3.1)	1 (3.1)	0
Constipation	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Abdominal distension	1 (3.1)	0	1 (3.1)	0	0
Abdominal pain upper	1 (3.1)	0	1 (3.1)	0	0
Abdominal tenderness	1 (3.1)	1 (3.1)	0	0	0
Dyspepsia	1 (3.1)	0	1 (3.1)	0	0
Glossodynia	1 (3.1)	1 (3.1)	0	0	0
Ileus	1 (3.1)	0	0	1 (3.1)	0
Intestinal obstruction	1 (3.1)	0	0	1 (3.1)	0
Pancreatitis	1 (3.1)	0	1 (3.1)	0	0
General disorders and administration site conditions					
-Total	13 (40.6)	3 (9.4)	5 (15.6)	5 (15.6)	0
Pyrexia	9 (28.1)	1 (3.1)	4 (12.5)	4 (12.5)	0
Fatigue	3 (9.4)	3 (9.4)	0	0	0
Catheter site pain	2 (6.3)	0	2 (6.3)	0	0
Malaise	2 (6.3)	0	2 (6.3)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Generalised oedema	1 (3.1)	0	1 (3.1)	0	0
Injection site haematoma	1 (3.1)	1 (3.1)	0	0	0
Oedema peripheral	1 (3.1)	1 (3.1)	0	0	0
Pain	1 (3.1)	0	0	1 (3.1)	0
Hepatobiliary disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Hyperbilirubinaemia	1 (3.1)	0	1 (3.1)	0	0
Immune system disorders					
-Total	29 (90.6)	1 (3.1)	18 (56.3)	5 (15.6)	5 (15.6)
Cytokine release syndrome	25 (78.1)	3 (9.4)	15 (46.9)	2 (6.3)	5 (15.6)
Hypogammaglobulinaemia	15 (46.9)	1 (3.1)	11 (34.4)	3 (9.4)	0
Haemophagocytic lymphohistiocytosis	1 (3.1)	0	1 (3.1)	0	0
Infections and infestations					
-Total	14 (43.8)	3 (9.4)	6 (18.8)	4 (12.5)	1 (3.1)
Clostridium difficile infection	4 (12.5)	0	4 (12.5)	0	0
Rhinovirus infection	2 (6.3)	2 (6.3)	0	0	0
Catheter site cellulitis	1 (3.1)	1 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile colitis	1 (3.1)	0	0	1 (3.1)	0
Cytomegalovirus infection	1 (3.1)	1 (3.1)	0	0	0
Enterococcal infection	1 (3.1)	1 (3.1)	0	0	0
Folliculitis	1 (3.1)	0	1 (3.1)	0	0
Fungal skin infection	1 (3.1)	1 (3.1)	0	0	0
Gastroenteritis	1 (3.1)	0	1 (3.1)	0	0
Gastroenteritis norovirus	1 (3.1)	0	1 (3.1)	0	0
Influenza	1 (3.1)	1 (3.1)	0	0	0
Oral candidiasis	1 (3.1)	1 (3.1)	0	0	0
Orchitis	1 (3.1)	1 (3.1)	0	0	0
Septic embolus	1 (3.1)	0	0	0	1 (3.1)
Skin infection	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal infection	1 (3.1)	0	0	1 (3.1)	0
Upper respiratory tract infection	1 (3.1)	0	1 (3.1)	0	0
Urinary tract infection enterococcal	1 (3.1)	0	0	1 (3.1)	0
Vulvovaginal candidiasis	1 (3.1)	1 (3.1)	0	0	0
Injury, poisoning and procedural complications					

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (12.5)	2 (6.3)	1 (3.1)	0	1 (3.1)
Transfusion reaction	2 (6.3)	2 (6.3)	0	0	0
Infusion related reaction	1 (3.1)	0	1 (3.1)	0	0
Procedural pain	1 (3.1)	0	1 (3.1)	0	0
Procedural site reaction	1 (3.1)	1 (3.1)	0	0	0
Subdural haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Transfusion related complication	1 (3.1)	0	0	0	1 (3.1)
Investigations					
-Total	28 (87.5)	2 (6.3)	1 (3.1)	6 (18.8)	19 (59.4)
White blood cell count decreased	17 (53.1)	0	0	7 (21.9)	10 (31.3)
Neutrophil count decreased	14 (43.8)	0	0	3 (9.4)	11 (34.4)
Platelet count decreased	10 (31.3)	1 (3.1)	0	1 (3.1)	8 (25.0)
Alanine aminotransferase increased	7 (21.9)	3 (9.4)	0	4 (12.5)	0
Aspartate aminotransferase increased	7 (21.9)	2 (6.3)	0	4 (12.5)	1 (3.1)
Lymphocyte count decreased	6 (18.8)	0	0	3 (9.4)	3 (9.4)
Blood bilirubin increased	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Blood creatinine increased	3 (9.4)	2 (6.3)	1 (3.1)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prothrombin time prolonged	3 (9.4)	3 (9.4)	0	0	0
Activated partial thromboplastin time prolonged	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Blood immunoglobulin a decreased	2 (6.3)	2 (6.3)	0	0	0
Blood immunoglobulin m decreased	2 (6.3)	2 (6.3)	0	0	0
Blood lactic acid increased	1 (3.1)	0	0	0	1 (3.1)
C-reactive protein increased	1 (3.1)	0	0	1 (3.1)	0
Cardiac murmur	1 (3.1)	1 (3.1)	0	0	0
Haemoglobin decreased	1 (3.1)	0	0	1 (3.1)	0
Hepatic enzyme increased	1 (3.1)	0	1 (3.1)	0	0
Lipase increased	1 (3.1)	0	0	0	1 (3.1)
Pulmonary function test decreased	1 (3.1)	0	1 (3.1)	0	0
Serum ferritin increased	1 (3.1)	0	1 (3.1)	0	0
Metabolism and nutrition disorders					
-Total	17 (53.1)	2 (6.3)	6 (18.8)	7 (21.9)	2 (6.3)
Decreased appetite	7 (21.9)	1 (3.1)	3 (9.4)	3 (9.4)	0
Hypokalaemia	7 (21.9)	1 (3.1)	2 (6.3)	4 (12.5)	0
Hypophosphataemia	4 (12.5)	1 (3.1)	0	3 (9.4)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	3 (9.4)	3 (9.4)	0	0	0
Dehydration	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Hyperglycaemia	2 (6.3)	0	2 (6.3)	0	0
Hyperuricaemia	2 (6.3)	1 (3.1)	0	0	1 (3.1)
Hypocalcaemia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Fluid overload	1 (3.1)	1 (3.1)	0	0	0
Hypernatraemia	1 (3.1)	0	0	0	1 (3.1)
Hypertriglyceridaemia	1 (3.1)	0	0	1 (3.1)	0
Hyponatraemia	1 (3.1)	0	0	1 (3.1)	0
Musculoskeletal and connective tissue disorders					
-Total	6 (18.8)	2 (6.3)	3 (9.4)	1 (3.1)	0
Pain in extremity	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Arthralgia	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Coccydynia	1 (3.1)	1 (3.1)	0	0	0
Muscular weakness	1 (3.1)	0	1 (3.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.1)	0	1 (3.1)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin papilloma	1 (3.1)	0	1 (3.1)	0	0
Nervous system disorders					
-Total	17 (53.1)	8 (25.0)	5 (15.6)	3 (9.4)	1 (3.1)
Headache	13 (40.6)	9 (28.1)	3 (9.4)	1 (3.1)	0
Dizziness	1 (3.1)	1 (3.1)	0	0	0
Dysarthria	1 (3.1)	0	1 (3.1)	0	0
Embolic stroke	1 (3.1)	0	0	0	1 (3.1)
Encephalopathy	1 (3.1)	0	0	1 (3.1)	0
Migraine	1 (3.1)	0	1 (3.1)	0	0
Seizure	1 (3.1)	0	0	1 (3.1)	0
Somnolence	1 (3.1)	1 (3.1)	0	0	0
Tremor	1 (3.1)	1 (3.1)	0	0	0
Product issues					
-Total	1 (3.1)	1 (3.1)	0	0	0
Device occlusion	1 (3.1)	1 (3.1)	0	0	0
Psychiatric disorders					
-Total	7 (21.9)	4 (12.5)	3 (9.4)	0	0
Anxiety	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Confusional state	2 (6.3)	1 (3.1)	1 (3.1)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	1 (3.1)	1 (3.1)	0	0	0
Hallucination	1 (3.1)	1 (3.1)	0	0	0
Mental status changes	1 (3.1)	1 (3.1)	0	0	0
Panic attack	1 (3.1)	0	1 (3.1)	0	0
Renal and urinary disorders					
-Total	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Acute kidney injury	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Reproductive system and breast disorders					
-Total	1 (3.1)	1 (3.1)	0	0	0
Vulvovaginal adhesion	1 (3.1)	1 (3.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	13 (40.6)	6 (18.8)	4 (12.5)	3 (9.4)	0
Hypoxia	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Cough	3 (9.4)	3 (9.4)	0	0	0
Epistaxis	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Tachypnoea	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Nasal congestion	1 (3.1)	1 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal plaque	1 (3.1)	1 (3.1)	0	0	0
Pharyngeal ulceration	1 (3.1)	0	1 (3.1)	0	0
Pleural effusion	1 (3.1)	0	1 (3.1)	0	0
Pulmonary oedema	1 (3.1)	1 (3.1)	0	0	0
Respiratory depression	1 (3.1)	0	1 (3.1)	0	0
Wheezing	1 (3.1)	0	1 (3.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (28.1)	8 (25.0)	1 (3.1)	0	0
Dry skin	3 (9.4)	3 (9.4)	0	0	0
Erythema	2 (6.3)	2 (6.3)	0	0	0
Pruritus	2 (6.3)	2 (6.3)	0	0	0
Hyperhidrosis	1 (3.1)	1 (3.1)	0	0	0
Ingrowing nail	1 (3.1)	0	1 (3.1)	0	0
Livedo reticularis	1 (3.1)	1 (3.1)	0	0	0
Rash	1 (3.1)	1 (3.1)	0	0	0
Rash follicular	1 (3.1)	1 (3.1)	0	0	0
Rash papular	1 (3.1)	1 (3.1)	0	0	0
Rash vesicular	1 (3.1)	1 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	9 (28.1)	2 (6.3)	2 (6.3)	4 (12.5)	1 (3.1)
Hypotension	5 (15.6)	1 (3.1)	0	3 (9.4)	1 (3.1)
Hypertension	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Embolism	1 (3.1)	0	0	1 (3.1)	0
Flushing	1 (3.1)	1 (3.1)	0	0	0
Orthostatic hypotension	1 (3.1)	0	1 (3.1)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174q
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (96.9)	2 (6.3)	4 (12.5)	7 (21.9)	18 (56.3)
Blood and lymphatic system disorders					
-Total	23 (71.9)	2 (6.3)	2 (6.3)	12 (37.5)	7 (21.9)
Anaemia	16 (50.0)	2 (6.3)	4 (12.5)	9 (28.1)	1 (3.1)
Febrile neutropenia	12 (37.5)	0	0	12 (37.5)	0
Thrombocytopenia	7 (21.9)	0	0	2 (6.3)	5 (15.6)
Neutropenia	6 (18.8)	0	0	2 (6.3)	4 (12.5)
Disseminated intravascular coagulation	2 (6.3)	0	2 (6.3)	0	0
Lymphopenia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Coagulopathy	1 (3.1)	1 (3.1)	0	0	0
Cardiac disorders					

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (43.8)	5 (15.6)	7 (21.9)	2 (6.3)	0
Tachycardia	10 (31.3)	4 (12.5)	4 (12.5)	2 (6.3)	0
Sinus tachycardia	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Pericardial effusion	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Bradycardia	1 (3.1)	0	1 (3.1)	0	0
Left ventricular dysfunction	1 (3.1)	0	0	1 (3.1)	0
Palpitations	1 (3.1)	1 (3.1)	0	0	0
Sinus bradycardia	1 (3.1)	1 (3.1)	0	0	0
Ventricular tachycardia	1 (3.1)	0	1 (3.1)	0	0
Ear and labyrinth disorders					
-Total	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Ear pain	1 (3.1)	1 (3.1)	0	0	0
Hypoacusis	1 (3.1)	0	1 (3.1)	0	0
Endocrine disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Adrenal insufficiency	1 (3.1)	0	1 (3.1)	0	0
Eye disorders					
-Total	8 (25.0)	3 (9.4)	5 (15.6)	0	0
Periorbital oedema	4 (12.5)	3 (9.4)	1 (3.1)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctival haemorrhage	3 (9.4)	3 (9.4)	0	0	0
Eye pain	1 (3.1)	0	1 (3.1)	0	0
Ocular hypertension	1 (3.1)	0	1 (3.1)	0	0
Papilloedema	1 (3.1)	0	1 (3.1)	0	0
Retinal haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Uveitis	1 (3.1)	0	1 (3.1)	0	0
Vision blurred	1 (3.1)	0	1 (3.1)	0	0
Visual impairment	1 (3.1)	0	1 (3.1)	0	0
Gastrointestinal disorders					
-Total	19 (59.4)	5 (15.6)	9 (28.1)	5 (15.6)	0
Nausea	11 (34.4)	4 (12.5)	5 (15.6)	2 (6.3)	0
Vomiting	11 (34.4)	6 (18.8)	5 (15.6)	0	0
Diarrhoea	10 (31.3)	6 (18.8)	4 (12.5)	0	0
Abdominal pain	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Constipation	2 (6.3)	2 (6.3)	0	0	0
Dysphagia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Haematemesis	2 (6.3)	2 (6.3)	0	0	0
Stomatitis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Abdominal discomfort	1 (3.1)	1 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal distension	1 (3.1)	0	1 (3.1)	0	0
Abdominal pain lower	1 (3.1)	0	1 (3.1)	0	0
Abdominal pain upper	1 (3.1)	0	1 (3.1)	0	0
Anal incontinence	1 (3.1)	1 (3.1)	0	0	0
Ascites	1 (3.1)	0	0	1 (3.1)	0
Flatulence	1 (3.1)	1 (3.1)	0	0	0
Gastrointestinal haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Gastrooesophageal reflux disease	1 (3.1)	1 (3.1)	0	0	0
Lip pain	1 (3.1)	0	1 (3.1)	0	0
Mouth haemorrhage	1 (3.1)	0	0	1 (3.1)	0
Pancreatitis	1 (3.1)	0	0	1 (3.1)	0
Tooth socket haemorrhage	1 (3.1)	1 (3.1)	0	0	0
General disorders and administration site conditions					
-Total	19 (59.4)	9 (28.1)	5 (15.6)	4 (12.5)	1 (3.1)
Fatigue	10 (31.3)	7 (21.9)	2 (6.3)	1 (3.1)	0
Chills	8 (25.0)	8 (25.0)	0	0	0
Pyrexia	7 (21.9)	2 (6.3)	3 (9.4)	1 (3.1)	1 (3.1)
Face oedema	2 (6.3)	0	1 (3.1)	1 (3.1)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Asthenia	1 (3.1)	1 (3.1)	0	0	0
Catheter site extravasation	1 (3.1)	0	1 (3.1)	0	0
Catheter site pain	1 (3.1)	1 (3.1)	0	0	0
Facial pain	1 (3.1)	0	1 (3.1)	0	0
Generalised oedema	1 (3.1)	0	1 (3.1)	0	0
Localised oedema	1 (3.1)	0	0	1 (3.1)	0
Malaise	1 (3.1)	0	1 (3.1)	0	0
Mucosal haemorrhage	1 (3.1)	0	1 (3.1)	0	0
Multiple organ dysfunction syndrome	1 (3.1)	0	0	1 (3.1)	0
Non-cardiac chest pain	1 (3.1)	1 (3.1)	0	0	0
Oedema peripheral	1 (3.1)	0	0	1 (3.1)	0
Peripheral swelling	1 (3.1)	0	1 (3.1)	0	0
Physical deconditioning	1 (3.1)	0	0	1 (3.1)	0
Hepatobiliary disorders					
-Total	6 (18.8)	3 (9.4)	1 (3.1)	2 (6.3)	0
Hepatomegaly	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Hyperbilirubinaemia	2 (6.3)	0	0	2 (6.3)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gallbladder enlargement	1 (3.1)	1 (3.1)	0	0	0
Hepatosplenomegaly	1 (3.1)	1 (3.1)	0	0	0
Immune system disorders					
-Total	28 (87.5)	4 (12.5)	12 (37.5)	6 (18.8)	6 (18.8)
Cytokine release syndrome	25 (78.1)	3 (9.4)	10 (31.3)	6 (18.8)	6 (18.8)
Hypogammaglobulinaemia	10 (31.3)	2 (6.3)	7 (21.9)	1 (3.1)	0
Drug hypersensitivity	1 (3.1)	0	1 (3.1)	0	0
Graft versus host disease in skin	1 (3.1)	1 (3.1)	0	0	0
Infections and infestations					
-Total	12 (37.5)	2 (6.3)	8 (25.0)	2 (6.3)	0
Clostridium difficile colitis	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Pneumonia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Acute sinusitis	1 (3.1)	0	1 (3.1)	0	0
Body tinea	1 (3.1)	1 (3.1)	0	0	0
Gastroenteritis	1 (3.1)	0	0	1 (3.1)	0
Herpes simplex	1 (3.1)	1 (3.1)	0	0	0
Human herpesvirus 6 infection	1 (3.1)	0	1 (3.1)	0	0
Hypopyon	1 (3.1)	0	1 (3.1)	0	0
Pharyngitis	1 (3.1)	0	1 (3.1)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (3.1)	1 (3.1)	0	0	0
Staphylococcal infection	1 (3.1)	1 (3.1)	0	0	0
Streptococcal infection	1 (3.1)	0	1 (3.1)	0	0
Viral infection	1 (3.1)	0	1 (3.1)	0	0
Viral upper respiratory tract infection	1 (3.1)	0	1 (3.1)	0	0
Injury, poisoning and procedural complications					
-Total	11 (34.4)	6 (18.8)	4 (12.5)	1 (3.1)	0
Procedural pain	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Contusion	1 (3.1)	1 (3.1)	0	0	0
Incision site pain	1 (3.1)	1 (3.1)	0	0	0
Infusion related reaction	1 (3.1)	0	1 (3.1)	0	0
Limb injury	1 (3.1)	1 (3.1)	0	0	0
Mouth injury	1 (3.1)	1 (3.1)	0	0	0
Post procedural haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Procedural complication	1 (3.1)	1 (3.1)	0	0	0
Procedural headache	1 (3.1)	0	1 (3.1)	0	0
Skin abrasion	1 (3.1)	1 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stoma site irritation	1 (3.1)	1 (3.1)	0	0	0
Tibia fracture	1 (3.1)	0	1 (3.1)	0	0
Tongue injury	1 (3.1)	1 (3.1)	0	0	0
Tracheal haemorrhage	1 (3.1)	0	0	1 (3.1)	0
Transfusion reaction	1 (3.1)	0	1 (3.1)	0	0
Investigations					
-Total	24 (75.0)	2 (6.3)	3 (9.4)	7 (21.9)	12 (37.5)
White blood cell count decreased	13 (40.6)	3 (9.4)	1 (3.1)	3 (9.4)	6 (18.8)
Alanine aminotransferase increased	12 (37.5)	2 (6.3)	3 (9.4)	7 (21.9)	0
Aspartate aminotransferase increased	11 (34.4)	1 (3.1)	4 (12.5)	3 (9.4)	3 (9.4)
Neutrophil count decreased	11 (34.4)	0	2 (6.3)	1 (3.1)	8 (25.0)
International normalised ratio increased	9 (28.1)	8 (25.0)	0	1 (3.1)	0
Platelet count decreased	9 (28.1)	2 (6.3)	2 (6.3)	1 (3.1)	4 (12.5)
Lymphocyte count decreased	8 (25.0)	1 (3.1)	2 (6.3)	3 (9.4)	2 (6.3)
Blood creatinine increased	6 (18.8)	3 (9.4)	1 (3.1)	2 (6.3)	0
Prothrombin time prolonged	6 (18.8)	2 (6.3)	3 (9.4)	1 (3.1)	0
Blood bilirubin increased	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	4 (12.5)	0	1 (3.1)	2 (6.3)	1 (3.1)
Activated partial thromboplastin time prolonged	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Blood urea increased	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Blood immunoglobulin m decreased	2 (6.3)	2 (6.3)	0	0	0
Blood phosphorus increased	2 (6.3)	2 (6.3)	0	0	0
Transaminases increased	2 (6.3)	2 (6.3)	0	0	0
Blood bicarbonate decreased	1 (3.1)	0	1 (3.1)	0	0
Blood immunoglobulin a decreased	1 (3.1)	1 (3.1)	0	0	0
Blood immunoglobulin g decreased	1 (3.1)	0	1 (3.1)	0	0
Blood magnesium decreased	1 (3.1)	0	0	1 (3.1)	0
Blood phosphorus decreased	1 (3.1)	1 (3.1)	0	0	0
Blood sodium increased	1 (3.1)	0	1 (3.1)	0	0
Blood uric acid increased	1 (3.1)	1 (3.1)	0	0	0
Culture stool positive	1 (3.1)	1 (3.1)	0	0	0
Fibrin d dimer increased	1 (3.1)	1 (3.1)	0	0	0
Lipase increased	1 (3.1)	0	0	0	1 (3.1)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Norovirus test positive	1 (3.1)	1 (3.1)	0	0	0
Protein total decreased	1 (3.1)	0	0	1 (3.1)	0
Metabolism and nutrition disorders					
-Total	22 (68.8)	3 (9.4)	4 (12.5)	14 (43.8)	1 (3.1)
Decreased appetite	13 (40.6)	3 (9.4)	1 (3.1)	9 (28.1)	0
Hypokalaemia	9 (28.1)	2 (6.3)	4 (12.5)	3 (9.4)	0
Hyperphosphataemia	5 (15.6)	5 (15.6)	0	0	0
Hypoalbuminaemia	5 (15.6)	1 (3.1)	3 (9.4)	1 (3.1)	0
Hypophosphataemia	5 (15.6)	1 (3.1)	0	3 (9.4)	1 (3.1)
Hypernatraemia	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Acidosis	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Fluid overload	2 (6.3)	0	2 (6.3)	0	0
Dehydration	1 (3.1)	0	0	1 (3.1)	0
Hyperalbuminaemia	1 (3.1)	1 (3.1)	0	0	0
Hypercalcaemia	1 (3.1)	1 (3.1)	0	0	0
Hyperchloraemia	1 (3.1)	1 (3.1)	0	0	0
Hyperglycaemia	1 (3.1)	0	0	1 (3.1)	0
Hypermagnesaemia	1 (3.1)	1 (3.1)	0	0	0
Hypertriglyceridaemia	1 (3.1)	1 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	1 (3.1)	1 (3.1)	0	0	0
Hypocalcaemia	1 (3.1)	0	0	1 (3.1)	0
Hypomagnesaemia	1 (3.1)	1 (3.1)	0	0	0
Hyponatraemia	1 (3.1)	0	0	1 (3.1)	0
Malnutrition	1 (3.1)	0	0	1 (3.1)	0
Metabolic acidosis	1 (3.1)	0	1 (3.1)	0	0
Metabolic alkalosis	1 (3.1)	1 (3.1)	0	0	0
Tumour lysis syndrome	1 (3.1)	0	0	1 (3.1)	0
Musculoskeletal and connective tissue disorders					
-Total	9 (28.1)	6 (18.8)	3 (9.4)	0	0
Myalgia	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Musculoskeletal pain	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Arthralgia	2 (6.3)	2 (6.3)	0	0	0
Limb discomfort	1 (3.1)	1 (3.1)	0	0	0
Muscle spasms	1 (3.1)	1 (3.1)	0	0	0
Musculoskeletal chest pain	1 (3.1)	1 (3.1)	0	0	0
Osteopenia	1 (3.1)	0	1 (3.1)	0	0
Pain in extremity	1 (3.1)	1 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	16 (50.0)	9 (28.1)	6 (18.8)	1 (3.1)	0
Headache	11 (34.4)	7 (21.9)	3 (9.4)	1 (3.1)	0
Dizziness	3 (9.4)	3 (9.4)	0	0	0
Encephalopathy	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Seizure	2 (6.3)	0	2 (6.3)	0	0
Asterixis	1 (3.1)	1 (3.1)	0	0	0
Ataxia	1 (3.1)	0	1 (3.1)	0	0
Depressed level of consciousness	1 (3.1)	1 (3.1)	0	0	0
Dysarthria	1 (3.1)	1 (3.1)	0	0	0
Idiopathic intracranial hypertension	1 (3.1)	0	1 (3.1)	0	0
Myoclonus	1 (3.1)	1 (3.1)	0	0	0
Neuropathy peripheral	1 (3.1)	0	1 (3.1)	0	0
Pleocytosis	1 (3.1)	1 (3.1)	0	0	0
Tremor	1 (3.1)	1 (3.1)	0	0	0
Psychiatric disorders					
-Total	9 (28.1)	4 (12.5)	4 (12.5)	1 (3.1)	0
Anxiety	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Confusional state	4 (12.5)	2 (6.3)	2 (6.3)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Agitation	2 (6.3)	0	2 (6.3)	0	0
Irritability	2 (6.3)	2 (6.3)	0	0	0
Adjustment disorder	1 (3.1)	0	1 (3.1)	0	0
Hallucination	1 (3.1)	0	1 (3.1)	0	0
Insomnia	1 (3.1)	0	1 (3.1)	0	0
Listless	1 (3.1)	1 (3.1)	0	0	0
Suicidal ideation	1 (3.1)	1 (3.1)	0	0	0
Renal and urinary disorders					
-Total	9 (28.1)	1 (3.1)	1 (3.1)	3 (9.4)	4 (12.5)
Acute kidney injury	5 (15.6)	0	0	2 (6.3)	3 (9.4)
Haematuria	4 (12.5)	0	2 (6.3)	1 (3.1)	1 (3.1)
Dysuria	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Oliguria	2 (6.3)	0	0	2 (6.3)	0
Pollakiuria	1 (3.1)	1 (3.1)	0	0	0
Renal failure	1 (3.1)	0	0	0	1 (3.1)
Renal impairment	1 (3.1)	0	0	1 (3.1)	0
Reproductive system and breast disorders					

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Oedema genital	1 (3.1)	0	1 (3.1)	0	0
Vulvovaginal adhesion	1 (3.1)	1 (3.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	15 (46.9)	4 (12.5)	2 (6.3)	2 (6.3)	7 (21.9)
Pleural effusion	7 (21.9)	2 (6.3)	3 (9.4)	2 (6.3)	0
Hypoxia	6 (18.8)	0	1 (3.1)	2 (6.3)	3 (9.4)
Cough	5 (15.6)	5 (15.6)	0	0	0
Pulmonary oedema	5 (15.6)	0	0	3 (9.4)	2 (6.3)
Epistaxis	4 (12.5)	1 (3.1)	1 (3.1)	1 (3.1)	1 (3.1)
Respiratory failure	3 (9.4)	0	0	0	3 (9.4)
Tachypnoea	3 (9.4)	2 (6.3)	0	1 (3.1)	0
Dyspnoea	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Haemoptysis	2 (6.3)	1 (3.1)	0	0	1 (3.1)
Oropharyngeal pain	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Atelectasis	1 (3.1)	1 (3.1)	0	0	0
Interstitial lung disease	1 (3.1)	0	0	0	1 (3.1)
Respiratory distress	1 (3.1)	0	0	0	1 (3.1)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis allergic	1 (3.1)	1 (3.1)	0	0	0
Rhinorrhoea	1 (3.1)	1 (3.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	12 (37.5)	7 (21.9)	3 (9.4)	2 (6.3)	0
Petechiae	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Rash	3 (9.4)	3 (9.4)	0	0	0
Rash maculo-papular	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Hyperhidrosis	2 (6.3)	2 (6.3)	0	0	0
Dermatitis diaper	1 (3.1)	1 (3.1)	0	0	0
Dry skin	1 (3.1)	1 (3.1)	0	0	0
Ecchymosis	1 (3.1)	0	0	1 (3.1)	0
Erythema	1 (3.1)	1 (3.1)	0	0	0
Ingrowing nail	1 (3.1)	0	1 (3.1)	0	0
Macule	1 (3.1)	1 (3.1)	0	0	0
Night sweats	1 (3.1)	0	1 (3.1)	0	0
Rash erythematous	1 (3.1)	1 (3.1)	0	0	0
Rash macular	1 (3.1)	1 (3.1)	0	0	0
Rash papular	1 (3.1)	1 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin exfoliation	1 (3.1)	1 (3.1)	0	0	0
Skin fissures	1 (3.1)	1 (3.1)	0	0	0
Skin irritation	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	15 (46.9)	1 (3.1)	3 (9.4)	4 (12.5)	7 (21.9)
Hypotension	11 (34.4)	0	0	4 (12.5)	7 (21.9)
Hypertension	6 (18.8)	0	5 (15.6)	1 (3.1)	0
Capillary leak syndrome	1 (3.1)	0	0	0	1 (3.1)
Flushing	1 (3.1)	1 (3.1)	0	0	0
Haematoma	1 (3.1)	0	1 (3.1)	0	0
Orthostatic hypotension	1 (3.1)	1 (3.1)	0	0	0
Secondary hypertension	1 (3.1)	0	1 (3.1)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174q
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=29		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (86.2)	2 (6.9)	10 (34.5)	8 (27.6)	5 (17.2)
Blood and lymphatic system disorders					
-Total	5 (17.2)	1 (3.4)	2 (6.9)	1 (3.4)	1 (3.4)
Anaemia	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Febrile neutropenia	1 (3.4)	0	0	1 (3.4)	0
Lymphadenopathy	1 (3.4)	0	1 (3.4)	0	0
Neutropenia	1 (3.4)	0	0	0	1 (3.4)
Thrombocytopenia	1 (3.4)	0	1 (3.4)	0	0
Endocrine disorders					
-Total	1 (3.4)	1 (3.4)	0	0	0
Adrenal insufficiency	1 (3.4)	1 (3.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	5 (17.2)	4 (13.8)	1 (3.4)	0	0
Dry eye	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Conjunctivitis allergic	1 (3.4)	1 (3.4)	0	0	0
Ocular hyperaemia	1 (3.4)	1 (3.4)	0	0	0
Vision blurred	1 (3.4)	1 (3.4)	0	0	0
Gastrointestinal disorders					
-Total	11 (37.9)	6 (20.7)	2 (6.9)	3 (10.3)	0
Diarrhoea	7 (24.1)	5 (17.2)	1 (3.4)	1 (3.4)	0
Vomiting	6 (20.7)	2 (6.9)	2 (6.9)	2 (6.9)	0
Abdominal pain	4 (13.8)	2 (6.9)	1 (3.4)	1 (3.4)	0
Nausea	4 (13.8)	1 (3.4)	1 (3.4)	2 (6.9)	0
Oral pain	2 (6.9)	1 (3.4)	0	1 (3.4)	0
General disorders and administration site conditions					
-Total	12 (41.4)	9 (31.0)	2 (6.9)	1 (3.4)	0
Pyrexia	7 (24.1)	5 (17.2)	1 (3.4)	1 (3.4)	0
Fatigue	2 (6.9)	2 (6.9)	0	0	0
Catheter site pain	1 (3.4)	0	1 (3.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Crying	1 (3.4)	1 (3.4)	0	0	0
Generalised oedema	1 (3.4)	1 (3.4)	0	0	0
Influenza like illness	1 (3.4)	1 (3.4)	0	0	0
Malaise	1 (3.4)	1 (3.4)	0	0	0
Oedema peripheral	1 (3.4)	1 (3.4)	0	0	0
Immune system disorders					
-Total	8 (27.6)	2 (6.9)	6 (20.7)	0	0
Hypogammaglobulinaemia	4 (13.8)	0	4 (13.8)	0	0
Seasonal allergy	2 (6.9)	2 (6.9)	0	0	0
Graft versus host disease	1 (3.4)	0	1 (3.4)	0	0
Graft versus host disease in gastrointestinal tract	1 (3.4)	0	1 (3.4)	0	0
Immunodeficiency common variable	1 (3.4)	0	1 (3.4)	0	0
Infections and infestations					
-Total	19 (65.5)	3 (10.3)	10 (34.5)	4 (13.8)	2 (6.9)
Upper respiratory tract infection	4 (13.8)	1 (3.4)	3 (10.3)	0	0
Ear infection	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Gastroenteritis	2 (6.9)	0	2 (6.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=29		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	2 (6.9)	0	2 (6.9)	0	0
Rhinovirus infection	2 (6.9)	2 (6.9)	0	0	0
Sinusitis	2 (6.9)	0	2 (6.9)	0	0
Urinary tract infection	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Viral upper respiratory tract infection	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Bacterial sepsis	1 (3.4)	0	0	0	1 (3.4)
Cytomegalovirus infection	1 (3.4)	1 (3.4)	0	0	0
Enterovirus infection	1 (3.4)	0	0	1 (3.4)	0
Escherichia urinary tract infection	1 (3.4)	0	0	1 (3.4)	0
Gastroenteritis norovirus	1 (3.4)	0	1 (3.4)	0	0
Gastroenteritis viral	1 (3.4)	1 (3.4)	0	0	0
Molluscum contagiosum	1 (3.4)	1 (3.4)	0	0	0
Oral herpes	1 (3.4)	0	1 (3.4)	0	0
Otitis media acute	1 (3.4)	0	1 (3.4)	0	0
Parainfluenzae virus infection	1 (3.4)	0	0	1 (3.4)	0
Rhinitis	1 (3.4)	1 (3.4)	0	0	0
Rotavirus infection	1 (3.4)	0	0	1 (3.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=29		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (3.4)	0	0	0	1 (3.4)
Subcutaneous abscess	1 (3.4)	0	1 (3.4)	0	0
Tinea capitis	1 (3.4)	1 (3.4)	0	0	0
Viral infection	1 (3.4)	1 (3.4)	0	0	0
Injury, poisoning and procedural complications					
-Total	6 (20.7)	3 (10.3)	3 (10.3)	0	0
Contusion	2 (6.9)	2 (6.9)	0	0	0
Infusion related reaction	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Procedural pain	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Arthropod bite	1 (3.4)	1 (3.4)	0	0	0
Procedural nausea	1 (3.4)	0	1 (3.4)	0	0
Skin abrasion	1 (3.4)	1 (3.4)	0	0	0
Skin laceration	1 (3.4)	0	1 (3.4)	0	0
Sunburn	1 (3.4)	1 (3.4)	0	0	0
Investigations					
-Total	11 (37.9)	2 (6.9)	3 (10.3)	5 (17.2)	1 (3.4)
Neutrophil count decreased	3 (10.3)	1 (3.4)	0	2 (6.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=29		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	3 (10.3)	1 (3.4)	0	1 (3.4)	1 (3.4)
Weight increased	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Aspartate aminotransferase increased	1 (3.4)	0	0	1 (3.4)	0
Blood bilirubin increased	1 (3.4)	0	0	1 (3.4)	0
Blood creatinine increased	1 (3.4)	1 (3.4)	0	0	0
Blood magnesium decreased	1 (3.4)	1 (3.4)	0	0	0
Lymphocyte count decreased	1 (3.4)	0	1 (3.4)	0	0
Oxygen saturation decreased	1 (3.4)	1 (3.4)	0	0	0
Platelet count decreased	1 (3.4)	1 (3.4)	0	0	0
Serum ferritin increased	1 (3.4)	0	1 (3.4)	0	0
Weight decreased	1 (3.4)	1 (3.4)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (24.1)	3 (10.3)	1 (3.4)	2 (6.9)	1 (3.4)
Decreased appetite	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Hyperphosphataemia	2 (6.9)	2 (6.9)	0	0	0
Hypokalaemia	2 (6.9)	1 (3.4)	0	0	1 (3.4)
Dehydration	1 (3.4)	0	0	1 (3.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=29		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	1 (3.4)	0	0	1 (3.4)	0
Hypophosphataemia	1 (3.4)	0	0	1 (3.4)	0
Iron overload	1 (3.4)	0	0	1 (3.4)	0
Musculoskeletal and connective tissue disorders					
-Total	10 (34.5)	6 (20.7)	4 (13.8)	0	0
Pain in extremity	5 (17.2)	3 (10.3)	2 (6.9)	0	0
Arthralgia	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Muscular weakness	2 (6.9)	2 (6.9)	0	0	0
Flank pain	1 (3.4)	0	1 (3.4)	0	0
Musculoskeletal chest pain	1 (3.4)	1 (3.4)	0	0	0
Pain in jaw	1 (3.4)	1 (3.4)	0	0	0
Toe walking	1 (3.4)	1 (3.4)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.4)	0	1 (3.4)	0	0
Myelodysplastic syndrome	1 (3.4)	0	1 (3.4)	0	0
Nervous system disorders					
-Total	5 (17.2)	4 (13.8)	1 (3.4)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	3 (10.3)	2 (6.9)	1 (3.4)	0	0
Dizziness	2 (6.9)	2 (6.9)	0	0	0
Peroneal nerve palsy	1 (3.4)	1 (3.4)	0	0	0
Psychiatric disorders					
-Total	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Depression	2 (6.9)	2 (6.9)	0	0	0
Anxiety	1 (3.4)	1 (3.4)	0	0	0
Sleep disorder	1 (3.4)	0	1 (3.4)	0	0
Renal and urinary disorders					
-Total	3 (10.3)	1 (3.4)	0	2 (6.9)	0
Acute kidney injury	1 (3.4)	0	0	1 (3.4)	0
Calculus urinary	1 (3.4)	0	1 (3.4)	0	0
Haematuria	1 (3.4)	0	0	1 (3.4)	0
Nephrolithiasis	1 (3.4)	0	0	1 (3.4)	0
Urinary incontinence	1 (3.4)	1 (3.4)	0	0	0
Reproductive system and breast disorders					
-Total	1 (3.4)	0	0	1 (3.4)	0
Vaginal haemorrhage	1 (3.4)	0	0	1 (3.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=29		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	11 (37.9)	7 (24.1)	2 (6.9)	1 (3.4)	1 (3.4)
Cough	5 (17.2)	4 (13.8)	1 (3.4)	0	0
Epistaxis	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Nasal congestion	2 (6.9)	2 (6.9)	0	0	0
Oropharyngeal pain	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Rhinorrhoea	2 (6.9)	2 (6.9)	0	0	0
Acute respiratory failure	1 (3.4)	0	0	0	1 (3.4)
Dysphonia	1 (3.4)	1 (3.4)	0	0	0
Pharyngeal erythema	1 (3.4)	1 (3.4)	0	0	0
Pharyngeal lesion	1 (3.4)	0	0	1 (3.4)	0
Rhinitis allergic	1 (3.4)	0	1 (3.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (27.6)	4 (13.8)	4 (13.8)	0	0
Rash	3 (10.3)	1 (3.4)	2 (6.9)	0	0
Alopecia	1 (3.4)	0	1 (3.4)	0	0
Dermatitis	1 (3.4)	1 (3.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	1 (3.4)	1 (3.4)	0	0	0
Erythema	1 (3.4)	1 (3.4)	0	0	0
Keloid scar	1 (3.4)	0	1 (3.4)	0	0
Petechiae	1 (3.4)	1 (3.4)	0	0	0
Pruritus	1 (3.4)	1 (3.4)	0	0	0
Rash erythematous	1 (3.4)	0	1 (3.4)	0	0
Rash maculo-papular	1 (3.4)	1 (3.4)	0	0	0
Rash pruritic	1 (3.4)	1 (3.4)	0	0	0
Vascular disorders					
-Total	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Hypertension	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Hot flush	1 (3.4)	1 (3.4)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174q
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=27		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (77.8)	2 (7.4)	6 (22.2)	8 (29.6)	5 (18.5)
Blood and lymphatic system disorders					
-Total	6 (22.2)	0	1 (3.7)	2 (7.4)	3 (11.1)
Neutropenia	3 (11.1)	0	0	1 (3.7)	2 (7.4)
Febrile neutropenia	2 (7.4)	0	0	2 (7.4)	0
Eosinophilia	1 (3.7)	0	0	1 (3.7)	0
Leukopenia	1 (3.7)	0	0	0	1 (3.7)
Lymphopenia	1 (3.7)	0	1 (3.7)	0	0
Thrombocytopenia	1 (3.7)	0	0	1 (3.7)	0
Cardiac disorders					
-Total	1 (3.7)	0	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	1 (3.7)	0	1 (3.7)	0	0
Gastrointestinal disorders					
-Total	5 (18.5)	3 (11.1)	1 (3.7)	1 (3.7)	0
Vomiting	3 (11.1)	3 (11.1)	0	0	0
Nausea	2 (7.4)	0	2 (7.4)	0	0
Abdominal pain upper	1 (3.7)	1 (3.7)	0	0	0
Diarrhoea	1 (3.7)	1 (3.7)	0	0	0
Enterocolitis	1 (3.7)	0	0	1 (3.7)	0
Pigmentation lip	1 (3.7)	1 (3.7)	0	0	0
General disorders and administration site conditions					
-Total	5 (18.5)	4 (14.8)	1 (3.7)	0	0
Pyrexia	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Acquired gene mutation	1 (3.7)	1 (3.7)	0	0	0
Chills	1 (3.7)	1 (3.7)	0	0	0
Influenza like illness	1 (3.7)	1 (3.7)	0	0	0
Pain	1 (3.7)	1 (3.7)	0	0	0
Immune system disorders					
-Total	6 (22.2)	1 (3.7)	4 (14.8)	1 (3.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	4 (14.8)	0	3 (11.1)	1 (3.7)	0
Graft versus host disease	1 (3.7)	1 (3.7)	0	0	0
Immunodeficiency common variable	1 (3.7)	0	1 (3.7)	0	0
Infections and infestations					
-Total	14 (51.9)	3 (11.1)	5 (18.5)	6 (22.2)	0
Upper respiratory tract infection	3 (11.1)	2 (7.4)	0	1 (3.7)	0
Urinary tract infection	2 (7.4)	0	1 (3.7)	1 (3.7)	0
Cellulitis of male external genital organ	1 (3.7)	0	0	1 (3.7)	0
Cholecystitis infective	1 (3.7)	0	0	1 (3.7)	0
Corona virus infection	1 (3.7)	0	0	1 (3.7)	0
Gastroenteritis	1 (3.7)	1 (3.7)	0	0	0
Herpes zoster	1 (3.7)	0	0	1 (3.7)	0
Influenza	1 (3.7)	0	1 (3.7)	0	0
Otitis externa	1 (3.7)	0	1 (3.7)	0	0
Otitis media	1 (3.7)	0	1 (3.7)	0	0
Parainfluenzae virus infection	1 (3.7)	1 (3.7)	0	0	0
Paronychia	1 (3.7)	1 (3.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash pustular	1 (3.7)	0	1 (3.7)	0	0
Respiratory syncytial virus infection	1 (3.7)	0	0	1 (3.7)	0
Vascular device infection	1 (3.7)	0	0	1 (3.7)	0
Vulvovaginal mycotic infection	1 (3.7)	0	1 (3.7)	0	0
Injury, poisoning and procedural complications					
-Total	2 (7.4)	0	2 (7.4)	0	0
Foot fracture	1 (3.7)	0	1 (3.7)	0	0
Radius fracture	1 (3.7)	0	1 (3.7)	0	0
Investigations					
-Total	12 (44.4)	4 (14.8)	2 (7.4)	3 (11.1)	3 (11.1)
Neutrophil count decreased	5 (18.5)	1 (3.7)	0	1 (3.7)	3 (11.1)
Weight decreased	3 (11.1)	0	3 (11.1)	0	0
Alanine aminotransferase increased	2 (7.4)	0	0	2 (7.4)	0
Aspartate aminotransferase increased	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Haemoglobin decreased	2 (7.4)	2 (7.4)	0	0	0
Platelet count decreased	2 (7.4)	2 (7.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Blood urea increased	1 (3.7)	1 (3.7)	0	0	0
Blood uric acid increased	1 (3.7)	1 (3.7)	0	0	0
Lymphocyte count decreased	1 (3.7)	1 (3.7)	0	0	0
Transaminases increased	1 (3.7)	1 (3.7)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (11.1)	2 (7.4)	0	1 (3.7)	0
Hyperalbuminaemia	1 (3.7)	1 (3.7)	0	0	0
Hypercalcaemia	1 (3.7)	1 (3.7)	0	0	0
Tumour lysis syndrome	1 (3.7)	0	0	1 (3.7)	0
Vitamin d deficiency	1 (3.7)	1 (3.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	6 (22.2)	5 (18.5)	1 (3.7)	0	0
Pain in extremity	3 (11.1)	3 (11.1)	0	0	0
Joint range of motion decreased	2 (7.4)	2 (7.4)	0	0	0
Back pain	1 (3.7)	1 (3.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=27		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscle spasms	1 (3.7)	1 (3.7)	0	0	0
Osteonecrosis	1 (3.7)	0	1 (3.7)	0	0
Nervous system disorders					
-Total	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Headache	2 (7.4)	2 (7.4)	0	0	0
Dizziness	1 (3.7)	1 (3.7)	0	0	0
Peroneal nerve palsy	1 (3.7)	0	1 (3.7)	0	0
Reproductive system and breast disorders					
-Total	1 (3.7)	0	1 (3.7)	0	0
Scrotal pain	1 (3.7)	0	1 (3.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (25.9)	4 (14.8)	2 (7.4)	1 (3.7)	0
Cough	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Nasal congestion	2 (7.4)	2 (7.4)	0	0	0
Rhinitis allergic	2 (7.4)	2 (7.4)	0	0	0
Rhinorrhoea	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Oropharyngeal pain	1 (3.7)	1 (3.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=27				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	1 (3.7)	0	0	1 (3.7)	0
Skin and subcutaneous tissue disorders					
-Total	8 (29.6)	6 (22.2)	1 (3.7)	1 (3.7)	0
Dermatitis acneiform	1 (3.7)	0	0	1 (3.7)	0
Dermatitis atopic	1 (3.7)	1 (3.7)	0	0	0
Eczema	1 (3.7)	1 (3.7)	0	0	0
Erythema	1 (3.7)	1 (3.7)	0	0	0
Hyperhidrosis	1 (3.7)	1 (3.7)	0	0	0
Ingrowing nail	1 (3.7)	1 (3.7)	0	0	0
Macule	1 (3.7)	1 (3.7)	0	0	0
Papule	1 (3.7)	1 (3.7)	0	0	0
Rash	1 (3.7)	0	1 (3.7)	0	0
Rash maculo-papular	1 (3.7)	1 (3.7)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174q
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=18		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (72.2)	3 (16.7)	2 (11.1)	5 (27.8)	3 (16.7)
Blood and lymphatic system disorders					
-Total	1 (5.6)	0	0	0	1 (5.6)
Febrile neutropenia	1 (5.6)	0	0	0	1 (5.6)
Gastrointestinal disorders					
-Total	2 (11.1)	0	2 (11.1)	0	0
Abdominal pain	1 (5.6)	0	1 (5.6)	0	0
Diarrhoea	1 (5.6)	0	1 (5.6)	0	0
Nausea	1 (5.6)	0	1 (5.6)	0	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Chills	1 (5.6)	0	1 (5.6)	0	0
Cyst	1 (5.6)	0	0	1 (5.6)	0
Pyrexia	1 (5.6)	0	1 (5.6)	0	0
Immune system disorders					
-Total	2 (11.1)	0	2 (11.1)	0	0
Chronic graft versus host disease	1 (5.6)	0	1 (5.6)	0	0
Immunodeficiency	1 (5.6)	0	1 (5.6)	0	0
Infections and infestations					
-Total	5 (27.8)	0	3 (16.7)	1 (5.6)	1 (5.6)
Campylobacter infection	1 (5.6)	0	0	1 (5.6)	0
Clostridium difficile infection	1 (5.6)	0	0	1 (5.6)	0
Otitis media acute	1 (5.6)	0	1 (5.6)	0	0
Pneumonia	1 (5.6)	0	1 (5.6)	0	0
Respiratory tract infection	1 (5.6)	0	0	0	1 (5.6)
Respiratory tract infection viral	1 (5.6)	0	0	1 (5.6)	0
Sinusitis	1 (5.6)	0	1 (5.6)	0	0
Skin infection	1 (5.6)	0	1 (5.6)	0	0
Urinary tract infection	1 (5.6)	0	1 (5.6)	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal candidiasis	1 (5.6)	0	1 (5.6)	0	0
Injury, poisoning and procedural complications					
-Total	1 (5.6)	0	0	1 (5.6)	0
Procedural pain	1 (5.6)	0	0	1 (5.6)	0
Investigations					
-Total	4 (22.2)	1 (5.6)	0	2 (11.1)	1 (5.6)
Lymphocyte count decreased	2 (11.1)	1 (5.6)	0	1 (5.6)	0
White blood cell count decreased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Alanine aminotransferase increased	1 (5.6)	0	0	1 (5.6)	0
Aspartate aminotransferase increased	1 (5.6)	1 (5.6)	0	0	0
Blood alkaline phosphatase increased	1 (5.6)	1 (5.6)	0	0	0
Blood lactate dehydrogenase increased	1 (5.6)	1 (5.6)	0	0	0
C-reactive protein increased	1 (5.6)	1 (5.6)	0	0	0
Neutrophil count decreased	1 (5.6)	1 (5.6)	0	0	0
Platelet count decreased	1 (5.6)	0	0	1 (5.6)	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=18		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Hypokalaemia	1 (5.6)	0	0	1 (5.6)	0
Vitamin d deficiency	1 (5.6)	1 (5.6)	0	0	0
Nervous system disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Disturbance in attention	1 (5.6)	1 (5.6)	0	0	0
Dizziness	1 (5.6)	1 (5.6)	0	0	0
Headache	1 (5.6)	0	1 (5.6)	0	0
Renal and urinary disorders					
-Total	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Acute kidney injury	1 (5.6)	0	0	1 (5.6)	0
Haematuria	1 (5.6)	1 (5.6)	0	0	0
Reproductive system and breast disorders					
-Total	1 (5.6)	0	0	1 (5.6)	0
Ovarian failure	1 (5.6)	0	0	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders					

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (16.7)	3 (16.7)	0	0	0
Cough	1 (5.6)	1 (5.6)	0	0	0
Epistaxis	1 (5.6)	1 (5.6)	0	0	0
Oropharyngeal pain	1 (5.6)	1 (5.6)	0	0	0
Rhinorrhoea	1 (5.6)	1 (5.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (16.7)	3 (16.7)	0	0	0
Acne	1 (5.6)	1 (5.6)	0	0	0
Papule	1 (5.6)	1 (5.6)	0	0	0
Pruritus	1 (5.6)	1 (5.6)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174q
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=16		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (56.3)	1 (6.3)	4 (25.0)	3 (18.8)	1 (6.3)
Blood and lymphatic system disorders					
-Total	1 (6.3)	1 (6.3)	0	0	0
Thrombocytopenia	1 (6.3)	1 (6.3)	0	0	0
Ear and labyrinth disorders					
-Total	1 (6.3)	0	1 (6.3)	0	0
Tympanic membrane perforation	1 (6.3)	0	1 (6.3)	0	0
Gastrointestinal disorders					
-Total	1 (6.3)	0	1 (6.3)	0	0
Diarrhoea	1 (6.3)	0	1 (6.3)	0	0
Infections and infestations					

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=16		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (37.5)	2 (12.5)	2 (12.5)	2 (12.5)	0
Otitis media	3 (18.8)	0	2 (12.5)	1 (6.3)	0
Sinusitis	2 (12.5)	0	2 (12.5)	0	0
Upper respiratory tract infection	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Cellulitis of male external genital organ	1 (6.3)	0	0	1 (6.3)	0
Gingivitis	1 (6.3)	1 (6.3)	0	0	0
Haemophilus infection	1 (6.3)	0	1 (6.3)	0	0
Meningitis aseptic	1 (6.3)	0	1 (6.3)	0	0
Otitis media acute	1 (6.3)	0	1 (6.3)	0	0
Pneumonia	1 (6.3)	0	1 (6.3)	0	0
Urinary tract infection	1 (6.3)	0	0	1 (6.3)	0
Viral infection	1 (6.3)	1 (6.3)	0	0	0
Investigations					
-Total	4 (25.0)	0	2 (12.5)	2 (12.5)	0
Alanine aminotransferase increased	2 (12.5)	0	1 (6.3)	1 (6.3)	0
White blood cell count decreased	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Aspartate aminotransferase increased	1 (6.3)	0	0	1 (6.3)	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=16		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (6.3)	1 (6.3)	0	0	0
Neutrophil count decreased	1 (6.3)	0	1 (6.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (6.3)	0	1 (6.3)	0	0
Neck pain	1 (6.3)	0	1 (6.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (6.3)	0	0	0	1 (6.3)
Glioblastoma multiforme	1 (6.3)	0	0	0	1 (6.3)
Nervous system disorders					
-Total	1 (6.3)	0	0	1 (6.3)	0
Seizure	1 (6.3)	0	0	1 (6.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (6.3)	1 (6.3)	0	0	0
Cough	1 (6.3)	1 (6.3)	0	0	0
Rhinitis allergic	1 (6.3)	1 (6.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174q
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	1 (3.1)	6 (18.8)	25 (78.1)
Blood and lymphatic system disorders					
-Total	22 (68.8)	0	1 (3.1)	15 (46.9)	6 (18.8)
Febrile neutropenia	12 (37.5)	0	0	11 (34.4)	1 (3.1)
Anaemia	11 (34.4)	1 (3.1)	0	10 (31.3)	0
Neutropenia	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Disseminated intravascular coagulation	2 (6.3)	0	0	2 (6.3)	0
Thrombocytopenia	2 (6.3)	0	1 (3.1)	0	1 (3.1)
Lymphadenopathy	1 (3.1)	0	1 (3.1)	0	0
Lymphopenia	1 (3.1)	0	0	0	1 (3.1)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	1 (3.1)	0	0	0	1 (3.1)
Cardiac disorders					
-Total	8 (25.0)	6 (18.8)	2 (6.3)	0	0
Tachycardia	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Sinus tachycardia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Atrioventricular block second degree	1 (3.1)	1 (3.1)	0	0	0
Cardiac dysfunction	1 (3.1)	1 (3.1)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.1)	1 (3.1)	0	0	0
Ear pain	1 (3.1)	1 (3.1)	0	0	0
Endocrine disorders					
-Total	1 (3.1)	1 (3.1)	0	0	0
Adrenal insufficiency	1 (3.1)	1 (3.1)	0	0	0
Eye disorders					
-Total	10 (31.3)	7 (21.9)	3 (9.4)	0	0
Vision blurred	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Dry eye	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Eye pain	2 (6.3)	1 (3.1)	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Photophobia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Conjunctivitis allergic	1 (3.1)	1 (3.1)	0	0	0
Ocular hyperaemia	1 (3.1)	1 (3.1)	0	0	0
Retinal haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Uveitis	1 (3.1)	0	1 (3.1)	0	0
Gastrointestinal disorders					
-Total	21 (65.6)	7 (21.9)	7 (21.9)	7 (21.9)	0
Vomiting	14 (43.8)	8 (25.0)	3 (9.4)	3 (9.4)	0
Nausea	13 (40.6)	2 (6.3)	8 (25.0)	3 (9.4)	0
Diarrhoea	12 (37.5)	6 (18.8)	4 (12.5)	2 (6.3)	0
Abdominal pain	8 (25.0)	4 (12.5)	3 (9.4)	1 (3.1)	0
Constipation	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Oral pain	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Abdominal distension	1 (3.1)	0	1 (3.1)	0	0
Abdominal pain upper	1 (3.1)	0	1 (3.1)	0	0
Abdominal tenderness	1 (3.1)	1 (3.1)	0	0	0
Dyspepsia	1 (3.1)	0	1 (3.1)	0	0
Glossodynia	1 (3.1)	1 (3.1)	0	0	0
Ileus	1 (3.1)	0	0	1 (3.1)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Intestinal obstruction	1 (3.1)	0	0	1 (3.1)	0
Pancreatitis	1 (3.1)	0	1 (3.1)	0	0
General disorders and administration site conditions					
-Total	20 (62.5)	5 (15.6)	8 (25.0)	7 (21.9)	0
Pyrexia	15 (46.9)	4 (12.5)	6 (18.8)	5 (15.6)	0
Fatigue	5 (15.6)	5 (15.6)	0	0	0
Catheter site pain	3 (9.4)	0	3 (9.4)	0	0
Malaise	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Generalised oedema	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Oedema peripheral	2 (6.3)	2 (6.3)	0	0	0
Catheter site haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Chills	1 (3.1)	0	1 (3.1)	0	0
Crying	1 (3.1)	1 (3.1)	0	0	0
Cyst	1 (3.1)	0	0	1 (3.1)	0
Influenza like illness	1 (3.1)	1 (3.1)	0	0	0
Injection site haematoma	1 (3.1)	1 (3.1)	0	0	0
Pain	1 (3.1)	0	0	1 (3.1)	0
Hepatobiliary disorders					

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.1)	0	1 (3.1)	0	0
Hyperbilirubinaemia	1 (3.1)	0	1 (3.1)	0	0
Immune system disorders					
-Total	29 (90.6)	1 (3.1)	18 (56.3)	5 (15.6)	5 (15.6)
Cytokine release syndrome	25 (78.1)	3 (9.4)	15 (46.9)	2 (6.3)	5 (15.6)
Hypogammaglobulinaemia	19 (59.4)	1 (3.1)	15 (46.9)	3 (9.4)	0
Seasonal allergy	2 (6.3)	2 (6.3)	0	0	0
Chronic graft versus host disease	1 (3.1)	0	1 (3.1)	0	0
Graft versus host disease	1 (3.1)	0	1 (3.1)	0	0
Graft versus host disease in gastrointestinal tract	1 (3.1)	0	1 (3.1)	0	0
Haemophagocytic lymphohistiocytosis	1 (3.1)	0	1 (3.1)	0	0
Immunodeficiency	1 (3.1)	0	1 (3.1)	0	0
Immunodeficiency common variable	1 (3.1)	0	1 (3.1)	0	0
Infections and infestations					
-Total	24 (75.0)	3 (9.4)	11 (34.4)	6 (18.8)	4 (12.5)
Clostridium difficile infection	5 (15.6)	0	4 (12.5)	1 (3.1)	0
Rhinovirus infection	4 (12.5)	4 (12.5)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	4 (12.5)	1 (3.1)	3 (9.4)	0	0
Gastroenteritis	3 (9.4)	0	3 (9.4)	0	0
Influenza	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Urinary tract infection	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Cytomegalovirus infection	2 (6.3)	2 (6.3)	0	0	0
Ear infection	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Sinusitis	2 (6.3)	0	2 (6.3)	0	0
Skin infection	2 (6.3)	0	2 (6.3)	0	0
Viral upper respiratory tract infection	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Vulvovaginal candidiasis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Bacterial sepsis	1 (3.1)	0	0	0	1 (3.1)
Campylobacter infection	1 (3.1)	0	0	1 (3.1)	0
Catheter site cellulitis	1 (3.1)	1 (3.1)	0	0	0
Catheter site infection	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile colitis	1 (3.1)	0	0	1 (3.1)	0
Enterococcal infection	1 (3.1)	1 (3.1)	0	0	0
Enterovirus infection	1 (3.1)	0	0	1 (3.1)	0
Escherichia urinary tract infection	1 (3.1)	0	0	1 (3.1)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Folliculitis	1 (3.1)	0	1 (3.1)	0	0
Fungal skin infection	1 (3.1)	1 (3.1)	0	0	0
Gastroenteritis norovirus	1 (3.1)	0	1 (3.1)	0	0
Gastroenteritis viral	1 (3.1)	1 (3.1)	0	0	0
Molluscum contagiosum	1 (3.1)	1 (3.1)	0	0	0
Oral candidiasis	1 (3.1)	1 (3.1)	0	0	0
Oral herpes	1 (3.1)	0	1 (3.1)	0	0
Orchitis	1 (3.1)	1 (3.1)	0	0	0
Otitis media acute	1 (3.1)	0	1 (3.1)	0	0
Parainfluenzae virus infection	1 (3.1)	0	0	1 (3.1)	0
Pneumonia	1 (3.1)	0	1 (3.1)	0	0
Respiratory tract infection	1 (3.1)	0	0	0	1 (3.1)
Respiratory tract infection viral	1 (3.1)	0	0	1 (3.1)	0
Rhinitis	1 (3.1)	1 (3.1)	0	0	0
Rotavirus infection	1 (3.1)	0	0	1 (3.1)	0
Sepsis	1 (3.1)	0	0	0	1 (3.1)
Septic embolus	1 (3.1)	0	0	0	1 (3.1)
Staphylococcal infection	1 (3.1)	0	0	1 (3.1)	0
Subcutaneous abscess	1 (3.1)	0	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tinea capitis	1 (3.1)	1 (3.1)	0	0	0
Urinary tract infection enterococcal	1 (3.1)	0	0	1 (3.1)	0
Viral infection	1 (3.1)	1 (3.1)	0	0	0
Injury, poisoning and procedural complications					
-Total	10 (31.3)	5 (15.6)	3 (9.4)	1 (3.1)	1 (3.1)
Infusion related reaction	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Procedural pain	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Contusion	2 (6.3)	2 (6.3)	0	0	0
Transfusion reaction	2 (6.3)	2 (6.3)	0	0	0
Arthropod bite	1 (3.1)	1 (3.1)	0	0	0
Procedural nausea	1 (3.1)	0	1 (3.1)	0	0
Procedural site reaction	1 (3.1)	1 (3.1)	0	0	0
Skin abrasion	1 (3.1)	1 (3.1)	0	0	0
Skin laceration	1 (3.1)	0	1 (3.1)	0	0
Subdural haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Sunburn	1 (3.1)	1 (3.1)	0	0	0
Transfusion related complication	1 (3.1)	0	0	0	1 (3.1)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	30 (93.8)	0	2 (6.3)	8 (25.0)	20 (62.5)
White blood cell count decreased	21 (65.6)	1 (3.1)	0	8 (25.0)	12 (37.5)
Neutrophil count decreased	15 (46.9)	1 (3.1)	0	3 (9.4)	11 (34.4)
Platelet count decreased	11 (34.4)	1 (3.1)	0	2 (6.3)	8 (25.0)
Alanine aminotransferase increased	8 (25.0)	3 (9.4)	0	5 (15.6)	0
Aspartate aminotransferase increased	8 (25.0)	3 (9.4)	0	4 (12.5)	1 (3.1)
Lymphocyte count decreased	8 (25.0)	0	1 (3.1)	4 (12.5)	3 (9.4)
Blood bilirubin increased	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0
Blood creatinine increased	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Prothrombin time prolonged	3 (9.4)	3 (9.4)	0	0	0
Activated partial thromboplastin time prolonged	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Blood immunoglobulin a decreased	2 (6.3)	2 (6.3)	0	0	0
Blood immunoglobulin m decreased	2 (6.3)	2 (6.3)	0	0	0
C-reactive protein increased	2 (6.3)	1 (3.1)	0	1 (3.1)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	2 (6.3)	0	2 (6.3)	0	0
Weight increased	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Blood alkaline phosphatase increased	1 (3.1)	1 (3.1)	0	0	0
Blood lactate dehydrogenase increased	1 (3.1)	1 (3.1)	0	0	0
Blood lactic acid increased	1 (3.1)	0	0	0	1 (3.1)
Blood magnesium decreased	1 (3.1)	1 (3.1)	0	0	0
Cardiac murmur	1 (3.1)	1 (3.1)	0	0	0
Haemoglobin decreased	1 (3.1)	0	0	1 (3.1)	0
Hepatic enzyme increased	1 (3.1)	0	1 (3.1)	0	0
Lipase increased	1 (3.1)	0	0	0	1 (3.1)
Oxygen saturation decreased	1 (3.1)	1 (3.1)	0	0	0
Pulmonary function test decreased	1 (3.1)	0	1 (3.1)	0	0
Weight decreased	1 (3.1)	1 (3.1)	0	0	0
Metabolism and nutrition disorders					
-Total	20 (62.5)	4 (12.5)	4 (12.5)	9 (28.1)	3 (9.4)
Hypokalaemia	10 (31.3)	2 (6.3)	2 (6.3)	5 (15.6)	1 (3.1)
Decreased appetite	9 (28.1)	2 (6.3)	4 (12.5)	3 (9.4)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	5 (15.6)	1 (3.1)	0	4 (12.5)	0
Dehydration	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Hyperphosphataemia	3 (9.4)	3 (9.4)	0	0	0
Hyperglycaemia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Hyperuricaemia	2 (6.3)	1 (3.1)	0	0	1 (3.1)
Hypocalcaemia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Fluid overload	1 (3.1)	1 (3.1)	0	0	0
Hypernatraemia	1 (3.1)	0	0	0	1 (3.1)
Hypertriglyceridaemia	1 (3.1)	0	0	1 (3.1)	0
Hyponatraemia	1 (3.1)	0	0	1 (3.1)	0
Iron overload	1 (3.1)	0	0	1 (3.1)	0
Vitamin d deficiency	1 (3.1)	1 (3.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	12 (37.5)	5 (15.6)	6 (18.8)	1 (3.1)	0
Pain in extremity	7 (21.9)	3 (9.4)	4 (12.5)	0	0
Arthralgia	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Muscular weakness	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Coccydynia	1 (3.1)	1 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flank pain	1 (3.1)	0	1 (3.1)	0	0
Musculoskeletal chest pain	1 (3.1)	1 (3.1)	0	0	0
Pain in jaw	1 (3.1)	1 (3.1)	0	0	0
Toe walking	1 (3.1)	1 (3.1)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (6.3)	0	2 (6.3)	0	0
Myelodysplastic syndrome	1 (3.1)	0	1 (3.1)	0	0
Skin papilloma	1 (3.1)	0	1 (3.1)	0	0
Nervous system disorders					
-Total	17 (53.1)	8 (25.0)	5 (15.6)	3 (9.4)	1 (3.1)
Headache	13 (40.6)	8 (25.0)	4 (12.5)	1 (3.1)	0
Dizziness	2 (6.3)	2 (6.3)	0	0	0
Disturbance in attention	1 (3.1)	1 (3.1)	0	0	0
Dysarthria	1 (3.1)	0	1 (3.1)	0	0
Embolic stroke	1 (3.1)	0	0	0	1 (3.1)
Encephalopathy	1 (3.1)	0	0	1 (3.1)	0
Migraine	1 (3.1)	0	1 (3.1)	0	0
Peroneal nerve palsy	1 (3.1)	1 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (3.1)	0	0	1 (3.1)	0
Somnolence	1 (3.1)	1 (3.1)	0	0	0
Tremor	1 (3.1)	1 (3.1)	0	0	0
Product issues					
-Total	1 (3.1)	1 (3.1)	0	0	0
Device occlusion	1 (3.1)	1 (3.1)	0	0	0
Psychiatric disorders					
-Total	8 (25.0)	4 (12.5)	4 (12.5)	0	0
Anxiety	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Confusional state	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Depression	2 (6.3)	2 (6.3)	0	0	0
Delirium	1 (3.1)	1 (3.1)	0	0	0
Hallucination	1 (3.1)	1 (3.1)	0	0	0
Mental status changes	1 (3.1)	1 (3.1)	0	0	0
Panic attack	1 (3.1)	0	1 (3.1)	0	0
Sleep disorder	1 (3.1)	0	1 (3.1)	0	0
Renal and urinary disorders					
-Total	6 (18.8)	2 (6.3)	1 (3.1)	3 (9.4)	0
Acute kidney injury	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Calculus urinary	1 (3.1)	0	1 (3.1)	0	0
Haematuria	1 (3.1)	0	0	1 (3.1)	0
Nephrolithiasis	1 (3.1)	0	0	1 (3.1)	0
Urinary incontinence	1 (3.1)	1 (3.1)	0	0	0
Reproductive system and breast disorders					
-Total	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Ovarian failure	1 (3.1)	0	0	1 (3.1)	0
Vaginal haemorrhage	1 (3.1)	0	0	1 (3.1)	0
Vulvovaginal adhesion	1 (3.1)	1 (3.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	19 (59.4)	9 (28.1)	5 (15.6)	4 (12.5)	1 (3.1)
Cough	7 (21.9)	6 (18.8)	1 (3.1)	0	0
Epistaxis	6 (18.8)	3 (9.4)	0	3 (9.4)	0
Hypoxia	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Nasal congestion	3 (9.4)	3 (9.4)	0	0	0
Oropharyngeal pain	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Rhinorrhoea	3 (9.4)	3 (9.4)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Acute respiratory failure	1 (3.1)	0	0	0	1 (3.1)
Dysphonia	1 (3.1)	1 (3.1)	0	0	0
Oropharyngeal plaque	1 (3.1)	1 (3.1)	0	0	0
Pharyngeal erythema	1 (3.1)	1 (3.1)	0	0	0
Pharyngeal lesion	1 (3.1)	0	0	1 (3.1)	0
Pharyngeal ulceration	1 (3.1)	0	1 (3.1)	0	0
Pleural effusion	1 (3.1)	0	1 (3.1)	0	0
Pulmonary oedema	1 (3.1)	1 (3.1)	0	0	0
Respiratory depression	1 (3.1)	0	1 (3.1)	0	0
Rhinitis allergic	1 (3.1)	0	1 (3.1)	0	0
Wheezing	1 (3.1)	0	1 (3.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	14 (43.8)	9 (28.1)	5 (15.6)	0	0
Dry skin	4 (12.5)	4 (12.5)	0	0	0
Pruritus	4 (12.5)	4 (12.5)	0	0	0
Rash	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Erythema	3 (9.4)	3 (9.4)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acne	1 (3.1)	1 (3.1)	0	0	0
Alopecia	1 (3.1)	0	1 (3.1)	0	0
Dermatitis	1 (3.1)	1 (3.1)	0	0	0
Hyperhidrosis	1 (3.1)	1 (3.1)	0	0	0
Ingrowing nail	1 (3.1)	0	1 (3.1)	0	0
Keloid scar	1 (3.1)	0	1 (3.1)	0	0
Livedo reticularis	1 (3.1)	1 (3.1)	0	0	0
Papule	1 (3.1)	1 (3.1)	0	0	0
Petechiae	1 (3.1)	1 (3.1)	0	0	0
Rash erythematous	1 (3.1)	0	1 (3.1)	0	0
Rash follicular	1 (3.1)	1 (3.1)	0	0	0
Rash maculo-papular	1 (3.1)	1 (3.1)	0	0	0
Rash papular	1 (3.1)	1 (3.1)	0	0	0
Rash pruritic	1 (3.1)	1 (3.1)	0	0	0
Rash vesicular	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	10 (31.3)	2 (6.3)	3 (9.4)	4 (12.5)	1 (3.1)
Hypertension	6 (18.8)	3 (9.4)	3 (9.4)	0	0
Hypotension	5 (15.6)	1 (3.1)	0	3 (9.4)	1 (3.1)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Embolism	1 (3.1)	0	0	1 (3.1)	0
Flushing	1 (3.1)	1 (3.1)	0	0	0
Hot flush	1 (3.1)	1 (3.1)	0	0	0
Orthostatic hypotension	1 (3.1)	0	1 (3.1)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174q
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	4 (12.5)	6 (18.8)	22 (68.8)
Blood and lymphatic system disorders					
-Total	26 (81.3)	2 (6.3)	2 (6.3)	12 (37.5)	10 (31.3)
Anaemia	16 (50.0)	2 (6.3)	4 (12.5)	9 (28.1)	1 (3.1)
Febrile neutropenia	12 (37.5)	0	0	12 (37.5)	0
Neutropenia	8 (25.0)	0	0	2 (6.3)	6 (18.8)
Thrombocytopenia	8 (25.0)	0	0	3 (9.4)	5 (15.6)
Lymphopenia	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Disseminated intravascular coagulation	2 (6.3)	0	2 (6.3)	0	0
Coagulopathy	1 (3.1)	1 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eosinophilia	1 (3.1)	0	0	1 (3.1)	0
Leukopenia	1 (3.1)	0	0	0	1 (3.1)
Cardiac disorders					
-Total	15 (46.9)	5 (15.6)	8 (25.0)	2 (6.3)	0
Tachycardia	10 (31.3)	4 (12.5)	4 (12.5)	2 (6.3)	0
Sinus tachycardia	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Pericardial effusion	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Bradycardia	1 (3.1)	0	1 (3.1)	0	0
Left ventricular dysfunction	1 (3.1)	0	0	1 (3.1)	0
Palpitations	1 (3.1)	1 (3.1)	0	0	0
Sinus bradycardia	1 (3.1)	1 (3.1)	0	0	0
Ventricular tachycardia	1 (3.1)	0	1 (3.1)	0	0
Ear and labyrinth disorders					
-Total	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Ear pain	1 (3.1)	1 (3.1)	0	0	0
Hypoacusis	1 (3.1)	0	1 (3.1)	0	0
Tympanic membrane perforation	1 (3.1)	0	1 (3.1)	0	0
Endocrine disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	1 (3.1)	0	1 (3.1)	0	0
Eye disorders					
-Total	8 (25.0)	3 (9.4)	5 (15.6)	0	0
Periorbital oedema	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Conjunctival haemorrhage	3 (9.4)	3 (9.4)	0	0	0
Eye pain	1 (3.1)	0	1 (3.1)	0	0
Ocular hypertension	1 (3.1)	0	1 (3.1)	0	0
Papilloedema	1 (3.1)	0	1 (3.1)	0	0
Retinal haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Uveitis	1 (3.1)	0	1 (3.1)	0	0
Vision blurred	1 (3.1)	0	1 (3.1)	0	0
Visual impairment	1 (3.1)	0	1 (3.1)	0	0
Gastrointestinal disorders					
-Total	22 (68.8)	6 (18.8)	10 (31.3)	6 (18.8)	0
Vomiting	13 (40.6)	8 (25.0)	5 (15.6)	0	0
Diarrhoea	12 (37.5)	7 (21.9)	5 (15.6)	0	0
Nausea	12 (37.5)	4 (12.5)	6 (18.8)	2 (6.3)	0
Abdominal pain	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Abdominal pain upper	2 (6.3)	1 (3.1)	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	2 (6.3)	2 (6.3)	0	0	0
Dysphagia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Haematemesis	2 (6.3)	2 (6.3)	0	0	0
Stomatitis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Abdominal discomfort	1 (3.1)	1 (3.1)	0	0	0
Abdominal distension	1 (3.1)	0	1 (3.1)	0	0
Abdominal pain lower	1 (3.1)	0	1 (3.1)	0	0
Anal incontinence	1 (3.1)	1 (3.1)	0	0	0
Ascites	1 (3.1)	0	0	1 (3.1)	0
Enterocolitis	1 (3.1)	0	0	1 (3.1)	0
Flatulence	1 (3.1)	1 (3.1)	0	0	0
Gastrointestinal haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Gastrooesophageal reflux disease	1 (3.1)	1 (3.1)	0	0	0
Lip pain	1 (3.1)	0	1 (3.1)	0	0
Mouth haemorrhage	1 (3.1)	0	0	1 (3.1)	0
Pancreatitis	1 (3.1)	0	0	1 (3.1)	0
Pigmentation lip	1 (3.1)	1 (3.1)	0	0	0
Tooth socket haemorrhage	1 (3.1)	1 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	22 (68.8)	11 (34.4)	6 (18.8)	4 (12.5)	1 (3.1)
Fatigue	10 (31.3)	7 (21.9)	2 (6.3)	1 (3.1)	0
Pyrexia	10 (31.3)	4 (12.5)	4 (12.5)	1 (3.1)	1 (3.1)
Chills	9 (28.1)	9 (28.1)	0	0	0
Pain	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Face oedema	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Acquired gene mutation	1 (3.1)	1 (3.1)	0	0	0
Asthenia	1 (3.1)	1 (3.1)	0	0	0
Catheter site extravasation	1 (3.1)	0	1 (3.1)	0	0
Catheter site pain	1 (3.1)	1 (3.1)	0	0	0
Facial pain	1 (3.1)	0	1 (3.1)	0	0
Generalised oedema	1 (3.1)	0	1 (3.1)	0	0
Influenza like illness	1 (3.1)	1 (3.1)	0	0	0
Localised oedema	1 (3.1)	0	0	1 (3.1)	0
Malaise	1 (3.1)	0	1 (3.1)	0	0
Mucosal haemorrhage	1 (3.1)	0	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	1 (3.1)	0	0	1 (3.1)	0
Non-cardiac chest pain	1 (3.1)	1 (3.1)	0	0	0
Oedema peripheral	1 (3.1)	0	0	1 (3.1)	0
Peripheral swelling	1 (3.1)	0	1 (3.1)	0	0
Physical deconditioning	1 (3.1)	0	0	1 (3.1)	0
Hepatobiliary disorders					
-Total	6 (18.8)	3 (9.4)	1 (3.1)	2 (6.3)	0
Hepatomegaly	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Hyperbilirubinaemia	2 (6.3)	0	0	2 (6.3)	0
Gallbladder enlargement	1 (3.1)	1 (3.1)	0	0	0
Hepatosplenomegaly	1 (3.1)	1 (3.1)	0	0	0
Immune system disorders					
-Total	29 (90.6)	4 (12.5)	13 (40.6)	6 (18.8)	6 (18.8)
Cytokine release syndrome	25 (78.1)	3 (9.4)	10 (31.3)	6 (18.8)	6 (18.8)
Hypogammaglobulinaemia	13 (40.6)	2 (6.3)	9 (28.1)	2 (6.3)	0
Drug hypersensitivity	1 (3.1)	0	1 (3.1)	0	0
Graft versus host disease	1 (3.1)	1 (3.1)	0	0	0
Graft versus host disease in skin	1 (3.1)	1 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immunodeficiency common variable	1 (3.1)	0	1 (3.1)	0	0
Infections and infestations					
-Total	22 (68.8)	4 (12.5)	10 (31.3)	8 (25.0)	0
Upper respiratory tract infection	5 (15.6)	3 (9.4)	1 (3.1)	1 (3.1)	0
Otitis media	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Clostridium difficile colitis	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Pneumonia	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Gastroenteritis	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Sinusitis	2 (6.3)	0	2 (6.3)	0	0
Urinary tract infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Viral infection	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Acute sinusitis	1 (3.1)	0	1 (3.1)	0	0
Body tinea	1 (3.1)	1 (3.1)	0	0	0
Cellulitis of male external genital organ	1 (3.1)	0	0	1 (3.1)	0
Cholecystitis infective	1 (3.1)	0	0	1 (3.1)	0
Corona virus infection	1 (3.1)	0	0	1 (3.1)	0
Gingivitis	1 (3.1)	1 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophilus infection	1 (3.1)	0	1 (3.1)	0	0
Herpes simplex	1 (3.1)	1 (3.1)	0	0	0
Herpes zoster	1 (3.1)	0	0	1 (3.1)	0
Human herpesvirus 6 infection	1 (3.1)	0	1 (3.1)	0	0
Hypopyon	1 (3.1)	0	1 (3.1)	0	0
Influenza	1 (3.1)	0	1 (3.1)	0	0
Meningitis aseptic	1 (3.1)	0	1 (3.1)	0	0
Otitis externa	1 (3.1)	0	1 (3.1)	0	0
Otitis media acute	1 (3.1)	0	1 (3.1)	0	0
Parainfluenzae virus infection	1 (3.1)	1 (3.1)	0	0	0
Paronychia	1 (3.1)	1 (3.1)	0	0	0
Pharyngitis	1 (3.1)	0	1 (3.1)	0	0
Rash pustular	1 (3.1)	0	1 (3.1)	0	0
Respiratory syncytial virus infection	1 (3.1)	0	0	1 (3.1)	0
Rhinovirus infection	1 (3.1)	1 (3.1)	0	0	0
Staphylococcal infection	1 (3.1)	1 (3.1)	0	0	0
Streptococcal infection	1 (3.1)	0	1 (3.1)	0	0
Vascular device infection	1 (3.1)	0	0	1 (3.1)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (3.1)	0	1 (3.1)	0	0
Vulvovaginal mycotic infection	1 (3.1)	0	1 (3.1)	0	0
Injury, poisoning and procedural complications					
-Total	12 (37.5)	6 (18.8)	5 (15.6)	1 (3.1)	0
Procedural pain	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Contusion	1 (3.1)	1 (3.1)	0	0	0
Foot fracture	1 (3.1)	0	1 (3.1)	0	0
Incision site pain	1 (3.1)	1 (3.1)	0	0	0
Infusion related reaction	1 (3.1)	0	1 (3.1)	0	0
Limb injury	1 (3.1)	1 (3.1)	0	0	0
Mouth injury	1 (3.1)	1 (3.1)	0	0	0
Post procedural haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Procedural complication	1 (3.1)	1 (3.1)	0	0	0
Procedural headache	1 (3.1)	0	1 (3.1)	0	0
Radius fracture	1 (3.1)	0	1 (3.1)	0	0
Skin abrasion	1 (3.1)	1 (3.1)	0	0	0
Stoma site irritation	1 (3.1)	1 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tibia fracture	1 (3.1)	0	1 (3.1)	0	0
Tongue injury	1 (3.1)	1 (3.1)	0	0	0
Tracheal haemorrhage	1 (3.1)	0	0	1 (3.1)	0
Transfusion reaction	1 (3.1)	0	1 (3.1)	0	0
Investigations					
-Total	26 (81.3)	2 (6.3)	3 (9.4)	7 (21.9)	14 (43.8)
White blood cell count decreased	14 (43.8)	3 (9.4)	1 (3.1)	4 (12.5)	6 (18.8)
Alanine aminotransferase increased	13 (40.6)	2 (6.3)	2 (6.3)	9 (28.1)	0
Neutrophil count decreased	13 (40.6)	0	2 (6.3)	1 (3.1)	10 (31.3)
Aspartate aminotransferase increased	12 (37.5)	1 (3.1)	4 (12.5)	4 (12.5)	3 (9.4)
International normalised ratio increased	9 (28.1)	8 (25.0)	0	1 (3.1)	0
Platelet count decreased	9 (28.1)	2 (6.3)	2 (6.3)	1 (3.1)	4 (12.5)
Lymphocyte count decreased	8 (25.0)	1 (3.1)	2 (6.3)	3 (9.4)	2 (6.3)
Blood creatinine increased	6 (18.8)	3 (9.4)	1 (3.1)	2 (6.3)	0
Prothrombin time prolonged	6 (18.8)	2 (6.3)	3 (9.4)	1 (3.1)	0
Blood bilirubin increased	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Blood fibrinogen decreased	4 (12.5)	0	1 (3.1)	2 (6.3)	1 (3.1)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Blood urea increased	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Transaminases increased	3 (9.4)	3 (9.4)	0	0	0
Weight decreased	3 (9.4)	0	3 (9.4)	0	0
Blood immunoglobulin m decreased	2 (6.3)	2 (6.3)	0	0	0
Blood phosphorus increased	2 (6.3)	2 (6.3)	0	0	0
Blood uric acid increased	2 (6.3)	2 (6.3)	0	0	0
Haemoglobin decreased	2 (6.3)	2 (6.3)	0	0	0
Blood bicarbonate decreased	1 (3.1)	0	1 (3.1)	0	0
Blood immunoglobulin a decreased	1 (3.1)	1 (3.1)	0	0	0
Blood immunoglobulin g decreased	1 (3.1)	0	1 (3.1)	0	0
Blood magnesium decreased	1 (3.1)	0	0	1 (3.1)	0
Blood phosphorus decreased	1 (3.1)	1 (3.1)	0	0	0
Blood sodium increased	1 (3.1)	0	1 (3.1)	0	0
Culture stool positive	1 (3.1)	1 (3.1)	0	0	0
Fibrin d dimer increased	1 (3.1)	1 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lipase increased	1 (3.1)	0	0	0	1 (3.1)
Norovirus test positive	1 (3.1)	1 (3.1)	0	0	0
Protein total decreased	1 (3.1)	0	0	1 (3.1)	0
Metabolism and nutrition disorders					
-Total	23 (71.9)	4 (12.5)	4 (12.5)	14 (43.8)	1 (3.1)
Decreased appetite	13 (40.6)	3 (9.4)	1 (3.1)	9 (28.1)	0
Hypokalaemia	9 (28.1)	2 (6.3)	4 (12.5)	3 (9.4)	0
Hyperphosphataemia	5 (15.6)	5 (15.6)	0	0	0
Hypoalbuminaemia	5 (15.6)	1 (3.1)	3 (9.4)	1 (3.1)	0
Hypophosphataemia	5 (15.6)	1 (3.1)	0	3 (9.4)	1 (3.1)
Hypernatraemia	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Acidosis	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Fluid overload	2 (6.3)	0	2 (6.3)	0	0
Tumour lysis syndrome	2 (6.3)	0	0	2 (6.3)	0
Dehydration	1 (3.1)	0	0	1 (3.1)	0
Hyperalbuminaemia	1 (3.1)	1 (3.1)	0	0	0
Hypercalcaemia	1 (3.1)	1 (3.1)	0	0	0
Hyperchloraemia	1 (3.1)	1 (3.1)	0	0	0
Hyperglycaemia	1 (3.1)	0	0	1 (3.1)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypermagnesaemia	1 (3.1)	1 (3.1)	0	0	0
Hypertriglyceridaemia	1 (3.1)	1 (3.1)	0	0	0
Hyperuricaemia	1 (3.1)	1 (3.1)	0	0	0
Hypocalcaemia	1 (3.1)	0	0	1 (3.1)	0
Hypomagnesaemia	1 (3.1)	1 (3.1)	0	0	0
Hyponatraemia	1 (3.1)	0	0	1 (3.1)	0
Malnutrition	1 (3.1)	0	0	1 (3.1)	0
Metabolic acidosis	1 (3.1)	0	1 (3.1)	0	0
Metabolic alkalosis	1 (3.1)	1 (3.1)	0	0	0
Vitamin d deficiency	1 (3.1)	1 (3.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	13 (40.6)	9 (28.1)	4 (12.5)	0	0
Myalgia	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Pain in extremity	4 (12.5)	4 (12.5)	0	0	0
Musculoskeletal pain	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Arthralgia	2 (6.3)	2 (6.3)	0	0	0
Joint range of motion decreased	2 (6.3)	2 (6.3)	0	0	0
Muscle spasms	2 (6.3)	2 (6.3)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	1 (3.1)	1 (3.1)	0	0	0
Limb discomfort	1 (3.1)	1 (3.1)	0	0	0
Musculoskeletal chest pain	1 (3.1)	1 (3.1)	0	0	0
Neck pain	1 (3.1)	0	1 (3.1)	0	0
Osteonecrosis	1 (3.1)	0	1 (3.1)	0	0
Osteopenia	1 (3.1)	0	1 (3.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (3.1)	0	0	0	1 (3.1)
Glioblastoma multiforme	1 (3.1)	0	0	0	1 (3.1)
Nervous system disorders					
-Total	18 (56.3)	9 (28.1)	7 (21.9)	2 (6.3)	0
Headache	11 (34.4)	7 (21.9)	3 (9.4)	1 (3.1)	0
Dizziness	4 (12.5)	4 (12.5)	0	0	0
Encephalopathy	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Seizure	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Asterixis	1 (3.1)	1 (3.1)	0	0	0
Ataxia	1 (3.1)	0	1 (3.1)	0	0
Depressed level of consciousness	1 (3.1)	1 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysarthria	1 (3.1)	1 (3.1)	0	0	0
Idiopathic intracranial hypertension	1 (3.1)	0	1 (3.1)	0	0
Myoclonus	1 (3.1)	1 (3.1)	0	0	0
Neuropathy peripheral	1 (3.1)	0	1 (3.1)	0	0
Peroneal nerve palsy	1 (3.1)	0	1 (3.1)	0	0
Pleocytosis	1 (3.1)	1 (3.1)	0	0	0
Tremor	1 (3.1)	1 (3.1)	0	0	0
Psychiatric disorders					
-Total	9 (28.1)	4 (12.5)	4 (12.5)	1 (3.1)	0
Anxiety	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Confusional state	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Delirium	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Agitation	2 (6.3)	0	2 (6.3)	0	0
Irritability	2 (6.3)	2 (6.3)	0	0	0
Adjustment disorder	1 (3.1)	0	1 (3.1)	0	0
Hallucination	1 (3.1)	0	1 (3.1)	0	0
Insomnia	1 (3.1)	0	1 (3.1)	0	0
Listless	1 (3.1)	1 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Suicidal ideation	1 (3.1)	1 (3.1)	0	0	0
Renal and urinary disorders					
-Total	9 (28.1)	1 (3.1)	1 (3.1)	3 (9.4)	4 (12.5)
Acute kidney injury	5 (15.6)	0	0	2 (6.3)	3 (9.4)
Haematuria	4 (12.5)	0	2 (6.3)	1 (3.1)	1 (3.1)
Dysuria	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Oliguria	2 (6.3)	0	0	2 (6.3)	0
Pollakiuria	1 (3.1)	1 (3.1)	0	0	0
Renal failure	1 (3.1)	0	0	0	1 (3.1)
Renal impairment	1 (3.1)	0	0	1 (3.1)	0
Reproductive system and breast disorders					
-Total	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Oedema genital	1 (3.1)	0	1 (3.1)	0	0
Scrotal pain	1 (3.1)	0	1 (3.1)	0	0
Vulvovaginal adhesion	1 (3.1)	1 (3.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	19 (59.4)	5 (15.6)	4 (12.5)	3 (9.4)	7 (21.9)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	7 (21.9)	6 (18.8)	1 (3.1)	0	0
Pleural effusion	7 (21.9)	2 (6.3)	3 (9.4)	2 (6.3)	0
Hypoxia	6 (18.8)	0	1 (3.1)	2 (6.3)	3 (9.4)
Pulmonary oedema	6 (18.8)	0	0	4 (12.5)	2 (6.3)
Epistaxis	4 (12.5)	1 (3.1)	1 (3.1)	1 (3.1)	1 (3.1)
Oropharyngeal pain	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Respiratory failure	3 (9.4)	0	0	0	3 (9.4)
Rhinitis allergic	3 (9.4)	3 (9.4)	0	0	0
Rhinorrhoea	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Tachypnoea	3 (9.4)	2 (6.3)	0	1 (3.1)	0
Dyspnoea	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Haemoptysis	2 (6.3)	1 (3.1)	0	0	1 (3.1)
Nasal congestion	2 (6.3)	2 (6.3)	0	0	0
Atelectasis	1 (3.1)	1 (3.1)	0	0	0
Interstitial lung disease	1 (3.1)	0	0	0	1 (3.1)
Respiratory distress	1 (3.1)	0	0	0	1 (3.1)
Skin and subcutaneous tissue disorders					
-Total	16 (50.0)	9 (28.1)	4 (12.5)	3 (9.4)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Rash maculo-papular	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Hyperhidrosis	3 (9.4)	3 (9.4)	0	0	0
Petechiae	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Erythema	2 (6.3)	2 (6.3)	0	0	0
Ingrowing nail	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Macule	2 (6.3)	2 (6.3)	0	0	0
Dermatitis acneiform	1 (3.1)	0	0	1 (3.1)	0
Dermatitis atopic	1 (3.1)	1 (3.1)	0	0	0
Dermatitis diaper	1 (3.1)	1 (3.1)	0	0	0
Dry skin	1 (3.1)	1 (3.1)	0	0	0
Ecchymosis	1 (3.1)	0	0	1 (3.1)	0
Eczema	1 (3.1)	1 (3.1)	0	0	0
Night sweats	1 (3.1)	0	1 (3.1)	0	0
Papule	1 (3.1)	1 (3.1)	0	0	0
Rash erythematous	1 (3.1)	1 (3.1)	0	0	0
Rash macular	1 (3.1)	1 (3.1)	0	0	0
Rash papular	1 (3.1)	1 (3.1)	0	0	0
Skin exfoliation	1 (3.1)	1 (3.1)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin fissures	1 (3.1)	1 (3.1)	0	0	0
Skin irritation	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	15 (46.9)	1 (3.1)	3 (9.4)	4 (12.5)	7 (21.9)
Hypotension	11 (34.4)	0	0	4 (12.5)	7 (21.9)
Hypertension	6 (18.8)	0	5 (15.6)	1 (3.1)	0
Capillary leak syndrome	1 (3.1)	0	0	0	1 (3.1)
Flushing	1 (3.1)	1 (3.1)	0	0	0
Haematoma	1 (3.1)	0	1 (3.1)	0	0
Orthostatic hypotension	1 (3.1)	1 (3.1)	0	0	0
Secondary hypertension	1 (3.1)	0	1 (3.1)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 0

			All patients N=7		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	1 (14.3)	0	6 (85.7)
Blood and lymphatic system disorders					
-Total	5 (71.4)	1 (14.3)	0	2 (28.6)	2 (28.6)
Anaemia	4 (57.1)	2 (28.6)	0	1 (14.3)	1 (14.3)
Febrile neutropenia	2 (28.6)	0	0	2 (28.6)	0
Neutropenia	2 (28.6)	0	0	0	2 (28.6)
Thrombocytopenia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Cardiac disorders					
-Total	3 (42.9)	2 (28.6)	0	1 (14.3)	0
Tachycardia	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0
Palpitations	1 (14.3)	1 (14.3)	0	0	0
Pericardial effusion	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Eye pain	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal disorders					
-Total	4 (57.1)	2 (28.6)	1 (14.3)	1 (14.3)	0
Diarrhoea	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Nausea	3 (42.9)	1 (14.3)	1 (14.3)	1 (14.3)	0
Vomiting	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
General disorders and administration site conditions					
-Total	3 (42.9)	0	0	2 (28.6)	1 (14.3)
Pyrexia	3 (42.9)	0	1 (14.3)	1 (14.3)	1 (14.3)
Asthenia	1 (14.3)	1 (14.3)	0	0	0
Chills	1 (14.3)	1 (14.3)	0	0	0
Pain	1 (14.3)	0	0	1 (14.3)	0
Hepatobiliary disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Hepatomegaly	1 (14.3)	0	1 (14.3)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	7 (100)	0	4 (57.1)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)	0	0
Infections and infestations					
-Total	2 (28.6)	0	2 (28.6)	0	0
Gastroenteritis	1 (14.3)	0	1 (14.3)	0	0
Viral infection	1 (14.3)	0	1 (14.3)	0	0
Injury, poisoning and procedural complications					
-Total	1 (14.3)	0	0	1 (14.3)	0
Tracheal haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Investigations					
-Total	7 (100)	1 (14.3)	1 (14.3)	1 (14.3)	4 (57.1)
Neutrophil count decreased	4 (57.1)	0	1 (14.3)	0	3 (42.9)
White blood cell count decreased	4 (57.1)	1 (14.3)	0	1 (14.3)	2 (28.6)
Lymphocyte count decreased	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (14.3)	0	0	0	1 (14.3)
Blood creatinine increased	1 (14.3)	0	1 (14.3)	0	0
Blood fibrinogen decreased	1 (14.3)	0	1 (14.3)	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0
Blood magnesium decreased	1 (14.3)	0	0	1 (14.3)	0
Blood phosphorus increased	1 (14.3)	1 (14.3)	0	0	0
Blood uric acid increased	1 (14.3)	1 (14.3)	0	0	0
Cardiac murmur	1 (14.3)	1 (14.3)	0	0	0
Fibrin d dimer increased	1 (14.3)	1 (14.3)	0	0	0
International normalised ratio increased	1 (14.3)	1 (14.3)	0	0	0
Prothrombin time prolonged	1 (14.3)	0	1 (14.3)	0	0
Metabolism and nutrition disorders					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Decreased appetite	3 (42.9)	1 (14.3)	1 (14.3)	1 (14.3)	0
Hypokalaemia	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Hypernatraemia	1 (14.3)	0	1 (14.3)	0	0
Hypoalbuminaemia	1 (14.3)	1 (14.3)	0	0	0
Hypophosphataemia	1 (14.3)	0	0	1 (14.3)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Arthralgia	1 (14.3)	0	0	1 (14.3)	0
Nervous system disorders					
-Total	4 (57.1)	4 (57.1)	0	0	0
Headache	3 (42.9)	3 (42.9)	0	0	0
Dizziness	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Confusional state	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Delirium	1 (14.3)	1 (14.3)	0	0	0
Renal and urinary disorders					
-Total	2 (28.6)	0	0	0	2 (28.6)
Haematuria	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Acute kidney injury	1 (14.3)	0	0	0	1 (14.3)
Oliguria	1 (14.3)	0	0	1 (14.3)	0
Renal failure	1 (14.3)	0	0	0	1 (14.3)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	3 (42.9)	1 (14.3)	0	0	2 (28.6)
Cough	2 (28.6)	2 (28.6)	0	0	0
Hypoxia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Dyspnoea	1 (14.3)	0	0	0	1 (14.3)
Epistaxis	1 (14.3)	0	0	0	1 (14.3)
Haemoptysis	1 (14.3)	0	0	0	1 (14.3)
Interstitial lung disease	1 (14.3)	0	0	0	1 (14.3)
Pleural effusion	1 (14.3)	0	1 (14.3)	0	0
Pulmonary oedema	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Skin and subcutaneous tissue disorders					
-Total	4 (57.1)	4 (57.1)	0	0	0
Dermatitis diaper	1 (14.3)	1 (14.3)	0	0	0
Dry skin	1 (14.3)	1 (14.3)	0	0	0
Erythema	1 (14.3)	1 (14.3)	0	0	0
Livedo reticularis	1 (14.3)	1 (14.3)	0	0	0
Rash maculo-papular	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	4 (57.1)	0	0	2 (28.6)	2 (28.6)
Hypotension	4 (57.1)	0	0	2 (28.6)	2 (28.6)
Haematoma	1 (14.3)	0	1 (14.3)	0	0
Hypertension	1 (14.3)	0	1 (14.3)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (95.0)	1 (5.0)	1 (5.0)	5 (25.0)	12 (60.0)
Blood and lymphatic system disorders					
-Total	14 (70.0)	0	2 (10.0)	10 (50.0)	2 (10.0)
Febrile neutropenia	9 (45.0)	0	0	9 (45.0)	0
Anaemia	8 (40.0)	0	2 (10.0)	6 (30.0)	0
Disseminated intravascular coagulation	3 (15.0)	0	1 (5.0)	2 (10.0)	0
Neutropenia	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Lymphopenia	1 (5.0)	0	0	0	1 (5.0)
Cardiac disorders					
-Total	6 (30.0)	2 (10.0)	4 (20.0)	0	0
Tachycardia	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Sinus tachycardia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Bradycardia	1 (5.0)	0	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pericardial effusion	1 (5.0)	0	1 (5.0)	0	0
Ventricular tachycardia	1 (5.0)	0	1 (5.0)	0	0
Endocrine disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Adrenal insufficiency	1 (5.0)	0	1 (5.0)	0	0
Eye disorders					
-Total	4 (20.0)	2 (10.0)	2 (10.0)	0	0
Conjunctival haemorrhage	2 (10.0)	2 (10.0)	0	0	0
Periorbital oedema	2 (10.0)	2 (10.0)	0	0	0
Retinal haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Uveitis	1 (5.0)	0	1 (5.0)	0	0
Vision blurred	1 (5.0)	0	1 (5.0)	0	0
Gastrointestinal disorders					
-Total	13 (65.0)	4 (20.0)	4 (20.0)	5 (25.0)	0
Vomiting	7 (35.0)	4 (20.0)	2 (10.0)	1 (5.0)	0
Diarrhoea	6 (30.0)	3 (15.0)	2 (10.0)	1 (5.0)	0
Constipation	5 (25.0)	5 (25.0)	0	0	0
Nausea	5 (25.0)	1 (5.0)	3 (15.0)	1 (5.0)	0
Abdominal pain	2 (10.0)	2 (10.0)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphagia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Abdominal pain upper	1 (5.0)	0	1 (5.0)	0	0
Flatulence	1 (5.0)	1 (5.0)	0	0	0
Gastrooesophageal reflux disease	1 (5.0)	1 (5.0)	0	0	0
Glossodynia	1 (5.0)	1 (5.0)	0	0	0
Haematemesis	1 (5.0)	1 (5.0)	0	0	0
Ileus	1 (5.0)	0	0	1 (5.0)	0
Pancreatitis	1 (5.0)	0	1 (5.0)	0	0
Tooth socket haemorrhage	1 (5.0)	1 (5.0)	0	0	0
General disorders and administration site conditions					
-Total	12 (60.0)	5 (25.0)	2 (10.0)	5 (25.0)	0
Fatigue	5 (25.0)	5 (25.0)	0	0	0
Pyrexia	5 (25.0)	1 (5.0)	1 (5.0)	3 (15.0)	0
Catheter site haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Catheter site pain	1 (5.0)	0	1 (5.0)	0	0
Chills	1 (5.0)	1 (5.0)	0	0	0
Face oedema	1 (5.0)	0	0	1 (5.0)	0
Generalised oedema	1 (5.0)	0	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injection site haematoma	1 (5.0)	1 (5.0)	0	0	0
Localised oedema	1 (5.0)	0	0	1 (5.0)	0
Mucosal haemorrhage	1 (5.0)	0	1 (5.0)	0	0
Multiple organ dysfunction syndrome	1 (5.0)	0	0	1 (5.0)	0
Oedema peripheral	1 (5.0)	0	0	1 (5.0)	0
Pain	1 (5.0)	0	1 (5.0)	0	0
Physical deconditioning	1 (5.0)	0	0	1 (5.0)	0
Hepatobiliary disorders					
-Total	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Gallbladder enlargement	1 (5.0)	1 (5.0)	0	0	0
Hepatosplenomegaly	1 (5.0)	1 (5.0)	0	0	0
Hyperbilirubinaemia	1 (5.0)	0	0	1 (5.0)	0
Immune system disorders					
-Total	16 (80.0)	1 (5.0)	7 (35.0)	3 (15.0)	5 (25.0)
Cytokine release syndrome	16 (80.0)	2 (10.0)	7 (35.0)	2 (10.0)	5 (25.0)
Hypogammaglobulinaemia	6 (30.0)	0	5 (25.0)	1 (5.0)	0
Infections and infestations					
-Total	7 (35.0)	1 (5.0)	2 (10.0)	4 (20.0)	0
Clostridium difficile infection	2 (10.0)	0	2 (10.0)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Catheter site cellulitis	1 (5.0)	1 (5.0)	0	0	0
Clostridium difficile colitis	1 (5.0)	0	0	1 (5.0)	0
Cytomegalovirus infection	1 (5.0)	1 (5.0)	0	0	0
Enterococcal infection	1 (5.0)	1 (5.0)	0	0	0
Gastroenteritis	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis norovirus	1 (5.0)	0	1 (5.0)	0	0
Influenza	1 (5.0)	1 (5.0)	0	0	0
Pharyngitis	1 (5.0)	0	1 (5.0)	0	0
Pneumonia	1 (5.0)	0	0	1 (5.0)	0
Streptococcal infection	1 (5.0)	0	1 (5.0)	0	0
Injury, poisoning and procedural complications					
-Total	5 (25.0)	4 (20.0)	0	0	1 (5.0)
Contusion	1 (5.0)	1 (5.0)	0	0	0
Post procedural haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Procedural complication	1 (5.0)	1 (5.0)	0	0	0
Subdural haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Transfusion reaction	1 (5.0)	1 (5.0)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion related complication	1 (5.0)	0	0	0	1 (5.0)
Investigations					
-Total	15 (75.0)	0	0	4 (20.0)	11 (55.0)
White blood cell count decreased	10 (50.0)	2 (10.0)	0	4 (20.0)	4 (20.0)
Platelet count decreased	9 (45.0)	0	2 (10.0)	1 (5.0)	6 (30.0)
Neutrophil count decreased	8 (40.0)	0	0	2 (10.0)	6 (30.0)
Alanine aminotransferase increased	7 (35.0)	2 (10.0)	1 (5.0)	4 (20.0)	0
Aspartate aminotransferase increased	7 (35.0)	1 (5.0)	2 (10.0)	3 (15.0)	1 (5.0)
Lymphocyte count decreased	6 (30.0)	0	0	3 (15.0)	3 (15.0)
Blood creatinine increased	4 (20.0)	2 (10.0)	1 (5.0)	1 (5.0)	0
Activated partial thromboplastin time prolonged	3 (15.0)	1 (5.0)	2 (10.0)	0	0
International normalised ratio increased	3 (15.0)	3 (15.0)	0	0	0
Prothrombin time prolonged	3 (15.0)	3 (15.0)	0	0	0
Blood bilirubin increased	2 (10.0)	0	2 (10.0)	0	0
Blood fibrinogen decreased	1 (5.0)	0	0	0	1 (5.0)
Blood immunoglobulin a decreased	1 (5.0)	1 (5.0)	0	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Blood phosphorus decreased	1 (5.0)	1 (5.0)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood phosphorus increased	1 (5.0)	1 (5.0)	0	0	0
Blood urea increased	1 (5.0)	0	0	1 (5.0)	0
Haemoglobin decreased	1 (5.0)	0	0	1 (5.0)	0
Hepatic enzyme increased	1 (5.0)	0	1 (5.0)	0	0
Lipase increased	1 (5.0)	0	0	0	1 (5.0)
Protein total decreased	1 (5.0)	0	0	1 (5.0)	0
Metabolism and nutrition disorders					
-Total	11 (55.0)	1 (5.0)	1 (5.0)	7 (35.0)	2 (10.0)
Decreased appetite	4 (20.0)	0	1 (5.0)	3 (15.0)	0
Hyperphosphataemia	4 (20.0)	4 (20.0)	0	0	0
Hypernatraemia	3 (15.0)	1 (5.0)	1 (5.0)	0	1 (5.0)
Hypokalaemia	3 (15.0)	0	0	3 (15.0)	0
Acidosis	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Dehydration	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Hyperglycaemia	2 (10.0)	0	2 (10.0)	0	0
Hyperuricaemia	2 (10.0)	1 (5.0)	0	0	1 (5.0)
Hypophosphataemia	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Hyperalbuminaemia	1 (5.0)	1 (5.0)	0	0	0
Hypercalcaemia	1 (5.0)	1 (5.0)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperchloraemia	1 (5.0)	1 (5.0)	0	0	0
Hypermagnesaemia	1 (5.0)	1 (5.0)	0	0	0
Hypertriglyceridaemia	1 (5.0)	0	0	1 (5.0)	0
Hypoalbuminaemia	1 (5.0)	0	1 (5.0)	0	0
Hypocalcaemia	1 (5.0)	1 (5.0)	0	0	0
Metabolic alkalosis	1 (5.0)	1 (5.0)	0	0	0
Tumour lysis syndrome	1 (5.0)	0	0	1 (5.0)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Arthralgia	2 (10.0)	2 (10.0)	0	0	0
Coccydynia	1 (5.0)	1 (5.0)	0	0	0
Muscular weakness	1 (5.0)	0	1 (5.0)	0	0
Musculoskeletal chest pain	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal pain	1 (5.0)	0	1 (5.0)	0	0
Nervous system disorders					
-Total	12 (60.0)	6 (30.0)	5 (25.0)	1 (5.0)	0
Headache	9 (45.0)	6 (30.0)	3 (15.0)	0	0
Dysarthria	2 (10.0)	1 (5.0)	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Tremor	2 (10.0)	2 (10.0)	0	0	0
Asterixis	1 (5.0)	1 (5.0)	0	0	0
Ataxia	1 (5.0)	0	1 (5.0)	0	0
Depressed level of consciousness	1 (5.0)	1 (5.0)	0	0	0
Dizziness	1 (5.0)	1 (5.0)	0	0	0
Neuropathy peripheral	1 (5.0)	0	1 (5.0)	0	0
Pleocytosis	1 (5.0)	1 (5.0)	0	0	0
Seizure	1 (5.0)	0	1 (5.0)	0	0
Somnolence	1 (5.0)	1 (5.0)	0	0	0
Product issues					
-Total	1 (5.0)	1 (5.0)	0	0	0
Device occlusion	1 (5.0)	1 (5.0)	0	0	0
Psychiatric disorders					
-Total	4 (20.0)	2 (10.0)	2 (10.0)	0	0
Delirium	2 (10.0)	0	2 (10.0)	0	0
Adjustment disorder	1 (5.0)	0	1 (5.0)	0	0
Agitation	1 (5.0)	0	1 (5.0)	0	0
Anxiety	1 (5.0)	0	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	1 (5.0)	1 (5.0)	0	0	0
Hallucination	1 (5.0)	1 (5.0)	0	0	0
Insomnia	1 (5.0)	0	1 (5.0)	0	0
Irritability	1 (5.0)	1 (5.0)	0	0	0
Suicidal ideation	1 (5.0)	1 (5.0)	0	0	0
Renal and urinary disorders					
-Total	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0
Acute kidney injury	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Renal impairment	1 (5.0)	0	0	1 (5.0)	0
Reproductive system and breast disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Vulvovaginal adhesion	1 (5.0)	1 (5.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (45.0)	4 (20.0)	0	3 (15.0)	2 (10.0)
Epistaxis	3 (15.0)	0	1 (5.0)	2 (10.0)	0
Pleural effusion	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Pulmonary oedema	3 (15.0)	1 (5.0)	0	1 (5.0)	1 (5.0)
Tachypnoea	3 (15.0)	2 (10.0)	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	2 (10.0)	0	0	2 (10.0)	0
Cough	1 (5.0)	1 (5.0)	0	0	0
Haemoptysis	1 (5.0)	1 (5.0)	0	0	0
Nasal congestion	1 (5.0)	1 (5.0)	0	0	0
Oropharyngeal pain	1 (5.0)	0	1 (5.0)	0	0
Oropharyngeal plaque	1 (5.0)	1 (5.0)	0	0	0
Respiratory distress	1 (5.0)	0	0	0	1 (5.0)
Respiratory failure	1 (5.0)	0	0	0	1 (5.0)
Rhinorrhoea	1 (5.0)	1 (5.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (40.0)	6 (30.0)	1 (5.0)	1 (5.0)	0
Dry skin	3 (15.0)	3 (15.0)	0	0	0
Hyperhidrosis	3 (15.0)	3 (15.0)	0	0	0
Petechiae	2 (10.0)	2 (10.0)	0	0	0
Ecchymosis	1 (5.0)	0	0	1 (5.0)	0
Erythema	1 (5.0)	1 (5.0)	0	0	0
Ingrowing nail	1 (5.0)	0	1 (5.0)	0	0
Macule	1 (5.0)	1 (5.0)	0	0	0
Pruritus	1 (5.0)	1 (5.0)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	1 (5.0)	1 (5.0)	0	0	0
Rash erythematous	1 (5.0)	1 (5.0)	0	0	0
Rash macular	1 (5.0)	1 (5.0)	0	0	0
Rash papular	1 (5.0)	1 (5.0)	0	0	0
Rash vesicular	1 (5.0)	1 (5.0)	0	0	0
Skin exfoliation	1 (5.0)	1 (5.0)	0	0	0
Skin fissures	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	6 (30.0)	0	2 (10.0)	1 (5.0)	3 (15.0)
Hypotension	4 (20.0)	0	0	1 (5.0)	3 (15.0)
Hypertension	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Capillary leak syndrome	1 (5.0)	0	0	0	1 (5.0)
Flushing	1 (5.0)	1 (5.0)	0	0	0
Orthostatic hypotension	1 (5.0)	0	1 (5.0)	0	0
Secondary hypertension	1 (5.0)	0	1 (5.0)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency

of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=21		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (100)	0	1 (4.8)	7 (33.3)	13 (61.9)
Blood and lymphatic system disorders					
-Total	15 (71.4)	1 (4.8)	0	9 (42.9)	5 (23.8)
Febrile neutropenia	8 (38.1)	0	0	8 (38.1)	0
Anaemia	7 (33.3)	0	2 (9.5)	5 (23.8)	0
Thrombocytopenia	4 (19.0)	0	0	0	4 (19.0)
Neutropenia	3 (14.3)	0	0	2 (9.5)	1 (4.8)
Lymphopenia	2 (9.5)	0	1 (4.8)	1 (4.8)	0
Coagulopathy	1 (4.8)	1 (4.8)	0	0	0
Disseminated intravascular coagulation	1 (4.8)	0	1 (4.8)	0	0
Pancytopenia	1 (4.8)	0	0	0	1 (4.8)
Cardiac disorders					

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (33.3)	3 (14.3)	4 (19.0)	0	0
Tachycardia	5 (23.8)	2 (9.5)	3 (14.3)	0	0
Atrioventricular block second degree	1 (4.8)	1 (4.8)	0	0	0
Sinus bradycardia	1 (4.8)	1 (4.8)	0	0	0
Sinus tachycardia	1 (4.8)	0	1 (4.8)	0	0
Ear and labyrinth disorders					
-Total	1 (4.8)	0	1 (4.8)	0	0
Hypoacusis	1 (4.8)	0	1 (4.8)	0	0
Eye disorders					
-Total	5 (23.8)	3 (14.3)	2 (9.5)	0	0
Eye pain	2 (9.5)	0	2 (9.5)	0	0
Photophobia	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Vision blurred	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Conjunctival haemorrhage	1 (4.8)	1 (4.8)	0	0	0
Periorbital oedema	1 (4.8)	1 (4.8)	0	0	0
Retinal haemorrhage	1 (4.8)	1 (4.8)	0	0	0
Gastrointestinal disorders					
-Total	10 (47.6)	2 (9.5)	4 (19.0)	4 (19.0)	0
Nausea	7 (33.3)	1 (4.8)	5 (23.8)	1 (4.8)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	7 (33.3)	3 (14.3)	2 (9.5)	2 (9.5)	0
Diarrhoea	4 (19.0)	2 (9.5)	2 (9.5)	0	0
Abdominal pain	2 (9.5)	1 (4.8)	0	1 (4.8)	0
Abdominal discomfort	1 (4.8)	1 (4.8)	0	0	0
Abdominal pain upper	1 (4.8)	0	1 (4.8)	0	0
Anal incontinence	1 (4.8)	1 (4.8)	0	0	0
Ascites	1 (4.8)	0	0	1 (4.8)	0
Constipation	1 (4.8)	0	1 (4.8)	0	0
Dyspepsia	1 (4.8)	0	1 (4.8)	0	0
Gastrointestinal haemorrhage	1 (4.8)	1 (4.8)	0	0	0
Intestinal obstruction	1 (4.8)	0	0	1 (4.8)	0
Pancreatitis	1 (4.8)	0	0	1 (4.8)	0
Stomatitis	1 (4.8)	0	1 (4.8)	0	0
General disorders and administration site conditions					
-Total	9 (42.9)	4 (19.0)	5 (23.8)	0	0
Chills	5 (23.8)	5 (23.8)	0	0	0
Pyrexia	5 (23.8)	1 (4.8)	4 (19.0)	0	0
Fatigue	3 (14.3)	2 (9.5)	1 (4.8)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=21		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	2 (9.5)	0	2 (9.5)	0	0
Catheter site pain	1 (4.8)	0	1 (4.8)	0	0
Non-cardiac chest pain	1 (4.8)	1 (4.8)	0	0	0
Hepatobiliary disorders					
-Total	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Hepatomegaly	1 (4.8)	1 (4.8)	0	0	0
Hyperbilirubinaemia	1 (4.8)	0	1 (4.8)	0	0
Immune system disorders					
-Total	20 (95.2)	0	13 (61.9)	6 (28.6)	1 (4.8)
Cytokine release syndrome	18 (85.7)	1 (4.8)	12 (57.1)	4 (19.0)	1 (4.8)
Hypogammaglobulinaemia	10 (47.6)	1 (4.8)	6 (28.6)	3 (14.3)	0
Drug hypersensitivity	1 (4.8)	0	1 (4.8)	0	0
Infections and infestations					
-Total	9 (42.9)	1 (4.8)	5 (23.8)	2 (9.5)	1 (4.8)
Rhinovirus infection	3 (14.3)	3 (14.3)	0	0	0
Clostridium difficile colitis	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Acute sinusitis	1 (4.8)	0	1 (4.8)	0	0
Catheter site infection	1 (4.8)	0	0	1 (4.8)	0
Clostridium difficile infection	1 (4.8)	0	1 (4.8)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Folliculitis	1 (4.8)	0	1 (4.8)	0	0
Orchitis	1 (4.8)	1 (4.8)	0	0	0
Pneumonia	1 (4.8)	0	1 (4.8)	0	0
Septic embolus	1 (4.8)	0	0	0	1 (4.8)
Upper respiratory tract infection	1 (4.8)	0	1 (4.8)	0	0
Urinary tract infection enterococcal	1 (4.8)	0	0	1 (4.8)	0
Viral upper respiratory tract infection	1 (4.8)	0	1 (4.8)	0	0
Injury, poisoning and procedural complications					
-Total	4 (19.0)	3 (14.3)	1 (4.8)	0	0
Incision site pain	1 (4.8)	1 (4.8)	0	0	0
Procedural pain	1 (4.8)	1 (4.8)	0	0	0
Stoma site irritation	1 (4.8)	1 (4.8)	0	0	0
Tibia fracture	1 (4.8)	0	1 (4.8)	0	0
Transfusion reaction	1 (4.8)	1 (4.8)	0	0	0
Investigations					
-Total	17 (81.0)	1 (4.8)	0	8 (38.1)	8 (38.1)
White blood cell count decreased	10 (47.6)	0	0	3 (14.3)	7 (33.3)
Alanine aminotransferase increased	7 (33.3)	2 (9.5)	0	5 (23.8)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	7 (33.3)	0	0	2 (9.5)	5 (23.8)
Platelet count decreased	5 (23.8)	2 (9.5)	0	1 (4.8)	2 (9.5)
Aspartate aminotransferase increased	4 (19.0)	1 (4.8)	0	3 (14.3)	0
Prothrombin time prolonged	4 (19.0)	2 (9.5)	1 (4.8)	1 (4.8)	0
Lymphocyte count decreased	3 (14.3)	0	0	1 (4.8)	2 (9.5)
Blood bilirubin increased	2 (9.5)	0	1 (4.8)	1 (4.8)	0
Blood fibrinogen decreased	2 (9.5)	0	0	2 (9.5)	0
International normalised ratio increased	2 (9.5)	1 (4.8)	0	1 (4.8)	0
Transaminases increased	2 (9.5)	2 (9.5)	0	0	0
Blood creatinine increased	1 (4.8)	1 (4.8)	0	0	0
Blood immunoglobulin g decreased	1 (4.8)	0	1 (4.8)	0	0
Blood immunoglobulin m decreased	1 (4.8)	1 (4.8)	0	0	0
Blood sodium increased	1 (4.8)	0	1 (4.8)	0	0
Blood urea increased	1 (4.8)	1 (4.8)	0	0	0
C-reactive protein increased	1 (4.8)	0	0	1 (4.8)	0
Lipase increased	1 (4.8)	0	0	0	1 (4.8)
Metabolism and nutrition disorders					
-Total	14 (66.7)	1 (4.8)	3 (14.3)	9 (42.9)	1 (4.8)
Decreased appetite	9 (42.9)	1 (4.8)	2 (9.5)	6 (28.6)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	5 (23.8)	1 (4.8)	2 (9.5)	2 (9.5)	0
Hypophosphataemia	4 (19.0)	0	0	3 (14.3)	1 (4.8)
Hyperphosphataemia	2 (9.5)	2 (9.5)	0	0	0
Hyponatraemia	2 (9.5)	0	0	2 (9.5)	0
Dehydration	1 (4.8)	0	0	1 (4.8)	0
Fluid overload	1 (4.8)	0	1 (4.8)	0	0
Hyperglycaemia	1 (4.8)	0	0	1 (4.8)	0
Hypertriglyceridaemia	1 (4.8)	1 (4.8)	0	0	0
Hypoalbuminaemia	1 (4.8)	0	0	1 (4.8)	0
Hypomagnesaemia	1 (4.8)	1 (4.8)	0	0	0
Malnutrition	1 (4.8)	0	0	1 (4.8)	0
Metabolic acidosis	1 (4.8)	0	1 (4.8)	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (19.0)	2 (9.5)	2 (9.5)	0	0
Limb discomfort	1 (4.8)	1 (4.8)	0	0	0
Musculoskeletal pain	1 (4.8)	1 (4.8)	0	0	0
Myalgia	1 (4.8)	1 (4.8)	0	0	0
Osteopenia	1 (4.8)	0	1 (4.8)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	1 (4.8)	0	1 (4.8)	0	0
Nervous system disorders					
-Total	9 (42.9)	3 (14.3)	3 (14.3)	2 (9.5)	1 (4.8)
Headache	6 (28.6)	3 (14.3)	1 (4.8)	2 (9.5)	0
Embolic stroke	1 (4.8)	0	0	0	1 (4.8)
Encephalopathy	1 (4.8)	0	0	1 (4.8)	0
Migraine	1 (4.8)	0	1 (4.8)	0	0
Seizure	1 (4.8)	0	1 (4.8)	0	0
Psychiatric disorders					
-Total	6 (28.6)	3 (14.3)	3 (14.3)	0	0
Anxiety	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Confusional state	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Delirium	1 (4.8)	1 (4.8)	0	0	0
Mental status changes	1 (4.8)	1 (4.8)	0	0	0
Panic attack	1 (4.8)	0	1 (4.8)	0	0
Renal and urinary disorders					
-Total	4 (19.0)	1 (4.8)	1 (4.8)	1 (4.8)	1 (4.8)
Acute kidney injury	2 (9.5)	0	0	1 (4.8)	1 (4.8)
Dysuria	2 (9.5)	1 (4.8)	1 (4.8)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	1 (4.8)	0	1 (4.8)	0	0
Pollakiuria	1 (4.8)	1 (4.8)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (33.3)	2 (9.5)	2 (9.5)	1 (4.8)	2 (9.5)
Cough	3 (14.3)	3 (14.3)	0	0	0
Hypoxia	3 (14.3)	0	1 (4.8)	1 (4.8)	1 (4.8)
Pleural effusion	2 (9.5)	1 (4.8)	0	1 (4.8)	0
Atelectasis	1 (4.8)	1 (4.8)	0	0	0
Epistaxis	1 (4.8)	1 (4.8)	0	0	0
Pharyngeal ulceration	1 (4.8)	0	1 (4.8)	0	0
Pulmonary oedema	1 (4.8)	0	0	1 (4.8)	0
Respiratory depression	1 (4.8)	0	1 (4.8)	0	0
Respiratory failure	1 (4.8)	0	0	0	1 (4.8)
Rhinitis allergic	1 (4.8)	1 (4.8)	0	0	0
Tachypnoea	1 (4.8)	1 (4.8)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (23.8)	3 (14.3)	1 (4.8)	1 (4.8)	0
Rash maculo-papular	2 (9.5)	0	1 (4.8)	1 (4.8)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	1 (4.8)	1 (4.8)	0	0	0
Ingrowing nail	1 (4.8)	0	1 (4.8)	0	0
Pruritus	1 (4.8)	1 (4.8)	0	0	0
Rash	1 (4.8)	1 (4.8)	0	0	0
Vascular disorders					
-Total	8 (38.1)	2 (9.5)	2 (9.5)	3 (14.3)	1 (4.8)
Hypertension	4 (19.0)	1 (4.8)	3 (14.3)	0	0
Hypotension	4 (19.0)	0	0	3 (14.3)	1 (4.8)
Orthostatic hypotension	1 (4.8)	1 (4.8)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

			All patients N=16		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (100)	1 (6.3)	4 (25.0)	2 (12.5)	9 (56.3)
Blood and lymphatic system disorders					
-Total	9 (56.3)	0	1 (6.3)	6 (37.5)	2 (12.5)
Anaemia	8 (50.0)	1 (6.3)	1 (6.3)	6 (37.5)	0
Febrile neutropenia	3 (18.8)	0	0	3 (18.8)	0
Thrombocytopenia	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Neutropenia	1 (6.3)	0	0	0	1 (6.3)
Cardiac disorders					
-Total	6 (37.5)	4 (25.0)	1 (6.3)	1 (6.3)	0
Tachycardia	5 (31.3)	3 (18.8)	1 (6.3)	1 (6.3)	0
Sinus tachycardia	2 (12.5)	2 (12.5)	0	0	0
Cardiac dysfunction	1 (6.3)	1 (6.3)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear and labyrinth disorders					
-Total	2 (12.5)	2 (12.5)	0	0	0
Ear pain	2 (12.5)	2 (12.5)	0	0	0
Eye disorders					
-Total	3 (18.8)	0	3 (18.8)	0	0
Ocular hypertension	1 (6.3)	0	1 (6.3)	0	0
Papilloedema	1 (6.3)	0	1 (6.3)	0	0
Periorbital oedema	1 (6.3)	0	1 (6.3)	0	0
Uveitis	1 (6.3)	0	1 (6.3)	0	0
Visual impairment	1 (6.3)	0	1 (6.3)	0	0
Gastrointestinal disorders					
-Total	9 (56.3)	3 (18.8)	5 (31.3)	1 (6.3)	0
Nausea	6 (37.5)	3 (18.8)	3 (18.8)	0	0
Abdominal pain	5 (31.3)	3 (18.8)	2 (12.5)	0	0
Diarrhoea	5 (31.3)	4 (25.0)	1 (6.3)	0	0
Vomiting	5 (31.3)	5 (31.3)	0	0	0
Abdominal distension	2 (12.5)	0	2 (12.5)	0	0
Abdominal pain lower	1 (6.3)	0	1 (6.3)	0	0
Abdominal tenderness	1 (6.3)	1 (6.3)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematemesis	1 (6.3)	1 (6.3)	0	0	0
Lip pain	1 (6.3)	0	1 (6.3)	0	0
Mouth haemorrhage	1 (6.3)	0	0	1 (6.3)	0
Stomatitis	1 (6.3)	1 (6.3)	0	0	0
General disorders and administration site conditions					
-Total	8 (50.0)	3 (18.8)	3 (18.8)	2 (12.5)	0
Fatigue	5 (31.3)	3 (18.8)	1 (6.3)	1 (6.3)	0
Pyrexia	3 (18.8)	1 (6.3)	1 (6.3)	1 (6.3)	0
Catheter site extravasation	1 (6.3)	0	1 (6.3)	0	0
Catheter site pain	1 (6.3)	1 (6.3)	0	0	0
Chills	1 (6.3)	1 (6.3)	0	0	0
Face oedema	1 (6.3)	0	1 (6.3)	0	0
Facial pain	1 (6.3)	0	1 (6.3)	0	0
Generalised oedema	1 (6.3)	0	1 (6.3)	0	0
Malaise	1 (6.3)	0	1 (6.3)	0	0
Oedema peripheral	1 (6.3)	1 (6.3)	0	0	0
Pain	1 (6.3)	0	0	1 (6.3)	0
Peripheral swelling	1 (6.3)	0	1 (6.3)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	1 (6.3)	0	0	1 (6.3)	0
Hepatomegaly	1 (6.3)	0	1 (6.3)	0	0
Hyperbilirubinaemia	1 (6.3)	0	0	1 (6.3)	0
Immune system disorders					
-Total	14 (87.5)	4 (25.0)	6 (37.5)	2 (12.5)	2 (12.5)
Cytokine release syndrome	11 (68.8)	3 (18.8)	4 (25.0)	2 (12.5)	2 (12.5)
Hypogammaglobulinaemia	5 (31.3)	2 (12.5)	3 (18.8)	0	0
Graft versus host disease in skin	1 (6.3)	1 (6.3)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (6.3)	0	1 (6.3)	0	0
Infections and infestations					
-Total	8 (50.0)	3 (18.8)	5 (31.3)	0	0
Body tinea	1 (6.3)	1 (6.3)	0	0	0
Clostridium difficile colitis	1 (6.3)	0	1 (6.3)	0	0
Clostridium difficile infection	1 (6.3)	0	1 (6.3)	0	0
Fungal skin infection	1 (6.3)	1 (6.3)	0	0	0
Herpes simplex	1 (6.3)	1 (6.3)	0	0	0
Human herpesvirus 6 infection	1 (6.3)	0	1 (6.3)	0	0
Hypopyon	1 (6.3)	0	1 (6.3)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral candidiasis	1 (6.3)	1 (6.3)	0	0	0
Skin infection	1 (6.3)	0	1 (6.3)	0	0
Vulvovaginal candidiasis	1 (6.3)	1 (6.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	5 (31.3)	1 (6.3)	4 (25.0)	0	0
Infusion related reaction	2 (12.5)	0	2 (12.5)	0	0
Procedural pain	2 (12.5)	0	2 (12.5)	0	0
Limb injury	1 (6.3)	1 (6.3)	0	0	0
Mouth injury	1 (6.3)	1 (6.3)	0	0	0
Procedural headache	1 (6.3)	0	1 (6.3)	0	0
Procedural site reaction	1 (6.3)	1 (6.3)	0	0	0
Skin abrasion	1 (6.3)	1 (6.3)	0	0	0
Tongue injury	1 (6.3)	1 (6.3)	0	0	0
Transfusion reaction	1 (6.3)	0	1 (6.3)	0	0
Investigations					
-Total	13 (81.3)	2 (12.5)	3 (18.8)	0	8 (50.0)
Aspartate aminotransferase increased	6 (37.5)	1 (6.3)	2 (12.5)	1 (6.3)	2 (12.5)
Neutrophil count decreased	6 (37.5)	0	1 (6.3)	0	5 (31.3)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

			All patients N=16		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	6 (37.5)	0	1 (6.3)	2 (12.5)	3 (18.8)
Alanine aminotransferase increased	5 (31.3)	1 (6.3)	2 (12.5)	2 (12.5)	0
Platelet count decreased	5 (31.3)	1 (6.3)	0	0	4 (25.0)
Blood bilirubin increased	3 (18.8)	2 (12.5)	0	1 (6.3)	0
Blood creatinine increased	3 (18.8)	2 (12.5)	0	1 (6.3)	0
International normalised ratio increased	3 (18.8)	3 (18.8)	0	0	0
Lymphocyte count decreased	3 (18.8)	0	1 (6.3)	2 (12.5)	0
Blood immunoglobulin a decreased	2 (12.5)	2 (12.5)	0	0	0
Activated partial thromboplastin time prolonged	1 (6.3)	1 (6.3)	0	0	0
Blood bicarbonate decreased	1 (6.3)	0	1 (6.3)	0	0
Blood immunoglobulin m decreased	1 (6.3)	1 (6.3)	0	0	0
Blood lactic acid increased	1 (6.3)	0	0	0	1 (6.3)
Blood urea increased	1 (6.3)	0	1 (6.3)	0	0
Culture stool positive	1 (6.3)	1 (6.3)	0	0	0
Norovirus test positive	1 (6.3)	1 (6.3)	0	0	0
Prothrombin time prolonged	1 (6.3)	0	1 (6.3)	0	0
Pulmonary function test decreased	1 (6.3)	0	1 (6.3)	0	0
Serum ferritin increased	1 (6.3)	0	1 (6.3)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	10 (62.5)	2 (12.5)	4 (25.0)	4 (25.0)	0
Hypokalaemia	6 (37.5)	1 (6.3)	3 (18.8)	2 (12.5)	0
Decreased appetite	4 (25.0)	2 (12.5)	0	2 (12.5)	0
Fluid overload	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Hyperphosphataemia	2 (12.5)	2 (12.5)	0	0	0
Hypoalbuminaemia	2 (12.5)	0	2 (12.5)	0	0
Hypocalcaemia	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Hypophosphataemia	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Hyperuricaemia	1 (6.3)	1 (6.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (43.8)	5 (31.3)	2 (12.5)	0	0
Myalgia	4 (25.0)	3 (18.8)	1 (6.3)	0	0
Pain in extremity	3 (18.8)	2 (12.5)	1 (6.3)	0	0
Arthralgia	1 (6.3)	1 (6.3)	0	0	0
Muscle spasms	1 (6.3)	1 (6.3)	0	0	0
Musculoskeletal pain	1 (6.3)	1 (6.3)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (6.3)	0	1 (6.3)	0	0
Skin papilloma	1 (6.3)	0	1 (6.3)	0	0
Nervous system disorders					
-Total	8 (50.0)	4 (25.0)	3 (18.8)	1 (6.3)	0
Headache	6 (37.5)	4 (25.0)	2 (12.5)	0	0
Dizziness	2 (12.5)	2 (12.5)	0	0	0
Encephalopathy	1 (6.3)	1 (6.3)	0	0	0
Idiopathic intracranial hypertension	1 (6.3)	0	1 (6.3)	0	0
Myoclonus	1 (6.3)	1 (6.3)	0	0	0
Seizure	1 (6.3)	0	0	1 (6.3)	0
Psychiatric disorders					
-Total	3 (18.8)	1 (6.3)	1 (6.3)	1 (6.3)	0
Anxiety	3 (18.8)	1 (6.3)	1 (6.3)	1 (6.3)	0
Agitation	1 (6.3)	0	1 (6.3)	0	0
Confusional state	1 (6.3)	0	1 (6.3)	0	0
Hallucination	1 (6.3)	0	1 (6.3)	0	0
Irritability	1 (6.3)	1 (6.3)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

			All patients N=16		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Listless	1 (6.3)	1 (6.3)	0	0	0
Renal and urinary disorders					
-Total	1 (6.3)	0	0	0	1 (6.3)
Acute kidney injury	1 (6.3)	0	0	0	1 (6.3)
Haematuria	1 (6.3)	0	1 (6.3)	0	0
Oliguria	1 (6.3)	0	0	1 (6.3)	0
Reproductive system and breast disorders					
-Total	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Oedema genital	1 (6.3)	0	1 (6.3)	0	0
Vulvovaginal adhesion	1 (6.3)	1 (6.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (56.3)	3 (18.8)	4 (25.0)	1 (6.3)	1 (6.3)
Hypoxia	3 (18.8)	0	2 (12.5)	0	1 (6.3)
Cough	2 (12.5)	2 (12.5)	0	0	0
Epistaxis	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Pleural effusion	2 (12.5)	0	2 (12.5)	0	0
Dyspnoea	1 (6.3)	0	0	1 (6.3)	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	1 (6.3)	1 (6.3)	0	0	0
Pulmonary oedema	1 (6.3)	0	0	1 (6.3)	0
Tachypnoea	1 (6.3)	0	0	1 (6.3)	0
Wheezing	1 (6.3)	0	1 (6.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (25.0)	2 (12.5)	2 (12.5)	0	0
Rash	2 (12.5)	2 (12.5)	0	0	0
Night sweats	1 (6.3)	0	1 (6.3)	0	0
Petechiae	1 (6.3)	0	1 (6.3)	0	0
Rash follicular	1 (6.3)	1 (6.3)	0	0	0
Rash papular	1 (6.3)	1 (6.3)	0	0	0
Skin irritation	1 (6.3)	1 (6.3)	0	0	0
Vascular disorders					
-Total	6 (37.5)	1 (6.3)	1 (6.3)	2 (12.5)	2 (12.5)
Hypotension	4 (25.0)	1 (6.3)	0	1 (6.3)	2 (12.5)
Hypertension	3 (18.8)	0	2 (12.5)	1 (6.3)	0
Embolism	1 (6.3)	0	0	1 (6.3)	0
Flushing	1 (6.3)	1 (6.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	2 (40.0)	2 (40.0)	0
Endocrine disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Adrenal insufficiency	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal disorders					
-Total	4 (80.0)	2 (40.0)	0	2 (40.0)	0
Diarrhoea	2 (40.0)	2 (40.0)	0	0	0
Oral pain	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Vomiting	2 (40.0)	2 (40.0)	0	0	0
Abdominal pain	1 (20.0)	1 (20.0)	0	0	0
Enterocolitis	1 (20.0)	0	0	1 (20.0)	0
Nausea	1 (20.0)	0	1 (20.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	3 (60.0)	2 (40.0)	1 (20.0)	0	0
Catheter site pain	1 (20.0)	0	1 (20.0)	0	0
Fatigue	1 (20.0)	1 (20.0)	0	0	0
Pyrexia	1 (20.0)	1 (20.0)	0	0	0
Immune system disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Graft versus host disease	1 (20.0)	0	1 (20.0)	0	0
Infections and infestations					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Upper respiratory tract infection	2 (40.0)	0	2 (40.0)	0	0
Corona virus infection	1 (20.0)	0	0	1 (20.0)	0
Ear infection	1 (20.0)	1 (20.0)	0	0	0
Respiratory syncytial virus infection	1 (20.0)	0	0	1 (20.0)	0
Rhinovirus infection	1 (20.0)	1 (20.0)	0	0	0
Tinea capitis	1 (20.0)	1 (20.0)	0	0	0
Viral infection	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	1 (20.0)	0	1 (20.0)	0	0
Contusion	1 (20.0)	1 (20.0)	0	0	0
Infusion related reaction	1 (20.0)	0	1 (20.0)	0	0
Procedural nausea	1 (20.0)	0	1 (20.0)	0	0
Sunburn	1 (20.0)	1 (20.0)	0	0	0
Investigations					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Blood bilirubin increased	1 (20.0)	0	0	1 (20.0)	0
Blood magnesium decreased	1 (20.0)	1 (20.0)	0	0	0
Weight decreased	1 (20.0)	1 (20.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (60.0)	3 (60.0)	0	0	0
Pain in extremity	2 (40.0)	2 (40.0)	0	0	0
Arthralgia	1 (20.0)	1 (20.0)	0	0	0
Muscular weakness	1 (20.0)	1 (20.0)	0	0	0
Pain in jaw	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0
Headache	1 (20.0)	1 (20.0)	0	0	0
Peroneal nerve palsy	1 (20.0)	1 (20.0)	0	0	0
Psychiatric disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Anxiety	1 (20.0)	1 (20.0)	0	0	0
Depression	1 (20.0)	1 (20.0)	0	0	0
Sleep disorder	1 (20.0)	0	1 (20.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (80.0)	2 (40.0)	1 (20.0)	1 (20.0)	0
Rhinorrhoea	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Cough	1 (20.0)	1 (20.0)	0	0	0
Epistaxis	1 (20.0)	0	0	1 (20.0)	0
Nasal congestion	1 (20.0)	1 (20.0)	0	0	0
Oropharyngeal pain	1 (20.0)	0	1 (20.0)	0	0
Pharyngeal erythema	1 (20.0)	1 (20.0)	0	0	0
Pharyngeal lesion	1 (20.0)	0	0	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Alopecia	1 (20.0)	0	1 (20.0)	0	0
Erythema	1 (20.0)	1 (20.0)	0	0	0
Rash erythematous	1 (20.0)	0	1 (20.0)	0	0
Vascular disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Hypertension	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Hot flush	1 (20.0)	1 (20.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

			All patients N=19		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (89.5)	2 (10.5)	5 (26.3)	5 (26.3)	5 (26.3)
Blood and lymphatic system disorders					
-Total	3 (15.8)	0	0	1 (5.3)	2 (10.5)
Febrile neutropenia	2 (10.5)	0	0	2 (10.5)	0
Anaemia	1 (5.3)	0	0	1 (5.3)	0
Leukopenia	1 (5.3)	0	0	0	1 (5.3)
Neutropenia	1 (5.3)	0	0	0	1 (5.3)
Eye disorders					
-Total	2 (10.5)	2 (10.5)	0	0	0
Dry eye	1 (5.3)	1 (5.3)	0	0	0
Vision blurred	1 (5.3)	1 (5.3)	0	0	0
Gastrointestinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (15.8)	2 (10.5)	0	1 (5.3)	0
Diarrhoea	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Nausea	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Abdominal pain	1 (5.3)	0	1 (5.3)	0	0
Vomiting	1 (5.3)	0	0	1 (5.3)	0
General disorders and administration site conditions					
-Total	3 (15.8)	2 (10.5)	0	1 (5.3)	0
Acquired gene mutation	1 (5.3)	1 (5.3)	0	0	0
Generalised oedema	1 (5.3)	1 (5.3)	0	0	0
Oedema peripheral	1 (5.3)	1 (5.3)	0	0	0
Pyrexia	1 (5.3)	0	0	1 (5.3)	0
Immune system disorders					
-Total	6 (31.6)	1 (5.3)	4 (21.1)	1 (5.3)	0
Hypogammaglobulinaemia	3 (15.8)	0	2 (10.5)	1 (5.3)	0
Immunodeficiency common variable	2 (10.5)	0	2 (10.5)	0	0
Graft versus host disease in gastrointestinal tract	1 (5.3)	0	1 (5.3)	0	0
Seasonal allergy	1 (5.3)	1 (5.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	14 (73.7)	3 (15.8)	7 (36.8)	3 (15.8)	1 (5.3)
Gastroenteritis	2 (10.5)	0	2 (10.5)	0	0
Influenza	2 (10.5)	0	2 (10.5)	0	0
Urinary tract infection	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Escherichia urinary tract infection	1 (5.3)	0	0	1 (5.3)	0
Gastroenteritis norovirus	1 (5.3)	0	1 (5.3)	0	0
Herpes zoster	1 (5.3)	0	0	1 (5.3)	0
Oral herpes	1 (5.3)	0	1 (5.3)	0	0
Parainfluenzae virus infection	1 (5.3)	1 (5.3)	0	0	0
Rash pustular	1 (5.3)	0	1 (5.3)	0	0
Rhinitis	1 (5.3)	1 (5.3)	0	0	0
Rhinovirus infection	1 (5.3)	1 (5.3)	0	0	0
Sepsis	1 (5.3)	0	0	0	1 (5.3)
Subcutaneous abscess	1 (5.3)	0	1 (5.3)	0	0
Upper respiratory tract infection	1 (5.3)	1 (5.3)	0	0	0
Viral upper respiratory tract infection	1 (5.3)	0	0	1 (5.3)	0
Vulvovaginal mycotic infection	1 (5.3)	0	1 (5.3)	0	0
Investigations					

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (42.1)	3 (15.8)	1 (5.3)	3 (15.8)	1 (5.3)
Neutrophil count decreased	3 (15.8)	0	0	2 (10.5)	1 (5.3)
Aspartate aminotransferase increased	2 (10.5)	0	0	2 (10.5)	0
White blood cell count decreased	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Blood creatinine increased	1 (5.3)	1 (5.3)	0	0	0
Blood urea increased	1 (5.3)	1 (5.3)	0	0	0
Platelet count decreased	1 (5.3)	1 (5.3)	0	0	0
Serum ferritin increased	1 (5.3)	0	1 (5.3)	0	0
Weight increased	1 (5.3)	1 (5.3)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (26.3)	3 (15.8)	0	1 (5.3)	1 (5.3)
Hypokalaemia	2 (10.5)	1 (5.3)	0	0	1 (5.3)
Decreased appetite	1 (5.3)	1 (5.3)	0	0	0
Hyperalbuminaemia	1 (5.3)	1 (5.3)	0	0	0
Hypercalcaemia	1 (5.3)	1 (5.3)	0	0	0
Hyperglycaemia	1 (5.3)	0	0	1 (5.3)	0
Hyperphosphataemia	1 (5.3)	1 (5.3)	0	0	0
Hypophosphataemia	1 (5.3)	0	0	1 (5.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Iron overload	1 (5.3)	0	0	1 (5.3)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (26.3)	2 (10.5)	3 (15.8)	0	0
Pain in extremity	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Flank pain	1 (5.3)	0	1 (5.3)	0	0
Muscular weakness	1 (5.3)	1 (5.3)	0	0	0
Musculoskeletal chest pain	1 (5.3)	1 (5.3)	0	0	0
Osteonecrosis	1 (5.3)	0	1 (5.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (5.3)	0	1 (5.3)	0	0
Myelodysplastic syndrome	1 (5.3)	0	1 (5.3)	0	0
Psychiatric disorders					
-Total	1 (5.3)	1 (5.3)	0	0	0
Depression	1 (5.3)	1 (5.3)	0	0	0
Renal and urinary disorders					
-Total	2 (10.5)	0	0	2 (10.5)	0
Acute kidney injury	1 (5.3)	0	0	1 (5.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Calculus urinary	1 (5.3)	0	1 (5.3)	0	0
Haematuria	1 (5.3)	0	0	1 (5.3)	0
Nephrolithiasis	1 (5.3)	0	0	1 (5.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (26.3)	3 (15.8)	0	1 (5.3)	1 (5.3)
Acute respiratory failure	1 (5.3)	0	0	0	1 (5.3)
Cough	1 (5.3)	1 (5.3)	0	0	0
Epistaxis	1 (5.3)	1 (5.3)	0	0	0
Nasal congestion	1 (5.3)	1 (5.3)	0	0	0
Oropharyngeal pain	1 (5.3)	1 (5.3)	0	0	0
Pulmonary oedema	1 (5.3)	0	0	1 (5.3)	0
Skin and subcutaneous tissue disorders					
-Total	7 (36.8)	5 (26.3)	2 (10.5)	0	0
Rash	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Dry skin	1 (5.3)	1 (5.3)	0	0	0
Eczema	1 (5.3)	1 (5.3)	0	0	0
Keloid scar	1 (5.3)	0	1 (5.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Papule	1 (5.3)	1 (5.3)	0	0	0
Petechiae	1 (5.3)	1 (5.3)	0	0	0
Rash pruritic	1 (5.3)	1 (5.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

			All patients N=18		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (77.8)	1 (5.6)	4 (22.2)	6 (33.3)	3 (16.7)
Blood and lymphatic system disorders					
-Total	4 (22.2)	0	2 (11.1)	1 (5.6)	1 (5.6)
Neutropenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Febrile neutropenia	1 (5.6)	0	0	1 (5.6)	0
Lymphadenopathy	1 (5.6)	0	1 (5.6)	0	0
Thrombocytopenia	1 (5.6)	0	1 (5.6)	0	0
Eye disorders					
-Total	1 (5.6)	1 (5.6)	0	0	0
Conjunctivitis allergic	1 (5.6)	1 (5.6)	0	0	0
Gastrointestinal disorders					
-Total	4 (22.2)	2 (11.1)	1 (5.6)	1 (5.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	3 (16.7)	2 (11.1)	0	1 (5.6)	0
Vomiting	3 (16.7)	2 (11.1)	0	1 (5.6)	0
Nausea	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Abdominal pain	1 (5.6)	0	0	1 (5.6)	0
General disorders and administration site conditions					
-Total	5 (27.8)	4 (22.2)	1 (5.6)	0	0
Pyrexia	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Influenza like illness	1 (5.6)	1 (5.6)	0	0	0
Malaise	1 (5.6)	1 (5.6)	0	0	0
Immune system disorders					
-Total	4 (22.2)	1 (5.6)	3 (16.7)	0	0
Hypogammaglobulinaemia	3 (16.7)	0	3 (16.7)	0	0
Seasonal allergy	1 (5.6)	1 (5.6)	0	0	0
Infections and infestations					
-Total	9 (50.0)	2 (11.1)	4 (22.2)	2 (11.1)	1 (5.6)
Bacterial sepsis	1 (5.6)	0	0	0	1 (5.6)
Cholecystitis infective	1 (5.6)	0	0	1 (5.6)	0
Gastroenteritis	1 (5.6)	1 (5.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis viral	1 (5.6)	1 (5.6)	0	0	0
Influenza	1 (5.6)	0	1 (5.6)	0	0
Molluscum contagiosum	1 (5.6)	1 (5.6)	0	0	0
Otitis externa	1 (5.6)	0	1 (5.6)	0	0
Parainfluenzae virus infection	1 (5.6)	0	0	1 (5.6)	0
Paronychia	1 (5.6)	1 (5.6)	0	0	0
Sinusitis	1 (5.6)	0	1 (5.6)	0	0
Upper respiratory tract infection	1 (5.6)	0	1 (5.6)	0	0
Urinary tract infection	1 (5.6)	0	1 (5.6)	0	0
Viral upper respiratory tract infection	1 (5.6)	1 (5.6)	0	0	0
Injury, poisoning and procedural complications					
-Total	5 (27.8)	2 (11.1)	3 (16.7)	0	0
Procedural pain	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Arthropod bite	1 (5.6)	1 (5.6)	0	0	0
Foot fracture	1 (5.6)	0	1 (5.6)	0	0
Infusion related reaction	1 (5.6)	1 (5.6)	0	0	0
Radius fracture	1 (5.6)	0	1 (5.6)	0	0
Skin abrasion	1 (5.6)	1 (5.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	8 (44.4)	1 (5.6)	2 (11.1)	3 (16.7)	2 (11.1)
Weight decreased	3 (16.7)	0	3 (16.7)	0	0
Neutrophil count decreased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
White blood cell count decreased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Alanine aminotransferase increased	1 (5.6)	0	0	1 (5.6)	0
Aspartate aminotransferase increased	1 (5.6)	1 (5.6)	0	0	0
Haemoglobin decreased	1 (5.6)	1 (5.6)	0	0	0
Oxygen saturation decreased	1 (5.6)	1 (5.6)	0	0	0
Platelet count decreased	1 (5.6)	1 (5.6)	0	0	0
Transaminases increased	1 (5.6)	1 (5.6)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (5.6)	0	0	1 (5.6)	0
Tumour lysis syndrome	1 (5.6)	0	0	1 (5.6)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (22.2)	3 (16.7)	1 (5.6)	0	0
Pain in extremity	2 (11.1)	2 (11.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	1 (5.6)	0	1 (5.6)	0	0
Toe walking	1 (5.6)	1 (5.6)	0	0	0
Nervous system disorders					
-Total	4 (22.2)	3 (16.7)	1 (5.6)	0	0
Dizziness	2 (11.1)	2 (11.1)	0	0	0
Headache	2 (11.1)	2 (11.1)	0	0	0
Peroneal nerve palsy	1 (5.6)	0	1 (5.6)	0	0
Reproductive system and breast disorders					
-Total	1 (5.6)	0	0	1 (5.6)	0
Vaginal haemorrhage	1 (5.6)	0	0	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (33.3)	4 (22.2)	2 (11.1)	0	0
Cough	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Rhinitis allergic	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Rhinorrhoea	2 (11.1)	2 (11.1)	0	0	0
Dysphonia	1 (5.6)	1 (5.6)	0	0	0
Nasal congestion	1 (5.6)	1 (5.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	1 (5.6)	1 (5.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (22.2)	2 (11.1)	1 (5.6)	1 (5.6)	0
Dermatitis	1 (5.6)	1 (5.6)	0	0	0
Dermatitis acneiform	1 (5.6)	0	0	1 (5.6)	0
Erythema	1 (5.6)	1 (5.6)	0	0	0
Hyperhidrosis	1 (5.6)	1 (5.6)	0	0	0
Ingrowing nail	1 (5.6)	1 (5.6)	0	0	0
Rash	1 (5.6)	0	1 (5.6)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (78.6)	1 (7.1)	5 (35.7)	3 (21.4)	2 (14.3)
Blood and lymphatic system disorders					
-Total	4 (28.6)	1 (7.1)	1 (7.1)	1 (7.1)	1 (7.1)
Anaemia	1 (7.1)	1 (7.1)	0	0	0
Eosinophilia	1 (7.1)	0	0	1 (7.1)	0
Lymphopenia	1 (7.1)	0	1 (7.1)	0	0
Neutropenia	1 (7.1)	0	0	0	1 (7.1)
Thrombocytopenia	1 (7.1)	0	0	1 (7.1)	0
Cardiac disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0
Sinus tachycardia	1 (7.1)	0	1 (7.1)	0	0
Eye disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Dry eye	1 (7.1)	0	1 (7.1)	0	0
Ocular hyperaemia	1 (7.1)	1 (7.1)	0	0	0
Gastrointestinal disorders					
-Total	5 (35.7)	3 (21.4)	2 (14.3)	0	0
Vomiting	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Abdominal pain	1 (7.1)	1 (7.1)	0	0	0
Abdominal pain upper	1 (7.1)	1 (7.1)	0	0	0
Diarrhoea	1 (7.1)	1 (7.1)	0	0	0
Nausea	1 (7.1)	0	1 (7.1)	0	0
Pigmentation lip	1 (7.1)	1 (7.1)	0	0	0
General disorders and administration site conditions					
-Total	6 (42.9)	5 (35.7)	1 (7.1)	0	0
Pyrexia	5 (35.7)	4 (28.6)	1 (7.1)	0	0
Chills	1 (7.1)	1 (7.1)	0	0	0
Crying	1 (7.1)	1 (7.1)	0	0	0
Fatigue	1 (7.1)	1 (7.1)	0	0	0
Influenza like illness	1 (7.1)	1 (7.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	1 (7.1)	1 (7.1)	0	0	0
Immune system disorders					
-Total	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Hypogammaglobulinaemia	2 (14.3)	0	2 (14.3)	0	0
Graft versus host disease	1 (7.1)	1 (7.1)	0	0	0
Infections and infestations					
-Total	6 (42.9)	0	2 (14.3)	4 (28.6)	0
Upper respiratory tract infection	3 (21.4)	2 (14.3)	0	1 (7.1)	0
Cellulitis of male external genital organ	1 (7.1)	0	0	1 (7.1)	0
Cytomegalovirus infection	1 (7.1)	1 (7.1)	0	0	0
Ear infection	1 (7.1)	0	1 (7.1)	0	0
Enterovirus infection	1 (7.1)	0	0	1 (7.1)	0
Otitis media	1 (7.1)	0	1 (7.1)	0	0
Otitis media acute	1 (7.1)	0	1 (7.1)	0	0
Rotavirus infection	1 (7.1)	0	0	1 (7.1)	0
Sinusitis	1 (7.1)	0	1 (7.1)	0	0
Urinary tract infection	1 (7.1)	0	0	1 (7.1)	0
Vascular device infection	1 (7.1)	0	0	1 (7.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Contusion	1 (7.1)	1 (7.1)	0	0	0
Skin laceration	1 (7.1)	0	1 (7.1)	0	0
Investigations					
-Total	5 (35.7)	1 (7.1)	2 (14.3)	1 (7.1)	1 (7.1)
Neutrophil count decreased	3 (21.4)	2 (14.3)	0	0	1 (7.1)
Lymphocyte count decreased	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Alanine aminotransferase increased	1 (7.1)	0	0	1 (7.1)	0
Blood uric acid increased	1 (7.1)	1 (7.1)	0	0	0
Haemoglobin decreased	1 (7.1)	1 (7.1)	0	0	0
Platelet count decreased	1 (7.1)	1 (7.1)	0	0	0
Weight increased	1 (7.1)	0	1 (7.1)	0	0
White blood cell count decreased	1 (7.1)	1 (7.1)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (28.6)	2 (14.3)	1 (7.1)	1 (7.1)	0
Decreased appetite	1 (7.1)	0	1 (7.1)	0	0
Dehydration	1 (7.1)	0	0	1 (7.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

			All patients N=14		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	1 (7.1)	1 (7.1)	0	0	0
Vitamin d deficiency	1 (7.1)	1 (7.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (28.6)	3 (21.4)	1 (7.1)	0	0
Joint range of motion decreased	2 (14.3)	2 (14.3)	0	0	0
Pain in extremity	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Back pain	1 (7.1)	1 (7.1)	0	0	0
Muscle spasms	1 (7.1)	1 (7.1)	0	0	0
Nervous system disorders					
-Total	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Headache	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Dizziness	1 (7.1)	1 (7.1)	0	0	0
Renal and urinary disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Urinary incontinence	1 (7.1)	1 (7.1)	0	0	0
Reproductive system and breast disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Scrotal pain	1 (7.1)	0	1 (7.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Cough	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Nasal congestion	1 (7.1)	1 (7.1)	0	0	0
Rhinitis allergic	1 (7.1)	1 (7.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (28.6)	3 (21.4)	1 (7.1)	0	0
Rash maculo-papular	2 (14.3)	2 (14.3)	0	0	0
Dermatitis atopic	1 (7.1)	1 (7.1)	0	0	0
Macule	1 (7.1)	1 (7.1)	0	0	0
Pruritus	1 (7.1)	1 (7.1)	0	0	0
Rash	1 (7.1)	0	1 (7.1)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

			All patients N=5		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (40.0)	0	1 (20.0)	0	1 (20.0)
Infections and infestations					
-Total	1 (20.0)	0	1 (20.0)	0	0
Skin infection	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	1 (20.0)	0	0	0	1 (20.0)
White blood cell count decreased	1 (20.0)	0	0	0	1 (20.0)

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (63.6)	2 (18.2)	2 (18.2)	2 (18.2)	1 (9.1)
Ear and labyrinth disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Tympanic membrane perforation	1 (9.1)	0	1 (9.1)	0	0
Immune system disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Chronic graft versus host disease	1 (9.1)	0	1 (9.1)	0	0
Infections and infestations					
-Total	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Otitis media	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Gingivitis	1 (9.1)	1 (9.1)	0	0	0
Haemophilus infection	1 (9.1)	0	1 (9.1)	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

			All patients N=11		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis aseptic	1 (9.1)	0	1 (9.1)	0	0
Otitis media acute	1 (9.1)	0	1 (9.1)	0	0
Pneumonia	1 (9.1)	0	1 (9.1)	0	0
Sinusitis	1 (9.1)	0	1 (9.1)	0	0
Viral infection	1 (9.1)	1 (9.1)	0	0	0
Investigations					
-Total	1 (9.1)	0	0	1 (9.1)	0
White blood cell count decreased	1 (9.1)	0	0	1 (9.1)	0
Metabolism and nutrition disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Vitamin d deficiency	1 (9.1)	1 (9.1)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (9.1)	0	0	0	1 (9.1)
Glioblastoma multiforme	1 (9.1)	0	0	0	1 (9.1)
Nervous system disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Seizure	1 (9.1)	0	0	1 (9.1)	0
Renal and urinary disorders					

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (9.1)	1 (9.1)	0	0	0
Haematuria	1 (9.1)	1 (9.1)	0	0	0
Reproductive system and breast disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Ovarian failure	1 (9.1)	0	0	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Epistaxis	1 (9.1)	1 (9.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Papule	1 (9.1)	1 (9.1)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

			All patients N=10		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (60.0)	0	1 (10.0)	3 (30.0)	2 (20.0)
Blood and lymphatic system disorders					
-Total	1 (10.0)	0	0	0	1 (10.0)
Febrile neutropenia	1 (10.0)	0	0	0	1 (10.0)
Gastrointestinal disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Nausea	1 (10.0)	0	1 (10.0)	0	0
General disorders and administration site conditions					
-Total	1 (10.0)	0	1 (10.0)	0	0
Chills	1 (10.0)	0	1 (10.0)	0	0
Pyrexia	1 (10.0)	0	1 (10.0)	0	0
Immune system disorders					

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (10.0)	0	1 (10.0)	0	0
Immunodeficiency	1 (10.0)	0	1 (10.0)	0	0
Infections and infestations					
-Total	3 (30.0)	0	2 (20.0)	0	1 (10.0)
Sinusitis	2 (20.0)	0	2 (20.0)	0	0
Pneumonia	1 (10.0)	0	1 (10.0)	0	0
Respiratory tract infection	1 (10.0)	0	0	0	1 (10.0)
Upper respiratory tract infection	1 (10.0)	0	1 (10.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (10.0)	0	0	1 (10.0)	0
Procedural pain	1 (10.0)	0	0	1 (10.0)	0
Investigations					
-Total	4 (40.0)	0	1 (10.0)	3 (30.0)	0
Alanine aminotransferase increased	3 (30.0)	0	1 (10.0)	2 (20.0)	0
Aspartate aminotransferase increased	2 (20.0)	1 (10.0)	0	1 (10.0)	0
Blood alkaline phosphatase increased	1 (10.0)	1 (10.0)	0	0	0
Blood lactate dehydrogenase increased	1 (10.0)	1 (10.0)	0	0	0
C-reactive protein increased	1 (10.0)	1 (10.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (10.0)	0	0	1 (10.0)	0
Platelet count decreased	1 (10.0)	0	0	1 (10.0)	0
White blood cell count decreased	1 (10.0)	0	0	1 (10.0)	0
Metabolism and nutrition disorders					
-Total	1 (10.0)	0	0	1 (10.0)	0
Hypokalaemia	1 (10.0)	0	0	1 (10.0)	0
Nervous system disorders					
-Total	1 (10.0)	1 (10.0)	0	0	0
Disturbance in attention	1 (10.0)	1 (10.0)	0	0	0
Renal and urinary disorders					
-Total	1 (10.0)	0	0	1 (10.0)	0
Acute kidney injury	1 (10.0)	0	0	1 (10.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (10.0)	1 (10.0)	0	0	0
Cough	1 (10.0)	1 (10.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (20.0)	2 (20.0)	0	0	0
Acne	1 (10.0)	1 (10.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

			All patients N=10		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	1 (10.0)	1 (10.0)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

			All patients N=8		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (87.5)	2 (25.0)	2 (25.0)	3 (37.5)	0
Blood and lymphatic system disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Thrombocytopenia	1 (12.5)	1 (12.5)	0	0	0
Gastrointestinal disorders					
-Total	2 (25.0)	0	2 (25.0)	0	0
Diarrhoea	2 (25.0)	0	2 (25.0)	0	0
Abdominal pain	1 (12.5)	0	1 (12.5)	0	0
General disorders and administration site conditions					
-Total	1 (12.5)	0	0	1 (12.5)	0
Cyst	1 (12.5)	0	0	1 (12.5)	0
Infections and infestations					

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (50.0)	1 (12.5)	1 (12.5)	2 (25.0)	0
Urinary tract infection	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Campylobacter infection	1 (12.5)	0	0	1 (12.5)	0
Cellulitis of male external genital organ	1 (12.5)	0	0	1 (12.5)	0
Clostridium difficile infection	1 (12.5)	0	0	1 (12.5)	0
Otitis media	1 (12.5)	0	1 (12.5)	0	0
Otitis media acute	1 (12.5)	0	1 (12.5)	0	0
Respiratory tract infection viral	1 (12.5)	0	0	1 (12.5)	0
Upper respiratory tract infection	1 (12.5)	1 (12.5)	0	0	0
Vulvovaginal candidiasis	1 (12.5)	0	1 (12.5)	0	0
Investigations					
-Total	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Lymphocyte count decreased	2 (25.0)	2 (25.0)	0	0	0
Neutrophil count decreased	2 (25.0)	1 (12.5)	1 (12.5)	0	0
White blood cell count decreased	1 (12.5)	1 (12.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Neck pain	1 (12.5)	0	1 (12.5)	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Dizziness	1 (12.5)	1 (12.5)	0	0	0
Headache	1 (12.5)	0	1 (12.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (25.0)	2 (25.0)	0	0	0
Cough	1 (12.5)	1 (12.5)	0	0	0
Oropharyngeal pain	1 (12.5)	1 (12.5)	0	0	0
Rhinitis allergic	1 (12.5)	1 (12.5)	0	0	0
Rhinorrhoea	1 (12.5)	1 (12.5)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

			All patients N=7		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	1 (14.3)	0	6 (85.7)
Blood and lymphatic system disorders					
-Total	5 (71.4)	1 (14.3)	0	2 (28.6)	2 (28.6)
Anaemia	4 (57.1)	2 (28.6)	0	1 (14.3)	1 (14.3)
Febrile neutropenia	2 (28.6)	0	0	2 (28.6)	0
Neutropenia	2 (28.6)	0	0	0	2 (28.6)
Thrombocytopenia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Cardiac disorders					
-Total	3 (42.9)	2 (28.6)	0	1 (14.3)	0
Tachycardia	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0
Palpitations	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pericardial effusion	1 (14.3)	1 (14.3)	0	0	0
Endocrine disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Adrenal insufficiency	1 (14.3)	1 (14.3)	0	0	0
Eye disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Eye pain	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal disorders					
-Total	6 (85.7)	2 (28.6)	1 (14.3)	3 (42.9)	0
Vomiting	5 (71.4)	3 (42.9)	2 (28.6)	0	0
Diarrhoea	4 (57.1)	3 (42.9)	1 (14.3)	0	0
Nausea	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Oral pain	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Abdominal pain	1 (14.3)	1 (14.3)	0	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Enterocolitis	1 (14.3)	0	0	1 (14.3)	0
General disorders and administration site conditions					
-Total	5 (71.4)	1 (14.3)	1 (14.3)	2 (28.6)	1 (14.3)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	4 (57.1)	1 (14.3)	1 (14.3)	1 (14.3)	1 (14.3)
Asthenia	1 (14.3)	1 (14.3)	0	0	0
Catheter site pain	1 (14.3)	0	1 (14.3)	0	0
Chills	1 (14.3)	1 (14.3)	0	0	0
Fatigue	1 (14.3)	1 (14.3)	0	0	0
Pain	1 (14.3)	0	0	1 (14.3)	0
Hepatobiliary disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Hepatomegaly	1 (14.3)	0	1 (14.3)	0	0
Immune system disorders					
-Total	7 (100)	0	4 (57.1)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)	0	0
Graft versus host disease	1 (14.3)	0	1 (14.3)	0	0
Infections and infestations					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Upper respiratory tract infection	2 (28.6)	0	2 (28.6)	0	0
Viral infection	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Corona virus infection	1 (14.3)	0	0	1 (14.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	1 (14.3)	1 (14.3)	0	0	0
Gastroenteritis	1 (14.3)	0	1 (14.3)	0	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	1 (14.3)	0	0	0
Skin infection	1 (14.3)	0	1 (14.3)	0	0
Tinea capitis	1 (14.3)	1 (14.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Contusion	1 (14.3)	1 (14.3)	0	0	0
Infusion related reaction	1 (14.3)	0	1 (14.3)	0	0
Procedural nausea	1 (14.3)	0	1 (14.3)	0	0
Sunburn	1 (14.3)	1 (14.3)	0	0	0
Tracheal haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Investigations					
-Total	7 (100)	0	1 (14.3)	2 (28.6)	4 (57.1)
Neutrophil count decreased	4 (57.1)	0	1 (14.3)	0	3 (42.9)
White blood cell count decreased	4 (57.1)	1 (14.3)	0	0	3 (42.9)
Blood magnesium decreased	2 (28.6)	1 (14.3)	0	1 (14.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0	0	0
Aspartate aminotransferase increased	1 (14.3)	0	0	0	1 (14.3)
Blood bilirubin increased	1 (14.3)	0	0	1 (14.3)	0
Blood creatinine increased	1 (14.3)	0	1 (14.3)	0	0
Blood fibrinogen decreased	1 (14.3)	0	1 (14.3)	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0
Blood phosphorus increased	1 (14.3)	1 (14.3)	0	0	0
Blood uric acid increased	1 (14.3)	1 (14.3)	0	0	0
Cardiac murmur	1 (14.3)	1 (14.3)	0	0	0
Fibrin d dimer increased	1 (14.3)	1 (14.3)	0	0	0
International normalised ratio increased	1 (14.3)	1 (14.3)	0	0	0
Prothrombin time prolonged	1 (14.3)	0	1 (14.3)	0	0
Weight decreased	1 (14.3)	1 (14.3)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Decreased appetite	3 (42.9)	1 (14.3)	1 (14.3)	1 (14.3)	0
Hypokalaemia	2 (28.6)	1 (14.3)	1 (14.3)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	1 (14.3)	0	1 (14.3)	0	0
Hypoalbuminaemia	1 (14.3)	1 (14.3)	0	0	0
Hypophosphataemia	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (42.9)	2 (28.6)	0	1 (14.3)	0
Pain in extremity	2 (28.6)	2 (28.6)	0	0	0
Arthralgia	1 (14.3)	0	0	1 (14.3)	0
Muscular weakness	1 (14.3)	1 (14.3)	0	0	0
Pain in jaw	1 (14.3)	1 (14.3)	0	0	0
Nervous system disorders					
-Total	4 (57.1)	4 (57.1)	0	0	0
Headache	3 (42.9)	3 (42.9)	0	0	0
Dizziness	1 (14.3)	1 (14.3)	0	0	0
Peroneal nerve palsy	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Confusional state	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Anxiety	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	1 (14.3)	1 (14.3)	0	0	0
Depression	1 (14.3)	1 (14.3)	0	0	0
Sleep disorder	1 (14.3)	0	1 (14.3)	0	0
Renal and urinary disorders					
-Total	2 (28.6)	0	0	0	2 (28.6)
Haematuria	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Acute kidney injury	1 (14.3)	0	0	0	1 (14.3)
Oliguria	1 (14.3)	0	0	1 (14.3)	0
Renal failure	1 (14.3)	0	0	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders					
-Total	6 (85.7)	2 (28.6)	1 (14.3)	1 (14.3)	2 (28.6)
Cough	3 (42.9)	3 (42.9)	0	0	0
Epistaxis	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Hypoxia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Rhinorrhoea	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Dyspnoea	1 (14.3)	0	0	0	1 (14.3)
Haemoptysis	1 (14.3)	0	0	0	1 (14.3)
Interstitial lung disease	1 (14.3)	0	0	0	1 (14.3)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	1 (14.3)	1 (14.3)	0	0	0
Oropharyngeal pain	1 (14.3)	0	1 (14.3)	0	0
Pharyngeal erythema	1 (14.3)	1 (14.3)	0	0	0
Pharyngeal lesion	1 (14.3)	0	0	1 (14.3)	0
Pleural effusion	1 (14.3)	0	1 (14.3)	0	0
Pulmonary oedema	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Skin and subcutaneous tissue disorders					
-Total	4 (57.1)	3 (42.9)	1 (14.3)	0	0
Erythema	2 (28.6)	2 (28.6)	0	0	0
Alopecia	1 (14.3)	0	1 (14.3)	0	0
Dermatitis diaper	1 (14.3)	1 (14.3)	0	0	0
Dry skin	1 (14.3)	1 (14.3)	0	0	0
Livedo reticularis	1 (14.3)	1 (14.3)	0	0	0
Rash erythematous	1 (14.3)	0	1 (14.3)	0	0
Rash maculo-papular	1 (14.3)	1 (14.3)	0	0	0
Vascular disorders					
-Total	5 (71.4)	0	1 (14.3)	2 (28.6)	2 (28.6)
Hypotension	4 (57.1)	0	0	2 (28.6)	2 (28.6)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Haematoma	1 (14.3)	0	1 (14.3)	0	0
Hot flush	1 (14.3)	1 (14.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (100)	0	2 (10.0)	3 (15.0)	15 (75.0)
Blood and lymphatic system disorders					
-Total	15 (75.0)	0	1 (5.0)	10 (50.0)	4 (20.0)
Febrile neutropenia	10 (50.0)	0	0	10 (50.0)	0
Anaemia	8 (40.0)	0	1 (5.0)	7 (35.0)	0
Disseminated intravascular coagulation	3 (15.0)	0	1 (5.0)	2 (10.0)	0
Neutropenia	3 (15.0)	0	0	1 (5.0)	2 (10.0)
Leukopenia	1 (5.0)	0	0	0	1 (5.0)
Lymphopenia	1 (5.0)	0	0	0	1 (5.0)
Cardiac disorders					
-Total	6 (30.0)	2 (10.0)	4 (20.0)	0	0
Tachycardia	3 (15.0)	2 (10.0)	1 (5.0)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Bradycardia	1 (5.0)	0	1 (5.0)	0	0
Pericardial effusion	1 (5.0)	0	1 (5.0)	0	0
Ventricular tachycardia	1 (5.0)	0	1 (5.0)	0	0
Ear and labyrinth disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Tympanic membrane perforation	1 (5.0)	0	1 (5.0)	0	0
Endocrine disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Adrenal insufficiency	1 (5.0)	0	1 (5.0)	0	0
Eye disorders					
-Total	6 (30.0)	4 (20.0)	2 (10.0)	0	0
Conjunctival haemorrhage	2 (10.0)	2 (10.0)	0	0	0
Periorbital oedema	2 (10.0)	2 (10.0)	0	0	0
Vision blurred	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Dry eye	1 (5.0)	1 (5.0)	0	0	0
Retinal haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Uveitis	1 (5.0)	0	1 (5.0)	0	0
Gastrointestinal disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (65.0)	4 (20.0)	4 (20.0)	5 (25.0)	0
Diarrhoea	7 (35.0)	3 (15.0)	3 (15.0)	1 (5.0)	0
Nausea	7 (35.0)	2 (10.0)	3 (15.0)	2 (10.0)	0
Vomiting	7 (35.0)	4 (20.0)	2 (10.0)	1 (5.0)	0
Constipation	5 (25.0)	5 (25.0)	0	0	0
Abdominal pain	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Dysphagia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Abdominal pain upper	1 (5.0)	0	1 (5.0)	0	0
Flatulence	1 (5.0)	1 (5.0)	0	0	0
Gastrooesophageal reflux disease	1 (5.0)	1 (5.0)	0	0	0
Glossodynia	1 (5.0)	1 (5.0)	0	0	0
Haematemesis	1 (5.0)	1 (5.0)	0	0	0
Ileus	1 (5.0)	0	0	1 (5.0)	0
Pancreatitis	1 (5.0)	0	1 (5.0)	0	0
Tooth socket haemorrhage	1 (5.0)	1 (5.0)	0	0	0
General disorders and administration site conditions					
-Total	13 (65.0)	5 (25.0)	2 (10.0)	6 (30.0)	0
Pyrexia	6 (30.0)	1 (5.0)	1 (5.0)	4 (20.0)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	5 (25.0)	5 (25.0)	0	0	0
Generalised oedema	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Oedema peripheral	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Acquired gene mutation	1 (5.0)	1 (5.0)	0	0	0
Catheter site haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Catheter site pain	1 (5.0)	0	1 (5.0)	0	0
Chills	1 (5.0)	1 (5.0)	0	0	0
Face oedema	1 (5.0)	0	0	1 (5.0)	0
Injection site haematoma	1 (5.0)	1 (5.0)	0	0	0
Localised oedema	1 (5.0)	0	0	1 (5.0)	0
Mucosal haemorrhage	1 (5.0)	0	1 (5.0)	0	0
Multiple organ dysfunction syndrome	1 (5.0)	0	0	1 (5.0)	0
Pain	1 (5.0)	0	1 (5.0)	0	0
Physical deconditioning	1 (5.0)	0	0	1 (5.0)	0
Hepatobiliary disorders					
-Total	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Gallbladder enlargement	1 (5.0)	1 (5.0)	0	0	0
Hepatosplenomegaly	1 (5.0)	1 (5.0)	0	0	0
Hyperbilirubinaemia	1 (5.0)	0	0	1 (5.0)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	16 (80.0)	1 (5.0)	7 (35.0)	3 (15.0)	5 (25.0)
Cytokine release syndrome	16 (80.0)	2 (10.0)	7 (35.0)	2 (10.0)	5 (25.0)
Hypogammaglobulinaemia	9 (45.0)	0	7 (35.0)	2 (10.0)	0
Immunodeficiency common variable	2 (10.0)	0	2 (10.0)	0	0
Chronic graft versus host disease	1 (5.0)	0	1 (5.0)	0	0
Graft versus host disease in gastrointestinal tract	1 (5.0)	0	1 (5.0)	0	0
Seasonal allergy	1 (5.0)	1 (5.0)	0	0	0
Infections and infestations					
-Total	17 (85.0)	2 (10.0)	7 (35.0)	7 (35.0)	1 (5.0)
Gastroenteritis	3 (15.0)	0	2 (10.0)	1 (5.0)	0
Influenza	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Clostridium difficile infection	2 (10.0)	0	2 (10.0)	0	0
Otitis media	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Pneumonia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Staphylococcal infection	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Urinary tract infection	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Catheter site cellulitis	1 (5.0)	1 (5.0)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	1 (5.0)	0	0	1 (5.0)	0
Cytomegalovirus infection	1 (5.0)	1 (5.0)	0	0	0
Enterococcal infection	1 (5.0)	1 (5.0)	0	0	0
Escherichia urinary tract infection	1 (5.0)	0	0	1 (5.0)	0
Gastroenteritis norovirus	1 (5.0)	0	1 (5.0)	0	0
Gingivitis	1 (5.0)	1 (5.0)	0	0	0
Haemophilus infection	1 (5.0)	0	1 (5.0)	0	0
Herpes zoster	1 (5.0)	0	0	1 (5.0)	0
Meningitis aseptic	1 (5.0)	0	1 (5.0)	0	0
Oral herpes	1 (5.0)	0	1 (5.0)	0	0
Otitis media acute	1 (5.0)	0	1 (5.0)	0	0
Parainfluenzae virus infection	1 (5.0)	1 (5.0)	0	0	0
Pharyngitis	1 (5.0)	0	1 (5.0)	0	0
Rash pustular	1 (5.0)	0	1 (5.0)	0	0
Rhinitis	1 (5.0)	1 (5.0)	0	0	0
Rhinovirus infection	1 (5.0)	1 (5.0)	0	0	0
Sepsis	1 (5.0)	0	0	0	1 (5.0)
Sinusitis	1 (5.0)	0	1 (5.0)	0	0
Streptococcal infection	1 (5.0)	0	1 (5.0)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Subcutaneous abscess	1 (5.0)	0	1 (5.0)	0	0
Upper respiratory tract infection	1 (5.0)	1 (5.0)	0	0	0
Viral infection	1 (5.0)	1 (5.0)	0	0	0
Viral upper respiratory tract infection	1 (5.0)	0	0	1 (5.0)	0
Vulvovaginal mycotic infection	1 (5.0)	0	1 (5.0)	0	0
Injury, poisoning and procedural complications					
-Total	5 (25.0)	4 (20.0)	0	0	1 (5.0)
Contusion	1 (5.0)	1 (5.0)	0	0	0
Post procedural haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Procedural complication	1 (5.0)	1 (5.0)	0	0	0
Subdural haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Transfusion reaction	1 (5.0)	1 (5.0)	0	0	0
Transfusion related complication	1 (5.0)	0	0	0	1 (5.0)
Investigations					
-Total	16 (80.0)	0	0	4 (20.0)	12 (60.0)
White blood cell count decreased	11 (55.0)	2 (10.0)	0	5 (25.0)	4 (20.0)
Neutrophil count decreased	9 (45.0)	0	0	2 (10.0)	7 (35.0)
Platelet count decreased	9 (45.0)	0	2 (10.0)	1 (5.0)	6 (30.0)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

			All patients N=20		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	7 (35.0)	2 (10.0)	1 (5.0)	4 (20.0)	0
Aspartate aminotransferase increased	7 (35.0)	1 (5.0)	2 (10.0)	3 (15.0)	1 (5.0)
Lymphocyte count decreased	6 (30.0)	0	0	3 (15.0)	3 (15.0)
Blood creatinine increased	4 (20.0)	2 (10.0)	1 (5.0)	1 (5.0)	0
Activated partial thromboplastin time prolonged	3 (15.0)	1 (5.0)	2 (10.0)	0	0
International normalised ratio increased	3 (15.0)	3 (15.0)	0	0	0
Prothrombin time prolonged	3 (15.0)	3 (15.0)	0	0	0
Blood bilirubin increased	2 (10.0)	0	2 (10.0)	0	0
Blood fibrinogen decreased	1 (5.0)	0	0	0	1 (5.0)
Blood immunoglobulin a decreased	1 (5.0)	1 (5.0)	0	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Blood phosphorus decreased	1 (5.0)	1 (5.0)	0	0	0
Blood phosphorus increased	1 (5.0)	1 (5.0)	0	0	0
Blood urea increased	1 (5.0)	0	0	1 (5.0)	0
Haemoglobin decreased	1 (5.0)	0	0	1 (5.0)	0
Hepatic enzyme increased	1 (5.0)	0	1 (5.0)	0	0
Lipase increased	1 (5.0)	0	0	0	1 (5.0)
Protein total decreased	1 (5.0)	0	0	1 (5.0)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	1 (5.0)	0	1 (5.0)	0	0
Weight increased	1 (5.0)	1 (5.0)	0	0	0
Metabolism and nutrition disorders					
-Total	13 (65.0)	3 (15.0)	0	7 (35.0)	3 (15.0)
Decreased appetite	5 (25.0)	1 (5.0)	1 (5.0)	3 (15.0)	0
Hypokalaemia	5 (25.0)	1 (5.0)	0	3 (15.0)	1 (5.0)
Hyperphosphataemia	4 (20.0)	4 (20.0)	0	0	0
Hypernatraemia	3 (15.0)	1 (5.0)	1 (5.0)	0	1 (5.0)
Hypophosphataemia	3 (15.0)	1 (5.0)	0	2 (10.0)	0
Acidosis	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Dehydration	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Hyperglycaemia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Hyperuricaemia	2 (10.0)	1 (5.0)	0	0	1 (5.0)
Hyperalbuminaemia	1 (5.0)	1 (5.0)	0	0	0
Hypercalcaemia	1 (5.0)	1 (5.0)	0	0	0
Hyperchloraemia	1 (5.0)	1 (5.0)	0	0	0
Hypermagnesaemia	1 (5.0)	1 (5.0)	0	0	0
Hypertriglyceridaemia	1 (5.0)	0	0	1 (5.0)	0
Hypoalbuminaemia	1 (5.0)	0	1 (5.0)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	1 (5.0)	1 (5.0)	0	0	0
Iron overload	1 (5.0)	0	0	1 (5.0)	0
Metabolic alkalosis	1 (5.0)	1 (5.0)	0	0	0
Tumour lysis syndrome	1 (5.0)	0	0	1 (5.0)	0
Vitamin d deficiency	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (35.0)	2 (10.0)	5 (25.0)	0	0
Arthralgia	2 (10.0)	2 (10.0)	0	0	0
Muscular weakness	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Musculoskeletal chest pain	2 (10.0)	2 (10.0)	0	0	0
Pain in extremity	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Coccydynia	1 (5.0)	1 (5.0)	0	0	0
Flank pain	1 (5.0)	0	1 (5.0)	0	0
Musculoskeletal pain	1 (5.0)	0	1 (5.0)	0	0
Osteonecrosis	1 (5.0)	0	1 (5.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (10.0)	0	1 (5.0)	0	1 (5.0)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Glioblastoma multiforme	1 (5.0)	0	0	0	1 (5.0)
Myelodysplastic syndrome	1 (5.0)	0	1 (5.0)	0	0
Nervous system disorders					
-Total	13 (65.0)	6 (30.0)	5 (25.0)	2 (10.0)	0
Headache	9 (45.0)	6 (30.0)	3 (15.0)	0	0
Dysarthria	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Encephalopathy	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Seizure	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Tremor	2 (10.0)	2 (10.0)	0	0	0
Asterixis	1 (5.0)	1 (5.0)	0	0	0
Ataxia	1 (5.0)	0	1 (5.0)	0	0
Depressed level of consciousness	1 (5.0)	1 (5.0)	0	0	0
Dizziness	1 (5.0)	1 (5.0)	0	0	0
Neuropathy peripheral	1 (5.0)	0	1 (5.0)	0	0
Pleocytosis	1 (5.0)	1 (5.0)	0	0	0
Somnolence	1 (5.0)	1 (5.0)	0	0	0
Product issues					
-Total	1 (5.0)	1 (5.0)	0	0	0
Device occlusion	1 (5.0)	1 (5.0)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	5 (25.0)	3 (15.0)	2 (10.0)	0	0
Delirium	2 (10.0)	0	2 (10.0)	0	0
Adjustment disorder	1 (5.0)	0	1 (5.0)	0	0
Agitation	1 (5.0)	0	1 (5.0)	0	0
Anxiety	1 (5.0)	0	1 (5.0)	0	0
Confusional state	1 (5.0)	1 (5.0)	0	0	0
Depression	1 (5.0)	1 (5.0)	0	0	0
Hallucination	1 (5.0)	1 (5.0)	0	0	0
Insomnia	1 (5.0)	0	1 (5.0)	0	0
Irritability	1 (5.0)	1 (5.0)	0	0	0
Suicidal ideation	1 (5.0)	1 (5.0)	0	0	0
Renal and urinary disorders					
-Total	6 (30.0)	1 (5.0)	1 (5.0)	4 (20.0)	0
Acute kidney injury	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0
Calculus urinary	1 (5.0)	0	1 (5.0)	0	0
Haematuria	1 (5.0)	0	0	1 (5.0)	0
Nephrolithiasis	1 (5.0)	0	0	1 (5.0)	0
Renal impairment	1 (5.0)	0	0	1 (5.0)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Ovarian failure	1 (5.0)	0	0	1 (5.0)	0
Vulvovaginal adhesion	1 (5.0)	1 (5.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	12 (60.0)	5 (25.0)	0	4 (20.0)	3 (15.0)
Epistaxis	5 (25.0)	2 (10.0)	1 (5.0)	2 (10.0)	0
Pulmonary oedema	4 (20.0)	1 (5.0)	0	2 (10.0)	1 (5.0)
Pleural effusion	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Tachypnoea	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Cough	2 (10.0)	2 (10.0)	0	0	0
Hypoxia	2 (10.0)	0	0	2 (10.0)	0
Nasal congestion	2 (10.0)	2 (10.0)	0	0	0
Oropharyngeal pain	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Acute respiratory failure	1 (5.0)	0	0	0	1 (5.0)
Haemoptysis	1 (5.0)	1 (5.0)	0	0	0
Oropharyngeal plaque	1 (5.0)	1 (5.0)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	1 (5.0)	0	0	0	1 (5.0)
Respiratory failure	1 (5.0)	0	0	0	1 (5.0)
Rhinorrhoea	1 (5.0)	1 (5.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (55.0)	7 (35.0)	3 (15.0)	1 (5.0)	0
Dry skin	4 (20.0)	4 (20.0)	0	0	0
Hyperhidrosis	3 (15.0)	3 (15.0)	0	0	0
Petechiae	3 (15.0)	3 (15.0)	0	0	0
Rash	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Papule	2 (10.0)	2 (10.0)	0	0	0
Ecchymosis	1 (5.0)	0	0	1 (5.0)	0
Eczema	1 (5.0)	1 (5.0)	0	0	0
Erythema	1 (5.0)	1 (5.0)	0	0	0
Ingrowing nail	1 (5.0)	0	1 (5.0)	0	0
Keloid scar	1 (5.0)	0	1 (5.0)	0	0
Macule	1 (5.0)	1 (5.0)	0	0	0
Pruritus	1 (5.0)	1 (5.0)	0	0	0
Rash erythematous	1 (5.0)	1 (5.0)	0	0	0
Rash macular	1 (5.0)	1 (5.0)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash papular	1 (5.0)	1 (5.0)	0	0	0
Rash pruritic	1 (5.0)	1 (5.0)	0	0	0
Rash vesicular	1 (5.0)	1 (5.0)	0	0	0
Skin exfoliation	1 (5.0)	1 (5.0)	0	0	0
Skin fissures	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	6 (30.0)	0	2 (10.0)	1 (5.0)	3 (15.0)
Hypotension	4 (20.0)	0	0	1 (5.0)	3 (15.0)
Hypertension	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Capillary leak syndrome	1 (5.0)	0	0	0	1 (5.0)
Flushing	1 (5.0)	1 (5.0)	0	0	0
Orthostatic hypotension	1 (5.0)	0	1 (5.0)	0	0
Secondary hypertension	1 (5.0)	0	1 (5.0)	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

			All patients N=21		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (100)	0	0	5 (23.8)	16 (76.2)
Blood and lymphatic system disorders					
-Total	17 (81.0)	1 (4.8)	1 (4.8)	8 (38.1)	7 (33.3)
Febrile neutropenia	9 (42.9)	0	0	8 (38.1)	1 (4.8)
Anaemia	7 (33.3)	0	2 (9.5)	5 (23.8)	0
Thrombocytopenia	5 (23.8)	0	1 (4.8)	0	4 (19.0)
Neutropenia	4 (19.0)	0	0	2 (9.5)	2 (9.5)
Lymphopenia	2 (9.5)	0	1 (4.8)	1 (4.8)	0
Coagulopathy	1 (4.8)	1 (4.8)	0	0	0
Disseminated intravascular coagulation	1 (4.8)	0	1 (4.8)	0	0
Lymphadenopathy	1 (4.8)	0	1 (4.8)	0	0
Pancytopenia	1 (4.8)	0	0	0	1 (4.8)

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	7 (33.3)	3 (14.3)	4 (19.0)	0	0
Tachycardia	5 (23.8)	2 (9.5)	3 (14.3)	0	0
Atrioventricular block second degree	1 (4.8)	1 (4.8)	0	0	0
Sinus bradycardia	1 (4.8)	1 (4.8)	0	0	0
Sinus tachycardia	1 (4.8)	0	1 (4.8)	0	0
Ear and labyrinth disorders					
-Total	1 (4.8)	0	1 (4.8)	0	0
Hypoacusis	1 (4.8)	0	1 (4.8)	0	0
Eye disorders					
-Total	6 (28.6)	4 (19.0)	2 (9.5)	0	0
Eye pain	2 (9.5)	0	2 (9.5)	0	0
Photophobia	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Vision blurred	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Conjunctival haemorrhage	1 (4.8)	1 (4.8)	0	0	0
Conjunctivitis allergic	1 (4.8)	1 (4.8)	0	0	0
Periorbital oedema	1 (4.8)	1 (4.8)	0	0	0
Retinal haemorrhage	1 (4.8)	1 (4.8)	0	0	0
Gastrointestinal disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (57.1)	3 (14.3)	5 (23.8)	4 (19.0)	0
Nausea	8 (38.1)	1 (4.8)	5 (23.8)	2 (9.5)	0
Vomiting	8 (38.1)	4 (19.0)	2 (9.5)	2 (9.5)	0
Diarrhoea	7 (33.3)	4 (19.0)	2 (9.5)	1 (4.8)	0
Abdominal pain	2 (9.5)	1 (4.8)	0	1 (4.8)	0
Abdominal discomfort	1 (4.8)	1 (4.8)	0	0	0
Abdominal pain upper	1 (4.8)	0	1 (4.8)	0	0
Anal incontinence	1 (4.8)	1 (4.8)	0	0	0
Ascites	1 (4.8)	0	0	1 (4.8)	0
Constipation	1 (4.8)	0	1 (4.8)	0	0
Dyspepsia	1 (4.8)	0	1 (4.8)	0	0
Gastrointestinal haemorrhage	1 (4.8)	1 (4.8)	0	0	0
Intestinal obstruction	1 (4.8)	0	0	1 (4.8)	0
Pancreatitis	1 (4.8)	0	0	1 (4.8)	0
Stomatitis	1 (4.8)	0	1 (4.8)	0	0
General disorders and administration site conditions					
-Total	12 (57.1)	5 (23.8)	7 (33.3)	0	0
Pyrexia	8 (38.1)	2 (9.5)	6 (28.6)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	6 (28.6)	5 (23.8)	1 (4.8)	0	0
Fatigue	3 (14.3)	2 (9.5)	1 (4.8)	0	0
Malaise	3 (14.3)	1 (4.8)	2 (9.5)	0	0
Catheter site pain	1 (4.8)	0	1 (4.8)	0	0
Influenza like illness	1 (4.8)	1 (4.8)	0	0	0
Non-cardiac chest pain	1 (4.8)	1 (4.8)	0	0	0
Hepatobiliary disorders					
-Total	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Hepatomegaly	1 (4.8)	1 (4.8)	0	0	0
Hyperbilirubinaemia	1 (4.8)	0	1 (4.8)	0	0
Immune system disorders					
-Total	20 (95.2)	0	13 (61.9)	6 (28.6)	1 (4.8)
Cytokine release syndrome	18 (85.7)	1 (4.8)	12 (57.1)	4 (19.0)	1 (4.8)
Hypogammaglobulinaemia	12 (57.1)	1 (4.8)	8 (38.1)	3 (14.3)	0
Drug hypersensitivity	1 (4.8)	0	1 (4.8)	0	0
Immunodeficiency	1 (4.8)	0	1 (4.8)	0	0
Seasonal allergy	1 (4.8)	1 (4.8)	0	0	0
Infections and infestations					
-Total	14 (66.7)	1 (4.8)	8 (38.1)	2 (9.5)	3 (14.3)

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	3 (14.3)	3 (14.3)	0	0	0
Clostridium difficile colitis	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Pneumonia	2 (9.5)	0	2 (9.5)	0	0
Sinusitis	2 (9.5)	0	2 (9.5)	0	0
Upper respiratory tract infection	2 (9.5)	0	2 (9.5)	0	0
Viral upper respiratory tract infection	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Acute sinusitis	1 (4.8)	0	1 (4.8)	0	0
Bacterial sepsis	1 (4.8)	0	0	0	1 (4.8)
Catheter site infection	1 (4.8)	0	0	1 (4.8)	0
Cholecystitis infective	1 (4.8)	0	0	1 (4.8)	0
Clostridium difficile infection	1 (4.8)	0	1 (4.8)	0	0
Folliculitis	1 (4.8)	0	1 (4.8)	0	0
Gastroenteritis	1 (4.8)	1 (4.8)	0	0	0
Gastroenteritis viral	1 (4.8)	1 (4.8)	0	0	0
Influenza	1 (4.8)	0	1 (4.8)	0	0
Molluscum contagiosum	1 (4.8)	1 (4.8)	0	0	0
Orchitis	1 (4.8)	1 (4.8)	0	0	0
Otitis externa	1 (4.8)	0	1 (4.8)	0	0
Parainfluenzae virus infection	1 (4.8)	0	0	1 (4.8)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	1 (4.8)	1 (4.8)	0	0	0
Respiratory tract infection	1 (4.8)	0	0	0	1 (4.8)
Septic embolus	1 (4.8)	0	0	0	1 (4.8)
Urinary tract infection	1 (4.8)	0	1 (4.8)	0	0
Urinary tract infection enterococcal	1 (4.8)	0	0	1 (4.8)	0
Injury, poisoning and procedural complications					
-Total	8 (38.1)	5 (23.8)	2 (9.5)	1 (4.8)	0
Procedural pain	3 (14.3)	2 (9.5)	0	1 (4.8)	0
Arthropod bite	1 (4.8)	1 (4.8)	0	0	0
Foot fracture	1 (4.8)	0	1 (4.8)	0	0
Incision site pain	1 (4.8)	1 (4.8)	0	0	0
Infusion related reaction	1 (4.8)	1 (4.8)	0	0	0
Radius fracture	1 (4.8)	0	1 (4.8)	0	0
Skin abrasion	1 (4.8)	1 (4.8)	0	0	0
Stoma site irritation	1 (4.8)	1 (4.8)	0	0	0
Tibia fracture	1 (4.8)	0	1 (4.8)	0	0
Transfusion reaction	1 (4.8)	1 (4.8)	0	0	0
Investigations					

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	20 (95.2)	1 (4.8)	0	9 (42.9)	10 (47.6)
White blood cell count decreased	13 (61.9)	0	0	5 (23.8)	8 (38.1)
Alanine aminotransferase increased	9 (42.9)	2 (9.5)	0	7 (33.3)	0
Neutrophil count decreased	8 (38.1)	0	0	2 (9.5)	6 (28.6)
Aspartate aminotransferase increased	6 (28.6)	2 (9.5)	0	4 (19.0)	0
Platelet count decreased	6 (28.6)	2 (9.5)	0	2 (9.5)	2 (9.5)
Lymphocyte count decreased	4 (19.0)	0	0	2 (9.5)	2 (9.5)
Prothrombin time prolonged	4 (19.0)	2 (9.5)	1 (4.8)	1 (4.8)	0
Transaminases increased	3 (14.3)	3 (14.3)	0	0	0
Weight decreased	3 (14.3)	0	3 (14.3)	0	0
Blood bilirubin increased	2 (9.5)	0	1 (4.8)	1 (4.8)	0
Blood fibrinogen decreased	2 (9.5)	0	0	2 (9.5)	0
C-reactive protein increased	2 (9.5)	1 (4.8)	0	1 (4.8)	0
International normalised ratio increased	2 (9.5)	1 (4.8)	0	1 (4.8)	0
Blood alkaline phosphatase increased	1 (4.8)	1 (4.8)	0	0	0
Blood creatinine increased	1 (4.8)	1 (4.8)	0	0	0
Blood immunoglobulin g decreased	1 (4.8)	0	1 (4.8)	0	0
Blood immunoglobulin m decreased	1 (4.8)	1 (4.8)	0	0	0
Blood lactate dehydrogenase increased	1 (4.8)	1 (4.8)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood sodium increased	1 (4.8)	0	1 (4.8)	0	0
Blood urea increased	1 (4.8)	1 (4.8)	0	0	0
Haemoglobin decreased	1 (4.8)	1 (4.8)	0	0	0
Lipase increased	1 (4.8)	0	0	0	1 (4.8)
Oxygen saturation decreased	1 (4.8)	1 (4.8)	0	0	0
Metabolism and nutrition disorders					
-Total	15 (71.4)	1 (4.8)	3 (14.3)	10 (47.6)	1 (4.8)
Decreased appetite	9 (42.9)	1 (4.8)	2 (9.5)	6 (28.6)	0
Hypokalaemia	6 (28.6)	1 (4.8)	2 (9.5)	3 (14.3)	0
Hypophosphataemia	4 (19.0)	0	0	3 (14.3)	1 (4.8)
Hyperphosphataemia	2 (9.5)	2 (9.5)	0	0	0
Hyponatraemia	2 (9.5)	0	0	2 (9.5)	0
Dehydration	1 (4.8)	0	0	1 (4.8)	0
Fluid overload	1 (4.8)	0	1 (4.8)	0	0
Hyperglycaemia	1 (4.8)	0	0	1 (4.8)	0
Hypertriglyceridaemia	1 (4.8)	1 (4.8)	0	0	0
Hypoalbuminaemia	1 (4.8)	0	0	1 (4.8)	0
Hypomagnesaemia	1 (4.8)	1 (4.8)	0	0	0
Malnutrition	1 (4.8)	0	0	1 (4.8)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	1 (4.8)	0	1 (4.8)	0	0
Tumour lysis syndrome	1 (4.8)	0	0	1 (4.8)	0
Musculoskeletal and connective tissue disorders					
-Total	7 (33.3)	5 (23.8)	2 (9.5)	0	0
Pain in extremity	3 (14.3)	2 (9.5)	1 (4.8)	0	0
Arthralgia	1 (4.8)	0	1 (4.8)	0	0
Limb discomfort	1 (4.8)	1 (4.8)	0	0	0
Musculoskeletal pain	1 (4.8)	1 (4.8)	0	0	0
Myalgia	1 (4.8)	1 (4.8)	0	0	0
Osteopenia	1 (4.8)	0	1 (4.8)	0	0
Toe walking	1 (4.8)	1 (4.8)	0	0	0
Nervous system disorders					
-Total	10 (47.6)	3 (14.3)	4 (19.0)	2 (9.5)	1 (4.8)
Headache	6 (28.6)	3 (14.3)	1 (4.8)	2 (9.5)	0
Dizziness	2 (9.5)	2 (9.5)	0	0	0
Disturbance in attention	1 (4.8)	1 (4.8)	0	0	0
Embolic stroke	1 (4.8)	0	0	0	1 (4.8)
Encephalopathy	1 (4.8)	0	0	1 (4.8)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Migraine	1 (4.8)	0	1 (4.8)	0	0
Peroneal nerve palsy	1 (4.8)	0	1 (4.8)	0	0
Seizure	1 (4.8)	0	1 (4.8)	0	0
Psychiatric disorders					
-Total	6 (28.6)	3 (14.3)	3 (14.3)	0	0
Anxiety	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Confusional state	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Delirium	1 (4.8)	1 (4.8)	0	0	0
Mental status changes	1 (4.8)	1 (4.8)	0	0	0
Panic attack	1 (4.8)	0	1 (4.8)	0	0
Renal and urinary disorders					
-Total	5 (23.8)	1 (4.8)	1 (4.8)	2 (9.5)	1 (4.8)
Acute kidney injury	3 (14.3)	0	0	2 (9.5)	1 (4.8)
Dysuria	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Haematuria	1 (4.8)	0	1 (4.8)	0	0
Pollakiuria	1 (4.8)	1 (4.8)	0	0	0
Reproductive system and breast disorders					
-Total	1 (4.8)	0	0	1 (4.8)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal haemorrhage	1 (4.8)	0	0	1 (4.8)	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (47.6)	3 (14.3)	4 (19.0)	1 (4.8)	2 (9.5)
Cough	5 (23.8)	4 (19.0)	1 (4.8)	0	0
Hypoxia	3 (14.3)	0	1 (4.8)	1 (4.8)	1 (4.8)
Rhinitis allergic	3 (14.3)	2 (9.5)	1 (4.8)	0	0
Pleural effusion	2 (9.5)	1 (4.8)	0	1 (4.8)	0
Rhinorrhoea	2 (9.5)	2 (9.5)	0	0	0
Atelectasis	1 (4.8)	1 (4.8)	0	0	0
Dysphonia	1 (4.8)	1 (4.8)	0	0	0
Epistaxis	1 (4.8)	1 (4.8)	0	0	0
Nasal congestion	1 (4.8)	1 (4.8)	0	0	0
Oropharyngeal pain	1 (4.8)	1 (4.8)	0	0	0
Pharyngeal ulceration	1 (4.8)	0	1 (4.8)	0	0
Pulmonary oedema	1 (4.8)	0	0	1 (4.8)	0
Respiratory depression	1 (4.8)	0	1 (4.8)	0	0
Respiratory failure	1 (4.8)	0	0	0	1 (4.8)
Tachypnoea	1 (4.8)	1 (4.8)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=21 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	8 (38.1)	4 (19.0)	2 (9.5)	2 (9.5)	0
Erythema	2 (9.5)	2 (9.5)	0	0	0
Ingrowing nail	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Pruritus	2 (9.5)	2 (9.5)	0	0	0
Rash	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Rash maculo-papular	2 (9.5)	0	1 (4.8)	1 (4.8)	0
Acne	1 (4.8)	1 (4.8)	0	0	0
Dermatitis	1 (4.8)	1 (4.8)	0	0	0
Dermatitis acneiform	1 (4.8)	0	0	1 (4.8)	0
Hyperhidrosis	1 (4.8)	1 (4.8)	0	0	0
Vascular disorders					
-Total	8 (38.1)	2 (9.5)	2 (9.5)	3 (14.3)	1 (4.8)
Hypertension	4 (19.0)	1 (4.8)	3 (14.3)	0	0
Hypotension	4 (19.0)	0	0	3 (14.3)	1 (4.8)
Orthostatic hypotension	1 (4.8)	1 (4.8)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 174r
Adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

			All patients N=16		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (100)	0	2 (12.5)	4 (25.0)	10 (62.5)
Blood and lymphatic system disorders					
-Total	11 (68.8)	0	1 (6.3)	7 (43.8)	3 (18.8)
Anaemia	8 (50.0)	1 (6.3)	1 (6.3)	6 (37.5)	0
Febrile neutropenia	3 (18.8)	0	0	3 (18.8)	0
Thrombocytopenia	3 (18.8)	0	0	2 (12.5)	1 (6.3)
Neutropenia	2 (12.5)	0	0	0	2 (12.5)
Eosinophilia	1 (6.3)	0	0	1 (6.3)	0
Lymphopenia	1 (6.3)	0	1 (6.3)	0	0
Cardiac disorders					
-Total	7 (43.8)	4 (25.0)	2 (12.5)	1 (6.3)	0
Tachycardia	5 (31.3)	3 (18.8)	1 (6.3)	1 (6.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	3 (18.8)	2 (12.5)	1 (6.3)	0	0
Cardiac dysfunction	1 (6.3)	1 (6.3)	0	0	0
Ear and labyrinth disorders					
-Total	2 (12.5)	2 (12.5)	0	0	0
Ear pain	2 (12.5)	2 (12.5)	0	0	0
Eye disorders					
-Total	5 (31.3)	1 (6.3)	4 (25.0)	0	0
Dry eye	1 (6.3)	0	1 (6.3)	0	0
Ocular hyperaemia	1 (6.3)	1 (6.3)	0	0	0
Ocular hypertension	1 (6.3)	0	1 (6.3)	0	0
Papilloedema	1 (6.3)	0	1 (6.3)	0	0
Periorbital oedema	1 (6.3)	0	1 (6.3)	0	0
Uveitis	1 (6.3)	0	1 (6.3)	0	0
Visual impairment	1 (6.3)	0	1 (6.3)	0	0
Gastrointestinal disorders					
-Total	12 (75.0)	4 (25.0)	7 (43.8)	1 (6.3)	0
Vomiting	7 (43.8)	5 (31.3)	2 (12.5)	0	0
Diarrhoea	6 (37.5)	3 (18.8)	3 (18.8)	0	0
Nausea	6 (37.5)	2 (12.5)	4 (25.0)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	5 (31.3)	2 (12.5)	3 (18.8)	0	0
Abdominal distension	2 (12.5)	0	2 (12.5)	0	0
Abdominal pain lower	1 (6.3)	0	1 (6.3)	0	0
Abdominal pain upper	1 (6.3)	1 (6.3)	0	0	0
Abdominal tenderness	1 (6.3)	1 (6.3)	0	0	0
Haematemesis	1 (6.3)	1 (6.3)	0	0	0
Lip pain	1 (6.3)	0	1 (6.3)	0	0
Mouth haemorrhage	1 (6.3)	0	0	1 (6.3)	0
Pigmentation lip	1 (6.3)	1 (6.3)	0	0	0
Stomatitis	1 (6.3)	1 (6.3)	0	0	0
General disorders and administration site conditions					
-Total	12 (75.0)	5 (31.3)	4 (25.0)	3 (18.8)	0
Pyrexia	7 (43.8)	4 (25.0)	2 (12.5)	1 (6.3)	0
Fatigue	6 (37.5)	4 (25.0)	1 (6.3)	1 (6.3)	0
Chills	2 (12.5)	2 (12.5)	0	0	0
Pain	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Catheter site extravasation	1 (6.3)	0	1 (6.3)	0	0
Catheter site pain	1 (6.3)	1 (6.3)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Crying	1 (6.3)	1 (6.3)	0	0	0
Cyst	1 (6.3)	0	0	1 (6.3)	0
Face oedema	1 (6.3)	0	1 (6.3)	0	0
Facial pain	1 (6.3)	0	1 (6.3)	0	0
Generalised oedema	1 (6.3)	0	1 (6.3)	0	0
Influenza like illness	1 (6.3)	1 (6.3)	0	0	0
Malaise	1 (6.3)	0	1 (6.3)	0	0
Oedema peripheral	1 (6.3)	1 (6.3)	0	0	0
Peripheral swelling	1 (6.3)	0	1 (6.3)	0	0
Hepatobiliary disorders					
-Total	1 (6.3)	0	0	1 (6.3)	0
Hepatomegaly	1 (6.3)	0	1 (6.3)	0	0
Hyperbilirubinaemia	1 (6.3)	0	0	1 (6.3)	0
Immune system disorders					
-Total	15 (93.8)	4 (25.0)	7 (43.8)	2 (12.5)	2 (12.5)
Cytokine release syndrome	11 (68.8)	3 (18.8)	4 (25.0)	2 (12.5)	2 (12.5)
Hypogammaglobulinaemia	7 (43.8)	2 (12.5)	5 (31.3)	0	0
Graft versus host disease	1 (6.3)	1 (6.3)	0	0	0
Graft versus host disease in skin	1 (6.3)	1 (6.3)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophagocytic lymphohistiocytosis	1 (6.3)	0	1 (6.3)	0	0
Infections and infestations					
-Total	11 (68.8)	3 (18.8)	4 (25.0)	4 (25.0)	0
Upper respiratory tract infection	4 (25.0)	3 (18.8)	0	1 (6.3)	0
Clostridium difficile infection	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Otitis media	2 (12.5)	0	2 (12.5)	0	0
Urinary tract infection	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Vulvovaginal candidiasis	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Body tinea	1 (6.3)	1 (6.3)	0	0	0
Campylobacter infection	1 (6.3)	0	0	1 (6.3)	0
Cellulitis of male external genital organ	1 (6.3)	0	0	1 (6.3)	0
Clostridium difficile colitis	1 (6.3)	0	1 (6.3)	0	0
Cytomegalovirus infection	1 (6.3)	1 (6.3)	0	0	0
Ear infection	1 (6.3)	0	1 (6.3)	0	0
Enterovirus infection	1 (6.3)	0	0	1 (6.3)	0
Fungal skin infection	1 (6.3)	1 (6.3)	0	0	0
Herpes simplex	1 (6.3)	1 (6.3)	0	0	0
Human herpesvirus 6 infection	1 (6.3)	0	1 (6.3)	0	0
Hypopyon	1 (6.3)	0	1 (6.3)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral candidiasis	1 (6.3)	1 (6.3)	0	0	0
Otitis media acute	1 (6.3)	0	1 (6.3)	0	0
Respiratory tract infection viral	1 (6.3)	0	0	1 (6.3)	0
Rotavirus infection	1 (6.3)	0	0	1 (6.3)	0
Sinusitis	1 (6.3)	0	1 (6.3)	0	0
Skin infection	1 (6.3)	0	1 (6.3)	0	0
Vascular device infection	1 (6.3)	0	0	1 (6.3)	0
Injury, poisoning and procedural complications					
-Total	7 (43.8)	2 (12.5)	5 (31.3)	0	0
Infusion related reaction	2 (12.5)	0	2 (12.5)	0	0
Procedural pain	2 (12.5)	0	2 (12.5)	0	0
Contusion	1 (6.3)	1 (6.3)	0	0	0
Limb injury	1 (6.3)	1 (6.3)	0	0	0
Mouth injury	1 (6.3)	1 (6.3)	0	0	0
Procedural headache	1 (6.3)	0	1 (6.3)	0	0
Procedural site reaction	1 (6.3)	1 (6.3)	0	0	0
Skin abrasion	1 (6.3)	1 (6.3)	0	0	0
Skin laceration	1 (6.3)	0	1 (6.3)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tongue injury	1 (6.3)	1 (6.3)	0	0	0
Transfusion reaction	1 (6.3)	0	1 (6.3)	0	0
Investigations					
-Total	13 (81.3)	1 (6.3)	4 (25.0)	0	8 (50.0)
Neutrophil count decreased	7 (43.8)	1 (6.3)	1 (6.3)	0	5 (31.3)
White blood cell count decreased	7 (43.8)	1 (6.3)	1 (6.3)	2 (12.5)	3 (18.8)
Aspartate aminotransferase increased	6 (37.5)	1 (6.3)	2 (12.5)	1 (6.3)	2 (12.5)
Alanine aminotransferase increased	5 (31.3)	1 (6.3)	1 (6.3)	3 (18.8)	0
Platelet count decreased	5 (31.3)	1 (6.3)	0	0	4 (25.0)
Lymphocyte count decreased	4 (25.0)	0	2 (12.5)	2 (12.5)	0
Blood bilirubin increased	3 (18.8)	2 (12.5)	0	1 (6.3)	0
Blood creatinine increased	3 (18.8)	2 (12.5)	0	1 (6.3)	0
International normalised ratio increased	3 (18.8)	3 (18.8)	0	0	0
Blood immunoglobulin a decreased	2 (12.5)	2 (12.5)	0	0	0
Activated partial thromboplastin time prolonged	1 (6.3)	1 (6.3)	0	0	0
Blood bicarbonate decreased	1 (6.3)	0	1 (6.3)	0	0
Blood immunoglobulin m decreased	1 (6.3)	1 (6.3)	0	0	0
Blood lactic acid increased	1 (6.3)	0	0	0	1 (6.3)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood urea increased	1 (6.3)	0	1 (6.3)	0	0
Blood uric acid increased	1 (6.3)	1 (6.3)	0	0	0
Culture stool positive	1 (6.3)	1 (6.3)	0	0	0
Haemoglobin decreased	1 (6.3)	1 (6.3)	0	0	0
Norovirus test positive	1 (6.3)	1 (6.3)	0	0	0
Prothrombin time prolonged	1 (6.3)	0	1 (6.3)	0	0
Pulmonary function test decreased	1 (6.3)	0	1 (6.3)	0	0
Serum ferritin increased	1 (6.3)	0	1 (6.3)	0	0
Weight increased	1 (6.3)	0	1 (6.3)	0	0
Metabolism and nutrition disorders					
-Total	11 (68.8)	3 (18.8)	3 (18.8)	5 (31.3)	0
Hypokalaemia	6 (37.5)	1 (6.3)	3 (18.8)	2 (12.5)	0
Decreased appetite	5 (31.3)	2 (12.5)	1 (6.3)	2 (12.5)	0
Fluid overload	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Hyperphosphataemia	2 (12.5)	2 (12.5)	0	0	0
Hypoalbuminaemia	2 (12.5)	0	2 (12.5)	0	0
Hypocalcaemia	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Hypophosphataemia	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Dehydration	1 (6.3)	0	0	1 (6.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	1 (6.3)	1 (6.3)	0	0	0
Vitamin d deficiency	1 (6.3)	1 (6.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	8 (50.0)	5 (31.3)	3 (18.8)	0	0
Myalgia	4 (25.0)	3 (18.8)	1 (6.3)	0	0
Pain in extremity	4 (25.0)	2 (12.5)	2 (12.5)	0	0
Joint range of motion decreased	2 (12.5)	2 (12.5)	0	0	0
Muscle spasms	2 (12.5)	2 (12.5)	0	0	0
Arthralgia	1 (6.3)	1 (6.3)	0	0	0
Back pain	1 (6.3)	1 (6.3)	0	0	0
Musculoskeletal pain	1 (6.3)	1 (6.3)	0	0	0
Neck pain	1 (6.3)	0	1 (6.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (6.3)	0	1 (6.3)	0	0
Skin papilloma	1 (6.3)	0	1 (6.3)	0	0
Nervous system disorders					
-Total	8 (50.0)	4 (25.0)	3 (18.8)	1 (6.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	6 (37.5)	3 (18.8)	3 (18.8)	0	0
Dizziness	2 (12.5)	2 (12.5)	0	0	0
Encephalopathy	1 (6.3)	1 (6.3)	0	0	0
Idiopathic intracranial hypertension	1 (6.3)	0	1 (6.3)	0	0
Myoclonus	1 (6.3)	1 (6.3)	0	0	0
Seizure	1 (6.3)	0	0	1 (6.3)	0
Psychiatric disorders					
-Total	3 (18.8)	1 (6.3)	1 (6.3)	1 (6.3)	0
Anxiety	3 (18.8)	1 (6.3)	1 (6.3)	1 (6.3)	0
Agitation	1 (6.3)	0	1 (6.3)	0	0
Confusional state	1 (6.3)	0	1 (6.3)	0	0
Hallucination	1 (6.3)	0	1 (6.3)	0	0
Irritability	1 (6.3)	1 (6.3)	0	0	0
Listless	1 (6.3)	1 (6.3)	0	0	0
Renal and urinary disorders					
-Total	2 (12.5)	1 (6.3)	0	0	1 (6.3)
Acute kidney injury	1 (6.3)	0	0	0	1 (6.3)
Haematuria	1 (6.3)	0	1 (6.3)	0	0
Oliguria	1 (6.3)	0	0	1 (6.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary incontinence	1 (6.3)	1 (6.3)	0	0	0
Reproductive system and breast disorders					
-Total	3 (18.8)	1 (6.3)	2 (12.5)	0	0
Oedema genital	1 (6.3)	0	1 (6.3)	0	0
Scrotal pain	1 (6.3)	0	1 (6.3)	0	0
Vulvovaginal adhesion	1 (6.3)	1 (6.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (62.5)	4 (25.0)	4 (25.0)	1 (6.3)	1 (6.3)
Cough	4 (25.0)	3 (18.8)	1 (6.3)	0	0
Hypoxia	3 (18.8)	0	2 (12.5)	0	1 (6.3)
Epistaxis	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Oropharyngeal pain	2 (12.5)	2 (12.5)	0	0	0
Pleural effusion	2 (12.5)	0	2 (12.5)	0	0
Dyspnoea	1 (6.3)	0	0	1 (6.3)	0
Nasal congestion	1 (6.3)	1 (6.3)	0	0	0
Pulmonary oedema	1 (6.3)	0	0	1 (6.3)	0
Rhinitis allergic	1 (6.3)	1 (6.3)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	1 (6.3)	1 (6.3)	0	0	0
Tachypnoea	1 (6.3)	0	0	1 (6.3)	0
Wheezing	1 (6.3)	0	1 (6.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (43.8)	4 (25.0)	3 (18.8)	0	0
Rash	3 (18.8)	2 (12.5)	1 (6.3)	0	0
Rash maculo-papular	2 (12.5)	2 (12.5)	0	0	0
Dermatitis atopic	1 (6.3)	1 (6.3)	0	0	0
Macule	1 (6.3)	1 (6.3)	0	0	0
Night sweats	1 (6.3)	0	1 (6.3)	0	0
Petechiae	1 (6.3)	0	1 (6.3)	0	0
Pruritus	1 (6.3)	1 (6.3)	0	0	0
Rash follicular	1 (6.3)	1 (6.3)	0	0	0
Rash papular	1 (6.3)	1 (6.3)	0	0	0
Skin irritation	1 (6.3)	1 (6.3)	0	0	0
Vascular disorders					
-Total	6 (37.5)	1 (6.3)	1 (6.3)	2 (12.5)	2 (12.5)
Hypotension	4 (25.0)	1 (6.3)	0	1 (6.3)	2 (12.5)
Hypertension	3 (18.8)	0	2 (12.5)	1 (6.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=16 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Embolism	1 (6.3)	0	0	1 (6.3)	0
Flushing	1 (6.3)	1 (6.3)	0	0	0

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175a
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (95.5)	2 (9.1)	4 (18.2)	7 (31.8)	8 (36.4)
Blood and lymphatic system disorders					
-Total	12 (54.5)	0	0	8 (36.4)	4 (18.2)
Anaemia	7 (31.8)	0	1 (4.5)	6 (27.3)	0
Febrile neutropenia	5 (22.7)	0	0	5 (22.7)	0
Thrombocytopenia	3 (13.6)	0	0	1 (4.5)	2 (9.1)
Neutropenia	2 (9.1)	0	0	0	2 (9.1)
Leukopenia	1 (4.5)	0	0	0	1 (4.5)
Endocrine disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Cushingoid	1 (4.5)	1 (4.5)	0	0	0
Gastrointestinal disorders					

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (13.6)	0	2 (9.1)	1 (4.5)	0
Colitis	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Nausea	1 (4.5)	0	1 (4.5)	0	0
Perianal erythema	1 (4.5)	0	1 (4.5)	0	0
General disorders and administration site conditions					
-Total	4 (18.2)	2 (9.1)	2 (9.1)	0	0
Catheter site pain	1 (4.5)	0	1 (4.5)	0	0
Gait disturbance	1 (4.5)	1 (4.5)	0	0	0
Injection site thrombosis	1 (4.5)	0	1 (4.5)	0	0
Oedema peripheral	1 (4.5)	1 (4.5)	0	0	0
Pain	1 (4.5)	0	1 (4.5)	0	0
Pyrexia	1 (4.5)	1 (4.5)	0	0	0
Hepatobiliary disorders					
-Total	1 (4.5)	0	0	1 (4.5)	0
Cholecystitis	1 (4.5)	0	0	1 (4.5)	0
Immune system disorders					
-Total	2 (9.1)	0	1 (4.5)	1 (4.5)	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypogammaglobulinaemia	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Anaphylactic reaction	1 (4.5)	0	0	1 (4.5)	0
Infections and infestations					
-Total	12 (54.5)	1 (4.5)	3 (13.6)	8 (36.4)	0
Upper respiratory tract infection	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Alpha haemolytic streptococcal infection	1 (4.5)	0	0	1 (4.5)	0
Bronchopulmonary aspergillosis	1 (4.5)	0	0	1 (4.5)	0
Clostridium difficile colitis	1 (4.5)	0	0	1 (4.5)	0
Conjunctivitis	1 (4.5)	0	1 (4.5)	0	0
Croup infectious	1 (4.5)	0	0	1 (4.5)	0
Cytomegalovirus viraemia	1 (4.5)	0	1 (4.5)	0	0
Device related infection	1 (4.5)	0	0	1 (4.5)	0
Enterococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Escherichia bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Escherichia infection	1 (4.5)	0	0	1 (4.5)	0
Metapneumovirus infection	1 (4.5)	0	1 (4.5)	0	0
Oral herpes	1 (4.5)	0	1 (4.5)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	1 (4.5)	0	1 (4.5)	0	0
Sinusitis	1 (4.5)	1 (4.5)	0	0	0
Staphylococcal infection	1 (4.5)	0	0	1 (4.5)	0
Streptococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Streptococcal infection	1 (4.5)	0	0	1 (4.5)	0
Injury, poisoning and procedural complications					
-Total	4 (18.2)	1 (4.5)	3 (13.6)	0	0
Procedural pain	1 (4.5)	0	1 (4.5)	0	0
Toxicity to various agents	1 (4.5)	0	1 (4.5)	0	0
Transfusion reaction	1 (4.5)	0	1 (4.5)	0	0
Wound	1 (4.5)	1 (4.5)	0	0	0
Investigations					
-Total	8 (36.4)	2 (9.1)	0	1 (4.5)	5 (22.7)
Neutrophil count decreased	4 (18.2)	0	0	0	4 (18.2)
White blood cell count decreased	4 (18.2)	1 (4.5)	0	0	3 (13.6)
Platelet count decreased	3 (13.6)	0	0	0	3 (13.6)
Alanine aminotransferase increased	1 (4.5)	0	0	1 (4.5)	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspartate aminotransferase increased	1 (4.5)	0	0	1 (4.5)	0
Blast cell count increased	1 (4.5)	0	0	1 (4.5)	0
Blood uric acid increased	1 (4.5)	1 (4.5)	0	0	0
Coronavirus test positive	1 (4.5)	1 (4.5)	0	0	0
Lymphocyte count decreased	1 (4.5)	0	0	1 (4.5)	0
White blood cell count increased	1 (4.5)	1 (4.5)	0	0	0
Metabolism and nutrition disorders					
-Total	6 (27.3)	0	1 (4.5)	3 (13.6)	2 (9.1)
Hyperuricaemia	4 (18.2)	2 (9.1)	0	1 (4.5)	1 (4.5)
Decreased appetite	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Dehydration	1 (4.5)	0	1 (4.5)	0	0
Hyperglycaemia	1 (4.5)	0	0	1 (4.5)	0
Hypocalcaemia	1 (4.5)	0	0	0	1 (4.5)
Hypokalaemia	1 (4.5)	1 (4.5)	0	0	0
Hypomagnesaemia	1 (4.5)	1 (4.5)	0	0	0
Hypophosphataemia	1 (4.5)	0	0	1 (4.5)	0
Tumour lysis syndrome	1 (4.5)	0	0	1 (4.5)	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal and connective tissue disorders					
-Total	5 (22.7)	1 (4.5)	3 (13.6)	1 (4.5)	0
Bone pain	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Pain in extremity	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Pain in jaw	2 (9.1)	0	2 (9.1)	0	0
Nervous system disorders					
-Total	1 (4.5)	0	1 (4.5)	0	0
Neuralgia	1 (4.5)	0	1 (4.5)	0	0
Psychiatric disorders					
-Total	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Insomnia	1 (4.5)	0	1 (4.5)	0	0
Irritability	1 (4.5)	1 (4.5)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (9.1)	0	1 (4.5)	0	1 (4.5)
Hypoxia	1 (4.5)	0	1 (4.5)	0	0
Idiopathic pneumonia syndrome	1 (4.5)	0	0	0	1 (4.5)
Pleural effusion	1 (4.5)	0	1 (4.5)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Dermatitis diaper	1 (4.5)	1 (4.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175a
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (76.9)	1 (2.6)	1 (2.6)	14 (35.9)	14 (35.9)
Blood and lymphatic system disorders					
-Total	21 (53.8)	0	0	17 (43.6)	4 (10.3)
Febrile neutropenia	12 (30.8)	0	0	12 (30.8)	0
Anaemia	9 (23.1)	0	1 (2.6)	8 (20.5)	0
Thrombocytopenia	4 (10.3)	0	0	1 (2.6)	3 (7.7)
Neutropenia	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Coagulopathy	1 (2.6)	0	0	1 (2.6)	0
Disseminated intravascular coagulation	1 (2.6)	0	0	1 (2.6)	0
Pancytopenia	1 (2.6)	0	0	0	1 (2.6)
Splenomegaly	1 (2.6)	1 (2.6)	0	0	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Bradycardia	1 (2.6)	1 (2.6)	0	0	0
Sinus tachycardia	1 (2.6)	0	0	1 (2.6)	0
Tachycardia	1 (2.6)	0	1 (2.6)	0	0
Endocrine disorders					
-Total	2 (5.1)	0	2 (5.1)	0	0
Adrenal insufficiency	1 (2.6)	0	1 (2.6)	0	0
Hyperthyroidism	1 (2.6)	0	1 (2.6)	0	0
Gastrointestinal disorders					
-Total	19 (48.7)	6 (15.4)	6 (15.4)	6 (15.4)	1 (2.6)
Abdominal pain	6 (15.4)	0	4 (10.3)	2 (5.1)	0
Vomiting	6 (15.4)	4 (10.3)	2 (5.1)	0	0
Stomatitis	5 (12.8)	1 (2.6)	0	3 (7.7)	1 (2.6)
Constipation	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Nausea	3 (7.7)	0	2 (5.1)	1 (2.6)	0
Colitis	2 (5.1)	0	0	2 (5.1)	0
Diarrhoea	2 (5.1)	1 (2.6)	0	1 (2.6)	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Anal fissure	1 (2.6)	0	1 (2.6)	0	0
Dry mouth	1 (2.6)	1 (2.6)	0	0	0
Haematemesis	1 (2.6)	0	1 (2.6)	0	0
Oral pain	1 (2.6)	0	1 (2.6)	0	0
Pancreatitis	1 (2.6)	0	1 (2.6)	0	0
Proctalgia	1 (2.6)	0	1 (2.6)	0	0
General disorders and administration site conditions					
-Total	12 (30.8)	6 (15.4)	4 (10.3)	1 (2.6)	1 (2.6)
Fatigue	5 (12.8)	3 (7.7)	1 (2.6)	1 (2.6)	0
Pyrexia	5 (12.8)	3 (7.7)	2 (5.1)	0	0
Non-cardiac chest pain	2 (5.1)	2 (5.1)	0	0	0
Asthenia	1 (2.6)	0	1 (2.6)	0	0
Catheter site bruise	1 (2.6)	1 (2.6)	0	0	0
Catheter site pain	1 (2.6)	1 (2.6)	0	0	0
Chills	1 (2.6)	1 (2.6)	0	0	0
Device related thrombosis	1 (2.6)	0	1 (2.6)	0	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	1 (2.6)	0	0	0	1 (2.6)
Hepatobiliary disorders					
-Total	1 (2.6)	0	1 (2.6)	0	0
Hyperbilirubinaemia	1 (2.6)	0	1 (2.6)	0	0
Immune system disorders					
-Total	3 (7.7)	0	2 (5.1)	1 (2.6)	0
Anaphylactic reaction	1 (2.6)	0	0	1 (2.6)	0
Drug hypersensitivity	1 (2.6)	0	1 (2.6)	0	0
Hypogammaglobulinaemia	1 (2.6)	0	1 (2.6)	0	0
Infections and infestations					
-Total	14 (35.9)	0	3 (7.7)	7 (17.9)	4 (10.3)
Device related infection	2 (5.1)	0	0	2 (5.1)	0
Oral herpes	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Staphylococcal bacteraemia	2 (5.1)	0	0	2 (5.1)	0
Bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Candida sepsis	1 (2.6)	0	0	0	1 (2.6)
Cellulitis	1 (2.6)	0	0	1 (2.6)	0
Clostridium difficile colitis	1 (2.6)	0	0	1 (2.6)	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (2.6)	0	1 (2.6)	0	0
Conjunctivitis	1 (2.6)	0	1 (2.6)	0	0
Escherichia bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Escherichia urinary tract infection	1 (2.6)	0	0	1 (2.6)	0
Fungal skin infection	1 (2.6)	0	1 (2.6)	0	0
Gastroenteritis	1 (2.6)	0	0	1 (2.6)	0
Human polyomavirus infection	1 (2.6)	0	0	0	1 (2.6)
Klebsiella infection	1 (2.6)	0	0	1 (2.6)	0
Klebsiella sepsis	1 (2.6)	0	0	0	1 (2.6)
Parainfluenzae virus infection	1 (2.6)	0	1 (2.6)	0	0
Pneumonia	1 (2.6)	0	1 (2.6)	0	0
Pneumonia fungal	1 (2.6)	0	0	1 (2.6)	0
Respiratory syncytial virus bronchitis	1 (2.6)	0	0	1 (2.6)	0
Sepsis	1 (2.6)	0	0	0	1 (2.6)
Injury, poisoning and procedural complications					
-Total	3 (7.7)	0	1 (2.6)	2 (5.1)	0
Procedural pain	2 (5.1)	0	0	2 (5.1)	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Extradural haematoma	1 (2.6)	0	0	1 (2.6)	0
Radiation skin injury	1 (2.6)	0	1 (2.6)	0	0
Subdural haematoma	1 (2.6)	0	0	1 (2.6)	0
Investigations					
-Total	18 (46.2)	1 (2.6)	3 (7.7)	4 (10.3)	10 (25.6)
Platelet count decreased	6 (15.4)	0	0	1 (2.6)	5 (12.8)
White blood cell count decreased	6 (15.4)	0	1 (2.6)	1 (2.6)	4 (10.3)
Alanine aminotransferase increased	5 (12.8)	0	1 (2.6)	4 (10.3)	0
Aspartate aminotransferase increased	4 (10.3)	1 (2.6)	1 (2.6)	2 (5.1)	0
Neutrophil count decreased	4 (10.3)	0	0	0	4 (10.3)
Blood bilirubin increased	1 (2.6)	0	0	1 (2.6)	0
Blood creatinine increased	1 (2.6)	1 (2.6)	0	0	0
Blood fibrinogen decreased	1 (2.6)	0	1 (2.6)	0	0
Blood immunoglobulin a increased	1 (2.6)	1 (2.6)	0	0	0
Blood immunoglobulin m decreased	1 (2.6)	1 (2.6)	0	0	0
Blood immunoglobulin m increased	1 (2.6)	1 (2.6)	0	0	0
Electrocardiogram qt prolonged	1 (2.6)	0	0	1 (2.6)	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	10 (25.6)	1 (2.6)	2 (5.1)	5 (12.8)	2 (5.1)
Decreased appetite	4 (10.3)	1 (2.6)	1 (2.6)	2 (5.1)	0
Dehydration	3 (7.7)	0	1 (2.6)	2 (5.1)	0
Hyperglycaemia	3 (7.7)	0	0	2 (5.1)	1 (2.6)
Hypokalaemia	3 (7.7)	0	0	1 (2.6)	2 (5.1)
Hypomagnesaemia	3 (7.7)	3 (7.7)	0	0	0
Hypernatraemia	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Hyperammonaemia	1 (2.6)	1 (2.6)	0	0	0
Hyperkalaemia	1 (2.6)	0	1 (2.6)	0	0
Hypoalbuminaemia	1 (2.6)	0	0	0	1 (2.6)
Hypocalcaemia	1 (2.6)	0	0	0	1 (2.6)
Hypophosphataemia	1 (2.6)	0	0	1 (2.6)	0
Malnutrition	1 (2.6)	0	1 (2.6)	0	0
Tumour lysis syndrome	1 (2.6)	0	0	1 (2.6)	0
Vitamin d deficiency	1 (2.6)	0	1 (2.6)	0	0
Musculoskeletal and connective tissue disorders					

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (20.5)	3 (7.7)	2 (5.1)	3 (7.7)	0
Pain in extremity	4 (10.3)	1 (2.6)	1 (2.6)	2 (5.1)	0
Back pain	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Neck pain	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Arthralgia	1 (2.6)	0	1 (2.6)	0	0
Muscle spasms	1 (2.6)	1 (2.6)	0	0	0
Musculoskeletal chest pain	1 (2.6)	1 (2.6)	0	0	0
Nervous system disorders					
-Total	8 (20.5)	2 (5.1)	2 (5.1)	4 (10.3)	0
Headache	7 (17.9)	2 (5.1)	2 (5.1)	3 (7.7)	0
Leukoencephalopathy	1 (2.6)	0	0	1 (2.6)	0
Psychiatric disorders					
-Total	5 (12.8)	2 (5.1)	2 (5.1)	1 (2.6)	0
Mental status changes	3 (7.7)	2 (5.1)	0	1 (2.6)	0
Confusional state	1 (2.6)	0	1 (2.6)	0	0
Depression	1 (2.6)	1 (2.6)	0	0	0
Insomnia	1 (2.6)	0	1 (2.6)	0	0
Renal and urinary disorders					

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (10.3)	1 (2.6)	0	1 (2.6)	2 (5.1)
Cystitis haemorrhagic	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Acute kidney injury	1 (2.6)	0	0	0	1 (2.6)
Haematuria	1 (2.6)	1 (2.6)	0	0	0
Reproductive system and breast disorders					
-Total	1 (2.6)	0	1 (2.6)	0	0
Scrotal pain	1 (2.6)	0	1 (2.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (12.8)	0	2 (5.1)	1 (2.6)	2 (5.1)
Hypoxia	3 (7.7)	0	2 (5.1)	0	1 (2.6)
Cough	1 (2.6)	1 (2.6)	0	0	0
Epistaxis	1 (2.6)	0	0	1 (2.6)	0
Pulmonary mass	1 (2.6)	0	1 (2.6)	0	0
Pulmonary oedema	1 (2.6)	0	0	0	1 (2.6)
Respiratory failure	1 (2.6)	0	0	0	1 (2.6)
Skin and subcutaneous tissue disorders					

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	7 (17.9)	5 (12.8)	2 (5.1)	0	0
Rash erythematous	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Rash papular	2 (5.1)	2 (5.1)	0	0	0
Cold sweat	1 (2.6)	1 (2.6)	0	0	0
Night sweats	1 (2.6)	1 (2.6)	0	0	0
Rash	1 (2.6)	1 (2.6)	0	0	0
Skin irritation	1 (2.6)	1 (2.6)	0	0	0
Urticaria	1 (2.6)	0	1 (2.6)	0	0
Vascular disorders					
-Total	6 (15.4)	1 (2.6)	0	4 (10.3)	1 (2.6)
Hypotension	5 (12.8)	0	0	4 (10.3)	1 (2.6)
Hypertension	1 (2.6)	1 (2.6)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of

all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175a
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (92.9)	0	1 (7.1)	5 (35.7)	7 (50.0)
Blood and lymphatic system disorders					
-Total	8 (57.1)	1 (7.1)	0	4 (28.6)	3 (21.4)
Anaemia	5 (35.7)	0	0	5 (35.7)	0
Thrombocytopenia	3 (21.4)	0	0	1 (7.1)	2 (14.3)
Neutropenia	2 (14.3)	0	0	0	2 (14.3)
Coagulopathy	1 (7.1)	1 (7.1)	0	0	0
Disseminated intravascular coagulation	1 (7.1)	0	0	1 (7.1)	0
Febrile neutropenia	1 (7.1)	0	0	1 (7.1)	0
Leukocytosis	1 (7.1)	1 (7.1)	0	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphopenia	1 (7.1)	0	0	0	1 (7.1)
Pancytopenia	1 (7.1)	0	0	0	1 (7.1)
Cardiac disorders					
-Total	6 (42.9)	0	2 (14.3)	2 (14.3)	2 (14.3)
Pericardial effusion	2 (14.3)	0	2 (14.3)	0	0
Tachycardia	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Bradycardia	1 (7.1)	0	0	0	1 (7.1)
Cardiovascular insufficiency	1 (7.1)	0	0	0	1 (7.1)
Left ventricular dysfunction	1 (7.1)	0	0	1 (7.1)	0
Right ventricular dysfunction	1 (7.1)	0	0	1 (7.1)	0
Sinus tachycardia	1 (7.1)	0	0	1 (7.1)	0
Ventricular tachycardia	1 (7.1)	0	0	1 (7.1)	0
Ear and labyrinth disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0
Deafness unilateral	1 (7.1)	0	1 (7.1)	0	0
Eye disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Photophobia	1 (7.1)	0	1 (7.1)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Retinopathy	1 (7.1)	0	1 (7.1)	0	0
Gastrointestinal disorders					
-Total	6 (42.9)	0	4 (28.6)	2 (14.3)	0
Nausea	6 (42.9)	0	4 (28.6)	2 (14.3)	0
Abdominal pain	3 (21.4)	1 (7.1)	1 (7.1)	1 (7.1)	0
Vomiting	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Constipation	2 (14.3)	2 (14.3)	0	0	0
Diarrhoea	1 (7.1)	0	1 (7.1)	0	0
Dyspepsia	1 (7.1)	0	1 (7.1)	0	0
Haematochezia	1 (7.1)	0	0	1 (7.1)	0
General disorders and administration site conditions					
-Total	10 (71.4)	3 (21.4)	2 (14.3)	4 (28.6)	1 (7.1)
Pyrexia	6 (42.9)	2 (14.3)	2 (14.3)	2 (14.3)	0
Catheter site pain	2 (14.3)	0	2 (14.3)	0	0
Fatigue	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Pain	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Chills	1 (7.1)	1 (7.1)	0	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Generalised oedema	1 (7.1)	1 (7.1)	0	0	0
Multiple organ dysfunction syndrome	1 (7.1)	0	0	0	1 (7.1)
Non-cardiac chest pain	1 (7.1)	0	0	1 (7.1)	0
Oedema peripheral	1 (7.1)	0	1 (7.1)	0	0
Physical deconditioning	1 (7.1)	0	0	1 (7.1)	0
Hepatobiliary disorders					
-Total	2 (14.3)	0	0	2 (14.3)	0
Hyperbilirubinaemia	2 (14.3)	0	0	2 (14.3)	0
Hepatic steatosis	1 (7.1)	0	1 (7.1)	0	0
Infections and infestations					
-Total	7 (50.0)	0	1 (7.1)	2 (14.3)	4 (28.6)
Abscess limb	1 (7.1)	0	0	1 (7.1)	0
Enterococcal bacteraemia	1 (7.1)	0	0	1 (7.1)	0
Escherichia sepsis	1 (7.1)	0	0	0	1 (7.1)
Escherichia urinary tract infection	1 (7.1)	0	1 (7.1)	0	0
Klebsiella sepsis	1 (7.1)	0	0	0	1 (7.1)
Pneumonia	1 (7.1)	0	0	0	1 (7.1)
Pneumonia fungal	1 (7.1)	0	1 (7.1)	0	0

Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (7.1)	0	1 (7.1)	0	0
Serratia infection	1 (7.1)	0	0	1 (7.1)	0
Staphylococcal scalded skin syndrome	1 (7.1)	0	1 (7.1)	0	0
Staphylococcal sepsis	1 (7.1)	0	0	0	1 (7.1)
Injury, poisoning and procedural complications					
-Total	2 (14.3)	0	2 (14.3)	0	0
Procedural hypertension	1 (7.1)	0	1 (7.1)	0	0
Procedural pain	1 (7.1)	0	1 (7.1)	0	0
Subdural haematoma	1 (7.1)	0	1 (7.1)	0	0
Transfusion reaction	1 (7.1)	1 (7.1)	0	0	0
Investigations					
-Total	5 (35.7)	0	0	2 (14.3)	3 (21.4)
Blood lactate dehydrogenase increased	2 (14.3)	0	0	2 (14.3)	0
White blood cell count decreased	2 (14.3)	0	0	0	2 (14.3)
Computerised tomogram thorax abnormal	1 (7.1)	0	0	1 (7.1)	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Electrocardiogram qt prolonged	1 (7.1)	0	0	1 (7.1)	0
Neutrophil count decreased	1 (7.1)	0	0	0	1 (7.1)
Platelet count decreased	1 (7.1)	0	0	0	1 (7.1)
Serum ferritin increased	1 (7.1)	0	0	1 (7.1)	0
Transaminases increased	1 (7.1)	0	0	1 (7.1)	0
Metabolism and nutrition disorders					
-Total	7 (50.0)	0	5 (35.7)	2 (14.3)	0
Hyperglycaemia	3 (21.4)	0	3 (21.4)	0	0
Decreased appetite	2 (14.3)	0	2 (14.3)	0	0
Fluid overload	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Hyperkalaemia	1 (7.1)	0	0	1 (7.1)	0
Hypocalcaemia	1 (7.1)	1 (7.1)	0	0	0
Hypokalaemia	1 (7.1)	0	0	1 (7.1)	0
Hypophosphataemia	1 (7.1)	0	1 (7.1)	0	0
Vitamin d deficiency	1 (7.1)	0	1 (7.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (35.7)	0	1 (7.1)	4 (28.6)	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain in extremity	3 (21.4)	0	0	3 (21.4)	0
Arthralgia	1 (7.1)	0	0	1 (7.1)	0
Back pain	1 (7.1)	0	0	1 (7.1)	0
Musculoskeletal pain	1 (7.1)	0	0	1 (7.1)	0
Myopathy	1 (7.1)	0	0	1 (7.1)	0
Myositis	1 (7.1)	0	0	1 (7.1)	0
Neck pain	1 (7.1)	0	1 (7.1)	0	0
Synovitis	1 (7.1)	0	1 (7.1)	0	0
Nervous system disorders					
-Total	6 (42.9)	1 (7.1)	4 (28.6)	0	1 (7.1)
Headache	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Hypoaesthesia	1 (7.1)	1 (7.1)	0	0	0
Hyporesponsive to stimuli	1 (7.1)	0	0	1 (7.1)	0
Neuropathy peripheral	1 (7.1)	1 (7.1)	0	0	0
Peripheral sensory neuropathy	1 (7.1)	0	1 (7.1)	0	0
Peroneal nerve palsy	1 (7.1)	1 (7.1)	0	0	0
Seizure	1 (7.1)	0	0	0	1 (7.1)
Visual field defect	1 (7.1)	0	1 (7.1)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Product issues					
-Total	1 (7.1)	0	1 (7.1)	0	0
Device occlusion	1 (7.1)	0	1 (7.1)	0	0
Psychiatric disorders					
-Total	4 (28.6)	0	3 (21.4)	1 (7.1)	0
Anxiety	2 (14.3)	0	2 (14.3)	0	0
Agitation	1 (7.1)	0	0	1 (7.1)	0
Confusional state	1 (7.1)	0	1 (7.1)	0	0
Depression	1 (7.1)	0	1 (7.1)	0	0
Renal and urinary disorders					
-Total	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Acute kidney injury	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Dysuria	1 (7.1)	0	1 (7.1)	0	0
Oliguria	1 (7.1)	0	0	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (28.6)	0	2 (14.3)	0	2 (14.3)
Hypoxia	3 (21.4)	0	1 (7.1)	2 (14.3)	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cough	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Epistaxis	2 (14.3)	0	2 (14.3)	0	0
Oropharyngeal pain	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Pleural effusion	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Aspiration	1 (7.1)	0	0	0	1 (7.1)
Atelectasis	1 (7.1)	0	1 (7.1)	0	0
Dyspnoea	1 (7.1)	0	0	1 (7.1)	0
Haemoptysis	1 (7.1)	0	0	1 (7.1)	0
Nasal congestion	1 (7.1)	1 (7.1)	0	0	0
Pulmonary alveolar haemorrhage	1 (7.1)	0	0	0	1 (7.1)
Pulmonary hypertension	1 (7.1)	0	0	1 (7.1)	0
Pulmonary oedema	1 (7.1)	0	0	0	1 (7.1)
Respiratory distress	1 (7.1)	0	0	0	1 (7.1)
Rhinorrhoea	1 (7.1)	1 (7.1)	0	0	0
Tachypnoea	1 (7.1)	0	0	1 (7.1)	0
Skin and subcutaneous tissue disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Alopecia	1 (7.1)	0	1 (7.1)	0	0
Rash erythematous	1 (7.1)	0	1 (7.1)	0	0
Vascular disorders					
-Total	4 (28.6)	1 (7.1)	0	1 (7.1)	2 (14.3)
Hypertension	3 (21.4)	1 (7.1)	1 (7.1)	1 (7.1)	0
Hypotension	2 (14.3)	0	0	0	2 (14.3)
Venous thrombosis limb	1 (7.1)	1 (7.1)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175b
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (80.0)	0	3 (7.5)	15 (37.5)	14 (35.0)
Blood and lymphatic system disorders					
-Total	21 (52.5)	0	0	15 (37.5)	6 (15.0)
Anaemia	11 (27.5)	0	0	11 (27.5)	0
Febrile neutropenia	9 (22.5)	0	0	9 (22.5)	0
Thrombocytopenia	6 (15.0)	0	0	1 (2.5)	5 (12.5)
Neutropenia	3 (7.5)	0	0	0	3 (7.5)
Disseminated intravascular coagulation	2 (5.0)	0	0	2 (5.0)	0
Leukopenia	1 (2.5)	0	0	0	1 (2.5)
Lymphopenia	1 (2.5)	0	0	0	1 (2.5)
Cardiac disorders					

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	6 (15.0)	1 (2.5)	1 (2.5)	2 (5.0)	2 (5.0)
Bradycardia	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Sinus tachycardia	2 (5.0)	0	0	2 (5.0)	0
Tachycardia	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Cardiovascular insufficiency	1 (2.5)	0	0	0	1 (2.5)
Right ventricular dysfunction	1 (2.5)	0	0	1 (2.5)	0
Ventricular tachycardia	1 (2.5)	0	0	1 (2.5)	0
Endocrine disorders					
-Total	2 (5.0)	0	2 (5.0)	0	0
Adrenal insufficiency	1 (2.5)	0	1 (2.5)	0	0
Hyperthyroidism	1 (2.5)	0	1 (2.5)	0	0
Eye disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0
Photophobia	1 (2.5)	0	1 (2.5)	0	0
Gastrointestinal disorders					
-Total	18 (45.0)	5 (12.5)	7 (17.5)	6 (15.0)	0
Vomiting	8 (20.0)	4 (10.0)	3 (7.5)	1 (2.5)	0
Abdominal pain	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nausea	5 (12.5)	0	3 (7.5)	2 (5.0)	0
Colitis	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Diarrhoea	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Stomatitis	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Gastrointestinal haemorrhage	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Constipation	1 (2.5)	1 (2.5)	0	0	0
Dry mouth	1 (2.5)	1 (2.5)	0	0	0
Dyspepsia	1 (2.5)	0	1 (2.5)	0	0
Haematemesis	1 (2.5)	0	1 (2.5)	0	0
Haematochezia	1 (2.5)	0	0	1 (2.5)	0
Oral pain	1 (2.5)	0	1 (2.5)	0	0
Pancreatitis	1 (2.5)	0	1 (2.5)	0	0
Perianal erythema	1 (2.5)	0	1 (2.5)	0	0
General disorders and administration site conditions					
-Total	15 (37.5)	6 (15.0)	4 (10.0)	3 (7.5)	2 (5.0)
Pyrexia	9 (22.5)	4 (10.0)	3 (7.5)	2 (5.0)	0
Fatigue	3 (7.5)	3 (7.5)	0	0	0

Gender: Male

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Chills	2 (5.0)	2 (5.0)	0	0	0
Multiple organ dysfunction syndrome	2 (5.0)	0	0	0	2 (5.0)
Non-cardiac chest pain	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Catheter site pain	1 (2.5)	1 (2.5)	0	0	0
Immune system disorders					
-Total	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Hypogammaglobulinaemia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Anaphylactic reaction	1 (2.5)	0	0	1 (2.5)	0
Infections and infestations					
-Total	16 (40.0)	0	4 (10.0)	7 (17.5)	5 (12.5)
Klebsiella sepsis	2 (5.0)	0	0	0	2 (5.0)
Bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Candida sepsis	1 (2.5)	0	0	0	1 (2.5)
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Conjunctivitis	1 (2.5)	0	1 (2.5)	0	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0

Gender: Male

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia infection	1 (2.5)	0	0	1 (2.5)	0
Gastroenteritis	1 (2.5)	0	0	1 (2.5)	0
Klebsiella infection	1 (2.5)	0	0	1 (2.5)	0
Metapneumovirus infection	1 (2.5)	0	1 (2.5)	0	0
Oral herpes	1 (2.5)	0	1 (2.5)	0	0
Pneumonia	1 (2.5)	0	0	0	1 (2.5)
Pneumonia fungal	1 (2.5)	0	0	1 (2.5)	0
Respiratory syncytial virus infection	1 (2.5)	0	1 (2.5)	0	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Serratia infection	1 (2.5)	0	0	1 (2.5)	0
Sinusitis	1 (2.5)	1 (2.5)	0	0	0
Staphylococcal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Streptococcal infection	1 (2.5)	0	0	1 (2.5)	0
Upper respiratory tract infection	1 (2.5)	0	1 (2.5)	0	0
Injury, poisoning and procedural complications					
-Total	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Procedural pain	2 (5.0)	0	0	2 (5.0)	0

Gender: Male

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Extradural haematoma	1 (2.5)	0	0	1 (2.5)	0
Radiation skin injury	1 (2.5)	0	1 (2.5)	0	0
Subdural haematoma	1 (2.5)	0	0	1 (2.5)	0
Investigations					
-Total	13 (32.5)	0	0	4 (10.0)	9 (22.5)
Neutrophil count decreased	4 (10.0)	0	0	0	4 (10.0)
Platelet count decreased	4 (10.0)	0	0	1 (2.5)	3 (7.5)
White blood cell count decreased	4 (10.0)	0	0	0	4 (10.0)
Aspartate aminotransferase increased	2 (5.0)	0	0	2 (5.0)	0
Blood lactate dehydrogenase increased	2 (5.0)	0	0	2 (5.0)	0
Electrocardiogram qt prolonged	2 (5.0)	0	0	2 (5.0)	0
Alanine aminotransferase increased	1 (2.5)	0	0	1 (2.5)	0
Blood bilirubin increased	1 (2.5)	0	0	1 (2.5)	0
Computerised tomogram thorax abnormal	1 (2.5)	0	0	1 (2.5)	0
Serum ferritin increased	1 (2.5)	0	0	1 (2.5)	0
Metabolism and nutrition disorders					

Gender: Male

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (35.0)	0	5 (12.5)	6 (15.0)	3 (7.5)
Decreased appetite	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Hyperglycaemia	4 (10.0)	0	2 (5.0)	1 (2.5)	1 (2.5)
Hypokalaemia	4 (10.0)	1 (2.5)	0	1 (2.5)	2 (5.0)
Dehydration	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Hyperkalaemia	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Hypernatraemia	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Hypomagnesaemia	2 (5.0)	2 (5.0)	0	0	0
Tumour lysis syndrome	2 (5.0)	0	0	2 (5.0)	0
Fluid overload	1 (2.5)	0	0	1 (2.5)	0
Hyperuricaemia	1 (2.5)	0	0	0	1 (2.5)
Hypoalbuminaemia	1 (2.5)	0	0	0	1 (2.5)
Hypocalcaemia	1 (2.5)	0	0	0	1 (2.5)
Hypophosphataemia	1 (2.5)	0	0	1 (2.5)	0
Malnutrition	1 (2.5)	0	1 (2.5)	0	0
Vitamin d deficiency	1 (2.5)	0	1 (2.5)	0	0
Musculoskeletal and connective tissue disorders					

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	10 (25.0)	3 (7.5)	3 (7.5)	4 (10.0)	0
Pain in extremity	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Back pain	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Neck pain	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Arthralgia	1 (2.5)	0	0	1 (2.5)	0
Bone pain	1 (2.5)	0	0	1 (2.5)	0
Muscle spasms	1 (2.5)	1 (2.5)	0	0	0
Musculoskeletal chest pain	1 (2.5)	1 (2.5)	0	0	0
Pain in jaw	1 (2.5)	0	1 (2.5)	0	0
Nervous system disorders					
-Total	6 (15.0)	1 (2.5)	2 (5.0)	2 (5.0)	1 (2.5)
Headache	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Hyporesponsive to stimuli	1 (2.5)	0	0	1 (2.5)	0
Leukoencephalopathy	1 (2.5)	0	0	1 (2.5)	0
Seizure	1 (2.5)	0	0	0	1 (2.5)
Product issues					
-Total	1 (2.5)	0	1 (2.5)	0	0
Device occlusion	1 (2.5)	0	1 (2.5)	0	0

Gender: Male

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	7 (17.5)	2 (5.0)	3 (7.5)	2 (5.0)	0
Mental status changes	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Agitation	1 (2.5)	0	0	1 (2.5)	0
Anxiety	1 (2.5)	0	1 (2.5)	0	0
Confusional state	1 (2.5)	0	1 (2.5)	0	0
Depression	1 (2.5)	1 (2.5)	0	0	0
Insomnia	1 (2.5)	0	1 (2.5)	0	0
Irritability	1 (2.5)	1 (2.5)	0	0	0
Renal and urinary disorders					
-Total	4 (10.0)	1 (2.5)	0	2 (5.0)	1 (2.5)
Acute kidney injury	2 (5.0)	0	0	1 (2.5)	1 (2.5)
Cystitis haemorrhagic	1 (2.5)	0	0	1 (2.5)	0
Haematuria	1 (2.5)	1 (2.5)	0	0	0
Oliguria	1 (2.5)	0	0	1 (2.5)	0
Reproductive system and breast disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0

Gender: Male

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Scrotal pain	1 (2.5)	0	1 (2.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (17.5)	0	2 (5.0)	1 (2.5)	4 (10.0)
Hypoxia	5 (12.5)	0	2 (5.0)	2 (5.0)	1 (2.5)
Cough	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Epistaxis	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Oropharyngeal pain	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Pulmonary oedema	2 (5.0)	0	0	0	2 (5.0)
Aspiration	1 (2.5)	0	0	0	1 (2.5)
Dyspnoea	1 (2.5)	0	0	1 (2.5)	0
Haemoptysis	1 (2.5)	0	0	1 (2.5)	0
Nasal congestion	1 (2.5)	1 (2.5)	0	0	0
Pleural effusion	1 (2.5)	0	1 (2.5)	0	0
Pulmonary alveolar haemorrhage	1 (2.5)	0	0	0	1 (2.5)
Pulmonary hypertension	1 (2.5)	0	0	1 (2.5)	0
Respiratory distress	1 (2.5)	0	0	0	1 (2.5)
Respiratory failure	1 (2.5)	0	0	0	1 (2.5)

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinorrhoea	1 (2.5)	1 (2.5)	0	0	0
Tachypnoea	1 (2.5)	0	0	1 (2.5)	0
Skin and subcutaneous tissue disorders					
-Total	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Rash papular	2 (5.0)	2 (5.0)	0	0	0
Dermatitis diaper	1 (2.5)	1 (2.5)	0	0	0
Rash erythematous	1 (2.5)	0	1 (2.5)	0	0
Skin irritation	1 (2.5)	1 (2.5)	0	0	0
Vascular disorders					
-Total	8 (20.0)	2 (5.0)	0	3 (7.5)	3 (7.5)
Hypotension	6 (15.0)	0	0	3 (7.5)	3 (7.5)
Hypertension	3 (7.5)	2 (5.0)	1 (2.5)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175b
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (91.4)	3 (8.6)	3 (8.6)	11 (31.4)	15 (42.9)
Blood and lymphatic system disorders					
-Total	20 (57.1)	1 (2.9)	0	14 (40.0)	5 (14.3)
Anaemia	10 (28.6)	0	2 (5.7)	8 (22.9)	0
Febrile neutropenia	9 (25.7)	0	0	9 (25.7)	0
Thrombocytopenia	4 (11.4)	0	0	2 (5.7)	2 (5.7)
Neutropenia	3 (8.6)	0	0	1 (2.9)	2 (5.7)
Coagulopathy	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Pancytopenia	2 (5.7)	0	0	0	2 (5.7)
Leukocytosis	1 (2.9)	1 (2.9)	0	0	0
Splenomegaly	1 (2.9)	1 (2.9)	0	0	0
Cardiac disorders					

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (8.6)	0	2 (5.7)	1 (2.9)	0
Pericardial effusion	2 (5.7)	0	2 (5.7)	0	0
Left ventricular dysfunction	1 (2.9)	0	0	1 (2.9)	0
Tachycardia	1 (2.9)	1 (2.9)	0	0	0
Ear and labyrinth disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Deafness unilateral	1 (2.9)	0	1 (2.9)	0	0
Endocrine disorders					
-Total	1 (2.9)	1 (2.9)	0	0	0
Cushingoid	1 (2.9)	1 (2.9)	0	0	0
Eye disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0
Retinopathy	1 (2.9)	0	1 (2.9)	0	0
Gastrointestinal disorders					
-Total	10 (28.6)	1 (2.9)	5 (14.3)	3 (8.6)	1 (2.9)
Nausea	5 (14.3)	0	4 (11.4)	1 (2.9)	0
Abdominal pain	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Constipation	4 (11.4)	2 (5.7)	2 (5.7)	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Stomatitis	2 (5.7)	0	0	1 (2.9)	1 (2.9)
Anal fissure	1 (2.9)	0	1 (2.9)	0	0
Colitis	1 (2.9)	0	0	1 (2.9)	0
Proctalgia	1 (2.9)	0	1 (2.9)	0	0
Vomiting	1 (2.9)	0	1 (2.9)	0	0
General disorders and administration site conditions					
-Total	11 (31.4)	5 (14.3)	4 (11.4)	2 (5.7)	0
Fatigue	4 (11.4)	1 (2.9)	2 (5.7)	1 (2.9)	0
Catheter site pain	3 (8.6)	0	3 (8.6)	0	0
Pyrexia	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Oedema peripheral	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Asthenia	1 (2.9)	0	1 (2.9)	0	0
Catheter site bruise	1 (2.9)	1 (2.9)	0	0	0
Device related thrombosis	1 (2.9)	0	1 (2.9)	0	0
Gait disturbance	1 (2.9)	1 (2.9)	0	0	0
Generalised oedema	1 (2.9)	1 (2.9)	0	0	0
Injection site thrombosis	1 (2.9)	0	1 (2.9)	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Non-cardiac chest pain	1 (2.9)	1 (2.9)	0	0	0
Physical deconditioning	1 (2.9)	0	0	1 (2.9)	0
Hepatobiliary disorders					
-Total	4 (11.4)	0	1 (2.9)	3 (8.6)	0
Hyperbilirubinaemia	3 (8.6)	0	1 (2.9)	2 (5.7)	0
Cholecystitis	1 (2.9)	0	0	1 (2.9)	0
Hepatic steatosis	1 (2.9)	0	1 (2.9)	0	0
Immune system disorders					
-Total	3 (8.6)	0	2 (5.7)	1 (2.9)	0
Anaphylactic reaction	1 (2.9)	0	0	1 (2.9)	0
Drug hypersensitivity	1 (2.9)	0	1 (2.9)	0	0
Hypogammaglobulinaemia	1 (2.9)	0	1 (2.9)	0	0
Infections and infestations					
-Total	17 (48.6)	1 (2.9)	3 (8.6)	10 (28.6)	3 (8.6)
Device related infection	2 (5.7)	0	0	2 (5.7)	0
Enterococcal bacteraemia	2 (5.7)	0	0	2 (5.7)	0
Escherichia urinary tract infection	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Oral herpes	2 (5.7)	0	1 (2.9)	1 (2.9)	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	1 (2.9)	0	0	1 (2.9)	0
Alpha haemolytic streptococcal infection	1 (2.9)	0	0	1 (2.9)	0
Bronchopulmonary aspergillosis	1 (2.9)	0	0	1 (2.9)	0
Cellulitis	1 (2.9)	0	0	1 (2.9)	0
Clostridium difficile colitis	1 (2.9)	0	0	1 (2.9)	0
Clostridium difficile infection	1 (2.9)	0	1 (2.9)	0	0
Conjunctivitis	1 (2.9)	0	1 (2.9)	0	0
Croup infectious	1 (2.9)	0	0	1 (2.9)	0
Cytomegalovirus viraemia	1 (2.9)	0	1 (2.9)	0	0
Escherichia bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Escherichia sepsis	1 (2.9)	0	0	0	1 (2.9)
Fungal skin infection	1 (2.9)	0	1 (2.9)	0	0
Human polyomavirus infection	1 (2.9)	0	0	0	1 (2.9)
Parainfluenzae virus infection	1 (2.9)	0	1 (2.9)	0	0
Pneumonia	1 (2.9)	0	1 (2.9)	0	0
Pneumonia fungal	1 (2.9)	0	1 (2.9)	0	0
Respiratory syncytial virus bronchitis	1 (2.9)	0	0	1 (2.9)	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinovirus infection	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal infection	1 (2.9)	0	0	1 (2.9)	0
Staphylococcal scalded skin syndrome	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal sepsis	1 (2.9)	0	0	0	1 (2.9)
Streptococcal bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Upper respiratory tract infection	1 (2.9)	1 (2.9)	0	0	0
Injury, poisoning and procedural complications					
-Total	6 (17.1)	1 (2.9)	5 (14.3)	0	0
Procedural pain	2 (5.7)	0	2 (5.7)	0	0
Transfusion reaction	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Procedural hypertension	1 (2.9)	0	1 (2.9)	0	0
Subdural haematoma	1 (2.9)	0	1 (2.9)	0	0
Toxicity to various agents	1 (2.9)	0	1 (2.9)	0	0
Wound	1 (2.9)	1 (2.9)	0	0	0
Investigations					
-Total	18 (51.4)	3 (8.6)	3 (8.6)	3 (8.6)	9 (25.7)

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	8 (22.9)	1 (2.9)	1 (2.9)	1 (2.9)	5 (14.3)
Platelet count decreased	6 (17.1)	0	0	0	6 (17.1)
Alanine aminotransferase increased	5 (14.3)	0	1 (2.9)	4 (11.4)	0
Neutrophil count decreased	5 (14.3)	0	0	0	5 (14.3)
Aspartate aminotransferase increased	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Blast cell count increased	1 (2.9)	0	0	1 (2.9)	0
Blood creatinine increased	1 (2.9)	1 (2.9)	0	0	0
Blood fibrinogen decreased	1 (2.9)	0	1 (2.9)	0	0
Blood immunoglobulin a increased	1 (2.9)	1 (2.9)	0	0	0
Blood immunoglobulin m decreased	1 (2.9)	1 (2.9)	0	0	0
Blood immunoglobulin m increased	1 (2.9)	1 (2.9)	0	0	0
Blood uric acid increased	1 (2.9)	1 (2.9)	0	0	0
Coronavirus test positive	1 (2.9)	1 (2.9)	0	0	0
Lymphocyte count decreased	1 (2.9)	0	0	1 (2.9)	0
Transaminases increased	1 (2.9)	0	0	1 (2.9)	0
White blood cell count increased	1 (2.9)	1 (2.9)	0	0	0
Metabolism and nutrition disorders					

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	9 (25.7)	1 (2.9)	3 (8.6)	4 (11.4)	1 (2.9)
Decreased appetite	4 (11.4)	1 (2.9)	2 (5.7)	1 (2.9)	0
Hyperglycaemia	3 (8.6)	0	1 (2.9)	2 (5.7)	0
Hyperuricaemia	3 (8.6)	2 (5.7)	0	1 (2.9)	0
Hypocalcaemia	2 (5.7)	1 (2.9)	0	0	1 (2.9)
Hypomagnesaemia	2 (5.7)	2 (5.7)	0	0	0
Hypophosphataemia	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Dehydration	1 (2.9)	0	1 (2.9)	0	0
Fluid overload	1 (2.9)	0	1 (2.9)	0	0
Hyperammonaemia	1 (2.9)	1 (2.9)	0	0	0
Hypokalaemia	1 (2.9)	0	0	1 (2.9)	0
Vitamin d deficiency	1 (2.9)	0	1 (2.9)	0	0
Musculoskeletal and connective tissue disorders					
-Total	8 (22.9)	1 (2.9)	3 (8.6)	4 (11.4)	0
Pain in extremity	4 (11.4)	1 (2.9)	1 (2.9)	2 (5.7)	0
Arthralgia	1 (2.9)	0	1 (2.9)	0	0
Back pain	1 (2.9)	0	0	1 (2.9)	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bone pain	1 (2.9)	0	1 (2.9)	0	0
Musculoskeletal pain	1 (2.9)	0	0	1 (2.9)	0
Myopathy	1 (2.9)	0	0	1 (2.9)	0
Myositis	1 (2.9)	0	0	1 (2.9)	0
Neck pain	1 (2.9)	0	1 (2.9)	0	0
Pain in jaw	1 (2.9)	0	1 (2.9)	0	0
Synovitis	1 (2.9)	0	1 (2.9)	0	0
Nervous system disorders					
-Total	9 (25.7)	2 (5.7)	5 (14.3)	2 (5.7)	0
Headache	5 (14.3)	1 (2.9)	2 (5.7)	2 (5.7)	0
Hypoaesthesia	1 (2.9)	1 (2.9)	0	0	0
Neuralgia	1 (2.9)	0	1 (2.9)	0	0
Neuropathy peripheral	1 (2.9)	1 (2.9)	0	0	0
Peripheral sensory neuropathy	1 (2.9)	0	1 (2.9)	0	0
Peroneal nerve palsy	1 (2.9)	1 (2.9)	0	0	0
Visual field defect	1 (2.9)	0	1 (2.9)	0	0
Psychiatric disorders					
-Total	4 (11.4)	1 (2.9)	3 (8.6)	0	0

Gender: Female

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	1 (2.9)	0	1 (2.9)	0	0
Confusional state	1 (2.9)	0	1 (2.9)	0	0
Depression	1 (2.9)	0	1 (2.9)	0	0
Insomnia	1 (2.9)	0	1 (2.9)	0	0
Mental status changes	1 (2.9)	1 (2.9)	0	0	0
Renal and urinary disorders					
-Total	2 (5.7)	0	1 (2.9)	0	1 (2.9)
Acute kidney injury	1 (2.9)	1 (2.9)	0	0	0
Cystitis haemorrhagic	1 (2.9)	0	0	0	1 (2.9)
Dysuria	1 (2.9)	0	1 (2.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (11.4)	0	3 (8.6)	0	1 (2.9)
Hypoxia	2 (5.7)	0	2 (5.7)	0	0
Pleural effusion	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Atelectasis	1 (2.9)	0	1 (2.9)	0	0
Cough	1 (2.9)	1 (2.9)	0	0	0
Epistaxis	1 (2.9)	0	1 (2.9)	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Idiopathic pneumonia syndrome	1 (2.9)	0	0	0	1 (2.9)
Pulmonary mass	1 (2.9)	0	1 (2.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (14.3)	2 (5.7)	3 (8.6)	0	0
Rash erythematous	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Alopecia	1 (2.9)	0	1 (2.9)	0	0
Cold sweat	1 (2.9)	1 (2.9)	0	0	0
Night sweats	1 (2.9)	1 (2.9)	0	0	0
Rash	1 (2.9)	1 (2.9)	0	0	0
Urticaria	1 (2.9)	0	1 (2.9)	0	0
Vascular disorders					
-Total	2 (5.7)	0	0	2 (5.7)	0
Hypertension	1 (2.9)	0	0	1 (2.9)	0
Hypotension	1 (2.9)	0	0	1 (2.9)	0
Venous thrombosis limb	1 (2.9)	1 (2.9)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175c
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (83.3)	3 (5.0)	4 (6.7)	19 (31.7)	24 (40.0)
Blood and lymphatic system disorders					
-Total	32 (53.3)	1 (1.7)	0	23 (38.3)	8 (13.3)
Anaemia	17 (28.3)	0	2 (3.3)	15 (25.0)	0
Febrile neutropenia	15 (25.0)	0	0	15 (25.0)	0
Thrombocytopenia	8 (13.3)	0	0	2 (3.3)	6 (10.0)
Neutropenia	4 (6.7)	0	0	0	4 (6.7)
Coagulopathy	1 (1.7)	1 (1.7)	0	0	0
Disseminated intravascular coagulation	1 (1.7)	0	0	1 (1.7)	0
Leukopenia	1 (1.7)	0	0	0	1 (1.7)
Splenomegaly	1 (1.7)	1 (1.7)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac disorders					
-Total	6 (10.0)	1 (1.7)	2 (3.3)	3 (5.0)	0
Tachycardia	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Bradycardia	1 (1.7)	1 (1.7)	0	0	0
Left ventricular dysfunction	1 (1.7)	0	0	1 (1.7)	0
Pericardial effusion	1 (1.7)	0	1 (1.7)	0	0
Sinus tachycardia	1 (1.7)	0	0	1 (1.7)	0
Ear and labyrinth disorders					
-Total	1 (1.7)	0	1 (1.7)	0	0
Deafness unilateral	1 (1.7)	0	1 (1.7)	0	0
Endocrine disorders					
-Total	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Adrenal insufficiency	1 (1.7)	0	1 (1.7)	0	0
Cushingoid	1 (1.7)	1 (1.7)	0	0	0
Hyperthyroidism	1 (1.7)	0	1 (1.7)	0	0
Gastrointestinal disorders					
-Total	20 (33.3)	4 (6.7)	9 (15.0)	6 (10.0)	1 (1.7)
Abdominal pain	6 (10.0)	1 (1.7)	4 (6.7)	1 (1.7)	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nausea	6 (10.0)	0	4 (6.7)	2 (3.3)	0
Vomiting	5 (8.3)	3 (5.0)	2 (3.3)	0	0
Colitis	4 (6.7)	1 (1.7)	0	3 (5.0)	0
Stomatitis	4 (6.7)	1 (1.7)	0	2 (3.3)	1 (1.7)
Constipation	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Diarrhoea	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Gastrointestinal haemorrhage	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Anal fissure	1 (1.7)	0	1 (1.7)	0	0
Dyspepsia	1 (1.7)	0	1 (1.7)	0	0
Haematemesis	1 (1.7)	0	1 (1.7)	0	0
Oral pain	1 (1.7)	0	1 (1.7)	0	0
Pancreatitis	1 (1.7)	0	1 (1.7)	0	0
Perianal erythema	1 (1.7)	0	1 (1.7)	0	0
Proctalgia	1 (1.7)	0	1 (1.7)	0	0
General disorders and administration site conditions					
-Total	20 (33.3)	9 (15.0)	7 (11.7)	3 (5.0)	1 (1.7)
Pyrexia	9 (15.0)	4 (6.7)	3 (5.0)	2 (3.3)	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fatigue	7 (11.7)	4 (6.7)	2 (3.3)	1 (1.7)	0
Catheter site pain	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Chills	2 (3.3)	2 (3.3)	0	0	0
Pain	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Asthenia	1 (1.7)	0	1 (1.7)	0	0
Gait disturbance	1 (1.7)	1 (1.7)	0	0	0
Generalised oedema	1 (1.7)	1 (1.7)	0	0	0
Injection site thrombosis	1 (1.7)	0	1 (1.7)	0	0
Multiple organ dysfunction syndrome	1 (1.7)	0	0	0	1 (1.7)
Non-cardiac chest pain	1 (1.7)	1 (1.7)	0	0	0
Hepatobiliary disorders					
-Total	2 (3.3)	0	0	2 (3.3)	0
Cholecystitis	1 (1.7)	0	0	1 (1.7)	0
Hyperbilirubinaemia	1 (1.7)	0	0	1 (1.7)	0
Immune system disorders					
-Total	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Hypogammaglobulinaemia	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Anaphylactic reaction	1 (1.7)	0	0	1 (1.7)	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections and infestations					
-Total	25 (41.7)	1 (1.7)	7 (11.7)	11 (18.3)	6 (10.0)
Clostridium difficile colitis	2 (3.3)	0	0	2 (3.3)	0
Enterococcal bacteraemia	2 (3.3)	0	0	2 (3.3)	0
Escherichia bacteraemia	2 (3.3)	0	0	2 (3.3)	0
Oral herpes	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Pneumonia	2 (3.3)	0	1 (1.7)	0	1 (1.7)
Staphylococcal bacteraemia	2 (3.3)	0	0	2 (3.3)	0
Upper respiratory tract infection	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Bronchopulmonary aspergillosis	1 (1.7)	0	0	1 (1.7)	0
Candida sepsis	1 (1.7)	0	0	0	1 (1.7)
Cellulitis	1 (1.7)	0	0	1 (1.7)	0
Clostridium difficile infection	1 (1.7)	0	1 (1.7)	0	0
Conjunctivitis	1 (1.7)	0	1 (1.7)	0	0
Croup infectious	1 (1.7)	0	0	1 (1.7)	0
Cytomegalovirus viraemia	1 (1.7)	0	1 (1.7)	0	0
Device related infection	1 (1.7)	0	0	1 (1.7)	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia sepsis	1 (1.7)	0	0	0	1 (1.7)
Escherichia urinary tract infection	1 (1.7)	0	1 (1.7)	0	0
Fungal skin infection	1 (1.7)	0	1 (1.7)	0	0
Human polyomavirus infection	1 (1.7)	0	0	0	1 (1.7)
Klebsiella infection	1 (1.7)	0	0	1 (1.7)	0
Klebsiella sepsis	1 (1.7)	0	0	0	1 (1.7)
Metapneumovirus infection	1 (1.7)	0	1 (1.7)	0	0
Parainfluenzae virus infection	1 (1.7)	0	1 (1.7)	0	0
Pneumonia fungal	1 (1.7)	0	0	1 (1.7)	0
Respiratory syncytial virus bronchitis	1 (1.7)	0	0	1 (1.7)	0
Respiratory syncytial virus infection	1 (1.7)	0	1 (1.7)	0	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Serratia infection	1 (1.7)	0	0	1 (1.7)	0
Sinusitis	1 (1.7)	1 (1.7)	0	0	0
Streptococcal bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Injury, poisoning and procedural complications					
-Total	7 (11.7)	1 (1.7)	5 (8.3)	1 (1.7)	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Procedural pain	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Transfusion reaction	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Radiation skin injury	1 (1.7)	0	1 (1.7)	0	0
Subdural haematoma	1 (1.7)	0	1 (1.7)	0	0
Toxicity to various agents	1 (1.7)	0	1 (1.7)	0	0
Wound	1 (1.7)	1 (1.7)	0	0	0
Investigations					
-Total	23 (38.3)	3 (5.0)	1 (1.7)	4 (6.7)	15 (25.0)
Platelet count decreased	9 (15.0)	0	0	1 (1.7)	8 (13.3)
White blood cell count decreased	9 (15.0)	1 (1.7)	0	1 (1.7)	7 (11.7)
Neutrophil count decreased	7 (11.7)	0	0	0	7 (11.7)
Alanine aminotransferase increased	4 (6.7)	0	1 (1.7)	3 (5.0)	0
Aspartate aminotransferase increased	3 (5.0)	1 (1.7)	0	2 (3.3)	0
Blast cell count increased	1 (1.7)	0	0	1 (1.7)	0
Blood bilirubin increased	1 (1.7)	0	0	1 (1.7)	0
Blood creatinine increased	1 (1.7)	1 (1.7)	0	0	0
Blood immunoglobulin a increased	1 (1.7)	1 (1.7)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood immunoglobulin m increased	1 (1.7)	1 (1.7)	0	0	0
Blood lactate dehydrogenase increased	1 (1.7)	0	0	1 (1.7)	0
Blood uric acid increased	1 (1.7)	1 (1.7)	0	0	0
Coronavirus test positive	1 (1.7)	1 (1.7)	0	0	0
Electrocardiogram qt prolonged	1 (1.7)	0	0	1 (1.7)	0
Lymphocyte count decreased	1 (1.7)	0	0	1 (1.7)	0
Serum ferritin increased	1 (1.7)	0	0	1 (1.7)	0
White blood cell count increased	1 (1.7)	1 (1.7)	0	0	0
Metabolism and nutrition disorders					
-Total	17 (28.3)	0	6 (10.0)	7 (11.7)	4 (6.7)
Decreased appetite	7 (11.7)	0	4 (6.7)	3 (5.0)	0
Hyperglycaemia	5 (8.3)	0	1 (1.7)	3 (5.0)	1 (1.7)
Hypokalaemia	5 (8.3)	1 (1.7)	0	2 (3.3)	2 (3.3)
Hyperuricaemia	4 (6.7)	2 (3.3)	0	1 (1.7)	1 (1.7)
Dehydration	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Hypomagnesaemia	3 (5.0)	3 (5.0)	0	0	0
Hypophosphataemia	3 (5.0)	0	1 (1.7)	2 (3.3)	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypernatraemia	2 (3.3)	0	0	1 (1.7)	1 (1.7)
Hypocalcaemia	2 (3.3)	0	0	0	2 (3.3)
Hyperammonaemia	1 (1.7)	1 (1.7)	0	0	0
Hyperkalaemia	1 (1.7)	0	1 (1.7)	0	0
Hypoalbuminaemia	1 (1.7)	0	0	0	1 (1.7)
Malnutrition	1 (1.7)	0	1 (1.7)	0	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0
Vitamin d deficiency	1 (1.7)	0	1 (1.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	11 (18.3)	3 (5.0)	3 (5.0)	5 (8.3)	0
Pain in extremity	7 (11.7)	2 (3.3)	1 (1.7)	4 (6.7)	0
Neck pain	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Back pain	1 (1.7)	1 (1.7)	0	0	0
Bone pain	1 (1.7)	0	0	1 (1.7)	0
Musculoskeletal chest pain	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal pain	1 (1.7)	0	0	1 (1.7)	0
Pain in jaw	1 (1.7)	0	1 (1.7)	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nervous system disorders					
-Total	10 (16.7)	2 (3.3)	5 (8.3)	3 (5.0)	0
Headache	5 (8.3)	1 (1.7)	2 (3.3)	2 (3.3)	0
Hypoaesthesia	1 (1.7)	1 (1.7)	0	0	0
Leukoencephalopathy	1 (1.7)	0	0	1 (1.7)	0
Neuralgia	1 (1.7)	0	1 (1.7)	0	0
Neuropathy peripheral	1 (1.7)	1 (1.7)	0	0	0
Peripheral sensory neuropathy	1 (1.7)	0	1 (1.7)	0	0
Peroneal nerve palsy	1 (1.7)	1 (1.7)	0	0	0
Visual field defect	1 (1.7)	0	1 (1.7)	0	0
Psychiatric disorders					
-Total	8 (13.3)	3 (5.0)	5 (8.3)	0	0
Confusional state	2 (3.3)	0	2 (3.3)	0	0
Insomnia	2 (3.3)	0	2 (3.3)	0	0
Mental status changes	2 (3.3)	2 (3.3)	0	0	0
Anxiety	1 (1.7)	0	1 (1.7)	0	0
Depression	1 (1.7)	1 (1.7)	0	0	0
Irritability	1 (1.7)	1 (1.7)	0	0	0

Race: White

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	4 (6.7)	1 (1.7)	0	1 (1.7)	2 (3.3)
Cystitis haemorrhagic	2 (3.3)	0	0	1 (1.7)	1 (1.7)
Acute kidney injury	1 (1.7)	0	0	0	1 (1.7)
Haematuria	1 (1.7)	1 (1.7)	0	0	0
Reproductive system and breast disorders					
-Total	1 (1.7)	0	1 (1.7)	0	0
Scrotal pain	1 (1.7)	0	1 (1.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (15.0)	0	5 (8.3)	0	4 (6.7)
Hypoxia	6 (10.0)	0	4 (6.7)	1 (1.7)	1 (1.7)
Pleural effusion	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Cough	2 (3.3)	2 (3.3)	0	0	0
Epistaxis	2 (3.3)	0	2 (3.3)	0	0
Aspiration	1 (1.7)	0	0	0	1 (1.7)
Atelectasis	1 (1.7)	0	1 (1.7)	0	0
Idiopathic pneumonia syndrome	1 (1.7)	0	0	0	1 (1.7)

Race: White

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	1 (1.7)	1 (1.7)	0	0	0
Oropharyngeal pain	1 (1.7)	1 (1.7)	0	0	0
Pulmonary mass	1 (1.7)	0	1 (1.7)	0	0
Pulmonary oedema	1 (1.7)	0	0	0	1 (1.7)
Respiratory failure	1 (1.7)	0	0	0	1 (1.7)
Rhinorrhoea	1 (1.7)	1 (1.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (11.7)	4 (6.7)	3 (5.0)	0	0
Rash erythematous	2 (3.3)	0	2 (3.3)	0	0
Rash papular	2 (3.3)	2 (3.3)	0	0	0
Alopecia	1 (1.7)	0	1 (1.7)	0	0
Dermatitis diaper	1 (1.7)	1 (1.7)	0	0	0
Skin irritation	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					
-Total	8 (13.3)	2 (3.3)	0	4 (6.7)	2 (3.3)
Hypotension	6 (10.0)	0	0	4 (6.7)	2 (3.3)
Hypertension	2 (3.3)	2 (3.3)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175c
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	2 (33.3)	3 (50.0)	1 (16.7)
Blood and lymphatic system disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Anaemia	1 (16.7)	0	0	1 (16.7)	0
Gastrointestinal disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Dry mouth	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	1 (16.7)	1 (16.7)	0	0	0
Oedema peripheral	1 (16.7)	1 (16.7)	0	0	0
Pyrexia	1 (16.7)	1 (16.7)	0	0	0

Race: Asian

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	4 (66.7)	0	0	4 (66.7)	0
Alpha haemolytic streptococcal infection	1 (16.7)	0	0	1 (16.7)	0
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Device related infection	1 (16.7)	0	0	1 (16.7)	0
Escherichia infection	1 (16.7)	0	0	1 (16.7)	0
Gastroenteritis	1 (16.7)	0	0	1 (16.7)	0
Oral herpes	1 (16.7)	0	1 (16.7)	0	0
Staphylococcal infection	1 (16.7)	0	0	1 (16.7)	0
Streptococcal infection	1 (16.7)	0	0	1 (16.7)	0
Investigations					
-Total	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Blood fibrinogen decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin m decreased	1 (16.7)	1 (16.7)	0	0	0
Neutrophil count decreased	1 (16.7)	0	0	0	1 (16.7)
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)
White blood cell count decreased	1 (16.7)	0	0	0	1 (16.7)

Race: Asian

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Dehydration	1 (16.7)	0	0	1 (16.7)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (33.3)	0	2 (33.3)	0	0
Bone pain	1 (16.7)	0	1 (16.7)	0	0
Pain in extremity	1 (16.7)	0	1 (16.7)	0	0
Pain in jaw	1 (16.7)	0	1 (16.7)	0	0
Nervous system disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Headache	1 (16.7)	1 (16.7)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of

all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175c
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Number of patients with at least one AE	8 (88.9)	0	0	4 (44.4)	4 (44.4)
Blood and lymphatic system disorders					
-Total	8 (88.9)	0	0	5 (55.6)	3 (33.3)
Anaemia	3 (33.3)	0	0	3 (33.3)	0
Febrile neutropenia	3 (33.3)	0	0	3 (33.3)	0
Neutropenia	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Pancytopenia	2 (22.2)	0	0	0	2 (22.2)
Thrombocytopenia	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Coagulopathy	1 (11.1)	0	0	1 (11.1)	0
Disseminated intravascular coagulation	1 (11.1)	0	0	1 (11.1)	0

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Leukocytosis	1 (11.1)	1 (11.1)	0	0	0
Lymphopenia	1 (11.1)	0	0	0	1 (11.1)
Cardiac disorders					
-Total	3 (33.3)	0	1 (11.1)	0	2 (22.2)
Bradycardia	1 (11.1)	0	0	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	0	0	1 (11.1)
Pericardial effusion	1 (11.1)	0	1 (11.1)	0	0
Right ventricular dysfunction	1 (11.1)	0	0	1 (11.1)	0
Sinus tachycardia	1 (11.1)	0	0	1 (11.1)	0
Tachycardia	1 (11.1)	1 (11.1)	0	0	0
Ventricular tachycardia	1 (11.1)	0	0	1 (11.1)	0
Eye disorders					
-Total	2 (22.2)	0	2 (22.2)	0	0
Photophobia	1 (11.1)	0	1 (11.1)	0	0
Retinopathy	1 (11.1)	0	1 (11.1)	0	0
Gastrointestinal disorders					
-Total	7 (77.8)	1 (11.1)	3 (33.3)	3 (33.3)	0
Nausea	4 (44.4)	0	3 (33.3)	1 (11.1)	0

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vomiting	4 (44.4)	1 (11.1)	2 (22.2)	1 (11.1)	0
Abdominal pain	3 (33.3)	0	1 (11.1)	2 (22.2)	0
Constipation	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Haematochezia	1 (11.1)	0	0	1 (11.1)	0
Stomatitis	1 (11.1)	0	0	1 (11.1)	0
General disorders and administration site conditions					
-Total	5 (55.6)	1 (11.1)	1 (11.1)	2 (22.2)	1 (11.1)
Non-cardiac chest pain	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Pyrexia	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Catheter site bruise	1 (11.1)	1 (11.1)	0	0	0
Catheter site pain	1 (11.1)	0	1 (11.1)	0	0
Device related thrombosis	1 (11.1)	0	1 (11.1)	0	0
Multiple organ dysfunction syndrome	1 (11.1)	0	0	0	1 (11.1)
Oedema peripheral	1 (11.1)	0	1 (11.1)	0	0
Pain	1 (11.1)	0	1 (11.1)	0	0
Physical deconditioning	1 (11.1)	0	0	1 (11.1)	0
Hepatobiliary disorders					

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Hyperbilirubinaemia	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Hepatic steatosis	1 (11.1)	0	1 (11.1)	0	0
Immune system disorders					
-Total	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Anaphylactic reaction	1 (11.1)	0	0	1 (11.1)	0
Drug hypersensitivity	1 (11.1)	0	1 (11.1)	0	0
Infections and infestations					
-Total	4 (44.4)	0	0	2 (22.2)	2 (22.2)
Abscess limb	1 (11.1)	0	0	1 (11.1)	0
Device related infection	1 (11.1)	0	0	1 (11.1)	0
Escherichia urinary tract infection	1 (11.1)	0	0	1 (11.1)	0
Klebsiella sepsis	1 (11.1)	0	0	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	1 (11.1)	0	0
Rhinovirus infection	1 (11.1)	0	1 (11.1)	0	0
Staphylococcal scalded skin syndrome	1 (11.1)	0	1 (11.1)	0	0
Staphylococcal sepsis	1 (11.1)	0	0	0	1 (11.1)

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Injury, poisoning and procedural complications					
-Total	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Procedural pain	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Extradural haematoma	1 (11.1)	0	0	1 (11.1)	0
Procedural hypertension	1 (11.1)	0	1 (11.1)	0	0
Subdural haematoma	1 (11.1)	0	0	1 (11.1)	0
Investigations					
-Total	6 (66.7)	0	1 (11.1)	3 (33.3)	2 (22.2)
Alanine aminotransferase increased	2 (22.2)	0	0	2 (22.2)	0
Aspartate aminotransferase increased	2 (22.2)	0	1 (11.1)	1 (11.1)	0
White blood cell count decreased	2 (22.2)	0	1 (11.1)	0	1 (11.1)
Blood lactate dehydrogenase increased	1 (11.1)	0	0	1 (11.1)	0
Computerised tomogram thorax abnormal	1 (11.1)	0	0	1 (11.1)	0
Electrocardiogram qt prolonged	1 (11.1)	0	0	1 (11.1)	0
Neutrophil count decreased	1 (11.1)	0	0	0	1 (11.1)

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Transaminases increased	1 (11.1)	0	0	1 (11.1)	0
Metabolism and nutrition disorders					
-Total	5 (55.6)	1 (11.1)	2 (22.2)	2 (22.2)	0
Fluid overload	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Hyperglycaemia	2 (22.2)	0	2 (22.2)	0	0
Decreased appetite	1 (11.1)	1 (11.1)	0	0	0
Hyperkalaemia	1 (11.1)	0	0	1 (11.1)	0
Hypocalcaemia	1 (11.1)	1 (11.1)	0	0	0
Hypomagnesaemia	1 (11.1)	1 (11.1)	0	0	0
Tumour lysis syndrome	1 (11.1)	0	0	1 (11.1)	0
Vitamin d deficiency	1 (11.1)	0	1 (11.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (55.6)	1 (11.1)	1 (11.1)	3 (33.3)	0
Arthralgia	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Back pain	2 (22.2)	0	0	2 (22.2)	0
Muscle spasms	1 (11.1)	1 (11.1)	0	0	0
Myopathy	1 (11.1)	0	0	1 (11.1)	0

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Myositis	1 (11.1)	0	0	1 (11.1)	0
Neck pain	1 (11.1)	0	1 (11.1)	0	0
Pain in extremity	1 (11.1)	0	0	1 (11.1)	0
Synovitis	1 (11.1)	0	1 (11.1)	0	0
Nervous system disorders					
-Total	4 (44.4)	0	2 (22.2)	1 (11.1)	1 (11.1)
Headache	4 (44.4)	0	2 (22.2)	2 (22.2)	0
Hyporesponsive to stimuli	1 (11.1)	0	0	1 (11.1)	0
Seizure	1 (11.1)	0	0	0	1 (11.1)
Product issues					
-Total	1 (11.1)	0	1 (11.1)	0	0
Device occlusion	1 (11.1)	0	1 (11.1)	0	0
Psychiatric disorders					
-Total	3 (33.3)	0	1 (11.1)	2 (22.2)	0
Agitation	1 (11.1)	0	0	1 (11.1)	0
Anxiety	1 (11.1)	0	1 (11.1)	0	0
Depression	1 (11.1)	0	1 (11.1)	0	0
Mental status changes	1 (11.1)	0	0	1 (11.1)	0

Race: Other

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Acute kidney injury	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Dysuria	1 (11.1)	0	1 (11.1)	0	0
Oliguria	1 (11.1)	0	0	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Cough	1 (11.1)	0	0	1 (11.1)	0
Dyspnoea	1 (11.1)	0	0	1 (11.1)	0
Epistaxis	1 (11.1)	0	0	1 (11.1)	0
Haemoptysis	1 (11.1)	0	0	1 (11.1)	0
Hypoxia	1 (11.1)	0	0	1 (11.1)	0
Oropharyngeal pain	1 (11.1)	0	0	1 (11.1)	0
Pulmonary alveolar haemorrhage	1 (11.1)	0	0	0	1 (11.1)
Pulmonary hypertension	1 (11.1)	0	0	1 (11.1)	0
Pulmonary oedema	1 (11.1)	0	0	0	1 (11.1)
Respiratory distress	1 (11.1)	0	0	0	1 (11.1)

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (11.1)	0	0	1 (11.1)	0
Skin and subcutaneous tissue disorders					
-Total	3 (33.3)	2 (22.2)	1 (11.1)	0	0
Cold sweat	1 (11.1)	1 (11.1)	0	0	0
Night sweats	1 (11.1)	1 (11.1)	0	0	0
Rash	1 (11.1)	1 (11.1)	0	0	0
Rash erythematous	1 (11.1)	1 (11.1)	0	0	0
Urticaria	1 (11.1)	0	1 (11.1)	0	0
Vascular disorders					
-Total	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Hypertension	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Hypotension	1 (11.1)	0	0	0	1 (11.1)
Venous thrombosis limb	1 (11.1)	1 (11.1)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175d
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (83.3)	2 (6.7)	1 (3.3)	10 (33.3)	12 (40.0)
Blood and lymphatic system disorders					
-Total	16 (53.3)	0	0	12 (40.0)	4 (13.3)
Anaemia	9 (30.0)	0	1 (3.3)	8 (26.7)	0
Febrile neutropenia	8 (26.7)	0	0	8 (26.7)	0
Neutropenia	3 (10.0)	0	0	1 (3.3)	2 (6.7)
Thrombocytopenia	3 (10.0)	0	0	1 (3.3)	2 (6.7)
Pancytopenia	1 (3.3)	0	0	0	1 (3.3)
Splenomegaly	1 (3.3)	1 (3.3)	0	0	0
Cardiac disorders					
-Total	4 (13.3)	1 (3.3)	0	2 (6.7)	1 (3.3)
Bradycardia	1 (3.3)	1 (3.3)	0	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiovascular insufficiency	1 (3.3)	0	0	0	1 (3.3)
Left ventricular dysfunction	1 (3.3)	0	0	1 (3.3)	0
Sinus tachycardia	1 (3.3)	0	0	1 (3.3)	0
Endocrine disorders					
-Total	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Adrenal insufficiency	1 (3.3)	0	1 (3.3)	0	0
Cushingoid	1 (3.3)	1 (3.3)	0	0	0
Hyperthyroidism	1 (3.3)	0	1 (3.3)	0	0
Gastrointestinal disorders					
-Total	11 (36.7)	2 (6.7)	5 (16.7)	4 (13.3)	0
Vomiting	5 (16.7)	2 (6.7)	3 (10.0)	0	0
Nausea	4 (13.3)	0	4 (13.3)	0	0
Abdominal pain	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Constipation	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Gastrointestinal haemorrhage	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Colitis	1 (3.3)	0	0	1 (3.3)	0
Stomatitis	1 (3.3)	0	0	1 (3.3)	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	8 (26.7)	3 (10.0)	3 (10.0)	1 (3.3)	1 (3.3)
Pyrexia	6 (20.0)	2 (6.7)	3 (10.0)	1 (3.3)	0
Non-cardiac chest pain	2 (6.7)	2 (6.7)	0	0	0
Catheter site bruise	1 (3.3)	1 (3.3)	0	0	0
Catheter site pain	1 (3.3)	1 (3.3)	0	0	0
Chills	1 (3.3)	1 (3.3)	0	0	0
Fatigue	1 (3.3)	1 (3.3)	0	0	0
Multiple organ dysfunction syndrome	1 (3.3)	0	0	0	1 (3.3)
Pain	1 (3.3)	0	1 (3.3)	0	0
Hepatobiliary disorders					
-Total	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Cholecystitis	1 (3.3)	0	0	1 (3.3)	0
Hyperbilirubinaemia	1 (3.3)	0	1 (3.3)	0	0
Immune system disorders					
-Total	4 (13.3)	0	3 (10.0)	1 (3.3)	0
Hypogammaglobulinaemia	2 (6.7)	0	2 (6.7)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anaphylactic reaction	1 (3.3)	0	0	1 (3.3)	0
Drug hypersensitivity	1 (3.3)	0	1 (3.3)	0	0
Infections and infestations					
-Total	13 (43.3)	0	2 (6.7)	7 (23.3)	4 (13.3)
Bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Candida sepsis	1 (3.3)	0	0	0	1 (3.3)
Clostridium difficile colitis	1 (3.3)	0	0	1 (3.3)	0
Conjunctivitis	1 (3.3)	0	1 (3.3)	0	0
Cytomegalovirus viraemia	1 (3.3)	0	1 (3.3)	0	0
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Enterococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Escherichia bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Escherichia sepsis	1 (3.3)	0	0	0	1 (3.3)
Escherichia urinary tract infection	1 (3.3)	0	0	1 (3.3)	0
Klebsiella sepsis	1 (3.3)	0	0	0	1 (3.3)
Parainfluenzae virus infection	1 (3.3)	0	1 (3.3)	0	0
Pneumonia	1 (3.3)	0	1 (3.3)	0	0
Pneumonia fungal	1 (3.3)	0	0	1 (3.3)	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus bronchitis	1 (3.3)	0	0	1 (3.3)	0
Sepsis	1 (3.3)	0	0	0	1 (3.3)
Serratia infection	1 (3.3)	0	0	1 (3.3)	0
Staphylococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Streptococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Injury, poisoning and procedural complications					
-Total	4 (13.3)	1 (3.3)	2 (6.7)	1 (3.3)	0
Extradural haematoma	1 (3.3)	0	0	1 (3.3)	0
Procedural pain	1 (3.3)	0	0	1 (3.3)	0
Radiation skin injury	1 (3.3)	0	1 (3.3)	0	0
Subdural haematoma	1 (3.3)	0	0	1 (3.3)	0
Transfusion reaction	1 (3.3)	0	1 (3.3)	0	0
Wound	1 (3.3)	1 (3.3)	0	0	0
Investigations					
-Total	14 (46.7)	1 (3.3)	2 (6.7)	4 (13.3)	7 (23.3)
Neutrophil count decreased	5 (16.7)	0	0	0	5 (16.7)
White blood cell count decreased	5 (16.7)	0	1 (3.3)	0	4 (13.3)

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	4 (13.3)	0	1 (3.3)	3 (10.0)	0
Platelet count decreased	4 (13.3)	0	0	1 (3.3)	3 (10.0)
Aspartate aminotransferase increased	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Blast cell count increased	1 (3.3)	0	0	1 (3.3)	0
Blood bilirubin increased	1 (3.3)	0	0	1 (3.3)	0
Blood creatinine increased	1 (3.3)	1 (3.3)	0	0	0
Blood immunoglobulin a increased	1 (3.3)	1 (3.3)	0	0	0
Blood immunoglobulin m increased	1 (3.3)	1 (3.3)	0	0	0
Blood lactate dehydrogenase increased	1 (3.3)	0	0	1 (3.3)	0
Coronavirus test positive	1 (3.3)	1 (3.3)	0	0	0
Electrocardiogram qt prolonged	1 (3.3)	0	0	1 (3.3)	0
Lymphocyte count decreased	1 (3.3)	0	0	1 (3.3)	0
Serum ferritin increased	1 (3.3)	0	0	1 (3.3)	0
White blood cell count increased	1 (3.3)	1 (3.3)	0	0	0
Metabolism and nutrition disorders					
-Total	11 (36.7)	1 (3.3)	4 (13.3)	4 (13.3)	2 (6.7)
Hyperglycaemia	5 (16.7)	0	2 (6.7)	3 (10.0)	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	4 (13.3)	1 (3.3)	2 (6.7)	1 (3.3)	0
Hypomagnesaemia	4 (13.3)	4 (13.3)	0	0	0
Hyperuricaemia	2 (6.7)	2 (6.7)	0	0	0
Hypokalaemia	2 (6.7)	0	0	1 (3.3)	1 (3.3)
Hypophosphataemia	2 (6.7)	0	0	2 (6.7)	0
Dehydration	1 (3.3)	0	1 (3.3)	0	0
Hyperammonaemia	1 (3.3)	1 (3.3)	0	0	0
Hyperkalaemia	1 (3.3)	0	1 (3.3)	0	0
Hypernatraemia	1 (3.3)	0	0	0	1 (3.3)
Hypocalcaemia	1 (3.3)	0	0	0	1 (3.3)
Malnutrition	1 (3.3)	0	1 (3.3)	0	0
Tumour lysis syndrome	1 (3.3)	0	0	1 (3.3)	0
Vitamin d deficiency	1 (3.3)	0	1 (3.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	8 (26.7)	3 (10.0)	3 (10.0)	2 (6.7)	0
Pain in extremity	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Back pain	2 (6.7)	1 (3.3)	0	1 (3.3)	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neck pain	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Arthralgia	1 (3.3)	0	1 (3.3)	0	0
Muscle spasms	1 (3.3)	1 (3.3)	0	0	0
Musculoskeletal chest pain	1 (3.3)	1 (3.3)	0	0	0
Pain in jaw	1 (3.3)	0	1 (3.3)	0	0
Nervous system disorders					
-Total	7 (23.3)	1 (3.3)	4 (13.3)	2 (6.7)	0
Headache	5 (16.7)	1 (3.3)	2 (6.7)	2 (6.7)	0
Neuralgia	1 (3.3)	0	1 (3.3)	0	0
Peripheral sensory neuropathy	1 (3.3)	0	1 (3.3)	0	0
Product issues					
-Total	1 (3.3)	0	1 (3.3)	0	0
Device occlusion	1 (3.3)	0	1 (3.3)	0	0
Psychiatric disorders					
-Total	4 (13.3)	2 (6.7)	1 (3.3)	1 (3.3)	0
Mental status changes	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Depression	1 (3.3)	1 (3.3)	0	0	0
Insomnia	1 (3.3)	0	1 (3.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	1 (3.3)	0	0	0	1 (3.3)
Acute kidney injury	1 (3.3)	0	0	0	1 (3.3)
Reproductive system and breast disorders					
-Total	1 (3.3)	0	1 (3.3)	0	0
Scrotal pain	1 (3.3)	0	1 (3.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (16.7)	0	2 (6.7)	1 (3.3)	2 (6.7)
Hypoxia	2 (6.7)	0	2 (6.7)	0	0
Cough	1 (3.3)	1 (3.3)	0	0	0
Epistaxis	1 (3.3)	0	0	1 (3.3)	0
Idiopathic pneumonia syndrome	1 (3.3)	0	0	0	1 (3.3)
Pulmonary mass	1 (3.3)	0	1 (3.3)	0	0
Pulmonary oedema	1 (3.3)	0	0	0	1 (3.3)
Respiratory failure	1 (3.3)	0	0	0	1 (3.3)
Skin and subcutaneous tissue disorders					

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (20.0)	5 (16.7)	1 (3.3)	0	0
Cold sweat	1 (3.3)	1 (3.3)	0	0	0
Dermatitis diaper	1 (3.3)	1 (3.3)	0	0	0
Night sweats	1 (3.3)	1 (3.3)	0	0	0
Rash	1 (3.3)	1 (3.3)	0	0	0
Rash erythematous	1 (3.3)	1 (3.3)	0	0	0
Rash papular	1 (3.3)	1 (3.3)	0	0	0
Skin irritation	1 (3.3)	1 (3.3)	0	0	0
Urticaria	1 (3.3)	0	1 (3.3)	0	0
Vascular disorders					
-Total	4 (13.3)	1 (3.3)	0	2 (6.7)	1 (3.3)
Hypotension	3 (10.0)	0	0	2 (6.7)	1 (3.3)
Hypertension	1 (3.3)	1 (3.3)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175d
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (86.7)	1 (2.2)	5 (11.1)	16 (35.6)	17 (37.8)
Blood and lymphatic system disorders					
-Total	25 (55.6)	1 (2.2)	0	17 (37.8)	7 (15.6)
Anaemia	12 (26.7)	0	1 (2.2)	11 (24.4)	0
Febrile neutropenia	10 (22.2)	0	0	10 (22.2)	0
Thrombocytopenia	7 (15.6)	0	0	2 (4.4)	5 (11.1)
Neutropenia	3 (6.7)	0	0	0	3 (6.7)
Coagulopathy	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Disseminated intravascular coagulation	2 (4.4)	0	0	2 (4.4)	0
Leukocytosis	1 (2.2)	1 (2.2)	0	0	0
Leukopenia	1 (2.2)	0	0	0	1 (2.2)

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphopenia	1 (2.2)	0	0	0	1 (2.2)
Pancytopenia	1 (2.2)	0	0	0	1 (2.2)
Cardiac disorders					
-Total	5 (11.1)	0	3 (6.7)	1 (2.2)	1 (2.2)
Tachycardia	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Pericardial effusion	2 (4.4)	0	2 (4.4)	0	0
Bradycardia	1 (2.2)	0	0	0	1 (2.2)
Right ventricular dysfunction	1 (2.2)	0	0	1 (2.2)	0
Sinus tachycardia	1 (2.2)	0	0	1 (2.2)	0
Ventricular tachycardia	1 (2.2)	0	0	1 (2.2)	0
Ear and labyrinth disorders					
-Total	1 (2.2)	0	1 (2.2)	0	0
Deafness unilateral	1 (2.2)	0	1 (2.2)	0	0
Eye disorders					
-Total	2 (4.4)	0	2 (4.4)	0	0
Photophobia	1 (2.2)	0	1 (2.2)	0	0
Retinopathy	1 (2.2)	0	1 (2.2)	0	0
Gastrointestinal disorders					

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	17 (37.8)	4 (8.9)	7 (15.6)	5 (11.1)	1 (2.2)
Abdominal pain	6 (13.3)	1 (2.2)	3 (6.7)	2 (4.4)	0
Nausea	6 (13.3)	0	3 (6.7)	3 (6.7)	0
Stomatitis	4 (8.9)	1 (2.2)	0	2 (4.4)	1 (2.2)
Vomiting	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Colitis	3 (6.7)	1 (2.2)	0	2 (4.4)	0
Constipation	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Diarrhoea	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Anal fissure	1 (2.2)	0	1 (2.2)	0	0
Dry mouth	1 (2.2)	1 (2.2)	0	0	0
Dyspepsia	1 (2.2)	0	1 (2.2)	0	0
Haematemesis	1 (2.2)	0	1 (2.2)	0	0
Haematochezia	1 (2.2)	0	0	1 (2.2)	0
Oral pain	1 (2.2)	0	1 (2.2)	0	0
Pancreatitis	1 (2.2)	0	1 (2.2)	0	0
Perianal erythema	1 (2.2)	0	1 (2.2)	0	0
Proctalgia	1 (2.2)	0	1 (2.2)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions					
-Total	18 (40.0)	8 (17.8)	5 (11.1)	4 (8.9)	1 (2.2)
Fatigue	6 (13.3)	3 (6.7)	2 (4.4)	1 (2.2)	0
Pyrexia	6 (13.3)	4 (8.9)	1 (2.2)	1 (2.2)	0
Catheter site pain	3 (6.7)	0	3 (6.7)	0	0
Oedema peripheral	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Pain	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Asthenia	1 (2.2)	0	1 (2.2)	0	0
Chills	1 (2.2)	1 (2.2)	0	0	0
Device related thrombosis	1 (2.2)	0	1 (2.2)	0	0
Gait disturbance	1 (2.2)	1 (2.2)	0	0	0
Generalised oedema	1 (2.2)	1 (2.2)	0	0	0
Injection site thrombosis	1 (2.2)	0	1 (2.2)	0	0
Multiple organ dysfunction syndrome	1 (2.2)	0	0	0	1 (2.2)
Non-cardiac chest pain	1 (2.2)	0	0	1 (2.2)	0
Physical deconditioning	1 (2.2)	0	0	1 (2.2)	0
Hepatobiliary disorders					

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (4.4)	0	0	2 (4.4)	0
Hyperbilirubinaemia	2 (4.4)	0	0	2 (4.4)	0
Hepatic steatosis	1 (2.2)	0	1 (2.2)	0	0
Immune system disorders					
-Total	1 (2.2)	0	0	1 (2.2)	0
Anaphylactic reaction	1 (2.2)	0	0	1 (2.2)	0
Hypogammaglobulinaemia	1 (2.2)	1 (2.2)	0	0	0
Infections and infestations					
-Total	20 (44.4)	1 (2.2)	5 (11.1)	10 (22.2)	4 (8.9)
Oral herpes	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Device related infection	2 (4.4)	0	0	2 (4.4)	0
Upper respiratory tract infection	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Abscess limb	1 (2.2)	0	0	1 (2.2)	0
Alpha haemolytic streptococcal infection	1 (2.2)	0	0	1 (2.2)	0
Bronchopulmonary aspergillosis	1 (2.2)	0	0	1 (2.2)	0
Cellulitis	1 (2.2)	0	0	1 (2.2)	0
Clostridium difficile colitis	1 (2.2)	0	0	1 (2.2)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile infection	1 (2.2)	0	1 (2.2)	0	0
Conjunctivitis	1 (2.2)	0	1 (2.2)	0	0
Croup infectious	1 (2.2)	0	0	1 (2.2)	0
Enterococcal bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Escherichia bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Escherichia infection	1 (2.2)	0	0	1 (2.2)	0
Escherichia urinary tract infection	1 (2.2)	0	1 (2.2)	0	0
Fungal skin infection	1 (2.2)	0	1 (2.2)	0	0
Gastroenteritis	1 (2.2)	0	0	1 (2.2)	0
Human polyomavirus infection	1 (2.2)	0	0	0	1 (2.2)
Klebsiella infection	1 (2.2)	0	0	1 (2.2)	0
Klebsiella sepsis	1 (2.2)	0	0	0	1 (2.2)
Metapneumovirus infection	1 (2.2)	0	1 (2.2)	0	0
Pneumonia	1 (2.2)	0	0	0	1 (2.2)
Pneumonia fungal	1 (2.2)	0	1 (2.2)	0	0
Respiratory syncytial virus infection	1 (2.2)	0	1 (2.2)	0	0
Rhinovirus infection	1 (2.2)	0	1 (2.2)	0	0
Sinusitis	1 (2.2)	1 (2.2)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal infection	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal scalded skin syndrome	1 (2.2)	0	1 (2.2)	0	0
Staphylococcal sepsis	1 (2.2)	0	0	0	1 (2.2)
Streptococcal infection	1 (2.2)	0	0	1 (2.2)	0
Injury, poisoning and procedural complications					
-Total	5 (11.1)	0	4 (8.9)	1 (2.2)	0
Procedural pain	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Procedural hypertension	1 (2.2)	0	1 (2.2)	0	0
Subdural haematoma	1 (2.2)	0	1 (2.2)	0	0
Toxicity to various agents	1 (2.2)	0	1 (2.2)	0	0
Transfusion reaction	1 (2.2)	1 (2.2)	0	0	0
Investigations					
-Total	17 (37.8)	2 (4.4)	1 (2.2)	3 (6.7)	11 (24.4)
White blood cell count decreased	7 (15.6)	1 (2.2)	0	1 (2.2)	5 (11.1)
Platelet count decreased	6 (13.3)	0	0	0	6 (13.3)
Neutrophil count decreased	4 (8.9)	0	0	0	4 (8.9)

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspartate aminotransferase increased	3 (6.7)	1 (2.2)	0	2 (4.4)	0
Alanine aminotransferase increased	2 (4.4)	0	0	2 (4.4)	0
Blood fibrinogen decreased	1 (2.2)	0	1 (2.2)	0	0
Blood immunoglobulin m decreased	1 (2.2)	1 (2.2)	0	0	0
Blood lactate dehydrogenase increased	1 (2.2)	0	0	1 (2.2)	0
Blood uric acid increased	1 (2.2)	1 (2.2)	0	0	0
Computerised tomogram thorax abnormal	1 (2.2)	0	0	1 (2.2)	0
Electrocardiogram qt prolonged	1 (2.2)	0	0	1 (2.2)	0
Transaminases increased	1 (2.2)	0	0	1 (2.2)	0
Metabolism and nutrition disorders					
-Total	12 (26.7)	0	4 (8.9)	6 (13.3)	2 (4.4)
Decreased appetite	4 (8.9)	0	2 (4.4)	2 (4.4)	0
Dehydration	3 (6.7)	0	1 (2.2)	2 (4.4)	0
Hypokalaemia	3 (6.7)	1 (2.2)	0	1 (2.2)	1 (2.2)
Fluid overload	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Hyperglycaemia	2 (4.4)	0	1 (2.2)	0	1 (2.2)

Ethnicity: Other

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	2 (4.4)	0	0	1 (2.2)	1 (2.2)
Hypocalcaemia	2 (4.4)	1 (2.2)	0	0	1 (2.2)
Hyperkalaemia	1 (2.2)	0	0	1 (2.2)	0
Hypernatraemia	1 (2.2)	0	0	1 (2.2)	0
Hypoalbuminaemia	1 (2.2)	0	0	0	1 (2.2)
Hypophosphataemia	1 (2.2)	0	1 (2.2)	0	0
Tumour lysis syndrome	1 (2.2)	0	0	1 (2.2)	0
Vitamin d deficiency	1 (2.2)	0	1 (2.2)	0	0
Musculoskeletal and connective tissue disorders					
-Total	10 (22.2)	1 (2.2)	3 (6.7)	6 (13.3)	0
Pain in extremity	6 (13.3)	1 (2.2)	1 (2.2)	4 (8.9)	0
Bone pain	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Arthralgia	1 (2.2)	0	0	1 (2.2)	0
Back pain	1 (2.2)	0	0	1 (2.2)	0
Musculoskeletal pain	1 (2.2)	0	0	1 (2.2)	0
Myopathy	1 (2.2)	0	0	1 (2.2)	0
Myositis	1 (2.2)	0	0	1 (2.2)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neck pain	1 (2.2)	0	1 (2.2)	0	0
Pain in jaw	1 (2.2)	0	1 (2.2)	0	0
Synovitis	1 (2.2)	0	1 (2.2)	0	0
Nervous system disorders					
-Total	8 (17.8)	2 (4.4)	3 (6.7)	2 (4.4)	1 (2.2)
Headache	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Hypoaesthesia	1 (2.2)	1 (2.2)	0	0	0
Hyporesponsive to stimuli	1 (2.2)	0	0	1 (2.2)	0
Leukoencephalopathy	1 (2.2)	0	0	1 (2.2)	0
Neuropathy peripheral	1 (2.2)	1 (2.2)	0	0	0
Peroneal nerve palsy	1 (2.2)	1 (2.2)	0	0	0
Seizure	1 (2.2)	0	0	0	1 (2.2)
Visual field defect	1 (2.2)	0	1 (2.2)	0	0
Psychiatric disorders					
-Total	7 (15.6)	1 (2.2)	5 (11.1)	1 (2.2)	0
Anxiety	2 (4.4)	0	2 (4.4)	0	0
Confusional state	2 (4.4)	0	2 (4.4)	0	0
Agitation	1 (2.2)	0	0	1 (2.2)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Depression	1 (2.2)	0	1 (2.2)	0	0
Insomnia	1 (2.2)	0	1 (2.2)	0	0
Irritability	1 (2.2)	1 (2.2)	0	0	0
Mental status changes	1 (2.2)	1 (2.2)	0	0	0
Renal and urinary disorders					
-Total	5 (11.1)	1 (2.2)	1 (2.2)	2 (4.4)	1 (2.2)
Acute kidney injury	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Cystitis haemorrhagic	2 (4.4)	0	0	1 (2.2)	1 (2.2)
Dysuria	1 (2.2)	0	1 (2.2)	0	0
Haematuria	1 (2.2)	1 (2.2)	0	0	0
Oliguria	1 (2.2)	0	0	1 (2.2)	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (13.3)	0	3 (6.7)	0	3 (6.7)
Hypoxia	5 (11.1)	0	2 (4.4)	2 (4.4)	1 (2.2)
Pleural effusion	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Cough	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Epistaxis	2 (4.4)	0	2 (4.4)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oropharyngeal pain	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Aspiration	1 (2.2)	0	0	0	1 (2.2)
Atelectasis	1 (2.2)	0	1 (2.2)	0	0
Dyspnoea	1 (2.2)	0	0	1 (2.2)	0
Haemoptysis	1 (2.2)	0	0	1 (2.2)	0
Nasal congestion	1 (2.2)	1 (2.2)	0	0	0
Pulmonary alveolar haemorrhage	1 (2.2)	0	0	0	1 (2.2)
Pulmonary hypertension	1 (2.2)	0	0	1 (2.2)	0
Pulmonary oedema	1 (2.2)	0	0	0	1 (2.2)
Respiratory distress	1 (2.2)	0	0	0	1 (2.2)
Rhinorrhoea	1 (2.2)	1 (2.2)	0	0	0
Tachypnoea	1 (2.2)	0	0	1 (2.2)	0
Skin and subcutaneous tissue disorders					
-Total	4 (8.9)	1 (2.2)	3 (6.7)	0	0
Rash erythematous	2 (4.4)	0	2 (4.4)	0	0
Alopecia	1 (2.2)	0	1 (2.2)	0	0
Rash papular	1 (2.2)	1 (2.2)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	6 (13.3)	1 (2.2)	0	3 (6.7)	2 (4.4)
Hypotension	4 (8.9)	0	0	2 (4.4)	2 (4.4)
Hypertension	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Venous thrombosis limb	1 (2.2)	1 (2.2)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175e
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	1 (12.5)	0	4 (50.0)	3 (37.5)
Blood and lymphatic system disorders					
-Total	5 (62.5)	0	0	5 (62.5)	0
Febrile neutropenia	3 (37.5)	0	0	3 (37.5)	0
Anaemia	2 (25.0)	0	0	2 (25.0)	0
Cardiac disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Tachycardia	1 (12.5)	0	0	1 (12.5)	0
Gastrointestinal disorders					
-Total	4 (50.0)	2 (25.0)	0	1 (12.5)	1 (12.5)
Abdominal pain	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Diarrhoea	2 (25.0)	1 (12.5)	1 (12.5)	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (25.0)	0	0	2 (25.0)	0
Stomatitis	2 (25.0)	1 (12.5)	0	0	1 (12.5)
Vomiting	2 (25.0)	2 (25.0)	0	0	0
Dyspepsia	1 (12.5)	0	1 (12.5)	0	0
General disorders and administration site conditions					
-Total	4 (50.0)	2 (25.0)	0	2 (25.0)	0
Fatigue	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Pyrexia	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Catheter site pain	1 (12.5)	1 (12.5)	0	0	0
Chills	1 (12.5)	1 (12.5)	0	0	0
Pain	1 (12.5)	0	0	1 (12.5)	0
Immune system disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypogammaglobulinaemia	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	2 (25.0)	0	0	0	2 (25.0)
Cellulitis	1 (12.5)	0	0	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (12.5)	0	1 (12.5)	0	0
Human polyomavirus infection	1 (12.5)	0	0	0	1 (12.5)
Oral herpes	1 (12.5)	0	0	1 (12.5)	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Injury, poisoning and procedural complications					
-Total	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Procedural pain	1 (12.5)	0	0	1 (12.5)	0
Wound	1 (12.5)	1 (12.5)	0	0	0
Investigations					
-Total	1 (12.5)	0	0	0	1 (12.5)
Neutrophil count decreased	1 (12.5)	0	0	0	1 (12.5)
White blood cell count decreased	1 (12.5)	0	0	0	1 (12.5)
Metabolism and nutrition disorders					
-Total	2 (25.0)	0	2 (25.0)	0	0
Decreased appetite	1 (12.5)	0	1 (12.5)	0	0
Dehydration	1 (12.5)	0	1 (12.5)	0	0
Hypomagnesaemia	1 (12.5)	1 (12.5)	0	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vitamin d deficiency	1 (12.5)	0	1 (12.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Pain in extremity	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Neck pain	1 (12.5)	0	1 (12.5)	0	0
Nervous system disorders					
-Total	2 (25.0)	0	2 (25.0)	0	0
Headache	2 (25.0)	0	2 (25.0)	0	0
Psychiatric disorders					
-Total	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Anxiety	1 (12.5)	0	1 (12.5)	0	0
Confusional state	1 (12.5)	0	1 (12.5)	0	0
Depression	1 (12.5)	1 (12.5)	0	0	0
Renal and urinary disorders					
-Total	1 (12.5)	0	0	0	1 (12.5)
Cystitis haemorrhagic	1 (12.5)	0	0	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders					

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (25.0)	0	1 (12.5)	0	1 (12.5)
Hypoxia	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Aspiration	1 (12.5)	0	0	0	1 (12.5)
Cough	1 (12.5)	1 (12.5)	0	0	0
Epistaxis	1 (12.5)	0	1 (12.5)	0	0
Nasal congestion	1 (12.5)	1 (12.5)	0	0	0
Oropharyngeal pain	1 (12.5)	1 (12.5)	0	0	0
Pleural effusion	1 (12.5)	0	1 (12.5)	0	0
Rhinorrhoea	1 (12.5)	1 (12.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (25.0)	2 (25.0)	0	0	0
Dermatitis diaper	1 (12.5)	1 (12.5)	0	0	0
Rash papular	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	3 (37.5)	1 (12.5)	0	1 (12.5)	1 (12.5)
Hypotension	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Hypertension	1 (12.5)	1 (12.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175e
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (83.6)	2 (3.0)	6 (9.0)	22 (32.8)	26 (38.8)
Blood and lymphatic system disorders					
-Total	36 (53.7)	1 (1.5)	0	24 (35.8)	11 (16.4)
Anaemia	19 (28.4)	0	2 (3.0)	17 (25.4)	0
Febrile neutropenia	15 (22.4)	0	0	15 (22.4)	0
Thrombocytopenia	10 (14.9)	0	0	3 (4.5)	7 (10.4)
Neutropenia	6 (9.0)	0	0	1 (1.5)	5 (7.5)
Coagulopathy	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Disseminated intravascular coagulation	2 (3.0)	0	0	2 (3.0)	0
Pancytopenia	2 (3.0)	0	0	0	2 (3.0)
Leukocytosis	1 (1.5)	1 (1.5)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (1.5)	0	0	0	1 (1.5)
Lymphopenia	1 (1.5)	0	0	0	1 (1.5)
Splenomegaly	1 (1.5)	1 (1.5)	0	0	0
Cardiac disorders					
-Total	8 (11.9)	1 (1.5)	3 (4.5)	2 (3.0)	2 (3.0)
Bradycardia	2 (3.0)	1 (1.5)	0	0	1 (1.5)
Pericardial effusion	2 (3.0)	0	2 (3.0)	0	0
Sinus tachycardia	2 (3.0)	0	0	2 (3.0)	0
Tachycardia	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Cardiovascular insufficiency	1 (1.5)	0	0	0	1 (1.5)
Left ventricular dysfunction	1 (1.5)	0	0	1 (1.5)	0
Right ventricular dysfunction	1 (1.5)	0	0	1 (1.5)	0
Ventricular tachycardia	1 (1.5)	0	0	1 (1.5)	0
Ear and labyrinth disorders					
-Total	1 (1.5)	0	1 (1.5)	0	0
Deafness unilateral	1 (1.5)	0	1 (1.5)	0	0
Endocrine disorders					
-Total	3 (4.5)	1 (1.5)	2 (3.0)	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	1 (1.5)	0	1 (1.5)	0	0
Cushingoid	1 (1.5)	1 (1.5)	0	0	0
Hyperthyroidism	1 (1.5)	0	1 (1.5)	0	0
Eye disorders					
-Total	2 (3.0)	0	2 (3.0)	0	0
Photophobia	1 (1.5)	0	1 (1.5)	0	0
Retinopathy	1 (1.5)	0	1 (1.5)	0	0
Gastrointestinal disorders					
-Total	24 (35.8)	4 (6.0)	12 (17.9)	8 (11.9)	0
Nausea	8 (11.9)	0	7 (10.4)	1 (1.5)	0
Abdominal pain	7 (10.4)	0	4 (6.0)	3 (4.5)	0
Vomiting	7 (10.4)	2 (3.0)	4 (6.0)	1 (1.5)	0
Constipation	5 (7.5)	3 (4.5)	2 (3.0)	0	0
Colitis	4 (6.0)	1 (1.5)	0	3 (4.5)	0
Stomatitis	3 (4.5)	0	0	3 (4.5)	0
Gastrointestinal haemorrhage	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Anal fissure	1 (1.5)	0	1 (1.5)	0	0
Diarrhoea	1 (1.5)	0	0	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry mouth	1 (1.5)	1 (1.5)	0	0	0
Haematemesis	1 (1.5)	0	1 (1.5)	0	0
Haematochezia	1 (1.5)	0	0	1 (1.5)	0
Oral pain	1 (1.5)	0	1 (1.5)	0	0
Pancreatitis	1 (1.5)	0	1 (1.5)	0	0
Perianal erythema	1 (1.5)	0	1 (1.5)	0	0
Proctalgia	1 (1.5)	0	1 (1.5)	0	0
General disorders and administration site conditions					
-Total	22 (32.8)	9 (13.4)	8 (11.9)	3 (4.5)	2 (3.0)
Pyrexia	10 (14.9)	5 (7.5)	4 (6.0)	1 (1.5)	0
Fatigue	5 (7.5)	3 (4.5)	2 (3.0)	0	0
Catheter site pain	3 (4.5)	0	3 (4.5)	0	0
Non-cardiac chest pain	3 (4.5)	2 (3.0)	0	1 (1.5)	0
Multiple organ dysfunction syndrome	2 (3.0)	0	0	0	2 (3.0)
Oedema peripheral	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Pain	2 (3.0)	0	2 (3.0)	0	0
Asthenia	1 (1.5)	0	1 (1.5)	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site bruise	1 (1.5)	1 (1.5)	0	0	0
Chills	1 (1.5)	1 (1.5)	0	0	0
Device related thrombosis	1 (1.5)	0	1 (1.5)	0	0
Gait disturbance	1 (1.5)	1 (1.5)	0	0	0
Generalised oedema	1 (1.5)	1 (1.5)	0	0	0
Injection site thrombosis	1 (1.5)	0	1 (1.5)	0	0
Physical deconditioning	1 (1.5)	0	0	1 (1.5)	0
Hepatobiliary disorders					
-Total	4 (6.0)	0	1 (1.5)	3 (4.5)	0
Hyperbilirubinaemia	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Cholecystitis	1 (1.5)	0	0	1 (1.5)	0
Hepatic steatosis	1 (1.5)	0	1 (1.5)	0	0
Immune system disorders					
-Total	4 (6.0)	0	2 (3.0)	2 (3.0)	0
Anaphylactic reaction	2 (3.0)	0	0	2 (3.0)	0
Hypogammaglobulinaemia	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Drug hypersensitivity	1 (1.5)	0	1 (1.5)	0	0
Infections and infestations					

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	31 (46.3)	1 (1.5)	7 (10.4)	17 (25.4)	6 (9.0)
Device related infection	3 (4.5)	0	0	3 (4.5)	0
Clostridium difficile colitis	2 (3.0)	0	0	2 (3.0)	0
Conjunctivitis	2 (3.0)	0	2 (3.0)	0	0
Enterococcal bacteraemia	2 (3.0)	0	0	2 (3.0)	0
Escherichia bacteraemia	2 (3.0)	0	0	2 (3.0)	0
Escherichia urinary tract infection	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Klebsiella sepsis	2 (3.0)	0	0	0	2 (3.0)
Oral herpes	2 (3.0)	0	2 (3.0)	0	0
Pneumonia fungal	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Staphylococcal bacteraemia	2 (3.0)	0	0	2 (3.0)	0
Upper respiratory tract infection	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Abscess limb	1 (1.5)	0	0	1 (1.5)	0
Alpha haemolytic streptococcal infection	1 (1.5)	0	0	1 (1.5)	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Candida sepsis	1 (1.5)	0	0	0	1 (1.5)

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Croup infectious	1 (1.5)	0	0	1 (1.5)	0
Cytomegalovirus viraemia	1 (1.5)	0	1 (1.5)	0	0
Escherichia infection	1 (1.5)	0	0	1 (1.5)	0
Escherichia sepsis	1 (1.5)	0	0	0	1 (1.5)
Fungal skin infection	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis	1 (1.5)	0	0	1 (1.5)	0
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Metapneumovirus infection	1 (1.5)	0	1 (1.5)	0	0
Parainfluenzae virus infection	1 (1.5)	0	1 (1.5)	0	0
Pneumonia	1 (1.5)	0	1 (1.5)	0	0
Respiratory syncytial virus bronchitis	1 (1.5)	0	0	1 (1.5)	0
Respiratory syncytial virus infection	1 (1.5)	0	1 (1.5)	0	0
Rhinovirus infection	1 (1.5)	0	1 (1.5)	0	0
Sepsis	1 (1.5)	0	0	0	1 (1.5)
Serratia infection	1 (1.5)	0	0	1 (1.5)	0
Sinusitis	1 (1.5)	1 (1.5)	0	0	0
Staphylococcal infection	1 (1.5)	0	0	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal scalded skin syndrome	1 (1.5)	0	1 (1.5)	0	0
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Streptococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Streptococcal infection	1 (1.5)	0	0	1 (1.5)	0
Injury, poisoning and procedural complications					
-Total	7 (10.4)	0	6 (9.0)	1 (1.5)	0
Procedural pain	3 (4.5)	0	2 (3.0)	1 (1.5)	0
Subdural haematoma	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Transfusion reaction	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Extradural haematoma	1 (1.5)	0	0	1 (1.5)	0
Procedural hypertension	1 (1.5)	0	1 (1.5)	0	0
Radiation skin injury	1 (1.5)	0	1 (1.5)	0	0
Toxicity to various agents	1 (1.5)	0	1 (1.5)	0	0
Investigations					
-Total	30 (44.8)	3 (4.5)	3 (4.5)	7 (10.4)	17 (25.4)
White blood cell count decreased	11 (16.4)	1 (1.5)	1 (1.5)	1 (1.5)	8 (11.9)
Platelet count decreased	10 (14.9)	0	0	1 (1.5)	9 (13.4)

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	8 (11.9)	0	0	0	8 (11.9)
Alanine aminotransferase increased	6 (9.0)	0	1 (1.5)	5 (7.5)	0
Aspartate aminotransferase increased	5 (7.5)	1 (1.5)	1 (1.5)	3 (4.5)	0
Blood lactate dehydrogenase increased	2 (3.0)	0	0	2 (3.0)	0
Electrocardiogram qt prolonged	2 (3.0)	0	0	2 (3.0)	0
Blast cell count increased	1 (1.5)	0	0	1 (1.5)	0
Blood bilirubin increased	1 (1.5)	0	0	1 (1.5)	0
Blood creatinine increased	1 (1.5)	1 (1.5)	0	0	0
Blood fibrinogen decreased	1 (1.5)	0	1 (1.5)	0	0
Blood immunoglobulin a increased	1 (1.5)	1 (1.5)	0	0	0
Blood immunoglobulin m decreased	1 (1.5)	1 (1.5)	0	0	0
Blood immunoglobulin m increased	1 (1.5)	1 (1.5)	0	0	0
Blood uric acid increased	1 (1.5)	1 (1.5)	0	0	0
Computerised tomogram thorax abnormal	1 (1.5)	0	0	1 (1.5)	0
Coronavirus test positive	1 (1.5)	1 (1.5)	0	0	0
Lymphocyte count decreased	1 (1.5)	0	0	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	1 (1.5)	0	0	1 (1.5)	0
Transaminases increased	1 (1.5)	0	0	1 (1.5)	0
White blood cell count increased	1 (1.5)	1 (1.5)	0	0	0
Metabolism and nutrition disorders					
-Total	21 (31.3)	1 (1.5)	6 (9.0)	10 (14.9)	4 (6.0)
Decreased appetite	7 (10.4)	1 (1.5)	3 (4.5)	3 (4.5)	0
Hyperglycaemia	7 (10.4)	0	3 (4.5)	3 (4.5)	1 (1.5)
Hypokalaemia	5 (7.5)	1 (1.5)	0	2 (3.0)	2 (3.0)
Hyperuricaemia	4 (6.0)	2 (3.0)	0	1 (1.5)	1 (1.5)
Dehydration	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Hypocalcaemia	3 (4.5)	1 (1.5)	0	0	2 (3.0)
Hypomagnesaemia	3 (4.5)	3 (4.5)	0	0	0
Hypophosphataemia	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Fluid overload	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Hyperkalaemia	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Hypernatraemia	2 (3.0)	0	0	1 (1.5)	1 (1.5)
Tumour lysis syndrome	2 (3.0)	0	0	2 (3.0)	0
Hyperammonaemia	1 (1.5)	1 (1.5)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	1 (1.5)	0	0	0	1 (1.5)
Malnutrition	1 (1.5)	0	1 (1.5)	0	0
Vitamin d deficiency	1 (1.5)	0	1 (1.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	15 (22.4)	3 (4.5)	5 (7.5)	7 (10.4)	0
Pain in extremity	7 (10.4)	1 (1.5)	2 (3.0)	4 (6.0)	0
Back pain	3 (4.5)	1 (1.5)	0	2 (3.0)	0
Arthralgia	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Bone pain	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Neck pain	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Pain in jaw	2 (3.0)	0	2 (3.0)	0	0
Muscle spasms	1 (1.5)	1 (1.5)	0	0	0
Musculoskeletal chest pain	1 (1.5)	1 (1.5)	0	0	0
Musculoskeletal pain	1 (1.5)	0	0	1 (1.5)	0
Myopathy	1 (1.5)	0	0	1 (1.5)	0
Myositis	1 (1.5)	0	0	1 (1.5)	0
Synovitis	1 (1.5)	0	1 (1.5)	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	13 (19.4)	3 (4.5)	5 (7.5)	4 (6.0)	1 (1.5)
Headache	8 (11.9)	2 (3.0)	2 (3.0)	4 (6.0)	0
Hypoaesthesia	1 (1.5)	1 (1.5)	0	0	0
Hyporesponsive to stimuli	1 (1.5)	0	0	1 (1.5)	0
Leukoencephalopathy	1 (1.5)	0	0	1 (1.5)	0
Neuralgia	1 (1.5)	0	1 (1.5)	0	0
Neuropathy peripheral	1 (1.5)	1 (1.5)	0	0	0
Peripheral sensory neuropathy	1 (1.5)	0	1 (1.5)	0	0
Peroneal nerve palsy	1 (1.5)	1 (1.5)	0	0	0
Seizure	1 (1.5)	0	0	0	1 (1.5)
Visual field defect	1 (1.5)	0	1 (1.5)	0	0
Product issues					
-Total	1 (1.5)	0	1 (1.5)	0	0
Device occlusion	1 (1.5)	0	1 (1.5)	0	0
Psychiatric disorders					
-Total	8 (11.9)	2 (3.0)	4 (6.0)	2 (3.0)	0
Mental status changes	3 (4.5)	2 (3.0)	0	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Insomnia	2 (3.0)	0	2 (3.0)	0	0
Agitation	1 (1.5)	0	0	1 (1.5)	0
Anxiety	1 (1.5)	0	1 (1.5)	0	0
Confusional state	1 (1.5)	0	1 (1.5)	0	0
Depression	1 (1.5)	0	1 (1.5)	0	0
Irritability	1 (1.5)	1 (1.5)	0	0	0
Renal and urinary disorders					
-Total	5 (7.5)	1 (1.5)	1 (1.5)	2 (3.0)	1 (1.5)
Acute kidney injury	3 (4.5)	1 (1.5)	0	1 (1.5)	1 (1.5)
Cystitis haemorrhagic	1 (1.5)	0	0	1 (1.5)	0
Dysuria	1 (1.5)	0	1 (1.5)	0	0
Haematuria	1 (1.5)	1 (1.5)	0	0	0
Oliguria	1 (1.5)	0	0	1 (1.5)	0
Reproductive system and breast disorders					
-Total	1 (1.5)	0	1 (1.5)	0	0
Scrotal pain	1 (1.5)	0	1 (1.5)	0	0
Respiratory, thoracic and mediastinal disorders					

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (13.4)	0	4 (6.0)	1 (1.5)	4 (6.0)
Hypoxia	5 (7.5)	0	3 (4.5)	1 (1.5)	1 (1.5)
Cough	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Epistaxis	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Pleural effusion	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Pulmonary oedema	2 (3.0)	0	0	0	2 (3.0)
Atelectasis	1 (1.5)	0	1 (1.5)	0	0
Dyspnoea	1 (1.5)	0	0	1 (1.5)	0
Haemoptysis	1 (1.5)	0	0	1 (1.5)	0
Idiopathic pneumonia syndrome	1 (1.5)	0	0	0	1 (1.5)
Oropharyngeal pain	1 (1.5)	0	0	1 (1.5)	0
Pulmonary alveolar haemorrhage	1 (1.5)	0	0	0	1 (1.5)
Pulmonary hypertension	1 (1.5)	0	0	1 (1.5)	0
Pulmonary mass	1 (1.5)	0	1 (1.5)	0	0
Respiratory distress	1 (1.5)	0	0	0	1 (1.5)
Respiratory failure	1 (1.5)	0	0	0	1 (1.5)
Tachypnoea	1 (1.5)	0	0	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	8 (11.9)	4 (6.0)	4 (6.0)	0	0
Rash erythematous	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Alopecia	1 (1.5)	0	1 (1.5)	0	0
Cold sweat	1 (1.5)	1 (1.5)	0	0	0
Night sweats	1 (1.5)	1 (1.5)	0	0	0
Rash	1 (1.5)	1 (1.5)	0	0	0
Rash papular	1 (1.5)	1 (1.5)	0	0	0
Skin irritation	1 (1.5)	1 (1.5)	0	0	0
Urticaria	1 (1.5)	0	1 (1.5)	0	0
Vascular disorders					
-Total	7 (10.4)	1 (1.5)	0	4 (6.0)	2 (3.0)
Hypotension	5 (7.5)	0	0	3 (4.5)	2 (3.0)
Hypertension	3 (4.5)	1 (1.5)	1 (1.5)	1 (1.5)	0
Venous thrombosis limb	1 (1.5)	1 (1.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175f
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	1 (50.0)	1 (50.0)	0
Cardiac disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Sinus tachycardia	1 (50.0)	0	0	1 (50.0)	0
General disorders and administration site conditions					
-Total	1 (50.0)	0	1 (50.0)	0	0
Fatigue	1 (50.0)	1 (50.0)	0	0	0
Non-cardiac chest pain	1 (50.0)	1 (50.0)	0	0	0
Pyrexia	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (50.0)	0	0	1 (50.0)	0
Investigations					
-Total	1 (50.0)	0	1 (50.0)	0	0
Blood fibrinogen decreased	1 (50.0)	0	1 (50.0)	0	0
Blood immunoglobulin m decreased	1 (50.0)	1 (50.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Decreased appetite	1 (50.0)	0	1 (50.0)	0	0
Nervous system disorders					
-Total	2 (100)	2 (100)	0	0	0
Headache	2 (100)	2 (100)	0	0	0
Reproductive system and breast disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Scrotal pain	1 (50.0)	0	1 (50.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Skin irritation	1 (50.0)	1 (50.0)	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Hypotension	1 (50.0)	0	0	1 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175f
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	62 (84.9)	3 (4.1)	5 (6.8)	25 (34.2)	29 (39.7)
Blood and lymphatic system disorders					
-Total	41 (56.2)	1 (1.4)	0	29 (39.7)	11 (15.1)
Anaemia	21 (28.8)	0	2 (2.7)	19 (26.0)	0
Febrile neutropenia	18 (24.7)	0	0	18 (24.7)	0
Thrombocytopenia	10 (13.7)	0	0	3 (4.1)	7 (9.6)
Neutropenia	6 (8.2)	0	0	1 (1.4)	5 (6.8)
Coagulopathy	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Disseminated intravascular coagulation	2 (2.7)	0	0	2 (2.7)	0
Pancytopenia	2 (2.7)	0	0	0	2 (2.7)
Leukocytosis	1 (1.4)	1 (1.4)	0	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Lymphopenia	1 (1.4)	0	0	0	1 (1.4)
Splenomegaly	1 (1.4)	1 (1.4)	0	0	0
Cardiac disorders					
-Total	8 (11.0)	1 (1.4)	3 (4.1)	2 (2.7)	2 (2.7)
Tachycardia	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Bradycardia	2 (2.7)	1 (1.4)	0	0	1 (1.4)
Pericardial effusion	2 (2.7)	0	2 (2.7)	0	0
Cardiovascular insufficiency	1 (1.4)	0	0	0	1 (1.4)
Left ventricular dysfunction	1 (1.4)	0	0	1 (1.4)	0
Right ventricular dysfunction	1 (1.4)	0	0	1 (1.4)	0
Sinus tachycardia	1 (1.4)	0	0	1 (1.4)	0
Ventricular tachycardia	1 (1.4)	0	0	1 (1.4)	0
Ear and labyrinth disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Deafness unilateral	1 (1.4)	0	1 (1.4)	0	0
Endocrine disorders					
-Total	3 (4.1)	1 (1.4)	2 (2.7)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	1 (1.4)	0	1 (1.4)	0	0
Cushingoid	1 (1.4)	1 (1.4)	0	0	0
Hyperthyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	2 (2.7)	0	2 (2.7)	0	0
Photophobia	1 (1.4)	0	1 (1.4)	0	0
Retinopathy	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	28 (38.4)	6 (8.2)	12 (16.4)	9 (12.3)	1 (1.4)
Nausea	10 (13.7)	0	7 (9.6)	3 (4.1)	0
Abdominal pain	9 (12.3)	1 (1.4)	5 (6.8)	3 (4.1)	0
Vomiting	9 (12.3)	4 (5.5)	4 (5.5)	1 (1.4)	0
Constipation	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Stomatitis	5 (6.8)	1 (1.4)	0	3 (4.1)	1 (1.4)
Colitis	4 (5.5)	1 (1.4)	0	3 (4.1)	0
Diarrhoea	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Gastrointestinal haemorrhage	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Anal fissure	1 (1.4)	0	1 (1.4)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry mouth	1 (1.4)	1 (1.4)	0	0	0
Dyspepsia	1 (1.4)	0	1 (1.4)	0	0
Haematemesis	1 (1.4)	0	1 (1.4)	0	0
Haematochezia	1 (1.4)	0	0	1 (1.4)	0
Oral pain	1 (1.4)	0	1 (1.4)	0	0
Pancreatitis	1 (1.4)	0	1 (1.4)	0	0
Perianal erythema	1 (1.4)	0	1 (1.4)	0	0
Proctalgia	1 (1.4)	0	1 (1.4)	0	0
General disorders and administration site conditions					
-Total	25 (34.2)	11 (15.1)	7 (9.6)	5 (6.8)	2 (2.7)
Pyrexia	11 (15.1)	6 (8.2)	3 (4.1)	2 (2.7)	0
Fatigue	6 (8.2)	3 (4.1)	2 (2.7)	1 (1.4)	0
Catheter site pain	4 (5.5)	1 (1.4)	3 (4.1)	0	0
Pain	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Chills	2 (2.7)	2 (2.7)	0	0	0
Multiple organ dysfunction syndrome	2 (2.7)	0	0	0	2 (2.7)
Non-cardiac chest pain	2 (2.7)	1 (1.4)	0	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Asthenia	1 (1.4)	0	1 (1.4)	0	0
Catheter site bruise	1 (1.4)	1 (1.4)	0	0	0
Device related thrombosis	1 (1.4)	0	1 (1.4)	0	0
Gait disturbance	1 (1.4)	1 (1.4)	0	0	0
Generalised oedema	1 (1.4)	1 (1.4)	0	0	0
Injection site thrombosis	1 (1.4)	0	1 (1.4)	0	0
Physical deconditioning	1 (1.4)	0	0	1 (1.4)	0
Hepatobiliary disorders					
-Total	4 (5.5)	0	1 (1.4)	3 (4.1)	0
Hyperbilirubinaemia	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Cholecystitis	1 (1.4)	0	0	1 (1.4)	0
Hepatic steatosis	1 (1.4)	0	1 (1.4)	0	0
Immune system disorders					
-Total	5 (6.8)	0	3 (4.1)	2 (2.7)	0
Hypogammaglobulinaemia	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Anaphylactic reaction	2 (2.7)	0	0	2 (2.7)	0
Drug hypersensitivity	1 (1.4)	0	1 (1.4)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	32 (43.8)	1 (1.4)	7 (9.6)	16 (21.9)	8 (11.0)
Device related infection	3 (4.1)	0	0	3 (4.1)	0
Oral herpes	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Clostridium difficile colitis	2 (2.7)	0	0	2 (2.7)	0
Conjunctivitis	2 (2.7)	0	2 (2.7)	0	0
Enterococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Escherichia bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Escherichia urinary tract infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Klebsiella sepsis	2 (2.7)	0	0	0	2 (2.7)
Pneumonia	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Pneumonia fungal	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Upper respiratory tract infection	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Clostridium difficile infection	1 (1.4)	0	1 (1.4)	0	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus viraemia	1 (1.4)	0	1 (1.4)	0	0
Escherichia infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis	1 (1.4)	0	0	1 (1.4)	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	1 (1.4)	0	0
Parainfluenzae virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Rhinovirus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	1 (1.4)	1 (1.4)	0	0	0
Staphylococcal infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	9 (12.3)	1 (1.4)	6 (8.2)	2 (2.7)	0
Procedural pain	4 (5.5)	0	2 (2.7)	2 (2.7)	0
Subdural haematoma	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Transfusion reaction	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Extradural haematoma	1 (1.4)	0	0	1 (1.4)	0
Procedural hypertension	1 (1.4)	0	1 (1.4)	0	0
Radiation skin injury	1 (1.4)	0	1 (1.4)	0	0
Toxicity to various agents	1 (1.4)	0	1 (1.4)	0	0
Wound	1 (1.4)	1 (1.4)	0	0	0
Investigations					

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	30 (41.1)	3 (4.1)	2 (2.7)	7 (9.6)	18 (24.7)
White blood cell count decreased	12 (16.4)	1 (1.4)	1 (1.4)	1 (1.4)	9 (12.3)
Platelet count decreased	10 (13.7)	0	0	1 (1.4)	9 (12.3)
Neutrophil count decreased	9 (12.3)	0	0	0	9 (12.3)
Alanine aminotransferase increased	6 (8.2)	0	1 (1.4)	5 (6.8)	0
Aspartate aminotransferase increased	5 (6.8)	1 (1.4)	1 (1.4)	3 (4.1)	0
Blood lactate dehydrogenase increased	2 (2.7)	0	0	2 (2.7)	0
Electrocardiogram qt prolonged	2 (2.7)	0	0	2 (2.7)	0
Blast cell count increased	1 (1.4)	0	0	1 (1.4)	0
Blood bilirubin increased	1 (1.4)	0	0	1 (1.4)	0
Blood creatinine increased	1 (1.4)	1 (1.4)	0	0	0
Blood immunoglobulin a increased	1 (1.4)	1 (1.4)	0	0	0
Blood immunoglobulin m increased	1 (1.4)	1 (1.4)	0	0	0
Blood uric acid increased	1 (1.4)	1 (1.4)	0	0	0
Computerised tomogram thorax abnormal	1 (1.4)	0	0	1 (1.4)	0
Coronavirus test positive	1 (1.4)	1 (1.4)	0	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (1.4)	0	0	1 (1.4)	0
Serum ferritin increased	1 (1.4)	0	0	1 (1.4)	0
Transaminases increased	1 (1.4)	0	0	1 (1.4)	0
White blood cell count increased	1 (1.4)	1 (1.4)	0	0	0
Metabolism and nutrition disorders					
-Total	22 (30.1)	1 (1.4)	7 (9.6)	10 (13.7)	4 (5.5)
Decreased appetite	7 (9.6)	1 (1.4)	3 (4.1)	3 (4.1)	0
Hyperglycaemia	7 (9.6)	0	3 (4.1)	3 (4.1)	1 (1.4)
Hypokalaemia	5 (6.8)	1 (1.4)	0	2 (2.7)	2 (2.7)
Dehydration	4 (5.5)	0	2 (2.7)	2 (2.7)	0
Hyperuricaemia	4 (5.5)	2 (2.7)	0	1 (1.4)	1 (1.4)
Hypomagnesaemia	4 (5.5)	4 (5.5)	0	0	0
Hypocalcaemia	3 (4.1)	1 (1.4)	0	0	2 (2.7)
Hypophosphataemia	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Fluid overload	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Hyperkalaemia	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Hypernatraemia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Tumour lysis syndrome	2 (2.7)	0	0	2 (2.7)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vitamin d deficiency	2 (2.7)	0	2 (2.7)	0	0
Hyperammonaemia	1 (1.4)	1 (1.4)	0	0	0
Hypoalbuminaemia	1 (1.4)	0	0	0	1 (1.4)
Malnutrition	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders					
-Total	18 (24.7)	4 (5.5)	6 (8.2)	8 (11.0)	0
Pain in extremity	9 (12.3)	2 (2.7)	2 (2.7)	5 (6.8)	0
Back pain	3 (4.1)	1 (1.4)	0	2 (2.7)	0
Neck pain	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Arthralgia	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Bone pain	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Pain in jaw	2 (2.7)	0	2 (2.7)	0	0
Muscle spasms	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal chest pain	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal pain	1 (1.4)	0	0	1 (1.4)	0
Myopathy	1 (1.4)	0	0	1 (1.4)	0
Myositis	1 (1.4)	0	0	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Synovitis	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	13 (17.8)	1 (1.4)	7 (9.6)	4 (5.5)	1 (1.4)
Headache	8 (11.0)	0	4 (5.5)	4 (5.5)	0
Hypoaesthesia	1 (1.4)	1 (1.4)	0	0	0
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Leukoencephalopathy	1 (1.4)	0	0	1 (1.4)	0
Neuralgia	1 (1.4)	0	1 (1.4)	0	0
Neuropathy peripheral	1 (1.4)	1 (1.4)	0	0	0
Peripheral sensory neuropathy	1 (1.4)	0	1 (1.4)	0	0
Peroneal nerve palsy	1 (1.4)	1 (1.4)	0	0	0
Seizure	1 (1.4)	0	0	0	1 (1.4)
Visual field defect	1 (1.4)	0	1 (1.4)	0	0
Product issues					
-Total	1 (1.4)	0	1 (1.4)	0	0
Device occlusion	1 (1.4)	0	1 (1.4)	0	0
Psychiatric disorders					
-Total	11 (15.1)	3 (4.1)	6 (8.2)	2 (2.7)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Anxiety	2 (2.7)	0	2 (2.7)	0	0
Confusional state	2 (2.7)	0	2 (2.7)	0	0
Depression	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Insomnia	2 (2.7)	0	2 (2.7)	0	0
Agitation	1 (1.4)	0	0	1 (1.4)	0
Irritability	1 (1.4)	1 (1.4)	0	0	0
Renal and urinary disorders					
-Total	6 (8.2)	1 (1.4)	1 (1.4)	2 (2.7)	2 (2.7)
Acute kidney injury	3 (4.1)	1 (1.4)	0	1 (1.4)	1 (1.4)
Cystitis haemorrhagic	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Dysuria	1 (1.4)	0	1 (1.4)	0	0
Haematuria	1 (1.4)	1 (1.4)	0	0	0
Oliguria	1 (1.4)	0	0	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (15.1)	0	5 (6.8)	1 (1.4)	5 (6.8)
Hypoxia	7 (9.6)	0	4 (5.5)	2 (2.7)	1 (1.4)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Epistaxis	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Pleural effusion	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Oropharyngeal pain	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Pulmonary oedema	2 (2.7)	0	0	0	2 (2.7)
Aspiration	1 (1.4)	0	0	0	1 (1.4)
Atelectasis	1 (1.4)	0	1 (1.4)	0	0
Dyspnoea	1 (1.4)	0	0	1 (1.4)	0
Haemoptysis	1 (1.4)	0	0	1 (1.4)	0
Idiopathic pneumonia syndrome	1 (1.4)	0	0	0	1 (1.4)
Nasal congestion	1 (1.4)	1 (1.4)	0	0	0
Pulmonary alveolar haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Pulmonary hypertension	1 (1.4)	0	0	1 (1.4)	0
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	0	0	1 (1.4)
Respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Rhinorrhoea	1 (1.4)	1 (1.4)	0	0	0
Tachypnoea	1 (1.4)	0	0	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	9 (12.3)	5 (6.8)	4 (5.5)	0	0
Rash erythematous	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Rash papular	2 (2.7)	2 (2.7)	0	0	0
Alopecia	1 (1.4)	0	1 (1.4)	0	0
Cold sweat	1 (1.4)	1 (1.4)	0	0	0
Dermatitis diaper	1 (1.4)	1 (1.4)	0	0	0
Night sweats	1 (1.4)	1 (1.4)	0	0	0
Rash	1 (1.4)	1 (1.4)	0	0	0
Urticaria	1 (1.4)	0	1 (1.4)	0	0
Vascular disorders					
-Total	9 (12.3)	2 (2.7)	0	4 (5.5)	3 (4.1)
Hypotension	6 (8.2)	0	0	3 (4.1)	3 (4.1)
Hypertension	4 (5.5)	2 (2.7)	1 (1.4)	1 (1.4)	0
Venous thrombosis limb	1 (1.4)	1 (1.4)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175g
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	2 (66.7)	1 (33.3)
Blood and lymphatic system disorders					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Febrile neutropenia	1 (33.3)	0	0	1 (33.3)	0
Leukopenia	1 (33.3)	0	0	0	1 (33.3)
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Cardiac disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Tachycardia	1 (33.3)	0	0	1 (33.3)	0
Gastrointestinal disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Abdominal pain	1 (33.3)	1 (33.3)	0	0	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	1 (33.3)	1 (33.3)	0	0	0
Diarrhoea	1 (33.3)	0	1 (33.3)	0	0
Dyspepsia	1 (33.3)	0	1 (33.3)	0	0
Nausea	1 (33.3)	0	0	1 (33.3)	0
Perianal erythema	1 (33.3)	0	1 (33.3)	0	0
General disorders and administration site conditions					
-Total	1 (33.3)	1 (33.3)	0	0	0
Chills	1 (33.3)	1 (33.3)	0	0	0
Fatigue	1 (33.3)	1 (33.3)	0	0	0
Pyrexia	1 (33.3)	1 (33.3)	0	0	0
Infections and infestations					
-Total	1 (33.3)	0	0	1 (33.3)	0
Escherichia bacteraemia	1 (33.3)	0	0	1 (33.3)	0
Sinusitis	1 (33.3)	1 (33.3)	0	0	0
Investigations					
-Total	2 (66.7)	0	0	2 (66.7)	0
Aspartate aminotransferase increased	2 (66.7)	1 (33.3)	0	1 (33.3)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (33.3)	0	0	1 (33.3)	0
Metabolism and nutrition disorders					
-Total	2 (66.7)	0	1 (33.3)	0	1 (33.3)
Decreased appetite	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Hyperuricaemia	1 (33.3)	0	0	0	1 (33.3)
Hypokalaemia	1 (33.3)	1 (33.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Bone pain	1 (33.3)	0	0	1 (33.3)	0
Neck pain	1 (33.3)	0	1 (33.3)	0	0
Nervous system disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Headache	1 (33.3)	0	1 (33.3)	0	0
Psychiatric disorders					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Anxiety	1 (33.3)	0	1 (33.3)	0	0
Irritability	1 (33.3)	1 (33.3)	0	0	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Cough	1 (33.3)	1 (33.3)	0	0	0
Hypoxia	1 (33.3)	0	1 (33.3)	0	0
Nasal congestion	1 (33.3)	1 (33.3)	0	0	0
Oropharyngeal pain	1 (33.3)	1 (33.3)	0	0	0
Rhinorrhoea	1 (33.3)	1 (33.3)	0	0	0
Vascular disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Hypertension	1 (33.3)	1 (33.3)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175g
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	61 (84.7)	3 (4.2)	6 (8.3)	24 (33.3)	28 (38.9)
Blood and lymphatic system disorders					
-Total	39 (54.2)	1 (1.4)	0	28 (38.9)	10 (13.9)
Anaemia	21 (29.2)	0	2 (2.8)	19 (26.4)	0
Febrile neutropenia	17 (23.6)	0	0	17 (23.6)	0
Thrombocytopenia	10 (13.9)	0	0	3 (4.2)	7 (9.7)
Neutropenia	5 (6.9)	0	0	1 (1.4)	4 (5.6)
Coagulopathy	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Disseminated intravascular coagulation	2 (2.8)	0	0	2 (2.8)	0
Pancytopenia	2 (2.8)	0	0	0	2 (2.8)
Leukocytosis	1 (1.4)	1 (1.4)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (1.4)	0	0	0	1 (1.4)
Splenomegaly	1 (1.4)	1 (1.4)	0	0	0
Cardiac disorders					
-Total	8 (11.1)	1 (1.4)	3 (4.2)	2 (2.8)	2 (2.8)
Bradycardia	2 (2.8)	1 (1.4)	0	0	1 (1.4)
Pericardial effusion	2 (2.8)	0	2 (2.8)	0	0
Sinus tachycardia	2 (2.8)	0	0	2 (2.8)	0
Tachycardia	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Cardiovascular insufficiency	1 (1.4)	0	0	0	1 (1.4)
Left ventricular dysfunction	1 (1.4)	0	0	1 (1.4)	0
Right ventricular dysfunction	1 (1.4)	0	0	1 (1.4)	0
Ventricular tachycardia	1 (1.4)	0	0	1 (1.4)	0
Ear and labyrinth disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Deafness unilateral	1 (1.4)	0	1 (1.4)	0	0
Endocrine disorders					
-Total	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Adrenal insufficiency	1 (1.4)	0	1 (1.4)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cushingoid	1 (1.4)	1 (1.4)	0	0	0
Hyperthyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	2 (2.8)	0	2 (2.8)	0	0
Photophobia	1 (1.4)	0	1 (1.4)	0	0
Retinopathy	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	26 (36.1)	6 (8.3)	11 (15.3)	8 (11.1)	1 (1.4)
Nausea	9 (12.5)	0	7 (9.7)	2 (2.8)	0
Vomiting	9 (12.5)	4 (5.6)	4 (5.6)	1 (1.4)	0
Abdominal pain	8 (11.1)	0	5 (6.9)	3 (4.2)	0
Constipation	5 (6.9)	3 (4.2)	2 (2.8)	0	0
Stomatitis	5 (6.9)	1 (1.4)	0	3 (4.2)	1 (1.4)
Colitis	3 (4.2)	0	0	3 (4.2)	0
Diarrhoea	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Gastrointestinal haemorrhage	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Anal fissure	1 (1.4)	0	1 (1.4)	0	0
Dry mouth	1 (1.4)	1 (1.4)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematemesis	1 (1.4)	0	1 (1.4)	0	0
Haematochezia	1 (1.4)	0	0	1 (1.4)	0
Oral pain	1 (1.4)	0	1 (1.4)	0	0
Pancreatitis	1 (1.4)	0	1 (1.4)	0	0
Proctalgia	1 (1.4)	0	1 (1.4)	0	0
General disorders and administration site conditions					
-Total	25 (34.7)	10 (13.9)	8 (11.1)	5 (6.9)	2 (2.8)
Pyrexia	11 (15.3)	5 (6.9)	4 (5.6)	2 (2.8)	0
Fatigue	6 (8.3)	3 (4.2)	2 (2.8)	1 (1.4)	0
Catheter site pain	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Non-cardiac chest pain	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Pain	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Multiple organ dysfunction syndrome	2 (2.8)	0	0	0	2 (2.8)
Oedema peripheral	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Asthenia	1 (1.4)	0	1 (1.4)	0	0
Catheter site bruise	1 (1.4)	1 (1.4)	0	0	0
Chills	1 (1.4)	1 (1.4)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related thrombosis	1 (1.4)	0	1 (1.4)	0	0
Gait disturbance	1 (1.4)	1 (1.4)	0	0	0
Generalised oedema	1 (1.4)	1 (1.4)	0	0	0
Injection site thrombosis	1 (1.4)	0	1 (1.4)	0	0
Physical deconditioning	1 (1.4)	0	0	1 (1.4)	0
Hepatobiliary disorders					
-Total	4 (5.6)	0	1 (1.4)	3 (4.2)	0
Hyperbilirubinaemia	3 (4.2)	0	1 (1.4)	2 (2.8)	0
Cholecystitis	1 (1.4)	0	0	1 (1.4)	0
Hepatic steatosis	1 (1.4)	0	1 (1.4)	0	0
Immune system disorders					
-Total	5 (6.9)	0	3 (4.2)	2 (2.8)	0
Hypogammaglobulinaemia	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Anaphylactic reaction	2 (2.8)	0	0	2 (2.8)	0
Drug hypersensitivity	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	32 (44.4)	1 (1.4)	7 (9.7)	16 (22.2)	8 (11.1)
Device related infection	3 (4.2)	0	0	3 (4.2)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Clostridium difficile colitis	2 (2.8)	0	0	2 (2.8)	0
Conjunctivitis	2 (2.8)	0	2 (2.8)	0	0
Enterococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Escherichia urinary tract infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Klebsiella sepsis	2 (2.8)	0	0	0	2 (2.8)
Pneumonia	2 (2.8)	0	1 (1.4)	0	1 (1.4)
Pneumonia fungal	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Upper respiratory tract infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Clostridium difficile infection	1 (1.4)	0	1 (1.4)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus viraemia	1 (1.4)	0	1 (1.4)	0	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis	1 (1.4)	0	0	1 (1.4)	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	1 (1.4)	0	0
Parainfluenzae virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Rhinovirus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal infection	1 (1.4)	0	0	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	9 (12.5)	1 (1.4)	6 (8.3)	2 (2.8)	0
Procedural pain	4 (5.6)	0	2 (2.8)	2 (2.8)	0
Subdural haematoma	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Transfusion reaction	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Extradural haematoma	1 (1.4)	0	0	1 (1.4)	0
Procedural hypertension	1 (1.4)	0	1 (1.4)	0	0
Radiation skin injury	1 (1.4)	0	1 (1.4)	0	0
Toxicity to various agents	1 (1.4)	0	1 (1.4)	0	0
Wound	1 (1.4)	1 (1.4)	0	0	0
Investigations					
-Total	29 (40.3)	3 (4.2)	3 (4.2)	5 (6.9)	18 (25.0)
White blood cell count decreased	12 (16.7)	1 (1.4)	1 (1.4)	1 (1.4)	9 (12.5)

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	10 (13.9)	0	0	1 (1.4)	9 (12.5)
Neutrophil count decreased	9 (12.5)	0	0	0	9 (12.5)
Alanine aminotransferase increased	5 (6.9)	0	1 (1.4)	4 (5.6)	0
Aspartate aminotransferase increased	3 (4.2)	0	1 (1.4)	2 (2.8)	0
Blood lactate dehydrogenase increased	2 (2.8)	0	0	2 (2.8)	0
Electrocardiogram qt prolonged	2 (2.8)	0	0	2 (2.8)	0
Blast cell count increased	1 (1.4)	0	0	1 (1.4)	0
Blood bilirubin increased	1 (1.4)	0	0	1 (1.4)	0
Blood creatinine increased	1 (1.4)	1 (1.4)	0	0	0
Blood fibrinogen decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin a increased	1 (1.4)	1 (1.4)	0	0	0
Blood immunoglobulin m decreased	1 (1.4)	1 (1.4)	0	0	0
Blood immunoglobulin m increased	1 (1.4)	1 (1.4)	0	0	0
Blood uric acid increased	1 (1.4)	1 (1.4)	0	0	0
Computerised tomogram thorax abnormal	1 (1.4)	0	0	1 (1.4)	0
Coronavirus test positive	1 (1.4)	1 (1.4)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (1.4)	0	0	1 (1.4)	0
Serum ferritin increased	1 (1.4)	0	0	1 (1.4)	0
Transaminases increased	1 (1.4)	0	0	1 (1.4)	0
White blood cell count increased	1 (1.4)	1 (1.4)	0	0	0
Metabolism and nutrition disorders					
-Total	21 (29.2)	1 (1.4)	7 (9.7)	10 (13.9)	3 (4.2)
Hyperglycaemia	7 (9.7)	0	3 (4.2)	3 (4.2)	1 (1.4)
Decreased appetite	6 (8.3)	1 (1.4)	3 (4.2)	2 (2.8)	0
Dehydration	4 (5.6)	0	2 (2.8)	2 (2.8)	0
Hypokalaemia	4 (5.6)	0	0	2 (2.8)	2 (2.8)
Hypomagnesaemia	4 (5.6)	4 (5.6)	0	0	0
Hyperuricaemia	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Hypocalcaemia	3 (4.2)	1 (1.4)	0	0	2 (2.8)
Hypophosphataemia	3 (4.2)	0	1 (1.4)	2 (2.8)	0
Fluid overload	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Hyperkalaemia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Hypernatraemia	2 (2.8)	0	0	1 (1.4)	1 (1.4)
Tumour lysis syndrome	2 (2.8)	0	0	2 (2.8)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vitamin d deficiency	2 (2.8)	0	2 (2.8)	0	0
Hyperammonaemia	1 (1.4)	1 (1.4)	0	0	0
Hypoalbuminaemia	1 (1.4)	0	0	0	1 (1.4)
Malnutrition	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders					
-Total	16 (22.2)	4 (5.6)	5 (6.9)	7 (9.7)	0
Pain in extremity	9 (12.5)	2 (2.8)	2 (2.8)	5 (6.9)	0
Back pain	3 (4.2)	1 (1.4)	0	2 (2.8)	0
Arthralgia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Neck pain	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Pain in jaw	2 (2.8)	0	2 (2.8)	0	0
Bone pain	1 (1.4)	0	1 (1.4)	0	0
Muscle spasms	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal chest pain	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal pain	1 (1.4)	0	0	1 (1.4)	0
Myopathy	1 (1.4)	0	0	1 (1.4)	0
Myositis	1 (1.4)	0	0	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Synovitis	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	14 (19.4)	3 (4.2)	6 (8.3)	4 (5.6)	1 (1.4)
Headache	9 (12.5)	2 (2.8)	3 (4.2)	4 (5.6)	0
Hypoaesthesia	1 (1.4)	1 (1.4)	0	0	0
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Leukoencephalopathy	1 (1.4)	0	0	1 (1.4)	0
Neuralgia	1 (1.4)	0	1 (1.4)	0	0
Neuropathy peripheral	1 (1.4)	1 (1.4)	0	0	0
Peripheral sensory neuropathy	1 (1.4)	0	1 (1.4)	0	0
Peroneal nerve palsy	1 (1.4)	1 (1.4)	0	0	0
Seizure	1 (1.4)	0	0	0	1 (1.4)
Visual field defect	1 (1.4)	0	1 (1.4)	0	0
Product issues					
-Total	1 (1.4)	0	1 (1.4)	0	0
Device occlusion	1 (1.4)	0	1 (1.4)	0	0
Psychiatric disorders					
-Total	9 (12.5)	2 (2.8)	5 (6.9)	2 (2.8)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Confusional state	2 (2.8)	0	2 (2.8)	0	0
Depression	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Insomnia	2 (2.8)	0	2 (2.8)	0	0
Agitation	1 (1.4)	0	0	1 (1.4)	0
Anxiety	1 (1.4)	0	1 (1.4)	0	0
Renal and urinary disorders					
-Total	6 (8.3)	1 (1.4)	1 (1.4)	2 (2.8)	2 (2.8)
Acute kidney injury	3 (4.2)	1 (1.4)	0	1 (1.4)	1 (1.4)
Cystitis haemorrhagic	2 (2.8)	0	0	1 (1.4)	1 (1.4)
Dysuria	1 (1.4)	0	1 (1.4)	0	0
Haematuria	1 (1.4)	1 (1.4)	0	0	0
Oliguria	1 (1.4)	0	0	1 (1.4)	0
Reproductive system and breast disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Scrotal pain	1 (1.4)	0	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders					

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (13.9)	0	4 (5.6)	1 (1.4)	5 (6.9)
Hypoxia	6 (8.3)	0	3 (4.2)	2 (2.8)	1 (1.4)
Epistaxis	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Pleural effusion	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Cough	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Pulmonary oedema	2 (2.8)	0	0	0	2 (2.8)
Aspiration	1 (1.4)	0	0	0	1 (1.4)
Atelectasis	1 (1.4)	0	1 (1.4)	0	0
Dyspnoea	1 (1.4)	0	0	1 (1.4)	0
Haemoptysis	1 (1.4)	0	0	1 (1.4)	0
Idiopathic pneumonia syndrome	1 (1.4)	0	0	0	1 (1.4)
Oropharyngeal pain	1 (1.4)	0	0	1 (1.4)	0
Pulmonary alveolar haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Pulmonary hypertension	1 (1.4)	0	0	1 (1.4)	0
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	0	0	1 (1.4)
Respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Tachypnoea	1 (1.4)	0	0	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	10 (13.9)	6 (8.3)	4 (5.6)	0	0
Rash erythematous	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Rash papular	2 (2.8)	2 (2.8)	0	0	0
Alopecia	1 (1.4)	0	1 (1.4)	0	0
Cold sweat	1 (1.4)	1 (1.4)	0	0	0
Dermatitis diaper	1 (1.4)	1 (1.4)	0	0	0
Night sweats	1 (1.4)	1 (1.4)	0	0	0
Rash	1 (1.4)	1 (1.4)	0	0	0
Skin irritation	1 (1.4)	1 (1.4)	0	0	0
Urticaria	1 (1.4)	0	1 (1.4)	0	0
Vascular disorders					
-Total	9 (12.5)	1 (1.4)	0	5 (6.9)	3 (4.2)
Hypotension	7 (9.7)	0	0	4 (5.6)	3 (4.2)
Hypertension	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Venous thrombosis limb	1 (1.4)	1 (1.4)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
/vob/CCTL019/haq/haq_eu_5/pgm/saf/t175_gd_b2205.sas@@/main/3 29SEP20:16:58 Final

Table 175h
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Blood and lymphatic system disorders					
-Total	1 (100)	0	0	1 (100)	0
Febrile neutropenia	1 (100)	0	0	1 (100)	0
Cardiac disorders					
-Total	1 (100)	0	1 (100)	0	0
Tachycardia	1 (100)	0	1 (100)	0	0
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Haematemesis	1 (100)	0	1 (100)	0	0
Vomiting	1 (100)	0	1 (100)	0	0
Psychiatric disorders					

Hypodiploidy: Yes

Primary system organ class Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (100)	0	1 (100)	0	0
Insomnia	1 (100)	0	1 (100)	0	0
Mental status changes	1 (100)	1 (100)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	0	1 (100)	0	0
Rash erythematous	1 (100)	0	1 (100)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175h
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	63 (85.1)	3 (4.1)	6 (8.1)	25 (33.8)	29 (39.2)
Blood and lymphatic system disorders					
-Total	40 (54.1)	1 (1.4)	0	28 (37.8)	11 (14.9)
Anaemia	21 (28.4)	0	2 (2.7)	19 (25.7)	0
Febrile neutropenia	17 (23.0)	0	0	17 (23.0)	0
Thrombocytopenia	10 (13.5)	0	0	3 (4.1)	7 (9.5)
Neutropenia	6 (8.1)	0	0	1 (1.4)	5 (6.8)
Coagulopathy	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Disseminated intravascular coagulation	2 (2.7)	0	0	2 (2.7)	0
Pancytopenia	2 (2.7)	0	0	0	2 (2.7)
Leukocytosis	1 (1.4)	1 (1.4)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Lymphopenia	1 (1.4)	0	0	0	1 (1.4)
Splenomegaly	1 (1.4)	1 (1.4)	0	0	0
Cardiac disorders					
-Total	8 (10.8)	1 (1.4)	2 (2.7)	3 (4.1)	2 (2.7)
Bradycardia	2 (2.7)	1 (1.4)	0	0	1 (1.4)
Pericardial effusion	2 (2.7)	0	2 (2.7)	0	0
Sinus tachycardia	2 (2.7)	0	0	2 (2.7)	0
Tachycardia	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Cardiovascular insufficiency	1 (1.4)	0	0	0	1 (1.4)
Left ventricular dysfunction	1 (1.4)	0	0	1 (1.4)	0
Right ventricular dysfunction	1 (1.4)	0	0	1 (1.4)	0
Ventricular tachycardia	1 (1.4)	0	0	1 (1.4)	0
Ear and labyrinth disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Deafness unilateral	1 (1.4)	0	1 (1.4)	0	0
Endocrine disorders					
-Total	3 (4.1)	1 (1.4)	2 (2.7)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Adrenal insufficiency	1 (1.4)	0	1 (1.4)	0	0
Cushingoid	1 (1.4)	1 (1.4)	0	0	0
Hyperthyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	2 (2.7)	0	2 (2.7)	0	0
Photophobia	1 (1.4)	0	1 (1.4)	0	0
Retinopathy	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	27 (36.5)	6 (8.1)	11 (14.9)	9 (12.2)	1 (1.4)
Nausea	10 (13.5)	0	7 (9.5)	3 (4.1)	0
Abdominal pain	9 (12.2)	1 (1.4)	5 (6.8)	3 (4.1)	0
Vomiting	8 (10.8)	4 (5.4)	3 (4.1)	1 (1.4)	0
Constipation	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Stomatitis	5 (6.8)	1 (1.4)	0	3 (4.1)	1 (1.4)
Colitis	4 (5.4)	1 (1.4)	0	3 (4.1)	0
Diarrhoea	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Gastrointestinal haemorrhage	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Anal fissure	1 (1.4)	0	1 (1.4)	0	0

Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry mouth	1 (1.4)	1 (1.4)	0	0	0
Dyspepsia	1 (1.4)	0	1 (1.4)	0	0
Haematochezia	1 (1.4)	0	0	1 (1.4)	0
Oral pain	1 (1.4)	0	1 (1.4)	0	0
Pancreatitis	1 (1.4)	0	1 (1.4)	0	0
Perianal erythema	1 (1.4)	0	1 (1.4)	0	0
Proctalgia	1 (1.4)	0	1 (1.4)	0	0
General disorders and administration site conditions					
-Total	26 (35.1)	11 (14.9)	8 (10.8)	5 (6.8)	2 (2.7)
Pyrexia	12 (16.2)	6 (8.1)	4 (5.4)	2 (2.7)	0
Fatigue	7 (9.5)	4 (5.4)	2 (2.7)	1 (1.4)	0
Catheter site pain	4 (5.4)	1 (1.4)	3 (4.1)	0	0
Non-cardiac chest pain	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Pain	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Chills	2 (2.7)	2 (2.7)	0	0	0
Multiple organ dysfunction syndrome	2 (2.7)	0	0	0	2 (2.7)
Oedema peripheral	2 (2.7)	1 (1.4)	1 (1.4)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Asthenia	1 (1.4)	0	1 (1.4)	0	0
Catheter site bruise	1 (1.4)	1 (1.4)	0	0	0
Device related thrombosis	1 (1.4)	0	1 (1.4)	0	0
Gait disturbance	1 (1.4)	1 (1.4)	0	0	0
Generalised oedema	1 (1.4)	1 (1.4)	0	0	0
Injection site thrombosis	1 (1.4)	0	1 (1.4)	0	0
Physical deconditioning	1 (1.4)	0	0	1 (1.4)	0
Hepatobiliary disorders					
-Total	4 (5.4)	0	1 (1.4)	3 (4.1)	0
Hyperbilirubinaemia	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Cholecystitis	1 (1.4)	0	0	1 (1.4)	0
Hepatic steatosis	1 (1.4)	0	1 (1.4)	0	0
Immune system disorders					
-Total	5 (6.8)	0	3 (4.1)	2 (2.7)	0
Hypogammaglobulinaemia	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Anaphylactic reaction	2 (2.7)	0	0	2 (2.7)	0
Drug hypersensitivity	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					

Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	33 (44.6)	1 (1.4)	7 (9.5)	17 (23.0)	8 (10.8)
Device related infection	3 (4.1)	0	0	3 (4.1)	0
Oral herpes	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Clostridium difficile colitis	2 (2.7)	0	0	2 (2.7)	0
Conjunctivitis	2 (2.7)	0	2 (2.7)	0	0
Enterococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Escherichia bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Escherichia urinary tract infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Klebsiella sepsis	2 (2.7)	0	0	0	2 (2.7)
Pneumonia	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Pneumonia fungal	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Upper respiratory tract infection	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Clostridium difficile infection	1 (1.4)	0	1 (1.4)	0	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus viraemia	1 (1.4)	0	1 (1.4)	0	0
Escherichia infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis	1 (1.4)	0	0	1 (1.4)	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	1 (1.4)	0	0
Parainfluenzae virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Rhinovirus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0

Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	1 (1.4)	1 (1.4)	0	0	0
Staphylococcal infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	9 (12.2)	1 (1.4)	6 (8.1)	2 (2.7)	0
Procedural pain	4 (5.4)	0	2 (2.7)	2 (2.7)	0
Subdural haematoma	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Transfusion reaction	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Extradural haematoma	1 (1.4)	0	0	1 (1.4)	0
Procedural hypertension	1 (1.4)	0	1 (1.4)	0	0
Radiation skin injury	1 (1.4)	0	1 (1.4)	0	0
Toxicity to various agents	1 (1.4)	0	1 (1.4)	0	0
Wound	1 (1.4)	1 (1.4)	0	0	0
Investigations					

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	31 (41.9)	3 (4.1)	3 (4.1)	7 (9.5)	18 (24.3)
White blood cell count decreased	12 (16.2)	1 (1.4)	1 (1.4)	1 (1.4)	9 (12.2)
Platelet count decreased	10 (13.5)	0	0	1 (1.4)	9 (12.2)
Neutrophil count decreased	9 (12.2)	0	0	0	9 (12.2)
Alanine aminotransferase increased	6 (8.1)	0	1 (1.4)	5 (6.8)	0
Aspartate aminotransferase increased	5 (6.8)	1 (1.4)	1 (1.4)	3 (4.1)	0
Blood lactate dehydrogenase increased	2 (2.7)	0	0	2 (2.7)	0
Electrocardiogram qt prolonged	2 (2.7)	0	0	2 (2.7)	0
Blast cell count increased	1 (1.4)	0	0	1 (1.4)	0
Blood bilirubin increased	1 (1.4)	0	0	1 (1.4)	0
Blood creatinine increased	1 (1.4)	1 (1.4)	0	0	0
Blood fibrinogen decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin a increased	1 (1.4)	1 (1.4)	0	0	0
Blood immunoglobulin m decreased	1 (1.4)	1 (1.4)	0	0	0
Blood immunoglobulin m increased	1 (1.4)	1 (1.4)	0	0	0
Blood uric acid increased	1 (1.4)	1 (1.4)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Computerised tomogram thorax abnormal	1 (1.4)	0	0	1 (1.4)	0
Coronavirus test positive	1 (1.4)	1 (1.4)	0	0	0
Lymphocyte count decreased	1 (1.4)	0	0	1 (1.4)	0
Serum ferritin increased	1 (1.4)	0	0	1 (1.4)	0
Transaminases increased	1 (1.4)	0	0	1 (1.4)	0
White blood cell count increased	1 (1.4)	1 (1.4)	0	0	0
Metabolism and nutrition disorders					
-Total	23 (31.1)	1 (1.4)	8 (10.8)	10 (13.5)	4 (5.4)
Decreased appetite	8 (10.8)	1 (1.4)	4 (5.4)	3 (4.1)	0
Hyperglycaemia	7 (9.5)	0	3 (4.1)	3 (4.1)	1 (1.4)
Hypokalaemia	5 (6.8)	1 (1.4)	0	2 (2.7)	2 (2.7)
Dehydration	4 (5.4)	0	2 (2.7)	2 (2.7)	0
Hyperuricaemia	4 (5.4)	2 (2.7)	0	1 (1.4)	1 (1.4)
Hypomagnesaemia	4 (5.4)	4 (5.4)	0	0	0
Hypocalcaemia	3 (4.1)	1 (1.4)	0	0	2 (2.7)
Hypophosphataemia	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Fluid overload	2 (2.7)	0	1 (1.4)	1 (1.4)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperkalaemia	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Hypernatraemia	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Tumour lysis syndrome	2 (2.7)	0	0	2 (2.7)	0
Vitamin d deficiency	2 (2.7)	0	2 (2.7)	0	0
Hyperammonaemia	1 (1.4)	1 (1.4)	0	0	0
Hypoalbuminaemia	1 (1.4)	0	0	0	1 (1.4)
Malnutrition	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders					
-Total	18 (24.3)	4 (5.4)	6 (8.1)	8 (10.8)	0
Pain in extremity	9 (12.2)	2 (2.7)	2 (2.7)	5 (6.8)	0
Back pain	3 (4.1)	1 (1.4)	0	2 (2.7)	0
Neck pain	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Arthralgia	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Bone pain	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Pain in jaw	2 (2.7)	0	2 (2.7)	0	0
Muscle spasms	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal chest pain	1 (1.4)	1 (1.4)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal pain	1 (1.4)	0	0	1 (1.4)	0
Myopathy	1 (1.4)	0	0	1 (1.4)	0
Myositis	1 (1.4)	0	0	1 (1.4)	0
Synovitis	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	15 (20.3)	3 (4.1)	7 (9.5)	4 (5.4)	1 (1.4)
Headache	10 (13.5)	2 (2.7)	4 (5.4)	4 (5.4)	0
Hypoaesthesia	1 (1.4)	1 (1.4)	0	0	0
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Leukoencephalopathy	1 (1.4)	0	0	1 (1.4)	0
Neuralgia	1 (1.4)	0	1 (1.4)	0	0
Neuropathy peripheral	1 (1.4)	1 (1.4)	0	0	0
Peripheral sensory neuropathy	1 (1.4)	0	1 (1.4)	0	0
Peroneal nerve palsy	1 (1.4)	1 (1.4)	0	0	0
Seizure	1 (1.4)	0	0	0	1 (1.4)
Visual field defect	1 (1.4)	0	1 (1.4)	0	0
Product issues					
-Total	1 (1.4)	0	1 (1.4)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device occlusion	1 (1.4)	0	1 (1.4)	0	0
Psychiatric disorders					
-Total	10 (13.5)	3 (4.1)	5 (6.8)	2 (2.7)	0
Anxiety	2 (2.7)	0	2 (2.7)	0	0
Confusional state	2 (2.7)	0	2 (2.7)	0	0
Depression	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Mental status changes	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Agitation	1 (1.4)	0	0	1 (1.4)	0
Insomnia	1 (1.4)	0	1 (1.4)	0	0
Irritability	1 (1.4)	1 (1.4)	0	0	0
Renal and urinary disorders					
-Total	6 (8.1)	1 (1.4)	1 (1.4)	2 (2.7)	2 (2.7)
Acute kidney injury	3 (4.1)	1 (1.4)	0	1 (1.4)	1 (1.4)
Cystitis haemorrhagic	2 (2.7)	0	0	1 (1.4)	1 (1.4)
Dysuria	1 (1.4)	0	1 (1.4)	0	0
Haematuria	1 (1.4)	1 (1.4)	0	0	0
Oliguria	1 (1.4)	0	0	1 (1.4)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Reproductive system and breast disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Scrotal pain	1 (1.4)	0	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (14.9)	0	5 (6.8)	1 (1.4)	5 (6.8)
Hypoxia	7 (9.5)	0	4 (5.4)	2 (2.7)	1 (1.4)
Cough	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Epistaxis	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Pleural effusion	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Oropharyngeal pain	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Pulmonary oedema	2 (2.7)	0	0	0	2 (2.7)
Aspiration	1 (1.4)	0	0	0	1 (1.4)
Atelectasis	1 (1.4)	0	1 (1.4)	0	0
Dyspnoea	1 (1.4)	0	0	1 (1.4)	0
Haemoptysis	1 (1.4)	0	0	1 (1.4)	0
Idiopathic pneumonia syndrome	1 (1.4)	0	0	0	1 (1.4)
Nasal congestion	1 (1.4)	1 (1.4)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary alveolar haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Pulmonary hypertension	1 (1.4)	0	0	1 (1.4)	0
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	0	0	1 (1.4)
Respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Rhinorrhoea	1 (1.4)	1 (1.4)	0	0	0
Tachypnoea	1 (1.4)	0	0	1 (1.4)	0
Skin and subcutaneous tissue disorders					
-Total	9 (12.2)	6 (8.1)	3 (4.1)	0	0
Rash erythematous	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Rash papular	2 (2.7)	2 (2.7)	0	0	0
Alopecia	1 (1.4)	0	1 (1.4)	0	0
Cold sweat	1 (1.4)	1 (1.4)	0	0	0
Dermatitis diaper	1 (1.4)	1 (1.4)	0	0	0
Night sweats	1 (1.4)	1 (1.4)	0	0	0
Rash	1 (1.4)	1 (1.4)	0	0	0
Skin irritation	1 (1.4)	1 (1.4)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urticaria	1 (1.4)	0	1 (1.4)	0	0
Vascular disorders					
-Total	10 (13.5)	2 (2.7)	0	5 (6.8)	3 (4.1)
Hypotension	7 (9.5)	0	0	4 (5.4)	3 (4.1)
Hypertension	4 (5.4)	2 (2.7)	1 (1.4)	1 (1.4)	0
Venous thrombosis limb	1 (1.4)	1 (1.4)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175i
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	1 (25.0)	1 (25.0)	1 (25.0)	1 (25.0)
Blood and lymphatic system disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Anaemia	1 (25.0)	0	0	1 (25.0)	0
Endocrine disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Cushingoid	1 (25.0)	1 (25.0)	0	0	0
Gastrointestinal disorders					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Colitis	1 (25.0)	0	0	1 (25.0)	0
Dry mouth	1 (25.0)	1 (25.0)	0	0	0
Hepatobiliary disorders					

BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (25.0)	0	0	1 (25.0)	0
Cholecystitis	1 (25.0)	0	0	1 (25.0)	0
Immune system disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Hypogammaglobulinaemia	1 (25.0)	0	1 (25.0)	0	0
Infections and infestations					
-Total	2 (50.0)	0	0	2 (50.0)	0
Cytomegalovirus viraemia	1 (25.0)	0	1 (25.0)	0	0
Enterococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Gastroenteritis	1 (25.0)	0	0	1 (25.0)	0
Streptococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Investigations					
-Total	3 (75.0)	1 (25.0)	1 (25.0)	0	1 (25.0)
Alanine aminotransferase increased	1 (25.0)	0	0	1 (25.0)	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0	0	0
Blood fibrinogen decreased	1 (25.0)	0	1 (25.0)	0	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0	0	0
Coronavirus test positive	1 (25.0)	1 (25.0)	0	0	0

BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (25.0)	0	0	1 (25.0)	0
Neutrophil count decreased	1 (25.0)	0	0	0	1 (25.0)
Platelet count decreased	1 (25.0)	0	0	0	1 (25.0)
White blood cell count decreased	1 (25.0)	0	0	0	1 (25.0)
Metabolism and nutrition disorders					
-Total	2 (50.0)	0	0	2 (50.0)	0
Dehydration	1 (25.0)	0	0	1 (25.0)	0
Hyperglycaemia	1 (25.0)	0	0	1 (25.0)	0
Hyperuricaemia	1 (25.0)	1 (25.0)	0	0	0
Nervous system disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Headache	1 (25.0)	1 (25.0)	0	0	0
Neuralgia	1 (25.0)	0	1 (25.0)	0	0
Psychiatric disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Insomnia	1 (25.0)	0	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders					

BCR-ABL1-like: Yes

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (25.0)	0	0	0	1 (25.0)
Idiopathic pneumonia syndrome	1 (25.0)	0	0	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175i
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	60 (84.5)	2 (2.8)	5 (7.0)	25 (35.2)	28 (39.4)
Blood and lymphatic system disorders					
-Total	40 (56.3)	1 (1.4)	0	28 (39.4)	11 (15.5)
Anaemia	20 (28.2)	0	2 (2.8)	18 (25.4)	0
Febrile neutropenia	18 (25.4)	0	0	18 (25.4)	0
Thrombocytopenia	10 (14.1)	0	0	3 (4.2)	7 (9.9)
Neutropenia	6 (8.5)	0	0	1 (1.4)	5 (7.0)
Coagulopathy	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Disseminated intravascular coagulation	2 (2.8)	0	0	2 (2.8)	0
Pancytopenia	2 (2.8)	0	0	0	2 (2.8)
Leukocytosis	1 (1.4)	1 (1.4)	0	0	0

BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Lymphopenia	1 (1.4)	0	0	0	1 (1.4)
Splenomegaly	1 (1.4)	1 (1.4)	0	0	0
Cardiac disorders					
-Total	9 (12.7)	1 (1.4)	3 (4.2)	3 (4.2)	2 (2.8)
Tachycardia	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Bradycardia	2 (2.8)	1 (1.4)	0	0	1 (1.4)
Pericardial effusion	2 (2.8)	0	2 (2.8)	0	0
Sinus tachycardia	2 (2.8)	0	0	2 (2.8)	0
Cardiovascular insufficiency	1 (1.4)	0	0	0	1 (1.4)
Left ventricular dysfunction	1 (1.4)	0	0	1 (1.4)	0
Right ventricular dysfunction	1 (1.4)	0	0	1 (1.4)	0
Ventricular tachycardia	1 (1.4)	0	0	1 (1.4)	0
Ear and labyrinth disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Deafness unilateral	1 (1.4)	0	1 (1.4)	0	0
Endocrine disorders					
-Total	2 (2.8)	0	2 (2.8)	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	1 (1.4)	0	1 (1.4)	0	0
Hyperthyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	2 (2.8)	0	2 (2.8)	0	0
Photophobia	1 (1.4)	0	1 (1.4)	0	0
Retinopathy	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	26 (36.6)	5 (7.0)	12 (16.9)	8 (11.3)	1 (1.4)
Nausea	10 (14.1)	0	7 (9.9)	3 (4.2)	0
Abdominal pain	9 (12.7)	1 (1.4)	5 (7.0)	3 (4.2)	0
Vomiting	9 (12.7)	4 (5.6)	4 (5.6)	1 (1.4)	0
Constipation	5 (7.0)	3 (4.2)	2 (2.8)	0	0
Stomatitis	5 (7.0)	1 (1.4)	0	3 (4.2)	1 (1.4)
Colitis	3 (4.2)	1 (1.4)	0	2 (2.8)	0
Diarrhoea	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Gastrointestinal haemorrhage	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Anal fissure	1 (1.4)	0	1 (1.4)	0	0
Dyspepsia	1 (1.4)	0	1 (1.4)	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematemesis	1 (1.4)	0	1 (1.4)	0	0
Haematochezia	1 (1.4)	0	0	1 (1.4)	0
Oral pain	1 (1.4)	0	1 (1.4)	0	0
Pancreatitis	1 (1.4)	0	1 (1.4)	0	0
Perianal erythema	1 (1.4)	0	1 (1.4)	0	0
Proctalgia	1 (1.4)	0	1 (1.4)	0	0
General disorders and administration site conditions					
-Total	26 (36.6)	11 (15.5)	8 (11.3)	5 (7.0)	2 (2.8)
Pyrexia	12 (16.9)	6 (8.5)	4 (5.6)	2 (2.8)	0
Fatigue	7 (9.9)	4 (5.6)	2 (2.8)	1 (1.4)	0
Catheter site pain	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Non-cardiac chest pain	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Pain	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Chills	2 (2.8)	2 (2.8)	0	0	0
Multiple organ dysfunction syndrome	2 (2.8)	0	0	0	2 (2.8)
Oedema peripheral	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Asthenia	1 (1.4)	0	1 (1.4)	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site bruise	1 (1.4)	1 (1.4)	0	0	0
Device related thrombosis	1 (1.4)	0	1 (1.4)	0	0
Gait disturbance	1 (1.4)	1 (1.4)	0	0	0
Generalised oedema	1 (1.4)	1 (1.4)	0	0	0
Injection site thrombosis	1 (1.4)	0	1 (1.4)	0	0
Physical deconditioning	1 (1.4)	0	0	1 (1.4)	0
Hepatobiliary disorders					
-Total	3 (4.2)	0	1 (1.4)	2 (2.8)	0
Hyperbilirubinaemia	3 (4.2)	0	1 (1.4)	2 (2.8)	0
Hepatic steatosis	1 (1.4)	0	1 (1.4)	0	0
Immune system disorders					
-Total	4 (5.6)	0	2 (2.8)	2 (2.8)	0
Anaphylactic reaction	2 (2.8)	0	0	2 (2.8)	0
Hypogammaglobulinaemia	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Drug hypersensitivity	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	31 (43.7)	1 (1.4)	7 (9.9)	15 (21.1)	8 (11.3)
Device related infection	3 (4.2)	0	0	3 (4.2)	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Clostridium difficile colitis	2 (2.8)	0	0	2 (2.8)	0
Conjunctivitis	2 (2.8)	0	2 (2.8)	0	0
Escherichia bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Escherichia urinary tract infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Klebsiella sepsis	2 (2.8)	0	0	0	2 (2.8)
Pneumonia	2 (2.8)	0	1 (1.4)	0	1 (1.4)
Pneumonia fungal	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Upper respiratory tract infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Clostridium difficile infection	1 (1.4)	0	1 (1.4)	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Enterococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Metapneumovirus infection	1 (1.4)	0	1 (1.4)	0	0
Parainfluenzae virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Rhinovirus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0
Sinusitis	1 (1.4)	1 (1.4)	0	0	0
Staphylococcal infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	9 (12.7)	1 (1.4)	6 (8.5)	2 (2.8)	0
Procedural pain	4 (5.6)	0	2 (2.8)	2 (2.8)	0
Subdural haematoma	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Transfusion reaction	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Extradural haematoma	1 (1.4)	0	0	1 (1.4)	0
Procedural hypertension	1 (1.4)	0	1 (1.4)	0	0
Radiation skin injury	1 (1.4)	0	1 (1.4)	0	0
Toxicity to various agents	1 (1.4)	0	1 (1.4)	0	0
Wound	1 (1.4)	1 (1.4)	0	0	0
Investigations					
-Total	28 (39.4)	2 (2.8)	2 (2.8)	7 (9.9)	17 (23.9)
White blood cell count decreased	11 (15.5)	1 (1.4)	1 (1.4)	1 (1.4)	8 (11.3)
Platelet count decreased	9 (12.7)	0	0	1 (1.4)	8 (11.3)
Neutrophil count decreased	8 (11.3)	0	0	0	8 (11.3)

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	5 (7.0)	0	1 (1.4)	4 (5.6)	0
Aspartate aminotransferase increased	5 (7.0)	1 (1.4)	1 (1.4)	3 (4.2)	0
Blood lactate dehydrogenase increased	2 (2.8)	0	0	2 (2.8)	0
Electrocardiogram qt prolonged	2 (2.8)	0	0	2 (2.8)	0
Blast cell count increased	1 (1.4)	0	0	1 (1.4)	0
Blood bilirubin increased	1 (1.4)	0	0	1 (1.4)	0
Blood immunoglobulin a increased	1 (1.4)	1 (1.4)	0	0	0
Blood immunoglobulin m increased	1 (1.4)	1 (1.4)	0	0	0
Blood uric acid increased	1 (1.4)	1 (1.4)	0	0	0
Computerised tomogram thorax abnormal	1 (1.4)	0	0	1 (1.4)	0
Serum ferritin increased	1 (1.4)	0	0	1 (1.4)	0
Transaminases increased	1 (1.4)	0	0	1 (1.4)	0
White blood cell count increased	1 (1.4)	1 (1.4)	0	0	0
Metabolism and nutrition disorders					
-Total	21 (29.6)	1 (1.4)	8 (11.3)	8 (11.3)	4 (5.6)
Decreased appetite	8 (11.3)	1 (1.4)	4 (5.6)	3 (4.2)	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	6 (8.5)	0	3 (4.2)	2 (2.8)	1 (1.4)
Hypokalaemia	5 (7.0)	1 (1.4)	0	2 (2.8)	2 (2.8)
Hypomagnesaemia	4 (5.6)	4 (5.6)	0	0	0
Dehydration	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Hyperuricaemia	3 (4.2)	1 (1.4)	0	1 (1.4)	1 (1.4)
Hypocalcaemia	3 (4.2)	1 (1.4)	0	0	2 (2.8)
Hypophosphataemia	3 (4.2)	0	1 (1.4)	2 (2.8)	0
Fluid overload	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Hyperkalaemia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Hypernatraemia	2 (2.8)	0	0	1 (1.4)	1 (1.4)
Tumour lysis syndrome	2 (2.8)	0	0	2 (2.8)	0
Vitamin d deficiency	2 (2.8)	0	2 (2.8)	0	0
Hyperammonaemia	1 (1.4)	1 (1.4)	0	0	0
Hypoalbuminaemia	1 (1.4)	0	0	0	1 (1.4)
Malnutrition	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders					
-Total	18 (25.4)	4 (5.6)	6 (8.5)	8 (11.3)	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	9 (12.7)	2 (2.8)	2 (2.8)	5 (7.0)	0
Back pain	3 (4.2)	1 (1.4)	0	2 (2.8)	0
Neck pain	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Arthralgia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Bone pain	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Pain in jaw	2 (2.8)	0	2 (2.8)	0	0
Muscle spasms	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal chest pain	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal pain	1 (1.4)	0	0	1 (1.4)	0
Myopathy	1 (1.4)	0	0	1 (1.4)	0
Myositis	1 (1.4)	0	0	1 (1.4)	0
Synovitis	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	13 (18.3)	2 (2.8)	6 (8.5)	4 (5.6)	1 (1.4)
Headache	9 (12.7)	1 (1.4)	4 (5.6)	4 (5.6)	0
Hypoaesthesia	1 (1.4)	1 (1.4)	0	0	0
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Leukoencephalopathy	1 (1.4)	0	0	1 (1.4)	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neuropathy peripheral	1 (1.4)	1 (1.4)	0	0	0
Peripheral sensory neuropathy	1 (1.4)	0	1 (1.4)	0	0
Peroneal nerve palsy	1 (1.4)	1 (1.4)	0	0	0
Seizure	1 (1.4)	0	0	0	1 (1.4)
Visual field defect	1 (1.4)	0	1 (1.4)	0	0
Product issues					
-Total	1 (1.4)	0	1 (1.4)	0	0
Device occlusion	1 (1.4)	0	1 (1.4)	0	0
Psychiatric disorders					
-Total	10 (14.1)	3 (4.2)	5 (7.0)	2 (2.8)	0
Mental status changes	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Anxiety	2 (2.8)	0	2 (2.8)	0	0
Confusional state	2 (2.8)	0	2 (2.8)	0	0
Depression	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Agitation	1 (1.4)	0	0	1 (1.4)	0
Insomnia	1 (1.4)	0	1 (1.4)	0	0
Irritability	1 (1.4)	1 (1.4)	0	0	0
Renal and urinary disorders					

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (8.5)	1 (1.4)	1 (1.4)	2 (2.8)	2 (2.8)
Acute kidney injury	3 (4.2)	1 (1.4)	0	1 (1.4)	1 (1.4)
Cystitis haemorrhagic	2 (2.8)	0	0	1 (1.4)	1 (1.4)
Dysuria	1 (1.4)	0	1 (1.4)	0	0
Haematuria	1 (1.4)	1 (1.4)	0	0	0
Oliguria	1 (1.4)	0	0	1 (1.4)	0
Reproductive system and breast disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Scrotal pain	1 (1.4)	0	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (14.1)	0	5 (7.0)	1 (1.4)	4 (5.6)
Hypoxia	7 (9.9)	0	4 (5.6)	2 (2.8)	1 (1.4)
Cough	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Epistaxis	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Pleural effusion	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Oropharyngeal pain	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Pulmonary oedema	2 (2.8)	0	0	0	2 (2.8)

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspiration	1 (1.4)	0	0	0	1 (1.4)
Atelectasis	1 (1.4)	0	1 (1.4)	0	0
Dyspnoea	1 (1.4)	0	0	1 (1.4)	0
Haemoptysis	1 (1.4)	0	0	1 (1.4)	0
Nasal congestion	1 (1.4)	1 (1.4)	0	0	0
Pulmonary alveolar haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Pulmonary hypertension	1 (1.4)	0	0	1 (1.4)	0
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	0	0	1 (1.4)
Respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Rhinorrhoea	1 (1.4)	1 (1.4)	0	0	0
Tachypnoea	1 (1.4)	0	0	1 (1.4)	0
Skin and subcutaneous tissue disorders					
-Total	10 (14.1)	6 (8.5)	4 (5.6)	0	0
Rash erythematous	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Rash papular	2 (2.8)	2 (2.8)	0	0	0
Alopecia	1 (1.4)	0	1 (1.4)	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cold sweat	1 (1.4)	1 (1.4)	0	0	0
Dermatitis diaper	1 (1.4)	1 (1.4)	0	0	0
Night sweats	1 (1.4)	1 (1.4)	0	0	0
Rash	1 (1.4)	1 (1.4)	0	0	0
Skin irritation	1 (1.4)	1 (1.4)	0	0	0
Urticaria	1 (1.4)	0	1 (1.4)	0	0
Vascular disorders					
-Total	10 (14.1)	2 (2.8)	0	5 (7.0)	3 (4.2)
Hypotension	7 (9.9)	0	0	4 (5.6)	3 (4.2)
Hypertension	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Venous thrombosis limb	1 (1.4)	1 (1.4)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175j
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (90.9)	2 (9.1)	2 (9.1)	8 (36.4)	8 (36.4)
Blood and lymphatic system disorders					
-Total	10 (45.5)	0	0	5 (22.7)	5 (22.7)
Febrile neutropenia	5 (22.7)	0	0	5 (22.7)	0
Neutropenia	4 (18.2)	0	0	0	4 (18.2)
Anaemia	3 (13.6)	0	1 (4.5)	2 (9.1)	0
Thrombocytopenia	3 (13.6)	0	0	0	3 (13.6)
Coagulopathy	1 (4.5)	0	0	1 (4.5)	0
Leukopenia	1 (4.5)	0	0	0	1 (4.5)
Cardiac disorders					
-Total	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Bradycardia	1 (4.5)	1 (4.5)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	1 (4.5)	0	0	1 (4.5)	0
Endocrine disorders					
-Total	1 (4.5)	0	1 (4.5)	0	0
Adrenal insufficiency	1 (4.5)	0	1 (4.5)	0	0
Gastrointestinal disorders					
-Total	10 (45.5)	3 (13.6)	4 (18.2)	3 (13.6)	0
Nausea	3 (13.6)	0	3 (13.6)	0	0
Constipation	2 (9.1)	2 (9.1)	0	0	0
Gastrointestinal haemorrhage	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Stomatitis	2 (9.1)	0	0	2 (9.1)	0
Vomiting	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Colitis	1 (4.5)	1 (4.5)	0	0	0
Dry mouth	1 (4.5)	1 (4.5)	0	0	0
Perianal erythema	1 (4.5)	0	1 (4.5)	0	0
General disorders and administration site conditions					
-Total	7 (31.8)	2 (9.1)	5 (22.7)	0	0
Pyrexia	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Fatigue	2 (9.1)	1 (4.5)	1 (4.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site pain	1 (4.5)	0	1 (4.5)	0	0
Chills	1 (4.5)	1 (4.5)	0	0	0
Device related thrombosis	1 (4.5)	0	1 (4.5)	0	0
Gait disturbance	1 (4.5)	1 (4.5)	0	0	0
Non-cardiac chest pain	1 (4.5)	1 (4.5)	0	0	0
Pain	1 (4.5)	0	1 (4.5)	0	0
Infections and infestations					
-Total	12 (54.5)	1 (4.5)	4 (18.2)	5 (22.7)	2 (9.1)
Conjunctivitis	2 (9.1)	0	2 (9.1)	0	0
Device related infection	2 (9.1)	0	0	2 (9.1)	0
Upper respiratory tract infection	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Alpha haemolytic streptococcal infection	1 (4.5)	0	0	1 (4.5)	0
Bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Candida sepsis	1 (4.5)	0	0	0	1 (4.5)
Escherichia bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Escherichia urinary tract infection	1 (4.5)	0	1 (4.5)	0	0
Gastroenteritis	1 (4.5)	0	0	1 (4.5)	0
Parainfluenzae virus infection	1 (4.5)	0	1 (4.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (4.5)	0	0	1 (4.5)	0
Sepsis	1 (4.5)	0	0	0	1 (4.5)
Sinusitis	1 (4.5)	1 (4.5)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Toxicity to various agents	1 (4.5)	0	1 (4.5)	0	0
Wound	1 (4.5)	1 (4.5)	0	0	0
Investigations					
-Total	4 (18.2)	0	0	1 (4.5)	3 (13.6)
Platelet count decreased	2 (9.1)	0	0	0	2 (9.1)
White blood cell count decreased	2 (9.1)	0	0	0	2 (9.1)
Aspartate aminotransferase increased	1 (4.5)	0	0	1 (4.5)	0
Metabolism and nutrition disorders					
-Total	7 (31.8)	0	3 (13.6)	2 (9.1)	2 (9.1)
Decreased appetite	3 (13.6)	0	2 (9.1)	1 (4.5)	0
Hyperuricaemia	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Hypokalaemia	2 (9.1)	1 (4.5)	0	0	1 (4.5)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (4.5)	0	0	1 (4.5)	0
Hyperglycaemia	1 (4.5)	0	1 (4.5)	0	0
Hypernatraemia	1 (4.5)	0	0	0	1 (4.5)
Hypomagnesaemia	1 (4.5)	1 (4.5)	0	0	0
Hypophosphataemia	1 (4.5)	0	0	1 (4.5)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Bone pain	1 (4.5)	0	0	1 (4.5)	0
Pain in extremity	1 (4.5)	1 (4.5)	0	0	0
Nervous system disorders					
-Total	2 (9.1)	2 (9.1)	0	0	0
Headache	1 (4.5)	1 (4.5)	0	0	0
Neuropathy peripheral	1 (4.5)	1 (4.5)	0	0	0
Peroneal nerve palsy	1 (4.5)	1 (4.5)	0	0	0
Psychiatric disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Irritability	1 (4.5)	1 (4.5)	0	0	0
Renal and urinary disorders					

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.5)	0	0	0	1 (4.5)
Acute kidney injury	1 (4.5)	0	0	0	1 (4.5)
Reproductive system and breast disorders					
-Total	1 (4.5)	0	1 (4.5)	0	0
Scrotal pain	1 (4.5)	0	1 (4.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (9.1)	0	1 (4.5)	0	1 (4.5)
Hypoxia	1 (4.5)	0	1 (4.5)	0	0
Pulmonary oedema	1 (4.5)	0	0	0	1 (4.5)
Respiratory failure	1 (4.5)	0	0	0	1 (4.5)
Skin and subcutaneous tissue disorders					
-Total	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Alopecia	1 (4.5)	0	1 (4.5)	0	0
Rash papular	1 (4.5)	1 (4.5)	0	0	0
Skin irritation	1 (4.5)	1 (4.5)	0	0	0
Vascular disorders					
-Total	4 (18.2)	1 (4.5)	0	2 (9.1)	1 (4.5)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	3 (13.6)	0	0	2 (9.1)	1 (4.5)
Hypertension	1 (4.5)	1 (4.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175j
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	44 (83.0)	1 (1.9)	4 (7.5)	18 (34.0)	21 (39.6)
Blood and lymphatic system disorders					
-Total	31 (58.5)	1 (1.9)	0	24 (45.3)	6 (11.3)
Anaemia	18 (34.0)	0	1 (1.9)	17 (32.1)	0
Febrile neutropenia	13 (24.5)	0	0	13 (24.5)	0
Thrombocytopenia	7 (13.2)	0	0	3 (5.7)	4 (7.5)
Disseminated intravascular coagulation	2 (3.8)	0	0	2 (3.8)	0
Neutropenia	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Pancytopenia	2 (3.8)	0	0	0	2 (3.8)
Coagulopathy	1 (1.9)	1 (1.9)	0	0	0
Leukocytosis	1 (1.9)	1 (1.9)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (1.9)	0	0	0	1 (1.9)
Splenomegaly	1 (1.9)	1 (1.9)	0	0	0
Cardiac disorders					
-Total	7 (13.2)	0	3 (5.7)	2 (3.8)	2 (3.8)
Tachycardia	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Pericardial effusion	2 (3.8)	0	2 (3.8)	0	0
Bradycardia	1 (1.9)	0	0	0	1 (1.9)
Cardiovascular insufficiency	1 (1.9)	0	0	0	1 (1.9)
Left ventricular dysfunction	1 (1.9)	0	0	1 (1.9)	0
Right ventricular dysfunction	1 (1.9)	0	0	1 (1.9)	0
Sinus tachycardia	1 (1.9)	0	0	1 (1.9)	0
Ventricular tachycardia	1 (1.9)	0	0	1 (1.9)	0
Ear and labyrinth disorders					
-Total	1 (1.9)	0	1 (1.9)	0	0
Deafness unilateral	1 (1.9)	0	1 (1.9)	0	0
Endocrine disorders					
-Total	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Cushingoid	1 (1.9)	1 (1.9)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperthyroidism	1 (1.9)	0	1 (1.9)	0	0
Eye disorders					
-Total	2 (3.8)	0	2 (3.8)	0	0
Photophobia	1 (1.9)	0	1 (1.9)	0	0
Retinopathy	1 (1.9)	0	1 (1.9)	0	0
Gastrointestinal disorders					
-Total	18 (34.0)	3 (5.7)	8 (15.1)	6 (11.3)	1 (1.9)
Abdominal pain	9 (17.0)	1 (1.9)	5 (9.4)	3 (5.7)	0
Nausea	7 (13.2)	0	4 (7.5)	3 (5.7)	0
Vomiting	7 (13.2)	3 (5.7)	3 (5.7)	1 (1.9)	0
Colitis	3 (5.7)	0	0	3 (5.7)	0
Constipation	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Diarrhoea	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Stomatitis	3 (5.7)	1 (1.9)	0	1 (1.9)	1 (1.9)
Anal fissure	1 (1.9)	0	1 (1.9)	0	0
Dyspepsia	1 (1.9)	0	1 (1.9)	0	0
Haematemesis	1 (1.9)	0	1 (1.9)	0	0
Haematochezia	1 (1.9)	0	0	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral pain	1 (1.9)	0	1 (1.9)	0	0
Pancreatitis	1 (1.9)	0	1 (1.9)	0	0
Proctalgia	1 (1.9)	0	1 (1.9)	0	0
General disorders and administration site conditions					
-Total	19 (35.8)	9 (17.0)	3 (5.7)	5 (9.4)	2 (3.8)
Pyrexia	9 (17.0)	5 (9.4)	2 (3.8)	2 (3.8)	0
Fatigue	5 (9.4)	3 (5.7)	1 (1.9)	1 (1.9)	0
Catheter site pain	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Multiple organ dysfunction syndrome	2 (3.8)	0	0	0	2 (3.8)
Non-cardiac chest pain	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Oedema peripheral	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Pain	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Asthenia	1 (1.9)	0	1 (1.9)	0	0
Catheter site bruise	1 (1.9)	1 (1.9)	0	0	0
Chills	1 (1.9)	1 (1.9)	0	0	0
Generalised oedema	1 (1.9)	1 (1.9)	0	0	0
Injection site thrombosis	1 (1.9)	0	1 (1.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Physical deconditioning	1 (1.9)	0	0	1 (1.9)	0
Hepatobiliary disorders					
-Total	4 (7.5)	0	1 (1.9)	3 (5.7)	0
Hyperbilirubinaemia	3 (5.7)	0	1 (1.9)	2 (3.8)	0
Cholecystitis	1 (1.9)	0	0	1 (1.9)	0
Hepatic steatosis	1 (1.9)	0	1 (1.9)	0	0
Immune system disorders					
-Total	5 (9.4)	0	3 (5.7)	2 (3.8)	0
Hypogammaglobulinaemia	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Anaphylactic reaction	2 (3.8)	0	0	2 (3.8)	0
Drug hypersensitivity	1 (1.9)	0	1 (1.9)	0	0
Infections and infestations					
-Total	21 (39.6)	0	3 (5.7)	12 (22.6)	6 (11.3)
Oral herpes	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Clostridium difficile colitis	2 (3.8)	0	0	2 (3.8)	0
Enterococcal bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Klebsiella sepsis	2 (3.8)	0	0	0	2 (3.8)
Pneumonia	2 (3.8)	0	1 (1.9)	0	1 (1.9)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Abscess limb	1 (1.9)	0	0	1 (1.9)	0
Bronchopulmonary aspergillosis	1 (1.9)	0	0	1 (1.9)	0
Cellulitis	1 (1.9)	0	0	1 (1.9)	0
Clostridium difficile infection	1 (1.9)	0	1 (1.9)	0	0
Croup infectious	1 (1.9)	0	0	1 (1.9)	0
Cytomegalovirus viraemia	1 (1.9)	0	1 (1.9)	0	0
Device related infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Escherichia infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia sepsis	1 (1.9)	0	0	0	1 (1.9)
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Fungal skin infection	1 (1.9)	0	1 (1.9)	0	0
Human polyomavirus infection	1 (1.9)	0	0	0	1 (1.9)
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Metapneumovirus infection	1 (1.9)	0	1 (1.9)	0	0
Pneumonia fungal	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus bronchitis	1 (1.9)	0	0	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (1.9)	0	1 (1.9)	0	0
Rhinovirus infection	1 (1.9)	0	1 (1.9)	0	0
Serratia infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal scalded skin syndrome	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal sepsis	1 (1.9)	0	0	0	1 (1.9)
Streptococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Streptococcal infection	1 (1.9)	0	0	1 (1.9)	0
Injury, poisoning and procedural complications					
-Total	7 (13.2)	0	5 (9.4)	2 (3.8)	0
Procedural pain	4 (7.5)	0	2 (3.8)	2 (3.8)	0
Subdural haematoma	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Transfusion reaction	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Extradural haematoma	1 (1.9)	0	0	1 (1.9)	0
Procedural hypertension	1 (1.9)	0	1 (1.9)	0	0
Radiation skin injury	1 (1.9)	0	1 (1.9)	0	0
Investigations					

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	27 (50.9)	3 (5.7)	3 (5.7)	6 (11.3)	15 (28.3)
White blood cell count decreased	10 (18.9)	1 (1.9)	1 (1.9)	1 (1.9)	7 (13.2)
Neutrophil count decreased	9 (17.0)	0	0	0	9 (17.0)
Platelet count decreased	8 (15.1)	0	0	1 (1.9)	7 (13.2)
Alanine aminotransferase increased	6 (11.3)	0	1 (1.9)	5 (9.4)	0
Aspartate aminotransferase increased	4 (7.5)	1 (1.9)	1 (1.9)	2 (3.8)	0
Blood lactate dehydrogenase increased	2 (3.8)	0	0	2 (3.8)	0
Electrocardiogram qt prolonged	2 (3.8)	0	0	2 (3.8)	0
Blast cell count increased	1 (1.9)	0	0	1 (1.9)	0
Blood bilirubin increased	1 (1.9)	0	0	1 (1.9)	0
Blood creatinine increased	1 (1.9)	1 (1.9)	0	0	0
Blood fibrinogen decreased	1 (1.9)	0	1 (1.9)	0	0
Blood immunoglobulin a increased	1 (1.9)	1 (1.9)	0	0	0
Blood immunoglobulin m decreased	1 (1.9)	1 (1.9)	0	0	0
Blood immunoglobulin m increased	1 (1.9)	1 (1.9)	0	0	0
Blood uric acid increased	1 (1.9)	1 (1.9)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Computerised tomogram thorax abnormal	1 (1.9)	0	0	1 (1.9)	0
Coronavirus test positive	1 (1.9)	1 (1.9)	0	0	0
Lymphocyte count decreased	1 (1.9)	0	0	1 (1.9)	0
Serum ferritin increased	1 (1.9)	0	0	1 (1.9)	0
Transaminases increased	1 (1.9)	0	0	1 (1.9)	0
White blood cell count increased	1 (1.9)	1 (1.9)	0	0	0
Metabolism and nutrition disorders					
-Total	16 (30.2)	1 (1.9)	5 (9.4)	8 (15.1)	2 (3.8)
Hyperglycaemia	6 (11.3)	0	2 (3.8)	3 (5.7)	1 (1.9)
Decreased appetite	5 (9.4)	1 (1.9)	2 (3.8)	2 (3.8)	0
Dehydration	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Hypocalcaemia	3 (5.7)	1 (1.9)	0	0	2 (3.8)
Hypokalaemia	3 (5.7)	0	0	2 (3.8)	1 (1.9)
Hypomagnesaemia	3 (5.7)	3 (5.7)	0	0	0
Fluid overload	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Hyperkalaemia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Hyperuricaemia	2 (3.8)	2 (3.8)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Tumour lysis syndrome	2 (3.8)	0	0	2 (3.8)	0
Vitamin d deficiency	2 (3.8)	0	2 (3.8)	0	0
Hyperammonaemia	1 (1.9)	1 (1.9)	0	0	0
Hypernatraemia	1 (1.9)	0	0	1 (1.9)	0
Hypoalbuminaemia	1 (1.9)	0	0	0	1 (1.9)
Malnutrition	1 (1.9)	0	1 (1.9)	0	0
Musculoskeletal and connective tissue disorders					
-Total	16 (30.2)	3 (5.7)	6 (11.3)	7 (13.2)	0
Pain in extremity	8 (15.1)	1 (1.9)	2 (3.8)	5 (9.4)	0
Back pain	3 (5.7)	1 (1.9)	0	2 (3.8)	0
Neck pain	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Arthralgia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Pain in jaw	2 (3.8)	0	2 (3.8)	0	0
Bone pain	1 (1.9)	0	1 (1.9)	0	0
Muscle spasms	1 (1.9)	1 (1.9)	0	0	0
Musculoskeletal chest pain	1 (1.9)	1 (1.9)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal pain	1 (1.9)	0	0	1 (1.9)	0
Myopathy	1 (1.9)	0	0	1 (1.9)	0
Myositis	1 (1.9)	0	0	1 (1.9)	0
Synovitis	1 (1.9)	0	1 (1.9)	0	0
Nervous system disorders					
-Total	13 (24.5)	1 (1.9)	7 (13.2)	4 (7.5)	1 (1.9)
Headache	9 (17.0)	1 (1.9)	4 (7.5)	4 (7.5)	0
Hypoaesthesia	1 (1.9)	1 (1.9)	0	0	0
Hyporesponsive to stimuli	1 (1.9)	0	0	1 (1.9)	0
Leukoencephalopathy	1 (1.9)	0	0	1 (1.9)	0
Neuralgia	1 (1.9)	0	1 (1.9)	0	0
Peripheral sensory neuropathy	1 (1.9)	0	1 (1.9)	0	0
Seizure	1 (1.9)	0	0	0	1 (1.9)
Visual field defect	1 (1.9)	0	1 (1.9)	0	0
Product issues					
-Total	1 (1.9)	0	1 (1.9)	0	0
Device occlusion	1 (1.9)	0	1 (1.9)	0	0
Psychiatric disorders					

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (18.9)	2 (3.8)	6 (11.3)	2 (3.8)	0
Mental status changes	3 (5.7)	2 (3.8)	0	1 (1.9)	0
Anxiety	2 (3.8)	0	2 (3.8)	0	0
Confusional state	2 (3.8)	0	2 (3.8)	0	0
Depression	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Insomnia	2 (3.8)	0	2 (3.8)	0	0
Agitation	1 (1.9)	0	0	1 (1.9)	0
Renal and urinary disorders					
-Total	5 (9.4)	1 (1.9)	1 (1.9)	2 (3.8)	1 (1.9)
Acute kidney injury	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Cystitis haemorrhagic	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Dysuria	1 (1.9)	0	1 (1.9)	0	0
Haematuria	1 (1.9)	1 (1.9)	0	0	0
Oliguria	1 (1.9)	0	0	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (17.0)	0	4 (7.5)	1 (1.9)	4 (7.5)
Hypoxia	6 (11.3)	0	3 (5.7)	2 (3.8)	1 (1.9)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	3 (5.7)	2 (3.8)	0	1 (1.9)	0
Epistaxis	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Pleural effusion	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Oropharyngeal pain	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Aspiration	1 (1.9)	0	0	0	1 (1.9)
Atelectasis	1 (1.9)	0	1 (1.9)	0	0
Dyspnoea	1 (1.9)	0	0	1 (1.9)	0
Haemoptysis	1 (1.9)	0	0	1 (1.9)	0
Idiopathic pneumonia syndrome	1 (1.9)	0	0	0	1 (1.9)
Nasal congestion	1 (1.9)	1 (1.9)	0	0	0
Pulmonary alveolar haemorrhage	1 (1.9)	0	0	0	1 (1.9)
Pulmonary hypertension	1 (1.9)	0	0	1 (1.9)	0
Pulmonary mass	1 (1.9)	0	1 (1.9)	0	0
Pulmonary oedema	1 (1.9)	0	0	0	1 (1.9)
Respiratory distress	1 (1.9)	0	0	0	1 (1.9)
Rhinorrhoea	1 (1.9)	1 (1.9)	0	0	0
Tachypnoea	1 (1.9)	0	0	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	7 (13.2)	4 (7.5)	3 (5.7)	0	0
Rash erythematous	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Cold sweat	1 (1.9)	1 (1.9)	0	0	0
Dermatitis diaper	1 (1.9)	1 (1.9)	0	0	0
Night sweats	1 (1.9)	1 (1.9)	0	0	0
Rash	1 (1.9)	1 (1.9)	0	0	0
Rash papular	1 (1.9)	1 (1.9)	0	0	0
Urticaria	1 (1.9)	0	1 (1.9)	0	0
Vascular disorders					
-Total	6 (11.3)	1 (1.9)	0	3 (5.7)	2 (3.8)
Hypotension	4 (7.5)	0	0	2 (3.8)	2 (3.8)
Hypertension	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Venous thrombosis limb	1 (1.9)	1 (1.9)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175k
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=75				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	64 (85.3)	3 (4.0)	6 (8.0)	26 (34.7)	29 (38.7)
Blood and lymphatic system disorders					
-Total	41 (54.7)	1 (1.3)	0	29 (38.7)	11 (14.7)
Anaemia	21 (28.0)	0	2 (2.7)	19 (25.3)	0
Febrile neutropenia	18 (24.0)	0	0	18 (24.0)	0
Thrombocytopenia	10 (13.3)	0	0	3 (4.0)	7 (9.3)
Neutropenia	6 (8.0)	0	0	1 (1.3)	5 (6.7)
Coagulopathy	2 (2.7)	1 (1.3)	0	1 (1.3)	0
Disseminated intravascular coagulation	2 (2.7)	0	0	2 (2.7)	0
Pancytopenia	2 (2.7)	0	0	0	2 (2.7)
Leukocytosis	1 (1.3)	1 (1.3)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Leukopenia	1 (1.3)	0	0	0	1 (1.3)
Lymphopenia	1 (1.3)	0	0	0	1 (1.3)
Splenomegaly	1 (1.3)	1 (1.3)	0	0	0
Cardiac disorders					
-Total	9 (12.0)	1 (1.3)	3 (4.0)	3 (4.0)	2 (2.7)
Tachycardia	3 (4.0)	1 (1.3)	1 (1.3)	1 (1.3)	0
Bradycardia	2 (2.7)	1 (1.3)	0	0	1 (1.3)
Pericardial effusion	2 (2.7)	0	2 (2.7)	0	0
Sinus tachycardia	2 (2.7)	0	0	2 (2.7)	0
Cardiovascular insufficiency	1 (1.3)	0	0	0	1 (1.3)
Left ventricular dysfunction	1 (1.3)	0	0	1 (1.3)	0
Right ventricular dysfunction	1 (1.3)	0	0	1 (1.3)	0
Ventricular tachycardia	1 (1.3)	0	0	1 (1.3)	0
Ear and labyrinth disorders					
-Total	1 (1.3)	0	1 (1.3)	0	0
Deafness unilateral	1 (1.3)	0	1 (1.3)	0	0
Endocrine disorders					
-Total	3 (4.0)	1 (1.3)	2 (2.7)	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Adrenal insufficiency	1 (1.3)	0	1 (1.3)	0	0
Cushingoid	1 (1.3)	1 (1.3)	0	0	0
Hyperthyroidism	1 (1.3)	0	1 (1.3)	0	0
Eye disorders					
-Total	2 (2.7)	0	2 (2.7)	0	0
Photophobia	1 (1.3)	0	1 (1.3)	0	0
Retinopathy	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal disorders					
-Total	28 (37.3)	6 (8.0)	12 (16.0)	9 (12.0)	1 (1.3)
Nausea	10 (13.3)	0	7 (9.3)	3 (4.0)	0
Abdominal pain	9 (12.0)	1 (1.3)	5 (6.7)	3 (4.0)	0
Vomiting	9 (12.0)	4 (5.3)	4 (5.3)	1 (1.3)	0
Constipation	5 (6.7)	3 (4.0)	2 (2.7)	0	0
Stomatitis	5 (6.7)	1 (1.3)	0	3 (4.0)	1 (1.3)
Colitis	4 (5.3)	1 (1.3)	0	3 (4.0)	0
Diarrhoea	3 (4.0)	1 (1.3)	1 (1.3)	1 (1.3)	0
Gastrointestinal haemorrhage	2 (2.7)	1 (1.3)	0	1 (1.3)	0
Anal fissure	1 (1.3)	0	1 (1.3)	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dry mouth	1 (1.3)	1 (1.3)	0	0	0
Dyspepsia	1 (1.3)	0	1 (1.3)	0	0
Haematemesis	1 (1.3)	0	1 (1.3)	0	0
Haematochezia	1 (1.3)	0	0	1 (1.3)	0
Oral pain	1 (1.3)	0	1 (1.3)	0	0
Pancreatitis	1 (1.3)	0	1 (1.3)	0	0
Perianal erythema	1 (1.3)	0	1 (1.3)	0	0
Proctalgia	1 (1.3)	0	1 (1.3)	0	0
General disorders and administration site conditions					
-Total	26 (34.7)	11 (14.7)	8 (10.7)	5 (6.7)	2 (2.7)
Pyrexia	12 (16.0)	6 (8.0)	4 (5.3)	2 (2.7)	0
Fatigue	7 (9.3)	4 (5.3)	2 (2.7)	1 (1.3)	0
Catheter site pain	4 (5.3)	1 (1.3)	3 (4.0)	0	0
Non-cardiac chest pain	3 (4.0)	2 (2.7)	0	1 (1.3)	0
Pain	3 (4.0)	0	2 (2.7)	1 (1.3)	0
Chills	2 (2.7)	2 (2.7)	0	0	0
Multiple organ dysfunction syndrome	2 (2.7)	0	0	0	2 (2.7)

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oedema peripheral	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Asthenia	1 (1.3)	0	1 (1.3)	0	0
Catheter site bruise	1 (1.3)	1 (1.3)	0	0	0
Device related thrombosis	1 (1.3)	0	1 (1.3)	0	0
Gait disturbance	1 (1.3)	1 (1.3)	0	0	0
Generalised oedema	1 (1.3)	1 (1.3)	0	0	0
Injection site thrombosis	1 (1.3)	0	1 (1.3)	0	0
Physical deconditioning	1 (1.3)	0	0	1 (1.3)	0
Hepatobiliary disorders					
-Total	4 (5.3)	0	1 (1.3)	3 (4.0)	0
Hyperbilirubinaemia	3 (4.0)	0	1 (1.3)	2 (2.7)	0
Cholecystitis	1 (1.3)	0	0	1 (1.3)	0
Hepatic steatosis	1 (1.3)	0	1 (1.3)	0	0
Immune system disorders					
-Total	5 (6.7)	0	3 (4.0)	2 (2.7)	0
Hypogammaglobulinaemia	3 (4.0)	1 (1.3)	2 (2.7)	0	0
Anaphylactic reaction	2 (2.7)	0	0	2 (2.7)	0
Drug hypersensitivity	1 (1.3)	0	1 (1.3)	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections and infestations					
-Total	33 (44.0)	1 (1.3)	7 (9.3)	17 (22.7)	8 (10.7)
Device related infection	3 (4.0)	0	0	3 (4.0)	0
Oral herpes	3 (4.0)	0	2 (2.7)	1 (1.3)	0
Clostridium difficile colitis	2 (2.7)	0	0	2 (2.7)	0
Conjunctivitis	2 (2.7)	0	2 (2.7)	0	0
Enterococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Escherichia bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Escherichia urinary tract infection	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Klebsiella sepsis	2 (2.7)	0	0	0	2 (2.7)
Pneumonia	2 (2.7)	0	1 (1.3)	0	1 (1.3)
Pneumonia fungal	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Upper respiratory tract infection	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Abscess limb	1 (1.3)	0	0	1 (1.3)	0
Alpha haemolytic streptococcal infection	1 (1.3)	0	0	1 (1.3)	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0
Candida sepsis	1 (1.3)	0	0	0	1 (1.3)
Cellulitis	1 (1.3)	0	0	1 (1.3)	0
Clostridium difficile infection	1 (1.3)	0	1 (1.3)	0	0
Croup infectious	1 (1.3)	0	0	1 (1.3)	0
Cytomegalovirus viraemia	1 (1.3)	0	1 (1.3)	0	0
Escherichia infection	1 (1.3)	0	0	1 (1.3)	0
Escherichia sepsis	1 (1.3)	0	0	0	1 (1.3)
Fungal skin infection	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis	1 (1.3)	0	0	1 (1.3)	0
Human polyomavirus infection	1 (1.3)	0	0	0	1 (1.3)
Klebsiella infection	1 (1.3)	0	0	1 (1.3)	0
Metapneumovirus infection	1 (1.3)	0	1 (1.3)	0	0
Parainfluenzae virus infection	1 (1.3)	0	1 (1.3)	0	0
Respiratory syncytial virus bronchitis	1 (1.3)	0	0	1 (1.3)	0
Respiratory syncytial virus infection	1 (1.3)	0	1 (1.3)	0	0
Rhinovirus infection	1 (1.3)	0	1 (1.3)	0	0
Sepsis	1 (1.3)	0	0	0	1 (1.3)

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serratia infection	1 (1.3)	0	0	1 (1.3)	0
Sinusitis	1 (1.3)	1 (1.3)	0	0	0
Staphylococcal infection	1 (1.3)	0	0	1 (1.3)	0
Staphylococcal scalded skin syndrome	1 (1.3)	0	1 (1.3)	0	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)
Streptococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Streptococcal infection	1 (1.3)	0	0	1 (1.3)	0
Injury, poisoning and procedural complications					
-Total	9 (12.0)	1 (1.3)	6 (8.0)	2 (2.7)	0
Procedural pain	4 (5.3)	0	2 (2.7)	2 (2.7)	0
Subdural haematoma	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Transfusion reaction	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Extradural haematoma	1 (1.3)	0	0	1 (1.3)	0
Procedural hypertension	1 (1.3)	0	1 (1.3)	0	0
Radiation skin injury	1 (1.3)	0	1 (1.3)	0	0
Toxicity to various agents	1 (1.3)	0	1 (1.3)	0	0
Wound	1 (1.3)	1 (1.3)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Investigations					
-Total	31 (41.3)	3 (4.0)	3 (4.0)	7 (9.3)	18 (24.0)
White blood cell count decreased	12 (16.0)	1 (1.3)	1 (1.3)	1 (1.3)	9 (12.0)
Platelet count decreased	10 (13.3)	0	0	1 (1.3)	9 (12.0)
Neutrophil count decreased	9 (12.0)	0	0	0	9 (12.0)
Alanine aminotransferase increased	6 (8.0)	0	1 (1.3)	5 (6.7)	0
Aspartate aminotransferase increased	5 (6.7)	1 (1.3)	1 (1.3)	3 (4.0)	0
Blood lactate dehydrogenase increased	2 (2.7)	0	0	2 (2.7)	0
Electrocardiogram qt prolonged	2 (2.7)	0	0	2 (2.7)	0
Blast cell count increased	1 (1.3)	0	0	1 (1.3)	0
Blood bilirubin increased	1 (1.3)	0	0	1 (1.3)	0
Blood creatinine increased	1 (1.3)	1 (1.3)	0	0	0
Blood fibrinogen decreased	1 (1.3)	0	1 (1.3)	0	0
Blood immunoglobulin a increased	1 (1.3)	1 (1.3)	0	0	0
Blood immunoglobulin m decreased	1 (1.3)	1 (1.3)	0	0	0
Blood immunoglobulin m increased	1 (1.3)	1 (1.3)	0	0	0
Blood uric acid increased	1 (1.3)	1 (1.3)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Computerised tomogram thorax abnormal	1 (1.3)	0	0	1 (1.3)	0
Coronavirus test positive	1 (1.3)	1 (1.3)	0	0	0
Lymphocyte count decreased	1 (1.3)	0	0	1 (1.3)	0
Serum ferritin increased	1 (1.3)	0	0	1 (1.3)	0
Transaminases increased	1 (1.3)	0	0	1 (1.3)	0
White blood cell count increased	1 (1.3)	1 (1.3)	0	0	0
Metabolism and nutrition disorders					
-Total	23 (30.7)	1 (1.3)	8 (10.7)	10 (13.3)	4 (5.3)
Decreased appetite	8 (10.7)	1 (1.3)	4 (5.3)	3 (4.0)	0
Hyperglycaemia	7 (9.3)	0	3 (4.0)	3 (4.0)	1 (1.3)
Hypokalaemia	5 (6.7)	1 (1.3)	0	2 (2.7)	2 (2.7)
Dehydration	4 (5.3)	0	2 (2.7)	2 (2.7)	0
Hyperuricaemia	4 (5.3)	2 (2.7)	0	1 (1.3)	1 (1.3)
Hypomagnesaemia	4 (5.3)	4 (5.3)	0	0	0
Hypocalcaemia	3 (4.0)	1 (1.3)	0	0	2 (2.7)
Hypophosphataemia	3 (4.0)	0	1 (1.3)	2 (2.7)	0
Fluid overload	2 (2.7)	0	1 (1.3)	1 (1.3)	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperkalaemia	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Hypernatraemia	2 (2.7)	0	0	1 (1.3)	1 (1.3)
Tumour lysis syndrome	2 (2.7)	0	0	2 (2.7)	0
Vitamin d deficiency	2 (2.7)	0	2 (2.7)	0	0
Hyperammonaemia	1 (1.3)	1 (1.3)	0	0	0
Hypoalbuminaemia	1 (1.3)	0	0	0	1 (1.3)
Malnutrition	1 (1.3)	0	1 (1.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	18 (24.0)	4 (5.3)	6 (8.0)	8 (10.7)	0
Pain in extremity	9 (12.0)	2 (2.7)	2 (2.7)	5 (6.7)	0
Back pain	3 (4.0)	1 (1.3)	0	2 (2.7)	0
Neck pain	3 (4.0)	1 (1.3)	2 (2.7)	0	0
Arthralgia	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Bone pain	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Pain in jaw	2 (2.7)	0	2 (2.7)	0	0
Muscle spasms	1 (1.3)	1 (1.3)	0	0	0
Musculoskeletal chest pain	1 (1.3)	1 (1.3)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal pain	1 (1.3)	0	0	1 (1.3)	0
Myopathy	1 (1.3)	0	0	1 (1.3)	0
Myositis	1 (1.3)	0	0	1 (1.3)	0
Synovitis	1 (1.3)	0	1 (1.3)	0	0
Nervous system disorders					
-Total	15 (20.0)	3 (4.0)	7 (9.3)	4 (5.3)	1 (1.3)
Headache	10 (13.3)	2 (2.7)	4 (5.3)	4 (5.3)	0
Hypoaesthesia	1 (1.3)	1 (1.3)	0	0	0
Hyporesponsive to stimuli	1 (1.3)	0	0	1 (1.3)	0
Leukoencephalopathy	1 (1.3)	0	0	1 (1.3)	0
Neuralgia	1 (1.3)	0	1 (1.3)	0	0
Neuropathy peripheral	1 (1.3)	1 (1.3)	0	0	0
Peripheral sensory neuropathy	1 (1.3)	0	1 (1.3)	0	0
Peroneal nerve palsy	1 (1.3)	1 (1.3)	0	0	0
Seizure	1 (1.3)	0	0	0	1 (1.3)
Visual field defect	1 (1.3)	0	1 (1.3)	0	0
Product issues					
-Total	1 (1.3)	0	1 (1.3)	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device occlusion	1 (1.3)	0	1 (1.3)	0	0
Psychiatric disorders					
-Total	11 (14.7)	3 (4.0)	6 (8.0)	2 (2.7)	0
Mental status changes	3 (4.0)	2 (2.7)	0	1 (1.3)	0
Anxiety	2 (2.7)	0	2 (2.7)	0	0
Confusional state	2 (2.7)	0	2 (2.7)	0	0
Depression	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Insomnia	2 (2.7)	0	2 (2.7)	0	0
Agitation	1 (1.3)	0	0	1 (1.3)	0
Irritability	1 (1.3)	1 (1.3)	0	0	0
Renal and urinary disorders					
-Total	6 (8.0)	1 (1.3)	1 (1.3)	2 (2.7)	2 (2.7)
Acute kidney injury	3 (4.0)	1 (1.3)	0	1 (1.3)	1 (1.3)
Cystitis haemorrhagic	2 (2.7)	0	0	1 (1.3)	1 (1.3)
Dysuria	1 (1.3)	0	1 (1.3)	0	0
Haematuria	1 (1.3)	1 (1.3)	0	0	0
Oliguria	1 (1.3)	0	0	1 (1.3)	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Reproductive system and breast disorders					
-Total	1 (1.3)	0	1 (1.3)	0	0
Scrotal pain	1 (1.3)	0	1 (1.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (14.7)	0	5 (6.7)	1 (1.3)	5 (6.7)
Hypoxia	7 (9.3)	0	4 (5.3)	2 (2.7)	1 (1.3)
Cough	3 (4.0)	2 (2.7)	0	1 (1.3)	0
Epistaxis	3 (4.0)	0	2 (2.7)	1 (1.3)	0
Pleural effusion	3 (4.0)	1 (1.3)	2 (2.7)	0	0
Oropharyngeal pain	2 (2.7)	1 (1.3)	0	1 (1.3)	0
Pulmonary oedema	2 (2.7)	0	0	0	2 (2.7)
Aspiration	1 (1.3)	0	0	0	1 (1.3)
Atelectasis	1 (1.3)	0	1 (1.3)	0	0
Dyspnoea	1 (1.3)	0	0	1 (1.3)	0
Haemoptysis	1 (1.3)	0	0	1 (1.3)	0
Idiopathic pneumonia syndrome	1 (1.3)	0	0	0	1 (1.3)
Nasal congestion	1 (1.3)	1 (1.3)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary alveolar haemorrhage	1 (1.3)	0	0	0	1 (1.3)
Pulmonary hypertension	1 (1.3)	0	0	1 (1.3)	0
Pulmonary mass	1 (1.3)	0	1 (1.3)	0	0
Respiratory distress	1 (1.3)	0	0	0	1 (1.3)
Respiratory failure	1 (1.3)	0	0	0	1 (1.3)
Rhinorrhoea	1 (1.3)	1 (1.3)	0	0	0
Tachypnoea	1 (1.3)	0	0	1 (1.3)	0
Skin and subcutaneous tissue disorders					
-Total	10 (13.3)	6 (8.0)	4 (5.3)	0	0
Rash erythematous	3 (4.0)	1 (1.3)	2 (2.7)	0	0
Rash papular	2 (2.7)	2 (2.7)	0	0	0
Alopecia	1 (1.3)	0	1 (1.3)	0	0
Cold sweat	1 (1.3)	1 (1.3)	0	0	0
Dermatitis diaper	1 (1.3)	1 (1.3)	0	0	0
Night sweats	1 (1.3)	1 (1.3)	0	0	0
Rash	1 (1.3)	1 (1.3)	0	0	0
Skin irritation	1 (1.3)	1 (1.3)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urticaria	1 (1.3)	0	1 (1.3)	0	0
Vascular disorders					
-Total	10 (13.3)	2 (2.7)	0	5 (6.7)	3 (4.0)
Hypotension	7 (9.3)	0	0	4 (5.3)	3 (4.0)
Hypertension	4 (5.3)	2 (2.7)	1 (1.3)	1 (1.3)	0
Venous thrombosis limb	1 (1.3)	1 (1.3)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175l
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (87.5)	2 (6.3)	2 (6.3)	13 (40.6)	11 (34.4)
Blood and lymphatic system disorders					
-Total	19 (59.4)	1 (3.1)	0	14 (43.8)	4 (12.5)
Anaemia	10 (31.3)	0	0	10 (31.3)	0
Febrile neutropenia	6 (18.8)	0	0	6 (18.8)	0
Thrombocytopenia	5 (15.6)	0	0	2 (6.3)	3 (9.4)
Coagulopathy	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Disseminated intravascular coagulation	1 (3.1)	0	0	1 (3.1)	0
Leukocytosis	1 (3.1)	1 (3.1)	0	0	0
Pancytopenia	1 (3.1)	0	0	0	1 (3.1)
Splenomegaly	1 (3.1)	1 (3.1)	0	0	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	6 (18.8)	1 (3.1)	2 (6.3)	2 (6.3)	1 (3.1)
Pericardial effusion	2 (6.3)	0	2 (6.3)	0	0
Bradycardia	1 (3.1)	1 (3.1)	0	0	0
Cardiovascular insufficiency	1 (3.1)	0	0	0	1 (3.1)
Left ventricular dysfunction	1 (3.1)	0	0	1 (3.1)	0
Sinus tachycardia	1 (3.1)	0	0	1 (3.1)	0
Tachycardia	1 (3.1)	1 (3.1)	0	0	0
Ear and labyrinth disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Deafness unilateral	1 (3.1)	0	1 (3.1)	0	0
Endocrine disorders					
-Total	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Cushingoid	1 (3.1)	1 (3.1)	0	0	0
Hyperthyroidism	1 (3.1)	0	1 (3.1)	0	0
Eye disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Retinopathy	1 (3.1)	0	1 (3.1)	0	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	12 (37.5)	3 (9.4)	4 (12.5)	5 (15.6)	0
Abdominal pain	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Colitis	3 (9.4)	0	0	3 (9.4)	0
Nausea	3 (9.4)	0	3 (9.4)	0	0
Stomatitis	3 (9.4)	0	0	3 (9.4)	0
Vomiting	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Constipation	2 (6.3)	2 (6.3)	0	0	0
Diarrhoea	1 (3.1)	0	0	1 (3.1)	0
Gastrointestinal haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Oral pain	1 (3.1)	0	1 (3.1)	0	0
Pancreatitis	1 (3.1)	0	1 (3.1)	0	0
General disorders and administration site conditions					
-Total	12 (37.5)	6 (18.8)	3 (9.4)	1 (3.1)	2 (6.3)
Pyrexia	6 (18.8)	3 (9.4)	3 (9.4)	0	0
Fatigue	2 (6.3)	2 (6.3)	0	0	0
Multiple organ dysfunction syndrome	2 (6.3)	0	0	0	2 (6.3)

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oedema peripheral	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Catheter site pain	1 (3.1)	0	1 (3.1)	0	0
Chills	1 (3.1)	1 (3.1)	0	0	0
Device related thrombosis	1 (3.1)	0	1 (3.1)	0	0
Gait disturbance	1 (3.1)	1 (3.1)	0	0	0
Generalised oedema	1 (3.1)	1 (3.1)	0	0	0
Non-cardiac chest pain	1 (3.1)	1 (3.1)	0	0	0
Pain	1 (3.1)	0	1 (3.1)	0	0
Physical deconditioning	1 (3.1)	0	0	1 (3.1)	0
Hepatobiliary disorders					
-Total	3 (9.4)	0	0	3 (9.4)	0
Hyperbilirubinaemia	2 (6.3)	0	0	2 (6.3)	0
Cholecystitis	1 (3.1)	0	0	1 (3.1)	0
Hepatic steatosis	1 (3.1)	0	1 (3.1)	0	0
Immune system disorders					
-Total	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Hypogammaglobulinaemia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Anaphylactic reaction	1 (3.1)	0	0	1 (3.1)	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections and infestations					
-Total	16 (50.0)	1 (3.1)	2 (6.3)	8 (25.0)	5 (15.6)
Enterococcal bacteraemia	2 (6.3)	0	0	2 (6.3)	0
Klebsiella sepsis	2 (6.3)	0	0	0	2 (6.3)
Staphylococcal bacteraemia	2 (6.3)	0	0	2 (6.3)	0
Abscess limb	1 (3.1)	0	0	1 (3.1)	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile colitis	1 (3.1)	0	0	1 (3.1)	0
Conjunctivitis	1 (3.1)	0	1 (3.1)	0	0
Croup infectious	1 (3.1)	0	0	1 (3.1)	0
Cytomegalovirus viraemia	1 (3.1)	0	1 (3.1)	0	0
Device related infection	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia sepsis	1 (3.1)	0	0	0	1 (3.1)
Escherichia urinary tract infection	1 (3.1)	0	0	1 (3.1)	0
Fungal skin infection	1 (3.1)	0	1 (3.1)	0	0
Klebsiella infection	1 (3.1)	0	0	1 (3.1)	0
Oral herpes	1 (3.1)	0	1 (3.1)	0	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (3.1)	0	1 (3.1)	0	0
Pneumonia fungal	1 (3.1)	0	1 (3.1)	0	0
Respiratory syncytial virus bronchitis	1 (3.1)	0	0	1 (3.1)	0
Rhinovirus infection	1 (3.1)	0	1 (3.1)	0	0
Sepsis	1 (3.1)	0	0	0	1 (3.1)
Staphylococcal scalded skin syndrome	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal sepsis	1 (3.1)	0	0	0	1 (3.1)
Streptococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Upper respiratory tract infection	1 (3.1)	1 (3.1)	0	0	0
Injury, poisoning and procedural complications					
-Total	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Procedural pain	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Subdural haematoma	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Extradural haematoma	1 (3.1)	0	0	1 (3.1)	0
Procedural hypertension	1 (3.1)	0	1 (3.1)	0	0
Toxicity to various agents	1 (3.1)	0	1 (3.1)	0	0
Transfusion reaction	1 (3.1)	1 (3.1)	0	0	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	15 (46.9)	1 (3.1)	3 (9.4)	4 (12.5)	7 (21.9)
Alanine aminotransferase increased	4 (12.5)	0	1 (3.1)	3 (9.4)	0
Neutrophil count decreased	4 (12.5)	0	0	0	4 (12.5)
Platelet count decreased	3 (9.4)	0	0	0	3 (9.4)
White blood cell count decreased	3 (9.4)	0	1 (3.1)	0	2 (6.3)
Aspartate aminotransferase increased	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Blood creatinine increased	1 (3.1)	1 (3.1)	0	0	0
Blood fibrinogen decreased	1 (3.1)	0	1 (3.1)	0	0
Blood immunoglobulin a increased	1 (3.1)	1 (3.1)	0	0	0
Blood immunoglobulin m decreased	1 (3.1)	1 (3.1)	0	0	0
Blood immunoglobulin m increased	1 (3.1)	1 (3.1)	0	0	0
Coronavirus test positive	1 (3.1)	1 (3.1)	0	0	0
Electrocardiogram qt prolonged	1 (3.1)	0	0	1 (3.1)	0
Lymphocyte count decreased	1 (3.1)	0	0	1 (3.1)	0
Transaminases increased	1 (3.1)	0	0	1 (3.1)	0
Metabolism and nutrition disorders					

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (31.3)	0	3 (9.4)	6 (18.8)	1 (3.1)
Hyperglycaemia	5 (15.6)	0	2 (6.3)	2 (6.3)	1 (3.1)
Decreased appetite	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Hypocalcaemia	2 (6.3)	1 (3.1)	0	0	1 (3.1)
Hypokalaemia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Tumour lysis syndrome	2 (6.3)	0	0	2 (6.3)	0
Dehydration	1 (3.1)	0	0	1 (3.1)	0
Fluid overload	1 (3.1)	0	1 (3.1)	0	0
Hyperammonaemia	1 (3.1)	1 (3.1)	0	0	0
Hypernatraemia	1 (3.1)	0	0	1 (3.1)	0
Hyperuricaemia	1 (3.1)	1 (3.1)	0	0	0
Hypoalbuminaemia	1 (3.1)	0	0	0	1 (3.1)
Hypophosphataemia	1 (3.1)	0	1 (3.1)	0	0
Vitamin d deficiency	1 (3.1)	0	1 (3.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (21.9)	2 (6.3)	2 (6.3)	3 (9.4)	0
Pain in extremity	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Arthralgia	1 (3.1)	0	1 (3.1)	0	0
Bone pain	1 (3.1)	0	1 (3.1)	0	0
Muscle spasms	1 (3.1)	1 (3.1)	0	0	0
Musculoskeletal pain	1 (3.1)	0	0	1 (3.1)	0
Myopathy	1 (3.1)	0	0	1 (3.1)	0
Myositis	1 (3.1)	0	0	1 (3.1)	0
Neck pain	1 (3.1)	0	1 (3.1)	0	0
Synovitis	1 (3.1)	0	1 (3.1)	0	0
Nervous system disorders					
-Total	10 (31.3)	2 (6.3)	5 (15.6)	3 (9.4)	0
Headache	6 (18.8)	2 (6.3)	2 (6.3)	2 (6.3)	0
Hypoaesthesia	1 (3.1)	1 (3.1)	0	0	0
Leukoencephalopathy	1 (3.1)	0	0	1 (3.1)	0
Neuralgia	1 (3.1)	0	1 (3.1)	0	0
Peripheral sensory neuropathy	1 (3.1)	0	1 (3.1)	0	0
Visual field defect	1 (3.1)	0	1 (3.1)	0	0
Product issues					
-Total	1 (3.1)	0	1 (3.1)	0	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device occlusion	1 (3.1)	0	1 (3.1)	0	0
Psychiatric disorders					
-Total	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Mental status changes	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Anxiety	1 (3.1)	0	1 (3.1)	0	0
Depression	1 (3.1)	0	1 (3.1)	0	0
Insomnia	1 (3.1)	0	1 (3.1)	0	0
Renal and urinary disorders					
-Total	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Acute kidney injury	1 (3.1)	1 (3.1)	0	0	0
Cystitis haemorrhagic	1 (3.1)	0	0	1 (3.1)	0
Dysuria	1 (3.1)	0	1 (3.1)	0	0
Haematuria	1 (3.1)	1 (3.1)	0	0	0
Reproductive system and breast disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Scrotal pain	1 (3.1)	0	1 (3.1)	0	0
Respiratory, thoracic and mediastinal disorders					

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (18.8)	0	3 (9.4)	1 (3.1)	2 (6.3)
Hypoxia	3 (9.4)	0	2 (6.3)	0	1 (3.1)
Epistaxis	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Atelectasis	1 (3.1)	0	1 (3.1)	0	0
Cough	1 (3.1)	1 (3.1)	0	0	0
Idiopathic pneumonia syndrome	1 (3.1)	0	0	0	1 (3.1)
Pleural effusion	1 (3.1)	1 (3.1)	0	0	0
Pulmonary mass	1 (3.1)	0	1 (3.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Rash erythematous	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Rash papular	1 (3.1)	1 (3.1)	0	0	0
Skin irritation	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	5 (15.6)	1 (3.1)	0	4 (12.5)	0
Hypotension	3 (9.4)	0	0	3 (9.4)	0
Hypertension	2 (6.3)	1 (3.1)	0	1 (3.1)	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Venous thrombosis limb	1 (3.1)	1 (3.1)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175l
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (83.7)	1 (2.3)	4 (9.3)	13 (30.2)	18 (41.9)
Blood and lymphatic system disorders					
-Total	22 (51.2)	0	0	15 (34.9)	7 (16.3)
Febrile neutropenia	12 (27.9)	0	0	12 (27.9)	0
Anaemia	11 (25.6)	0	2 (4.7)	9 (20.9)	0
Neutropenia	6 (14.0)	0	0	1 (2.3)	5 (11.6)
Thrombocytopenia	5 (11.6)	0	0	1 (2.3)	4 (9.3)
Disseminated intravascular coagulation	1 (2.3)	0	0	1 (2.3)	0
Leukopenia	1 (2.3)	0	0	0	1 (2.3)
Lymphopenia	1 (2.3)	0	0	0	1 (2.3)
Pancytopenia	1 (2.3)	0	0	0	1 (2.3)

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	3 (7.0)	0	1 (2.3)	1 (2.3)	1 (2.3)
Tachycardia	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Bradycardia	1 (2.3)	0	0	0	1 (2.3)
Right ventricular dysfunction	1 (2.3)	0	0	1 (2.3)	0
Sinus tachycardia	1 (2.3)	0	0	1 (2.3)	0
Ventricular tachycardia	1 (2.3)	0	0	1 (2.3)	0
Endocrine disorders					
-Total	1 (2.3)	0	1 (2.3)	0	0
Adrenal insufficiency	1 (2.3)	0	1 (2.3)	0	0
Eye disorders					
-Total	1 (2.3)	0	1 (2.3)	0	0
Photophobia	1 (2.3)	0	1 (2.3)	0	0
Gastrointestinal disorders					
-Total	16 (37.2)	3 (7.0)	8 (18.6)	4 (9.3)	1 (2.3)
Nausea	7 (16.3)	0	4 (9.3)	3 (7.0)	0
Vomiting	6 (14.0)	2 (4.7)	3 (7.0)	1 (2.3)	0
Abdominal pain	5 (11.6)	1 (2.3)	2 (4.7)	2 (4.7)	0

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Diarrhoea	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Stomatitis	2 (4.7)	1 (2.3)	0	0	1 (2.3)
Anal fissure	1 (2.3)	0	1 (2.3)	0	0
Colitis	1 (2.3)	1 (2.3)	0	0	0
Dry mouth	1 (2.3)	1 (2.3)	0	0	0
Dyspepsia	1 (2.3)	0	1 (2.3)	0	0
Gastrointestinal haemorrhage	1 (2.3)	0	0	1 (2.3)	0
Haematemesis	1 (2.3)	0	1 (2.3)	0	0
Haematochezia	1 (2.3)	0	0	1 (2.3)	0
Perianal erythema	1 (2.3)	0	1 (2.3)	0	0
Proctalgia	1 (2.3)	0	1 (2.3)	0	0
General disorders and administration site conditions					
-Total	14 (32.6)	5 (11.6)	5 (11.6)	4 (9.3)	0
Pyrexia	6 (14.0)	3 (7.0)	1 (2.3)	2 (4.7)	0
Fatigue	5 (11.6)	2 (4.7)	2 (4.7)	1 (2.3)	0
Catheter site pain	3 (7.0)	1 (2.3)	2 (4.7)	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Non-cardiac chest pain	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Pain	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Asthenia	1 (2.3)	0	1 (2.3)	0	0
Catheter site bruise	1 (2.3)	1 (2.3)	0	0	0
Chills	1 (2.3)	1 (2.3)	0	0	0
Injection site thrombosis	1 (2.3)	0	1 (2.3)	0	0
Hepatobiliary disorders					
-Total	1 (2.3)	0	1 (2.3)	0	0
Hyperbilirubinaemia	1 (2.3)	0	1 (2.3)	0	0
Immune system disorders					
-Total	3 (7.0)	0	2 (4.7)	1 (2.3)	0
Anaphylactic reaction	1 (2.3)	0	0	1 (2.3)	0
Drug hypersensitivity	1 (2.3)	0	1 (2.3)	0	0
Hypogammaglobulinaemia	1 (2.3)	0	1 (2.3)	0	0
Infections and infestations					
-Total	17 (39.5)	0	5 (11.6)	9 (20.9)	3 (7.0)
Device related infection	2 (4.7)	0	0	2 (4.7)	0
Oral herpes	2 (4.7)	0	1 (2.3)	1 (2.3)	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Alpha haemolytic streptococcal infection	1 (2.3)	0	0	1 (2.3)	0
Bronchopulmonary aspergillosis	1 (2.3)	0	0	1 (2.3)	0
Candida sepsis	1 (2.3)	0	0	0	1 (2.3)
Cellulitis	1 (2.3)	0	0	1 (2.3)	0
Clostridium difficile colitis	1 (2.3)	0	0	1 (2.3)	0
Clostridium difficile infection	1 (2.3)	0	1 (2.3)	0	0
Conjunctivitis	1 (2.3)	0	1 (2.3)	0	0
Escherichia bacteraemia	1 (2.3)	0	0	1 (2.3)	0
Escherichia infection	1 (2.3)	0	0	1 (2.3)	0
Escherichia urinary tract infection	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis	1 (2.3)	0	0	1 (2.3)	0
Human polyomavirus infection	1 (2.3)	0	0	0	1 (2.3)
Metapneumovirus infection	1 (2.3)	0	1 (2.3)	0	0
Parainfluenzae virus infection	1 (2.3)	0	1 (2.3)	0	0
Pneumonia	1 (2.3)	0	0	0	1 (2.3)
Pneumonia fungal	1 (2.3)	0	0	1 (2.3)	0
Respiratory syncytial virus infection	1 (2.3)	0	1 (2.3)	0	0

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serratia infection	1 (2.3)	0	0	1 (2.3)	0
Sinusitis	1 (2.3)	1 (2.3)	0	0	0
Staphylococcal infection	1 (2.3)	0	0	1 (2.3)	0
Streptococcal infection	1 (2.3)	0	0	1 (2.3)	0
Upper respiratory tract infection	1 (2.3)	0	1 (2.3)	0	0
Injury, poisoning and procedural complications					
-Total	5 (11.6)	1 (2.3)	3 (7.0)	1 (2.3)	0
Procedural pain	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Radiation skin injury	1 (2.3)	0	1 (2.3)	0	0
Transfusion reaction	1 (2.3)	0	1 (2.3)	0	0
Wound	1 (2.3)	1 (2.3)	0	0	0
Investigations					
-Total	16 (37.2)	2 (4.7)	0	3 (7.0)	11 (25.6)
White blood cell count decreased	9 (20.9)	1 (2.3)	0	1 (2.3)	7 (16.3)
Platelet count decreased	7 (16.3)	0	0	1 (2.3)	6 (14.0)
Neutrophil count decreased	5 (11.6)	0	0	0	5 (11.6)
Aspartate aminotransferase increased	3 (7.0)	0	1 (2.3)	2 (4.7)	0

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	2 (4.7)	0	0	2 (4.7)	0
Blood lactate dehydrogenase increased	2 (4.7)	0	0	2 (4.7)	0
Blast cell count increased	1 (2.3)	0	0	1 (2.3)	0
Blood bilirubin increased	1 (2.3)	0	0	1 (2.3)	0
Blood uric acid increased	1 (2.3)	1 (2.3)	0	0	0
Computerised tomogram thorax abnormal	1 (2.3)	0	0	1 (2.3)	0
Electrocardiogram qt prolonged	1 (2.3)	0	0	1 (2.3)	0
Serum ferritin increased	1 (2.3)	0	0	1 (2.3)	0
White blood cell count increased	1 (2.3)	1 (2.3)	0	0	0
Metabolism and nutrition disorders					
-Total	13 (30.2)	1 (2.3)	5 (11.6)	4 (9.3)	3 (7.0)
Decreased appetite	5 (11.6)	1 (2.3)	3 (7.0)	1 (2.3)	0
Hypomagnesaemia	4 (9.3)	4 (9.3)	0	0	0
Dehydration	3 (7.0)	0	2 (4.7)	1 (2.3)	0
Hyperuricaemia	3 (7.0)	1 (2.3)	0	1 (2.3)	1 (2.3)
Hypokalaemia	3 (7.0)	1 (2.3)	0	1 (2.3)	1 (2.3)
Hyperglycaemia	2 (4.7)	0	1 (2.3)	1 (2.3)	0

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Hypophosphataemia	2 (4.7)	0	0	2 (4.7)	0
Fluid overload	1 (2.3)	0	0	1 (2.3)	0
Hypernatraemia	1 (2.3)	0	0	0	1 (2.3)
Hypocalcaemia	1 (2.3)	0	0	0	1 (2.3)
Malnutrition	1 (2.3)	0	1 (2.3)	0	0
Vitamin d deficiency	1 (2.3)	0	1 (2.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	11 (25.6)	2 (4.7)	4 (9.3)	5 (11.6)	0
Pain in extremity	5 (11.6)	1 (2.3)	1 (2.3)	3 (7.0)	0
Back pain	3 (7.0)	1 (2.3)	0	2 (4.7)	0
Neck pain	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Pain in jaw	2 (4.7)	0	2 (4.7)	0	0
Arthralgia	1 (2.3)	0	0	1 (2.3)	0
Bone pain	1 (2.3)	0	0	1 (2.3)	0
Musculoskeletal chest pain	1 (2.3)	1 (2.3)	0	0	0
Nervous system disorders					

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (11.6)	1 (2.3)	2 (4.7)	1 (2.3)	1 (2.3)
Headache	4 (9.3)	0	2 (4.7)	2 (4.7)	0
Hyporesponsive to stimuli	1 (2.3)	0	0	1 (2.3)	0
Neuropathy peripheral	1 (2.3)	1 (2.3)	0	0	0
Peroneal nerve palsy	1 (2.3)	1 (2.3)	0	0	0
Seizure	1 (2.3)	0	0	0	1 (2.3)
Psychiatric disorders					
-Total	7 (16.3)	2 (4.7)	4 (9.3)	1 (2.3)	0
Confusional state	2 (4.7)	0	2 (4.7)	0	0
Agitation	1 (2.3)	0	0	1 (2.3)	0
Anxiety	1 (2.3)	0	1 (2.3)	0	0
Depression	1 (2.3)	1 (2.3)	0	0	0
Insomnia	1 (2.3)	0	1 (2.3)	0	0
Irritability	1 (2.3)	1 (2.3)	0	0	0
Mental status changes	1 (2.3)	1 (2.3)	0	0	0
Renal and urinary disorders					
-Total	3 (7.0)	0	0	1 (2.3)	2 (4.7)
Acute kidney injury	2 (4.7)	0	0	1 (2.3)	1 (2.3)

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cystitis haemorrhagic	1 (2.3)	0	0	0	1 (2.3)
Oliguria	1 (2.3)	0	0	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (11.6)	0	2 (4.7)	0	3 (7.0)
Hypoxia	4 (9.3)	0	2 (4.7)	2 (4.7)	0
Cough	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Oropharyngeal pain	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Pleural effusion	2 (4.7)	0	2 (4.7)	0	0
Pulmonary oedema	2 (4.7)	0	0	0	2 (4.7)
Aspiration	1 (2.3)	0	0	0	1 (2.3)
Dyspnoea	1 (2.3)	0	0	1 (2.3)	0
Epistaxis	1 (2.3)	0	1 (2.3)	0	0
Haemoptysis	1 (2.3)	0	0	1 (2.3)	0
Nasal congestion	1 (2.3)	1 (2.3)	0	0	0
Pulmonary alveolar haemorrhage	1 (2.3)	0	0	0	1 (2.3)
Pulmonary hypertension	1 (2.3)	0	0	1 (2.3)	0
Respiratory distress	1 (2.3)	0	0	0	1 (2.3)

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	1 (2.3)	0	0	0	1 (2.3)
Rhinorrhoea	1 (2.3)	1 (2.3)	0	0	0
Tachypnoea	1 (2.3)	0	0	1 (2.3)	0
Skin and subcutaneous tissue disorders					
-Total	6 (14.0)	3 (7.0)	3 (7.0)	0	0
Alopecia	1 (2.3)	0	1 (2.3)	0	0
Cold sweat	1 (2.3)	1 (2.3)	0	0	0
Dermatitis diaper	1 (2.3)	1 (2.3)	0	0	0
Night sweats	1 (2.3)	1 (2.3)	0	0	0
Rash	1 (2.3)	1 (2.3)	0	0	0
Rash erythematous	1 (2.3)	0	1 (2.3)	0	0
Rash papular	1 (2.3)	1 (2.3)	0	0	0
Urticaria	1 (2.3)	0	1 (2.3)	0	0
Vascular disorders					
-Total	5 (11.6)	1 (2.3)	0	1 (2.3)	3 (7.0)
Hypotension	4 (9.3)	0	0	1 (2.3)	3 (7.0)
Hypertension	2 (4.7)	1 (2.3)	1 (2.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175m
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (83.3)	0	2 (11.1)	7 (38.9)	6 (33.3)
Blood and lymphatic system disorders					
-Total	7 (38.9)	0	0	5 (27.8)	2 (11.1)
Anaemia	5 (27.8)	0	1 (5.6)	4 (22.2)	0
Febrile neutropenia	3 (16.7)	0	0	3 (16.7)	0
Neutropenia	1 (5.6)	0	0	0	1 (5.6)
Thrombocytopenia	1 (5.6)	0	0	0	1 (5.6)
Cardiac disorders					
-Total	1 (5.6)	1 (5.6)	0	0	0
Bradycardia	1 (5.6)	1 (5.6)	0	0	0
Gastrointestinal disorders					
-Total	4 (22.2)	0	3 (16.7)	1 (5.6)	0

Eligibility for SCT: Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (11.1)	0	2 (11.1)	0	0
Abdominal pain	1 (5.6)	0	1 (5.6)	0	0
Constipation	1 (5.6)	1 (5.6)	0	0	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0	0	0
Stomatitis	1 (5.6)	0	0	1 (5.6)	0
Vomiting	1 (5.6)	0	1 (5.6)	0	0
General disorders and administration site conditions					
-Total	5 (27.8)	1 (5.6)	2 (11.1)	2 (11.1)	0
Pyrexia	3 (16.7)	1 (5.6)	0	2 (11.1)	0
Catheter site pain	2 (11.1)	0	2 (11.1)	0	0
Fatigue	1 (5.6)	0	1 (5.6)	0	0
Injection site thrombosis	1 (5.6)	0	1 (5.6)	0	0
Pain	1 (5.6)	0	0	1 (5.6)	0
Infections and infestations					
-Total	9 (50.0)	0	2 (11.1)	6 (33.3)	1 (5.6)
Conjunctivitis	2 (11.1)	0	2 (11.1)	0	0
Device related infection	2 (11.1)	0	0	2 (11.1)	0

Eligibility for SCT: Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia urinary tract infection	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Alpha haemolytic streptococcal infection	1 (5.6)	0	0	1 (5.6)	0
Bronchopulmonary aspergillosis	1 (5.6)	0	0	1 (5.6)	0
Clostridium difficile colitis	1 (5.6)	0	0	1 (5.6)	0
Escherichia infection	1 (5.6)	0	0	1 (5.6)	0
Pneumonia	1 (5.6)	0	0	0	1 (5.6)
Streptococcal infection	1 (5.6)	0	0	1 (5.6)	0
Injury, poisoning and procedural complications					
-Total	3 (16.7)	0	3 (16.7)	0	0
Procedural pain	1 (5.6)	0	1 (5.6)	0	0
Radiation skin injury	1 (5.6)	0	1 (5.6)	0	0
Transfusion reaction	1 (5.6)	0	1 (5.6)	0	0
Investigations					
-Total	8 (44.4)	2 (11.1)	1 (5.6)	1 (5.6)	4 (22.2)
White blood cell count decreased	5 (27.8)	1 (5.6)	1 (5.6)	0	3 (16.7)
Platelet count decreased	3 (16.7)	0	0	1 (5.6)	2 (11.1)
Neutrophil count decreased	2 (11.1)	0	0	0	2 (11.1)

Eligibility for SCT: Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blast cell count increased	1 (5.6)	0	0	1 (5.6)	0
Blood bilirubin increased	1 (5.6)	0	0	1 (5.6)	0
Blood lactate dehydrogenase increased	1 (5.6)	0	0	1 (5.6)	0
Blood uric acid increased	1 (5.6)	1 (5.6)	0	0	0
Serum ferritin increased	1 (5.6)	0	0	1 (5.6)	0
White blood cell count increased	1 (5.6)	1 (5.6)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (27.8)	0	3 (16.7)	1 (5.6)	1 (5.6)
Decreased appetite	2 (11.1)	0	2 (11.1)	0	0
Hyperglycaemia	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Dehydration	1 (5.6)	0	1 (5.6)	0	0
Hyperkalaemia	1 (5.6)	0	1 (5.6)	0	0
Hyperuricaemia	1 (5.6)	1 (5.6)	0	0	0
Hypocalcaemia	1 (5.6)	0	0	0	1 (5.6)
Hypokalaemia	1 (5.6)	0	0	1 (5.6)	0
Hypomagnesaemia	1 (5.6)	1 (5.6)	0	0	0
Hypophosphataemia	1 (5.6)	0	0	1 (5.6)	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Malnutrition	1 (5.6)	0	1 (5.6)	0	0
Musculoskeletal and connective tissue disorders					
-Total	6 (33.3)	1 (5.6)	4 (22.2)	1 (5.6)	0
Neck pain	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain in extremity	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Pain in jaw	2 (11.1)	0	2 (11.1)	0	0
Arthralgia	1 (5.6)	0	1 (5.6)	0	0
Back pain	1 (5.6)	1 (5.6)	0	0	0
Musculoskeletal chest pain	1 (5.6)	1 (5.6)	0	0	0
Nervous system disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Headache	1 (5.6)	0	1 (5.6)	0	0
Neuropathy peripheral	1 (5.6)	1 (5.6)	0	0	0
Peroneal nerve palsy	1 (5.6)	1 (5.6)	0	0	0
Psychiatric disorders					
-Total	1 (5.6)	0	1 (5.6)	0	0
Confusional state	1 (5.6)	0	1 (5.6)	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	3 (16.7)	0	2 (11.1)	0	1 (5.6)
Hypoxia	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Pleural effusion	2 (11.1)	0	2 (11.1)	0	0
Aspiration	1 (5.6)	0	0	0	1 (5.6)
Epistaxis	1 (5.6)	0	1 (5.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (22.2)	3 (16.7)	1 (5.6)	0	0
Alopecia	1 (5.6)	0	1 (5.6)	0	0
Dermatitis diaper	1 (5.6)	1 (5.6)	0	0	0
Rash erythematous	1 (5.6)	1 (5.6)	0	0	0
Rash papular	1 (5.6)	1 (5.6)	0	0	0
Vascular disorders					
-Total	2 (11.1)	1 (5.6)	0	0	1 (5.6)
Hypertension	1 (5.6)	1 (5.6)	0	0	0
Hypotension	1 (5.6)	0	0	0	1 (5.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175m
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	49 (86.0)	3 (5.3)	4 (7.0)	19 (33.3)	23 (40.4)
Blood and lymphatic system disorders					
-Total	34 (59.6)	1 (1.8)	0	24 (42.1)	9 (15.8)
Anaemia	16 (28.1)	0	1 (1.8)	15 (26.3)	0
Febrile neutropenia	15 (26.3)	0	0	15 (26.3)	0
Thrombocytopenia	9 (15.8)	0	0	3 (5.3)	6 (10.5)
Neutropenia	5 (8.8)	0	0	1 (1.8)	4 (7.0)
Coagulopathy	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Disseminated intravascular coagulation	2 (3.5)	0	0	2 (3.5)	0
Pancytopenia	2 (3.5)	0	0	0	2 (3.5)
Leukocytosis	1 (1.8)	1 (1.8)	0	0	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Leukopenia	1 (1.8)	0	0	0	1 (1.8)
Lymphopenia	1 (1.8)	0	0	0	1 (1.8)
Splenomegaly	1 (1.8)	1 (1.8)	0	0	0
Cardiac disorders					
-Total	8 (14.0)	0	3 (5.3)	3 (5.3)	2 (3.5)
Tachycardia	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Pericardial effusion	2 (3.5)	0	2 (3.5)	0	0
Sinus tachycardia	2 (3.5)	0	0	2 (3.5)	0
Bradycardia	1 (1.8)	0	0	0	1 (1.8)
Cardiovascular insufficiency	1 (1.8)	0	0	0	1 (1.8)
Left ventricular dysfunction	1 (1.8)	0	0	1 (1.8)	0
Right ventricular dysfunction	1 (1.8)	0	0	1 (1.8)	0
Ventricular tachycardia	1 (1.8)	0	0	1 (1.8)	0
Ear and labyrinth disorders					
-Total	1 (1.8)	0	1 (1.8)	0	0
Deafness unilateral	1 (1.8)	0	1 (1.8)	0	0
Endocrine disorders					
-Total	3 (5.3)	1 (1.8)	2 (3.5)	0	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Adrenal insufficiency	1 (1.8)	0	1 (1.8)	0	0
Cushingoid	1 (1.8)	1 (1.8)	0	0	0
Hyperthyroidism	1 (1.8)	0	1 (1.8)	0	0
Eye disorders					
-Total	2 (3.5)	0	2 (3.5)	0	0
Photophobia	1 (1.8)	0	1 (1.8)	0	0
Retinopathy	1 (1.8)	0	1 (1.8)	0	0
Gastrointestinal disorders					
-Total	24 (42.1)	6 (10.5)	9 (15.8)	8 (14.0)	1 (1.8)
Abdominal pain	8 (14.0)	1 (1.8)	4 (7.0)	3 (5.3)	0
Nausea	8 (14.0)	0	5 (8.8)	3 (5.3)	0
Vomiting	8 (14.0)	4 (7.0)	3 (5.3)	1 (1.8)	0
Colitis	4 (7.0)	1 (1.8)	0	3 (5.3)	0
Constipation	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Stomatitis	4 (7.0)	1 (1.8)	0	2 (3.5)	1 (1.8)
Diarrhoea	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Anal fissure	1 (1.8)	0	1 (1.8)	0	0
Dry mouth	1 (1.8)	1 (1.8)	0	0	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dyspepsia	1 (1.8)	0	1 (1.8)	0	0
Gastrointestinal haemorrhage	1 (1.8)	0	0	1 (1.8)	0
Haematemesis	1 (1.8)	0	1 (1.8)	0	0
Haematochezia	1 (1.8)	0	0	1 (1.8)	0
Oral pain	1 (1.8)	0	1 (1.8)	0	0
Pancreatitis	1 (1.8)	0	1 (1.8)	0	0
Perianal erythema	1 (1.8)	0	1 (1.8)	0	0
Proctalgia	1 (1.8)	0	1 (1.8)	0	0
General disorders and administration site conditions					
-Total	21 (36.8)	10 (17.5)	6 (10.5)	3 (5.3)	2 (3.5)
Pyrexia	9 (15.8)	5 (8.8)	4 (7.0)	0	0
Fatigue	6 (10.5)	4 (7.0)	1 (1.8)	1 (1.8)	0
Non-cardiac chest pain	3 (5.3)	2 (3.5)	0	1 (1.8)	0
Catheter site pain	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Chills	2 (3.5)	2 (3.5)	0	0	0
Multiple organ dysfunction syndrome	2 (3.5)	0	0	0	2 (3.5)
Oedema peripheral	2 (3.5)	1 (1.8)	1 (1.8)	0	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain	2 (3.5)	0	2 (3.5)	0	0
Asthenia	1 (1.8)	0	1 (1.8)	0	0
Catheter site bruise	1 (1.8)	1 (1.8)	0	0	0
Device related thrombosis	1 (1.8)	0	1 (1.8)	0	0
Gait disturbance	1 (1.8)	1 (1.8)	0	0	0
Generalised oedema	1 (1.8)	1 (1.8)	0	0	0
Physical deconditioning	1 (1.8)	0	0	1 (1.8)	0
Hepatobiliary disorders					
-Total	4 (7.0)	0	1 (1.8)	3 (5.3)	0
Hyperbilirubinaemia	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Cholecystitis	1 (1.8)	0	0	1 (1.8)	0
Hepatic steatosis	1 (1.8)	0	1 (1.8)	0	0
Immune system disorders					
-Total	5 (8.8)	0	3 (5.3)	2 (3.5)	0
Hypogammaglobulinaemia	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Anaphylactic reaction	2 (3.5)	0	0	2 (3.5)	0
Drug hypersensitivity	1 (1.8)	0	1 (1.8)	0	0
Infections and infestations					

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	24 (42.1)	1 (1.8)	5 (8.8)	11 (19.3)	7 (12.3)
Oral herpes	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Enterococcal bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Escherichia bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Klebsiella sepsis	2 (3.5)	0	0	0	2 (3.5)
Pneumonia fungal	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Staphylococcal bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Upper respiratory tract infection	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Abscess limb	1 (1.8)	0	0	1 (1.8)	0
Bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Candida sepsis	1 (1.8)	0	0	0	1 (1.8)
Cellulitis	1 (1.8)	0	0	1 (1.8)	0
Clostridium difficile colitis	1 (1.8)	0	0	1 (1.8)	0
Clostridium difficile infection	1 (1.8)	0	1 (1.8)	0	0
Croup infectious	1 (1.8)	0	0	1 (1.8)	0
Cytomegalovirus viraemia	1 (1.8)	0	1 (1.8)	0	0
Device related infection	1 (1.8)	0	0	1 (1.8)	0
Escherichia sepsis	1 (1.8)	0	0	0	1 (1.8)

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal skin infection	1 (1.8)	0	1 (1.8)	0	0
Gastroenteritis	1 (1.8)	0	0	1 (1.8)	0
Human polyomavirus infection	1 (1.8)	0	0	0	1 (1.8)
Klebsiella infection	1 (1.8)	0	0	1 (1.8)	0
Metapneumovirus infection	1 (1.8)	0	1 (1.8)	0	0
Parainfluenzae virus infection	1 (1.8)	0	1 (1.8)	0	0
Pneumonia	1 (1.8)	0	1 (1.8)	0	0
Respiratory syncytial virus bronchitis	1 (1.8)	0	0	1 (1.8)	0
Respiratory syncytial virus infection	1 (1.8)	0	1 (1.8)	0	0
Rhinovirus infection	1 (1.8)	0	1 (1.8)	0	0
Sepsis	1 (1.8)	0	0	0	1 (1.8)
Serratia infection	1 (1.8)	0	0	1 (1.8)	0
Sinusitis	1 (1.8)	1 (1.8)	0	0	0
Staphylococcal infection	1 (1.8)	0	0	1 (1.8)	0
Staphylococcal scalded skin syndrome	1 (1.8)	0	1 (1.8)	0	0
Staphylococcal sepsis	1 (1.8)	0	0	0	1 (1.8)
Streptococcal bacteraemia	1 (1.8)	0	0	1 (1.8)	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	6 (10.5)	1 (1.8)	3 (5.3)	2 (3.5)	0
Procedural pain	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Subdural haematoma	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Extradural haematoma	1 (1.8)	0	0	1 (1.8)	0
Procedural hypertension	1 (1.8)	0	1 (1.8)	0	0
Toxicity to various agents	1 (1.8)	0	1 (1.8)	0	0
Transfusion reaction	1 (1.8)	1 (1.8)	0	0	0
Wound	1 (1.8)	1 (1.8)	0	0	0
Investigations					
-Total	23 (40.4)	1 (1.8)	2 (3.5)	6 (10.5)	14 (24.6)
Neutrophil count decreased	7 (12.3)	0	0	0	7 (12.3)
Platelet count decreased	7 (12.3)	0	0	0	7 (12.3)
White blood cell count decreased	7 (12.3)	0	0	1 (1.8)	6 (10.5)
Alanine aminotransferase increased	6 (10.5)	0	1 (1.8)	5 (8.8)	0
Aspartate aminotransferase increased	5 (8.8)	1 (1.8)	1 (1.8)	3 (5.3)	0
Electrocardiogram qt prolonged	2 (3.5)	0	0	2 (3.5)	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood creatinine increased	1 (1.8)	1 (1.8)	0	0	0
Blood fibrinogen decreased	1 (1.8)	0	1 (1.8)	0	0
Blood immunoglobulin a increased	1 (1.8)	1 (1.8)	0	0	0
Blood immunoglobulin m decreased	1 (1.8)	1 (1.8)	0	0	0
Blood immunoglobulin m increased	1 (1.8)	1 (1.8)	0	0	0
Blood lactate dehydrogenase increased	1 (1.8)	0	0	1 (1.8)	0
Computerised tomogram thorax abnormal	1 (1.8)	0	0	1 (1.8)	0
Coronavirus test positive	1 (1.8)	1 (1.8)	0	0	0
Lymphocyte count decreased	1 (1.8)	0	0	1 (1.8)	0
Transaminases increased	1 (1.8)	0	0	1 (1.8)	0
Metabolism and nutrition disorders					
-Total	18 (31.6)	1 (1.8)	5 (8.8)	9 (15.8)	3 (5.3)
Decreased appetite	6 (10.5)	1 (1.8)	2 (3.5)	3 (5.3)	0
Hyperglycaemia	5 (8.8)	0	2 (3.5)	2 (3.5)	1 (1.8)
Hypokalaemia	4 (7.0)	1 (1.8)	0	1 (1.8)	2 (3.5)
Dehydration	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Hyperuricaemia	3 (5.3)	1 (1.8)	0	1 (1.8)	1 (1.8)

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypomagnesaemia	3 (5.3)	3 (5.3)	0	0	0
Fluid overload	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Hypernatraemia	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Hypocalcaemia	2 (3.5)	1 (1.8)	0	0	1 (1.8)
Hypophosphataemia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Tumour lysis syndrome	2 (3.5)	0	0	2 (3.5)	0
Vitamin d deficiency	2 (3.5)	0	2 (3.5)	0	0
Hyperammonaemia	1 (1.8)	1 (1.8)	0	0	0
Hyperkalaemia	1 (1.8)	0	0	1 (1.8)	0
Hypoalbuminaemia	1 (1.8)	0	0	0	1 (1.8)
Musculoskeletal and connective tissue disorders					
-Total	12 (21.1)	3 (5.3)	2 (3.5)	7 (12.3)	0
Pain in extremity	7 (12.3)	2 (3.5)	1 (1.8)	4 (7.0)	0
Back pain	2 (3.5)	0	0	2 (3.5)	0
Bone pain	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Arthralgia	1 (1.8)	0	0	1 (1.8)	0
Muscle spasms	1 (1.8)	1 (1.8)	0	0	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal pain	1 (1.8)	0	0	1 (1.8)	0
Myopathy	1 (1.8)	0	0	1 (1.8)	0
Myositis	1 (1.8)	0	0	1 (1.8)	0
Neck pain	1 (1.8)	0	1 (1.8)	0	0
Synovitis	1 (1.8)	0	1 (1.8)	0	0
Nervous system disorders					
-Total	13 (22.8)	2 (3.5)	6 (10.5)	4 (7.0)	1 (1.8)
Headache	9 (15.8)	2 (3.5)	3 (5.3)	4 (7.0)	0
Hypoaesthesia	1 (1.8)	1 (1.8)	0	0	0
Hyporesponsive to stimuli	1 (1.8)	0	0	1 (1.8)	0
Leukoencephalopathy	1 (1.8)	0	0	1 (1.8)	0
Neuralgia	1 (1.8)	0	1 (1.8)	0	0
Peripheral sensory neuropathy	1 (1.8)	0	1 (1.8)	0	0
Seizure	1 (1.8)	0	0	0	1 (1.8)
Visual field defect	1 (1.8)	0	1 (1.8)	0	0
Product issues					
-Total	1 (1.8)	0	1 (1.8)	0	0
Device occlusion	1 (1.8)	0	1 (1.8)	0	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Psychiatric disorders					
-Total	10 (17.5)	3 (5.3)	5 (8.8)	2 (3.5)	0
Mental status changes	3 (5.3)	2 (3.5)	0	1 (1.8)	0
Anxiety	2 (3.5)	0	2 (3.5)	0	0
Depression	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Insomnia	2 (3.5)	0	2 (3.5)	0	0
Agitation	1 (1.8)	0	0	1 (1.8)	0
Confusional state	1 (1.8)	0	1 (1.8)	0	0
Irritability	1 (1.8)	1 (1.8)	0	0	0
Renal and urinary disorders					
-Total	6 (10.5)	1 (1.8)	1 (1.8)	2 (3.5)	2 (3.5)
Acute kidney injury	3 (5.3)	1 (1.8)	0	1 (1.8)	1 (1.8)
Cystitis haemorrhagic	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Dysuria	1 (1.8)	0	1 (1.8)	0	0
Haematuria	1 (1.8)	1 (1.8)	0	0	0
Oliguria	1 (1.8)	0	0	1 (1.8)	0
Reproductive system and breast disorders					

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (1.8)	0	1 (1.8)	0	0
Scrotal pain	1 (1.8)	0	1 (1.8)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (14.0)	0	3 (5.3)	1 (1.8)	4 (7.0)
Hypoxia	4 (7.0)	0	2 (3.5)	1 (1.8)	1 (1.8)
Cough	3 (5.3)	2 (3.5)	0	1 (1.8)	0
Epistaxis	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Oropharyngeal pain	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Pulmonary oedema	2 (3.5)	0	0	0	2 (3.5)
Atelectasis	1 (1.8)	0	1 (1.8)	0	0
Dyspnoea	1 (1.8)	0	0	1 (1.8)	0
Haemoptysis	1 (1.8)	0	0	1 (1.8)	0
Idiopathic pneumonia syndrome	1 (1.8)	0	0	0	1 (1.8)
Nasal congestion	1 (1.8)	1 (1.8)	0	0	0
Pleural effusion	1 (1.8)	1 (1.8)	0	0	0
Pulmonary alveolar haemorrhage	1 (1.8)	0	0	0	1 (1.8)
Pulmonary hypertension	1 (1.8)	0	0	1 (1.8)	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary mass	1 (1.8)	0	1 (1.8)	0	0
Respiratory distress	1 (1.8)	0	0	0	1 (1.8)
Respiratory failure	1 (1.8)	0	0	0	1 (1.8)
Rhinorrhoea	1 (1.8)	1 (1.8)	0	0	0
Tachypnoea	1 (1.8)	0	0	1 (1.8)	0
Skin and subcutaneous tissue disorders					
-Total	6 (10.5)	3 (5.3)	3 (5.3)	0	0
Rash erythematous	2 (3.5)	0	2 (3.5)	0	0
Cold sweat	1 (1.8)	1 (1.8)	0	0	0
Night sweats	1 (1.8)	1 (1.8)	0	0	0
Rash	1 (1.8)	1 (1.8)	0	0	0
Rash papular	1 (1.8)	1 (1.8)	0	0	0
Skin irritation	1 (1.8)	1 (1.8)	0	0	0
Urticaria	1 (1.8)	0	1 (1.8)	0	0
Vascular disorders					
-Total	8 (14.0)	1 (1.8)	0	5 (8.8)	2 (3.5)
Hypotension	6 (10.5)	0	0	4 (7.0)	2 (3.5)

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Venous thrombosis limb	1 (1.8)	1 (1.8)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175n
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (68.2)	1 (4.5)	1 (4.5)	7 (31.8)	6 (27.3)
Blood and lymphatic system disorders					
-Total	11 (50.0)	0	0	8 (36.4)	3 (13.6)
Anaemia	7 (31.8)	0	0	7 (31.8)	0
Febrile neutropenia	4 (18.2)	0	0	4 (18.2)	0
Thrombocytopenia	4 (18.2)	0	0	1 (4.5)	3 (13.6)
Disseminated intravascular coagulation	1 (4.5)	0	0	1 (4.5)	0
Lymphopenia	1 (4.5)	0	0	0	1 (4.5)
Neutropenia	1 (4.5)	0	0	0	1 (4.5)
Cardiac disorders					
-Total	3 (13.6)	1 (4.5)	1 (4.5)	0	1 (4.5)

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	2 (9.1)	1 (4.5)	0	0	1 (4.5)
Right ventricular dysfunction	1 (4.5)	0	0	1 (4.5)	0
Sinus tachycardia	1 (4.5)	0	0	1 (4.5)	0
Tachycardia	1 (4.5)	0	1 (4.5)	0	0
Ventricular tachycardia	1 (4.5)	0	0	1 (4.5)	0
Eye disorders					
-Total	1 (4.5)	0	1 (4.5)	0	0
Photophobia	1 (4.5)	0	1 (4.5)	0	0
Gastrointestinal disorders					
-Total	9 (40.9)	3 (13.6)	3 (13.6)	3 (13.6)	0
Vomiting	4 (18.2)	2 (9.1)	1 (4.5)	1 (4.5)	0
Abdominal pain	3 (13.6)	0	1 (4.5)	2 (9.1)	0
Stomatitis	3 (13.6)	1 (4.5)	0	2 (9.1)	0
Diarrhoea	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Nausea	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Colitis	1 (4.5)	0	0	1 (4.5)	0
Dry mouth	1 (4.5)	1 (4.5)	0	0	0
Gastrointestinal haemorrhage	1 (4.5)	1 (4.5)	0	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematemesis	1 (4.5)	0	1 (4.5)	0	0
Haematochezia	1 (4.5)	0	0	1 (4.5)	0
Oral pain	1 (4.5)	0	1 (4.5)	0	0
Pancreatitis	1 (4.5)	0	1 (4.5)	0	0
General disorders and administration site conditions					
-Total	6 (27.3)	4 (18.2)	1 (4.5)	1 (4.5)	0
Catheter site pain	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Fatigue	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Pyrexia	2 (9.1)	2 (9.1)	0	0	0
Non-cardiac chest pain	1 (4.5)	0	0	1 (4.5)	0
Oedema peripheral	1 (4.5)	1 (4.5)	0	0	0
Immune system disorders					
-Total	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Hypogammaglobulinaemia	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Anaphylactic reaction	1 (4.5)	0	0	1 (4.5)	0
Infections and infestations					
-Total	5 (22.7)	0	2 (9.1)	3 (13.6)	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	1 (4.5)	0	1 (4.5)	0	0
Croup infectious	1 (4.5)	0	0	1 (4.5)	0
Escherichia urinary tract infection	1 (4.5)	0	1 (4.5)	0	0
Gastroenteritis	1 (4.5)	0	0	1 (4.5)	0
Oral herpes	1 (4.5)	0	1 (4.5)	0	0
Staphylococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Injury, poisoning and procedural complications					
-Total	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Procedural pain	1 (4.5)	0	0	1 (4.5)	0
Wound	1 (4.5)	1 (4.5)	0	0	0
Investigations					
-Total	5 (22.7)	0	0	0	5 (22.7)
Neutrophil count decreased	3 (13.6)	0	0	0	3 (13.6)
White blood cell count decreased	3 (13.6)	0	0	0	3 (13.6)
Blood lactate dehydrogenase increased	1 (4.5)	0	0	1 (4.5)	0
Computerised tomogram thorax abnormal	1 (4.5)	0	0	1 (4.5)	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	1 (4.5)	0	0	1 (4.5)	0
Platelet count decreased	1 (4.5)	0	0	0	1 (4.5)
Metabolism and nutrition disorders					
-Total	6 (27.3)	0	2 (9.1)	4 (18.2)	0
Dehydration	3 (13.6)	0	1 (4.5)	2 (9.1)	0
Decreased appetite	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Fluid overload	1 (4.5)	0	0	1 (4.5)	0
Hyperkalaemia	1 (4.5)	0	0	1 (4.5)	0
Hypomagnesaemia	1 (4.5)	1 (4.5)	0	0	0
Tumour lysis syndrome	1 (4.5)	0	0	1 (4.5)	0
Vitamin d deficiency	1 (4.5)	0	1 (4.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (18.2)	1 (4.5)	1 (4.5)	2 (9.1)	0
Pain in extremity	4 (18.2)	1 (4.5)	1 (4.5)	2 (9.1)	0
Arthralgia	1 (4.5)	0	0	1 (4.5)	0
Back pain	1 (4.5)	0	0	1 (4.5)	0
Bone pain	1 (4.5)	0	1 (4.5)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	3 (13.6)	1 (4.5)	1 (4.5)	0	1 (4.5)
Headache	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Hyporesponsive to stimuli	1 (4.5)	0	0	1 (4.5)	0
Neuropathy peripheral	1 (4.5)	1 (4.5)	0	0	0
Peroneal nerve palsy	1 (4.5)	1 (4.5)	0	0	0
Seizure	1 (4.5)	0	0	0	1 (4.5)
Psychiatric disorders					
-Total	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Agitation	1 (4.5)	0	0	1 (4.5)	0
Depression	1 (4.5)	1 (4.5)	0	0	0
Insomnia	1 (4.5)	0	1 (4.5)	0	0
Mental status changes	1 (4.5)	1 (4.5)	0	0	0
Renal and urinary disorders					
-Total	2 (9.1)	0	0	2 (9.1)	0
Acute kidney injury	1 (4.5)	0	0	1 (4.5)	0
Cystitis haemorrhagic	1 (4.5)	0	0	1 (4.5)	0
Oliguria	1 (4.5)	0	0	1 (4.5)	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	2 (9.1)	0	1 (4.5)	0	1 (4.5)
Hypoxia	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Cough	1 (4.5)	0	0	1 (4.5)	0
Dyspnoea	1 (4.5)	0	0	1 (4.5)	0
Haemoptysis	1 (4.5)	0	0	1 (4.5)	0
Oropharyngeal pain	1 (4.5)	0	0	1 (4.5)	0
Pulmonary alveolar haemorrhage	1 (4.5)	0	0	0	1 (4.5)
Pulmonary hypertension	1 (4.5)	0	0	1 (4.5)	0
Pulmonary oedema	1 (4.5)	0	0	0	1 (4.5)
Respiratory distress	1 (4.5)	0	0	0	1 (4.5)
Tachypnoea	1 (4.5)	0	0	1 (4.5)	0
Skin and subcutaneous tissue disorders					
-Total	5 (22.7)	3 (13.6)	2 (9.1)	0	0
Rash papular	2 (9.1)	2 (9.1)	0	0	0
Alopecia	1 (4.5)	0	1 (4.5)	0	0
Dermatitis diaper	1 (4.5)	1 (4.5)	0	0	0

Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash erythematous	1 (4.5)	0	1 (4.5)	0	0
Vascular disorders					
-Total	2 (9.1)	1 (4.5)	0	0	1 (4.5)
Hypertension	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Hypotension	1 (4.5)	0	0	0	1 (4.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175n
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	49 (92.5)	2 (3.8)	5 (9.4)	19 (35.8)	23 (43.4)
Blood and lymphatic system disorders					
-Total	30 (56.6)	1 (1.9)	0	21 (39.6)	8 (15.1)
Anaemia	14 (26.4)	0	2 (3.8)	12 (22.6)	0
Febrile neutropenia	14 (26.4)	0	0	14 (26.4)	0
Thrombocytopenia	6 (11.3)	0	0	2 (3.8)	4 (7.5)
Neutropenia	5 (9.4)	0	0	1 (1.9)	4 (7.5)
Coagulopathy	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Pancytopenia	2 (3.8)	0	0	0	2 (3.8)
Disseminated intravascular coagulation	1 (1.9)	0	0	1 (1.9)	0
Leukocytosis	1 (1.9)	1 (1.9)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (1.9)	0	0	0	1 (1.9)
Splenomegaly	1 (1.9)	1 (1.9)	0	0	0
Cardiac disorders					
-Total	6 (11.3)	0	2 (3.8)	3 (5.7)	1 (1.9)
Pericardial effusion	2 (3.8)	0	2 (3.8)	0	0
Tachycardia	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Cardiovascular insufficiency	1 (1.9)	0	0	0	1 (1.9)
Left ventricular dysfunction	1 (1.9)	0	0	1 (1.9)	0
Sinus tachycardia	1 (1.9)	0	0	1 (1.9)	0
Ear and labyrinth disorders					
-Total	1 (1.9)	0	1 (1.9)	0	0
Deafness unilateral	1 (1.9)	0	1 (1.9)	0	0
Endocrine disorders					
-Total	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Adrenal insufficiency	1 (1.9)	0	1 (1.9)	0	0
Cushingoid	1 (1.9)	1 (1.9)	0	0	0
Hyperthyroidism	1 (1.9)	0	1 (1.9)	0	0
Eye disorders					

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.9)	0	1 (1.9)	0	0
Retinopathy	1 (1.9)	0	1 (1.9)	0	0
Gastrointestinal disorders					
-Total	19 (35.8)	3 (5.7)	9 (17.0)	6 (11.3)	1 (1.9)
Nausea	8 (15.1)	0	6 (11.3)	2 (3.8)	0
Abdominal pain	6 (11.3)	1 (1.9)	4 (7.5)	1 (1.9)	0
Constipation	5 (9.4)	3 (5.7)	2 (3.8)	0	0
Vomiting	5 (9.4)	2 (3.8)	3 (5.7)	0	0
Colitis	3 (5.7)	1 (1.9)	0	2 (3.8)	0
Stomatitis	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Anal fissure	1 (1.9)	0	1 (1.9)	0	0
Diarrhoea	1 (1.9)	0	1 (1.9)	0	0
Dyspepsia	1 (1.9)	0	1 (1.9)	0	0
Gastrointestinal haemorrhage	1 (1.9)	0	0	1 (1.9)	0
Perianal erythema	1 (1.9)	0	1 (1.9)	0	0
Proctalgia	1 (1.9)	0	1 (1.9)	0	0
General disorders and administration site conditions					

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	20 (37.7)	7 (13.2)	7 (13.2)	4 (7.5)	2 (3.8)
Pyrexia	10 (18.9)	4 (7.5)	4 (7.5)	2 (3.8)	0
Fatigue	5 (9.4)	3 (5.7)	1 (1.9)	1 (1.9)	0
Pain	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Catheter site pain	2 (3.8)	0	2 (3.8)	0	0
Chills	2 (3.8)	2 (3.8)	0	0	0
Multiple organ dysfunction syndrome	2 (3.8)	0	0	0	2 (3.8)
Non-cardiac chest pain	2 (3.8)	2 (3.8)	0	0	0
Asthenia	1 (1.9)	0	1 (1.9)	0	0
Catheter site bruise	1 (1.9)	1 (1.9)	0	0	0
Device related thrombosis	1 (1.9)	0	1 (1.9)	0	0
Gait disturbance	1 (1.9)	1 (1.9)	0	0	0
Generalised oedema	1 (1.9)	1 (1.9)	0	0	0
Injection site thrombosis	1 (1.9)	0	1 (1.9)	0	0
Oedema peripheral	1 (1.9)	0	1 (1.9)	0	0
Physical deconditioning	1 (1.9)	0	0	1 (1.9)	0
Hepatobiliary disorders					
-Total	4 (7.5)	0	1 (1.9)	3 (5.7)	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	3 (5.7)	0	1 (1.9)	2 (3.8)	0
Cholecystitis	1 (1.9)	0	0	1 (1.9)	0
Hepatic steatosis	1 (1.9)	0	1 (1.9)	0	0
Immune system disorders					
-Total	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Anaphylactic reaction	1 (1.9)	0	0	1 (1.9)	0
Drug hypersensitivity	1 (1.9)	0	1 (1.9)	0	0
Hypogammaglobulinaemia	1 (1.9)	0	1 (1.9)	0	0
Infections and infestations					
-Total	28 (52.8)	1 (1.9)	5 (9.4)	14 (26.4)	8 (15.1)
Device related infection	3 (5.7)	0	0	3 (5.7)	0
Clostridium difficile colitis	2 (3.8)	0	0	2 (3.8)	0
Enterococcal bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Escherichia bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Klebsiella sepsis	2 (3.8)	0	0	0	2 (3.8)
Oral herpes	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Pneumonia	2 (3.8)	0	1 (1.9)	0	1 (1.9)
Pneumonia fungal	2 (3.8)	0	1 (1.9)	1 (1.9)	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Abscess limb	1 (1.9)	0	0	1 (1.9)	0
Alpha haemolytic streptococcal infection	1 (1.9)	0	0	1 (1.9)	0
Bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Bronchopulmonary aspergillosis	1 (1.9)	0	0	1 (1.9)	0
Candida sepsis	1 (1.9)	0	0	0	1 (1.9)
Cellulitis	1 (1.9)	0	0	1 (1.9)	0
Clostridium difficile infection	1 (1.9)	0	1 (1.9)	0	0
Conjunctivitis	1 (1.9)	0	1 (1.9)	0	0
Cytomegalovirus viraemia	1 (1.9)	0	1 (1.9)	0	0
Escherichia infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia sepsis	1 (1.9)	0	0	0	1 (1.9)
Escherichia urinary tract infection	1 (1.9)	0	0	1 (1.9)	0
Fungal skin infection	1 (1.9)	0	1 (1.9)	0	0
Human polyomavirus infection	1 (1.9)	0	0	0	1 (1.9)
Klebsiella infection	1 (1.9)	0	0	1 (1.9)	0
Metapneumovirus infection	1 (1.9)	0	1 (1.9)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus bronchitis	1 (1.9)	0	0	1 (1.9)	0
Respiratory syncytial virus infection	1 (1.9)	0	1 (1.9)	0	0
Rhinovirus infection	1 (1.9)	0	1 (1.9)	0	0
Sepsis	1 (1.9)	0	0	0	1 (1.9)
Serratia infection	1 (1.9)	0	0	1 (1.9)	0
Sinusitis	1 (1.9)	1 (1.9)	0	0	0
Staphylococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal infection	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal scalded skin syndrome	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal sepsis	1 (1.9)	0	0	0	1 (1.9)
Streptococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Streptococcal infection	1 (1.9)	0	0	1 (1.9)	0
Injury, poisoning and procedural complications					
-Total	7 (13.2)	0	6 (11.3)	1 (1.9)	0
Procedural pain	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Subdural haematoma	2 (3.8)	0	1 (1.9)	1 (1.9)	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion reaction	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Extradural haematoma	1 (1.9)	0	0	1 (1.9)	0
Procedural hypertension	1 (1.9)	0	1 (1.9)	0	0
Radiation skin injury	1 (1.9)	0	1 (1.9)	0	0
Toxicity to various agents	1 (1.9)	0	1 (1.9)	0	0
Investigations					
-Total	26 (49.1)	3 (5.7)	3 (5.7)	7 (13.2)	13 (24.5)
Platelet count decreased	9 (17.0)	0	0	1 (1.9)	8 (15.1)
White blood cell count decreased	9 (17.0)	1 (1.9)	1 (1.9)	1 (1.9)	6 (11.3)
Alanine aminotransferase increased	6 (11.3)	0	1 (1.9)	5 (9.4)	0
Neutrophil count decreased	6 (11.3)	0	0	0	6 (11.3)
Aspartate aminotransferase increased	5 (9.4)	1 (1.9)	1 (1.9)	3 (5.7)	0
Blast cell count increased	1 (1.9)	0	0	1 (1.9)	0
Blood bilirubin increased	1 (1.9)	0	0	1 (1.9)	0
Blood creatinine increased	1 (1.9)	1 (1.9)	0	0	0
Blood fibrinogen decreased	1 (1.9)	0	1 (1.9)	0	0
Blood immunoglobulin a increased	1 (1.9)	1 (1.9)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (1.9)	1 (1.9)	0	0	0
Blood immunoglobulin m increased	1 (1.9)	1 (1.9)	0	0	0
Blood lactate dehydrogenase increased	1 (1.9)	0	0	1 (1.9)	0
Blood uric acid increased	1 (1.9)	1 (1.9)	0	0	0
Coronavirus test positive	1 (1.9)	1 (1.9)	0	0	0
Electrocardiogram qt prolonged	1 (1.9)	0	0	1 (1.9)	0
Lymphocyte count decreased	1 (1.9)	0	0	1 (1.9)	0
Serum ferritin increased	1 (1.9)	0	0	1 (1.9)	0
Transaminases increased	1 (1.9)	0	0	1 (1.9)	0
White blood cell count increased	1 (1.9)	1 (1.9)	0	0	0
Metabolism and nutrition disorders					
-Total	17 (32.1)	1 (1.9)	6 (11.3)	6 (11.3)	4 (7.5)
Hyperglycaemia	7 (13.2)	0	3 (5.7)	3 (5.7)	1 (1.9)
Decreased appetite	6 (11.3)	1 (1.9)	3 (5.7)	2 (3.8)	0
Hypokalaemia	5 (9.4)	1 (1.9)	0	2 (3.8)	2 (3.8)
Hyperuricaemia	4 (7.5)	2 (3.8)	0	1 (1.9)	1 (1.9)
Hypocalcaemia	3 (5.7)	1 (1.9)	0	0	2 (3.8)

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypomagnesaemia	3 (5.7)	3 (5.7)	0	0	0
Hypophosphataemia	3 (5.7)	0	1 (1.9)	2 (3.8)	0
Hypernatraemia	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Dehydration	1 (1.9)	0	1 (1.9)	0	0
Fluid overload	1 (1.9)	0	1 (1.9)	0	0
Hyperammonaemia	1 (1.9)	1 (1.9)	0	0	0
Hyperkalaemia	1 (1.9)	0	1 (1.9)	0	0
Hypoalbuminaemia	1 (1.9)	0	0	0	1 (1.9)
Malnutrition	1 (1.9)	0	1 (1.9)	0	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0
Vitamin d deficiency	1 (1.9)	0	1 (1.9)	0	0
Musculoskeletal and connective tissue disorders					
-Total	14 (26.4)	3 (5.7)	5 (9.4)	6 (11.3)	0
Pain in extremity	5 (9.4)	1 (1.9)	1 (1.9)	3 (5.7)	0
Neck pain	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Back pain	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Pain in jaw	2 (3.8)	0	2 (3.8)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	1 (1.9)	0	1 (1.9)	0	0
Bone pain	1 (1.9)	0	0	1 (1.9)	0
Muscle spasms	1 (1.9)	1 (1.9)	0	0	0
Musculoskeletal chest pain	1 (1.9)	1 (1.9)	0	0	0
Musculoskeletal pain	1 (1.9)	0	0	1 (1.9)	0
Myopathy	1 (1.9)	0	0	1 (1.9)	0
Myositis	1 (1.9)	0	0	1 (1.9)	0
Synovitis	1 (1.9)	0	1 (1.9)	0	0
Nervous system disorders					
-Total	12 (22.6)	2 (3.8)	6 (11.3)	4 (7.5)	0
Headache	8 (15.1)	2 (3.8)	3 (5.7)	3 (5.7)	0
Hypoaesthesia	1 (1.9)	1 (1.9)	0	0	0
Leukoencephalopathy	1 (1.9)	0	0	1 (1.9)	0
Neuralgia	1 (1.9)	0	1 (1.9)	0	0
Peripheral sensory neuropathy	1 (1.9)	0	1 (1.9)	0	0
Visual field defect	1 (1.9)	0	1 (1.9)	0	0
Product issues					
-Total	1 (1.9)	0	1 (1.9)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device occlusion	1 (1.9)	0	1 (1.9)	0	0
Psychiatric disorders					
-Total	8 (15.1)	2 (3.8)	5 (9.4)	1 (1.9)	0
Anxiety	2 (3.8)	0	2 (3.8)	0	0
Confusional state	2 (3.8)	0	2 (3.8)	0	0
Mental status changes	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Depression	1 (1.9)	0	1 (1.9)	0	0
Insomnia	1 (1.9)	0	1 (1.9)	0	0
Irritability	1 (1.9)	1 (1.9)	0	0	0
Renal and urinary disorders					
-Total	4 (7.5)	1 (1.9)	1 (1.9)	0	2 (3.8)
Acute kidney injury	2 (3.8)	1 (1.9)	0	0	1 (1.9)
Cystitis haemorrhagic	1 (1.9)	0	0	0	1 (1.9)
Dysuria	1 (1.9)	0	1 (1.9)	0	0
Haematuria	1 (1.9)	1 (1.9)	0	0	0
Reproductive system and breast disorders					
-Total	1 (1.9)	0	1 (1.9)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Scrotal pain	1 (1.9)	0	1 (1.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (17.0)	0	4 (7.5)	1 (1.9)	4 (7.5)
Hypoxia	5 (9.4)	0	3 (5.7)	1 (1.9)	1 (1.9)
Epistaxis	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Pleural effusion	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Cough	2 (3.8)	2 (3.8)	0	0	0
Aspiration	1 (1.9)	0	0	0	1 (1.9)
Atelectasis	1 (1.9)	0	1 (1.9)	0	0
Idiopathic pneumonia syndrome	1 (1.9)	0	0	0	1 (1.9)
Nasal congestion	1 (1.9)	1 (1.9)	0	0	0
Oropharyngeal pain	1 (1.9)	1 (1.9)	0	0	0
Pulmonary mass	1 (1.9)	0	1 (1.9)	0	0
Pulmonary oedema	1 (1.9)	0	0	0	1 (1.9)
Respiratory failure	1 (1.9)	0	0	0	1 (1.9)
Rhinorrhoea	1 (1.9)	1 (1.9)	0	0	0
Skin and subcutaneous tissue disorders					

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (9.4)	3 (5.7)	2 (3.8)	0	0
Rash erythematous	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Cold sweat	1 (1.9)	1 (1.9)	0	0	0
Night sweats	1 (1.9)	1 (1.9)	0	0	0
Rash	1 (1.9)	1 (1.9)	0	0	0
Skin irritation	1 (1.9)	1 (1.9)	0	0	0
Urticaria	1 (1.9)	0	1 (1.9)	0	0
Vascular disorders					
-Total	8 (15.1)	1 (1.9)	0	5 (9.4)	2 (3.8)
Hypotension	6 (11.3)	0	0	4 (7.5)	2 (3.8)
Hypertension	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Venous thrombosis limb	1 (1.9)	1 (1.9)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of

all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175o
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	0	3 (42.9)	3 (42.9)
Blood and lymphatic system disorders					
-Total	5 (71.4)	0	0	3 (42.9)	2 (28.6)
Anaemia	2 (28.6)	0	0	2 (28.6)	0
Febrile neutropenia	2 (28.6)	0	0	2 (28.6)	0
Neutropenia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Leukopenia	1 (14.3)	0	0	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	0	0	1 (14.3)
Gastrointestinal disorders					
-Total	4 (57.1)	1 (14.3)	3 (42.9)	0	0
Vomiting	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Abdominal pain	1 (14.3)	0	1 (14.3)	0	0

Baseline extramedullary disease presence: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	1 (14.3)	1 (14.3)	0	0	0
Constipation	1 (14.3)	0	1 (14.3)	0	0
Nausea	1 (14.3)	0	1 (14.3)	0	0
Perianal erythema	1 (14.3)	0	1 (14.3)	0	0
Hepatobiliary disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Hyperbilirubinaemia	1 (14.3)	0	1 (14.3)	0	0
Immune system disorders					
-Total	2 (28.6)	0	0	2 (28.6)	0
Anaphylactic reaction	2 (28.6)	0	0	2 (28.6)	0
Hypogammaglobulinaemia	1 (14.3)	1 (14.3)	0	0	0
Infections and infestations					
-Total	3 (42.9)	0	0	3 (42.9)	0
Device related infection	1 (14.3)	0	0	1 (14.3)	0
Escherichia bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Escherichia infection	1 (14.3)	0	0	1 (14.3)	0
Sinusitis	1 (14.3)	1 (14.3)	0	0	0
Streptococcal infection	1 (14.3)	0	0	1 (14.3)	0

Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Injury, poisoning and procedural complications					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Extradural haematoma	1 (14.3)	0	0	1 (14.3)	0
Procedural pain	1 (14.3)	0	0	1 (14.3)	0
Radiation skin injury	1 (14.3)	0	1 (14.3)	0	0
Subdural haematoma	1 (14.3)	0	0	1 (14.3)	0
Investigations					
-Total	4 (57.1)	0	0	3 (42.9)	1 (14.3)
Aspartate aminotransferase increased	3 (42.9)	0	1 (14.3)	2 (28.6)	0
Alanine aminotransferase increased	2 (28.6)	0	0	2 (28.6)	0
Blood bilirubin increased	1 (14.3)	0	0	1 (14.3)	0
Platelet count decreased	1 (14.3)	0	0	0	1 (14.3)
White blood cell count decreased	1 (14.3)	0	0	0	1 (14.3)
Metabolism and nutrition disorders					
-Total	4 (57.1)	0	0	3 (42.9)	1 (14.3)
Hypokalaemia	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Tumour lysis syndrome	2 (28.6)	0	0	2 (28.6)	0

Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Decreased appetite	1 (14.3)	0	0	1 (14.3)	0
Hyperglycaemia	1 (14.3)	0	0	1 (14.3)	0
Hyperkalaemia	1 (14.3)	0	1 (14.3)	0	0
Hyperuricaemia	1 (14.3)	0	0	0	1 (14.3)
Malnutrition	1 (14.3)	0	1 (14.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Back pain	1 (14.3)	1 (14.3)	0	0	0
Bone pain	1 (14.3)	0	0	1 (14.3)	0
Muscle spasms	1 (14.3)	1 (14.3)	0	0	0
Musculoskeletal chest pain	1 (14.3)	1 (14.3)	0	0	0
Pain in extremity	1 (14.3)	0	1 (14.3)	0	0
Pain in jaw	1 (14.3)	0	1 (14.3)	0	0
Nervous system disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Headache	1 (14.3)	0	0	1 (14.3)	0
Psychiatric disorders					

Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Irritability	1 (14.3)	1 (14.3)	0	0	0
Mental status changes	1 (14.3)	0	0	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Epistaxis	1 (14.3)	0	0	1 (14.3)	0
Skin and subcutaneous tissue disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Urticaria	1 (14.3)	0	1 (14.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175o
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	58 (85.3)	3 (4.4)	6 (8.8)	23 (33.8)	26 (38.2)
Blood and lymphatic system disorders					
-Total	36 (52.9)	1 (1.5)	0	26 (38.2)	9 (13.2)
Anaemia	19 (27.9)	0	2 (2.9)	17 (25.0)	0
Febrile neutropenia	16 (23.5)	0	0	16 (23.5)	0
Thrombocytopenia	9 (13.2)	0	0	3 (4.4)	6 (8.8)
Neutropenia	4 (5.9)	0	0	0	4 (5.9)
Coagulopathy	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Disseminated intravascular coagulation	2 (2.9)	0	0	2 (2.9)	0
Pancytopenia	2 (2.9)	0	0	0	2 (2.9)
Leukocytosis	1 (1.5)	1 (1.5)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68				
	All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphopenia	1 (1.5)	0	0	0	1 (1.5)
Splenomegaly	1 (1.5)	1 (1.5)	0	0	0
Cardiac disorders					
-Total	9 (13.2)	1 (1.5)	3 (4.4)	3 (4.4)	2 (2.9)
Tachycardia	3 (4.4)	1 (1.5)	1 (1.5)	1 (1.5)	0
Bradycardia	2 (2.9)	1 (1.5)	0	0	1 (1.5)
Pericardial effusion	2 (2.9)	0	2 (2.9)	0	0
Sinus tachycardia	2 (2.9)	0	0	2 (2.9)	0
Cardiovascular insufficiency	1 (1.5)	0	0	0	1 (1.5)
Left ventricular dysfunction	1 (1.5)	0	0	1 (1.5)	0
Right ventricular dysfunction	1 (1.5)	0	0	1 (1.5)	0
Ventricular tachycardia	1 (1.5)	0	0	1 (1.5)	0
Ear and labyrinth disorders					
-Total	1 (1.5)	0	1 (1.5)	0	0
Deafness unilateral	1 (1.5)	0	1 (1.5)	0	0
Endocrine disorders					
-Total	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Adrenal insufficiency	1 (1.5)	0	1 (1.5)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68				
	All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cushingoid	1 (1.5)	1 (1.5)	0	0	0
Hyperthyroidism	1 (1.5)	0	1 (1.5)	0	0
Eye disorders					
-Total	2 (2.9)	0	2 (2.9)	0	0
Photophobia	1 (1.5)	0	1 (1.5)	0	0
Retinopathy	1 (1.5)	0	1 (1.5)	0	0
Gastrointestinal disorders					
-Total	24 (35.3)	5 (7.4)	9 (13.2)	9 (13.2)	1 (1.5)
Nausea	9 (13.2)	0	6 (8.8)	3 (4.4)	0
Abdominal pain	8 (11.8)	1 (1.5)	4 (5.9)	3 (4.4)	0
Vomiting	7 (10.3)	3 (4.4)	3 (4.4)	1 (1.5)	0
Stomatitis	5 (7.4)	1 (1.5)	0	3 (4.4)	1 (1.5)
Constipation	4 (5.9)	3 (4.4)	1 (1.5)	0	0
Colitis	3 (4.4)	0	0	3 (4.4)	0
Diarrhoea	3 (4.4)	1 (1.5)	1 (1.5)	1 (1.5)	0
Gastrointestinal haemorrhage	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Anal fissure	1 (1.5)	0	1 (1.5)	0	0
Dry mouth	1 (1.5)	1 (1.5)	0	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspepsia	1 (1.5)	0	1 (1.5)	0	0
Haematemesis	1 (1.5)	0	1 (1.5)	0	0
Haematochezia	1 (1.5)	0	0	1 (1.5)	0
Oral pain	1 (1.5)	0	1 (1.5)	0	0
Pancreatitis	1 (1.5)	0	1 (1.5)	0	0
Proctalgia	1 (1.5)	0	1 (1.5)	0	0
General disorders and administration site conditions					
-Total	26 (38.2)	11 (16.2)	8 (11.8)	5 (7.4)	2 (2.9)
Pyrexia	12 (17.6)	6 (8.8)	4 (5.9)	2 (2.9)	0
Fatigue	7 (10.3)	4 (5.9)	2 (2.9)	1 (1.5)	0
Catheter site pain	4 (5.9)	1 (1.5)	3 (4.4)	0	0
Non-cardiac chest pain	3 (4.4)	2 (2.9)	0	1 (1.5)	0
Pain	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Chills	2 (2.9)	2 (2.9)	0	0	0
Multiple organ dysfunction syndrome	2 (2.9)	0	0	0	2 (2.9)
Oedema peripheral	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Asthenia	1 (1.5)	0	1 (1.5)	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site bruise	1 (1.5)	1 (1.5)	0	0	0
Device related thrombosis	1 (1.5)	0	1 (1.5)	0	0
Gait disturbance	1 (1.5)	1 (1.5)	0	0	0
Generalised oedema	1 (1.5)	1 (1.5)	0	0	0
Injection site thrombosis	1 (1.5)	0	1 (1.5)	0	0
Physical deconditioning	1 (1.5)	0	0	1 (1.5)	0
Hepatobiliary disorders					
-Total	3 (4.4)	0	0	3 (4.4)	0
Hyperbilirubinaemia	2 (2.9)	0	0	2 (2.9)	0
Cholecystitis	1 (1.5)	0	0	1 (1.5)	0
Hepatic steatosis	1 (1.5)	0	1 (1.5)	0	0
Immune system disorders					
-Total	3 (4.4)	0	3 (4.4)	0	0
Hypogammaglobulinaemia	2 (2.9)	0	2 (2.9)	0	0
Drug hypersensitivity	1 (1.5)	0	1 (1.5)	0	0
Infections and infestations					
-Total	30 (44.1)	1 (1.5)	7 (10.3)	14 (20.6)	8 (11.8)
Oral herpes	3 (4.4)	0	2 (2.9)	1 (1.5)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile colitis	2 (2.9)	0	0	2 (2.9)	0
Conjunctivitis	2 (2.9)	0	2 (2.9)	0	0
Device related infection	2 (2.9)	0	0	2 (2.9)	0
Enterococcal bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Escherichia urinary tract infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Klebsiella sepsis	2 (2.9)	0	0	0	2 (2.9)
Pneumonia	2 (2.9)	0	1 (1.5)	0	1 (1.5)
Pneumonia fungal	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Staphylococcal bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Upper respiratory tract infection	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Abscess limb	1 (1.5)	0	0	1 (1.5)	0
Alpha haemolytic streptococcal infection	1 (1.5)	0	0	1 (1.5)	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Candida sepsis	1 (1.5)	0	0	0	1 (1.5)
Cellulitis	1 (1.5)	0	0	1 (1.5)	0
Clostridium difficile infection	1 (1.5)	0	1 (1.5)	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Croup infectious	1 (1.5)	0	0	1 (1.5)	0
Cytomegalovirus viraemia	1 (1.5)	0	1 (1.5)	0	0
Escherichia bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Escherichia sepsis	1 (1.5)	0	0	0	1 (1.5)
Fungal skin infection	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis	1 (1.5)	0	0	1 (1.5)	0
Human polyomavirus infection	1 (1.5)	0	0	0	1 (1.5)
Klebsiella infection	1 (1.5)	0	0	1 (1.5)	0
Metapneumovirus infection	1 (1.5)	0	1 (1.5)	0	0
Parainfluenzae virus infection	1 (1.5)	0	1 (1.5)	0	0
Respiratory syncytial virus bronchitis	1 (1.5)	0	0	1 (1.5)	0
Respiratory syncytial virus infection	1 (1.5)	0	1 (1.5)	0	0
Rhinovirus infection	1 (1.5)	0	1 (1.5)	0	0
Sepsis	1 (1.5)	0	0	0	1 (1.5)
Serratia infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal infection	1 (1.5)	0	0	1 (1.5)	0
Staphylococcal scalded skin syndrome	1 (1.5)	0	1 (1.5)	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Streptococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Injury, poisoning and procedural complications					
-Total	7 (10.3)	1 (1.5)	5 (7.4)	1 (1.5)	0
Procedural pain	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Transfusion reaction	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Procedural hypertension	1 (1.5)	0	1 (1.5)	0	0
Subdural haematoma	1 (1.5)	0	1 (1.5)	0	0
Toxicity to various agents	1 (1.5)	0	1 (1.5)	0	0
Wound	1 (1.5)	1 (1.5)	0	0	0
Investigations					
-Total	27 (39.7)	3 (4.4)	3 (4.4)	4 (5.9)	17 (25.0)
White blood cell count decreased	11 (16.2)	1 (1.5)	1 (1.5)	1 (1.5)	8 (11.8)
Neutrophil count decreased	9 (13.2)	0	0	0	9 (13.2)
Platelet count decreased	9 (13.2)	0	0	1 (1.5)	8 (11.8)
Alanine aminotransferase increased	4 (5.9)	0	1 (1.5)	3 (4.4)	0
Aspartate aminotransferase increased	2 (2.9)	1 (1.5)	0	1 (1.5)	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	2 (2.9)	0	0	2 (2.9)	0
Electrocardiogram qt prolonged	2 (2.9)	0	0	2 (2.9)	0
Blast cell count increased	1 (1.5)	0	0	1 (1.5)	0
Blood creatinine increased	1 (1.5)	1 (1.5)	0	0	0
Blood fibrinogen decreased	1 (1.5)	0	1 (1.5)	0	0
Blood immunoglobulin a increased	1 (1.5)	1 (1.5)	0	0	0
Blood immunoglobulin m decreased	1 (1.5)	1 (1.5)	0	0	0
Blood immunoglobulin m increased	1 (1.5)	1 (1.5)	0	0	0
Blood uric acid increased	1 (1.5)	1 (1.5)	0	0	0
Computerised tomogram thorax abnormal	1 (1.5)	0	0	1 (1.5)	0
Coronavirus test positive	1 (1.5)	1 (1.5)	0	0	0
Lymphocyte count decreased	1 (1.5)	0	0	1 (1.5)	0
Serum ferritin increased	1 (1.5)	0	0	1 (1.5)	0
Transaminases increased	1 (1.5)	0	0	1 (1.5)	0
White blood cell count increased	1 (1.5)	1 (1.5)	0	0	0
Metabolism and nutrition disorders					
-Total	19 (27.9)	1 (1.5)	8 (11.8)	7 (10.3)	3 (4.4)

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Decreased appetite	7 (10.3)	1 (1.5)	4 (5.9)	2 (2.9)	0
Hyperglycaemia	6 (8.8)	0	3 (4.4)	2 (2.9)	1 (1.5)
Dehydration	4 (5.9)	0	2 (2.9)	2 (2.9)	0
Hypomagnesaemia	4 (5.9)	4 (5.9)	0	0	0
Hyperuricaemia	3 (4.4)	2 (2.9)	0	1 (1.5)	0
Hypocalcaemia	3 (4.4)	1 (1.5)	0	0	2 (2.9)
Hypokalaemia	3 (4.4)	0	0	1 (1.5)	2 (2.9)
Hypophosphataemia	3 (4.4)	0	1 (1.5)	2 (2.9)	0
Fluid overload	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Hypernatraemia	2 (2.9)	0	0	1 (1.5)	1 (1.5)
Vitamin d deficiency	2 (2.9)	0	2 (2.9)	0	0
Hyperammonaemia	1 (1.5)	1 (1.5)	0	0	0
Hyperkalaemia	1 (1.5)	0	0	1 (1.5)	0
Hypoalbuminaemia	1 (1.5)	0	0	0	1 (1.5)
Musculoskeletal and connective tissue disorders					
-Total	14 (20.6)	3 (4.4)	4 (5.9)	7 (10.3)	0
Pain in extremity	8 (11.8)	2 (2.9)	1 (1.5)	5 (7.4)	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neck pain	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Arthralgia	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Back pain	2 (2.9)	0	0	2 (2.9)	0
Bone pain	1 (1.5)	0	1 (1.5)	0	0
Musculoskeletal pain	1 (1.5)	0	0	1 (1.5)	0
Myopathy	1 (1.5)	0	0	1 (1.5)	0
Myositis	1 (1.5)	0	0	1 (1.5)	0
Pain in jaw	1 (1.5)	0	1 (1.5)	0	0
Synovitis	1 (1.5)	0	1 (1.5)	0	0
Nervous system disorders					
-Total	14 (20.6)	3 (4.4)	7 (10.3)	3 (4.4)	1 (1.5)
Headache	9 (13.2)	2 (2.9)	4 (5.9)	3 (4.4)	0
Hypoaesthesia	1 (1.5)	1 (1.5)	0	0	0
Hyporesponsive to stimuli	1 (1.5)	0	0	1 (1.5)	0
Leukoencephalopathy	1 (1.5)	0	0	1 (1.5)	0
Neuralgia	1 (1.5)	0	1 (1.5)	0	0
Neuropathy peripheral	1 (1.5)	1 (1.5)	0	0	0
Peripheral sensory neuropathy	1 (1.5)	0	1 (1.5)	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Peroneal nerve palsy	1 (1.5)	1 (1.5)	0	0	0
Seizure	1 (1.5)	0	0	0	1 (1.5)
Visual field defect	1 (1.5)	0	1 (1.5)	0	0
Product issues					
-Total	1 (1.5)	0	1 (1.5)	0	0
Device occlusion	1 (1.5)	0	1 (1.5)	0	0
Psychiatric disorders					
-Total	9 (13.2)	2 (2.9)	6 (8.8)	1 (1.5)	0
Anxiety	2 (2.9)	0	2 (2.9)	0	0
Confusional state	2 (2.9)	0	2 (2.9)	0	0
Depression	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Insomnia	2 (2.9)	0	2 (2.9)	0	0
Mental status changes	2 (2.9)	2 (2.9)	0	0	0
Agitation	1 (1.5)	0	0	1 (1.5)	0
Renal and urinary disorders					
-Total	6 (8.8)	1 (1.5)	1 (1.5)	2 (2.9)	2 (2.9)
Acute kidney injury	3 (4.4)	1 (1.5)	0	1 (1.5)	1 (1.5)
Cystitis haemorrhagic	2 (2.9)	0	0	1 (1.5)	1 (1.5)

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysuria	1 (1.5)	0	1 (1.5)	0	0
Haematuria	1 (1.5)	1 (1.5)	0	0	0
Oliguria	1 (1.5)	0	0	1 (1.5)	0
Reproductive system and breast disorders					
-Total	1 (1.5)	0	1 (1.5)	0	0
Scrotal pain	1 (1.5)	0	1 (1.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (14.7)	0	5 (7.4)	0	5 (7.4)
Hypoxia	7 (10.3)	0	4 (5.9)	2 (2.9)	1 (1.5)
Cough	3 (4.4)	2 (2.9)	0	1 (1.5)	0
Pleural effusion	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Epistaxis	2 (2.9)	0	2 (2.9)	0	0
Oropharyngeal pain	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Pulmonary oedema	2 (2.9)	0	0	0	2 (2.9)
Aspiration	1 (1.5)	0	0	0	1 (1.5)
Atelectasis	1 (1.5)	0	1 (1.5)	0	0
Dyspnoea	1 (1.5)	0	0	1 (1.5)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemoptysis	1 (1.5)	0	0	1 (1.5)	0
Idiopathic pneumonia syndrome	1 (1.5)	0	0	0	1 (1.5)
Nasal congestion	1 (1.5)	1 (1.5)	0	0	0
Pulmonary alveolar haemorrhage	1 (1.5)	0	0	0	1 (1.5)
Pulmonary hypertension	1 (1.5)	0	0	1 (1.5)	0
Pulmonary mass	1 (1.5)	0	1 (1.5)	0	0
Respiratory distress	1 (1.5)	0	0	0	1 (1.5)
Respiratory failure	1 (1.5)	0	0	0	1 (1.5)
Rhinorrhoea	1 (1.5)	1 (1.5)	0	0	0
Tachypnoea	1 (1.5)	0	0	1 (1.5)	0
Skin and subcutaneous tissue disorders					
-Total	9 (13.2)	6 (8.8)	3 (4.4)	0	0
Rash erythematous	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Rash papular	2 (2.9)	2 (2.9)	0	0	0
Alopecia	1 (1.5)	0	1 (1.5)	0	0
Cold sweat	1 (1.5)	1 (1.5)	0	0	0
Dermatitis diaper	1 (1.5)	1 (1.5)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Night sweats	1 (1.5)	1 (1.5)	0	0	0
Rash	1 (1.5)	1 (1.5)	0	0	0
Skin irritation	1 (1.5)	1 (1.5)	0	0	0
Vascular disorders					
-Total	10 (14.7)	2 (2.9)	0	5 (7.4)	3 (4.4)
Hypotension	7 (10.3)	0	0	4 (5.9)	3 (4.4)
Hypertension	4 (5.9)	2 (2.9)	1 (1.5)	1 (1.5)	0
Venous thrombosis limb	1 (1.5)	1 (1.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175p
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	0	1 (25.0)	2 (50.0)	0
Blood and lymphatic system disorders					
-Total	2 (50.0)	0	0	2 (50.0)	0
Anaemia	1 (25.0)	0	0	1 (25.0)	0
Febrile neutropenia	1 (25.0)	0	0	1 (25.0)	0
Cardiac disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Bradycardia	1 (25.0)	1 (25.0)	0	0	0
Gastrointestinal disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Gastrointestinal haemorrhage	1 (25.0)	1 (25.0)	0	0	0
Stomatitis	1 (25.0)	0	0	1 (25.0)	0

Down syndrome: Yes

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections and infestations					
-Total	2 (50.0)	0	2 (50.0)	0	0
Conjunctivitis	1 (25.0)	0	1 (25.0)	0	0
Metapneumovirus infection	1 (25.0)	0	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (50.0)	2 (50.0)	0	0	0
Dermatitis diaper	1 (25.0)	1 (25.0)	0	0	0
Rash papular	1 (25.0)	1 (25.0)	0	0	0
Vascular disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Hypertension	1 (25.0)	1 (25.0)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175p
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	61 (85.9)	3 (4.2)	5 (7.0)	24 (33.8)	29 (40.8)
Blood and lymphatic system disorders					
-Total	39 (54.9)	1 (1.4)	0	27 (38.0)	11 (15.5)
Anaemia	20 (28.2)	0	2 (2.8)	18 (25.4)	0
Febrile neutropenia	17 (23.9)	0	0	17 (23.9)	0
Thrombocytopenia	10 (14.1)	0	0	3 (4.2)	7 (9.9)
Neutropenia	6 (8.5)	0	0	1 (1.4)	5 (7.0)
Coagulopathy	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Disseminated intravascular coagulation	2 (2.8)	0	0	2 (2.8)	0
Pancytopenia	2 (2.8)	0	0	0	2 (2.8)
Leukocytosis	1 (1.4)	1 (1.4)	0	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Lymphopenia	1 (1.4)	0	0	0	1 (1.4)
Splenomegaly	1 (1.4)	1 (1.4)	0	0	0
Cardiac disorders					
-Total	8 (11.3)	0	3 (4.2)	3 (4.2)	2 (2.8)
Tachycardia	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Pericardial effusion	2 (2.8)	0	2 (2.8)	0	0
Sinus tachycardia	2 (2.8)	0	0	2 (2.8)	0
Bradycardia	1 (1.4)	0	0	0	1 (1.4)
Cardiovascular insufficiency	1 (1.4)	0	0	0	1 (1.4)
Left ventricular dysfunction	1 (1.4)	0	0	1 (1.4)	0
Right ventricular dysfunction	1 (1.4)	0	0	1 (1.4)	0
Ventricular tachycardia	1 (1.4)	0	0	1 (1.4)	0
Ear and labyrinth disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Deafness unilateral	1 (1.4)	0	1 (1.4)	0	0
Endocrine disorders					
-Total	3 (4.2)	1 (1.4)	2 (2.8)	0	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	1 (1.4)	0	1 (1.4)	0	0
Cushingoid	1 (1.4)	1 (1.4)	0	0	0
Hyperthyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	2 (2.8)	0	2 (2.8)	0	0
Photophobia	1 (1.4)	0	1 (1.4)	0	0
Retinopathy	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	27 (38.0)	6 (8.5)	12 (16.9)	8 (11.3)	1 (1.4)
Nausea	10 (14.1)	0	7 (9.9)	3 (4.2)	0
Abdominal pain	9 (12.7)	1 (1.4)	5 (7.0)	3 (4.2)	0
Vomiting	9 (12.7)	4 (5.6)	4 (5.6)	1 (1.4)	0
Constipation	5 (7.0)	3 (4.2)	2 (2.8)	0	0
Colitis	4 (5.6)	1 (1.4)	0	3 (4.2)	0
Stomatitis	4 (5.6)	1 (1.4)	0	2 (2.8)	1 (1.4)
Diarrhoea	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Anal fissure	1 (1.4)	0	1 (1.4)	0	0
Dry mouth	1 (1.4)	1 (1.4)	0	0	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspepsia	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Haematemesis	1 (1.4)	0	1 (1.4)	0	0
Haematochezia	1 (1.4)	0	0	1 (1.4)	0
Oral pain	1 (1.4)	0	1 (1.4)	0	0
Pancreatitis	1 (1.4)	0	1 (1.4)	0	0
Perianal erythema	1 (1.4)	0	1 (1.4)	0	0
Proctalgia	1 (1.4)	0	1 (1.4)	0	0
General disorders and administration site conditions					
-Total	26 (36.6)	11 (15.5)	8 (11.3)	5 (7.0)	2 (2.8)
Pyrexia	12 (16.9)	6 (8.5)	4 (5.6)	2 (2.8)	0
Fatigue	7 (9.9)	4 (5.6)	2 (2.8)	1 (1.4)	0
Catheter site pain	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Non-cardiac chest pain	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Pain	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Chills	2 (2.8)	2 (2.8)	0	0	0
Multiple organ dysfunction syndrome	2 (2.8)	0	0	0	2 (2.8)

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oedema peripheral	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Asthenia	1 (1.4)	0	1 (1.4)	0	0
Catheter site bruise	1 (1.4)	1 (1.4)	0	0	0
Device related thrombosis	1 (1.4)	0	1 (1.4)	0	0
Gait disturbance	1 (1.4)	1 (1.4)	0	0	0
Generalised oedema	1 (1.4)	1 (1.4)	0	0	0
Injection site thrombosis	1 (1.4)	0	1 (1.4)	0	0
Physical deconditioning	1 (1.4)	0	0	1 (1.4)	0
Hepatobiliary disorders					
-Total	4 (5.6)	0	1 (1.4)	3 (4.2)	0
Hyperbilirubinaemia	3 (4.2)	0	1 (1.4)	2 (2.8)	0
Cholecystitis	1 (1.4)	0	0	1 (1.4)	0
Hepatic steatosis	1 (1.4)	0	1 (1.4)	0	0
Immune system disorders					
-Total	5 (7.0)	0	3 (4.2)	2 (2.8)	0
Hypogammaglobulinaemia	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Anaphylactic reaction	2 (2.8)	0	0	2 (2.8)	0
Drug hypersensitivity	1 (1.4)	0	1 (1.4)	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections and infestations					
-Total	31 (43.7)	1 (1.4)	5 (7.0)	17 (23.9)	8 (11.3)
Device related infection	3 (4.2)	0	0	3 (4.2)	0
Oral herpes	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Clostridium difficile colitis	2 (2.8)	0	0	2 (2.8)	0
Enterococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Escherichia bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Escherichia urinary tract infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Klebsiella sepsis	2 (2.8)	0	0	0	2 (2.8)
Pneumonia	2 (2.8)	0	1 (1.4)	0	1 (1.4)
Pneumonia fungal	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Upper respiratory tract infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Clostridium difficile infection	1 (1.4)	0	1 (1.4)	0	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus viraemia	1 (1.4)	0	1 (1.4)	0	0
Escherichia infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis	1 (1.4)	0	0	1 (1.4)	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Klebsiella infection	1 (1.4)	0	0	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Rhinovirus infection	1 (1.4)	0	1 (1.4)	0	0
Sepsis	1 (1.4)	0	0	0	1 (1.4)
Serratia infection	1 (1.4)	0	0	1 (1.4)	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	1 (1.4)	1 (1.4)	0	0	0
Staphylococcal infection	1 (1.4)	0	0	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	9 (12.7)	1 (1.4)	6 (8.5)	2 (2.8)	0
Procedural pain	4 (5.6)	0	2 (2.8)	2 (2.8)	0
Subdural haematoma	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Transfusion reaction	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Extradural haematoma	1 (1.4)	0	0	1 (1.4)	0
Procedural hypertension	1 (1.4)	0	1 (1.4)	0	0
Radiation skin injury	1 (1.4)	0	1 (1.4)	0	0
Toxicity to various agents	1 (1.4)	0	1 (1.4)	0	0
Wound	1 (1.4)	1 (1.4)	0	0	0
Investigations					

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	31 (43.7)	3 (4.2)	3 (4.2)	7 (9.9)	18 (25.4)
White blood cell count decreased	12 (16.9)	1 (1.4)	1 (1.4)	1 (1.4)	9 (12.7)
Platelet count decreased	10 (14.1)	0	0	1 (1.4)	9 (12.7)
Neutrophil count decreased	9 (12.7)	0	0	0	9 (12.7)
Alanine aminotransferase increased	6 (8.5)	0	1 (1.4)	5 (7.0)	0
Aspartate aminotransferase increased	5 (7.0)	1 (1.4)	1 (1.4)	3 (4.2)	0
Blood lactate dehydrogenase increased	2 (2.8)	0	0	2 (2.8)	0
Electrocardiogram qt prolonged	2 (2.8)	0	0	2 (2.8)	0
Blast cell count increased	1 (1.4)	0	0	1 (1.4)	0
Blood bilirubin increased	1 (1.4)	0	0	1 (1.4)	0
Blood creatinine increased	1 (1.4)	1 (1.4)	0	0	0
Blood fibrinogen decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin a increased	1 (1.4)	1 (1.4)	0	0	0
Blood immunoglobulin m decreased	1 (1.4)	1 (1.4)	0	0	0
Blood immunoglobulin m increased	1 (1.4)	1 (1.4)	0	0	0
Blood uric acid increased	1 (1.4)	1 (1.4)	0	0	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Computerised tomogram thorax abnormal	1 (1.4)	0	0	1 (1.4)	0
Coronavirus test positive	1 (1.4)	1 (1.4)	0	0	0
Lymphocyte count decreased	1 (1.4)	0	0	1 (1.4)	0
Serum ferritin increased	1 (1.4)	0	0	1 (1.4)	0
Transaminases increased	1 (1.4)	0	0	1 (1.4)	0
White blood cell count increased	1 (1.4)	1 (1.4)	0	0	0
Metabolism and nutrition disorders					
-Total	23 (32.4)	1 (1.4)	8 (11.3)	10 (14.1)	4 (5.6)
Decreased appetite	8 (11.3)	1 (1.4)	4 (5.6)	3 (4.2)	0
Hyperglycaemia	7 (9.9)	0	3 (4.2)	3 (4.2)	1 (1.4)
Hypokalaemia	5 (7.0)	1 (1.4)	0	2 (2.8)	2 (2.8)
Dehydration	4 (5.6)	0	2 (2.8)	2 (2.8)	0
Hyperuricaemia	4 (5.6)	2 (2.8)	0	1 (1.4)	1 (1.4)
Hypomagnesaemia	4 (5.6)	4 (5.6)	0	0	0
Hypocalcaemia	3 (4.2)	1 (1.4)	0	0	2 (2.8)
Hypophosphataemia	3 (4.2)	0	1 (1.4)	2 (2.8)	0
Fluid overload	2 (2.8)	0	1 (1.4)	1 (1.4)	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperkalaemia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Hypernatraemia	2 (2.8)	0	0	1 (1.4)	1 (1.4)
Tumour lysis syndrome	2 (2.8)	0	0	2 (2.8)	0
Vitamin d deficiency	2 (2.8)	0	2 (2.8)	0	0
Hyperammonaemia	1 (1.4)	1 (1.4)	0	0	0
Hypoalbuminaemia	1 (1.4)	0	0	0	1 (1.4)
Malnutrition	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders					
-Total	18 (25.4)	4 (5.6)	6 (8.5)	8 (11.3)	0
Pain in extremity	9 (12.7)	2 (2.8)	2 (2.8)	5 (7.0)	0
Back pain	3 (4.2)	1 (1.4)	0	2 (2.8)	0
Neck pain	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Arthralgia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Bone pain	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Pain in jaw	2 (2.8)	0	2 (2.8)	0	0
Muscle spasms	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal chest pain	1 (1.4)	1 (1.4)	0	0	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal pain	1 (1.4)	0	0	1 (1.4)	0
Myopathy	1 (1.4)	0	0	1 (1.4)	0
Myositis	1 (1.4)	0	0	1 (1.4)	0
Synovitis	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	15 (21.1)	3 (4.2)	7 (9.9)	4 (5.6)	1 (1.4)
Headache	10 (14.1)	2 (2.8)	4 (5.6)	4 (5.6)	0
Hypoaesthesia	1 (1.4)	1 (1.4)	0	0	0
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Leukoencephalopathy	1 (1.4)	0	0	1 (1.4)	0
Neuralgia	1 (1.4)	0	1 (1.4)	0	0
Neuropathy peripheral	1 (1.4)	1 (1.4)	0	0	0
Peripheral sensory neuropathy	1 (1.4)	0	1 (1.4)	0	0
Peroneal nerve palsy	1 (1.4)	1 (1.4)	0	0	0
Seizure	1 (1.4)	0	0	0	1 (1.4)
Visual field defect	1 (1.4)	0	1 (1.4)	0	0
Product issues					
-Total	1 (1.4)	0	1 (1.4)	0	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device occlusion	1 (1.4)	0	1 (1.4)	0	0
Psychiatric disorders					
-Total	11 (15.5)	3 (4.2)	6 (8.5)	2 (2.8)	0
Mental status changes	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Anxiety	2 (2.8)	0	2 (2.8)	0	0
Confusional state	2 (2.8)	0	2 (2.8)	0	0
Depression	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Insomnia	2 (2.8)	0	2 (2.8)	0	0
Agitation	1 (1.4)	0	0	1 (1.4)	0
Irritability	1 (1.4)	1 (1.4)	0	0	0
Renal and urinary disorders					
-Total	6 (8.5)	1 (1.4)	1 (1.4)	2 (2.8)	2 (2.8)
Acute kidney injury	3 (4.2)	1 (1.4)	0	1 (1.4)	1 (1.4)
Cystitis haemorrhagic	2 (2.8)	0	0	1 (1.4)	1 (1.4)
Dysuria	1 (1.4)	0	1 (1.4)	0	0
Haematuria	1 (1.4)	1 (1.4)	0	0	0
Oliguria	1 (1.4)	0	0	1 (1.4)	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Scrotal pain	1 (1.4)	0	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (14.1)	0	4 (5.6)	1 (1.4)	5 (7.0)
Hypoxia	6 (8.5)	0	3 (4.2)	2 (2.8)	1 (1.4)
Cough	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Epistaxis	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Pleural effusion	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Oropharyngeal pain	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Pulmonary oedema	2 (2.8)	0	0	0	2 (2.8)
Aspiration	1 (1.4)	0	0	0	1 (1.4)
Atelectasis	1 (1.4)	0	1 (1.4)	0	0
Dyspnoea	1 (1.4)	0	0	1 (1.4)	0
Haemoptysis	1 (1.4)	0	0	1 (1.4)	0
Idiopathic pneumonia syndrome	1 (1.4)	0	0	0	1 (1.4)
Nasal congestion	1 (1.4)	1 (1.4)	0	0	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary alveolar haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Pulmonary hypertension	1 (1.4)	0	0	1 (1.4)	0
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	0	0	1 (1.4)
Respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Rhinorrhoea	1 (1.4)	1 (1.4)	0	0	0
Tachypnoea	1 (1.4)	0	0	1 (1.4)	0
Skin and subcutaneous tissue disorders					
-Total	8 (11.3)	4 (5.6)	4 (5.6)	0	0
Rash erythematous	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Alopecia	1 (1.4)	0	1 (1.4)	0	0
Cold sweat	1 (1.4)	1 (1.4)	0	0	0
Night sweats	1 (1.4)	1 (1.4)	0	0	0
Rash	1 (1.4)	1 (1.4)	0	0	0
Rash papular	1 (1.4)	1 (1.4)	0	0	0
Skin irritation	1 (1.4)	1 (1.4)	0	0	0
Urticaria	1 (1.4)	0	1 (1.4)	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	9 (12.7)	1 (1.4)	0	5 (7.0)	3 (4.2)
Hypotension	7 (9.9)	0	0	4 (5.6)	3 (4.2)
Hypertension	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Venous thrombosis limb	1 (1.4)	1 (1.4)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175q
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (87.5)	2 (6.3)	3 (9.4)	13 (40.6)	10 (31.3)
Blood and lymphatic system disorders					
-Total	18 (56.3)	0	0	16 (50.0)	2 (6.3)
Febrile neutropenia	9 (28.1)	0	0	9 (28.1)	0
Anaemia	7 (21.9)	0	1 (3.1)	6 (18.8)	0
Neutropenia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Coagulopathy	1 (3.1)	0	0	1 (3.1)	0
Leukocytosis	1 (3.1)	1 (3.1)	0	0	0
Pancytopenia	1 (3.1)	0	0	0	1 (3.1)
Splenomegaly	1 (3.1)	1 (3.1)	0	0	0
Thrombocytopenia	1 (3.1)	0	0	1 (3.1)	0
Cardiac disorders					

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Bradycardia	1 (3.1)	1 (3.1)	0	0	0
Pericardial effusion	1 (3.1)	0	1 (3.1)	0	0
Tachycardia	1 (3.1)	1 (3.1)	0	0	0
Endocrine disorders					
-Total	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Cushingoid	1 (3.1)	1 (3.1)	0	0	0
Hyperthyroidism	1 (3.1)	0	1 (3.1)	0	0
Eye disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Retinopathy	1 (3.1)	0	1 (3.1)	0	0
Gastrointestinal disorders					
-Total	13 (40.6)	4 (12.5)	6 (18.8)	3 (9.4)	0
Nausea	5 (15.6)	0	5 (15.6)	0	0
Vomiting	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Abdominal pain	3 (9.4)	0	3 (9.4)	0	0
Constipation	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Stomatitis	3 (9.4)	1 (3.1)	0	2 (6.3)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	1 (3.1)	0	0	1 (3.1)	0
Diarrhoea	1 (3.1)	1 (3.1)	0	0	0
Gastrointestinal haemorrhage	1 (3.1)	1 (3.1)	0	0	0
General disorders and administration site conditions					
-Total	10 (31.3)	3 (9.4)	5 (15.6)	2 (6.3)	0
Catheter site pain	4 (12.5)	1 (3.1)	3 (9.4)	0	0
Pyrexia	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Fatigue	2 (6.3)	0	2 (6.3)	0	0
Oedema peripheral	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Asthenia	1 (3.1)	0	1 (3.1)	0	0
Device related thrombosis	1 (3.1)	0	1 (3.1)	0	0
Gait disturbance	1 (3.1)	1 (3.1)	0	0	0
Injection site thrombosis	1 (3.1)	0	1 (3.1)	0	0
Pain	1 (3.1)	0	1 (3.1)	0	0
Physical deconditioning	1 (3.1)	0	0	1 (3.1)	0
Hepatobiliary disorders					
-Total	3 (9.4)	0	1 (3.1)	2 (6.3)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Cholecystitis	1 (3.1)	0	0	1 (3.1)	0
Hepatic steatosis	1 (3.1)	0	1 (3.1)	0	0
Immune system disorders					
-Total	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Hypogammaglobulinaemia	2 (6.3)	0	2 (6.3)	0	0
Anaphylactic reaction	1 (3.1)	0	0	1 (3.1)	0
Infections and infestations					
-Total	14 (43.8)	1 (3.1)	5 (15.6)	7 (21.9)	1 (3.1)
Device related infection	3 (9.4)	0	0	3 (9.4)	0
Conjunctivitis	2 (6.3)	0	2 (6.3)	0	0
Escherichia urinary tract infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Upper respiratory tract infection	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Abscess limb	1 (3.1)	0	0	1 (3.1)	0
Alpha haemolytic streptococcal infection	1 (3.1)	0	0	1 (3.1)	0
Croup infectious	1 (3.1)	0	0	1 (3.1)	0
Cytomegalovirus viraemia	1 (3.1)	0	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Parainfluenzae virus infection	1 (3.1)	0	1 (3.1)	0	0
Pneumonia	1 (3.1)	0	1 (3.1)	0	0
Pneumonia fungal	1 (3.1)	0	1 (3.1)	0	0
Respiratory syncytial virus bronchitis	1 (3.1)	0	0	1 (3.1)	0
Respiratory syncytial virus infection	1 (3.1)	0	1 (3.1)	0	0
Rhinovirus infection	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal scalded skin syndrome	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal sepsis	1 (3.1)	0	0	0	1 (3.1)
Streptococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Injury, poisoning and procedural complications					
-Total	7 (21.9)	1 (3.1)	4 (12.5)	2 (6.3)	0
Procedural pain	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Extradural haematoma	1 (3.1)	0	0	1 (3.1)	0
Procedural hypertension	1 (3.1)	0	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Radiation skin injury	1 (3.1)	0	1 (3.1)	0	0
Subdural haematoma	1 (3.1)	0	0	1 (3.1)	0
Toxicity to various agents	1 (3.1)	0	1 (3.1)	0	0
Wound	1 (3.1)	1 (3.1)	0	0	0
Investigations					
-Total	17 (53.1)	1 (3.1)	2 (6.3)	6 (18.8)	8 (25.0)
White blood cell count decreased	7 (21.9)	1 (3.1)	1 (3.1)	1 (3.1)	4 (12.5)
Alanine aminotransferase increased	6 (18.8)	0	1 (3.1)	5 (15.6)	0
Platelet count decreased	6 (18.8)	0	0	0	6 (18.8)
Aspartate aminotransferase increased	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0
Neutrophil count decreased	4 (12.5)	0	0	0	4 (12.5)
Blood bilirubin increased	1 (3.1)	0	0	1 (3.1)	0
Blood immunoglobulin a increased	1 (3.1)	1 (3.1)	0	0	0
Blood immunoglobulin m increased	1 (3.1)	1 (3.1)	0	0	0
Blood lactate dehydrogenase increased	1 (3.1)	0	0	1 (3.1)	0
Coronavirus test positive	1 (3.1)	1 (3.1)	0	0	0
Electrocardiogram qt prolonged	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (3.1)	0	0	1 (3.1)	0
Serum ferritin increased	1 (3.1)	0	0	1 (3.1)	0
Transaminases increased	1 (3.1)	0	0	1 (3.1)	0
Metabolism and nutrition disorders					
-Total	8 (25.0)	0	4 (12.5)	4 (12.5)	0
Hyperglycaemia	4 (12.5)	0	1 (3.1)	3 (9.4)	0
Decreased appetite	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Dehydration	2 (6.3)	0	2 (6.3)	0	0
Vitamin d deficiency	2 (6.3)	0	2 (6.3)	0	0
Fluid overload	1 (3.1)	0	1 (3.1)	0	0
Hyperammonaemia	1 (3.1)	1 (3.1)	0	0	0
Hyperkalaemia	1 (3.1)	0	1 (3.1)	0	0
Hyperuricaemia	1 (3.1)	1 (3.1)	0	0	0
Hypocalcaemia	1 (3.1)	1 (3.1)	0	0	0
Hypokalaemia	1 (3.1)	0	0	1 (3.1)	0
Hypomagnesaemia	1 (3.1)	1 (3.1)	0	0	0
Malnutrition	1 (3.1)	0	1 (3.1)	0	0
Tumour lysis syndrome	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	8 (25.0)	3 (9.4)	3 (9.4)	2 (6.3)	0
Pain in extremity	5 (15.6)	2 (6.3)	2 (6.3)	1 (3.1)	0
Arthralgia	1 (3.1)	0	1 (3.1)	0	0
Back pain	1 (3.1)	1 (3.1)	0	0	0
Bone pain	1 (3.1)	0	1 (3.1)	0	0
Muscle spasms	1 (3.1)	1 (3.1)	0	0	0
Musculoskeletal chest pain	1 (3.1)	1 (3.1)	0	0	0
Myopathy	1 (3.1)	0	0	1 (3.1)	0
Myositis	1 (3.1)	0	0	1 (3.1)	0
Neck pain	1 (3.1)	0	1 (3.1)	0	0
Synovitis	1 (3.1)	0	1 (3.1)	0	0
Nervous system disorders					
-Total	8 (25.0)	1 (3.1)	4 (12.5)	3 (9.4)	0
Headache	6 (18.8)	0	3 (9.4)	3 (9.4)	0
Neuralgia	1 (3.1)	0	1 (3.1)	0	0
Neuropathy peripheral	1 (3.1)	1 (3.1)	0	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Peroneal nerve palsy	1 (3.1)	1 (3.1)	0	0	0
Psychiatric disorders					
-Total	6 (18.8)	2 (6.3)	3 (9.4)	1 (3.1)	0
Depression	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Mental status changes	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Anxiety	1 (3.1)	0	1 (3.1)	0	0
Confusional state	1 (3.1)	0	1 (3.1)	0	0
Insomnia	1 (3.1)	0	1 (3.1)	0	0
Renal and urinary disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Acute kidney injury	1 (3.1)	1 (3.1)	0	0	0
Dysuria	1 (3.1)	0	1 (3.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (12.5)	0	2 (6.3)	1 (3.1)	1 (3.1)
Hypoxia	2 (6.3)	0	2 (6.3)	0	0
Cough	1 (3.1)	1 (3.1)	0	0	0
Epistaxis	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Idiopathic pneumonia syndrome	1 (3.1)	0	0	0	1 (3.1)
Pulmonary mass	1 (3.1)	0	1 (3.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (15.6)	3 (9.4)	2 (6.3)	0	0
Rash papular	2 (6.3)	2 (6.3)	0	0	0
Alopecia	1 (3.1)	0	1 (3.1)	0	0
Rash erythematous	1 (3.1)	1 (3.1)	0	0	0
Urticaria	1 (3.1)	0	1 (3.1)	0	0
Vascular disorders					
-Total	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Hypertension	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Venous thrombosis limb	1 (3.1)	1 (3.1)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175q
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (84.4)	1 (3.1)	2 (6.3)	12 (37.5)	12 (37.5)
Blood and lymphatic system disorders					
-Total	18 (56.3)	1 (3.1)	0	11 (34.4)	6 (18.8)
Anaemia	10 (31.3)	0	1 (3.1)	9 (28.1)	0
Febrile neutropenia	8 (25.0)	0	0	8 (25.0)	0
Thrombocytopenia	5 (15.6)	0	0	1 (3.1)	4 (12.5)
Neutropenia	2 (6.3)	0	0	0	2 (6.3)
Coagulopathy	1 (3.1)	1 (3.1)	0	0	0
Leukopenia	1 (3.1)	0	0	0	1 (3.1)
Pancytopenia	1 (3.1)	0	0	0	1 (3.1)
Cardiac disorders					
-Total	5 (15.6)	0	2 (6.3)	3 (9.4)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Left ventricular dysfunction	1 (3.1)	0	0	1 (3.1)	0
Pericardial effusion	1 (3.1)	0	1 (3.1)	0	0
Sinus tachycardia	1 (3.1)	0	0	1 (3.1)	0
Ear and labyrinth disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Deafness unilateral	1 (3.1)	0	1 (3.1)	0	0
Gastrointestinal disorders					
-Total	9 (28.1)	2 (6.3)	4 (12.5)	2 (6.3)	1 (3.1)
Abdominal pain	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Nausea	2 (6.3)	0	0	2 (6.3)	0
Vomiting	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Anal fissure	1 (3.1)	0	1 (3.1)	0	0
Colitis	1 (3.1)	1 (3.1)	0	0	0
Constipation	1 (3.1)	0	1 (3.1)	0	0
Diarrhoea	1 (3.1)	0	1 (3.1)	0	0
Dry mouth	1 (3.1)	1 (3.1)	0	0	0
Dyspepsia	1 (3.1)	0	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haematemesis	1 (3.1)	0	1 (3.1)	0	0
Oral pain	1 (3.1)	0	1 (3.1)	0	0
Pancreatitis	1 (3.1)	0	1 (3.1)	0	0
Perianal erythema	1 (3.1)	0	1 (3.1)	0	0
Proctalgia	1 (3.1)	0	1 (3.1)	0	0
Stomatitis	1 (3.1)	0	0	0	1 (3.1)
General disorders and administration site conditions					
-Total	11 (34.4)	8 (25.0)	2 (6.3)	1 (3.1)	0
Pyrexia	7 (21.9)	5 (15.6)	2 (6.3)	0	0
Fatigue	5 (15.6)	4 (12.5)	0	1 (3.1)	0
Non-cardiac chest pain	2 (6.3)	2 (6.3)	0	0	0
Catheter site bruise	1 (3.1)	1 (3.1)	0	0	0
Chills	1 (3.1)	1 (3.1)	0	0	0
Generalised oedema	1 (3.1)	1 (3.1)	0	0	0
Hepatobiliary disorders					
-Total	1 (3.1)	0	0	1 (3.1)	0
Hyperbilirubinaemia	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Immune system disorders					
-Total	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Anaphylactic reaction	1 (3.1)	0	0	1 (3.1)	0
Drug hypersensitivity	1 (3.1)	0	1 (3.1)	0	0
Hypogammaglobulinaemia	1 (3.1)	1 (3.1)	0	0	0
Infections and infestations					
-Total	12 (37.5)	0	2 (6.3)	8 (25.0)	2 (6.3)
Oral herpes	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Bronchopulmonary aspergillosis	1 (3.1)	0	0	1 (3.1)	0
Cellulitis	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile colitis	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile infection	1 (3.1)	0	1 (3.1)	0	0
Enterococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia sepsis	1 (3.1)	0	0	0	1 (3.1)
Fungal skin infection	1 (3.1)	0	1 (3.1)	0	0
Gastroenteritis	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human polyomavirus infection	1 (3.1)	0	0	0	1 (3.1)
Metapneumovirus infection	1 (3.1)	0	1 (3.1)	0	0
Serratia infection	1 (3.1)	0	0	1 (3.1)	0
Sinusitis	1 (3.1)	1 (3.1)	0	0	0
Staphylococcal infection	1 (3.1)	0	0	1 (3.1)	0
Injury, poisoning and procedural complications					
-Total	2 (6.3)	0	2 (6.3)	0	0
Transfusion reaction	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Subdural haematoma	1 (3.1)	0	1 (3.1)	0	0
Investigations					
-Total	10 (31.3)	2 (6.3)	1 (3.1)	1 (3.1)	6 (18.8)
White blood cell count decreased	4 (12.5)	0	0	0	4 (12.5)
Neutrophil count decreased	3 (9.4)	0	0	0	3 (9.4)
Platelet count decreased	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Aspartate aminotransferase increased	1 (3.1)	0	0	1 (3.1)	0
Blast cell count increased	1 (3.1)	0	0	1 (3.1)	0
Blood creatinine increased	1 (3.1)	1 (3.1)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood fibrinogen decreased	1 (3.1)	0	1 (3.1)	0	0
Blood immunoglobulin m decreased	1 (3.1)	1 (3.1)	0	0	0
Blood uric acid increased	1 (3.1)	1 (3.1)	0	0	0
White blood cell count increased	1 (3.1)	1 (3.1)	0	0	0
Metabolism and nutrition disorders					
-Total	9 (28.1)	1 (3.1)	2 (6.3)	4 (12.5)	2 (6.3)
Decreased appetite	5 (15.6)	1 (3.1)	3 (9.4)	1 (3.1)	0
Hyperuricaemia	3 (9.4)	1 (3.1)	0	1 (3.1)	1 (3.1)
Hypokalaemia	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Hypomagnesaemia	2 (6.3)	2 (6.3)	0	0	0
Hypophosphataemia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Dehydration	1 (3.1)	0	0	1 (3.1)	0
Hypocalcaemia	1 (3.1)	0	0	0	1 (3.1)
Tumour lysis syndrome	1 (3.1)	0	0	1 (3.1)	0
Musculoskeletal and connective tissue disorders					
-Total	7 (21.9)	1 (3.1)	2 (6.3)	4 (12.5)	0
Neck pain	2 (6.3)	1 (3.1)	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain in extremity	2 (6.3)	0	0	2 (6.3)	0
Back pain	1 (3.1)	0	0	1 (3.1)	0
Bone pain	1 (3.1)	0	0	1 (3.1)	0
Musculoskeletal pain	1 (3.1)	0	0	1 (3.1)	0
Pain in jaw	1 (3.1)	0	1 (3.1)	0	0
Nervous system disorders					
-Total	5 (15.6)	2 (6.3)	3 (9.4)	0	0
Headache	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Hypoaesthesia	1 (3.1)	1 (3.1)	0	0	0
Peripheral sensory neuropathy	1 (3.1)	0	1 (3.1)	0	0
Visual field defect	1 (3.1)	0	1 (3.1)	0	0
Psychiatric disorders					
-Total	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Anxiety	1 (3.1)	0	1 (3.1)	0	0
Insomnia	1 (3.1)	0	1 (3.1)	0	0
Irritability	1 (3.1)	1 (3.1)	0	0	0
Mental status changes	1 (3.1)	1 (3.1)	0	0	0
Renal and urinary disorders					

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.1)	0	0	0	1 (3.1)
Cystitis haemorrhagic	1 (3.1)	0	0	0	1 (3.1)
Reproductive system and breast disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Scrotal pain	1 (3.1)	0	1 (3.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (9.4)	0	3 (9.4)	0	0
Hypoxia	2 (6.3)	0	2 (6.3)	0	0
Pleural effusion	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Atelectasis	1 (3.1)	0	1 (3.1)	0	0
Cough	1 (3.1)	1 (3.1)	0	0	0
Epistaxis	1 (3.1)	0	1 (3.1)	0	0
Nasal congestion	1 (3.1)	1 (3.1)	0	0	0
Oropharyngeal pain	1 (3.1)	1 (3.1)	0	0	0
Rhinorrhoea	1 (3.1)	1 (3.1)	0	0	0
Skin and subcutaneous tissue disorders					

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (15.6)	3 (9.4)	2 (6.3)	0	0
Rash erythematous	2 (6.3)	0	2 (6.3)	0	0
Cold sweat	1 (3.1)	1 (3.1)	0	0	0
Dermatitis diaper	1 (3.1)	1 (3.1)	0	0	0
Night sweats	1 (3.1)	1 (3.1)	0	0	0
Rash	1 (3.1)	1 (3.1)	0	0	0
Skin irritation	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Hypotension	2 (6.3)	0	0	2 (6.3)	0
Hypertension	1 (3.1)	1 (3.1)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175q
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (81.8)	0	1 (9.1)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Febrile neutropenia	1 (9.1)	0	0	1 (9.1)	0
Lymphopenia	1 (9.1)	0	0	0	1 (9.1)
Cardiac disorders					

Time since enrollment to CTL019 infusion: Missing

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (18.2)	0	0	0	2 (18.2)
Bradycardia	1 (9.1)	0	0	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	0	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	0	0	1 (9.1)	0
Sinus tachycardia	1 (9.1)	0	0	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	0	0	1 (9.1)	0
Endocrine disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Adrenal insufficiency	1 (9.1)	0	1 (9.1)	0	0
Eye disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Photophobia	1 (9.1)	0	1 (9.1)	0	0
Gastrointestinal disorders					
-Total	6 (54.5)	0	2 (18.2)	4 (36.4)	0
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (9.1)	1 (9.1)	0	0	0
Diarrhoea	1 (9.1)	0	0	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	0	0	1 (9.1)	0
Haematochezia	1 (9.1)	0	0	1 (9.1)	0
Stomatitis	1 (9.1)	0	0	1 (9.1)	0
General disorders and administration site conditions					
-Total	5 (45.5)	0	1 (9.1)	2 (18.2)	2 (18.2)
Multiple organ dysfunction syndrome	2 (18.2)	0	0	0	2 (18.2)
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pyrexia	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Chills	1 (9.1)	1 (9.1)	0	0	0
Non-cardiac chest pain	1 (9.1)	0	0	1 (9.1)	0
Infections and infestations					
-Total	7 (63.6)	0	0	2 (18.2)	5 (45.5)
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Candida sepsis	1 (9.1)	0	0	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	0	0	1 (9.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia infection	1 (9.1)	0	0	1 (9.1)	0
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Oral herpes	1 (9.1)	0	1 (9.1)	0	0
Pneumonia	1 (9.1)	0	0	0	1 (9.1)
Pneumonia fungal	1 (9.1)	0	0	1 (9.1)	0
Sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Streptococcal infection	1 (9.1)	0	0	1 (9.1)	0
Investigations					
-Total	4 (36.4)	0	0	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Blood lactate dehydrogenase increased	1 (9.1)	0	0	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	0	0	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	0	0	1 (9.1)	0
Platelet count decreased	1 (9.1)	0	0	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (54.5)	0	2 (18.2)	2 (18.2)	2 (18.2)
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Hypokalaemia	2 (18.2)	0	0	0	2 (18.2)
Decreased appetite	1 (9.1)	0	0	1 (9.1)	0
Dehydration	1 (9.1)	0	0	1 (9.1)	0
Fluid overload	1 (9.1)	0	0	1 (9.1)	0
Hyperkalaemia	1 (9.1)	0	0	1 (9.1)	0
Hypoalbuminaemia	1 (9.1)	0	0	0	1 (9.1)
Hypocalcaemia	1 (9.1)	0	0	0	1 (9.1)
Hypomagnesaemia	1 (9.1)	1 (9.1)	0	0	0
Hypophosphataemia	1 (9.1)	0	0	1 (9.1)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Arthralgia	1 (9.1)	0	0	1 (9.1)	0
Back pain	1 (9.1)	0	0	1 (9.1)	0

Time since enrollment to CTL019 infusion: Missing

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain in jaw	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Headache	1 (9.1)	0	0	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	0	0	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	0	0	1 (9.1)	0
Seizure	1 (9.1)	0	0	0	1 (9.1)
Product issues					
-Total	1 (9.1)	0	1 (9.1)	0	0
Device occlusion	1 (9.1)	0	1 (9.1)	0	0
Psychiatric disorders					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Agitation	1 (9.1)	0	0	1 (9.1)	0
Confusional state	1 (9.1)	0	1 (9.1)	0	0
Renal and urinary disorders					
-Total	4 (36.4)	1 (9.1)	0	2 (18.2)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Cystitis haemorrhagic	1 (9.1)	0	0	1 (9.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	1 (9.1)	1 (9.1)	0	0	0
Oliguria	1 (9.1)	0	0	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (36.4)	0	0	0	4 (36.4)
Hypoxia	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Aspiration	1 (9.1)	0	0	0	1 (9.1)
Cough	1 (9.1)	0	0	1 (9.1)	0
Dyspnoea	1 (9.1)	0	0	1 (9.1)	0
Epistaxis	1 (9.1)	0	1 (9.1)	0	0
Haemoptysis	1 (9.1)	0	0	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	0	0	1 (9.1)	0
Pleural effusion	1 (9.1)	0	1 (9.1)	0	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	0	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	0	0	1 (9.1)	0
Respiratory distress	1 (9.1)	0	0	0	1 (9.1)
Respiratory failure	1 (9.1)	0	0	0	1 (9.1)

Time since enrollment to CTL019 infusion: Missing

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (9.1)	0	0	1 (9.1)	0
Vascular disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Hypotension	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Hypertension	1 (9.1)	0	1 (9.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175r
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	1 (12.5)	0	4 (50.0)	3 (37.5)
Blood and lymphatic system disorders					
-Total	5 (62.5)	0	0	5 (62.5)	0
Febrile neutropenia	3 (37.5)	0	0	3 (37.5)	0
Anaemia	2 (25.0)	0	0	2 (25.0)	0
Cardiac disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Tachycardia	1 (12.5)	0	0	1 (12.5)	0
Gastrointestinal disorders					
-Total	4 (50.0)	2 (25.0)	0	1 (12.5)	1 (12.5)
Abdominal pain	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Diarrhoea	2 (25.0)	1 (12.5)	1 (12.5)	0	0

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (25.0)	0	0	2 (25.0)	0
Stomatitis	2 (25.0)	1 (12.5)	0	0	1 (12.5)
Vomiting	2 (25.0)	2 (25.0)	0	0	0
Dyspepsia	1 (12.5)	0	1 (12.5)	0	0
General disorders and administration site conditions					
-Total	4 (50.0)	2 (25.0)	0	2 (25.0)	0
Fatigue	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Pyrexia	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Catheter site pain	1 (12.5)	1 (12.5)	0	0	0
Chills	1 (12.5)	1 (12.5)	0	0	0
Pain	1 (12.5)	0	0	1 (12.5)	0
Immune system disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypogammaglobulinaemia	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	2 (25.0)	0	0	0	2 (25.0)
Cellulitis	1 (12.5)	0	0	1 (12.5)	0

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile infection	1 (12.5)	0	1 (12.5)	0	0
Human polyomavirus infection	1 (12.5)	0	0	0	1 (12.5)
Oral herpes	1 (12.5)	0	0	1 (12.5)	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Injury, poisoning and procedural complications					
-Total	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Procedural pain	1 (12.5)	0	0	1 (12.5)	0
Wound	1 (12.5)	1 (12.5)	0	0	0
Investigations					
-Total	1 (12.5)	0	0	0	1 (12.5)
Neutrophil count decreased	1 (12.5)	0	0	0	1 (12.5)
White blood cell count decreased	1 (12.5)	0	0	0	1 (12.5)
Metabolism and nutrition disorders					
-Total	2 (25.0)	0	2 (25.0)	0	0
Decreased appetite	1 (12.5)	0	1 (12.5)	0	0
Dehydration	1 (12.5)	0	1 (12.5)	0	0
Hypomagnesaemia	1 (12.5)	1 (12.5)	0	0	0

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vitamin d deficiency	1 (12.5)	0	1 (12.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Pain in extremity	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Neck pain	1 (12.5)	0	1 (12.5)	0	0
Nervous system disorders					
-Total	2 (25.0)	0	2 (25.0)	0	0
Headache	2 (25.0)	0	2 (25.0)	0	0
Psychiatric disorders					
-Total	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Anxiety	1 (12.5)	0	1 (12.5)	0	0
Confusional state	1 (12.5)	0	1 (12.5)	0	0
Depression	1 (12.5)	1 (12.5)	0	0	0
Renal and urinary disorders					
-Total	1 (12.5)	0	0	0	1 (12.5)
Cystitis haemorrhagic	1 (12.5)	0	0	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders					

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (25.0)	0	1 (12.5)	0	1 (12.5)
Hypoxia	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Aspiration	1 (12.5)	0	0	0	1 (12.5)
Cough	1 (12.5)	1 (12.5)	0	0	0
Epistaxis	1 (12.5)	0	1 (12.5)	0	0
Nasal congestion	1 (12.5)	1 (12.5)	0	0	0
Oropharyngeal pain	1 (12.5)	1 (12.5)	0	0	0
Pleural effusion	1 (12.5)	0	1 (12.5)	0	0
Rhinorrhoea	1 (12.5)	1 (12.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (25.0)	2 (25.0)	0	0	0
Dermatitis diaper	1 (12.5)	1 (12.5)	0	0	0
Rash papular	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	3 (37.5)	1 (12.5)	0	1 (12.5)	1 (12.5)
Hypotension	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Hypertension	1 (12.5)	1 (12.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175r
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (82.6)	1 (4.3)	3 (13.0)	7 (30.4)	8 (34.8)
Blood and lymphatic system disorders					
-Total	14 (60.9)	0	0	9 (39.1)	5 (21.7)
Febrile neutropenia	6 (26.1)	0	0	6 (26.1)	0
Anaemia	5 (21.7)	0	0	5 (21.7)	0
Neutropenia	2 (8.7)	0	0	0	2 (8.7)
Pancytopenia	2 (8.7)	0	0	0	2 (8.7)
Thrombocytopenia	2 (8.7)	0	0	0	2 (8.7)
Coagulopathy	1 (4.3)	0	0	1 (4.3)	0
Disseminated intravascular coagulation	1 (4.3)	0	0	1 (4.3)	0
Leukocytosis	1 (4.3)	1 (4.3)	0	0	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukopenia	1 (4.3)	0	0	0	1 (4.3)
Lymphopenia	1 (4.3)	0	0	0	1 (4.3)
Splenomegaly	1 (4.3)	1 (4.3)	0	0	0
Cardiac disorders					
-Total	3 (13.0)	0	2 (8.7)	0	1 (4.3)
Tachycardia	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Bradycardia	1 (4.3)	0	0	0	1 (4.3)
Pericardial effusion	1 (4.3)	0	1 (4.3)	0	0
Right ventricular dysfunction	1 (4.3)	0	0	1 (4.3)	0
Sinus tachycardia	1 (4.3)	0	0	1 (4.3)	0
Ventricular tachycardia	1 (4.3)	0	0	1 (4.3)	0
Eye disorders					
-Total	2 (8.7)	0	2 (8.7)	0	0
Photophobia	1 (4.3)	0	1 (4.3)	0	0
Retinopathy	1 (4.3)	0	1 (4.3)	0	0
Gastrointestinal disorders					
-Total	11 (47.8)	1 (4.3)	7 (30.4)	3 (13.0)	0
Abdominal pain	5 (21.7)	0	3 (13.0)	2 (8.7)	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	5 (21.7)	0	4 (17.4)	1 (4.3)	0
Vomiting	3 (13.0)	0	2 (8.7)	1 (4.3)	0
Constipation	2 (8.7)	2 (8.7)	0	0	0
Colitis	1 (4.3)	1 (4.3)	0	0	0
Dry mouth	1 (4.3)	1 (4.3)	0	0	0
Haematemesis	1 (4.3)	0	1 (4.3)	0	0
Haematochezia	1 (4.3)	0	0	1 (4.3)	0
Perianal erythema	1 (4.3)	0	1 (4.3)	0	0
Stomatitis	1 (4.3)	0	0	1 (4.3)	0
General disorders and administration site conditions					
-Total	6 (26.1)	1 (4.3)	3 (13.0)	2 (8.7)	0
Pyrexia	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Non-cardiac chest pain	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Catheter site bruise	1 (4.3)	1 (4.3)	0	0	0
Catheter site pain	1 (4.3)	0	1 (4.3)	0	0
Device related thrombosis	1 (4.3)	0	1 (4.3)	0	0
Oedema peripheral	1 (4.3)	0	1 (4.3)	0	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain	1 (4.3)	0	1 (4.3)	0	0
Physical deconditioning	1 (4.3)	0	0	1 (4.3)	0
Hepatobiliary disorders					
-Total	1 (4.3)	0	0	1 (4.3)	0
Hepatic steatosis	1 (4.3)	0	1 (4.3)	0	0
Hyperbilirubinaemia	1 (4.3)	0	0	1 (4.3)	0
Immune system disorders					
-Total	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Anaphylactic reaction	1 (4.3)	0	0	1 (4.3)	0
Drug hypersensitivity	1 (4.3)	0	1 (4.3)	0	0
Hypogammaglobulinaemia	1 (4.3)	1 (4.3)	0	0	0
Infections and infestations					
-Total	13 (56.5)	0	4 (17.4)	8 (34.8)	1 (4.3)
Device related infection	2 (8.7)	0	0	2 (8.7)	0
Escherichia bacteraemia	2 (8.7)	0	0	2 (8.7)	0
Abscess limb	1 (4.3)	0	0	1 (4.3)	0
Bronchopulmonary aspergillosis	1 (4.3)	0	0	1 (4.3)	0
Escherichia urinary tract infection	1 (4.3)	0	0	1 (4.3)	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (4.3)	0	0	1 (4.3)	0
Metapneumovirus infection	1 (4.3)	0	1 (4.3)	0	0
Parainfluenzae virus infection	1 (4.3)	0	1 (4.3)	0	0
Pneumonia	1 (4.3)	0	1 (4.3)	0	0
Pneumonia fungal	1 (4.3)	0	1 (4.3)	0	0
Respiratory syncytial virus bronchitis	1 (4.3)	0	0	1 (4.3)	0
Respiratory syncytial virus infection	1 (4.3)	0	1 (4.3)	0	0
Rhinovirus infection	1 (4.3)	0	1 (4.3)	0	0
Serratia infection	1 (4.3)	0	0	1 (4.3)	0
Sinusitis	1 (4.3)	1 (4.3)	0	0	0
Staphylococcal bacteraemia	1 (4.3)	0	0	1 (4.3)	0
Staphylococcal scalded skin syndrome	1 (4.3)	0	1 (4.3)	0	0
Staphylococcal sepsis	1 (4.3)	0	0	0	1 (4.3)
Upper respiratory tract infection	1 (4.3)	0	1 (4.3)	0	0
Injury, poisoning and procedural complications					
-Total	2 (8.7)	0	2 (8.7)	0	0
Procedural hypertension	1 (4.3)	0	1 (4.3)	0	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural pain	1 (4.3)	0	1 (4.3)	0	0
Radiation skin injury	1 (4.3)	0	1 (4.3)	0	0
Investigations					
-Total	10 (43.5)	2 (8.7)	2 (8.7)	2 (8.7)	4 (17.4)
Platelet count decreased	3 (13.0)	0	0	0	3 (13.0)
White blood cell count decreased	3 (13.0)	0	1 (4.3)	0	2 (8.7)
Alanine aminotransferase increased	1 (4.3)	0	1 (4.3)	0	0
Aspartate aminotransferase increased	1 (4.3)	0	0	1 (4.3)	0
Blood bilirubin increased	1 (4.3)	0	0	1 (4.3)	0
Blood creatinine increased	1 (4.3)	1 (4.3)	0	0	0
Blood immunoglobulin a increased	1 (4.3)	1 (4.3)	0	0	0
Blood immunoglobulin m increased	1 (4.3)	1 (4.3)	0	0	0
Blood lactate dehydrogenase increased	1 (4.3)	0	0	1 (4.3)	0
Blood uric acid increased	1 (4.3)	1 (4.3)	0	0	0
Computerised tomogram thorax abnormal	1 (4.3)	0	0	1 (4.3)	0
Electrocardiogram qt prolonged	1 (4.3)	0	0	1 (4.3)	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transaminases increased	1 (4.3)	0	0	1 (4.3)	0
Metabolism and nutrition disorders					
-Total	9 (39.1)	1 (4.3)	2 (8.7)	5 (21.7)	1 (4.3)
Hyperglycaemia	4 (17.4)	0	2 (8.7)	2 (8.7)	0
Decreased appetite	3 (13.0)	1 (4.3)	0	2 (8.7)	0
Fluid overload	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Hyperkalaemia	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Hypokalaemia	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Dehydration	1 (4.3)	0	0	1 (4.3)	0
Hyperammonaemia	1 (4.3)	1 (4.3)	0	0	0
Hyperuricaemia	1 (4.3)	0	0	0	1 (4.3)
Hypocalcaemia	1 (4.3)	1 (4.3)	0	0	0
Hypomagnesaemia	1 (4.3)	1 (4.3)	0	0	0
Malnutrition	1 (4.3)	0	1 (4.3)	0	0
Tumour lysis syndrome	1 (4.3)	0	0	1 (4.3)	0
Vitamin d deficiency	1 (4.3)	0	1 (4.3)	0	0
Musculoskeletal and connective tissue disorders					

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	6 (26.1)	0	2 (8.7)	4 (17.4)	0
Back pain	3 (13.0)	1 (4.3)	0	2 (8.7)	0
Arthralgia	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Pain in extremity	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Bone pain	1 (4.3)	0	0	1 (4.3)	0
Musculoskeletal chest pain	1 (4.3)	1 (4.3)	0	0	0
Myopathy	1 (4.3)	0	0	1 (4.3)	0
Myositis	1 (4.3)	0	0	1 (4.3)	0
Neck pain	1 (4.3)	0	1 (4.3)	0	0
Synovitis	1 (4.3)	0	1 (4.3)	0	0
Nervous system disorders					
-Total	4 (17.4)	0	2 (8.7)	1 (4.3)	1 (4.3)
Headache	4 (17.4)	0	2 (8.7)	2 (8.7)	0
Hyporesponsive to stimuli	1 (4.3)	0	0	1 (4.3)	0
Seizure	1 (4.3)	0	0	0	1 (4.3)
Psychiatric disorders					
-Total	5 (21.7)	2 (8.7)	2 (8.7)	1 (4.3)	0
Mental status changes	2 (8.7)	2 (8.7)	0	0	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	1 (4.3)	0	0	1 (4.3)	0
Anxiety	1 (4.3)	0	1 (4.3)	0	0
Depression	1 (4.3)	0	1 (4.3)	0	0
Insomnia	1 (4.3)	0	1 (4.3)	0	0
Irritability	1 (4.3)	1 (4.3)	0	0	0
Renal and urinary disorders					
-Total	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Acute kidney injury	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Dysuria	1 (4.3)	0	1 (4.3)	0	0
Oliguria	1 (4.3)	0	0	1 (4.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (13.0)	0	2 (8.7)	0	1 (4.3)
Hypoxia	3 (13.0)	0	2 (8.7)	1 (4.3)	0
Cough	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Dyspnoea	1 (4.3)	0	0	1 (4.3)	0
Haemoptysis	1 (4.3)	0	0	1 (4.3)	0
Oropharyngeal pain	1 (4.3)	0	0	1 (4.3)	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	1 (4.3)	0	1 (4.3)	0	0
Pulmonary alveolar haemorrhage	1 (4.3)	0	0	0	1 (4.3)
Pulmonary hypertension	1 (4.3)	0	0	1 (4.3)	0
Pulmonary mass	1 (4.3)	0	1 (4.3)	0	0
Pulmonary oedema	1 (4.3)	0	0	0	1 (4.3)
Respiratory distress	1 (4.3)	0	0	0	1 (4.3)
Tachypnoea	1 (4.3)	0	0	1 (4.3)	0
Skin and subcutaneous tissue disorders					
-Total	3 (13.0)	2 (8.7)	1 (4.3)	0	0
Rash erythematous	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Cold sweat	1 (4.3)	1 (4.3)	0	0	0
Night sweats	1 (4.3)	1 (4.3)	0	0	0
Rash	1 (4.3)	1 (4.3)	0	0	0
Vascular disorders					
-Total	2 (8.7)	0	0	1 (4.3)	1 (4.3)
Hypertension	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Hypotension	1 (4.3)	0	0	0	1 (4.3)

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Venous thrombosis limb	1 (4.3)	1 (4.3)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175r
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (87.5)	0	1 (4.2)	10 (41.7)	10 (41.7)
Blood and lymphatic system disorders					
-Total	12 (50.0)	0	0	8 (33.3)	4 (16.7)
Anaemia	7 (29.2)	0	2 (8.3)	5 (20.8)	0
Febrile neutropenia	7 (29.2)	0	0	7 (29.2)	0
Neutropenia	4 (16.7)	0	0	1 (4.2)	3 (12.5)
Thrombocytopenia	4 (16.7)	0	0	1 (4.2)	3 (12.5)
Cardiac disorders					
-Total	1 (4.2)	0	0	1 (4.2)	0
Left ventricular dysfunction	1 (4.2)	0	0	1 (4.2)	0
Endocrine disorders					

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.2)	0	1 (4.2)	0	0
Adrenal insufficiency	1 (4.2)	0	1 (4.2)	0	0
Gastrointestinal disorders					
-Total	6 (25.0)	1 (4.2)	4 (16.7)	1 (4.2)	0
Constipation	3 (12.5)	1 (4.2)	2 (8.3)	0	0
Nausea	2 (8.3)	0	2 (8.3)	0	0
Abdominal pain	1 (4.2)	0	1 (4.2)	0	0
Anal fissure	1 (4.2)	0	1 (4.2)	0	0
Gastrointestinal haemorrhage	1 (4.2)	0	0	1 (4.2)	0
Oral pain	1 (4.2)	0	1 (4.2)	0	0
Pancreatitis	1 (4.2)	0	1 (4.2)	0	0
Proctalgia	1 (4.2)	0	1 (4.2)	0	0
Vomiting	1 (4.2)	0	1 (4.2)	0	0
General disorders and administration site conditions					
-Total	8 (33.3)	4 (16.7)	3 (12.5)	1 (4.2)	0
Fatigue	4 (16.7)	2 (8.3)	2 (8.3)	0	0
Pyrexia	3 (12.5)	2 (8.3)	0	1 (4.2)	0

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site pain	2 (8.3)	0	2 (8.3)	0	0
Asthenia	1 (4.2)	0	1 (4.2)	0	0
Injection site thrombosis	1 (4.2)	0	1 (4.2)	0	0
Hepatobiliary disorders					
-Total	1 (4.2)	0	1 (4.2)	0	0
Hyperbilirubinaemia	1 (4.2)	0	1 (4.2)	0	0
Immune system disorders					
-Total	1 (4.2)	0	0	1 (4.2)	0
Anaphylactic reaction	1 (4.2)	0	0	1 (4.2)	0
Infections and infestations					
-Total	7 (29.2)	0	1 (4.2)	4 (16.7)	2 (8.3)
Alpha haemolytic streptococcal infection	1 (4.2)	0	0	1 (4.2)	0
Candida sepsis	1 (4.2)	0	0	0	1 (4.2)
Clostridium difficile colitis	1 (4.2)	0	0	1 (4.2)	0
Conjunctivitis	1 (4.2)	0	1 (4.2)	0	0
Device related infection	1 (4.2)	0	0	1 (4.2)	0
Escherichia infection	1 (4.2)	0	0	1 (4.2)	0

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia sepsis	1 (4.2)	0	0	0	1 (4.2)
Escherichia urinary tract infection	1 (4.2)	0	1 (4.2)	0	0
Oral herpes	1 (4.2)	0	1 (4.2)	0	0
Pneumonia fungal	1 (4.2)	0	0	1 (4.2)	0
Staphylococcal infection	1 (4.2)	0	0	1 (4.2)	0
Streptococcal infection	1 (4.2)	0	0	1 (4.2)	0
Injury, poisoning and procedural complications					
-Total	3 (12.5)	0	3 (12.5)	0	0
Procedural pain	1 (4.2)	0	1 (4.2)	0	0
Toxicity to various agents	1 (4.2)	0	1 (4.2)	0	0
Transfusion reaction	1 (4.2)	0	1 (4.2)	0	0
Investigations					
-Total	10 (41.7)	1 (4.2)	0	3 (12.5)	6 (25.0)
White blood cell count decreased	6 (25.0)	1 (4.2)	0	1 (4.2)	4 (16.7)
Neutrophil count decreased	4 (16.7)	0	0	0	4 (16.7)
Platelet count decreased	4 (16.7)	0	0	1 (4.2)	3 (12.5)
Alanine aminotransferase increased	3 (12.5)	0	0	3 (12.5)	0

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	3 (12.5)	1 (4.2)	1 (4.2)	1 (4.2)	0
Blast cell count increased	1 (4.2)	0	0	1 (4.2)	0
Blood lactate dehydrogenase increased	1 (4.2)	0	0	1 (4.2)	0
Serum ferritin increased	1 (4.2)	0	0	1 (4.2)	0
White blood cell count increased	1 (4.2)	1 (4.2)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (20.8)	0	2 (8.3)	1 (4.2)	2 (8.3)
Decreased appetite	2 (8.3)	0	2 (8.3)	0	0
Hyperuricaemia	2 (8.3)	1 (4.2)	0	1 (4.2)	0
Hypomagnesaemia	2 (8.3)	2 (8.3)	0	0	0
Hypophosphataemia	2 (8.3)	0	0	2 (8.3)	0
Dehydration	1 (4.2)	0	1 (4.2)	0	0
Hypernatraemia	1 (4.2)	0	0	0	1 (4.2)
Hypocalcaemia	1 (4.2)	0	0	0	1 (4.2)
Hypokalaemia	1 (4.2)	0	0	0	1 (4.2)
Musculoskeletal and connective tissue disorders					

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (16.7)	1 (4.2)	2 (8.3)	1 (4.2)	0
Pain in jaw	2 (8.3)	0	2 (8.3)	0	0
Neck pain	1 (4.2)	1 (4.2)	0	0	0
Pain in extremity	1 (4.2)	0	0	1 (4.2)	0
Nervous system disorders					
-Total	3 (12.5)	1 (4.2)	1 (4.2)	1 (4.2)	0
Headache	1 (4.2)	0	0	1 (4.2)	0
Neuropathy peripheral	1 (4.2)	1 (4.2)	0	0	0
Peripheral sensory neuropathy	1 (4.2)	0	1 (4.2)	0	0
Peroneal nerve palsy	1 (4.2)	1 (4.2)	0	0	0
Psychiatric disorders					
-Total	1 (4.2)	0	1 (4.2)	0	0
Confusional state	1 (4.2)	0	1 (4.2)	0	0
Renal and urinary disorders					
-Total	1 (4.2)	0	0	0	1 (4.2)
Acute kidney injury	1 (4.2)	0	0	0	1 (4.2)
Respiratory, thoracic and mediastinal disorders					

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.2)	0	0	0	1 (4.2)
Pulmonary oedema	1 (4.2)	0	0	0	1 (4.2)
Respiratory failure	1 (4.2)	0	0	0	1 (4.2)
Skin and subcutaneous tissue disorders					
-Total	2 (8.3)	0	2 (8.3)	0	0
Alopecia	1 (4.2)	0	1 (4.2)	0	0
Urticaria	1 (4.2)	0	1 (4.2)	0	0
Vascular disorders					
-Total	1 (4.2)	0	0	0	1 (4.2)
Hypotension	1 (4.2)	0	0	0	1 (4.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 175r
Adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (80.0)	1 (5.0)	2 (10.0)	5 (25.0)	8 (40.0)
Blood and lymphatic system disorders					
-Total	10 (50.0)	1 (5.0)	0	7 (35.0)	2 (10.0)
Anaemia	7 (35.0)	0	0	7 (35.0)	0
Thrombocytopenia	4 (20.0)	0	0	2 (10.0)	2 (10.0)
Febrile neutropenia	2 (10.0)	0	0	2 (10.0)	0
Coagulopathy	1 (5.0)	1 (5.0)	0	0	0
Disseminated intravascular coagulation	1 (5.0)	0	0	1 (5.0)	0
Cardiac disorders					
-Total	4 (20.0)	1 (5.0)	1 (5.0)	1 (5.0)	1 (5.0)

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (5.0)	1 (5.0)	0	0	0
Cardiovascular insufficiency	1 (5.0)	0	0	0	1 (5.0)
Pericardial effusion	1 (5.0)	0	1 (5.0)	0	0
Sinus tachycardia	1 (5.0)	0	0	1 (5.0)	0
Ear and labyrinth disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Deafness unilateral	1 (5.0)	0	1 (5.0)	0	0
Endocrine disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Cushingoid	1 (5.0)	1 (5.0)	0	0	0
Hyperthyroidism	1 (5.0)	0	1 (5.0)	0	0
Gastrointestinal disorders					
-Total	7 (35.0)	2 (10.0)	1 (5.0)	4 (20.0)	0
Colitis	3 (15.0)	0	0	3 (15.0)	0
Vomiting	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Stomatitis	2 (10.0)	0	0	2 (10.0)	0
Abdominal pain	1 (5.0)	0	0	1 (5.0)	0
Diarrhoea	1 (5.0)	0	0	1 (5.0)	0

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Nausea	1 (5.0)	0	1 (5.0)	0	0
General disorders and administration site conditions					
-Total	8 (40.0)	4 (20.0)	2 (10.0)	0	2 (10.0)
Pyrexia	4 (20.0)	2 (10.0)	2 (10.0)	0	0
Multiple organ dysfunction syndrome	2 (10.0)	0	0	0	2 (10.0)
Chills	1 (5.0)	1 (5.0)	0	0	0
Fatigue	1 (5.0)	1 (5.0)	0	0	0
Gait disturbance	1 (5.0)	1 (5.0)	0	0	0
Generalised oedema	1 (5.0)	1 (5.0)	0	0	0
Non-cardiac chest pain	1 (5.0)	1 (5.0)	0	0	0
Oedema peripheral	1 (5.0)	1 (5.0)	0	0	0
Pain	1 (5.0)	0	1 (5.0)	0	0
Hepatobiliary disorders					
-Total	2 (10.0)	0	0	2 (10.0)	0
Cholecystitis	1 (5.0)	0	0	1 (5.0)	0
Hyperbilirubinaemia	1 (5.0)	0	0	1 (5.0)	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Immune system disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Hypogammaglobulinaemia	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	11 (55.0)	1 (5.0)	2 (10.0)	5 (25.0)	3 (15.0)
Enterococcal bacteraemia	2 (10.0)	0	0	2 (10.0)	0
Klebsiella sepsis	2 (10.0)	0	0	0	2 (10.0)
Bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Clostridium difficile colitis	1 (5.0)	0	0	1 (5.0)	0
Conjunctivitis	1 (5.0)	0	1 (5.0)	0	0
Croup infectious	1 (5.0)	0	0	1 (5.0)	0
Cytomegalovirus viraemia	1 (5.0)	0	1 (5.0)	0	0
Fungal skin infection	1 (5.0)	0	1 (5.0)	0	0
Klebsiella infection	1 (5.0)	0	0	1 (5.0)	0
Oral herpes	1 (5.0)	0	1 (5.0)	0	0
Sepsis	1 (5.0)	0	0	0	1 (5.0)
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Streptococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (5.0)	1 (5.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Subdural haematoma	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Extradural haematoma	1 (5.0)	0	0	1 (5.0)	0
Procedural pain	1 (5.0)	0	0	1 (5.0)	0
Transfusion reaction	1 (5.0)	1 (5.0)	0	0	0
Investigations					
-Total	10 (50.0)	0	1 (5.0)	2 (10.0)	7 (35.0)
Neutrophil count decreased	4 (20.0)	0	0	0	4 (20.0)
Platelet count decreased	3 (15.0)	0	0	0	3 (15.0)
Alanine aminotransferase increased	2 (10.0)	0	0	2 (10.0)	0
White blood cell count decreased	2 (10.0)	0	0	0	2 (10.0)
Aspartate aminotransferase increased	1 (5.0)	0	0	1 (5.0)	0
Blood fibrinogen decreased	1 (5.0)	0	1 (5.0)	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Coronavirus test positive	1 (5.0)	1 (5.0)	0	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Electrocardiogram qt prolonged	1 (5.0)	0	0	1 (5.0)	0
Lymphocyte count decreased	1 (5.0)	0	0	1 (5.0)	0
Metabolism and nutrition disorders					
-Total	7 (35.0)	0	2 (10.0)	4 (20.0)	1 (5.0)
Hyperglycaemia	3 (15.0)	0	1 (5.0)	1 (5.0)	1 (5.0)
Decreased appetite	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Hypokalaemia	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Dehydration	1 (5.0)	0	0	1 (5.0)	0
Hypernatraemia	1 (5.0)	0	0	1 (5.0)	0
Hyperuricaemia	1 (5.0)	1 (5.0)	0	0	0
Hypoalbuminaemia	1 (5.0)	0	0	0	1 (5.0)
Hypocalcaemia	1 (5.0)	0	0	0	1 (5.0)
Hypophosphataemia	1 (5.0)	0	1 (5.0)	0	0
Tumour lysis syndrome	1 (5.0)	0	0	1 (5.0)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (25.0)	2 (10.0)	1 (5.0)	2 (10.0)	0
Pain in extremity	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bone pain	1 (5.0)	0	1 (5.0)	0	0
Muscle spasms	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal pain	1 (5.0)	0	0	1 (5.0)	0
Nervous system disorders					
-Total	6 (30.0)	2 (10.0)	2 (10.0)	2 (10.0)	0
Headache	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Hypoaesthesia	1 (5.0)	1 (5.0)	0	0	0
Leukoencephalopathy	1 (5.0)	0	0	1 (5.0)	0
Neuralgia	1 (5.0)	0	1 (5.0)	0	0
Visual field defect	1 (5.0)	0	1 (5.0)	0	0
Product issues					
-Total	1 (5.0)	0	1 (5.0)	0	0
Device occlusion	1 (5.0)	0	1 (5.0)	0	0
Psychiatric disorders					
-Total	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Insomnia	1 (5.0)	0	1 (5.0)	0	0
Mental status changes	1 (5.0)	0	0	1 (5.0)	0
Renal and urinary disorders					

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Cystitis haemorrhagic	1 (5.0)	0	0	1 (5.0)	0
Haematuria	1 (5.0)	1 (5.0)	0	0	0
Reproductive system and breast disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Scrotal pain	1 (5.0)	0	1 (5.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (25.0)	0	2 (10.0)	1 (5.0)	2 (10.0)
Epistaxis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Hypoxia	2 (10.0)	0	1 (5.0)	0	1 (5.0)
Atelectasis	1 (5.0)	0	1 (5.0)	0	0
Idiopathic pneumonia syndrome	1 (5.0)	0	0	0	1 (5.0)
Pleural effusion	1 (5.0)	1 (5.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Rash erythematous	1 (5.0)	0	1 (5.0)	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash papular	1 (5.0)	1 (5.0)	0	0	0
Skin irritation	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	4 (20.0)	1 (5.0)	0	3 (15.0)	0
Hypotension	3 (15.0)	0	0	3 (15.0)	0
Hypertension	1 (5.0)	1 (5.0)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176a
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: <10 years

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (70.0)	3 (15.0)	2 (10.0)	2 (10.0)	7 (35.0)
Blood and lymphatic system disorders					
-Total	6 (30.0)	0	0	3 (15.0)	3 (15.0)
Anaemia	3 (15.0)	0	0	3 (15.0)	0
Febrile neutropenia	3 (15.0)	0	0	3 (15.0)	0
Lymphopenia	1 (5.0)	0	0	0	1 (5.0)
Neutropenia	1 (5.0)	0	0	0	1 (5.0)
Thrombocytopenia	1 (5.0)	0	0	0	1 (5.0)
Cardiac disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Bradycardia	1 (5.0)	0	1 (5.0)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastrointestinal disorders					
-Total	6 (30.0)	3 (15.0)	3 (15.0)	0	0
Abdominal pain	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Constipation	2 (10.0)	2 (10.0)	0	0	0
Diarrhoea	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Nausea	2 (10.0)	1 (5.0)	1 (5.0)	0	0
General disorders and administration site conditions					
-Total	4 (20.0)	1 (5.0)	3 (15.0)	0	0
Pyrexia	3 (15.0)	0	3 (15.0)	0	0
Catheter site pain	1 (5.0)	1 (5.0)	0	0	0
Oedema peripheral	1 (5.0)	1 (5.0)	0	0	0
Infections and infestations					
-Total	3 (15.0)	0	1 (5.0)	2 (10.0)	0
Bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Device related infection	1 (5.0)	0	0	1 (5.0)	0
Pneumonia	1 (5.0)	0	1 (5.0)	0	0
Investigations					

Age: <10 years

Primary system organ class Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	9 (45.0)	0	1 (5.0)	2 (10.0)	6 (30.0)
White blood cell count decreased	6 (30.0)	0	0	1 (5.0)	5 (25.0)
Neutrophil count decreased	3 (15.0)	0	0	0	3 (15.0)
C-reactive protein increased	2 (10.0)	0	2 (10.0)	0	0
Lymphocyte count decreased	2 (10.0)	0	0	0	2 (10.0)
Platelet count decreased	2 (10.0)	0	1 (5.0)	0	1 (5.0)
Alanine aminotransferase increased	1 (5.0)	0	1 (5.0)	0	0
Blood lactic acid increased	1 (5.0)	0	1 (5.0)	0	0
International normalised ratio increased	1 (5.0)	1 (5.0)	0	0	0
Protein total decreased	1 (5.0)	0	0	1 (5.0)	0
Metabolism and nutrition disorders					
-Total	6 (30.0)	2 (10.0)	1 (5.0)	3 (15.0)	0
Hypokalaemia	2 (10.0)	0	0	2 (10.0)	0
Hypophosphataemia	2 (10.0)	2 (10.0)	0	0	0
Decreased appetite	1 (5.0)	0	1 (5.0)	0	0
Fluid overload	1 (5.0)	0	1 (5.0)	0	0
Hyperkalaemia	1 (5.0)	1 (5.0)	0	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypermagnesaemia	1 (5.0)	1 (5.0)	0	0	0
Hyperphosphataemia	1 (5.0)	1 (5.0)	0	0	0
Hypocalcaemia	1 (5.0)	1 (5.0)	0	0	0
Hypoglycaemia	1 (5.0)	0	0	1 (5.0)	0
Hypomagnesaemia	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Pain in jaw	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Myalgia	1 (5.0)	0	0	1 (5.0)	0
Nervous system disorders					
-Total	3 (15.0)	0	3 (15.0)	0	0
Headache	2 (10.0)	0	2 (10.0)	0	0
Hypotonia	1 (5.0)	0	1 (5.0)	0	0
Psychiatric disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Anxiety	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Irritability	1 (5.0)	1 (5.0)	0	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	3 (15.0)	0	0	3 (15.0)	0
Hypoxia	2 (10.0)	0	0	2 (10.0)	0
Tachypnoea	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Dyspnoea	1 (5.0)	1 (5.0)	0	0	0
Epistaxis	1 (5.0)	0	0	1 (5.0)	0
Skin and subcutaneous tissue disorders					
-Total	3 (15.0)	3 (15.0)	0	0	0
Alopecia	1 (5.0)	1 (5.0)	0	0	0
Rash	1 (5.0)	1 (5.0)	0	0	0
Rash erythematous	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Hypertension	1 (5.0)	0	0	1 (5.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176a
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=10 years to <18 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (90.9)	3 (9.1)	3 (9.1)	12 (36.4)	12 (36.4)
Blood and lymphatic system disorders					
-Total	10 (30.3)	0	0	8 (24.2)	2 (6.1)
Febrile neutropenia	5 (15.2)	0	0	5 (15.2)	0
Anaemia	2 (6.1)	0	0	2 (6.1)	0
Thrombocytopenia	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Disseminated intravascular coagulation	1 (3.0)	0	0	0	1 (3.0)
Hypofibrinogenaemia	1 (3.0)	0	0	0	1 (3.0)
Neutropenia	1 (3.0)	0	0	1 (3.0)	0
Pancytopenia	1 (3.0)	0	0	1 (3.0)	0

Age: >=10 years to <18 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Left ventricular dysfunction	1 (3.0)	0	0	1 (3.0)	0
Palpitations	1 (3.0)	1 (3.0)	0	0	0
Tachycardia	1 (3.0)	1 (3.0)	0	0	0
Eye disorders					
-Total	1 (3.0)	1 (3.0)	0	0	0
Eye irritation	1 (3.0)	1 (3.0)	0	0	0
Gastrointestinal disorders					
-Total	7 (21.2)	5 (15.2)	1 (3.0)	1 (3.0)	0
Nausea	3 (9.1)	3 (9.1)	0	0	0
Vomiting	2 (6.1)	2 (6.1)	0	0	0
Abdominal pain lower	1 (3.0)	1 (3.0)	0	0	0
Ascites	1 (3.0)	0	0	1 (3.0)	0
Diarrhoea	1 (3.0)	1 (3.0)	0	0	0
Gingival discomfort	1 (3.0)	1 (3.0)	0	0	0
Haematochezia	1 (3.0)	1 (3.0)	0	0	0
Oral mucosal blistering	1 (3.0)	1 (3.0)	0	0	0

Age: >=10 years to <18 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatic failure	1 (3.0)	0	1 (3.0)	0	0
General disorders and administration site conditions					
-Total	5 (15.2)	1 (3.0)	3 (9.1)	0	1 (3.0)
Pyrexia	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Chills	1 (3.0)	0	1 (3.0)	0	0
Device related thrombosis	1 (3.0)	0	1 (3.0)	0	0
Multiple organ dysfunction syndrome	1 (3.0)	0	0	0	1 (3.0)
Hepatobiliary disorders					
-Total	1 (3.0)	0	0	0	1 (3.0)
Hepatic failure	1 (3.0)	0	0	0	1 (3.0)
Immune system disorders					
-Total	1 (3.0)	1 (3.0)	0	0	0
Hypogammaglobulinaemia	1 (3.0)	1 (3.0)	0	0	0
Infections and infestations					
-Total	3 (9.1)	1 (3.0)	1 (3.0)	0	1 (3.0)
Bronchitis	1 (3.0)	0	1 (3.0)	0	0
Otitis media	1 (3.0)	0	1 (3.0)	0	0

Age: >=10 years to <18 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (3.0)	1 (3.0)	0	0	0
Staphylococcal infection	1 (3.0)	0	0	0	1 (3.0)
Viral upper respiratory tract infection	1 (3.0)	1 (3.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Infusion related reaction	1 (3.0)	1 (3.0)	0	0	0
Radiation skin injury	1 (3.0)	0	1 (3.0)	0	0
Investigations					
-Total	20 (60.6)	2 (6.1)	2 (6.1)	4 (12.1)	12 (36.4)
White blood cell count decreased	11 (33.3)	0	0	2 (6.1)	9 (27.3)
Neutrophil count decreased	7 (21.2)	0	0	0	7 (21.2)
Alanine aminotransferase increased	6 (18.2)	1 (3.0)	1 (3.0)	3 (9.1)	1 (3.0)
Aspartate aminotransferase increased	3 (9.1)	1 (3.0)	1 (3.0)	0	1 (3.0)
Lymphocyte count decreased	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Platelet count decreased	2 (6.1)	0	0	2 (6.1)	0
Weight increased	2 (6.1)	2 (6.1)	0	0	0

Age: >=10 years to <18 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	1 (3.0)	0	1 (3.0)	0	0
Blood bilirubin increased	1 (3.0)	0	0	0	1 (3.0)
Blood creatinine increased	1 (3.0)	1 (3.0)	0	0	0
Blood uric acid increased	1 (3.0)	1 (3.0)	0	0	0
International normalised ratio increased	1 (3.0)	0	1 (3.0)	0	0
Lipase increased	1 (3.0)	0	0	0	1 (3.0)
Weight decreased	1 (3.0)	1 (3.0)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (21.2)	3 (9.1)	1 (3.0)	1 (3.0)	2 (6.1)
Hypokalaemia	3 (9.1)	1 (3.0)	0	0	2 (6.1)
Hyperphosphataemia	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Decreased appetite	1 (3.0)	1 (3.0)	0	0	0
Hyperglycaemia	1 (3.0)	0	0	1 (3.0)	0
Hypernatraemia	1 (3.0)	0	0	0	1 (3.0)
Hyperuricaemia	1 (3.0)	1 (3.0)	0	0	0
Hypoalbuminaemia	1 (3.0)	0	1 (3.0)	0	0
Hypoglycaemia	1 (3.0)	0	1 (3.0)	0	0

Age: >=10 years to <18 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	1 (3.0)	1 (3.0)	0	0	0
Arthralgia	1 (3.0)	1 (3.0)	0	0	0
Nervous system disorders					
-Total	5 (15.2)	4 (12.1)	1 (3.0)	0	0
Headache	3 (9.1)	3 (9.1)	0	0	0
Dysgeusia	1 (3.0)	1 (3.0)	0	0	0
Somnolence	1 (3.0)	0	1 (3.0)	0	0
Product issues					
-Total	1 (3.0)	1 (3.0)	0	0	0
Device occlusion	1 (3.0)	1 (3.0)	0	0	0
Psychiatric disorders					
-Total	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Delirium	1 (3.0)	0	0	1 (3.0)	0
Depression	1 (3.0)	0	1 (3.0)	0	0
Renal and urinary disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0

Age: >=10 years to <18 years

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary retention	1 (3.0)	0	1 (3.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (12.1)	3 (9.1)	0	1 (3.0)	0
Cough	1 (3.0)	1 (3.0)	0	0	0
Hypoxia	1 (3.0)	0	0	1 (3.0)	0
Nasal congestion	1 (3.0)	1 (3.0)	0	0	0
Nasal discomfort	1 (3.0)	1 (3.0)	0	0	0
Pleural effusion	1 (3.0)	0	0	1 (3.0)	0
Rhinitis allergic	1 (3.0)	1 (3.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (21.2)	5 (15.2)	1 (3.0)	1 (3.0)	0
Alopecia	1 (3.0)	1 (3.0)	0	0	0
Dermatitis acneiform	1 (3.0)	0	1 (3.0)	0	0
Pruritus	1 (3.0)	1 (3.0)	0	0	0
Pruritus generalised	1 (3.0)	1 (3.0)	0	0	0
Rash macular	1 (3.0)	0	0	1 (3.0)	0
Rash pruritic	1 (3.0)	1 (3.0)	0	0	0

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=33 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin ulcer	1 (3.0)	1 (3.0)	0	0	0
Vascular disorders					
-Total	2 (6.1)	0	0	2 (6.1)	0
Hypotension	2 (6.1)	0	0	2 (6.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176a
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=18

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (87.5)	1 (12.5)	1 (12.5)	2 (25.0)	3 (37.5)
Blood and lymphatic system disorders					
-Total	3 (37.5)	0	1 (12.5)	0	2 (25.0)
Anaemia	2 (25.0)	0	2 (25.0)	0	0
Neutropenia	2 (25.0)	0	0	0	2 (25.0)
Febrile neutropenia	1 (12.5)	0	1 (12.5)	0	0
Gastrointestinal disorders					
-Total	4 (50.0)	1 (12.5)	3 (37.5)	0	0
Nausea	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Diarrhoea	1 (12.5)	0	1 (12.5)	0	0

Age: >=18

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (12.5)	0	1 (12.5)	0	0
General disorders and administration site conditions					
-Total	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Catheter site pain	1 (12.5)	1 (12.5)	0	0	0
Medical device pain	1 (12.5)	0	1 (12.5)	0	0
Pain	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	1 (12.5)	0	0	1 (12.5)	0
Device related infection	1 (12.5)	0	1 (12.5)	0	0
Necrotising fasciitis	1 (12.5)	0	0	1 (12.5)	0
Investigations					
-Total	2 (25.0)	0	0	0	2 (25.0)
White blood cell count decreased	2 (25.0)	0	0	0	2 (25.0)
Metabolism and nutrition disorders					
-Total	2 (25.0)	0	0	2 (25.0)	0
Decreased appetite	1 (12.5)	0	1 (12.5)	0	0
Fluid overload	1 (12.5)	0	1 (12.5)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperuricaemia	1 (12.5)	0	0	1 (12.5)	0
Hypomagnesaemia	1 (12.5)	0	1 (12.5)	0	0
Hypophosphataemia	1 (12.5)	1 (12.5)	0	0	0
Tumour lysis syndrome	1 (12.5)	0	0	1 (12.5)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Pain in extremity	1 (12.5)	0	0	1 (12.5)	0
Psychiatric disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Insomnia	1 (12.5)	0	1 (12.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (25.0)	0	2 (25.0)	0	0
Dyspnoea	1 (12.5)	0	1 (12.5)	0	0
Epistaxis	1 (12.5)	0	1 (12.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin haemorrhage	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Hypertension	1 (12.5)	1 (12.5)	0	0	0
Hypotension	1 (12.5)	0	0	1 (12.5)	0
Phlebitis	1 (12.5)	0	1 (12.5)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176b
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Male

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (75.9)	0	4 (13.8)	7 (24.1)	11 (37.9)
Blood and lymphatic system disorders					
-Total	10 (34.5)	0	1 (3.4)	6 (20.7)	3 (10.3)
Febrile neutropenia	6 (20.7)	0	1 (3.4)	5 (17.2)	0
Anaemia	4 (13.8)	0	2 (6.9)	2 (6.9)	0
Neutropenia	2 (6.9)	0	0	1 (3.4)	1 (3.4)
Disseminated intravascular coagulation	1 (3.4)	0	0	0	1 (3.4)
Lymphopenia	1 (3.4)	0	0	0	1 (3.4)
Pancytopenia	1 (3.4)	0	0	1 (3.4)	0
Thrombocytopenia	1 (3.4)	0	0	0	1 (3.4)

Gender: Male

Primary system organ class Preferred term	All patients N=29 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac disorders					
-Total	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Bradycardia	1 (3.4)	0	1 (3.4)	0	0
Palpitations	1 (3.4)	1 (3.4)	0	0	0
Gastrointestinal disorders					
-Total	8 (27.6)	4 (13.8)	3 (10.3)	1 (3.4)	0
Nausea	5 (17.2)	3 (10.3)	2 (6.9)	0	0
Vomiting	3 (10.3)	2 (6.9)	1 (3.4)	0	0
Ascites	1 (3.4)	0	0	1 (3.4)	0
Gingival discomfort	1 (3.4)	1 (3.4)	0	0	0
Pancreatic failure	1 (3.4)	0	1 (3.4)	0	0
General disorders and administration site conditions					
-Total	3 (10.3)	1 (3.4)	1 (3.4)	0	1 (3.4)
Pyrexia	3 (10.3)	1 (3.4)	2 (6.9)	0	0
Multiple organ dysfunction syndrome	1 (3.4)	0	0	0	1 (3.4)
Hepatobiliary disorders					
-Total	1 (3.4)	0	0	0	1 (3.4)

Gender: Male

Primary system organ class Preferred term	All patients N=29 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatic failure	1 (3.4)	0	0	0	1 (3.4)
Immune system disorders					
-Total	1 (3.4)	1 (3.4)	0	0	0
Hypogammaglobulinaemia	1 (3.4)	1 (3.4)	0	0	0
Infections and infestations					
-Total	4 (13.8)	1 (3.4)	2 (6.9)	0	1 (3.4)
Bronchitis	1 (3.4)	0	1 (3.4)	0	0
Otitis media	1 (3.4)	0	1 (3.4)	0	0
Parainfluenzae virus infection	1 (3.4)	1 (3.4)	0	0	0
Pneumonia	1 (3.4)	0	1 (3.4)	0	0
Staphylococcal infection	1 (3.4)	0	0	0	1 (3.4)
Viral upper respiratory tract infection	1 (3.4)	1 (3.4)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Infusion related reaction	1 (3.4)	1 (3.4)	0	0	0
Radiation skin injury	1 (3.4)	0	1 (3.4)	0	0
Investigations					

Gender: Male

Primary system organ class Preferred term	All patients N=29 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	13 (44.8)	0	1 (3.4)	3 (10.3)	9 (31.0)
White blood cell count decreased	9 (31.0)	0	0	2 (6.9)	7 (24.1)
Neutrophil count decreased	4 (13.8)	0	0	0	4 (13.8)
Alanine aminotransferase increased	3 (10.3)	0	1 (3.4)	1 (3.4)	1 (3.4)
Aspartate aminotransferase increased	2 (6.9)	0	1 (3.4)	0	1 (3.4)
Activated partial thromboplastin time prolonged	1 (3.4)	0	1 (3.4)	0	0
Blood bilirubin increased	1 (3.4)	0	0	0	1 (3.4)
Blood lactic acid increased	1 (3.4)	0	1 (3.4)	0	0
C-reactive protein increased	1 (3.4)	0	1 (3.4)	0	0
International normalised ratio increased	1 (3.4)	0	1 (3.4)	0	0
Platelet count decreased	1 (3.4)	0	1 (3.4)	0	0
Protein total decreased	1 (3.4)	0	0	1 (3.4)	0
Weight increased	1 (3.4)	1 (3.4)	0	0	0
Metabolism and nutrition disorders					
-Total	8 (27.6)	2 (6.9)	2 (6.9)	3 (10.3)	1 (3.4)
Hypokalaemia	3 (10.3)	1 (3.4)	0	1 (3.4)	1 (3.4)

Gender: Male

Primary system organ class Preferred term	All patients N=29 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Decreased appetite	2 (6.9)	0	2 (6.9)	0	0
Fluid overload	2 (6.9)	0	2 (6.9)	0	0
Hyperphosphataemia	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Hyperuricaemia	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Hypermagnesaemia	1 (3.4)	1 (3.4)	0	0	0
Hypernatraemia	1 (3.4)	0	0	0	1 (3.4)
Hypoalbuminaemia	1 (3.4)	0	1 (3.4)	0	0
Hypoglycaemia	1 (3.4)	0	1 (3.4)	0	0
Hypomagnesaemia	1 (3.4)	0	1 (3.4)	0	0
Hypophosphataemia	1 (3.4)	1 (3.4)	0	0	0
Tumour lysis syndrome	1 (3.4)	0	0	1 (3.4)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (3.4)	1 (3.4)	0	0	0
Arthralgia	1 (3.4)	1 (3.4)	0	0	0
Nervous system disorders					
-Total	3 (10.3)	0	3 (10.3)	0	0
Headache	1 (3.4)	0	1 (3.4)	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=29 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotonia	1 (3.4)	0	1 (3.4)	0	0
Somnolence	1 (3.4)	0	1 (3.4)	0	0
Psychiatric disorders					
-Total	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Delirium	1 (3.4)	0	0	1 (3.4)	0
Insomnia	1 (3.4)	0	1 (3.4)	0	0
Renal and urinary disorders					
-Total	1 (3.4)	0	1 (3.4)	0	0
Urinary retention	1 (3.4)	0	1 (3.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (17.2)	1 (3.4)	1 (3.4)	3 (10.3)	0
Epistaxis	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Hypoxia	2 (6.9)	0	0	2 (6.9)	0
Cough	1 (3.4)	1 (3.4)	0	0	0
Pleural effusion	1 (3.4)	0	0	1 (3.4)	0
Tachypnoea	1 (3.4)	0	0	1 (3.4)	0
Skin and subcutaneous tissue disorders					

Gender: Male

Primary system organ class Preferred term	All patients N=29 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	4 (13.8)	2 (6.9)	1 (3.4)	1 (3.4)	0
Alopecia	1 (3.4)	1 (3.4)	0	0	0
Dermatitis acneiform	1 (3.4)	0	1 (3.4)	0	0
Pruritus generalised	1 (3.4)	1 (3.4)	0	0	0
Rash macular	1 (3.4)	0	0	1 (3.4)	0
Vascular disorders					
-Total	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Hypertension	1 (3.4)	1 (3.4)	0	0	0
Hypotension	1 (3.4)	0	0	1 (3.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176b
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Female

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (90.6)	7 (21.9)	2 (6.3)	9 (28.1)	11 (34.4)
Blood and lymphatic system disorders					
-Total	9 (28.1)	0	0	5 (15.6)	4 (12.5)
Anaemia	3 (9.4)	0	0	3 (9.4)	0
Febrile neutropenia	3 (9.4)	0	0	3 (9.4)	0
Neutropenia	2 (6.3)	0	0	0	2 (6.3)
Thrombocytopenia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Hypofibrinogenaemia	1 (3.1)	0	0	0	1 (3.1)
Cardiac disorders					
-Total	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Left ventricular dysfunction	1 (3.1)	0	0	1 (3.1)	0

Gender: Female

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachycardia	1 (3.1)	1 (3.1)	0	0	0
Eye disorders					
-Total	1 (3.1)	1 (3.1)	0	0	0
Eye irritation	1 (3.1)	1 (3.1)	0	0	0
Gastrointestinal disorders					
-Total	9 (28.1)	5 (15.6)	4 (12.5)	0	0
Diarrhoea	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Nausea	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Abdominal pain	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Constipation	2 (6.3)	2 (6.3)	0	0	0
Abdominal pain lower	1 (3.1)	1 (3.1)	0	0	0
Haematochezia	1 (3.1)	1 (3.1)	0	0	0
Oral mucosal blistering	1 (3.1)	1 (3.1)	0	0	0
General disorders and administration site conditions					
-Total	9 (28.1)	2 (6.3)	7 (21.9)	0	0
Pyrexia	3 (9.4)	0	3 (9.4)	0	0
Catheter site pain	2 (6.3)	2 (6.3)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Chills	1 (3.1)	0	1 (3.1)	0	0
Device related thrombosis	1 (3.1)	0	1 (3.1)	0	0
Medical device pain	1 (3.1)	0	1 (3.1)	0	0
Oedema peripheral	1 (3.1)	1 (3.1)	0	0	0
Pain	1 (3.1)	0	1 (3.1)	0	0
Infections and infestations					
-Total	3 (9.4)	0	0	3 (9.4)	0
Device related infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Necrotising fasciitis	1 (3.1)	0	0	1 (3.1)	0
Investigations					
-Total	18 (56.3)	2 (6.3)	2 (6.3)	3 (9.4)	11 (34.4)
White blood cell count decreased	10 (31.3)	0	0	1 (3.1)	9 (28.1)
Neutrophil count decreased	6 (18.8)	0	0	0	6 (18.8)
Alanine aminotransferase increased	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0
Lymphocyte count decreased	4 (12.5)	0	0	1 (3.1)	3 (9.4)
Platelet count decreased	3 (9.4)	0	0	2 (6.3)	1 (3.1)

Gender: Female

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspartate aminotransferase increased	1 (3.1)	1 (3.1)	0	0	0
Blood creatinine increased	1 (3.1)	1 (3.1)	0	0	0
Blood uric acid increased	1 (3.1)	1 (3.1)	0	0	0
C-reactive protein increased	1 (3.1)	0	1 (3.1)	0	0
International normalised ratio increased	1 (3.1)	1 (3.1)	0	0	0
Lipase increased	1 (3.1)	0	0	0	1 (3.1)
Weight decreased	1 (3.1)	1 (3.1)	0	0	0
Weight increased	1 (3.1)	1 (3.1)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (21.9)	3 (9.4)	0	3 (9.4)	1 (3.1)
Hypokalaemia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Hypophosphataemia	2 (6.3)	2 (6.3)	0	0	0
Decreased appetite	1 (3.1)	1 (3.1)	0	0	0
Hyperglycaemia	1 (3.1)	0	0	1 (3.1)	0
Hyperkalaemia	1 (3.1)	1 (3.1)	0	0	0
Hyperphosphataemia	1 (3.1)	1 (3.1)	0	0	0
Hypocalcaemia	1 (3.1)	1 (3.1)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoglycaemia	1 (3.1)	0	0	1 (3.1)	0
Hypomagnesaemia	1 (3.1)	1 (3.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0
Pain in jaw	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Myalgia	1 (3.1)	0	0	1 (3.1)	0
Pain in extremity	1 (3.1)	0	0	1 (3.1)	0
Nervous system disorders					
-Total	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Headache	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Dysgeusia	1 (3.1)	1 (3.1)	0	0	0
Product issues					
-Total	1 (3.1)	1 (3.1)	0	0	0
Device occlusion	1 (3.1)	1 (3.1)	0	0	0
Psychiatric disorders					
-Total	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Anxiety	2 (6.3)	1 (3.1)	1 (3.1)	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Depression	1 (3.1)	0	1 (3.1)	0	0
Irritability	1 (3.1)	1 (3.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Dyspnoea	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Hypoxia	1 (3.1)	0	0	1 (3.1)	0
Nasal congestion	1 (3.1)	1 (3.1)	0	0	0
Nasal discomfort	1 (3.1)	1 (3.1)	0	0	0
Rhinitis allergic	1 (3.1)	1 (3.1)	0	0	0
Tachypnoea	1 (3.1)	0	1 (3.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (21.9)	7 (21.9)	0	0	0
Alopecia	1 (3.1)	1 (3.1)	0	0	0
Pruritus	1 (3.1)	1 (3.1)	0	0	0
Rash	1 (3.1)	1 (3.1)	0	0	0
Rash erythematous	1 (3.1)	1 (3.1)	0	0	0
Rash pruritic	1 (3.1)	1 (3.1)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Skin ulcer	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	4 (12.5)	0	1 (3.1)	3 (9.4)	0
Hypotension	2 (6.3)	0	0	2 (6.3)	0
Hypertension	1 (3.1)	0	0	1 (3.1)	0
Phlebitis	1 (3.1)	0	1 (3.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176c
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: White

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (84.0)	5 (10.0)	5 (10.0)	14 (28.0)	18 (36.0)
Blood and lymphatic system disorders					
-Total	17 (34.0)	0	1 (2.0)	10 (20.0)	6 (12.0)
Febrile neutropenia	8 (16.0)	0	1 (2.0)	7 (14.0)	0
Anaemia	7 (14.0)	0	2 (4.0)	5 (10.0)	0
Neutropenia	4 (8.0)	0	0	1 (2.0)	3 (6.0)
Thrombocytopenia	3 (6.0)	0	0	1 (2.0)	2 (4.0)
Disseminated intravascular coagulation	1 (2.0)	0	0	0	1 (2.0)
Lymphopenia	1 (2.0)	0	0	0	1 (2.0)
Pancytopenia	1 (2.0)	0	0	1 (2.0)	0

Race: White

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	3 (6.0)	1 (2.0)	1 (2.0)	1 (2.0)	0
Bradycardia	1 (2.0)	0	1 (2.0)	0	0
Left ventricular dysfunction	1 (2.0)	0	0	1 (2.0)	0
Palpitations	1 (2.0)	1 (2.0)	0	0	0
Eye disorders					
-Total	1 (2.0)	1 (2.0)	0	0	0
Eye irritation	1 (2.0)	1 (2.0)	0	0	0
Gastrointestinal disorders					
-Total	15 (30.0)	7 (14.0)	7 (14.0)	1 (2.0)	0
Nausea	6 (12.0)	3 (6.0)	3 (6.0)	0	0
Diarrhoea	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Vomiting	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Abdominal pain	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Constipation	2 (4.0)	2 (4.0)	0	0	0
Ascites	1 (2.0)	0	0	1 (2.0)	0
Gingival discomfort	1 (2.0)	1 (2.0)	0	0	0
Oral mucosal blistering	1 (2.0)	1 (2.0)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=50 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pancreatic failure	1 (2.0)	0	1 (2.0)	0	0
General disorders and administration site conditions					
-Total	8 (16.0)	2 (4.0)	5 (10.0)	0	1 (2.0)
Pyrexia	5 (10.0)	1 (2.0)	4 (8.0)	0	0
Catheter site pain	1 (2.0)	1 (2.0)	0	0	0
Medical device pain	1 (2.0)	0	1 (2.0)	0	0
Multiple organ dysfunction syndrome	1 (2.0)	0	0	0	1 (2.0)
Oedema peripheral	1 (2.0)	1 (2.0)	0	0	0
Pain	1 (2.0)	0	1 (2.0)	0	0
Hepatobiliary disorders					
-Total	1 (2.0)	0	0	0	1 (2.0)
Hepatic failure	1 (2.0)	0	0	0	1 (2.0)
Immune system disorders					
-Total	1 (2.0)	1 (2.0)	0	0	0
Hypogammaglobulinaemia	1 (2.0)	1 (2.0)	0	0	0
Infections and infestations					
-Total	7 (14.0)	1 (2.0)	2 (4.0)	3 (6.0)	1 (2.0)

Race: White

Primary system organ class Preferred term	All patients N=50 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related infection	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Bacteraemia	1 (2.0)	0	0	1 (2.0)	0
Bronchitis	1 (2.0)	0	1 (2.0)	0	0
Necrotising fasciitis	1 (2.0)	0	0	1 (2.0)	0
Otitis media	1 (2.0)	0	1 (2.0)	0	0
Parainfluenzae virus infection	1 (2.0)	1 (2.0)	0	0	0
Pneumonia	1 (2.0)	0	1 (2.0)	0	0
Staphylococcal infection	1 (2.0)	0	0	0	1 (2.0)
Viral upper respiratory tract infection	1 (2.0)	1 (2.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Infusion related reaction	1 (2.0)	1 (2.0)	0	0	0
Radiation skin injury	1 (2.0)	0	1 (2.0)	0	0
Investigations					
-Total	26 (52.0)	2 (4.0)	2 (4.0)	6 (12.0)	16 (32.0)
White blood cell count decreased	16 (32.0)	0	0	3 (6.0)	13 (26.0)
Neutrophil count decreased	10 (20.0)	0	0	0	10 (20.0)

Race: White

	All patients N=50				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	6 (12.0)	1 (2.0)	1 (2.0)	3 (6.0)	1 (2.0)
Lymphocyte count decreased	4 (8.0)	0	0	1 (2.0)	3 (6.0)
Platelet count decreased	3 (6.0)	0	1 (2.0)	2 (4.0)	0
Aspartate aminotransferase increased	2 (4.0)	0	1 (2.0)	0	1 (2.0)
C-reactive protein increased	2 (4.0)	0	2 (4.0)	0	0
International normalised ratio increased	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Weight increased	2 (4.0)	2 (4.0)	0	0	0
Activated partial thromboplastin time prolonged	1 (2.0)	0	1 (2.0)	0	0
Blood bilirubin increased	1 (2.0)	0	0	0	1 (2.0)
Blood creatinine increased	1 (2.0)	1 (2.0)	0	0	0
Blood lactic acid increased	1 (2.0)	0	1 (2.0)	0	0
Protein total decreased	1 (2.0)	0	0	1 (2.0)	0
Metabolism and nutrition disorders					
-Total	12 (24.0)	4 (8.0)	2 (4.0)	5 (10.0)	1 (2.0)
Hypokalaemia	4 (8.0)	1 (2.0)	0	2 (4.0)	1 (2.0)
Hyperphosphataemia	3 (6.0)	2 (4.0)	1 (2.0)	0	0

Race: White

Primary system organ class Preferred term	All patients N=50 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypophosphataemia	3 (6.0)	3 (6.0)	0	0	0
Decreased appetite	2 (4.0)	0	2 (4.0)	0	0
Fluid overload	2 (4.0)	0	2 (4.0)	0	0
Hyperuricaemia	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Hypoglycaemia	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Hypomagnesaemia	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Hyperkalaemia	1 (2.0)	1 (2.0)	0	0	0
Hypermagnesaemia	1 (2.0)	1 (2.0)	0	0	0
Hypernatraemia	1 (2.0)	0	0	0	1 (2.0)
Hypoalbuminaemia	1 (2.0)	0	1 (2.0)	0	0
Hypocalcaemia	1 (2.0)	1 (2.0)	0	0	0
Tumour lysis syndrome	1 (2.0)	0	0	1 (2.0)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (10.0)	2 (4.0)	1 (2.0)	2 (4.0)	0
Pain in jaw	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Arthralgia	1 (2.0)	1 (2.0)	0	0	0
Myalgia	1 (2.0)	0	0	1 (2.0)	0

Race: White

Primary system organ class Preferred term	All patients N=50 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain in extremity	1 (2.0)	0	0	1 (2.0)	0
Nervous system disorders					
-Total	7 (14.0)	3 (6.0)	4 (8.0)	0	0
Headache	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Dysgeusia	1 (2.0)	1 (2.0)	0	0	0
Hypotonia	1 (2.0)	0	1 (2.0)	0	0
Somnolence	1 (2.0)	0	1 (2.0)	0	0
Psychiatric disorders					
-Total	5 (10.0)	1 (2.0)	3 (6.0)	1 (2.0)	0
Anxiety	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Delirium	1 (2.0)	0	0	1 (2.0)	0
Depression	1 (2.0)	0	1 (2.0)	0	0
Insomnia	1 (2.0)	0	1 (2.0)	0	0
Irritability	1 (2.0)	1 (2.0)	0	0	0
Renal and urinary disorders					
-Total	1 (2.0)	0	1 (2.0)	0	0
Urinary retention	1 (2.0)	0	1 (2.0)	0	0

Race: White

Primary system organ class Preferred term	All patients N=50 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	8 (16.0)	2 (4.0)	2 (4.0)	4 (8.0)	0
Hypoxia	3 (6.0)	0	0	3 (6.0)	0
Dyspnoea	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Epistaxis	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Tachypnoea	2 (4.0)	0	1 (2.0)	1 (2.0)	0
Cough	1 (2.0)	1 (2.0)	0	0	0
Nasal congestion	1 (2.0)	1 (2.0)	0	0	0
Pleural effusion	1 (2.0)	0	0	1 (2.0)	0
Rhinitis allergic	1 (2.0)	1 (2.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (18.0)	7 (14.0)	1 (2.0)	1 (2.0)	0
Alopecia	2 (4.0)	2 (4.0)	0	0	0
Dermatitis acneiform	1 (2.0)	0	1 (2.0)	0	0
Pruritus	1 (2.0)	1 (2.0)	0	0	0
Rash	1 (2.0)	1 (2.0)	0	0	0
Rash erythematous	1 (2.0)	1 (2.0)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=50 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash macular	1 (2.0)	0	0	1 (2.0)	0
Skin haemorrhage	1 (2.0)	1 (2.0)	0	0	0
Skin ulcer	1 (2.0)	1 (2.0)	0	0	0
Vascular disorders					
-Total	5 (10.0)	1 (2.0)	1 (2.0)	3 (6.0)	0
Hypertension	2 (4.0)	1 (2.0)	0	1 (2.0)	0
Hypotension	2 (4.0)	0	0	2 (4.0)	0
Phlebitis	1 (2.0)	0	1 (2.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176c
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Asian

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	1 (20.0)	1 (20.0)	2 (40.0)
General disorders and administration site conditions					
-Total	1 (20.0)	0	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	3 (60.0)	0	1 (20.0)	0	2 (40.0)
White blood cell count decreased	2 (40.0)	0	0	0	2 (40.0)
Alanine aminotransferase increased	1 (20.0)	0	1 (20.0)	0	0
Aspartate aminotransferase increased	1 (20.0)	1 (20.0)	0	0	0
Blood uric acid increased	1 (20.0)	1 (20.0)	0	0	0

Race: Asian

Primary system organ class Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Platelet count decreased	1 (20.0)	0	0	0	1 (20.0)
Metabolism and nutrition disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Hyperglycaemia	1 (20.0)	0	0	1 (20.0)	0
Skin and subcutaneous tissue disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Pruritus generalised	1 (20.0)	1 (20.0)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176c
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Other

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (83.3)	2 (33.3)	0	1 (16.7)	2 (33.3)
Blood and lymphatic system disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Febrile neutropenia	1 (16.7)	0	0	1 (16.7)	0
Hypofibrinogenaemia	1 (16.7)	0	0	0	1 (16.7)
Cardiac disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Tachycardia	1 (16.7)	1 (16.7)	0	0	0
Gastrointestinal disorders					
-Total	2 (33.3)	2 (33.3)	0	0	0

Race: Other

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nausea	2 (33.3)	2 (33.3)	0	0	0
Abdominal pain lower	1 (16.7)	1 (16.7)	0	0	0
Diarrhoea	1 (16.7)	1 (16.7)	0	0	0
Haematochezia	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	3 (50.0)	1 (16.7)	2 (33.3)	0	0
Catheter site pain	1 (16.7)	1 (16.7)	0	0	0
Chills	1 (16.7)	0	1 (16.7)	0	0
Device related thrombosis	1 (16.7)	0	1 (16.7)	0	0
Investigations					
-Total	2 (33.3)	0	0	0	2 (33.3)
Lipase increased	1 (16.7)	0	0	0	1 (16.7)
Weight decreased	1 (16.7)	1 (16.7)	0	0	0
White blood cell count decreased	1 (16.7)	0	0	0	1 (16.7)
Metabolism and nutrition disorders					
-Total	2 (33.3)	1 (16.7)	0	0	1 (16.7)
Decreased appetite	1 (16.7)	1 (16.7)	0	0	0

Race: Other

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypokalaemia	1 (16.7)	0	0	0	1 (16.7)
Nervous system disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Headache	1 (16.7)	1 (16.7)	0	0	0
Product issues					
-Total	1 (16.7)	1 (16.7)	0	0	0
Device occlusion	1 (16.7)	1 (16.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Nasal discomfort	1 (16.7)	1 (16.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Rash pruritic	1 (16.7)	1 (16.7)	0	0	0
Vascular disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Hypotension	1 (16.7)	0	0	1 (16.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176d
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Hispanic or Latino

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (91.3)	4 (17.4)	2 (8.7)	5 (21.7)	10 (43.5)
Blood and lymphatic system disorders					
-Total	6 (26.1)	0	1 (4.3)	3 (13.0)	2 (8.7)
Febrile neutropenia	5 (21.7)	0	1 (4.3)	4 (17.4)	0
Anaemia	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Neutropenia	1 (4.3)	0	0	0	1 (4.3)
Thrombocytopenia	1 (4.3)	0	0	0	1 (4.3)
Cardiac disorders					
-Total	1 (4.3)	1 (4.3)	0	0	0
Tachycardia	1 (4.3)	1 (4.3)	0	0	0
Eye disorders					

Ethnicity: Hispanic or Latino

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.3)	1 (4.3)	0	0	0
Eye irritation	1 (4.3)	1 (4.3)	0	0	0
Gastrointestinal disorders					
-Total	8 (34.8)	4 (17.4)	4 (17.4)	0	0
Nausea	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Diarrhoea	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Vomiting	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Abdominal pain lower	1 (4.3)	1 (4.3)	0	0	0
Constipation	1 (4.3)	1 (4.3)	0	0	0
Haematochezia	1 (4.3)	1 (4.3)	0	0	0
Oral mucosal blistering	1 (4.3)	1 (4.3)	0	0	0
Pancreatic failure	1 (4.3)	0	1 (4.3)	0	0
General disorders and administration site conditions					
-Total	2 (8.7)	0	2 (8.7)	0	0
Chills	1 (4.3)	0	1 (4.3)	0	0
Pain	1 (4.3)	0	1 (4.3)	0	0
Immune system disorders					

Ethnicity: Hispanic or Latino

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.3)	1 (4.3)	0	0	0
Hypogammaglobulinaemia	1 (4.3)	1 (4.3)	0	0	0
Infections and infestations					
-Total	3 (13.0)	1 (4.3)	1 (4.3)	1 (4.3)	0
Bacteraemia	1 (4.3)	0	0	1 (4.3)	0
Otitis media	1 (4.3)	0	1 (4.3)	0	0
Parainfluenzae virus infection	1 (4.3)	1 (4.3)	0	0	0
Viral upper respiratory tract infection	1 (4.3)	1 (4.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (4.3)	0	1 (4.3)	0	0
Radiation skin injury	1 (4.3)	0	1 (4.3)	0	0
Investigations					
-Total	14 (60.9)	2 (8.7)	0	2 (8.7)	10 (43.5)
White blood cell count decreased	10 (43.5)	0	0	2 (8.7)	8 (34.8)
Neutrophil count decreased	6 (26.1)	0	0	0	6 (26.1)
Alanine aminotransferase increased	2 (8.7)	0	0	2 (8.7)	0
Blood creatinine increased	1 (4.3)	1 (4.3)	0	0	0

Ethnicity: Hispanic or Latino

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (4.3)	0	0	0	1 (4.3)
Weight decreased	1 (4.3)	1 (4.3)	0	0	0
Weight increased	1 (4.3)	1 (4.3)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (30.4)	3 (13.0)	1 (4.3)	3 (13.0)	0
Decreased appetite	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Hyperphosphataemia	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Hyperuricaemia	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Hypokalaemia	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Fluid overload	1 (4.3)	0	1 (4.3)	0	0
Hypomagnesaemia	1 (4.3)	0	1 (4.3)	0	0
Hypophosphataemia	1 (4.3)	1 (4.3)	0	0	0
Tumour lysis syndrome	1 (4.3)	0	0	1 (4.3)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (8.7)	2 (8.7)	0	0	0
Arthralgia	1 (4.3)	1 (4.3)	0	0	0
Pain in jaw	1 (4.3)	1 (4.3)	0	0	0

Ethnicity: Hispanic or Latino

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	2 (8.7)	2 (8.7)	0	0	0
Headache	2 (8.7)	2 (8.7)	0	0	0
Product issues					
-Total	1 (4.3)	1 (4.3)	0	0	0
Device occlusion	1 (4.3)	1 (4.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (13.0)	2 (8.7)	1 (4.3)	0	0
Cough	1 (4.3)	1 (4.3)	0	0	0
Epistaxis	1 (4.3)	0	1 (4.3)	0	0
Nasal discomfort	1 (4.3)	1 (4.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (8.7)	2 (8.7)	0	0	0
Pruritus	1 (4.3)	1 (4.3)	0	0	0
Rash pruritic	1 (4.3)	1 (4.3)	0	0	0
Vascular disorders					
-Total	3 (13.0)	1 (4.3)	1 (4.3)	1 (4.3)	0

Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (4.3)	1 (4.3)	0	0	0
Hypotension	1 (4.3)	0	0	1 (4.3)	0
Phlebitis	1 (4.3)	0	1 (4.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176d
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Other

	All patients N=38				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (78.9)	3 (7.9)	4 (10.5)	11 (28.9)	12 (31.6)
Blood and lymphatic system disorders					
-Total	13 (34.2)	0	0	8 (21.1)	5 (13.2)
Anaemia	5 (13.2)	0	1 (2.6)	4 (10.5)	0
Febrile neutropenia	4 (10.5)	0	0	4 (10.5)	0
Neutropenia	3 (7.9)	0	0	1 (2.6)	2 (5.3)
Thrombocytopenia	2 (5.3)	0	0	1 (2.6)	1 (2.6)
Disseminated intravascular coagulation	1 (2.6)	0	0	0	1 (2.6)
Hypofibrinogenaemia	1 (2.6)	0	0	0	1 (2.6)
Lymphopenia	1 (2.6)	0	0	0	1 (2.6)

Ethnicity: Other

Primary system organ class Preferred term	All patients N=38 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pancytopenia	1 (2.6)	0	0	1 (2.6)	0
Cardiac disorders					
-Total	3 (7.9)	1 (2.6)	1 (2.6)	1 (2.6)	0
Bradycardia	1 (2.6)	0	1 (2.6)	0	0
Left ventricular dysfunction	1 (2.6)	0	0	1 (2.6)	0
Palpitations	1 (2.6)	1 (2.6)	0	0	0
Gastrointestinal disorders					
-Total	9 (23.7)	5 (13.2)	3 (7.9)	1 (2.6)	0
Nausea	5 (13.2)	4 (10.5)	1 (2.6)	0	0
Abdominal pain	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Diarrhoea	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Ascites	1 (2.6)	0	0	1 (2.6)	0
Constipation	1 (2.6)	1 (2.6)	0	0	0
Gingival discomfort	1 (2.6)	1 (2.6)	0	0	0
Vomiting	1 (2.6)	1 (2.6)	0	0	0
General disorders and administration site conditions					
-Total	10 (26.3)	3 (7.9)	6 (15.8)	0	1 (2.6)

Ethnicity: Other

Primary system organ class Preferred term	All patients N=38 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pyrexia	6 (15.8)	1 (2.6)	5 (13.2)	0	0
Catheter site pain	2 (5.3)	2 (5.3)	0	0	0
Device related thrombosis	1 (2.6)	0	1 (2.6)	0	0
Medical device pain	1 (2.6)	0	1 (2.6)	0	0
Multiple organ dysfunction syndrome	1 (2.6)	0	0	0	1 (2.6)
Oedema peripheral	1 (2.6)	1 (2.6)	0	0	0
Hepatobiliary disorders					
-Total	1 (2.6)	0	0	0	1 (2.6)
Hepatic failure	1 (2.6)	0	0	0	1 (2.6)
Infections and infestations					
-Total	4 (10.5)	0	1 (2.6)	2 (5.3)	1 (2.6)
Device related infection	2 (5.3)	0	1 (2.6)	1 (2.6)	0
Bronchitis	1 (2.6)	0	1 (2.6)	0	0
Necrotising fasciitis	1 (2.6)	0	0	1 (2.6)	0
Pneumonia	1 (2.6)	0	1 (2.6)	0	0
Staphylococcal infection	1 (2.6)	0	0	0	1 (2.6)
Injury, poisoning and procedural complications					

Ethnicity: Other

Primary system organ class Preferred term	All patients N=38 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (2.6)	1 (2.6)	0	0	0
Infusion related reaction	1 (2.6)	1 (2.6)	0	0	0
Investigations					
-Total	17 (44.7)	0	3 (7.9)	4 (10.5)	10 (26.3)
White blood cell count decreased	9 (23.7)	0	0	1 (2.6)	8 (21.1)
Alanine aminotransferase increased	5 (13.2)	1 (2.6)	2 (5.3)	1 (2.6)	1 (2.6)
Neutrophil count decreased	4 (10.5)	0	0	0	4 (10.5)
Platelet count decreased	4 (10.5)	0	1 (2.6)	2 (5.3)	1 (2.6)
Aspartate aminotransferase increased	3 (7.9)	1 (2.6)	1 (2.6)	0	1 (2.6)
Lymphocyte count decreased	3 (7.9)	0	0	1 (2.6)	2 (5.3)
C-reactive protein increased	2 (5.3)	0	2 (5.3)	0	0
International normalised ratio increased	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Activated partial thromboplastin time prolonged	1 (2.6)	0	1 (2.6)	0	0
Blood bilirubin increased	1 (2.6)	0	0	0	1 (2.6)
Blood lactic acid increased	1 (2.6)	0	1 (2.6)	0	0
Blood uric acid increased	1 (2.6)	1 (2.6)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=38 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lipase increased	1 (2.6)	0	0	0	1 (2.6)
Protein total decreased	1 (2.6)	0	0	1 (2.6)	0
Weight increased	1 (2.6)	1 (2.6)	0	0	0
Metabolism and nutrition disorders					
-Total	8 (21.1)	2 (5.3)	1 (2.6)	3 (7.9)	2 (5.3)
Hypokalaemia	3 (7.9)	0	0	1 (2.6)	2 (5.3)
Hypoglycaemia	2 (5.3)	0	1 (2.6)	1 (2.6)	0
Hypophosphataemia	2 (5.3)	2 (5.3)	0	0	0
Decreased appetite	1 (2.6)	0	1 (2.6)	0	0
Fluid overload	1 (2.6)	0	1 (2.6)	0	0
Hyperglycaemia	1 (2.6)	0	0	1 (2.6)	0
Hyperkalaemia	1 (2.6)	1 (2.6)	0	0	0
Hypermagnesaemia	1 (2.6)	1 (2.6)	0	0	0
Hypernatraemia	1 (2.6)	0	0	0	1 (2.6)
Hyperphosphataemia	1 (2.6)	1 (2.6)	0	0	0
Hypoalbuminaemia	1 (2.6)	0	1 (2.6)	0	0
Hypocalcaemia	1 (2.6)	1 (2.6)	0	0	0
Hypomagnesaemia	1 (2.6)	1 (2.6)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=38 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal and connective tissue disorders					
-Total	3 (7.9)	0	1 (2.6)	2 (5.3)	0
Myalgia	1 (2.6)	0	0	1 (2.6)	0
Pain in extremity	1 (2.6)	0	0	1 (2.6)	0
Pain in jaw	1 (2.6)	0	1 (2.6)	0	0
Nervous system disorders					
-Total	6 (15.8)	2 (5.3)	4 (10.5)	0	0
Headache	3 (7.9)	1 (2.6)	2 (5.3)	0	0
Dysgeusia	1 (2.6)	1 (2.6)	0	0	0
Hypotonia	1 (2.6)	0	1 (2.6)	0	0
Somnolence	1 (2.6)	0	1 (2.6)	0	0
Psychiatric disorders					
-Total	5 (13.2)	1 (2.6)	3 (7.9)	1 (2.6)	0
Anxiety	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Delirium	1 (2.6)	0	0	1 (2.6)	0
Depression	1 (2.6)	0	1 (2.6)	0	0
Insomnia	1 (2.6)	0	1 (2.6)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=38 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Irritability	1 (2.6)	1 (2.6)	0	0	0
Renal and urinary disorders					
-Total	1 (2.6)	0	1 (2.6)	0	0
Urinary retention	1 (2.6)	0	1 (2.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (15.8)	1 (2.6)	1 (2.6)	4 (10.5)	0
Hypoxia	3 (7.9)	0	0	3 (7.9)	0
Dyspnoea	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Tachypnoea	2 (5.3)	0	1 (2.6)	1 (2.6)	0
Epistaxis	1 (2.6)	0	0	1 (2.6)	0
Nasal congestion	1 (2.6)	1 (2.6)	0	0	0
Pleural effusion	1 (2.6)	0	0	1 (2.6)	0
Rhinitis allergic	1 (2.6)	1 (2.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (23.7)	7 (18.4)	1 (2.6)	1 (2.6)	0
Alopecia	2 (5.3)	2 (5.3)	0	0	0
Dermatitis acneiform	1 (2.6)	0	1 (2.6)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=38 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pruritus generalised	1 (2.6)	1 (2.6)	0	0	0
Rash	1 (2.6)	1 (2.6)	0	0	0
Rash erythematous	1 (2.6)	1 (2.6)	0	0	0
Rash macular	1 (2.6)	0	0	1 (2.6)	0
Skin haemorrhage	1 (2.6)	1 (2.6)	0	0	0
Skin ulcer	1 (2.6)	1 (2.6)	0	0	0
Vascular disorders					
-Total	3 (7.9)	0	0	3 (7.9)	0
Hypotension	2 (5.3)	0	0	2 (5.3)	0
Hypertension	1 (2.6)	0	0	1 (2.6)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176e
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Primary refractory

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (57.1)	0	0	1 (14.3)	3 (42.9)
Blood and lymphatic system disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)
Anaemia	1 (14.3)	0	1 (14.3)	0	0
Neutropenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0
Gastrointestinal disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Vomiting	1 (14.3)	1 (14.3)	0	0	0

Response status at study entry: Primary refractory

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	1 (14.3)	0	1 (14.3)	0	0
Pyrexia	1 (14.3)	0	1 (14.3)	0	0
Investigations					
-Total	2 (28.6)	0	0	0	2 (28.6)
Neutrophil count decreased	2 (28.6)	0	0	0	2 (28.6)
White blood cell count decreased	2 (28.6)	0	0	0	2 (28.6)
Metabolism and nutrition disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Hypokalaemia	1 (14.3)	1 (14.3)	0	0	0
Nervous system disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Dysgeusia	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	2 (28.6)	0	2 (28.6)	0	0
Depression	1 (14.3)	0	1 (14.3)	0	0
Insomnia	1 (14.3)	0	1 (14.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176e
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Relapsed disease

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	47 (87.0)	7 (13.0)	6 (11.1)	15 (27.8)	19 (35.2)
Blood and lymphatic system disorders					
-Total	18 (33.3)	0	1 (1.9)	11 (20.4)	6 (11.1)
Febrile neutropenia	9 (16.7)	0	1 (1.9)	8 (14.8)	0
Anaemia	6 (11.1)	0	1 (1.9)	5 (9.3)	0
Neutropenia	3 (5.6)	0	0	1 (1.9)	2 (3.7)
Thrombocytopenia	3 (5.6)	0	0	1 (1.9)	2 (3.7)
Disseminated intravascular coagulation	1 (1.9)	0	0	0	1 (1.9)
Hypofibrinogenaemia	1 (1.9)	0	0	0	1 (1.9)
Lymphopenia	1 (1.9)	0	0	0	1 (1.9)

Response status at study entry: Relapsed disease

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	1 (1.9)	0	0	1 (1.9)	0
Cardiac disorders					
-Total	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Bradycardia	1 (1.9)	0	1 (1.9)	0	0
Palpitations	1 (1.9)	1 (1.9)	0	0	0
Tachycardia	1 (1.9)	1 (1.9)	0	0	0
Eye disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Eye irritation	1 (1.9)	1 (1.9)	0	0	0
Gastrointestinal disorders					
-Total	16 (29.6)	8 (14.8)	7 (13.0)	1 (1.9)	0
Nausea	8 (14.8)	5 (9.3)	3 (5.6)	0	0
Diarrhoea	4 (7.4)	2 (3.7)	2 (3.7)	0	0
Abdominal pain	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Constipation	2 (3.7)	2 (3.7)	0	0	0
Vomiting	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Abdominal pain lower	1 (1.9)	1 (1.9)	0	0	0
Ascites	1 (1.9)	0	0	1 (1.9)	0

Response status at study entry: Relapsed disease

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingival discomfort	1 (1.9)	1 (1.9)	0	0	0
Haematochezia	1 (1.9)	1 (1.9)	0	0	0
Oral mucosal blistering	1 (1.9)	1 (1.9)	0	0	0
Pancreatic failure	1 (1.9)	0	1 (1.9)	0	0
General disorders and administration site conditions					
-Total	11 (20.4)	3 (5.6)	7 (13.0)	0	1 (1.9)
Pyrexia	5 (9.3)	1 (1.9)	4 (7.4)	0	0
Catheter site pain	2 (3.7)	2 (3.7)	0	0	0
Chills	1 (1.9)	0	1 (1.9)	0	0
Device related thrombosis	1 (1.9)	0	1 (1.9)	0	0
Medical device pain	1 (1.9)	0	1 (1.9)	0	0
Multiple organ dysfunction syndrome	1 (1.9)	0	0	0	1 (1.9)
Oedema peripheral	1 (1.9)	1 (1.9)	0	0	0
Pain	1 (1.9)	0	1 (1.9)	0	0
Hepatobiliary disorders					
-Total	1 (1.9)	0	0	0	1 (1.9)
Hepatic failure	1 (1.9)	0	0	0	1 (1.9)

Response status at study entry: Relapsed disease

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Hypogammaglobulinaemia	1 (1.9)	1 (1.9)	0	0	0
Infections and infestations					
-Total	7 (13.0)	1 (1.9)	2 (3.7)	3 (5.6)	1 (1.9)
Device related infection	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Bronchitis	1 (1.9)	0	1 (1.9)	0	0
Necrotising fasciitis	1 (1.9)	0	0	1 (1.9)	0
Otitis media	1 (1.9)	0	1 (1.9)	0	0
Parainfluenzae virus infection	1 (1.9)	1 (1.9)	0	0	0
Pneumonia	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal infection	1 (1.9)	0	0	0	1 (1.9)
Viral upper respiratory tract infection	1 (1.9)	1 (1.9)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Infusion related reaction	1 (1.9)	1 (1.9)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Radiation skin injury	1 (1.9)	0	1 (1.9)	0	0
Investigations					
-Total	29 (53.7)	2 (3.7)	3 (5.6)	6 (11.1)	18 (33.3)
White blood cell count decreased	17 (31.5)	0	0	3 (5.6)	14 (25.9)
Neutrophil count decreased	8 (14.8)	0	0	0	8 (14.8)
Alanine aminotransferase increased	7 (13.0)	1 (1.9)	2 (3.7)	3 (5.6)	1 (1.9)
Lymphocyte count decreased	4 (7.4)	0	0	1 (1.9)	3 (5.6)
Platelet count decreased	4 (7.4)	0	1 (1.9)	2 (3.7)	1 (1.9)
Aspartate aminotransferase increased	3 (5.6)	1 (1.9)	1 (1.9)	0	1 (1.9)
C-reactive protein increased	2 (3.7)	0	2 (3.7)	0	0
International normalised ratio increased	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Weight increased	2 (3.7)	2 (3.7)	0	0	0
Activated partial thromboplastin time prolonged	1 (1.9)	0	1 (1.9)	0	0
Blood bilirubin increased	1 (1.9)	0	0	0	1 (1.9)
Blood creatinine increased	1 (1.9)	1 (1.9)	0	0	0
Blood lactic acid increased	1 (1.9)	0	1 (1.9)	0	0

Response status at study entry: Relapsed disease

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood uric acid increased	1 (1.9)	1 (1.9)	0	0	0
Lipase increased	1 (1.9)	0	0	0	1 (1.9)
Protein total decreased	1 (1.9)	0	0	1 (1.9)	0
Weight decreased	1 (1.9)	1 (1.9)	0	0	0
Metabolism and nutrition disorders					
-Total	14 (25.9)	4 (7.4)	2 (3.7)	6 (11.1)	2 (3.7)
Hypokalaemia	4 (7.4)	0	0	2 (3.7)	2 (3.7)
Decreased appetite	3 (5.6)	1 (1.9)	2 (3.7)	0	0
Hyperphosphataemia	3 (5.6)	2 (3.7)	1 (1.9)	0	0
Hypophosphataemia	3 (5.6)	3 (5.6)	0	0	0
Fluid overload	2 (3.7)	0	2 (3.7)	0	0
Hyperuricaemia	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Hypoglycaemia	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Hypomagnesaemia	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Hyperglycaemia	1 (1.9)	0	0	1 (1.9)	0
Hyperkalaemia	1 (1.9)	1 (1.9)	0	0	0
Hypermagnesaemia	1 (1.9)	1 (1.9)	0	0	0
Hypernatraemia	1 (1.9)	0	0	0	1 (1.9)

Response status at study entry: Relapsed disease

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	1 (1.9)	0	1 (1.9)	0	0
Hypocalcaemia	1 (1.9)	1 (1.9)	0	0	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (9.3)	2 (3.7)	1 (1.9)	2 (3.7)	0
Pain in jaw	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Arthralgia	1 (1.9)	1 (1.9)	0	0	0
Myalgia	1 (1.9)	0	0	1 (1.9)	0
Pain in extremity	1 (1.9)	0	0	1 (1.9)	0
Nervous system disorders					
-Total	7 (13.0)	3 (5.6)	4 (7.4)	0	0
Headache	5 (9.3)	3 (5.6)	2 (3.7)	0	0
Hypotonia	1 (1.9)	0	1 (1.9)	0	0
Somnolence	1 (1.9)	0	1 (1.9)	0	0
Product issues					
-Total	1 (1.9)	1 (1.9)	0	0	0
Device occlusion	1 (1.9)	1 (1.9)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	3 (5.6)	1 (1.9)	1 (1.9)	1 (1.9)	0
Anxiety	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Delirium	1 (1.9)	0	0	1 (1.9)	0
Irritability	1 (1.9)	1 (1.9)	0	0	0
Renal and urinary disorders					
-Total	1 (1.9)	0	1 (1.9)	0	0
Urinary retention	1 (1.9)	0	1 (1.9)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (16.7)	3 (5.6)	2 (3.7)	4 (7.4)	0
Hypoxia	3 (5.6)	0	0	3 (5.6)	0
Dyspnoea	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Epistaxis	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Tachypnoea	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Cough	1 (1.9)	1 (1.9)	0	0	0
Nasal congestion	1 (1.9)	1 (1.9)	0	0	0
Nasal discomfort	1 (1.9)	1 (1.9)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	1 (1.9)	0	0	1 (1.9)	0
Rhinitis allergic	1 (1.9)	1 (1.9)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (20.4)	9 (16.7)	1 (1.9)	1 (1.9)	0
Alopecia	2 (3.7)	2 (3.7)	0	0	0
Dermatitis acneiform	1 (1.9)	0	1 (1.9)	0	0
Pruritus	1 (1.9)	1 (1.9)	0	0	0
Pruritus generalised	1 (1.9)	1 (1.9)	0	0	0
Rash	1 (1.9)	1 (1.9)	0	0	0
Rash erythematous	1 (1.9)	1 (1.9)	0	0	0
Rash macular	1 (1.9)	0	0	1 (1.9)	0
Rash pruritic	1 (1.9)	1 (1.9)	0	0	0
Skin haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Skin ulcer	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					
-Total	6 (11.1)	1 (1.9)	1 (1.9)	4 (7.4)	0
Hypotension	3 (5.6)	0	0	3 (5.6)	0

Response status at study entry: Relapsed disease

	All patients N=54				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Phlebitis	1 (1.9)	0	1 (1.9)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176f
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	0	1 (50.0)	0
Investigations					
-Total	1 (50.0)	0	1 (50.0)	0	0
Alanine aminotransferase increased	1 (50.0)	0	1 (50.0)	0	0
Aspartate aminotransferase increased	1 (50.0)	1 (50.0)	0	0	0
Blood uric acid increased	1 (50.0)	1 (50.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Hyperglycaemia	1 (50.0)	0	0	1 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176f
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (84.7)	7 (11.9)	6 (10.2)	15 (25.4)	22 (37.3)
Blood and lymphatic system disorders					
-Total	19 (32.2)	0	1 (1.7)	11 (18.6)	7 (11.9)
Febrile neutropenia	9 (15.3)	0	1 (1.7)	8 (13.6)	0
Anaemia	7 (11.9)	0	2 (3.4)	5 (8.5)	0
Neutropenia	4 (6.8)	0	0	1 (1.7)	3 (5.1)
Thrombocytopenia	3 (5.1)	0	0	1 (1.7)	2 (3.4)
Disseminated intravascular coagulation	1 (1.7)	0	0	0	1 (1.7)
Hypofibrinogenaemia	1 (1.7)	0	0	0	1 (1.7)
Lymphopenia	1 (1.7)	0	0	0	1 (1.7)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	1 (1.7)	0	0	1 (1.7)	0
Cardiac disorders					
-Total	4 (6.8)	2 (3.4)	1 (1.7)	1 (1.7)	0
Bradycardia	1 (1.7)	0	1 (1.7)	0	0
Left ventricular dysfunction	1 (1.7)	0	0	1 (1.7)	0
Palpitations	1 (1.7)	1 (1.7)	0	0	0
Tachycardia	1 (1.7)	1 (1.7)	0	0	0
Eye disorders					
-Total	1 (1.7)	1 (1.7)	0	0	0
Eye irritation	1 (1.7)	1 (1.7)	0	0	0
Gastrointestinal disorders					
-Total	17 (28.8)	9 (15.3)	7 (11.9)	1 (1.7)	0
Nausea	8 (13.6)	5 (8.5)	3 (5.1)	0	0
Diarrhoea	4 (6.8)	2 (3.4)	2 (3.4)	0	0
Vomiting	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Abdominal pain	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Constipation	2 (3.4)	2 (3.4)	0	0	0
Abdominal pain lower	1 (1.7)	1 (1.7)	0	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	1 (1.7)	0	0	1 (1.7)	0
Gingival discomfort	1 (1.7)	1 (1.7)	0	0	0
Haematochezia	1 (1.7)	1 (1.7)	0	0	0
Oral mucosal blistering	1 (1.7)	1 (1.7)	0	0	0
Pancreatic failure	1 (1.7)	0	1 (1.7)	0	0
General disorders and administration site conditions					
-Total	12 (20.3)	3 (5.1)	8 (13.6)	0	1 (1.7)
Pyrexia	6 (10.2)	1 (1.7)	5 (8.5)	0	0
Catheter site pain	2 (3.4)	2 (3.4)	0	0	0
Chills	1 (1.7)	0	1 (1.7)	0	0
Device related thrombosis	1 (1.7)	0	1 (1.7)	0	0
Medical device pain	1 (1.7)	0	1 (1.7)	0	0
Multiple organ dysfunction syndrome	1 (1.7)	0	0	0	1 (1.7)
Oedema peripheral	1 (1.7)	1 (1.7)	0	0	0
Pain	1 (1.7)	0	1 (1.7)	0	0
Hepatobiliary disorders					
-Total	1 (1.7)	0	0	0	1 (1.7)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic failure	1 (1.7)	0	0	0	1 (1.7)
Immune system disorders					
-Total	1 (1.7)	1 (1.7)	0	0	0
Hypogammaglobulinaemia	1 (1.7)	1 (1.7)	0	0	0
Infections and infestations					
-Total	7 (11.9)	1 (1.7)	2 (3.4)	3 (5.1)	1 (1.7)
Device related infection	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Bronchitis	1 (1.7)	0	1 (1.7)	0	0
Necrotising fasciitis	1 (1.7)	0	0	1 (1.7)	0
Otitis media	1 (1.7)	0	1 (1.7)	0	0
Parainfluenzae virus infection	1 (1.7)	1 (1.7)	0	0	0
Pneumonia	1 (1.7)	0	1 (1.7)	0	0
Staphylococcal infection	1 (1.7)	0	0	0	1 (1.7)
Viral upper respiratory tract infection	1 (1.7)	1 (1.7)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (3.4)	1 (1.7)	1 (1.7)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infusion related reaction	1 (1.7)	1 (1.7)	0	0	0
Radiation skin injury	1 (1.7)	0	1 (1.7)	0	0
Investigations					
-Total	30 (50.8)	2 (3.4)	2 (3.4)	6 (10.2)	20 (33.9)
White blood cell count decreased	19 (32.2)	0	0	3 (5.1)	16 (27.1)
Neutrophil count decreased	10 (16.9)	0	0	0	10 (16.9)
Alanine aminotransferase increased	6 (10.2)	1 (1.7)	1 (1.7)	3 (5.1)	1 (1.7)
Lymphocyte count decreased	4 (6.8)	0	0	1 (1.7)	3 (5.1)
Platelet count decreased	4 (6.8)	0	1 (1.7)	2 (3.4)	1 (1.7)
Aspartate aminotransferase increased	2 (3.4)	0	1 (1.7)	0	1 (1.7)
C-reactive protein increased	2 (3.4)	0	2 (3.4)	0	0
International normalised ratio increased	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Weight increased	2 (3.4)	2 (3.4)	0	0	0
Activated partial thromboplastin time prolonged	1 (1.7)	0	1 (1.7)	0	0
Blood bilirubin increased	1 (1.7)	0	0	0	1 (1.7)
Blood creatinine increased	1 (1.7)	1 (1.7)	0	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactic acid increased	1 (1.7)	0	1 (1.7)	0	0
Lipase increased	1 (1.7)	0	0	0	1 (1.7)
Protein total decreased	1 (1.7)	0	0	1 (1.7)	0
Weight decreased	1 (1.7)	1 (1.7)	0	0	0
Metabolism and nutrition disorders					
-Total	14 (23.7)	5 (8.5)	2 (3.4)	5 (8.5)	2 (3.4)
Hypokalaemia	5 (8.5)	1 (1.7)	0	2 (3.4)	2 (3.4)
Decreased appetite	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Hyperphosphataemia	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Hypophosphataemia	3 (5.1)	3 (5.1)	0	0	0
Fluid overload	2 (3.4)	0	2 (3.4)	0	0
Hyperuricaemia	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Hypoglycaemia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Hypomagnesaemia	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Hyperkalaemia	1 (1.7)	1 (1.7)	0	0	0
Hypermagnesaemia	1 (1.7)	1 (1.7)	0	0	0
Hypernatraemia	1 (1.7)	0	0	0	1 (1.7)
Hypoalbuminaemia	1 (1.7)	0	1 (1.7)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	1 (1.7)	1 (1.7)	0	0	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (8.5)	2 (3.4)	1 (1.7)	2 (3.4)	0
Pain in jaw	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Arthralgia	1 (1.7)	1 (1.7)	0	0	0
Myalgia	1 (1.7)	0	0	1 (1.7)	0
Pain in extremity	1 (1.7)	0	0	1 (1.7)	0
Nervous system disorders					
-Total	8 (13.6)	4 (6.8)	4 (6.8)	0	0
Headache	5 (8.5)	3 (5.1)	2 (3.4)	0	0
Dysgeusia	1 (1.7)	1 (1.7)	0	0	0
Hypotonia	1 (1.7)	0	1 (1.7)	0	0
Somnolence	1 (1.7)	0	1 (1.7)	0	0
Product issues					
-Total	1 (1.7)	1 (1.7)	0	0	0
Device occlusion	1 (1.7)	1 (1.7)	0	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	5 (8.5)	1 (1.7)	3 (5.1)	1 (1.7)	0
Anxiety	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Delirium	1 (1.7)	0	0	1 (1.7)	0
Depression	1 (1.7)	0	1 (1.7)	0	0
Insomnia	1 (1.7)	0	1 (1.7)	0	0
Irritability	1 (1.7)	1 (1.7)	0	0	0
Renal and urinary disorders					
-Total	1 (1.7)	0	1 (1.7)	0	0
Urinary retention	1 (1.7)	0	1 (1.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (15.3)	3 (5.1)	2 (3.4)	4 (6.8)	0
Hypoxia	3 (5.1)	0	0	3 (5.1)	0
Dyspnoea	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Epistaxis	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Tachypnoea	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Cough	1 (1.7)	1 (1.7)	0	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	1 (1.7)	1 (1.7)	0	0	0
Nasal discomfort	1 (1.7)	1 (1.7)	0	0	0
Pleural effusion	1 (1.7)	0	0	1 (1.7)	0
Rhinitis allergic	1 (1.7)	1 (1.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (18.6)	9 (15.3)	1 (1.7)	1 (1.7)	0
Alopecia	2 (3.4)	2 (3.4)	0	0	0
Dermatitis acneiform	1 (1.7)	0	1 (1.7)	0	0
Pruritus	1 (1.7)	1 (1.7)	0	0	0
Pruritus generalised	1 (1.7)	1 (1.7)	0	0	0
Rash	1 (1.7)	1 (1.7)	0	0	0
Rash erythematous	1 (1.7)	1 (1.7)	0	0	0
Rash macular	1 (1.7)	0	0	1 (1.7)	0
Rash pruritic	1 (1.7)	1 (1.7)	0	0	0
Skin haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Skin ulcer	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (10.2)	1 (1.7)	1 (1.7)	4 (6.8)	0
Hypotension	3 (5.1)	0	0	3 (5.1)	0
Hypertension	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Phlebitis	1 (1.7)	0	1 (1.7)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176g
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	0	3 (100)
Blood and lymphatic system disorders					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Anaemia	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Febrile neutropenia	1 (33.3)	0	0	1 (33.3)	0
Lymphopenia	1 (33.3)	0	0	0	1 (33.3)
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Cardiac disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Bradycardia	1 (33.3)	0	1 (33.3)	0	0
Gastrointestinal disorders					

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (33.3)	1 (33.3)	0	0	0
Nausea	1 (33.3)	1 (33.3)	0	0	0
General disorders and administration site conditions					
-Total	1 (33.3)	0	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Infections and infestations					
-Total	1 (33.3)	0	1 (33.3)	0	0
Pneumonia	1 (33.3)	0	1 (33.3)	0	0
Investigations					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0	0	0
Blood lactic acid increased	1 (33.3)	0	1 (33.3)	0	0
C-reactive protein increased	1 (33.3)	0	1 (33.3)	0	0
Neutrophil count decreased	1 (33.3)	0	0	0	1 (33.3)
Platelet count decreased	1 (33.3)	0	0	1 (33.3)	0
Protein total decreased	1 (33.3)	0	0	1 (33.3)	0
White blood cell count decreased	1 (33.3)	0	0	0	1 (33.3)

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Fluid overload	1 (33.3)	0	1 (33.3)	0	0
Hypermagnesaemia	1 (33.3)	1 (33.3)	0	0	0
Hypokalaemia	1 (33.3)	0	0	1 (33.3)	0
Nervous system disorders					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Headache	1 (33.3)	1 (33.3)	0	0	0
Hypotonia	1 (33.3)	0	1 (33.3)	0	0
Psychiatric disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Insomnia	1 (33.3)	0	1 (33.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Hypoxia	1 (33.3)	0	0	1 (33.3)	0
Tachypnoea	1 (33.3)	0	0	1 (33.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176g
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: No

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (82.8)	7 (12.1)	6 (10.3)	16 (27.6)	19 (32.8)
Blood and lymphatic system disorders					
-Total	16 (27.6)	0	1 (1.7)	10 (17.2)	5 (8.6)
Febrile neutropenia	8 (13.8)	0	1 (1.7)	7 (12.1)	0
Anaemia	5 (8.6)	0	1 (1.7)	4 (6.9)	0
Neutropenia	3 (5.2)	0	0	1 (1.7)	2 (3.4)
Thrombocytopenia	3 (5.2)	0	0	1 (1.7)	2 (3.4)
Disseminated intravascular coagulation	1 (1.7)	0	0	0	1 (1.7)
Hypofibrinogenaemia	1 (1.7)	0	0	0	1 (1.7)
Pancytopenia	1 (1.7)	0	0	1 (1.7)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	3 (5.2)	2 (3.4)	0	1 (1.7)	0
Left ventricular dysfunction	1 (1.7)	0	0	1 (1.7)	0
Palpitations	1 (1.7)	1 (1.7)	0	0	0
Tachycardia	1 (1.7)	1 (1.7)	0	0	0
Eye disorders					
-Total	1 (1.7)	1 (1.7)	0	0	0
Eye irritation	1 (1.7)	1 (1.7)	0	0	0
Gastrointestinal disorders					
-Total	16 (27.6)	8 (13.8)	7 (12.1)	1 (1.7)	0
Nausea	7 (12.1)	4 (6.9)	3 (5.2)	0	0
Diarrhoea	4 (6.9)	2 (3.4)	2 (3.4)	0	0
Vomiting	3 (5.2)	2 (3.4)	1 (1.7)	0	0
Abdominal pain	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Constipation	2 (3.4)	2 (3.4)	0	0	0
Abdominal pain lower	1 (1.7)	1 (1.7)	0	0	0
Ascites	1 (1.7)	0	0	1 (1.7)	0
Gingival discomfort	1 (1.7)	1 (1.7)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematochezia	1 (1.7)	1 (1.7)	0	0	0
Oral mucosal blistering	1 (1.7)	1 (1.7)	0	0	0
Pancreatic failure	1 (1.7)	0	1 (1.7)	0	0
General disorders and administration site conditions					
-Total	11 (19.0)	3 (5.2)	7 (12.1)	0	1 (1.7)
Pyrexia	5 (8.6)	1 (1.7)	4 (6.9)	0	0
Catheter site pain	2 (3.4)	2 (3.4)	0	0	0
Chills	1 (1.7)	0	1 (1.7)	0	0
Device related thrombosis	1 (1.7)	0	1 (1.7)	0	0
Medical device pain	1 (1.7)	0	1 (1.7)	0	0
Multiple organ dysfunction syndrome	1 (1.7)	0	0	0	1 (1.7)
Oedema peripheral	1 (1.7)	1 (1.7)	0	0	0
Pain	1 (1.7)	0	1 (1.7)	0	0
Hepatobiliary disorders					
-Total	1 (1.7)	0	0	0	1 (1.7)
Hepatic failure	1 (1.7)	0	0	0	1 (1.7)
Immune system disorders					

Mixed-lineage leukemia rearrangement: No

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.7)	1 (1.7)	0	0	0
Hypogammaglobulinaemia	1 (1.7)	1 (1.7)	0	0	0
Infections and infestations					
-Total	6 (10.3)	1 (1.7)	1 (1.7)	3 (5.2)	1 (1.7)
Device related infection	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Bronchitis	1 (1.7)	0	1 (1.7)	0	0
Necrotising fasciitis	1 (1.7)	0	0	1 (1.7)	0
Otitis media	1 (1.7)	0	1 (1.7)	0	0
Parainfluenzae virus infection	1 (1.7)	1 (1.7)	0	0	0
Staphylococcal infection	1 (1.7)	0	0	0	1 (1.7)
Viral upper respiratory tract infection	1 (1.7)	1 (1.7)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Infusion related reaction	1 (1.7)	1 (1.7)	0	0	0
Radiation skin injury	1 (1.7)	0	1 (1.7)	0	0
Investigations					

Mixed-lineage leukemia rearrangement: No

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	29 (50.0)	2 (3.4)	3 (5.2)	5 (8.6)	19 (32.8)
White blood cell count decreased	18 (31.0)	0	0	3 (5.2)	15 (25.9)
Neutrophil count decreased	9 (15.5)	0	0	0	9 (15.5)
Alanine aminotransferase increased	6 (10.3)	0	2 (3.4)	3 (5.2)	1 (1.7)
Lymphocyte count decreased	4 (6.9)	0	0	1 (1.7)	3 (5.2)
Aspartate aminotransferase increased	3 (5.2)	1 (1.7)	1 (1.7)	0	1 (1.7)
Platelet count decreased	3 (5.2)	0	1 (1.7)	1 (1.7)	1 (1.7)
International normalised ratio increased	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Weight increased	2 (3.4)	2 (3.4)	0	0	0
Activated partial thromboplastin time prolonged	1 (1.7)	0	1 (1.7)	0	0
Blood bilirubin increased	1 (1.7)	0	0	0	1 (1.7)
Blood creatinine increased	1 (1.7)	1 (1.7)	0	0	0
Blood uric acid increased	1 (1.7)	1 (1.7)	0	0	0
C-reactive protein increased	1 (1.7)	0	1 (1.7)	0	0
Lipase increased	1 (1.7)	0	0	0	1 (1.7)
Weight decreased	1 (1.7)	1 (1.7)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	14 (24.1)	5 (8.6)	2 (3.4)	5 (8.6)	2 (3.4)
Hypokalaemia	4 (6.9)	1 (1.7)	0	1 (1.7)	2 (3.4)
Decreased appetite	3 (5.2)	1 (1.7)	2 (3.4)	0	0
Hyperphosphataemia	3 (5.2)	2 (3.4)	1 (1.7)	0	0
Hypophosphataemia	3 (5.2)	3 (5.2)	0	0	0
Hyperuricaemia	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Hypoglycaemia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Hypomagnesaemia	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Fluid overload	1 (1.7)	0	1 (1.7)	0	0
Hyperglycaemia	1 (1.7)	0	0	1 (1.7)	0
Hyperkalaemia	1 (1.7)	1 (1.7)	0	0	0
Hypernatraemia	1 (1.7)	0	0	0	1 (1.7)
Hypoalbuminaemia	1 (1.7)	0	1 (1.7)	0	0
Hypocalcaemia	1 (1.7)	1 (1.7)	0	0	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0
Musculoskeletal and connective tissue disorders					

Mixed-lineage leukemia rearrangement: No

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (8.6)	2 (3.4)	1 (1.7)	2 (3.4)	0
Pain in jaw	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Arthralgia	1 (1.7)	1 (1.7)	0	0	0
Myalgia	1 (1.7)	0	0	1 (1.7)	0
Pain in extremity	1 (1.7)	0	0	1 (1.7)	0
Nervous system disorders					
-Total	6 (10.3)	3 (5.2)	3 (5.2)	0	0
Headache	4 (6.9)	2 (3.4)	2 (3.4)	0	0
Dysgeusia	1 (1.7)	1 (1.7)	0	0	0
Somnolence	1 (1.7)	0	1 (1.7)	0	0
Product issues					
-Total	1 (1.7)	1 (1.7)	0	0	0
Device occlusion	1 (1.7)	1 (1.7)	0	0	0
Psychiatric disorders					
-Total	4 (6.9)	1 (1.7)	2 (3.4)	1 (1.7)	0
Anxiety	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Delirium	1 (1.7)	0	0	1 (1.7)	0
Depression	1 (1.7)	0	1 (1.7)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	1 (1.7)	1 (1.7)	0	0	0
Renal and urinary disorders					
-Total	1 (1.7)	0	1 (1.7)	0	0
Urinary retention	1 (1.7)	0	1 (1.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (13.8)	3 (5.2)	2 (3.4)	3 (5.2)	0
Dyspnoea	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Epistaxis	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Hypoxia	2 (3.4)	0	0	2 (3.4)	0
Cough	1 (1.7)	1 (1.7)	0	0	0
Nasal congestion	1 (1.7)	1 (1.7)	0	0	0
Nasal discomfort	1 (1.7)	1 (1.7)	0	0	0
Pleural effusion	1 (1.7)	0	0	1 (1.7)	0
Rhinitis allergic	1 (1.7)	1 (1.7)	0	0	0
Tachypnoea	1 (1.7)	0	1 (1.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (19.0)	9 (15.5)	1 (1.7)	1 (1.7)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=58				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alopecia	2 (3.4)	2 (3.4)	0	0	0
Dermatitis acneiform	1 (1.7)	0	1 (1.7)	0	0
Pruritus	1 (1.7)	1 (1.7)	0	0	0
Pruritus generalised	1 (1.7)	1 (1.7)	0	0	0
Rash	1 (1.7)	1 (1.7)	0	0	0
Rash erythematous	1 (1.7)	1 (1.7)	0	0	0
Rash macular	1 (1.7)	0	0	1 (1.7)	0
Rash pruritic	1 (1.7)	1 (1.7)	0	0	0
Skin haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Skin ulcer	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					
-Total	6 (10.3)	1 (1.7)	1 (1.7)	4 (6.9)	0
Hypotension	3 (5.2)	0	0	3 (5.2)	0
Hypertension	2 (3.4)	1 (1.7)	0	1 (1.7)	0
Phlebitis	1 (1.7)	0	1 (1.7)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176h
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Blood and lymphatic system disorders					
-Total	1 (100)	0	0	1 (100)	0
Febrile neutropenia	1 (100)	0	0	1 (100)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176h
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (83.3)	7 (11.7)	6 (10.0)	15 (25.0)	22 (36.7)
Blood and lymphatic system disorders					
-Total	18 (30.0)	0	1 (1.7)	10 (16.7)	7 (11.7)
Febrile neutropenia	8 (13.3)	0	1 (1.7)	7 (11.7)	0
Anaemia	7 (11.7)	0	2 (3.3)	5 (8.3)	0
Neutropenia	4 (6.7)	0	0	1 (1.7)	3 (5.0)
Thrombocytopenia	3 (5.0)	0	0	1 (1.7)	2 (3.3)
Disseminated intravascular coagulation	1 (1.7)	0	0	0	1 (1.7)
Hypofibrinogenaemia	1 (1.7)	0	0	0	1 (1.7)
Lymphopenia	1 (1.7)	0	0	0	1 (1.7)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pancytopenia	1 (1.7)	0	0	1 (1.7)	0
Cardiac disorders					
-Total	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Bradycardia	1 (1.7)	0	1 (1.7)	0	0
Left ventricular dysfunction	1 (1.7)	0	0	1 (1.7)	0
Palpitations	1 (1.7)	1 (1.7)	0	0	0
Tachycardia	1 (1.7)	1 (1.7)	0	0	0
Eye disorders					
-Total	1 (1.7)	1 (1.7)	0	0	0
Eye irritation	1 (1.7)	1 (1.7)	0	0	0
Gastrointestinal disorders					
-Total	17 (28.3)	9 (15.0)	7 (11.7)	1 (1.7)	0
Nausea	8 (13.3)	5 (8.3)	3 (5.0)	0	0
Diarrhoea	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Vomiting	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Abdominal pain	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Constipation	2 (3.3)	2 (3.3)	0	0	0
Abdominal pain lower	1 (1.7)	1 (1.7)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ascites	1 (1.7)	0	0	1 (1.7)	0
Gingival discomfort	1 (1.7)	1 (1.7)	0	0	0
Haematochezia	1 (1.7)	1 (1.7)	0	0	0
Oral mucosal blistering	1 (1.7)	1 (1.7)	0	0	0
Pancreatic failure	1 (1.7)	0	1 (1.7)	0	0
General disorders and administration site conditions					
-Total	12 (20.0)	3 (5.0)	8 (13.3)	0	1 (1.7)
Pyrexia	6 (10.0)	1 (1.7)	5 (8.3)	0	0
Catheter site pain	2 (3.3)	2 (3.3)	0	0	0
Chills	1 (1.7)	0	1 (1.7)	0	0
Device related thrombosis	1 (1.7)	0	1 (1.7)	0	0
Medical device pain	1 (1.7)	0	1 (1.7)	0	0
Multiple organ dysfunction syndrome	1 (1.7)	0	0	0	1 (1.7)
Oedema peripheral	1 (1.7)	1 (1.7)	0	0	0
Pain	1 (1.7)	0	1 (1.7)	0	0
Hepatobiliary disorders					
-Total	1 (1.7)	0	0	0	1 (1.7)

Hypodiploidy: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic failure	1 (1.7)	0	0	0	1 (1.7)
Immune system disorders					
-Total	1 (1.7)	1 (1.7)	0	0	0
Hypogammaglobulinaemia	1 (1.7)	1 (1.7)	0	0	0
Infections and infestations					
-Total	7 (11.7)	1 (1.7)	2 (3.3)	3 (5.0)	1 (1.7)
Device related infection	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Bronchitis	1 (1.7)	0	1 (1.7)	0	0
Necrotising fasciitis	1 (1.7)	0	0	1 (1.7)	0
Otitis media	1 (1.7)	0	1 (1.7)	0	0
Parainfluenzae virus infection	1 (1.7)	1 (1.7)	0	0	0
Pneumonia	1 (1.7)	0	1 (1.7)	0	0
Staphylococcal infection	1 (1.7)	0	0	0	1 (1.7)
Viral upper respiratory tract infection	1 (1.7)	1 (1.7)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (3.3)	1 (1.7)	1 (1.7)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infusion related reaction	1 (1.7)	1 (1.7)	0	0	0
Radiation skin injury	1 (1.7)	0	1 (1.7)	0	0
Investigations					
-Total	31 (51.7)	2 (3.3)	3 (5.0)	6 (10.0)	20 (33.3)
White blood cell count decreased	19 (31.7)	0	0	3 (5.0)	16 (26.7)
Neutrophil count decreased	10 (16.7)	0	0	0	10 (16.7)
Alanine aminotransferase increased	7 (11.7)	1 (1.7)	2 (3.3)	3 (5.0)	1 (1.7)
Lymphocyte count decreased	4 (6.7)	0	0	1 (1.7)	3 (5.0)
Platelet count decreased	4 (6.7)	0	1 (1.7)	2 (3.3)	1 (1.7)
Aspartate aminotransferase increased	3 (5.0)	1 (1.7)	1 (1.7)	0	1 (1.7)
C-reactive protein increased	2 (3.3)	0	2 (3.3)	0	0
International normalised ratio increased	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Weight increased	2 (3.3)	2 (3.3)	0	0	0
Activated partial thromboplastin time prolonged	1 (1.7)	0	1 (1.7)	0	0
Blood bilirubin increased	1 (1.7)	0	0	0	1 (1.7)
Blood creatinine increased	1 (1.7)	1 (1.7)	0	0	0

Hypodiploidy: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactic acid increased	1 (1.7)	0	1 (1.7)	0	0
Blood uric acid increased	1 (1.7)	1 (1.7)	0	0	0
Lipase increased	1 (1.7)	0	0	0	1 (1.7)
Protein total decreased	1 (1.7)	0	0	1 (1.7)	0
Weight decreased	1 (1.7)	1 (1.7)	0	0	0
Metabolism and nutrition disorders					
-Total	15 (25.0)	5 (8.3)	2 (3.3)	6 (10.0)	2 (3.3)
Hypokalaemia	5 (8.3)	1 (1.7)	0	2 (3.3)	2 (3.3)
Decreased appetite	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Hyperphosphataemia	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Hypophosphataemia	3 (5.0)	3 (5.0)	0	0	0
Fluid overload	2 (3.3)	0	2 (3.3)	0	0
Hyperuricaemia	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Hypoglycaemia	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Hypomagnesaemia	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Hyperglycaemia	1 (1.7)	0	0	1 (1.7)	0
Hyperkalaemia	1 (1.7)	1 (1.7)	0	0	0
Hypermagnesaemia	1 (1.7)	1 (1.7)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypernatraemia	1 (1.7)	0	0	0	1 (1.7)
Hypoalbuminaemia	1 (1.7)	0	1 (1.7)	0	0
Hypocalcaemia	1 (1.7)	1 (1.7)	0	0	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (8.3)	2 (3.3)	1 (1.7)	2 (3.3)	0
Pain in jaw	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Arthralgia	1 (1.7)	1 (1.7)	0	0	0
Myalgia	1 (1.7)	0	0	1 (1.7)	0
Pain in extremity	1 (1.7)	0	0	1 (1.7)	0
Nervous system disorders					
-Total	8 (13.3)	4 (6.7)	4 (6.7)	0	0
Headache	5 (8.3)	3 (5.0)	2 (3.3)	0	0
Dysgeusia	1 (1.7)	1 (1.7)	0	0	0
Hypotonia	1 (1.7)	0	1 (1.7)	0	0
Somnolence	1 (1.7)	0	1 (1.7)	0	0
Product issues					

Hypodiploidy: No

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.7)	1 (1.7)	0	0	0
Device occlusion	1 (1.7)	1 (1.7)	0	0	0
Psychiatric disorders					
-Total	5 (8.3)	1 (1.7)	3 (5.0)	1 (1.7)	0
Anxiety	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Delirium	1 (1.7)	0	0	1 (1.7)	0
Depression	1 (1.7)	0	1 (1.7)	0	0
Insomnia	1 (1.7)	0	1 (1.7)	0	0
Irritability	1 (1.7)	1 (1.7)	0	0	0
Renal and urinary disorders					
-Total	1 (1.7)	0	1 (1.7)	0	0
Urinary retention	1 (1.7)	0	1 (1.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (15.0)	3 (5.0)	2 (3.3)	4 (6.7)	0
Hypoxia	3 (5.0)	0	0	3 (5.0)	0
Dyspnoea	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Epistaxis	2 (3.3)	0	1 (1.7)	1 (1.7)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Cough	1 (1.7)	1 (1.7)	0	0	0
Nasal congestion	1 (1.7)	1 (1.7)	0	0	0
Nasal discomfort	1 (1.7)	1 (1.7)	0	0	0
Pleural effusion	1 (1.7)	0	0	1 (1.7)	0
Rhinitis allergic	1 (1.7)	1 (1.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (18.3)	9 (15.0)	1 (1.7)	1 (1.7)	0
Alopecia	2 (3.3)	2 (3.3)	0	0	0
Dermatitis acneiform	1 (1.7)	0	1 (1.7)	0	0
Pruritus	1 (1.7)	1 (1.7)	0	0	0
Pruritus generalised	1 (1.7)	1 (1.7)	0	0	0
Rash	1 (1.7)	1 (1.7)	0	0	0
Rash erythematous	1 (1.7)	1 (1.7)	0	0	0
Rash macular	1 (1.7)	0	0	1 (1.7)	0
Rash pruritic	1 (1.7)	1 (1.7)	0	0	0
Skin haemorrhage	1 (1.7)	1 (1.7)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin ulcer	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					
-Total	6 (10.0)	1 (1.7)	1 (1.7)	4 (6.7)	0
Hypotension	3 (5.0)	0	0	3 (5.0)	0
Hypertension	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Phlebitis	1 (1.7)	0	1 (1.7)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176i
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	1 (25.0)	0	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Febrile neutropenia	1 (25.0)	0	0	1 (25.0)	0
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
Eye disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Eye irritation	1 (25.0)	1 (25.0)	0	0	0
Infections and infestations					
-Total	1 (25.0)	0	0	1 (25.0)	0
Bacteraemia	1 (25.0)	0	0	1 (25.0)	0

BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	4 (100)	1 (25.0)	1 (25.0)	0	2 (50.0)
Alanine aminotransferase increased	1 (25.0)	0	1 (25.0)	0	0
Aspartate aminotransferase increased	1 (25.0)	1 (25.0)	0	0	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0	0	0
Blood uric acid increased	1 (25.0)	1 (25.0)	0	0	0
Lymphocyte count decreased	1 (25.0)	0	0	0	1 (25.0)
White blood cell count decreased	1 (25.0)	0	0	0	1 (25.0)
Metabolism and nutrition disorders					
-Total	2 (50.0)	0	0	2 (50.0)	0
Hyperglycaemia	1 (25.0)	0	0	1 (25.0)	0
Hypokalaemia	1 (25.0)	0	0	1 (25.0)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Pain in jaw	1 (25.0)	1 (25.0)	0	0	0
Skin and subcutaneous tissue disorders					

BCR-ABL1-like: Yes

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (25.0)	1 (25.0)	0	0	0
Pruritus generalised	1 (25.0)	1 (25.0)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176i
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	47 (82.5)	6 (10.5)	6 (10.5)	15 (26.3)	20 (35.1)
Blood and lymphatic system disorders					
-Total	18 (31.6)	0	1 (1.8)	11 (19.3)	6 (10.5)
Febrile neutropenia	8 (14.0)	0	1 (1.8)	7 (12.3)	0
Anaemia	7 (12.3)	0	2 (3.5)	5 (8.8)	0
Neutropenia	3 (5.3)	0	0	1 (1.8)	2 (3.5)
Thrombocytopenia	3 (5.3)	0	0	1 (1.8)	2 (3.5)
Disseminated intravascular coagulation	1 (1.8)	0	0	0	1 (1.8)
Hypofibrinogenaemia	1 (1.8)	0	0	0	1 (1.8)
Lymphopenia	1 (1.8)	0	0	0	1 (1.8)

BCR-ABL1-like: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	1 (1.8)	0	0	1 (1.8)	0
Cardiac disorders					
-Total	4 (7.0)	2 (3.5)	1 (1.8)	1 (1.8)	0
Bradycardia	1 (1.8)	0	1 (1.8)	0	0
Left ventricular dysfunction	1 (1.8)	0	0	1 (1.8)	0
Palpitations	1 (1.8)	1 (1.8)	0	0	0
Tachycardia	1 (1.8)	1 (1.8)	0	0	0
Gastrointestinal disorders					
-Total	17 (29.8)	9 (15.8)	7 (12.3)	1 (1.8)	0
Nausea	8 (14.0)	5 (8.8)	3 (5.3)	0	0
Diarrhoea	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Vomiting	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Abdominal pain	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Constipation	2 (3.5)	2 (3.5)	0	0	0
Abdominal pain lower	1 (1.8)	1 (1.8)	0	0	0
Ascites	1 (1.8)	0	0	1 (1.8)	0
Gingival discomfort	1 (1.8)	1 (1.8)	0	0	0
Haematochezia	1 (1.8)	1 (1.8)	0	0	0

BCR-ABL1-like: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral mucosal blistering	1 (1.8)	1 (1.8)	0	0	0
Pancreatic failure	1 (1.8)	0	1 (1.8)	0	0
General disorders and administration site conditions					
-Total	12 (21.1)	3 (5.3)	8 (14.0)	0	1 (1.8)
Pyrexia	6 (10.5)	1 (1.8)	5 (8.8)	0	0
Catheter site pain	2 (3.5)	2 (3.5)	0	0	0
Chills	1 (1.8)	0	1 (1.8)	0	0
Device related thrombosis	1 (1.8)	0	1 (1.8)	0	0
Medical device pain	1 (1.8)	0	1 (1.8)	0	0
Multiple organ dysfunction syndrome	1 (1.8)	0	0	0	1 (1.8)
Oedema peripheral	1 (1.8)	1 (1.8)	0	0	0
Pain	1 (1.8)	0	1 (1.8)	0	0
Hepatobiliary disorders					
-Total	1 (1.8)	0	0	0	1 (1.8)
Hepatic failure	1 (1.8)	0	0	0	1 (1.8)
Immune system disorders					
-Total	1 (1.8)	1 (1.8)	0	0	0

BCR-ABL1-like: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	1 (1.8)	1 (1.8)	0	0	0
Infections and infestations					
-Total	6 (10.5)	1 (1.8)	2 (3.5)	2 (3.5)	1 (1.8)
Device related infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Necrotising fasciitis	1 (1.8)	0	0	1 (1.8)	0
Otitis media	1 (1.8)	0	1 (1.8)	0	0
Parainfluenzae virus infection	1 (1.8)	1 (1.8)	0	0	0
Pneumonia	1 (1.8)	0	1 (1.8)	0	0
Staphylococcal infection	1 (1.8)	0	0	0	1 (1.8)
Viral upper respiratory tract infection	1 (1.8)	1 (1.8)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Infusion related reaction	1 (1.8)	1 (1.8)	0	0	0
Radiation skin injury	1 (1.8)	0	1 (1.8)	0	0
Investigations					
-Total	27 (47.4)	1 (1.8)	2 (3.5)	6 (10.5)	18 (31.6)

BCR-ABL1-like: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	18 (31.6)	0	0	3 (5.3)	15 (26.3)
Neutrophil count decreased	10 (17.5)	0	0	0	10 (17.5)
Alanine aminotransferase increased	6 (10.5)	1 (1.8)	1 (1.8)	3 (5.3)	1 (1.8)
Platelet count decreased	4 (7.0)	0	1 (1.8)	2 (3.5)	1 (1.8)
Lymphocyte count decreased	3 (5.3)	0	0	1 (1.8)	2 (3.5)
Aspartate aminotransferase increased	2 (3.5)	0	1 (1.8)	0	1 (1.8)
C-reactive protein increased	2 (3.5)	0	2 (3.5)	0	0
International normalised ratio increased	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Weight increased	2 (3.5)	2 (3.5)	0	0	0
Activated partial thromboplastin time prolonged	1 (1.8)	0	1 (1.8)	0	0
Blood bilirubin increased	1 (1.8)	0	0	0	1 (1.8)
Blood lactic acid increased	1 (1.8)	0	1 (1.8)	0	0
Lipase increased	1 (1.8)	0	0	0	1 (1.8)
Protein total decreased	1 (1.8)	0	0	1 (1.8)	0
Weight decreased	1 (1.8)	1 (1.8)	0	0	0
Metabolism and nutrition disorders					

BCR-ABL1-like: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (22.8)	5 (8.8)	2 (3.5)	4 (7.0)	2 (3.5)
Hypokalaemia	4 (7.0)	1 (1.8)	0	1 (1.8)	2 (3.5)
Decreased appetite	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Hyperphosphataemia	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Hypophosphataemia	3 (5.3)	3 (5.3)	0	0	0
Fluid overload	2 (3.5)	0	2 (3.5)	0	0
Hyperuricaemia	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Hypoglycaemia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Hypomagnesaemia	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Hyperkalaemia	1 (1.8)	1 (1.8)	0	0	0
Hypermagnesaemia	1 (1.8)	1 (1.8)	0	0	0
Hypernatraemia	1 (1.8)	0	0	0	1 (1.8)
Hypoalbuminaemia	1 (1.8)	0	1 (1.8)	0	0
Hypocalcaemia	1 (1.8)	1 (1.8)	0	0	0
Tumour lysis syndrome	1 (1.8)	0	0	1 (1.8)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (7.0)	1 (1.8)	1 (1.8)	2 (3.5)	0

BCR-ABL1-like: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	1 (1.8)	1 (1.8)	0	0	0
Myalgia	1 (1.8)	0	0	1 (1.8)	0
Pain in extremity	1 (1.8)	0	0	1 (1.8)	0
Pain in jaw	1 (1.8)	0	1 (1.8)	0	0
Nervous system disorders					
-Total	8 (14.0)	4 (7.0)	4 (7.0)	0	0
Headache	5 (8.8)	3 (5.3)	2 (3.5)	0	0
Dysgeusia	1 (1.8)	1 (1.8)	0	0	0
Hypotonia	1 (1.8)	0	1 (1.8)	0	0
Somnolence	1 (1.8)	0	1 (1.8)	0	0
Product issues					
-Total	1 (1.8)	1 (1.8)	0	0	0
Device occlusion	1 (1.8)	1 (1.8)	0	0	0
Psychiatric disorders					
-Total	5 (8.8)	1 (1.8)	3 (5.3)	1 (1.8)	0
Anxiety	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Delirium	1 (1.8)	0	0	1 (1.8)	0
Depression	1 (1.8)	0	1 (1.8)	0	0

BCR-ABL1-like: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Insomnia	1 (1.8)	0	1 (1.8)	0	0
Irritability	1 (1.8)	1 (1.8)	0	0	0
Renal and urinary disorders					
-Total	1 (1.8)	0	1 (1.8)	0	0
Urinary retention	1 (1.8)	0	1 (1.8)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (15.8)	3 (5.3)	2 (3.5)	4 (7.0)	0
Hypoxia	3 (5.3)	0	0	3 (5.3)	0
Dyspnoea	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Epistaxis	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Tachypnoea	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Cough	1 (1.8)	1 (1.8)	0	0	0
Nasal congestion	1 (1.8)	1 (1.8)	0	0	0
Nasal discomfort	1 (1.8)	1 (1.8)	0	0	0
Pleural effusion	1 (1.8)	0	0	1 (1.8)	0
Rhinitis allergic	1 (1.8)	1 (1.8)	0	0	0
Skin and subcutaneous tissue disorders					

BCR-ABL1-like: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (17.5)	8 (14.0)	1 (1.8)	1 (1.8)	0
Alopecia	2 (3.5)	2 (3.5)	0	0	0
Dermatitis acneiform	1 (1.8)	0	1 (1.8)	0	0
Pruritus	1 (1.8)	1 (1.8)	0	0	0
Rash	1 (1.8)	1 (1.8)	0	0	0
Rash erythematous	1 (1.8)	1 (1.8)	0	0	0
Rash macular	1 (1.8)	0	0	1 (1.8)	0
Rash pruritic	1 (1.8)	1 (1.8)	0	0	0
Skin haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Skin ulcer	1 (1.8)	1 (1.8)	0	0	0
Vascular disorders					
-Total	6 (10.5)	1 (1.8)	1 (1.8)	4 (7.0)	0
Hypotension	3 (5.3)	0	0	3 (5.3)	0
Hypertension	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Phlebitis	1 (1.8)	0	1 (1.8)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176j
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (83.3)	2 (11.1)	3 (16.7)	2 (11.1)	8 (44.4)
Blood and lymphatic system disorders					
-Total	6 (33.3)	0	0	3 (16.7)	3 (16.7)
Neutropenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Anaemia	1 (5.6)	0	0	1 (5.6)	0
Febrile neutropenia	1 (5.6)	0	0	1 (5.6)	0
Hypofibrinogenaemia	1 (5.6)	0	0	0	1 (5.6)
Lymphopenia	1 (5.6)	0	0	0	1 (5.6)
Pancytopenia	1 (5.6)	0	0	1 (5.6)	0
Cardiac disorders					
-Total	1 (5.6)	0	1 (5.6)	0	0
Bradycardia	1 (5.6)	0	1 (5.6)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	5 (27.8)	4 (22.2)	1 (5.6)	0	0
Diarrhoea	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Nausea	2 (11.1)	2 (11.1)	0	0	0
Abdominal pain	1 (5.6)	1 (5.6)	0	0	0
Constipation	1 (5.6)	1 (5.6)	0	0	0
Vomiting	1 (5.6)	1 (5.6)	0	0	0
General disorders and administration site conditions					
-Total	5 (27.8)	1 (5.6)	4 (22.2)	0	0
Pyrexia	3 (16.7)	0	3 (16.7)	0	0
Catheter site pain	1 (5.6)	1 (5.6)	0	0	0
Device related thrombosis	1 (5.6)	0	1 (5.6)	0	0
Oedema peripheral	1 (5.6)	1 (5.6)	0	0	0
Immune system disorders					
-Total	1 (5.6)	1 (5.6)	0	0	0
Hypogammaglobulinaemia	1 (5.6)	1 (5.6)	0	0	0
Infections and infestations					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (5.6)	0	1 (5.6)	0	0
Viral upper respiratory tract infection	1 (5.6)	1 (5.6)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (5.6)	0	1 (5.6)	0	0
Radiation skin injury	1 (5.6)	0	1 (5.6)	0	0
Investigations					
-Total	9 (50.0)	0	0	2 (11.1)	7 (38.9)
White blood cell count decreased	6 (33.3)	0	0	0	6 (33.3)
Neutrophil count decreased	3 (16.7)	0	0	0	3 (16.7)
Alanine aminotransferase increased	2 (11.1)	0	0	2 (11.1)	0
Blood lactic acid increased	1 (5.6)	0	1 (5.6)	0	0
C-reactive protein increased	1 (5.6)	0	1 (5.6)	0	0
Lipase increased	1 (5.6)	0	0	0	1 (5.6)
Lymphocyte count decreased	1 (5.6)	0	0	0	1 (5.6)
Protein total decreased	1 (5.6)	0	0	1 (5.6)	0
Metabolism and nutrition disorders					
-Total	5 (27.8)	2 (11.1)	1 (5.6)	1 (5.6)	1 (5.6)
Hypokalaemia	2 (11.1)	0	0	1 (5.6)	1 (5.6)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	1 (5.6)	0	1 (5.6)	0	0
Fluid overload	1 (5.6)	0	1 (5.6)	0	0
Hypermagnesaemia	1 (5.6)	1 (5.6)	0	0	0
Hyperphosphataemia	1 (5.6)	1 (5.6)	0	0	0
Hypophosphataemia	1 (5.6)	1 (5.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Arthralgia	1 (5.6)	1 (5.6)	0	0	0
Pain in jaw	1 (5.6)	0	1 (5.6)	0	0
Nervous system disorders					
-Total	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Headache	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Hypotonia	1 (5.6)	0	1 (5.6)	0	0
Psychiatric disorders					
-Total	1 (5.6)	1 (5.6)	0	0	0
Anxiety	1 (5.6)	1 (5.6)	0	0	0
Irritability	1 (5.6)	1 (5.6)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Cough	1 (5.6)	1 (5.6)	0	0	0
Hypoxia	1 (5.6)	0	0	1 (5.6)	0
Tachypnoea	1 (5.6)	0	0	1 (5.6)	0
Skin and subcutaneous tissue disorders					
-Total	2 (11.1)	2 (11.1)	0	0	0
Alopecia	1 (5.6)	1 (5.6)	0	0	0
Pruritus generalised	1 (5.6)	1 (5.6)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176j
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (83.7)	5 (11.6)	3 (7.0)	14 (32.6)	14 (32.6)
Blood and lymphatic system disorders					
-Total	13 (30.2)	0	1 (2.3)	8 (18.6)	4 (9.3)
Febrile neutropenia	8 (18.6)	0	1 (2.3)	7 (16.3)	0
Anaemia	6 (14.0)	0	2 (4.7)	4 (9.3)	0
Thrombocytopenia	3 (7.0)	0	0	1 (2.3)	2 (4.7)
Neutropenia	2 (4.7)	0	0	0	2 (4.7)
Disseminated intravascular coagulation	1 (2.3)	0	0	0	1 (2.3)
Cardiac disorders					
-Total	3 (7.0)	2 (4.7)	0	1 (2.3)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (2.3)	0	0	1 (2.3)	0
Palpitations	1 (2.3)	1 (2.3)	0	0	0
Tachycardia	1 (2.3)	1 (2.3)	0	0	0
Eye disorders					
-Total	1 (2.3)	1 (2.3)	0	0	0
Eye irritation	1 (2.3)	1 (2.3)	0	0	0
Gastrointestinal disorders					
-Total	12 (27.9)	5 (11.6)	6 (14.0)	1 (2.3)	0
Nausea	6 (14.0)	3 (7.0)	3 (7.0)	0	0
Diarrhoea	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Vomiting	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Abdominal pain	1 (2.3)	0	1 (2.3)	0	0
Abdominal pain lower	1 (2.3)	1 (2.3)	0	0	0
Ascites	1 (2.3)	0	0	1 (2.3)	0
Constipation	1 (2.3)	1 (2.3)	0	0	0
Gingival discomfort	1 (2.3)	1 (2.3)	0	0	0
Haematochezia	1 (2.3)	1 (2.3)	0	0	0
Oral mucosal blistering	1 (2.3)	1 (2.3)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatic failure	1 (2.3)	0	1 (2.3)	0	0
General disorders and administration site conditions					
-Total	7 (16.3)	2 (4.7)	4 (9.3)	0	1 (2.3)
Pyrexia	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Catheter site pain	1 (2.3)	1 (2.3)	0	0	0
Chills	1 (2.3)	0	1 (2.3)	0	0
Medical device pain	1 (2.3)	0	1 (2.3)	0	0
Multiple organ dysfunction syndrome	1 (2.3)	0	0	0	1 (2.3)
Pain	1 (2.3)	0	1 (2.3)	0	0
Hepatobiliary disorders					
-Total	1 (2.3)	0	0	0	1 (2.3)
Hepatic failure	1 (2.3)	0	0	0	1 (2.3)
Infections and infestations					
-Total	5 (11.6)	0	1 (2.3)	3 (7.0)	1 (2.3)
Device related infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Bacteraemia	1 (2.3)	0	0	1 (2.3)	0
Bronchitis	1 (2.3)	0	1 (2.3)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Necrotising fasciitis	1 (2.3)	0	0	1 (2.3)	0
Otitis media	1 (2.3)	0	1 (2.3)	0	0
Parainfluenzae virus infection	1 (2.3)	1 (2.3)	0	0	0
Staphylococcal infection	1 (2.3)	0	0	0	1 (2.3)
Injury, poisoning and procedural complications					
-Total	1 (2.3)	1 (2.3)	0	0	0
Infusion related reaction	1 (2.3)	1 (2.3)	0	0	0
Investigations					
-Total	22 (51.2)	2 (4.7)	3 (7.0)	4 (9.3)	13 (30.2)
White blood cell count decreased	13 (30.2)	0	0	3 (7.0)	10 (23.3)
Neutrophil count decreased	7 (16.3)	0	0	0	7 (16.3)
Alanine aminotransferase increased	5 (11.6)	1 (2.3)	2 (4.7)	1 (2.3)	1 (2.3)
Platelet count decreased	4 (9.3)	0	1 (2.3)	2 (4.7)	1 (2.3)
Aspartate aminotransferase increased	3 (7.0)	1 (2.3)	1 (2.3)	0	1 (2.3)
Lymphocyte count decreased	3 (7.0)	0	0	1 (2.3)	2 (4.7)
International normalised ratio increased	2 (4.7)	1 (2.3)	1 (2.3)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight increased	2 (4.7)	2 (4.7)	0	0	0
Activated partial thromboplastin time prolonged	1 (2.3)	0	1 (2.3)	0	0
Blood bilirubin increased	1 (2.3)	0	0	0	1 (2.3)
Blood creatinine increased	1 (2.3)	1 (2.3)	0	0	0
Blood uric acid increased	1 (2.3)	1 (2.3)	0	0	0
C-reactive protein increased	1 (2.3)	0	1 (2.3)	0	0
Weight decreased	1 (2.3)	1 (2.3)	0	0	0
Metabolism and nutrition disorders					
-Total	10 (23.3)	3 (7.0)	1 (2.3)	5 (11.6)	1 (2.3)
Hypokalaemia	3 (7.0)	1 (2.3)	0	1 (2.3)	1 (2.3)
Decreased appetite	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Hyperphosphataemia	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Hyperuricaemia	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Hypoglycaemia	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Hypomagnesaemia	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Hypophosphataemia	2 (4.7)	2 (4.7)	0	0	0
Fluid overload	1 (2.3)	0	1 (2.3)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	1 (2.3)	0	0	1 (2.3)	0
Hyperkalaemia	1 (2.3)	1 (2.3)	0	0	0
Hypernatraemia	1 (2.3)	0	0	0	1 (2.3)
Hypoalbuminaemia	1 (2.3)	0	1 (2.3)	0	0
Hypocalcaemia	1 (2.3)	1 (2.3)	0	0	0
Tumour lysis syndrome	1 (2.3)	0	0	1 (2.3)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (7.0)	1 (2.3)	0	2 (4.7)	0
Myalgia	1 (2.3)	0	0	1 (2.3)	0
Pain in extremity	1 (2.3)	0	0	1 (2.3)	0
Pain in jaw	1 (2.3)	1 (2.3)	0	0	0
Nervous system disorders					
-Total	5 (11.6)	3 (7.0)	2 (4.7)	0	0
Headache	3 (7.0)	2 (4.7)	1 (2.3)	0	0
Dysgeusia	1 (2.3)	1 (2.3)	0	0	0
Somnolence	1 (2.3)	0	1 (2.3)	0	0
Product issues					

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.3)	1 (2.3)	0	0	0
Device occlusion	1 (2.3)	1 (2.3)	0	0	0
Psychiatric disorders					
-Total	4 (9.3)	0	3 (7.0)	1 (2.3)	0
Anxiety	1 (2.3)	0	1 (2.3)	0	0
Delirium	1 (2.3)	0	0	1 (2.3)	0
Depression	1 (2.3)	0	1 (2.3)	0	0
Insomnia	1 (2.3)	0	1 (2.3)	0	0
Renal and urinary disorders					
-Total	1 (2.3)	0	1 (2.3)	0	0
Urinary retention	1 (2.3)	0	1 (2.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (16.3)	2 (4.7)	2 (4.7)	3 (7.0)	0
Dyspnoea	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Epistaxis	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Hypoxia	2 (4.7)	0	0	2 (4.7)	0
Nasal congestion	1 (2.3)	1 (2.3)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal discomfort	1 (2.3)	1 (2.3)	0	0	0
Pleural effusion	1 (2.3)	0	0	1 (2.3)	0
Rhinitis allergic	1 (2.3)	1 (2.3)	0	0	0
Tachypnoea	1 (2.3)	0	1 (2.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (20.9)	7 (16.3)	1 (2.3)	1 (2.3)	0
Alopecia	1 (2.3)	1 (2.3)	0	0	0
Dermatitis acneiform	1 (2.3)	0	1 (2.3)	0	0
Pruritus	1 (2.3)	1 (2.3)	0	0	0
Rash	1 (2.3)	1 (2.3)	0	0	0
Rash erythematous	1 (2.3)	1 (2.3)	0	0	0
Rash macular	1 (2.3)	0	0	1 (2.3)	0
Rash pruritic	1 (2.3)	1 (2.3)	0	0	0
Skin haemorrhage	1 (2.3)	1 (2.3)	0	0	0
Skin ulcer	1 (2.3)	1 (2.3)	0	0	0
Vascular disorders					
-Total	6 (14.0)	1 (2.3)	1 (2.3)	4 (9.3)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	3 (7.0)	0	0	3 (7.0)	0
Hypertension	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Phlebitis	1 (2.3)	0	1 (2.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176k
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: US

	All patients N=61				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (83.6)	7 (11.5)	6 (9.8)	16 (26.2)	22 (36.1)
Blood and lymphatic system disorders					
-Total	19 (31.1)	0	1 (1.6)	11 (18.0)	7 (11.5)
Febrile neutropenia	9 (14.8)	0	1 (1.6)	8 (13.1)	0
Anaemia	7 (11.5)	0	2 (3.3)	5 (8.2)	0
Neutropenia	4 (6.6)	0	0	1 (1.6)	3 (4.9)
Thrombocytopenia	3 (4.9)	0	0	1 (1.6)	2 (3.3)
Disseminated intravascular coagulation	1 (1.6)	0	0	0	1 (1.6)
Hypofibrinogenaemia	1 (1.6)	0	0	0	1 (1.6)
Lymphopenia	1 (1.6)	0	0	0	1 (1.6)

Region: US

Primary system organ class Preferred term	All patients N=61 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pancytopenia	1 (1.6)	0	0	1 (1.6)	0
Cardiac disorders					
-Total	4 (6.6)	2 (3.3)	1 (1.6)	1 (1.6)	0
Bradycardia	1 (1.6)	0	1 (1.6)	0	0
Left ventricular dysfunction	1 (1.6)	0	0	1 (1.6)	0
Palpitations	1 (1.6)	1 (1.6)	0	0	0
Tachycardia	1 (1.6)	1 (1.6)	0	0	0
Eye disorders					
-Total	1 (1.6)	1 (1.6)	0	0	0
Eye irritation	1 (1.6)	1 (1.6)	0	0	0
Gastrointestinal disorders					
-Total	17 (27.9)	9 (14.8)	7 (11.5)	1 (1.6)	0
Nausea	8 (13.1)	5 (8.2)	3 (4.9)	0	0
Diarrhoea	4 (6.6)	2 (3.3)	2 (3.3)	0	0
Vomiting	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Abdominal pain	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Constipation	2 (3.3)	2 (3.3)	0	0	0
Abdominal pain lower	1 (1.6)	1 (1.6)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=61 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ascites	1 (1.6)	0	0	1 (1.6)	0
Gingival discomfort	1 (1.6)	1 (1.6)	0	0	0
Haematochezia	1 (1.6)	1 (1.6)	0	0	0
Oral mucosal blistering	1 (1.6)	1 (1.6)	0	0	0
Pancreatic failure	1 (1.6)	0	1 (1.6)	0	0
General disorders and administration site conditions					
-Total	12 (19.7)	3 (4.9)	8 (13.1)	0	1 (1.6)
Pyrexia	6 (9.8)	1 (1.6)	5 (8.2)	0	0
Catheter site pain	2 (3.3)	2 (3.3)	0	0	0
Chills	1 (1.6)	0	1 (1.6)	0	0
Device related thrombosis	1 (1.6)	0	1 (1.6)	0	0
Medical device pain	1 (1.6)	0	1 (1.6)	0	0
Multiple organ dysfunction syndrome	1 (1.6)	0	0	0	1 (1.6)
Oedema peripheral	1 (1.6)	1 (1.6)	0	0	0
Pain	1 (1.6)	0	1 (1.6)	0	0
Hepatobiliary disorders					
-Total	1 (1.6)	0	0	0	1 (1.6)

Region: US

Primary system organ class Preferred term	All patients N=61 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatic failure	1 (1.6)	0	0	0	1 (1.6)
Immune system disorders					
-Total	1 (1.6)	1 (1.6)	0	0	0
Hypogammaglobulinaemia	1 (1.6)	1 (1.6)	0	0	0
Infections and infestations					
-Total	7 (11.5)	1 (1.6)	2 (3.3)	3 (4.9)	1 (1.6)
Device related infection	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Bacteraemia	1 (1.6)	0	0	1 (1.6)	0
Bronchitis	1 (1.6)	0	1 (1.6)	0	0
Necrotising fasciitis	1 (1.6)	0	0	1 (1.6)	0
Otitis media	1 (1.6)	0	1 (1.6)	0	0
Parainfluenzae virus infection	1 (1.6)	1 (1.6)	0	0	0
Pneumonia	1 (1.6)	0	1 (1.6)	0	0
Staphylococcal infection	1 (1.6)	0	0	0	1 (1.6)
Viral upper respiratory tract infection	1 (1.6)	1 (1.6)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (3.3)	1 (1.6)	1 (1.6)	0	0

Region: US

Primary system organ class Preferred term	All patients N=61 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Infusion related reaction	1 (1.6)	1 (1.6)	0	0	0
Radiation skin injury	1 (1.6)	0	1 (1.6)	0	0
Investigations					
-Total	31 (50.8)	2 (3.3)	3 (4.9)	6 (9.8)	20 (32.8)
White blood cell count decreased	19 (31.1)	0	0	3 (4.9)	16 (26.2)
Neutrophil count decreased	10 (16.4)	0	0	0	10 (16.4)
Alanine aminotransferase increased	7 (11.5)	1 (1.6)	2 (3.3)	3 (4.9)	1 (1.6)
Lymphocyte count decreased	4 (6.6)	0	0	1 (1.6)	3 (4.9)
Platelet count decreased	4 (6.6)	0	1 (1.6)	2 (3.3)	1 (1.6)
Aspartate aminotransferase increased	3 (4.9)	1 (1.6)	1 (1.6)	0	1 (1.6)
C-reactive protein increased	2 (3.3)	0	2 (3.3)	0	0
International normalised ratio increased	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Weight increased	2 (3.3)	2 (3.3)	0	0	0
Activated partial thromboplastin time prolonged	1 (1.6)	0	1 (1.6)	0	0
Blood bilirubin increased	1 (1.6)	0	0	0	1 (1.6)
Blood creatinine increased	1 (1.6)	1 (1.6)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=61 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood lactic acid increased	1 (1.6)	0	1 (1.6)	0	0
Blood uric acid increased	1 (1.6)	1 (1.6)	0	0	0
Lipase increased	1 (1.6)	0	0	0	1 (1.6)
Protein total decreased	1 (1.6)	0	0	1 (1.6)	0
Weight decreased	1 (1.6)	1 (1.6)	0	0	0
Metabolism and nutrition disorders					
-Total	15 (24.6)	5 (8.2)	2 (3.3)	6 (9.8)	2 (3.3)
Hypokalaemia	5 (8.2)	1 (1.6)	0	2 (3.3)	2 (3.3)
Decreased appetite	3 (4.9)	1 (1.6)	2 (3.3)	0	0
Hyperphosphataemia	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Hypophosphataemia	3 (4.9)	3 (4.9)	0	0	0
Fluid overload	2 (3.3)	0	2 (3.3)	0	0
Hyperuricaemia	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Hypoglycaemia	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Hypomagnesaemia	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Hyperglycaemia	1 (1.6)	0	0	1 (1.6)	0
Hyperkalaemia	1 (1.6)	1 (1.6)	0	0	0
Hypermagnesaemia	1 (1.6)	1 (1.6)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=61 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypernatraemia	1 (1.6)	0	0	0	1 (1.6)
Hypoalbuminaemia	1 (1.6)	0	1 (1.6)	0	0
Hypocalcaemia	1 (1.6)	1 (1.6)	0	0	0
Tumour lysis syndrome	1 (1.6)	0	0	1 (1.6)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (8.2)	2 (3.3)	1 (1.6)	2 (3.3)	0
Pain in jaw	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Arthralgia	1 (1.6)	1 (1.6)	0	0	0
Myalgia	1 (1.6)	0	0	1 (1.6)	0
Pain in extremity	1 (1.6)	0	0	1 (1.6)	0
Nervous system disorders					
-Total	8 (13.1)	4 (6.6)	4 (6.6)	0	0
Headache	5 (8.2)	3 (4.9)	2 (3.3)	0	0
Dysgeusia	1 (1.6)	1 (1.6)	0	0	0
Hypotonia	1 (1.6)	0	1 (1.6)	0	0
Somnolence	1 (1.6)	0	1 (1.6)	0	0
Product issues					

Region: US

Primary system organ class Preferred term	All patients N=61 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (1.6)	1 (1.6)	0	0	0
Device occlusion	1 (1.6)	1 (1.6)	0	0	0
Psychiatric disorders					
-Total	5 (8.2)	1 (1.6)	3 (4.9)	1 (1.6)	0
Anxiety	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Delirium	1 (1.6)	0	0	1 (1.6)	0
Depression	1 (1.6)	0	1 (1.6)	0	0
Insomnia	1 (1.6)	0	1 (1.6)	0	0
Irritability	1 (1.6)	1 (1.6)	0	0	0
Renal and urinary disorders					
-Total	1 (1.6)	0	1 (1.6)	0	0
Urinary retention	1 (1.6)	0	1 (1.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (14.8)	3 (4.9)	2 (3.3)	4 (6.6)	0
Hypoxia	3 (4.9)	0	0	3 (4.9)	0
Dyspnoea	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Epistaxis	2 (3.3)	0	1 (1.6)	1 (1.6)	0

Region: US

Primary system organ class Preferred term	All patients N=61 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Cough	1 (1.6)	1 (1.6)	0	0	0
Nasal congestion	1 (1.6)	1 (1.6)	0	0	0
Nasal discomfort	1 (1.6)	1 (1.6)	0	0	0
Pleural effusion	1 (1.6)	0	0	1 (1.6)	0
Rhinitis allergic	1 (1.6)	1 (1.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (18.0)	9 (14.8)	1 (1.6)	1 (1.6)	0
Alopecia	2 (3.3)	2 (3.3)	0	0	0
Dermatitis acneiform	1 (1.6)	0	1 (1.6)	0	0
Pruritus	1 (1.6)	1 (1.6)	0	0	0
Pruritus generalised	1 (1.6)	1 (1.6)	0	0	0
Rash	1 (1.6)	1 (1.6)	0	0	0
Rash erythematous	1 (1.6)	1 (1.6)	0	0	0
Rash macular	1 (1.6)	0	0	1 (1.6)	0
Rash pruritic	1 (1.6)	1 (1.6)	0	0	0
Skin haemorrhage	1 (1.6)	1 (1.6)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=61 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin ulcer	1 (1.6)	1 (1.6)	0	0	0
Vascular disorders					
-Total	6 (9.8)	1 (1.6)	1 (1.6)	4 (6.6)	0
Hypotension	3 (4.9)	0	0	3 (4.9)	0
Hypertension	2 (3.3)	1 (1.6)	0	1 (1.6)	0
Phlebitis	1 (1.6)	0	1 (1.6)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176l
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (82.1)	3 (10.7)	4 (14.3)	6 (21.4)	10 (35.7)
Blood and lymphatic system disorders					
-Total	8 (28.6)	0	0	5 (17.9)	3 (10.7)
Febrile neutropenia	4 (14.3)	0	0	4 (14.3)	0
Anaemia	3 (10.7)	0	0	3 (10.7)	0
Neutropenia	2 (7.1)	0	0	1 (3.6)	1 (3.6)
Disseminated intravascular coagulation	1 (3.6)	0	0	0	1 (3.6)
Hypofibrinogenaemia	1 (3.6)	0	0	0	1 (3.6)
Thrombocytopenia	1 (3.6)	0	0	0	1 (3.6)
Cardiac disorders					

Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.6)	1 (3.6)	0	0	0
Palpitations	1 (3.6)	1 (3.6)	0	0	0
Eye disorders					
-Total	1 (3.6)	1 (3.6)	0	0	0
Eye irritation	1 (3.6)	1 (3.6)	0	0	0
Gastrointestinal disorders					
-Total	6 (21.4)	4 (14.3)	1 (3.6)	1 (3.6)	0
Abdominal pain	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Nausea	2 (7.1)	2 (7.1)	0	0	0
Ascites	1 (3.6)	0	0	1 (3.6)	0
Constipation	1 (3.6)	1 (3.6)	0	0	0
Diarrhoea	1 (3.6)	1 (3.6)	0	0	0
Gingival discomfort	1 (3.6)	1 (3.6)	0	0	0
Oral mucosal blistering	1 (3.6)	1 (3.6)	0	0	0
General disorders and administration site conditions					
-Total	7 (25.0)	2 (7.1)	4 (14.3)	0	1 (3.6)
Pyrexia	3 (10.7)	1 (3.6)	2 (7.1)	0	0

Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site pain	1 (3.6)	1 (3.6)	0	0	0
Device related thrombosis	1 (3.6)	0	1 (3.6)	0	0
Medical device pain	1 (3.6)	0	1 (3.6)	0	0
Multiple organ dysfunction syndrome	1 (3.6)	0	0	0	1 (3.6)
Oedema peripheral	1 (3.6)	1 (3.6)	0	0	0
Pain	1 (3.6)	0	1 (3.6)	0	0
Hepatobiliary disorders					
-Total	1 (3.6)	0	0	0	1 (3.6)
Hepatic failure	1 (3.6)	0	0	0	1 (3.6)
Immune system disorders					
-Total	1 (3.6)	1 (3.6)	0	0	0
Hypogammaglobulinaemia	1 (3.6)	1 (3.6)	0	0	0
Infections and infestations					
-Total	6 (21.4)	1 (3.6)	1 (3.6)	3 (10.7)	1 (3.6)
Device related infection	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Bacteraemia	1 (3.6)	0	0	1 (3.6)	0
Bronchitis	1 (3.6)	0	1 (3.6)	0	0
Necrotising fasciitis	1 (3.6)	0	0	1 (3.6)	0

Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (3.6)	0	1 (3.6)	0	0
Parainfluenzae virus infection	1 (3.6)	1 (3.6)	0	0	0
Staphylococcal infection	1 (3.6)	0	0	0	1 (3.6)
Viral upper respiratory tract infection	1 (3.6)	1 (3.6)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Infusion related reaction	1 (3.6)	1 (3.6)	0	0	0
Radiation skin injury	1 (3.6)	0	1 (3.6)	0	0
Investigations					
-Total	16 (57.1)	2 (7.1)	3 (10.7)	1 (3.6)	10 (35.7)
White blood cell count decreased	7 (25.0)	0	0	1 (3.6)	6 (21.4)
Neutrophil count decreased	5 (17.9)	0	0	0	5 (17.9)
Alanine aminotransferase increased	4 (14.3)	1 (3.6)	1 (3.6)	1 (3.6)	1 (3.6)
Aspartate aminotransferase increased	3 (10.7)	1 (3.6)	1 (3.6)	0	1 (3.6)
Lymphocyte count decreased	3 (10.7)	0	0	0	3 (10.7)
Platelet count decreased	3 (10.7)	0	0	2 (7.1)	1 (3.6)

Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Weight increased	2 (7.1)	2 (7.1)	0	0	0
Activated partial thromboplastin time prolonged	1 (3.6)	0	1 (3.6)	0	0
Blood bilirubin increased	1 (3.6)	0	0	0	1 (3.6)
Blood creatinine increased	1 (3.6)	1 (3.6)	0	0	0
Blood uric acid increased	1 (3.6)	1 (3.6)	0	0	0
C-reactive protein increased	1 (3.6)	0	1 (3.6)	0	0
Lipase increased	1 (3.6)	0	0	0	1 (3.6)
Weight decreased	1 (3.6)	1 (3.6)	0	0	0
Metabolism and nutrition disorders					
-Total	9 (32.1)	3 (10.7)	1 (3.6)	3 (10.7)	2 (7.1)
Hypokalaemia	3 (10.7)	0	0	1 (3.6)	2 (7.1)
Hyperphosphataemia	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Hypoglycaemia	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Hypophosphataemia	2 (7.1)	2 (7.1)	0	0	0
Decreased appetite	1 (3.6)	1 (3.6)	0	0	0
Hyperglycaemia	1 (3.6)	0	0	1 (3.6)	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=28 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperkalaemia	1 (3.6)	1 (3.6)	0	0	0
Hypernatraemia	1 (3.6)	0	0	0	1 (3.6)
Hyperuricaemia	1 (3.6)	1 (3.6)	0	0	0
Hypoalbuminaemia	1 (3.6)	0	1 (3.6)	0	0
Hypocalcaemia	1 (3.6)	1 (3.6)	0	0	0
Hypomagnesaemia	1 (3.6)	1 (3.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (17.9)	2 (7.1)	1 (3.6)	2 (7.1)	0
Pain in jaw	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Arthralgia	1 (3.6)	1 (3.6)	0	0	0
Myalgia	1 (3.6)	0	0	1 (3.6)	0
Pain in extremity	1 (3.6)	0	0	1 (3.6)	0
Nervous system disorders					
-Total	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Headache	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Somnolence	1 (3.6)	0	1 (3.6)	0	0
Psychiatric disorders					

Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Anxiety	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Delirium	1 (3.6)	0	0	1 (3.6)	0
Irritability	1 (3.6)	1 (3.6)	0	0	0
Renal and urinary disorders					
-Total	1 (3.6)	0	1 (3.6)	0	0
Urinary retention	1 (3.6)	0	1 (3.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (17.9)	2 (7.1)	1 (3.6)	2 (7.1)	0
Dyspnoea	2 (7.1)	1 (3.6)	1 (3.6)	0	0
Hypoxia	2 (7.1)	0	0	2 (7.1)	0
Cough	1 (3.6)	1 (3.6)	0	0	0
Nasal congestion	1 (3.6)	1 (3.6)	0	0	0
Pleural effusion	1 (3.6)	0	0	1 (3.6)	0
Rhinitis allergic	1 (3.6)	1 (3.6)	0	0	0
Tachypnoea	1 (3.6)	0	1 (3.6)	0	0
Skin and subcutaneous tissue disorders					

Prior SCT therapy: Yes

	All patients N=28				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (25.0)	5 (17.9)	1 (3.6)	1 (3.6)	0
Alopecia	1 (3.6)	1 (3.6)	0	0	0
Dermatitis acneiform	1 (3.6)	0	1 (3.6)	0	0
Pruritus	1 (3.6)	1 (3.6)	0	0	0
Rash	1 (3.6)	1 (3.6)	0	0	0
Rash macular	1 (3.6)	0	0	1 (3.6)	0
Rash pruritic	1 (3.6)	1 (3.6)	0	0	0
Skin haemorrhage	1 (3.6)	1 (3.6)	0	0	0
Vascular disorders					
-Total	4 (14.3)	0	1 (3.6)	3 (10.7)	0
Hypotension	2 (7.1)	0	0	2 (7.1)	0
Hypertension	1 (3.6)	0	0	1 (3.6)	0
Phlebitis	1 (3.6)	0	1 (3.6)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176l
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: No

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (84.8)	4 (12.1)	2 (6.1)	10 (30.3)	12 (36.4)
Blood and lymphatic system disorders					
-Total	11 (33.3)	0	1 (3.0)	6 (18.2)	4 (12.1)
Febrile neutropenia	5 (15.2)	0	1 (3.0)	4 (12.1)	0
Anaemia	4 (12.1)	0	2 (6.1)	2 (6.1)	0
Neutropenia	2 (6.1)	0	0	0	2 (6.1)
Thrombocytopenia	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Lymphopenia	1 (3.0)	0	0	0	1 (3.0)
Pancytopenia	1 (3.0)	0	0	1 (3.0)	0
Cardiac disorders					
-Total	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0

Prior SCT therapy: No

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (3.0)	0	1 (3.0)	0	0
Left ventricular dysfunction	1 (3.0)	0	0	1 (3.0)	0
Tachycardia	1 (3.0)	1 (3.0)	0	0	0
Gastrointestinal disorders					
-Total	11 (33.3)	5 (15.2)	6 (18.2)	0	0
Nausea	6 (18.2)	3 (9.1)	3 (9.1)	0	0
Diarrhoea	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Vomiting	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Abdominal pain lower	1 (3.0)	1 (3.0)	0	0	0
Constipation	1 (3.0)	1 (3.0)	0	0	0
Haematochezia	1 (3.0)	1 (3.0)	0	0	0
Pancreatic failure	1 (3.0)	0	1 (3.0)	0	0
General disorders and administration site conditions					
-Total	5 (15.2)	1 (3.0)	4 (12.1)	0	0
Pyrexia	3 (9.1)	0	3 (9.1)	0	0
Catheter site pain	1 (3.0)	1 (3.0)	0	0	0
Chills	1 (3.0)	0	1 (3.0)	0	0

Prior SCT therapy: No

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	1 (3.0)	0	1 (3.0)	0	0
Pneumonia	1 (3.0)	0	1 (3.0)	0	0
Investigations					
-Total	15 (45.5)	0	0	5 (15.2)	10 (30.3)
White blood cell count decreased	12 (36.4)	0	0	2 (6.1)	10 (30.3)
Neutrophil count decreased	5 (15.2)	0	0	0	5 (15.2)
Alanine aminotransferase increased	3 (9.1)	0	1 (3.0)	2 (6.1)	0
Blood lactic acid increased	1 (3.0)	0	1 (3.0)	0	0
C-reactive protein increased	1 (3.0)	0	1 (3.0)	0	0
Lymphocyte count decreased	1 (3.0)	0	0	1 (3.0)	0
Platelet count decreased	1 (3.0)	0	1 (3.0)	0	0
Protein total decreased	1 (3.0)	0	0	1 (3.0)	0
Metabolism and nutrition disorders					
-Total	6 (18.2)	2 (6.1)	1 (3.0)	3 (9.1)	0
Decreased appetite	2 (6.1)	0	2 (6.1)	0	0
Fluid overload	2 (6.1)	0	2 (6.1)	0	0
Hypokalaemia	2 (6.1)	1 (3.0)	0	1 (3.0)	0

Prior SCT therapy: No

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypermagnesaemia	1 (3.0)	1 (3.0)	0	0	0
Hyperphosphataemia	1 (3.0)	1 (3.0)	0	0	0
Hyperuricaemia	1 (3.0)	0	0	1 (3.0)	0
Hypomagnesaemia	1 (3.0)	0	1 (3.0)	0	0
Hypophosphataemia	1 (3.0)	1 (3.0)	0	0	0
Tumour lysis syndrome	1 (3.0)	0	0	1 (3.0)	0
Nervous system disorders					
-Total	5 (15.2)	3 (9.1)	2 (6.1)	0	0
Headache	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Dysgeusia	1 (3.0)	1 (3.0)	0	0	0
Hypotonia	1 (3.0)	0	1 (3.0)	0	0
Product issues					
-Total	1 (3.0)	1 (3.0)	0	0	0
Device occlusion	1 (3.0)	1 (3.0)	0	0	0
Psychiatric disorders					
-Total	2 (6.1)	0	2 (6.1)	0	0
Depression	1 (3.0)	0	1 (3.0)	0	0
Insomnia	1 (3.0)	0	1 (3.0)	0	0

Prior SCT therapy: No

	All patients N=33				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	4 (12.1)	1 (3.0)	1 (3.0)	2 (6.1)	0
Epistaxis	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Hypoxia	1 (3.0)	0	0	1 (3.0)	0
Nasal discomfort	1 (3.0)	1 (3.0)	0	0	0
Tachypnoea	1 (3.0)	0	0	1 (3.0)	0
Skin and subcutaneous tissue disorders					
-Total	4 (12.1)	4 (12.1)	0	0	0
Alopecia	1 (3.0)	1 (3.0)	0	0	0
Pruritus generalised	1 (3.0)	1 (3.0)	0	0	0
Rash erythematous	1 (3.0)	1 (3.0)	0	0	0
Skin ulcer	1 (3.0)	1 (3.0)	0	0	0
Vascular disorders					
-Total	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Hypertension	1 (3.0)	1 (3.0)	0	0	0
Hypotension	1 (3.0)	0	0	1 (3.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176m
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: Yes

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (92.9)	2 (14.3)	2 (14.3)	3 (21.4)	6 (42.9)
Blood and lymphatic system disorders					
-Total	4 (28.6)	0	1 (7.1)	1 (7.1)	2 (14.3)
Anaemia	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Febrile neutropenia	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Neutropenia	1 (7.1)	0	0	0	1 (7.1)
Thrombocytopenia	1 (7.1)	0	0	0	1 (7.1)
Gastrointestinal disorders					
-Total	7 (50.0)	1 (7.1)	6 (42.9)	0	0
Nausea	3 (21.4)	0	3 (21.4)	0	0
Diarrhoea	2 (14.3)	0	2 (14.3)	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Constipation	1 (7.1)	1 (7.1)	0	0	0
Pancreatic failure	1 (7.1)	0	1 (7.1)	0	0
Vomiting	1 (7.1)	0	1 (7.1)	0	0
General disorders and administration site conditions					
-Total	1 (7.1)	0	1 (7.1)	0	0
Pyrexia	1 (7.1)	0	1 (7.1)	0	0
Immune system disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Hypogammaglobulinaemia	1 (7.1)	1 (7.1)	0	0	0
Infections and infestations					
-Total	1 (7.1)	1 (7.1)	0	0	0
Viral upper respiratory tract infection	1 (7.1)	1 (7.1)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (7.1)	0	1 (7.1)	0	0
Radiation skin injury	1 (7.1)	0	1 (7.1)	0	0
Investigations					
-Total	8 (57.1)	0	0	2 (14.3)	6 (42.9)

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	8 (57.1)	0	0	2 (14.3)	6 (42.9)
Neutrophil count decreased	2 (14.3)	0	0	0	2 (14.3)
Weight decreased	1 (7.1)	1 (7.1)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (35.7)	3 (21.4)	0	2 (14.3)	0
Decreased appetite	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Hyperphosphataemia	2 (14.3)	2 (14.3)	0	0	0
Fluid overload	1 (7.1)	0	1 (7.1)	0	0
Hyperuricaemia	1 (7.1)	0	0	1 (7.1)	0
Hypomagnesaemia	1 (7.1)	0	1 (7.1)	0	0
Hypophosphataemia	1 (7.1)	1 (7.1)	0	0	0
Tumour lysis syndrome	1 (7.1)	0	0	1 (7.1)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Arthralgia	1 (7.1)	1 (7.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (14.3)	1 (7.1)	1 (7.1)	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cough	1 (7.1)	1 (7.1)	0	0	0
Epistaxis	1 (7.1)	0	1 (7.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (14.3)	2 (14.3)	0	0	0
Rash erythematous	1 (7.1)	1 (7.1)	0	0	0
Rash pruritic	1 (7.1)	1 (7.1)	0	0	0
Vascular disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Hypertension	1 (7.1)	1 (7.1)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176m
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: No

	All patients N=47				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (80.9)	5 (10.6)	4 (8.5)	13 (27.7)	16 (34.0)
Blood and lymphatic system disorders					
-Total	15 (31.9)	0	0	10 (21.3)	5 (10.6)
Febrile neutropenia	7 (14.9)	0	0	7 (14.9)	0
Anaemia	5 (10.6)	0	1 (2.1)	4 (8.5)	0
Neutropenia	3 (6.4)	0	0	1 (2.1)	2 (4.3)
Thrombocytopenia	2 (4.3)	0	0	1 (2.1)	1 (2.1)
Disseminated intravascular coagulation	1 (2.1)	0	0	0	1 (2.1)
Hypofibrinogenaemia	1 (2.1)	0	0	0	1 (2.1)
Lymphopenia	1 (2.1)	0	0	0	1 (2.1)

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=47 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pancytopenia	1 (2.1)	0	0	1 (2.1)	0
Cardiac disorders					
-Total	4 (8.5)	2 (4.3)	1 (2.1)	1 (2.1)	0
Bradycardia	1 (2.1)	0	1 (2.1)	0	0
Left ventricular dysfunction	1 (2.1)	0	0	1 (2.1)	0
Palpitations	1 (2.1)	1 (2.1)	0	0	0
Tachycardia	1 (2.1)	1 (2.1)	0	0	0
Eye disorders					
-Total	1 (2.1)	1 (2.1)	0	0	0
Eye irritation	1 (2.1)	1 (2.1)	0	0	0
Gastrointestinal disorders					
-Total	10 (21.3)	8 (17.0)	1 (2.1)	1 (2.1)	0
Nausea	5 (10.6)	5 (10.6)	0	0	0
Abdominal pain	2 (4.3)	1 (2.1)	1 (2.1)	0	0
Diarrhoea	2 (4.3)	2 (4.3)	0	0	0
Vomiting	2 (4.3)	2 (4.3)	0	0	0
Abdominal pain lower	1 (2.1)	1 (2.1)	0	0	0
Ascites	1 (2.1)	0	0	1 (2.1)	0

Eligibility for SCT: No

	All patients N=47				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (2.1)	1 (2.1)	0	0	0
Gingival discomfort	1 (2.1)	1 (2.1)	0	0	0
Haematochezia	1 (2.1)	1 (2.1)	0	0	0
Oral mucosal blistering	1 (2.1)	1 (2.1)	0	0	0
General disorders and administration site conditions					
-Total	11 (23.4)	3 (6.4)	7 (14.9)	0	1 (2.1)
Pyrexia	5 (10.6)	1 (2.1)	4 (8.5)	0	0
Catheter site pain	2 (4.3)	2 (4.3)	0	0	0
Chills	1 (2.1)	0	1 (2.1)	0	0
Device related thrombosis	1 (2.1)	0	1 (2.1)	0	0
Medical device pain	1 (2.1)	0	1 (2.1)	0	0
Multiple organ dysfunction syndrome	1 (2.1)	0	0	0	1 (2.1)
Oedema peripheral	1 (2.1)	1 (2.1)	0	0	0
Pain	1 (2.1)	0	1 (2.1)	0	0
Hepatobiliary disorders					
-Total	1 (2.1)	0	0	0	1 (2.1)
Hepatic failure	1 (2.1)	0	0	0	1 (2.1)

Eligibility for SCT: No

	All patients N=47				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	6 (12.8)	0	2 (4.3)	3 (6.4)	1 (2.1)
Device related infection	2 (4.3)	0	1 (2.1)	1 (2.1)	0
Bacteraemia	1 (2.1)	0	0	1 (2.1)	0
Bronchitis	1 (2.1)	0	1 (2.1)	0	0
Necrotising fasciitis	1 (2.1)	0	0	1 (2.1)	0
Otitis media	1 (2.1)	0	1 (2.1)	0	0
Parainfluenzae virus infection	1 (2.1)	1 (2.1)	0	0	0
Pneumonia	1 (2.1)	0	1 (2.1)	0	0
Staphylococcal infection	1 (2.1)	0	0	0	1 (2.1)
Injury, poisoning and procedural complications					
-Total	1 (2.1)	1 (2.1)	0	0	0
Infusion related reaction	1 (2.1)	1 (2.1)	0	0	0
Investigations					
-Total	23 (48.9)	2 (4.3)	3 (6.4)	4 (8.5)	14 (29.8)
White blood cell count decreased	11 (23.4)	0	0	1 (2.1)	10 (21.3)
Neutrophil count decreased	8 (17.0)	0	0	0	8 (17.0)

Eligibility for SCT: No

	All patients N=47				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	7 (14.9)	1 (2.1)	2 (4.3)	3 (6.4)	1 (2.1)
Lymphocyte count decreased	4 (8.5)	0	0	1 (2.1)	3 (6.4)
Platelet count decreased	4 (8.5)	0	1 (2.1)	2 (4.3)	1 (2.1)
Aspartate aminotransferase increased	3 (6.4)	1 (2.1)	1 (2.1)	0	1 (2.1)
C-reactive protein increased	2 (4.3)	0	2 (4.3)	0	0
International normalised ratio increased	2 (4.3)	1 (2.1)	1 (2.1)	0	0
Weight increased	2 (4.3)	2 (4.3)	0	0	0
Activated partial thromboplastin time prolonged	1 (2.1)	0	1 (2.1)	0	0
Blood bilirubin increased	1 (2.1)	0	0	0	1 (2.1)
Blood creatinine increased	1 (2.1)	1 (2.1)	0	0	0
Blood lactic acid increased	1 (2.1)	0	1 (2.1)	0	0
Blood uric acid increased	1 (2.1)	1 (2.1)	0	0	0
Lipase increased	1 (2.1)	0	0	0	1 (2.1)
Protein total decreased	1 (2.1)	0	0	1 (2.1)	0
Metabolism and nutrition disorders					
-Total	10 (21.3)	2 (4.3)	2 (4.3)	4 (8.5)	2 (4.3)

Eligibility for SCT: No

	All patients N=47				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	5 (10.6)	1 (2.1)	0	2 (4.3)	2 (4.3)
Hypoglycaemia	2 (4.3)	0	1 (2.1)	1 (2.1)	0
Hypophosphataemia	2 (4.3)	2 (4.3)	0	0	0
Decreased appetite	1 (2.1)	0	1 (2.1)	0	0
Fluid overload	1 (2.1)	0	1 (2.1)	0	0
Hyperglycaemia	1 (2.1)	0	0	1 (2.1)	0
Hyperkalaemia	1 (2.1)	1 (2.1)	0	0	0
Hypermagnesaemia	1 (2.1)	1 (2.1)	0	0	0
Hypernatraemia	1 (2.1)	0	0	0	1 (2.1)
Hyperphosphataemia	1 (2.1)	0	1 (2.1)	0	0
Hyperuricaemia	1 (2.1)	1 (2.1)	0	0	0
Hypoalbuminaemia	1 (2.1)	0	1 (2.1)	0	0
Hypocalcaemia	1 (2.1)	1 (2.1)	0	0	0
Hypomagnesaemia	1 (2.1)	1 (2.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (8.5)	1 (2.1)	1 (2.1)	2 (4.3)	0
Pain in jaw	2 (4.3)	1 (2.1)	1 (2.1)	0	0

Eligibility for SCT: No

	All patients N=47				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	1 (2.1)	0	0	1 (2.1)	0
Pain in extremity	1 (2.1)	0	0	1 (2.1)	0
Nervous system disorders					
-Total	8 (17.0)	4 (8.5)	4 (8.5)	0	0
Headache	5 (10.6)	3 (6.4)	2 (4.3)	0	0
Dysgeusia	1 (2.1)	1 (2.1)	0	0	0
Hypotonia	1 (2.1)	0	1 (2.1)	0	0
Somnolence	1 (2.1)	0	1 (2.1)	0	0
Product issues					
-Total	1 (2.1)	1 (2.1)	0	0	0
Device occlusion	1 (2.1)	1 (2.1)	0	0	0
Psychiatric disorders					
-Total	5 (10.6)	1 (2.1)	3 (6.4)	1 (2.1)	0
Anxiety	2 (4.3)	1 (2.1)	1 (2.1)	0	0
Delirium	1 (2.1)	0	0	1 (2.1)	0
Depression	1 (2.1)	0	1 (2.1)	0	0
Insomnia	1 (2.1)	0	1 (2.1)	0	0
Irritability	1 (2.1)	1 (2.1)	0	0	0

Eligibility for SCT: No

	All patients N=47				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	1 (2.1)	0	1 (2.1)	0	0
Urinary retention	1 (2.1)	0	1 (2.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (14.9)	2 (4.3)	1 (2.1)	4 (8.5)	0
Hypoxia	3 (6.4)	0	0	3 (6.4)	0
Dyspnoea	2 (4.3)	1 (2.1)	1 (2.1)	0	0
Tachypnoea	2 (4.3)	0	1 (2.1)	1 (2.1)	0
Epistaxis	1 (2.1)	0	0	1 (2.1)	0
Nasal congestion	1 (2.1)	1 (2.1)	0	0	0
Nasal discomfort	1 (2.1)	1 (2.1)	0	0	0
Pleural effusion	1 (2.1)	0	0	1 (2.1)	0
Rhinitis allergic	1 (2.1)	1 (2.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (19.1)	7 (14.9)	1 (2.1)	1 (2.1)	0
Alopecia	2 (4.3)	2 (4.3)	0	0	0
Dermatitis acneiform	1 (2.1)	0	1 (2.1)	0	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=47 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pruritus	1 (2.1)	1 (2.1)	0	0	0
Pruritus generalised	1 (2.1)	1 (2.1)	0	0	0
Rash	1 (2.1)	1 (2.1)	0	0	0
Rash macular	1 (2.1)	0	0	1 (2.1)	0
Skin haemorrhage	1 (2.1)	1 (2.1)	0	0	0
Skin ulcer	1 (2.1)	1 (2.1)	0	0	0
Vascular disorders					
-Total	5 (10.6)	0	1 (2.1)	4 (8.5)	0
Hypotension	3 (6.4)	0	0	3 (6.4)	0
Hypertension	1 (2.1)	0	0	1 (2.1)	0
Phlebitis	1 (2.1)	0	1 (2.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176n
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: Low

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (76.2)	0	2 (9.5)	8 (38.1)	6 (28.6)
Blood and lymphatic system disorders					
-Total	6 (28.6)	0	0	4 (19.0)	2 (9.5)
Febrile neutropenia	3 (14.3)	0	0	3 (14.3)	0
Thrombocytopenia	2 (9.5)	0	0	1 (4.8)	1 (4.8)
Anaemia	1 (4.8)	0	0	1 (4.8)	0
Disseminated intravascular coagulation	1 (4.8)	0	0	0	1 (4.8)
Neutropenia	1 (4.8)	0	0	0	1 (4.8)
Pancytopenia	1 (4.8)	0	0	1 (4.8)	0
Cardiac disorders					

Baseline bone marrow tumor burden: Low

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.8)	1 (4.8)	0	0	0
Palpitations	1 (4.8)	1 (4.8)	0	0	0
Gastrointestinal disorders					
-Total	7 (33.3)	3 (14.3)	3 (14.3)	1 (4.8)	0
Nausea	3 (14.3)	2 (9.5)	1 (4.8)	0	0
Vomiting	3 (14.3)	2 (9.5)	1 (4.8)	0	0
Abdominal pain	1 (4.8)	0	1 (4.8)	0	0
Ascites	1 (4.8)	0	0	1 (4.8)	0
Constipation	1 (4.8)	1 (4.8)	0	0	0
Diarrhoea	1 (4.8)	0	1 (4.8)	0	0
Gingival discomfort	1 (4.8)	1 (4.8)	0	0	0
General disorders and administration site conditions					
-Total	2 (9.5)	1 (4.8)	0	0	1 (4.8)
Pyrexia	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Multiple organ dysfunction syndrome	1 (4.8)	0	0	0	1 (4.8)
Hepatobiliary disorders					
-Total	1 (4.8)	0	0	0	1 (4.8)

Baseline bone marrow tumor burden: Low

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic failure	1 (4.8)	0	0	0	1 (4.8)
Immune system disorders					
-Total	1 (4.8)	1 (4.8)	0	0	0
Hypogammaglobulinaemia	1 (4.8)	1 (4.8)	0	0	0
Infections and infestations					
-Total	3 (14.3)	1 (4.8)	0	1 (4.8)	1 (4.8)
Bronchitis	1 (4.8)	0	1 (4.8)	0	0
Device related infection	1 (4.8)	0	0	1 (4.8)	0
Staphylococcal infection	1 (4.8)	0	0	0	1 (4.8)
Viral upper respiratory tract infection	1 (4.8)	1 (4.8)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Infusion related reaction	1 (4.8)	1 (4.8)	0	0	0
Radiation skin injury	1 (4.8)	0	1 (4.8)	0	0
Investigations					
-Total	10 (47.6)	0	2 (9.5)	2 (9.5)	6 (28.6)
White blood cell count decreased	6 (28.6)	0	0	1 (4.8)	5 (23.8)

Baseline bone marrow tumor burden: Low

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	3 (14.3)	0	0	0	3 (14.3)
Alanine aminotransferase increased	2 (9.5)	0	0	1 (4.8)	1 (4.8)
Aspartate aminotransferase increased	2 (9.5)	0	1 (4.8)	0	1 (4.8)
International normalised ratio increased	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Activated partial thromboplastin time prolonged	1 (4.8)	0	1 (4.8)	0	0
Blood bilirubin increased	1 (4.8)	0	0	0	1 (4.8)
C-reactive protein increased	1 (4.8)	0	1 (4.8)	0	0
Platelet count decreased	1 (4.8)	0	0	0	1 (4.8)
Weight increased	1 (4.8)	1 (4.8)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (23.8)	2 (9.5)	0	2 (9.5)	1 (4.8)
Hypoglycaemia	2 (9.5)	0	1 (4.8)	1 (4.8)	0
Hypokalaemia	2 (9.5)	1 (4.8)	0	0	1 (4.8)
Decreased appetite	1 (4.8)	0	1 (4.8)	0	0
Hyperkalaemia	1 (4.8)	1 (4.8)	0	0	0
Hypernatraemia	1 (4.8)	0	0	0	1 (4.8)

Baseline bone marrow tumor burden: Low

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	1 (4.8)	1 (4.8)	0	0	0
Hyperuricaemia	1 (4.8)	0	0	1 (4.8)	0
Hypoalbuminaemia	1 (4.8)	0	1 (4.8)	0	0
Hypocalcaemia	1 (4.8)	1 (4.8)	0	0	0
Hypomagnesaemia	1 (4.8)	1 (4.8)	0	0	0
Hypophosphataemia	1 (4.8)	1 (4.8)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (9.5)	1 (4.8)	0	1 (4.8)	0
Arthralgia	1 (4.8)	1 (4.8)	0	0	0
Myalgia	1 (4.8)	0	0	1 (4.8)	0
Nervous system disorders					
-Total	2 (9.5)	0	2 (9.5)	0	0
Headache	1 (4.8)	0	1 (4.8)	0	0
Somnolence	1 (4.8)	0	1 (4.8)	0	0
Psychiatric disorders					
-Total	2 (9.5)	0	1 (4.8)	1 (4.8)	0
Anxiety	1 (4.8)	0	1 (4.8)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=21				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	1 (4.8)	0	0	1 (4.8)	0
Renal and urinary disorders					
-Total	1 (4.8)	0	1 (4.8)	0	0
Urinary retention	1 (4.8)	0	1 (4.8)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (14.3)	1 (4.8)	0	2 (9.5)	0
Hypoxia	2 (9.5)	0	0	2 (9.5)	0
Cough	1 (4.8)	1 (4.8)	0	0	0
Dyspnoea	1 (4.8)	1 (4.8)	0	0	0
Pleural effusion	1 (4.8)	0	0	1 (4.8)	0
Tachypnoea	1 (4.8)	0	1 (4.8)	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (19.0)	3 (14.3)	0	1 (4.8)	0
Alopecia	1 (4.8)	1 (4.8)	0	0	0
Pruritus generalised	1 (4.8)	1 (4.8)	0	0	0
Rash	1 (4.8)	1 (4.8)	0	0	0
Rash macular	1 (4.8)	0	0	1 (4.8)	0

Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=21 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	2 (9.5)	0	0	2 (9.5)	0
Hypertension	1 (4.8)	0	0	1 (4.8)	0
Hypotension	1 (4.8)	0	0	1 (4.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176n
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: High

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (87.5)	7 (17.5)	4 (10.0)	8 (20.0)	16 (40.0)
Blood and lymphatic system disorders					
-Total	13 (32.5)	0	1 (2.5)	7 (17.5)	5 (12.5)
Anaemia	6 (15.0)	0	2 (5.0)	4 (10.0)	0
Febrile neutropenia	6 (15.0)	0	1 (2.5)	5 (12.5)	0
Neutropenia	3 (7.5)	0	0	1 (2.5)	2 (5.0)
Hypofibrinogenaemia	1 (2.5)	0	0	0	1 (2.5)
Lymphopenia	1 (2.5)	0	0	0	1 (2.5)
Thrombocytopenia	1 (2.5)	0	0	0	1 (2.5)
Cardiac disorders					
-Total	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0

Baseline bone marrow tumor burden: High

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (2.5)	0	1 (2.5)	0	0
Left ventricular dysfunction	1 (2.5)	0	0	1 (2.5)	0
Tachycardia	1 (2.5)	1 (2.5)	0	0	0
Eye disorders					
-Total	1 (2.5)	1 (2.5)	0	0	0
Eye irritation	1 (2.5)	1 (2.5)	0	0	0
Gastrointestinal disorders					
-Total	10 (25.0)	6 (15.0)	4 (10.0)	0	0
Nausea	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Diarrhoea	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Abdominal pain	1 (2.5)	1 (2.5)	0	0	0
Abdominal pain lower	1 (2.5)	1 (2.5)	0	0	0
Constipation	1 (2.5)	1 (2.5)	0	0	0
Haematochezia	1 (2.5)	1 (2.5)	0	0	0
Oral mucosal blistering	1 (2.5)	1 (2.5)	0	0	0
Pancreatic failure	1 (2.5)	0	1 (2.5)	0	0
General disorders and administration site conditions					

Baseline bone marrow tumor burden: High

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (25.0)	2 (5.0)	8 (20.0)	0	0
Pyrexia	4 (10.0)	0	4 (10.0)	0	0
Catheter site pain	2 (5.0)	2 (5.0)	0	0	0
Chills	1 (2.5)	0	1 (2.5)	0	0
Device related thrombosis	1 (2.5)	0	1 (2.5)	0	0
Medical device pain	1 (2.5)	0	1 (2.5)	0	0
Oedema peripheral	1 (2.5)	1 (2.5)	0	0	0
Pain	1 (2.5)	0	1 (2.5)	0	0
Infections and infestations					
-Total	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Device related infection	1 (2.5)	0	1 (2.5)	0	0
Necrotising fasciitis	1 (2.5)	0	0	1 (2.5)	0
Otitis media	1 (2.5)	0	1 (2.5)	0	0
Parainfluenzae virus infection	1 (2.5)	1 (2.5)	0	0	0
Pneumonia	1 (2.5)	0	1 (2.5)	0	0
Investigations					
-Total	21 (52.5)	2 (5.0)	1 (2.5)	4 (10.0)	14 (35.0)

Baseline bone marrow tumor burden: High

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	13 (32.5)	0	0	2 (5.0)	11 (27.5)
Neutrophil count decreased	7 (17.5)	0	0	0	7 (17.5)
Alanine aminotransferase increased	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Lymphocyte count decreased	4 (10.0)	0	0	1 (2.5)	3 (7.5)
Platelet count decreased	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Aspartate aminotransferase increased	1 (2.5)	1 (2.5)	0	0	0
Blood creatinine increased	1 (2.5)	1 (2.5)	0	0	0
Blood lactic acid increased	1 (2.5)	0	1 (2.5)	0	0
Blood uric acid increased	1 (2.5)	1 (2.5)	0	0	0
C-reactive protein increased	1 (2.5)	0	1 (2.5)	0	0
Lipase increased	1 (2.5)	0	0	0	1 (2.5)
Protein total decreased	1 (2.5)	0	0	1 (2.5)	0
Weight decreased	1 (2.5)	1 (2.5)	0	0	0
Weight increased	1 (2.5)	1 (2.5)	0	0	0
Metabolism and nutrition disorders					
-Total	10 (25.0)	3 (7.5)	2 (5.0)	4 (10.0)	1 (2.5)
Hypokalaemia	3 (7.5)	0	0	2 (5.0)	1 (2.5)

Baseline bone marrow tumor burden: High

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Fluid overload	2 (5.0)	0	2 (5.0)	0	0
Hyperphosphataemia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Hypophosphataemia	2 (5.0)	2 (5.0)	0	0	0
Hyperglycaemia	1 (2.5)	0	0	1 (2.5)	0
Hypermagnesaemia	1 (2.5)	1 (2.5)	0	0	0
Hyperuricaemia	1 (2.5)	1 (2.5)	0	0	0
Hypomagnesaemia	1 (2.5)	0	1 (2.5)	0	0
Tumour lysis syndrome	1 (2.5)	0	0	1 (2.5)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Pain in jaw	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Pain in extremity	1 (2.5)	0	0	1 (2.5)	0
Nervous system disorders					
-Total	6 (15.0)	4 (10.0)	2 (5.0)	0	0
Headache	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Dysgeusia	1 (2.5)	1 (2.5)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotonia	1 (2.5)	0	1 (2.5)	0	0
Product issues					
-Total	1 (2.5)	1 (2.5)	0	0	0
Device occlusion	1 (2.5)	1 (2.5)	0	0	0
Psychiatric disorders					
-Total	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Anxiety	1 (2.5)	1 (2.5)	0	0	0
Depression	1 (2.5)	0	1 (2.5)	0	0
Insomnia	1 (2.5)	0	1 (2.5)	0	0
Irritability	1 (2.5)	1 (2.5)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (15.0)	2 (5.0)	2 (5.0)	2 (5.0)	0
Epistaxis	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Dyspnoea	1 (2.5)	0	1 (2.5)	0	0
Hypoxia	1 (2.5)	0	0	1 (2.5)	0
Nasal congestion	1 (2.5)	1 (2.5)	0	0	0
Nasal discomfort	1 (2.5)	1 (2.5)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis allergic	1 (2.5)	1 (2.5)	0	0	0
Tachypnoea	1 (2.5)	0	0	1 (2.5)	0
Skin and subcutaneous tissue disorders					
-Total	7 (17.5)	6 (15.0)	1 (2.5)	0	0
Alopecia	1 (2.5)	1 (2.5)	0	0	0
Dermatitis acneiform	1 (2.5)	0	1 (2.5)	0	0
Pruritus	1 (2.5)	1 (2.5)	0	0	0
Rash erythematous	1 (2.5)	1 (2.5)	0	0	0
Rash pruritic	1 (2.5)	1 (2.5)	0	0	0
Skin haemorrhage	1 (2.5)	1 (2.5)	0	0	0
Skin ulcer	1 (2.5)	1 (2.5)	0	0	0
Vascular disorders					
-Total	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Hypotension	2 (5.0)	0	0	2 (5.0)	0
Hypertension	1 (2.5)	1 (2.5)	0	0	0
Phlebitis	1 (2.5)	0	1 (2.5)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176o
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	1 (25.0)	0	0	2 (50.0)
Blood and lymphatic system disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Febrile neutropenia	1 (25.0)	0	0	1 (25.0)	0
Lymphopenia	1 (25.0)	0	0	0	1 (25.0)
Cardiac disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Bradycardia	1 (25.0)	0	1 (25.0)	0	0
Gastrointestinal disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Nausea	1 (25.0)	1 (25.0)	0	0	0

Baseline extramedullary disease presence: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatic failure	1 (25.0)	0	1 (25.0)	0	0
General disorders and administration site conditions					
-Total	1 (25.0)	0	1 (25.0)	0	0
Pyrexia	1 (25.0)	0	1 (25.0)	0	0
Infections and infestations					
-Total	1 (25.0)	0	1 (25.0)	0	0
Pneumonia	1 (25.0)	0	1 (25.0)	0	0
Investigations					
-Total	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Blood lactic acid increased	1 (25.0)	0	1 (25.0)	0	0
C-reactive protein increased	1 (25.0)	0	1 (25.0)	0	0
Protein total decreased	1 (25.0)	0	0	1 (25.0)	0
White blood cell count decreased	1 (25.0)	0	0	0	1 (25.0)
Metabolism and nutrition disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Fluid overload	1 (25.0)	0	1 (25.0)	0	0
Hypermagnesaemia	1 (25.0)	1 (25.0)	0	0	0

Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypokalaemia	1 (25.0)	0	0	1 (25.0)	0
Nervous system disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Hypotonia	1 (25.0)	0	1 (25.0)	0	0
Product issues					
-Total	1 (25.0)	1 (25.0)	0	0	0
Device occlusion	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Hypoxia	1 (25.0)	0	0	1 (25.0)	0
Tachypnoea	1 (25.0)	0	0	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of

all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176o
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (84.2)	6 (10.5)	6 (10.5)	16 (28.1)	20 (35.1)
Blood and lymphatic system disorders					
-Total	18 (31.6)	0	1 (1.8)	11 (19.3)	6 (10.5)
Febrile neutropenia	8 (14.0)	0	1 (1.8)	7 (12.3)	0
Anaemia	7 (12.3)	0	2 (3.5)	5 (8.8)	0
Neutropenia	4 (7.0)	0	0	1 (1.8)	3 (5.3)
Thrombocytopenia	3 (5.3)	0	0	1 (1.8)	2 (3.5)
Disseminated intravascular coagulation	1 (1.8)	0	0	0	1 (1.8)
Hypofibrinogenaemia	1 (1.8)	0	0	0	1 (1.8)
Pancytopenia	1 (1.8)	0	0	1 (1.8)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac disorders					
-Total	3 (5.3)	2 (3.5)	0	1 (1.8)	0
Left ventricular dysfunction	1 (1.8)	0	0	1 (1.8)	0
Palpitations	1 (1.8)	1 (1.8)	0	0	0
Tachycardia	1 (1.8)	1 (1.8)	0	0	0
Eye disorders					
-Total	1 (1.8)	1 (1.8)	0	0	0
Eye irritation	1 (1.8)	1 (1.8)	0	0	0
Gastrointestinal disorders					
-Total	15 (26.3)	8 (14.0)	6 (10.5)	1 (1.8)	0
Nausea	7 (12.3)	4 (7.0)	3 (5.3)	0	0
Diarrhoea	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Vomiting	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Abdominal pain	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Constipation	2 (3.5)	2 (3.5)	0	0	0
Abdominal pain lower	1 (1.8)	1 (1.8)	0	0	0
Ascites	1 (1.8)	0	0	1 (1.8)	0
Gingival discomfort	1 (1.8)	1 (1.8)	0	0	0

Baseline extramedullary disease presence: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematochezia	1 (1.8)	1 (1.8)	0	0	0
Oral mucosal blistering	1 (1.8)	1 (1.8)	0	0	0
General disorders and administration site conditions					
-Total	11 (19.3)	3 (5.3)	7 (12.3)	0	1 (1.8)
Pyrexia	5 (8.8)	1 (1.8)	4 (7.0)	0	0
Catheter site pain	2 (3.5)	2 (3.5)	0	0	0
Chills	1 (1.8)	0	1 (1.8)	0	0
Device related thrombosis	1 (1.8)	0	1 (1.8)	0	0
Medical device pain	1 (1.8)	0	1 (1.8)	0	0
Multiple organ dysfunction syndrome	1 (1.8)	0	0	0	1 (1.8)
Oedema peripheral	1 (1.8)	1 (1.8)	0	0	0
Pain	1 (1.8)	0	1 (1.8)	0	0
Hepatobiliary disorders					
-Total	1 (1.8)	0	0	0	1 (1.8)
Hepatic failure	1 (1.8)	0	0	0	1 (1.8)
Immune system disorders					
-Total	1 (1.8)	1 (1.8)	0	0	0

Baseline extramedullary disease presence: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	1 (1.8)	1 (1.8)	0	0	0
Infections and infestations					
-Total	6 (10.5)	1 (1.8)	1 (1.8)	3 (5.3)	1 (1.8)
Device related infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Necrotising fasciitis	1 (1.8)	0	0	1 (1.8)	0
Otitis media	1 (1.8)	0	1 (1.8)	0	0
Parainfluenzae virus infection	1 (1.8)	1 (1.8)	0	0	0
Staphylococcal infection	1 (1.8)	0	0	0	1 (1.8)
Viral upper respiratory tract infection	1 (1.8)	1 (1.8)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Infusion related reaction	1 (1.8)	1 (1.8)	0	0	0
Radiation skin injury	1 (1.8)	0	1 (1.8)	0	0
Investigations					
-Total	29 (50.9)	2 (3.5)	3 (5.3)	5 (8.8)	19 (33.3)

Baseline extramedullary disease presence: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	18 (31.6)	0	0	3 (5.3)	15 (26.3)
Neutrophil count decreased	10 (17.5)	0	0	0	10 (17.5)
Alanine aminotransferase increased	7 (12.3)	1 (1.8)	2 (3.5)	3 (5.3)	1 (1.8)
Lymphocyte count decreased	4 (7.0)	0	0	1 (1.8)	3 (5.3)
Platelet count decreased	4 (7.0)	0	1 (1.8)	2 (3.5)	1 (1.8)
Aspartate aminotransferase increased	3 (5.3)	1 (1.8)	1 (1.8)	0	1 (1.8)
International normalised ratio increased	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Weight increased	2 (3.5)	2 (3.5)	0	0	0
Activated partial thromboplastin time prolonged	1 (1.8)	0	1 (1.8)	0	0
Blood bilirubin increased	1 (1.8)	0	0	0	1 (1.8)
Blood creatinine increased	1 (1.8)	1 (1.8)	0	0	0
Blood uric acid increased	1 (1.8)	1 (1.8)	0	0	0
C-reactive protein increased	1 (1.8)	0	1 (1.8)	0	0
Lipase increased	1 (1.8)	0	0	0	1 (1.8)
Weight decreased	1 (1.8)	1 (1.8)	0	0	0
Metabolism and nutrition disorders					

Baseline extramedullary disease presence: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (24.6)	5 (8.8)	2 (3.5)	5 (8.8)	2 (3.5)
Hypokalaemia	4 (7.0)	1 (1.8)	0	1 (1.8)	2 (3.5)
Decreased appetite	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Hyperphosphataemia	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Hypophosphataemia	3 (5.3)	3 (5.3)	0	0	0
Hyperuricaemia	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Hypoglycaemia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Hypomagnesaemia	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Fluid overload	1 (1.8)	0	1 (1.8)	0	0
Hyperglycaemia	1 (1.8)	0	0	1 (1.8)	0
Hyperkalaemia	1 (1.8)	1 (1.8)	0	0	0
Hypernatraemia	1 (1.8)	0	0	0	1 (1.8)
Hypoalbuminaemia	1 (1.8)	0	1 (1.8)	0	0
Hypocalcaemia	1 (1.8)	1 (1.8)	0	0	0
Tumour lysis syndrome	1 (1.8)	0	0	1 (1.8)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (8.8)	2 (3.5)	1 (1.8)	2 (3.5)	0

Baseline extramedullary disease presence: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in jaw	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Arthralgia	1 (1.8)	1 (1.8)	0	0	0
Myalgia	1 (1.8)	0	0	1 (1.8)	0
Pain in extremity	1 (1.8)	0	0	1 (1.8)	0
Nervous system disorders					
-Total	7 (12.3)	4 (7.0)	3 (5.3)	0	0
Headache	5 (8.8)	3 (5.3)	2 (3.5)	0	0
Dysgeusia	1 (1.8)	1 (1.8)	0	0	0
Somnolence	1 (1.8)	0	1 (1.8)	0	0
Psychiatric disorders					
-Total	5 (8.8)	1 (1.8)	3 (5.3)	1 (1.8)	0
Anxiety	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Delirium	1 (1.8)	0	0	1 (1.8)	0
Depression	1 (1.8)	0	1 (1.8)	0	0
Insomnia	1 (1.8)	0	1 (1.8)	0	0
Irritability	1 (1.8)	1 (1.8)	0	0	0
Renal and urinary disorders					
-Total	1 (1.8)	0	1 (1.8)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urinary retention	1 (1.8)	0	1 (1.8)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (14.0)	3 (5.3)	2 (3.5)	3 (5.3)	0
Dyspnoea	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Epistaxis	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Hypoxia	2 (3.5)	0	0	2 (3.5)	0
Cough	1 (1.8)	1 (1.8)	0	0	0
Nasal congestion	1 (1.8)	1 (1.8)	0	0	0
Nasal discomfort	1 (1.8)	1 (1.8)	0	0	0
Pleural effusion	1 (1.8)	0	0	1 (1.8)	0
Rhinitis allergic	1 (1.8)	1 (1.8)	0	0	0
Tachypnoea	1 (1.8)	0	1 (1.8)	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (19.3)	9 (15.8)	1 (1.8)	1 (1.8)	0
Alopecia	2 (3.5)	2 (3.5)	0	0	0
Dermatitis acneiform	1 (1.8)	0	1 (1.8)	0	0
Pruritus	1 (1.8)	1 (1.8)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pruritus generalised	1 (1.8)	1 (1.8)	0	0	0
Rash	1 (1.8)	1 (1.8)	0	0	0
Rash erythematous	1 (1.8)	1 (1.8)	0	0	0
Rash macular	1 (1.8)	0	0	1 (1.8)	0
Rash pruritic	1 (1.8)	1 (1.8)	0	0	0
Skin haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Skin ulcer	1 (1.8)	1 (1.8)	0	0	0
Vascular disorders					
-Total	6 (10.5)	1 (1.8)	1 (1.8)	4 (7.0)	0
Hypotension	3 (5.3)	0	0	3 (5.3)	0
Hypertension	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Phlebitis	1 (1.8)	0	1 (1.8)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of

all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176p
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Blood and lymphatic system disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Thrombocytopenia	1 (25.0)	0	0	1 (25.0)	0
Immune system disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Hypogammaglobulinaemia	1 (25.0)	1 (25.0)	0	0	0
Infections and infestations					
-Total	1 (25.0)	1 (25.0)	0	0	0
Viral upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0

Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	1 (25.0)	0	1 (25.0)	0	0
Radiation skin injury	1 (25.0)	0	1 (25.0)	0	0
Metabolism and nutrition disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Hyperphosphataemia	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Arthralgia	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Cough	1 (25.0)	1 (25.0)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176p
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	49 (86.0)	7 (12.3)	5 (8.8)	15 (26.3)	22 (38.6)
Blood and lymphatic system disorders					
-Total	18 (31.6)	0	1 (1.8)	10 (17.5)	7 (12.3)
Febrile neutropenia	9 (15.8)	0	1 (1.8)	8 (14.0)	0
Anaemia	7 (12.3)	0	2 (3.5)	5 (8.8)	0
Neutropenia	4 (7.0)	0	0	1 (1.8)	3 (5.3)
Thrombocytopenia	2 (3.5)	0	0	0	2 (3.5)
Disseminated intravascular coagulation	1 (1.8)	0	0	0	1 (1.8)
Hypofibrinogenaemia	1 (1.8)	0	0	0	1 (1.8)
Lymphopenia	1 (1.8)	0	0	0	1 (1.8)

Down syndrome: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pancytopenia	1 (1.8)	0	0	1 (1.8)	0
Cardiac disorders					
-Total	4 (7.0)	2 (3.5)	1 (1.8)	1 (1.8)	0
Bradycardia	1 (1.8)	0	1 (1.8)	0	0
Left ventricular dysfunction	1 (1.8)	0	0	1 (1.8)	0
Palpitations	1 (1.8)	1 (1.8)	0	0	0
Tachycardia	1 (1.8)	1 (1.8)	0	0	0
Eye disorders					
-Total	1 (1.8)	1 (1.8)	0	0	0
Eye irritation	1 (1.8)	1 (1.8)	0	0	0
Gastrointestinal disorders					
-Total	17 (29.8)	9 (15.8)	7 (12.3)	1 (1.8)	0
Nausea	8 (14.0)	5 (8.8)	3 (5.3)	0	0
Diarrhoea	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Vomiting	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Abdominal pain	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Constipation	2 (3.5)	2 (3.5)	0	0	0
Abdominal pain lower	1 (1.8)	1 (1.8)	0	0	0

Down syndrome: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	1 (1.8)	0	0	1 (1.8)	0
Gingival discomfort	1 (1.8)	1 (1.8)	0	0	0
Haematochezia	1 (1.8)	1 (1.8)	0	0	0
Oral mucosal blistering	1 (1.8)	1 (1.8)	0	0	0
Pancreatic failure	1 (1.8)	0	1 (1.8)	0	0
General disorders and administration site conditions					
-Total	12 (21.1)	3 (5.3)	8 (14.0)	0	1 (1.8)
Pyrexia	6 (10.5)	1 (1.8)	5 (8.8)	0	0
Catheter site pain	2 (3.5)	2 (3.5)	0	0	0
Chills	1 (1.8)	0	1 (1.8)	0	0
Device related thrombosis	1 (1.8)	0	1 (1.8)	0	0
Medical device pain	1 (1.8)	0	1 (1.8)	0	0
Multiple organ dysfunction syndrome	1 (1.8)	0	0	0	1 (1.8)
Oedema peripheral	1 (1.8)	1 (1.8)	0	0	0
Pain	1 (1.8)	0	1 (1.8)	0	0
Hepatobiliary disorders					
-Total	1 (1.8)	0	0	0	1 (1.8)

Down syndrome: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic failure	1 (1.8)	0	0	0	1 (1.8)
Infections and infestations					
-Total	6 (10.5)	0	2 (3.5)	3 (5.3)	1 (1.8)
Device related infection	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Necrotising fasciitis	1 (1.8)	0	0	1 (1.8)	0
Otitis media	1 (1.8)	0	1 (1.8)	0	0
Parainfluenzae virus infection	1 (1.8)	1 (1.8)	0	0	0
Pneumonia	1 (1.8)	0	1 (1.8)	0	0
Staphylococcal infection	1 (1.8)	0	0	0	1 (1.8)
Injury, poisoning and procedural complications					
-Total	1 (1.8)	1 (1.8)	0	0	0
Infusion related reaction	1 (1.8)	1 (1.8)	0	0	0
Investigations					
-Total	31 (54.4)	2 (3.5)	3 (5.3)	6 (10.5)	20 (35.1)
White blood cell count decreased	19 (33.3)	0	0	3 (5.3)	16 (28.1)

Down syndrome: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	10 (17.5)	0	0	0	10 (17.5)
Alanine aminotransferase increased	7 (12.3)	1 (1.8)	2 (3.5)	3 (5.3)	1 (1.8)
Lymphocyte count decreased	4 (7.0)	0	0	1 (1.8)	3 (5.3)
Platelet count decreased	4 (7.0)	0	1 (1.8)	2 (3.5)	1 (1.8)
Aspartate aminotransferase increased	3 (5.3)	1 (1.8)	1 (1.8)	0	1 (1.8)
C-reactive protein increased	2 (3.5)	0	2 (3.5)	0	0
International normalised ratio increased	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Weight increased	2 (3.5)	2 (3.5)	0	0	0
Activated partial thromboplastin time prolonged	1 (1.8)	0	1 (1.8)	0	0
Blood bilirubin increased	1 (1.8)	0	0	0	1 (1.8)
Blood creatinine increased	1 (1.8)	1 (1.8)	0	0	0
Blood lactic acid increased	1 (1.8)	0	1 (1.8)	0	0
Blood uric acid increased	1 (1.8)	1 (1.8)	0	0	0
Lipase increased	1 (1.8)	0	0	0	1 (1.8)
Protein total decreased	1 (1.8)	0	0	1 (1.8)	0
Weight decreased	1 (1.8)	1 (1.8)	0	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders					
-Total	14 (24.6)	4 (7.0)	2 (3.5)	6 (10.5)	2 (3.5)
Hypokalaemia	5 (8.8)	1 (1.8)	0	2 (3.5)	2 (3.5)
Decreased appetite	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Hypophosphataemia	3 (5.3)	3 (5.3)	0	0	0
Fluid overload	2 (3.5)	0	2 (3.5)	0	0
Hyperphosphataemia	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Hyperuricaemia	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Hypoglycaemia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Hypomagnesaemia	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Hyperglycaemia	1 (1.8)	0	0	1 (1.8)	0
Hyperkalaemia	1 (1.8)	1 (1.8)	0	0	0
Hypermagnesaemia	1 (1.8)	1 (1.8)	0	0	0
Hypernatraemia	1 (1.8)	0	0	0	1 (1.8)
Hypoalbuminaemia	1 (1.8)	0	1 (1.8)	0	0
Hypocalcaemia	1 (1.8)	1 (1.8)	0	0	0
Tumour lysis syndrome	1 (1.8)	0	0	1 (1.8)	0

Down syndrome: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	4 (7.0)	1 (1.8)	1 (1.8)	2 (3.5)	0
Pain in jaw	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Myalgia	1 (1.8)	0	0	1 (1.8)	0
Pain in extremity	1 (1.8)	0	0	1 (1.8)	0
Nervous system disorders					
-Total	8 (14.0)	4 (7.0)	4 (7.0)	0	0
Headache	5 (8.8)	3 (5.3)	2 (3.5)	0	0
Dysgeusia	1 (1.8)	1 (1.8)	0	0	0
Hypotonia	1 (1.8)	0	1 (1.8)	0	0
Somnolence	1 (1.8)	0	1 (1.8)	0	0
Product issues					
-Total	1 (1.8)	1 (1.8)	0	0	0
Device occlusion	1 (1.8)	1 (1.8)	0	0	0
Psychiatric disorders					
-Total	5 (8.8)	1 (1.8)	3 (5.3)	1 (1.8)	0
Anxiety	2 (3.5)	1 (1.8)	1 (1.8)	0	0

Down syndrome: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	1 (1.8)	0	0	1 (1.8)	0
Depression	1 (1.8)	0	1 (1.8)	0	0
Insomnia	1 (1.8)	0	1 (1.8)	0	0
Irritability	1 (1.8)	1 (1.8)	0	0	0
Renal and urinary disorders					
-Total	1 (1.8)	0	1 (1.8)	0	0
Urinary retention	1 (1.8)	0	1 (1.8)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (14.0)	2 (3.5)	2 (3.5)	4 (7.0)	0
Hypoxia	3 (5.3)	0	0	3 (5.3)	0
Dyspnoea	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Epistaxis	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Tachypnoea	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Nasal congestion	1 (1.8)	1 (1.8)	0	0	0
Nasal discomfort	1 (1.8)	1 (1.8)	0	0	0
Pleural effusion	1 (1.8)	0	0	1 (1.8)	0
Rhinitis allergic	1 (1.8)	1 (1.8)	0	0	0

Down syndrome: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	11 (19.3)	9 (15.8)	1 (1.8)	1 (1.8)	0
Alopecia	2 (3.5)	2 (3.5)	0	0	0
Dermatitis acneiform	1 (1.8)	0	1 (1.8)	0	0
Pruritus	1 (1.8)	1 (1.8)	0	0	0
Pruritus generalised	1 (1.8)	1 (1.8)	0	0	0
Rash	1 (1.8)	1 (1.8)	0	0	0
Rash erythematous	1 (1.8)	1 (1.8)	0	0	0
Rash macular	1 (1.8)	0	0	1 (1.8)	0
Rash pruritic	1 (1.8)	1 (1.8)	0	0	0
Skin haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Skin ulcer	1 (1.8)	1 (1.8)	0	0	0
Vascular disorders					
-Total	6 (10.5)	1 (1.8)	1 (1.8)	4 (7.0)	0
Hypotension	3 (5.3)	0	0	3 (5.3)	0
Hypertension	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Phlebitis	1 (1.8)	0	1 (1.8)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176q
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: > Median

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (93.5)	4 (12.9)	3 (9.7)	8 (25.8)	14 (45.2)
Blood and lymphatic system disorders					
-Total	10 (32.3)	0	1 (3.2)	6 (19.4)	3 (9.7)
Anaemia	4 (12.9)	0	1 (3.2)	3 (9.7)	0
Febrile neutropenia	3 (9.7)	0	1 (3.2)	2 (6.5)	0
Neutropenia	2 (6.5)	0	0	0	2 (6.5)
Hypofibrinogenaemia	1 (3.2)	0	0	0	1 (3.2)
Pancytopenia	1 (3.2)	0	0	1 (3.2)	0
Thrombocytopenia	1 (3.2)	0	0	1 (3.2)	0
Gastrointestinal disorders					
-Total	12 (38.7)	6 (19.4)	6 (19.4)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	5 (16.1)	2 (6.5)	3 (9.7)	0	0
Vomiting	3 (9.7)	2 (6.5)	1 (3.2)	0	0
Abdominal pain	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Constipation	2 (6.5)	2 (6.5)	0	0	0
Diarrhoea	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Oral mucosal blistering	1 (3.2)	1 (3.2)	0	0	0
Pancreatic failure	1 (3.2)	0	1 (3.2)	0	0
General disorders and administration site conditions					
-Total	4 (12.9)	1 (3.2)	3 (9.7)	0	0
Pyrexia	2 (6.5)	0	2 (6.5)	0	0
Catheter site pain	1 (3.2)	1 (3.2)	0	0	0
Device related thrombosis	1 (3.2)	0	1 (3.2)	0	0
Oedema peripheral	1 (3.2)	1 (3.2)	0	0	0
Immune system disorders					
-Total	1 (3.2)	1 (3.2)	0	0	0
Hypogammaglobulinaemia	1 (3.2)	1 (3.2)	0	0	0
Infections and infestations					

Time since enrollment to CTL019 infusion: > Median

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (9.7)	1 (3.2)	0	2 (6.5)	0
Bacteraemia	1 (3.2)	0	0	1 (3.2)	0
Device related infection	1 (3.2)	0	0	1 (3.2)	0
Viral upper respiratory tract infection	1 (3.2)	1 (3.2)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (3.2)	0	1 (3.2)	0	0
Radiation skin injury	1 (3.2)	0	1 (3.2)	0	0
Investigations					
-Total	20 (64.5)	1 (3.2)	1 (3.2)	4 (12.9)	14 (45.2)
White blood cell count decreased	14 (45.2)	0	0	3 (9.7)	11 (35.5)
Neutrophil count decreased	6 (19.4)	0	0	0	6 (19.4)
Alanine aminotransferase increased	4 (12.9)	1 (3.2)	1 (3.2)	2 (6.5)	0
Lymphocyte count decreased	3 (9.7)	0	0	1 (3.2)	2 (6.5)
Platelet count decreased	3 (9.7)	0	1 (3.2)	1 (3.2)	1 (3.2)
C-reactive protein increased	1 (3.2)	0	1 (3.2)	0	0
International normalised ratio increased	1 (3.2)	1 (3.2)	0	0	0
Lipase increased	1 (3.2)	0	0	0	1 (3.2)

Time since enrollment to CTL019 infusion: > Median

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight decreased	1 (3.2)	1 (3.2)	0	0	0
Weight increased	1 (3.2)	1 (3.2)	0	0	0
Metabolism and nutrition disorders					
-Total	10 (32.3)	4 (12.9)	1 (3.2)	4 (12.9)	1 (3.2)
Decreased appetite	3 (9.7)	1 (3.2)	2 (6.5)	0	0
Hypokalaemia	3 (9.7)	1 (3.2)	0	1 (3.2)	1 (3.2)
Hypophosphataemia	3 (9.7)	3 (9.7)	0	0	0
Hypomagnesaemia	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Fluid overload	1 (3.2)	0	1 (3.2)	0	0
Hyperkalaemia	1 (3.2)	1 (3.2)	0	0	0
Hyperphosphataemia	1 (3.2)	1 (3.2)	0	0	0
Hyperuricaemia	1 (3.2)	0	0	1 (3.2)	0
Hypocalcaemia	1 (3.2)	1 (3.2)	0	0	0
Hypoglycaemia	1 (3.2)	0	0	1 (3.2)	0
Tumour lysis syndrome	1 (3.2)	0	0	1 (3.2)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (12.9)	2 (6.5)	1 (3.2)	1 (3.2)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in jaw	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Arthralgia	1 (3.2)	1 (3.2)	0	0	0
Myalgia	1 (3.2)	0	0	1 (3.2)	0
Nervous system disorders					
-Total	4 (12.9)	2 (6.5)	2 (6.5)	0	0
Headache	4 (12.9)	2 (6.5)	2 (6.5)	0	0
Product issues					
-Total	1 (3.2)	1 (3.2)	0	0	0
Device occlusion	1 (3.2)	1 (3.2)	0	0	0
Psychiatric disorders					
-Total	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Anxiety	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Irritability	1 (3.2)	1 (3.2)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (12.9)	1 (3.2)	1 (3.2)	2 (6.5)	0
Epistaxis	2 (6.5)	0	1 (3.2)	1 (3.2)	0
Cough	1 (3.2)	1 (3.2)	0	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=31				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	1 (3.2)	1 (3.2)	0	0	0
Hypoxia	1 (3.2)	0	0	1 (3.2)	0
Tachypnoea	1 (3.2)	0	1 (3.2)	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (12.9)	4 (12.9)	0	0	0
Pruritus	1 (3.2)	1 (3.2)	0	0	0
Rash	1 (3.2)	1 (3.2)	0	0	0
Rash pruritic	1 (3.2)	1 (3.2)	0	0	0
Skin ulcer	1 (3.2)	1 (3.2)	0	0	0
Vascular disorders					
-Total	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Hypertension	2 (6.5)	1 (3.2)	0	1 (3.2)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176q
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: <=Median

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (72.4)	3 (10.3)	3 (10.3)	8 (27.6)	7 (24.1)
Blood and lymphatic system disorders					
-Total	8 (27.6)	0	0	5 (17.2)	3 (10.3)
Febrile neutropenia	5 (17.2)	0	0	5 (17.2)	0
Anaemia	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Neutropenia	2 (6.9)	0	0	1 (3.4)	1 (3.4)
Lymphopenia	1 (3.4)	0	0	0	1 (3.4)
Thrombocytopenia	1 (3.4)	0	0	0	1 (3.4)
Cardiac disorders					
-Total	4 (13.8)	2 (6.9)	1 (3.4)	1 (3.4)	0
Bradycardia	1 (3.4)	0	1 (3.4)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (3.4)	0	0	1 (3.4)	0
Palpitations	1 (3.4)	1 (3.4)	0	0	0
Tachycardia	1 (3.4)	1 (3.4)	0	0	0
Eye disorders					
-Total	1 (3.4)	1 (3.4)	0	0	0
Eye irritation	1 (3.4)	1 (3.4)	0	0	0
Gastrointestinal disorders					
-Total	4 (13.8)	3 (10.3)	1 (3.4)	0	0
Nausea	3 (10.3)	3 (10.3)	0	0	0
Diarrhoea	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Abdominal pain lower	1 (3.4)	1 (3.4)	0	0	0
Gingival discomfort	1 (3.4)	1 (3.4)	0	0	0
Haematochezia	1 (3.4)	1 (3.4)	0	0	0
General disorders and administration site conditions					
-Total	7 (24.1)	2 (6.9)	5 (17.2)	0	0
Pyrexia	3 (10.3)	1 (3.4)	2 (6.9)	0	0
Catheter site pain	1 (3.4)	1 (3.4)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=29 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Chills	1 (3.4)	0	1 (3.4)	0	0
Medical device pain	1 (3.4)	0	1 (3.4)	0	0
Pain	1 (3.4)	0	1 (3.4)	0	0
Infections and infestations					
-Total	3 (10.3)	0	2 (6.9)	1 (3.4)	0
Device related infection	1 (3.4)	0	1 (3.4)	0	0
Necrotising fasciitis	1 (3.4)	0	0	1 (3.4)	0
Otitis media	1 (3.4)	0	1 (3.4)	0	0
Parainfluenzae virus infection	1 (3.4)	1 (3.4)	0	0	0
Pneumonia	1 (3.4)	0	1 (3.4)	0	0
Injury, poisoning and procedural complications					
-Total	1 (3.4)	1 (3.4)	0	0	0
Infusion related reaction	1 (3.4)	1 (3.4)	0	0	0
Investigations					
-Total	10 (34.5)	1 (3.4)	2 (6.9)	2 (6.9)	5 (17.2)
White blood cell count decreased	5 (17.2)	0	0	0	5 (17.2)
Neutrophil count decreased	3 (10.3)	0	0	0	3 (10.3)

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=29 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Alanine aminotransferase increased	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Aspartate aminotransferase increased	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Blood creatinine increased	1 (3.4)	1 (3.4)	0	0	0
Blood lactic acid increased	1 (3.4)	0	1 (3.4)	0	0
Blood uric acid increased	1 (3.4)	1 (3.4)	0	0	0
C-reactive protein increased	1 (3.4)	0	1 (3.4)	0	0
Lymphocyte count decreased	1 (3.4)	0	0	0	1 (3.4)
Platelet count decreased	1 (3.4)	0	0	1 (3.4)	0
Protein total decreased	1 (3.4)	0	0	1 (3.4)	0
Metabolism and nutrition disorders					
-Total	4 (13.8)	1 (3.4)	1 (3.4)	2 (6.9)	0
Hyperphosphataemia	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Fluid overload	1 (3.4)	0	1 (3.4)	0	0
Hyperglycaemia	1 (3.4)	0	0	1 (3.4)	0
Hypermagnesaemia	1 (3.4)	1 (3.4)	0	0	0
Hyperuricaemia	1 (3.4)	1 (3.4)	0	0	0
Hypokalaemia	1 (3.4)	0	0	1 (3.4)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	1 (3.4)	0	0	1 (3.4)	0
Pain in extremity	1 (3.4)	0	0	1 (3.4)	0
Nervous system disorders					
-Total	3 (10.3)	2 (6.9)	1 (3.4)	0	0
Dysgeusia	1 (3.4)	1 (3.4)	0	0	0
Headache	1 (3.4)	1 (3.4)	0	0	0
Hypotonia	1 (3.4)	0	1 (3.4)	0	0
Psychiatric disorders					
-Total	2 (6.9)	0	2 (6.9)	0	0
Depression	1 (3.4)	0	1 (3.4)	0	0
Insomnia	1 (3.4)	0	1 (3.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (13.8)	2 (6.9)	1 (3.4)	1 (3.4)	0
Dyspnoea	1 (3.4)	0	1 (3.4)	0	0
Hypoxia	1 (3.4)	0	0	1 (3.4)	0
Nasal congestion	1 (3.4)	1 (3.4)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=29				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal discomfort	1 (3.4)	1 (3.4)	0	0	0
Rhinitis allergic	1 (3.4)	1 (3.4)	0	0	0
Tachypnoea	1 (3.4)	0	0	1 (3.4)	0
Skin and subcutaneous tissue disorders					
-Total	7 (24.1)	5 (17.2)	1 (3.4)	1 (3.4)	0
Alopecia	2 (6.9)	2 (6.9)	0	0	0
Dermatitis acneiform	1 (3.4)	0	1 (3.4)	0	0
Pruritus generalised	1 (3.4)	1 (3.4)	0	0	0
Rash erythematous	1 (3.4)	1 (3.4)	0	0	0
Rash macular	1 (3.4)	0	0	1 (3.4)	0
Skin haemorrhage	1 (3.4)	1 (3.4)	0	0	0
Vascular disorders					
-Total	3 (10.3)	0	1 (3.4)	2 (6.9)	0
Hypotension	2 (6.9)	0	0	2 (6.9)	0
Phlebitis	1 (3.4)	0	1 (3.4)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176q
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: Missing

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Blood and lymphatic system disorders					
-Total	1 (100)	0	0	0	1 (100)
Anaemia	1 (100)	0	0	1 (100)	0
Disseminated intravascular coagulation	1 (100)	0	0	0	1 (100)
Febrile neutropenia	1 (100)	0	0	1 (100)	0
Thrombocytopenia	1 (100)	0	0	0	1 (100)
Gastrointestinal disorders					
-Total	1 (100)	0	0	1 (100)	0
Ascites	1 (100)	0	0	1 (100)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	1 (100)	0	0	0	1 (100)
Multiple organ dysfunction syndrome	1 (100)	0	0	0	1 (100)
Pyrexia	1 (100)	0	1 (100)	0	0
Hepatobiliary disorders					
-Total	1 (100)	0	0	0	1 (100)
Hepatic failure	1 (100)	0	0	0	1 (100)
Infections and infestations					
-Total	1 (100)	0	0	0	1 (100)
Bronchitis	1 (100)	0	1 (100)	0	0
Staphylococcal infection	1 (100)	0	0	0	1 (100)
Investigations					
-Total	1 (100)	0	0	0	1 (100)
Activated partial thromboplastin time prolonged	1 (100)	0	1 (100)	0	0
Alanine aminotransferase increased	1 (100)	0	0	0	1 (100)
Aspartate aminotransferase increased	1 (100)	0	0	0	1 (100)

Time since enrollment to CTL019 infusion: Missing

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (100)	0	0	0	1 (100)
International normalised ratio increased	1 (100)	0	1 (100)	0	0
Neutrophil count decreased	1 (100)	0	0	0	1 (100)
Weight increased	1 (100)	1 (100)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (100)	0	0	0	1 (100)
Hypernatraemia	1 (100)	0	0	0	1 (100)
Hypoalbuminaemia	1 (100)	0	1 (100)	0	0
Hypoglycaemia	1 (100)	0	1 (100)	0	0
Hypokalaemia	1 (100)	0	0	0	1 (100)
Nervous system disorders					
-Total	1 (100)	0	1 (100)	0	0
Somnolence	1 (100)	0	1 (100)	0	0
Psychiatric disorders					
-Total	1 (100)	0	0	1 (100)	0
Delirium	1 (100)	0	0	1 (100)	0
Renal and urinary disorders					

Time since enrollment to CTL019 infusion: Missing

Primary system organ class Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (100)	0	1 (100)	0	0
Urinary retention	1 (100)	0	1 (100)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	0	0	1 (100)	0
Hypoxia	1 (100)	0	0	1 (100)	0
Pleural effusion	1 (100)	0	0	1 (100)	0
Vascular disorders					
-Total	1 (100)	0	0	1 (100)	0
Hypotension	1 (100)	0	0	1 (100)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176r
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 0

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (57.1)	0	0	1 (14.3)	3 (42.9)
Blood and lymphatic system disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)
Anaemia	1 (14.3)	0	1 (14.3)	0	0
Neutropenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0
Gastrointestinal disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Vomiting	1 (14.3)	1 (14.3)	0	0	0

Number of previous relapses: 0

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	1 (14.3)	0	1 (14.3)	0	0
Pyrexia	1 (14.3)	0	1 (14.3)	0	0
Investigations					
-Total	2 (28.6)	0	0	0	2 (28.6)
Neutrophil count decreased	2 (28.6)	0	0	0	2 (28.6)
White blood cell count decreased	2 (28.6)	0	0	0	2 (28.6)
Metabolism and nutrition disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Hypokalaemia	1 (14.3)	1 (14.3)	0	0	0
Nervous system disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Dysgeusia	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	2 (28.6)	0	2 (28.6)	0	0
Depression	1 (14.3)	0	1 (14.3)	0	0
Insomnia	1 (14.3)	0	1 (14.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176r
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 1

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (89.5)	4 (21.1)	1 (5.3)	5 (26.3)	7 (36.8)
Blood and lymphatic system disorders					
-Total	6 (31.6)	0	0	4 (21.1)	2 (10.5)
Febrile neutropenia	3 (15.8)	0	0	3 (15.8)	0
Anaemia	1 (5.3)	0	0	1 (5.3)	0
Hypofibrinogenaemia	1 (5.3)	0	0	0	1 (5.3)
Lymphopenia	1 (5.3)	0	0	0	1 (5.3)
Thrombocytopenia	1 (5.3)	0	0	1 (5.3)	0
Cardiac disorders					
-Total	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Bradycardia	1 (5.3)	0	1 (5.3)	0	0

Number of previous relapses: 1

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (5.3)	1 (5.3)	0	0	0
Eye disorders					
-Total	1 (5.3)	1 (5.3)	0	0	0
Eye irritation	1 (5.3)	1 (5.3)	0	0	0
Gastrointestinal disorders					
-Total	6 (31.6)	4 (21.1)	2 (10.5)	0	0
Nausea	4 (21.1)	3 (15.8)	1 (5.3)	0	0
Abdominal pain lower	1 (5.3)	1 (5.3)	0	0	0
Diarrhoea	1 (5.3)	1 (5.3)	0	0	0
Haematochezia	1 (5.3)	1 (5.3)	0	0	0
Oral mucosal blistering	1 (5.3)	1 (5.3)	0	0	0
Pancreatic failure	1 (5.3)	0	1 (5.3)	0	0
Vomiting	1 (5.3)	0	1 (5.3)	0	0
General disorders and administration site conditions					
-Total	4 (21.1)	1 (5.3)	3 (15.8)	0	0
Catheter site pain	1 (5.3)	1 (5.3)	0	0	0
Chills	1 (5.3)	0	1 (5.3)	0	0

Number of previous relapses: 1

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related thrombosis	1 (5.3)	0	1 (5.3)	0	0
Pyrexia	1 (5.3)	0	1 (5.3)	0	0
Infections and infestations					
-Total	1 (5.3)	0	1 (5.3)	0	0
Pneumonia	1 (5.3)	0	1 (5.3)	0	0
Investigations					
-Total	10 (52.6)	2 (10.5)	0	2 (10.5)	6 (31.6)
White blood cell count decreased	6 (31.6)	0	0	1 (5.3)	5 (26.3)
Alanine aminotransferase increased	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Blood creatinine increased	1 (5.3)	1 (5.3)	0	0	0
Blood lactic acid increased	1 (5.3)	0	1 (5.3)	0	0
C-reactive protein increased	1 (5.3)	0	1 (5.3)	0	0
Lipase increased	1 (5.3)	0	0	0	1 (5.3)
Neutrophil count decreased	1 (5.3)	0	0	0	1 (5.3)
Platelet count decreased	1 (5.3)	0	1 (5.3)	0	0
Protein total decreased	1 (5.3)	0	0	1 (5.3)	0
Weight decreased	1 (5.3)	1 (5.3)	0	0	0
Weight increased	1 (5.3)	1 (5.3)	0	0	0

Number of previous relapses: 1

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	6 (31.6)	2 (10.5)	1 (5.3)	2 (10.5)	1 (5.3)
Decreased appetite	3 (15.8)	1 (5.3)	2 (10.5)	0	0
Hypokalaemia	2 (10.5)	0	0	1 (5.3)	1 (5.3)
Fluid overload	1 (5.3)	0	1 (5.3)	0	0
Hypermagnesaemia	1 (5.3)	1 (5.3)	0	0	0
Hyperphosphataemia	1 (5.3)	1 (5.3)	0	0	0
Hyperuricaemia	1 (5.3)	0	0	1 (5.3)	0
Nervous system disorders					
-Total	4 (21.1)	2 (10.5)	2 (10.5)	0	0
Headache	3 (15.8)	2 (10.5)	1 (5.3)	0	0
Hypotonia	1 (5.3)	0	1 (5.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (15.8)	1 (5.3)	0	2 (10.5)	0
Epistaxis	1 (5.3)	0	0	1 (5.3)	0
Hypoxia	1 (5.3)	0	0	1 (5.3)	0
Nasal discomfort	1 (5.3)	1 (5.3)	0	0	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=19 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (5.3)	0	0	1 (5.3)	0
Skin and subcutaneous tissue disorders					
-Total	4 (21.1)	4 (21.1)	0	0	0
Pruritus	1 (5.3)	1 (5.3)	0	0	0
Pruritus generalised	1 (5.3)	1 (5.3)	0	0	0
Rash erythematous	1 (5.3)	1 (5.3)	0	0	0
Rash pruritic	1 (5.3)	1 (5.3)	0	0	0
Vascular disorders					
-Total	1 (5.3)	0	0	1 (5.3)	0
Hypotension	1 (5.3)	0	0	1 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176r
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 2

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (84.2)	3 (15.8)	3 (15.8)	5 (26.3)	5 (26.3)
Blood and lymphatic system disorders					
-Total	6 (31.6)	0	1 (5.3)	3 (15.8)	2 (10.5)
Anaemia	3 (15.8)	0	1 (5.3)	2 (10.5)	0
Febrile neutropenia	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Neutropenia	1 (5.3)	0	0	0	1 (5.3)
Pancytopenia	1 (5.3)	0	0	1 (5.3)	0
Thrombocytopenia	1 (5.3)	0	0	0	1 (5.3)
Cardiac disorders					
-Total	1 (5.3)	1 (5.3)	0	0	0

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=19 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Palpitations	1 (5.3)	1 (5.3)	0	0	0
Gastrointestinal disorders					
-Total	7 (36.8)	3 (15.8)	4 (21.1)	0	0
Nausea	4 (21.1)	2 (10.5)	2 (10.5)	0	0
Diarrhoea	2 (10.5)	0	2 (10.5)	0	0
Constipation	1 (5.3)	1 (5.3)	0	0	0
Gingival discomfort	1 (5.3)	1 (5.3)	0	0	0
Vomiting	1 (5.3)	1 (5.3)	0	0	0
General disorders and administration site conditions					
-Total	3 (15.8)	1 (5.3)	2 (10.5)	0	0
Catheter site pain	1 (5.3)	1 (5.3)	0	0	0
Pain	1 (5.3)	0	1 (5.3)	0	0
Pyrexia	1 (5.3)	0	1 (5.3)	0	0
Injury, poisoning and procedural complications					
-Total	1 (5.3)	1 (5.3)	0	0	0
Infusion related reaction	1 (5.3)	1 (5.3)	0	0	0
Investigations					

Number of previous relapses: 2

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (52.6)	0	1 (5.3)	4 (21.1)	5 (26.3)
White blood cell count decreased	6 (31.6)	0	0	1 (5.3)	5 (26.3)
Alanine aminotransferase increased	3 (15.8)	1 (5.3)	0	2 (10.5)	0
Neutrophil count decreased	3 (15.8)	0	0	0	3 (15.8)
Aspartate aminotransferase increased	1 (5.3)	0	1 (5.3)	0	0
Lymphocyte count decreased	1 (5.3)	0	0	1 (5.3)	0
Platelet count decreased	1 (5.3)	0	0	1 (5.3)	0
Metabolism and nutrition disorders					
-Total	1 (5.3)	0	0	1 (5.3)	0
Fluid overload	1 (5.3)	0	1 (5.3)	0	0
Hypomagnesaemia	1 (5.3)	0	1 (5.3)	0	0
Hypophosphataemia	1 (5.3)	1 (5.3)	0	0	0
Tumour lysis syndrome	1 (5.3)	0	0	1 (5.3)	0
Nervous system disorders					
-Total	1 (5.3)	1 (5.3)	0	0	0
Headache	1 (5.3)	1 (5.3)	0	0	0
Product issues					

Number of previous relapses: 2

	All patients N=19				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.3)	1 (5.3)	0	0	0
Device occlusion	1 (5.3)	1 (5.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (5.3)	0	1 (5.3)	0	0
Epistaxis	1 (5.3)	0	1 (5.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (15.8)	3 (15.8)	0	0	0
Alopecia	2 (10.5)	2 (10.5)	0	0	0
Skin ulcer	1 (5.3)	1 (5.3)	0	0	0
Vascular disorders					
-Total	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Hypertension	1 (5.3)	1 (5.3)	0	0	0
Phlebitis	1 (5.3)	0	1 (5.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion

(for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 176r
Adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (87.5)	0	2 (12.5)	5 (31.3)	7 (43.8)
Blood and lymphatic system disorders					
-Total	6 (37.5)	0	0	4 (25.0)	2 (12.5)
Febrile neutropenia	4 (25.0)	0	0	4 (25.0)	0
Anaemia	2 (12.5)	0	0	2 (12.5)	0
Neutropenia	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Disseminated intravascular coagulation	1 (6.3)	0	0	0	1 (6.3)
Thrombocytopenia	1 (6.3)	0	0	0	1 (6.3)
Gastrointestinal disorders					
-Total	3 (18.8)	1 (6.3)	1 (6.3)	1 (6.3)	0

Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Ascites	1 (6.3)	0	0	1 (6.3)	0
Constipation	1 (6.3)	1 (6.3)	0	0	0
Diarrhoea	1 (6.3)	1 (6.3)	0	0	0
General disorders and administration site conditions					
-Total	4 (25.0)	1 (6.3)	2 (12.5)	0	1 (6.3)
Pyrexia	3 (18.8)	1 (6.3)	2 (12.5)	0	0
Medical device pain	1 (6.3)	0	1 (6.3)	0	0
Multiple organ dysfunction syndrome	1 (6.3)	0	0	0	1 (6.3)
Oedema peripheral	1 (6.3)	1 (6.3)	0	0	0
Hepatobiliary disorders					
-Total	1 (6.3)	0	0	0	1 (6.3)
Hepatic failure	1 (6.3)	0	0	0	1 (6.3)
Immune system disorders					
-Total	1 (6.3)	1 (6.3)	0	0	0
Hypogammaglobulinaemia	1 (6.3)	1 (6.3)	0	0	0
Infections and infestations					

Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (37.5)	1 (6.3)	1 (6.3)	3 (18.8)	1 (6.3)
Device related infection	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Bacteraemia	1 (6.3)	0	0	1 (6.3)	0
Bronchitis	1 (6.3)	0	1 (6.3)	0	0
Necrotising fasciitis	1 (6.3)	0	0	1 (6.3)	0
Otitis media	1 (6.3)	0	1 (6.3)	0	0
Parainfluenzae virus infection	1 (6.3)	1 (6.3)	0	0	0
Staphylococcal infection	1 (6.3)	0	0	0	1 (6.3)
Viral upper respiratory tract infection	1 (6.3)	1 (6.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (6.3)	0	1 (6.3)	0	0
Radiation skin injury	1 (6.3)	0	1 (6.3)	0	0
Investigations					
-Total	9 (56.3)	0	2 (12.5)	0	7 (43.8)
White blood cell count decreased	5 (31.3)	0	0	1 (6.3)	4 (25.0)
Neutrophil count decreased	4 (25.0)	0	0	0	4 (25.0)
Lymphocyte count decreased	3 (18.8)	0	0	0	3 (18.8)

Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	2 (12.5)	0	1 (6.3)	0	1 (6.3)
Aspartate aminotransferase increased	2 (12.5)	1 (6.3)	0	0	1 (6.3)
International normalised ratio increased	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Platelet count decreased	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Activated partial thromboplastin time prolonged	1 (6.3)	0	1 (6.3)	0	0
Blood bilirubin increased	1 (6.3)	0	0	0	1 (6.3)
Blood uric acid increased	1 (6.3)	1 (6.3)	0	0	0
C-reactive protein increased	1 (6.3)	0	1 (6.3)	0	0
Weight increased	1 (6.3)	1 (6.3)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (43.8)	2 (12.5)	1 (6.3)	3 (18.8)	1 (6.3)
Hyperphosphataemia	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Hypoglycaemia	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Hypokalaemia	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Hypophosphataemia	2 (12.5)	2 (12.5)	0	0	0
Hyperglycaemia	1 (6.3)	0	0	1 (6.3)	0

Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (6.3)	1 (6.3)	0	0	0
Hypernatraemia	1 (6.3)	0	0	0	1 (6.3)
Hyperuricaemia	1 (6.3)	1 (6.3)	0	0	0
Hypoalbuminaemia	1 (6.3)	0	1 (6.3)	0	0
Hypocalcaemia	1 (6.3)	1 (6.3)	0	0	0
Hypomagnesaemia	1 (6.3)	1 (6.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (31.3)	2 (12.5)	1 (6.3)	2 (12.5)	0
Pain in jaw	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Arthralgia	1 (6.3)	1 (6.3)	0	0	0
Myalgia	1 (6.3)	0	0	1 (6.3)	0
Pain in extremity	1 (6.3)	0	0	1 (6.3)	0
Nervous system disorders					
-Total	2 (12.5)	0	2 (12.5)	0	0
Headache	1 (6.3)	0	1 (6.3)	0	0
Somnolence	1 (6.3)	0	1 (6.3)	0	0
Psychiatric disorders					

Number of previous relapses: >=3

	All patients N=16				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (18.8)	1 (6.3)	1 (6.3)	1 (6.3)	0
Anxiety	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Delirium	1 (6.3)	0	0	1 (6.3)	0
Irritability	1 (6.3)	1 (6.3)	0	0	0
Renal and urinary disorders					
-Total	1 (6.3)	0	1 (6.3)	0	0
Urinary retention	1 (6.3)	0	1 (6.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (31.3)	2 (12.5)	1 (6.3)	2 (12.5)	0
Dyspnoea	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Hypoxia	2 (12.5)	0	0	2 (12.5)	0
Cough	1 (6.3)	1 (6.3)	0	0	0
Nasal congestion	1 (6.3)	1 (6.3)	0	0	0
Pleural effusion	1 (6.3)	0	0	1 (6.3)	0
Rhinitis allergic	1 (6.3)	1 (6.3)	0	0	0
Tachypnoea	1 (6.3)	0	1 (6.3)	0	0
Skin and subcutaneous tissue disorders					

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=16 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	4 (25.0)	2 (12.5)	1 (6.3)	1 (6.3)	0
Dermatitis acneiform	1 (6.3)	0	1 (6.3)	0	0
Rash	1 (6.3)	1 (6.3)	0	0	0
Rash macular	1 (6.3)	0	0	1 (6.3)	0
Skin haemorrhage	1 (6.3)	1 (6.3)	0	0	0
Vascular disorders					
-Total	3 (18.8)	0	0	3 (18.8)	0
Hypotension	2 (12.5)	0	0	2 (12.5)	0
Hypertension	1 (6.3)	0	0	1 (6.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started between the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177a
Adverse events by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: <10 years

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	0	1 (50.0)	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0
Escherichia infection	1 (50.0)	0	0	1 (50.0)	0
Streptococcal infection	1 (50.0)	0	0	1 (50.0)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Pain in jaw	1 (50.0)	0	1 (50.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177a
Adverse events by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=10 years to <18 years

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	0	0	4 (80.0)
Blood and lymphatic system disorders					
-Total	3 (60.0)	0	0	1 (20.0)	2 (40.0)
Anaemia	2 (40.0)	0	0	2 (40.0)	0
Disseminated intravascular coagulation	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Febrile neutropenia	2 (40.0)	0	0	2 (40.0)	0
Thrombocytopenia	2 (40.0)	0	0	0	2 (40.0)
Neutropenia	1 (20.0)	0	0	0	1 (20.0)
Endocrine disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Adrenal insufficiency	1 (20.0)	0	1 (20.0)	0	0

Age: >=10 years to <18 years

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	3 (60.0)	0	0	3 (60.0)	0
Colitis	2 (40.0)	0	0	2 (40.0)	0
Abdominal pain	1 (20.0)	0	0	1 (20.0)	0
Ascites	1 (20.0)	0	0	1 (20.0)	0
Diarrhoea	1 (20.0)	0	0	1 (20.0)	0
Gastrointestinal haemorrhage	1 (20.0)	0	0	1 (20.0)	0
Stomatitis	1 (20.0)	0	0	1 (20.0)	0
General disorders and administration site conditions					
-Total	3 (60.0)	0	1 (20.0)	0	2 (40.0)
Multiple organ dysfunction syndrome	2 (40.0)	0	0	0	2 (40.0)
Pyrexia	2 (40.0)	0	2 (40.0)	0	0
Chills	1 (20.0)	1 (20.0)	0	0	0
Hepatobiliary disorders					
-Total	1 (20.0)	0	0	0	1 (20.0)
Hepatic failure	1 (20.0)	0	0	0	1 (20.0)
Infections and infestations					

Age: >=10 years to <18 years

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (80.0)	0	0	0	4 (80.0)
Bronchitis	1 (20.0)	0	1 (20.0)	0	0
Candida sepsis	1 (20.0)	0	0	0	1 (20.0)
Clostridium difficile colitis	1 (20.0)	0	0	1 (20.0)	0
Klebsiella infection	1 (20.0)	0	0	1 (20.0)	0
Klebsiella sepsis	1 (20.0)	0	0	0	1 (20.0)
Oral herpes	1 (20.0)	0	1 (20.0)	0	0
Pneumonia fungal	1 (20.0)	0	0	1 (20.0)	0
Sepsis	1 (20.0)	0	0	0	1 (20.0)
Staphylococcal bacteraemia	1 (20.0)	0	0	1 (20.0)	0
Staphylococcal infection	1 (20.0)	0	0	0	1 (20.0)
Investigations					
-Total	2 (40.0)	0	0	0	2 (40.0)
Activated partial thromboplastin time prolonged	1 (20.0)	0	1 (20.0)	0	0
Alanine aminotransferase increased	1 (20.0)	0	0	0	1 (20.0)
Aspartate aminotransferase increased	1 (20.0)	0	0	0	1 (20.0)
Blood bilirubin increased	1 (20.0)	0	0	0	1 (20.0)

Age: >=10 years to <18 years

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	1 (20.0)	0	1 (20.0)	0	0
Neutrophil count decreased	1 (20.0)	0	0	0	1 (20.0)
Platelet count decreased	1 (20.0)	0	0	0	1 (20.0)
Weight increased	1 (20.0)	1 (20.0)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (60.0)	0	0	0	3 (60.0)
Hypernatraemia	3 (60.0)	0	0	1 (20.0)	2 (40.0)
Hypokalaemia	3 (60.0)	0	0	0	3 (60.0)
Hypoalbuminaemia	2 (40.0)	0	1 (20.0)	0	1 (20.0)
Decreased appetite	1 (20.0)	0	0	1 (20.0)	0
Dehydration	1 (20.0)	0	0	1 (20.0)	0
Hyperglycaemia	1 (20.0)	0	0	0	1 (20.0)
Hypocalcaemia	1 (20.0)	0	0	0	1 (20.0)
Hypoglycaemia	1 (20.0)	0	1 (20.0)	0	0
Hypomagnesaemia	1 (20.0)	1 (20.0)	0	0	0
Hypophosphataemia	1 (20.0)	0	0	1 (20.0)	0
Musculoskeletal and connective tissue disorders					

Age: >=10 years to <18 years

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (20.0)	0	0	1 (20.0)	0
Pain in extremity	1 (20.0)	0	0	1 (20.0)	0
Nervous system disorders					
-Total	2 (40.0)	0	1 (20.0)	1 (20.0)	0
Leukoencephalopathy	1 (20.0)	0	0	1 (20.0)	0
Somnolence	1 (20.0)	0	1 (20.0)	0	0
Psychiatric disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Delirium	1 (20.0)	0	0	1 (20.0)	0
Renal and urinary disorders					
-Total	3 (60.0)	1 (20.0)	0	1 (20.0)	1 (20.0)
Acute kidney injury	1 (20.0)	0	0	0	1 (20.0)
Cystitis haemorrhagic	1 (20.0)	0	0	1 (20.0)	0
Haematuria	1 (20.0)	1 (20.0)	0	0	0
Urinary retention	1 (20.0)	0	1 (20.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (60.0)	0	0	1 (20.0)	2 (40.0)

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Pleural effusion	1 (20.0)	0	0	1 (20.0)	0
Pulmonary oedema	1 (20.0)	0	0	0	1 (20.0)
Respiratory failure	1 (20.0)	0	0	0	1 (20.0)
Vascular disorders					
-Total	4 (80.0)	0	0	3 (60.0)	1 (20.0)
Hypotension	4 (80.0)	0	0	3 (60.0)	1 (20.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177a
Adverse events by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=18

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	1 (25.0)	0	3 (75.0)
Blood and lymphatic system disorders					
-Total	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Anaemia	2 (50.0)	0	0	2 (50.0)	0
Thrombocytopenia	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Disseminated intravascular coagulation	1 (25.0)	0	0	1 (25.0)	0
Lymphopenia	1 (25.0)	0	0	0	1 (25.0)
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
Cardiac disorders					
-Total	2 (50.0)	0	0	0	2 (50.0)

Age: >=18

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bradycardia	1 (25.0)	0	0	0	1 (25.0)
Cardiovascular insufficiency	1 (25.0)	0	0	0	1 (25.0)
Right ventricular dysfunction	1 (25.0)	0	0	1 (25.0)	0
Sinus tachycardia	1 (25.0)	0	0	1 (25.0)	0
Ventricular tachycardia	1 (25.0)	0	0	1 (25.0)	0
Eye disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Photophobia	1 (25.0)	0	1 (25.0)	0	0
Gastrointestinal disorders					
-Total	3 (75.0)	0	2 (50.0)	1 (25.0)	0
Nausea	3 (75.0)	0	2 (50.0)	1 (25.0)	0
Vomiting	3 (75.0)	0	2 (50.0)	1 (25.0)	0
Abdominal pain	1 (25.0)	0	0	1 (25.0)	0
Constipation	1 (25.0)	1 (25.0)	0	0	0
Haematochezia	1 (25.0)	0	0	1 (25.0)	0
General disorders and administration site conditions					
-Total	3 (75.0)	0	0	2 (50.0)	1 (25.0)

Age: >=18

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Multiple organ dysfunction syndrome	1 (25.0)	0	0	0	1 (25.0)
Non-cardiac chest pain	1 (25.0)	0	0	1 (25.0)	0
Pyrexia	1 (25.0)	0	0	1 (25.0)	0
Infections and infestations					
-Total	2 (50.0)	0	0	0	2 (50.0)
Klebsiella sepsis	1 (25.0)	0	0	0	1 (25.0)
Pneumonia	1 (25.0)	0	0	0	1 (25.0)
Investigations					
-Total	2 (50.0)	0	0	0	2 (50.0)
Blood lactate dehydrogenase increased	1 (25.0)	0	0	1 (25.0)	0
Computerised tomogram thorax abnormal	1 (25.0)	0	0	1 (25.0)	0
Electrocardiogram qt prolonged	1 (25.0)	0	0	1 (25.0)	0
Neutrophil count decreased	1 (25.0)	0	0	0	1 (25.0)
White blood cell count decreased	1 (25.0)	0	0	0	1 (25.0)
Metabolism and nutrition disorders					
-Total	3 (75.0)	0	2 (50.0)	1 (25.0)	0

Age: >=18

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperglycaemia	2 (50.0)	0	2 (50.0)	0	0
Fluid overload	1 (25.0)	0	0	1 (25.0)	0
Hyperkalaemia	1 (25.0)	0	0	1 (25.0)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Arthralgia	1 (25.0)	0	0	1 (25.0)	0
Back pain	1 (25.0)	0	0	1 (25.0)	0
Pain in extremity	1 (25.0)	0	0	1 (25.0)	0
Nervous system disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Headache	1 (25.0)	0	0	1 (25.0)	0
Hyporesponsive to stimuli	1 (25.0)	0	0	1 (25.0)	0
Seizure	1 (25.0)	0	0	0	1 (25.0)
Product issues					
-Total	1 (25.0)	0	1 (25.0)	0	0
Device occlusion	1 (25.0)	0	1 (25.0)	0	0
Psychiatric disorders					

Age: >=18

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Agitation	1 (25.0)	0	0	1 (25.0)	0
Confusional state	1 (25.0)	0	1 (25.0)	0	0
Renal and urinary disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Acute kidney injury	1 (25.0)	0	0	1 (25.0)	0
Oliguria	1 (25.0)	0	0	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (50.0)	0	0	0	2 (50.0)
Hypoxia	2 (50.0)	0	0	2 (50.0)	0
Aspiration	1 (25.0)	0	0	0	1 (25.0)
Cough	1 (25.0)	0	0	1 (25.0)	0
Dyspnoea	1 (25.0)	0	0	1 (25.0)	0
Epistaxis	1 (25.0)	0	1 (25.0)	0	0
Haemoptysis	1 (25.0)	0	0	1 (25.0)	0
Oropharyngeal pain	1 (25.0)	0	0	1 (25.0)	0
Pleural effusion	1 (25.0)	0	1 (25.0)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary alveolar haemorrhage	1 (25.0)	0	0	0	1 (25.0)
Pulmonary hypertension	1 (25.0)	0	0	1 (25.0)	0
Pulmonary oedema	1 (25.0)	0	0	0	1 (25.0)
Respiratory distress	1 (25.0)	0	0	0	1 (25.0)
Tachypnoea	1 (25.0)	0	0	1 (25.0)	0
Vascular disorders					
-Total	2 (50.0)	0	0	0	2 (50.0)
Hypotension	2 (50.0)	0	0	0	2 (50.0)
Hypertension	1 (25.0)	0	1 (25.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177b
Adverse events by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Male

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (90.0)	0	1 (10.0)	1 (10.0)	7 (70.0)
Blood and lymphatic system disorders					
-Total	5 (50.0)	0	0	2 (20.0)	3 (30.0)
Anaemia	4 (40.0)	0	0	4 (40.0)	0
Thrombocytopenia	4 (40.0)	0	0	1 (10.0)	3 (30.0)
Disseminated intravascular coagulation	3 (30.0)	0	0	2 (20.0)	1 (10.0)
Febrile neutropenia	2 (20.0)	0	0	2 (20.0)	0
Neutropenia	2 (20.0)	0	0	0	2 (20.0)
Lymphopenia	1 (10.0)	0	0	0	1 (10.0)
Cardiac disorders					
-Total	2 (20.0)	0	0	0	2 (20.0)

Gender: Male

Primary system organ class Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bradycardia	1 (10.0)	0	0	0	1 (10.0)
Cardiovascular insufficiency	1 (10.0)	0	0	0	1 (10.0)
Right ventricular dysfunction	1 (10.0)	0	0	1 (10.0)	0
Sinus tachycardia	1 (10.0)	0	0	1 (10.0)	0
Ventricular tachycardia	1 (10.0)	0	0	1 (10.0)	0
Endocrine disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Adrenal insufficiency	1 (10.0)	0	1 (10.0)	0	0
Eye disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Photophobia	1 (10.0)	0	1 (10.0)	0	0
Gastrointestinal disorders					
-Total	6 (60.0)	0	2 (20.0)	4 (40.0)	0
Nausea	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Vomiting	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Abdominal pain	2 (20.0)	0	0	2 (20.0)	0
Colitis	2 (20.0)	0	0	2 (20.0)	0
Ascites	1 (10.0)	0	0	1 (10.0)	0

Gender: Male

Primary system organ class Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Constipation	1 (10.0)	1 (10.0)	0	0	0
Diarrhoea	1 (10.0)	0	0	1 (10.0)	0
Gastrointestinal haemorrhage	1 (10.0)	0	0	1 (10.0)	0
Haematochezia	1 (10.0)	0	0	1 (10.0)	0
Stomatitis	1 (10.0)	0	0	1 (10.0)	0
General disorders and administration site conditions					
-Total	6 (60.0)	0	1 (10.0)	2 (20.0)	3 (30.0)
Multiple organ dysfunction syndrome	3 (30.0)	0	0	0	3 (30.0)
Pyrexia	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Pain	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Chills	1 (10.0)	1 (10.0)	0	0	0
Non-cardiac chest pain	1 (10.0)	0	0	1 (10.0)	0
Hepatobiliary disorders					
-Total	1 (10.0)	0	0	0	1 (10.0)
Hepatic failure	1 (10.0)	0	0	0	1 (10.0)
Infections and infestations					
-Total	7 (70.0)	0	0	1 (10.0)	6 (60.0)

Gender: Male

Primary system organ class Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella sepsis	2 (20.0)	0	0	0	2 (20.0)
Bronchitis	1 (10.0)	0	1 (10.0)	0	0
Candida sepsis	1 (10.0)	0	0	0	1 (10.0)
Clostridium difficile colitis	1 (10.0)	0	0	1 (10.0)	0
Escherichia infection	1 (10.0)	0	0	1 (10.0)	0
Klebsiella infection	1 (10.0)	0	0	1 (10.0)	0
Oral herpes	1 (10.0)	0	1 (10.0)	0	0
Pneumonia	1 (10.0)	0	0	0	1 (10.0)
Pneumonia fungal	1 (10.0)	0	0	1 (10.0)	0
Sepsis	1 (10.0)	0	0	0	1 (10.0)
Staphylococcal bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Staphylococcal infection	1 (10.0)	0	0	0	1 (10.0)
Streptococcal infection	1 (10.0)	0	0	1 (10.0)	0
Investigations					
-Total	4 (40.0)	0	0	0	4 (40.0)
Neutrophil count decreased	2 (20.0)	0	0	0	2 (20.0)
Activated partial thromboplastin time prolonged	1 (10.0)	0	1 (10.0)	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Alanine aminotransferase increased	1 (10.0)	0	0	0	1 (10.0)
Aspartate aminotransferase increased	1 (10.0)	0	0	0	1 (10.0)
Blood bilirubin increased	1 (10.0)	0	0	0	1 (10.0)
Blood lactate dehydrogenase increased	1 (10.0)	0	0	1 (10.0)	0
Computerised tomogram thorax abnormal	1 (10.0)	0	0	1 (10.0)	0
Electrocardiogram qt prolonged	1 (10.0)	0	0	1 (10.0)	0
International normalised ratio increased	1 (10.0)	0	1 (10.0)	0	0
Platelet count decreased	1 (10.0)	0	0	0	1 (10.0)
Weight increased	1 (10.0)	1 (10.0)	0	0	0
White blood cell count decreased	1 (10.0)	0	0	0	1 (10.0)
Metabolism and nutrition disorders					
-Total	6 (60.0)	0	2 (20.0)	1 (10.0)	3 (30.0)
Hyperglycaemia	3 (30.0)	0	2 (20.0)	0	1 (10.0)
Hypernatraemia	3 (30.0)	0	0	1 (10.0)	2 (20.0)
Hypokalaemia	3 (30.0)	0	0	0	3 (30.0)

Gender: Male

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	2 (20.0)	0	1 (10.0)	0	1 (10.0)
Decreased appetite	1 (10.0)	0	0	1 (10.0)	0
Dehydration	1 (10.0)	0	0	1 (10.0)	0
Fluid overload	1 (10.0)	0	0	1 (10.0)	0
Hyperkalaemia	1 (10.0)	0	0	1 (10.0)	0
Hypocalcaemia	1 (10.0)	0	0	0	1 (10.0)
Hypoglycaemia	1 (10.0)	0	1 (10.0)	0	0
Hypomagnesaemia	1 (10.0)	1 (10.0)	0	0	0
Hypophosphataemia	1 (10.0)	0	0	1 (10.0)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (30.0)	0	1 (10.0)	2 (20.0)	0
Pain in extremity	2 (20.0)	0	0	2 (20.0)	0
Arthralgia	1 (10.0)	0	0	1 (10.0)	0
Back pain	1 (10.0)	0	0	1 (10.0)	0
Pain in jaw	1 (10.0)	0	1 (10.0)	0	0
Nervous system disorders					
-Total	3 (30.0)	0	1 (10.0)	1 (10.0)	1 (10.0)

Gender: Male

Primary system organ class Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Headache	1 (10.0)	0	0	1 (10.0)	0
Hyporesponsive to stimuli	1 (10.0)	0	0	1 (10.0)	0
Leukoencephalopathy	1 (10.0)	0	0	1 (10.0)	0
Seizure	1 (10.0)	0	0	0	1 (10.0)
Somnolence	1 (10.0)	0	1 (10.0)	0	0
Product issues					
-Total	1 (10.0)	0	1 (10.0)	0	0
Device occlusion	1 (10.0)	0	1 (10.0)	0	0
Psychiatric disorders					
-Total	3 (30.0)	0	1 (10.0)	2 (20.0)	0
Agitation	1 (10.0)	0	0	1 (10.0)	0
Confusional state	1 (10.0)	0	1 (10.0)	0	0
Delirium	1 (10.0)	0	0	1 (10.0)	0
Renal and urinary disorders					
-Total	4 (40.0)	1 (10.0)	0	2 (20.0)	1 (10.0)
Acute kidney injury	2 (20.0)	0	0	1 (10.0)	1 (10.0)
Cystitis haemorrhagic	1 (10.0)	0	0	1 (10.0)	0
Haematuria	1 (10.0)	1 (10.0)	0	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oliguria	1 (10.0)	0	0	1 (10.0)	0
Urinary retention	1 (10.0)	0	1 (10.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (50.0)	0	0	1 (10.0)	4 (40.0)
Hypoxia	4 (40.0)	0	0	3 (30.0)	1 (10.0)
Pleural effusion	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Pulmonary oedema	2 (20.0)	0	0	0	2 (20.0)
Aspiration	1 (10.0)	0	0	0	1 (10.0)
Cough	1 (10.0)	0	0	1 (10.0)	0
Dyspnoea	1 (10.0)	0	0	1 (10.0)	0
Epistaxis	1 (10.0)	0	1 (10.0)	0	0
Haemoptysis	1 (10.0)	0	0	1 (10.0)	0
Oropharyngeal pain	1 (10.0)	0	0	1 (10.0)	0
Pulmonary alveolar haemorrhage	1 (10.0)	0	0	0	1 (10.0)
Pulmonary hypertension	1 (10.0)	0	0	1 (10.0)	0
Respiratory distress	1 (10.0)	0	0	0	1 (10.0)
Respiratory failure	1 (10.0)	0	0	0	1 (10.0)

Gender: Male

Primary system organ class Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (10.0)	0	0	1 (10.0)	0
Vascular disorders					
-Total	6 (60.0)	0	0	3 (30.0)	3 (30.0)
Hypotension	6 (60.0)	0	0	3 (30.0)	3 (30.0)
Hypertension	1 (10.0)	0	1 (10.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177c
Adverse events by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: White

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (75.0)	0	1 (12.5)	0	5 (62.5)
Blood and lymphatic system disorders					
-Total	3 (37.5)	0	0	1 (12.5)	2 (25.0)
Anaemia	2 (25.0)	0	0	2 (25.0)	0
Disseminated intravascular coagulation	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Febrile neutropenia	2 (25.0)	0	0	2 (25.0)	0
Thrombocytopenia	2 (25.0)	0	0	0	2 (25.0)
Neutropenia	1 (12.5)	0	0	0	1 (12.5)
Endocrine disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Adrenal insufficiency	1 (12.5)	0	1 (12.5)	0	0

Race: White

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastrointestinal disorders					
-Total	4 (50.0)	0	1 (12.5)	3 (37.5)	0
Colitis	2 (25.0)	0	0	2 (25.0)	0
Abdominal pain	1 (12.5)	0	0	1 (12.5)	0
Ascites	1 (12.5)	0	0	1 (12.5)	0
Constipation	1 (12.5)	1 (12.5)	0	0	0
Diarrhoea	1 (12.5)	0	0	1 (12.5)	0
Gastrointestinal haemorrhage	1 (12.5)	0	0	1 (12.5)	0
Nausea	1 (12.5)	0	1 (12.5)	0	0
Stomatitis	1 (12.5)	0	0	1 (12.5)	0
Vomiting	1 (12.5)	0	1 (12.5)	0	0
General disorders and administration site conditions					
-Total	4 (50.0)	0	1 (12.5)	1 (12.5)	2 (25.0)
Pyrexia	3 (37.5)	0	2 (25.0)	1 (12.5)	0
Multiple organ dysfunction syndrome	2 (25.0)	0	0	0	2 (25.0)
Chills	1 (12.5)	1 (12.5)	0	0	0
Pain	1 (12.5)	0	0	1 (12.5)	0

Race: White

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatobiliary disorders					
-Total	1 (12.5)	0	0	0	1 (12.5)
Hepatic failure	1 (12.5)	0	0	0	1 (12.5)
Infections and infestations					
-Total	5 (62.5)	0	0	0	5 (62.5)
Bronchitis	1 (12.5)	0	1 (12.5)	0	0
Candida sepsis	1 (12.5)	0	0	0	1 (12.5)
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0
Klebsiella infection	1 (12.5)	0	0	1 (12.5)	0
Klebsiella sepsis	1 (12.5)	0	0	0	1 (12.5)
Oral herpes	1 (12.5)	0	1 (12.5)	0	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Pneumonia fungal	1 (12.5)	0	0	1 (12.5)	0
Sepsis	1 (12.5)	0	0	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Investigations					
-Total	2 (25.0)	0	0	0	2 (25.0)

Race: White

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Activated partial thromboplastin time prolonged	1 (12.5)	0	1 (12.5)	0	0
Alanine aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)
Aspartate aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)
Blood bilirubin increased	1 (12.5)	0	0	0	1 (12.5)
International normalised ratio increased	1 (12.5)	0	1 (12.5)	0	0
Neutrophil count decreased	1 (12.5)	0	0	0	1 (12.5)
Platelet count decreased	1 (12.5)	0	0	0	1 (12.5)
Weight increased	1 (12.5)	1 (12.5)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (50.0)	0	1 (12.5)	0	3 (37.5)
Hypernatraemia	3 (37.5)	0	0	1 (12.5)	2 (25.0)
Hypokalaemia	3 (37.5)	0	0	0	3 (37.5)
Hyperglycaemia	2 (25.0)	0	1 (12.5)	0	1 (12.5)
Hypoalbuminaemia	2 (25.0)	0	1 (12.5)	0	1 (12.5)
Decreased appetite	1 (12.5)	0	0	1 (12.5)	0
Dehydration	1 (12.5)	0	0	1 (12.5)	0

Race: White

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypocalcaemia	1 (12.5)	0	0	0	1 (12.5)
Hypoglycaemia	1 (12.5)	0	1 (12.5)	0	0
Hypomagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Hypophosphataemia	1 (12.5)	0	0	1 (12.5)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Pain in extremity	1 (12.5)	0	0	1 (12.5)	0
Nervous system disorders					
-Total	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Leukoencephalopathy	1 (12.5)	0	0	1 (12.5)	0
Somnolence	1 (12.5)	0	1 (12.5)	0	0
Psychiatric disorders					
-Total	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Confusional state	1 (12.5)	0	1 (12.5)	0	0
Delirium	1 (12.5)	0	0	1 (12.5)	0
Renal and urinary disorders					
-Total	3 (37.5)	1 (12.5)	0	1 (12.5)	1 (12.5)

Race: White

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	1 (12.5)	0	0	0	1 (12.5)
Cystitis haemorrhagic	1 (12.5)	0	0	1 (12.5)	0
Haematuria	1 (12.5)	1 (12.5)	0	0	0
Urinary retention	1 (12.5)	0	1 (12.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (50.0)	0	0	1 (12.5)	3 (37.5)
Hypoxia	3 (37.5)	0	0	2 (25.0)	1 (12.5)
Pleural effusion	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Aspiration	1 (12.5)	0	0	0	1 (12.5)
Epistaxis	1 (12.5)	0	1 (12.5)	0	0
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)
Respiratory failure	1 (12.5)	0	0	0	1 (12.5)
Vascular disorders					
-Total	5 (62.5)	0	0	3 (37.5)	2 (25.0)
Hypotension	5 (62.5)	0	0	3 (37.5)	2 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177c
Adverse events by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Asian

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Infections and infestations					
-Total	1 (100)	0	0	1 (100)	0
Escherichia infection	1 (100)	0	0	1 (100)	0
Streptococcal infection	1 (100)	0	0	1 (100)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (100)	0	1 (100)	0	0
Pain in jaw	1 (100)	0	1 (100)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177c
Adverse events by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Other

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Anaemia	2 (100)	0	0	2 (100)	0
Thrombocytopenia	2 (100)	0	0	1 (50.0)	1 (50.0)
Disseminated intravascular coagulation	1 (50.0)	0	0	1 (50.0)	0
Lymphopenia	1 (50.0)	0	0	0	1 (50.0)
Neutropenia	1 (50.0)	0	0	0	1 (50.0)
Cardiac disorders					
-Total	2 (100)	0	0	0	2 (100)

Race: Other

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bradycardia	1 (50.0)	0	0	0	1 (50.0)
Cardiovascular insufficiency	1 (50.0)	0	0	0	1 (50.0)
Right ventricular dysfunction	1 (50.0)	0	0	1 (50.0)	0
Sinus tachycardia	1 (50.0)	0	0	1 (50.0)	0
Ventricular tachycardia	1 (50.0)	0	0	1 (50.0)	0
Eye disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Photophobia	1 (50.0)	0	1 (50.0)	0	0
Gastrointestinal disorders					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Nausea	2 (100)	0	1 (50.0)	1 (50.0)	0
Vomiting	2 (100)	0	1 (50.0)	1 (50.0)	0
Abdominal pain	1 (50.0)	0	0	1 (50.0)	0
Haematochezia	1 (50.0)	0	0	1 (50.0)	0
General disorders and administration site conditions					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Multiple organ dysfunction syndrome	1 (50.0)	0	0	0	1 (50.0)

Race: Other

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Non-cardiac chest pain	1 (50.0)	0	0	1 (50.0)	0
Pain	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Klebsiella sepsis	1 (50.0)	0	0	0	1 (50.0)
Investigations					
-Total	2 (100)	0	0	0	2 (100)
Blood lactate dehydrogenase increased	1 (50.0)	0	0	1 (50.0)	0
Computerised tomogram thorax abnormal	1 (50.0)	0	0	1 (50.0)	0
Electrocardiogram qt prolonged	1 (50.0)	0	0	1 (50.0)	0
Neutrophil count decreased	1 (50.0)	0	0	0	1 (50.0)
White blood cell count decreased	1 (50.0)	0	0	0	1 (50.0)
Metabolism and nutrition disorders					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Fluid overload	1 (50.0)	0	0	1 (50.0)	0
Hyperglycaemia	1 (50.0)	0	1 (50.0)	0	0
Hyperkalaemia	1 (50.0)	0	0	1 (50.0)	0

Race: Other

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Arthralgia	1 (50.0)	0	0	1 (50.0)	0
Back pain	1 (50.0)	0	0	1 (50.0)	0
Pain in extremity	1 (50.0)	0	0	1 (50.0)	0
Nervous system disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Headache	1 (50.0)	0	0	1 (50.0)	0
Hyporesponsive to stimuli	1 (50.0)	0	0	1 (50.0)	0
Seizure	1 (50.0)	0	0	0	1 (50.0)
Product issues					
-Total	1 (50.0)	0	1 (50.0)	0	0
Device occlusion	1 (50.0)	0	1 (50.0)	0	0
Psychiatric disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Agitation	1 (50.0)	0	0	1 (50.0)	0
Renal and urinary disorders					

Race: Other

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	0	1 (50.0)	0
Acute kidney injury	1 (50.0)	0	0	1 (50.0)	0
Oliguria	1 (50.0)	0	0	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Cough	1 (50.0)	0	0	1 (50.0)	0
Dyspnoea	1 (50.0)	0	0	1 (50.0)	0
Haemoptysis	1 (50.0)	0	0	1 (50.0)	0
Hypoxia	1 (50.0)	0	0	1 (50.0)	0
Oropharyngeal pain	1 (50.0)	0	0	1 (50.0)	0
Pulmonary alveolar haemorrhage	1 (50.0)	0	0	0	1 (50.0)
Pulmonary hypertension	1 (50.0)	0	0	1 (50.0)	0
Pulmonary oedema	1 (50.0)	0	0	0	1 (50.0)
Respiratory distress	1 (50.0)	0	0	0	1 (50.0)
Tachypnoea	1 (50.0)	0	0	1 (50.0)	0
Vascular disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)

Race: Other

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (50.0)	0	1 (50.0)	0	0
Hypotension	1 (50.0)	0	0	0	1 (50.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177d
Adverse events by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Hispanic or Latino

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	1 (20.0)	0	3 (60.0)
Blood and lymphatic system disorders					
-Total	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Thrombocytopenia	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Anaemia	1 (20.0)	0	0	1 (20.0)	0
Febrile neutropenia	1 (20.0)	0	0	1 (20.0)	0
Neutropenia	1 (20.0)	0	0	0	1 (20.0)
Cardiac disorders					
-Total	1 (20.0)	0	0	0	1 (20.0)
Cardiovascular insufficiency	1 (20.0)	0	0	0	1 (20.0)
Endocrine disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0

Ethnicity: Hispanic or Latino

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	1 (20.0)	0	1 (20.0)	0	0
Gastrointestinal disorders					
-Total	3 (60.0)	0	2 (40.0)	1 (20.0)	0
Nausea	2 (40.0)	0	2 (40.0)	0	0
Vomiting	2 (40.0)	0	2 (40.0)	0	0
Constipation	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal haemorrhage	1 (20.0)	0	0	1 (20.0)	0
General disorders and administration site conditions					
-Total	2 (40.0)	0	1 (20.0)	0	1 (20.0)
Chills	1 (20.0)	1 (20.0)	0	0	0
Multiple organ dysfunction syndrome	1 (20.0)	0	0	0	1 (20.0)
Pain	1 (20.0)	0	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	1 (20.0)	0	0
Infections and infestations					
-Total	3 (60.0)	0	0	0	3 (60.0)
Candida sepsis	1 (20.0)	0	0	0	1 (20.0)
Klebsiella sepsis	1 (20.0)	0	0	0	1 (20.0)

Ethnicity: Hispanic or Latino

	All patients N=5				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (20.0)	0	0	1 (20.0)	0
Sepsis	1 (20.0)	0	0	0	1 (20.0)
Investigations					
-Total	1 (20.0)	0	0	0	1 (20.0)
Neutrophil count decreased	1 (20.0)	0	0	0	1 (20.0)
Metabolism and nutrition disorders					
-Total	3 (60.0)	0	2 (40.0)	0	1 (20.0)
Hyperglycaemia	2 (40.0)	0	2 (40.0)	0	0
Hypernatraemia	1 (20.0)	0	0	0	1 (20.0)
Hypokalaemia	1 (20.0)	0	0	0	1 (20.0)
Hypomagnesaemia	1 (20.0)	1 (20.0)	0	0	0
Hypophosphataemia	1 (20.0)	0	0	1 (20.0)	0
Product issues					
-Total	1 (20.0)	0	1 (20.0)	0	0
Device occlusion	1 (20.0)	0	1 (20.0)	0	0
Renal and urinary disorders					
-Total	1 (20.0)	0	0	0	1 (20.0)
Acute kidney injury	1 (20.0)	0	0	0	1 (20.0)

Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	1 (20.0)	0	0	0	1 (20.0)
Pulmonary oedema	1 (20.0)	0	0	0	1 (20.0)
Respiratory failure	1 (20.0)	0	0	0	1 (20.0)
Vascular disorders					
-Total	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Hypotension	2 (40.0)	0	0	1 (20.0)	1 (20.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177d
Adverse events by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Other

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (83.3)	0	0	1 (16.7)	4 (66.7)
Blood and lymphatic system disorders					
-Total	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Anaemia	3 (50.0)	0	0	3 (50.0)	0
Disseminated intravascular coagulation	3 (50.0)	0	0	2 (33.3)	1 (16.7)
Thrombocytopenia	2 (33.3)	0	0	0	2 (33.3)
Febrile neutropenia	1 (16.7)	0	0	1 (16.7)	0
Lymphopenia	1 (16.7)	0	0	0	1 (16.7)
Neutropenia	1 (16.7)	0	0	0	1 (16.7)
Cardiac disorders					
-Total	1 (16.7)	0	0	0	1 (16.7)

Ethnicity: Other

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bradycardia	1 (16.7)	0	0	0	1 (16.7)
Right ventricular dysfunction	1 (16.7)	0	0	1 (16.7)	0
Sinus tachycardia	1 (16.7)	0	0	1 (16.7)	0
Ventricular tachycardia	1 (16.7)	0	0	1 (16.7)	0
Eye disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Photophobia	1 (16.7)	0	1 (16.7)	0	0
Gastrointestinal disorders					
-Total	3 (50.0)	0	0	3 (50.0)	0
Abdominal pain	2 (33.3)	0	0	2 (33.3)	0
Colitis	2 (33.3)	0	0	2 (33.3)	0
Ascites	1 (16.7)	0	0	1 (16.7)	0
Diarrhoea	1 (16.7)	0	0	1 (16.7)	0
Haematochezia	1 (16.7)	0	0	1 (16.7)	0
Nausea	1 (16.7)	0	0	1 (16.7)	0
Stomatitis	1 (16.7)	0	0	1 (16.7)	0
Vomiting	1 (16.7)	0	0	1 (16.7)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions					
-Total	4 (66.7)	0	0	2 (33.3)	2 (33.3)
Multiple organ dysfunction syndrome	2 (33.3)	0	0	0	2 (33.3)
Pyrexia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Non-cardiac chest pain	1 (16.7)	0	0	1 (16.7)	0
Pain	1 (16.7)	0	0	1 (16.7)	0
Hepatobiliary disorders					
-Total	1 (16.7)	0	0	0	1 (16.7)
Hepatic failure	1 (16.7)	0	0	0	1 (16.7)
Infections and infestations					
-Total	4 (66.7)	0	0	1 (16.7)	3 (50.0)
Bronchitis	1 (16.7)	0	1 (16.7)	0	0
Clostridium difficile colitis	1 (16.7)	0	0	1 (16.7)	0
Escherichia infection	1 (16.7)	0	0	1 (16.7)	0
Klebsiella infection	1 (16.7)	0	0	1 (16.7)	0
Klebsiella sepsis	1 (16.7)	0	0	0	1 (16.7)
Oral herpes	1 (16.7)	0	1 (16.7)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	1 (16.7)	0	0	0	1 (16.7)
Staphylococcal bacteraemia	1 (16.7)	0	0	1 (16.7)	0
Staphylococcal infection	1 (16.7)	0	0	0	1 (16.7)
Streptococcal infection	1 (16.7)	0	0	1 (16.7)	0
Investigations					
-Total	3 (50.0)	0	0	0	3 (50.0)
Activated partial thromboplastin time prolonged	1 (16.7)	0	1 (16.7)	0	0
Alanine aminotransferase increased	1 (16.7)	0	0	0	1 (16.7)
Aspartate aminotransferase increased	1 (16.7)	0	0	0	1 (16.7)
Blood bilirubin increased	1 (16.7)	0	0	0	1 (16.7)
Blood lactate dehydrogenase increased	1 (16.7)	0	0	1 (16.7)	0
Computerised tomogram thorax abnormal	1 (16.7)	0	0	1 (16.7)	0
Electrocardiogram qt prolonged	1 (16.7)	0	0	1 (16.7)	0
International normalised ratio increased	1 (16.7)	0	1 (16.7)	0	0
Neutrophil count decreased	1 (16.7)	0	0	0	1 (16.7)

Ethnicity: Other

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)
Weight increased	1 (16.7)	1 (16.7)	0	0	0
White blood cell count decreased	1 (16.7)	0	0	0	1 (16.7)
Metabolism and nutrition disorders					
-Total	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Hypernatraemia	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypoalbuminaemia	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Hypokalaemia	2 (33.3)	0	0	0	2 (33.3)
Decreased appetite	1 (16.7)	0	0	1 (16.7)	0
Dehydration	1 (16.7)	0	0	1 (16.7)	0
Fluid overload	1 (16.7)	0	0	1 (16.7)	0
Hyperglycaemia	1 (16.7)	0	0	0	1 (16.7)
Hyperkalaemia	1 (16.7)	0	0	1 (16.7)	0
Hypocalcaemia	1 (16.7)	0	0	0	1 (16.7)
Hypoglycaemia	1 (16.7)	0	1 (16.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (50.0)	0	1 (16.7)	2 (33.3)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain in extremity	2 (33.3)	0	0	2 (33.3)	0
Arthralgia	1 (16.7)	0	0	1 (16.7)	0
Back pain	1 (16.7)	0	0	1 (16.7)	0
Pain in jaw	1 (16.7)	0	1 (16.7)	0	0
Nervous system disorders					
-Total	3 (50.0)	0	1 (16.7)	1 (16.7)	1 (16.7)
Headache	1 (16.7)	0	0	1 (16.7)	0
Hyporesponsive to stimuli	1 (16.7)	0	0	1 (16.7)	0
Leukoencephalopathy	1 (16.7)	0	0	1 (16.7)	0
Seizure	1 (16.7)	0	0	0	1 (16.7)
Somnolence	1 (16.7)	0	1 (16.7)	0	0
Psychiatric disorders					
-Total	3 (50.0)	0	1 (16.7)	2 (33.3)	0
Agitation	1 (16.7)	0	0	1 (16.7)	0
Confusional state	1 (16.7)	0	1 (16.7)	0	0
Delirium	1 (16.7)	0	0	1 (16.7)	0
Renal and urinary disorders					
-Total	3 (50.0)	1 (16.7)	0	2 (33.3)	0

Ethnicity: Other

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (16.7)	0	0	1 (16.7)	0
Cystitis haemorrhagic	1 (16.7)	0	0	1 (16.7)	0
Haematuria	1 (16.7)	1 (16.7)	0	0	0
Oliguria	1 (16.7)	0	0	1 (16.7)	0
Urinary retention	1 (16.7)	0	1 (16.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (66.7)	0	0	1 (16.7)	3 (50.0)
Hypoxia	4 (66.7)	0	0	3 (50.0)	1 (16.7)
Pleural effusion	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Aspiration	1 (16.7)	0	0	0	1 (16.7)
Cough	1 (16.7)	0	0	1 (16.7)	0
Dyspnoea	1 (16.7)	0	0	1 (16.7)	0
Epistaxis	1 (16.7)	0	1 (16.7)	0	0
Haemoptysis	1 (16.7)	0	0	1 (16.7)	0
Oropharyngeal pain	1 (16.7)	0	0	1 (16.7)	0
Pulmonary alveolar haemorrhage	1 (16.7)	0	0	0	1 (16.7)
Pulmonary hypertension	1 (16.7)	0	0	1 (16.7)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary oedema	1 (16.7)	0	0	0	1 (16.7)
Respiratory distress	1 (16.7)	0	0	0	1 (16.7)
Tachypnoea	1 (16.7)	0	0	1 (16.7)	0
Vascular disorders					
-Total	4 (66.7)	0	0	2 (33.3)	2 (33.3)
Hypotension	4 (66.7)	0	0	2 (33.3)	2 (33.3)
Hypertension	1 (16.7)	0	1 (16.7)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177e
Adverse events by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Primary refractory

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
General disorders and administration site conditions					
-Total	1 (100)	0	0	1 (100)	0
Pain	1 (100)	0	0	1 (100)	0
Pyrexia	1 (100)	0	0	1 (100)	0
Infections and infestations					
-Total	1 (100)	0	0	0	1 (100)
Pneumonia	1 (100)	0	0	0	1 (100)
Psychiatric disorders					
-Total	1 (100)	0	1 (100)	0	0
Confusional state	1 (100)	0	1 (100)	0	0

Response status at study entry: Primary refractory

Primary system organ class Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	0	0	0	1 (100)
Aspiration	1 (100)	0	0	0	1 (100)
Epistaxis	1 (100)	0	1 (100)	0	0
Hypoxia	1 (100)	0	0	1 (100)	0
Pleural effusion	1 (100)	0	1 (100)	0	0
Vascular disorders					
-Total	1 (100)	0	0	0	1 (100)
Hypotension	1 (100)	0	0	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177e
Adverse events by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Relapsed disease

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (80.0)	0	1 (10.0)	1 (10.0)	6 (60.0)
Blood and lymphatic system disorders					
-Total	5 (50.0)	0	0	2 (20.0)	3 (30.0)
Anaemia	4 (40.0)	0	0	4 (40.0)	0
Thrombocytopenia	4 (40.0)	0	0	1 (10.0)	3 (30.0)
Disseminated intravascular coagulation	3 (30.0)	0	0	2 (20.0)	1 (10.0)
Febrile neutropenia	2 (20.0)	0	0	2 (20.0)	0
Neutropenia	2 (20.0)	0	0	0	2 (20.0)
Lymphopenia	1 (10.0)	0	0	0	1 (10.0)
Cardiac disorders					
-Total	2 (20.0)	0	0	0	2 (20.0)

Response status at study entry: Relapsed disease

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (10.0)	0	0	0	1 (10.0)
Cardiovascular insufficiency	1 (10.0)	0	0	0	1 (10.0)
Right ventricular dysfunction	1 (10.0)	0	0	1 (10.0)	0
Sinus tachycardia	1 (10.0)	0	0	1 (10.0)	0
Ventricular tachycardia	1 (10.0)	0	0	1 (10.0)	0
Endocrine disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Adrenal insufficiency	1 (10.0)	0	1 (10.0)	0	0
Eye disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Photophobia	1 (10.0)	0	1 (10.0)	0	0
Gastrointestinal disorders					
-Total	6 (60.0)	0	2 (20.0)	4 (40.0)	0
Nausea	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Vomiting	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Abdominal pain	2 (20.0)	0	0	2 (20.0)	0
Colitis	2 (20.0)	0	0	2 (20.0)	0
Ascites	1 (10.0)	0	0	1 (10.0)	0

Response status at study entry: Relapsed disease

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (10.0)	1 (10.0)	0	0	0
Diarrhoea	1 (10.0)	0	0	1 (10.0)	0
Gastrointestinal haemorrhage	1 (10.0)	0	0	1 (10.0)	0
Haematochezia	1 (10.0)	0	0	1 (10.0)	0
Stomatitis	1 (10.0)	0	0	1 (10.0)	0
General disorders and administration site conditions					
-Total	5 (50.0)	0	1 (10.0)	1 (10.0)	3 (30.0)
Multiple organ dysfunction syndrome	3 (30.0)	0	0	0	3 (30.0)
Pyrexia	2 (20.0)	0	2 (20.0)	0	0
Chills	1 (10.0)	1 (10.0)	0	0	0
Non-cardiac chest pain	1 (10.0)	0	0	1 (10.0)	0
Pain	1 (10.0)	0	1 (10.0)	0	0
Hepatobiliary disorders					
-Total	1 (10.0)	0	0	0	1 (10.0)
Hepatic failure	1 (10.0)	0	0	0	1 (10.0)
Infections and infestations					
-Total	6 (60.0)	0	0	1 (10.0)	5 (50.0)

Response status at study entry: Relapsed disease

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella sepsis	2 (20.0)	0	0	0	2 (20.0)
Bronchitis	1 (10.0)	0	1 (10.0)	0	0
Candida sepsis	1 (10.0)	0	0	0	1 (10.0)
Clostridium difficile colitis	1 (10.0)	0	0	1 (10.0)	0
Escherichia infection	1 (10.0)	0	0	1 (10.0)	0
Klebsiella infection	1 (10.0)	0	0	1 (10.0)	0
Oral herpes	1 (10.0)	0	1 (10.0)	0	0
Pneumonia fungal	1 (10.0)	0	0	1 (10.0)	0
Sepsis	1 (10.0)	0	0	0	1 (10.0)
Staphylococcal bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Staphylococcal infection	1 (10.0)	0	0	0	1 (10.0)
Streptococcal infection	1 (10.0)	0	0	1 (10.0)	0
Investigations					
-Total	4 (40.0)	0	0	0	4 (40.0)
Neutrophil count decreased	2 (20.0)	0	0	0	2 (20.0)
Activated partial thromboplastin time prolonged	1 (10.0)	0	1 (10.0)	0	0
Alanine aminotransferase increased	1 (10.0)	0	0	0	1 (10.0)

Response status at study entry: Relapsed disease

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (10.0)	0	0	0	1 (10.0)
Blood bilirubin increased	1 (10.0)	0	0	0	1 (10.0)
Blood lactate dehydrogenase increased	1 (10.0)	0	0	1 (10.0)	0
Computerised tomogram thorax abnormal	1 (10.0)	0	0	1 (10.0)	0
Electrocardiogram qt prolonged	1 (10.0)	0	0	1 (10.0)	0
International normalised ratio increased	1 (10.0)	0	1 (10.0)	0	0
Platelet count decreased	1 (10.0)	0	0	0	1 (10.0)
Weight increased	1 (10.0)	1 (10.0)	0	0	0
White blood cell count decreased	1 (10.0)	0	0	0	1 (10.0)
Metabolism and nutrition disorders					
-Total	6 (60.0)	0	2 (20.0)	1 (10.0)	3 (30.0)
Hyperglycaemia	3 (30.0)	0	2 (20.0)	0	1 (10.0)
Hypernatraemia	3 (30.0)	0	0	1 (10.0)	2 (20.0)
Hypokalaemia	3 (30.0)	0	0	0	3 (30.0)
Hypoalbuminaemia	2 (20.0)	0	1 (10.0)	0	1 (10.0)

Response status at study entry: Relapsed disease

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	1 (10.0)	0	0	1 (10.0)	0
Dehydration	1 (10.0)	0	0	1 (10.0)	0
Fluid overload	1 (10.0)	0	0	1 (10.0)	0
Hyperkalaemia	1 (10.0)	0	0	1 (10.0)	0
Hypocalcaemia	1 (10.0)	0	0	0	1 (10.0)
Hypoglycaemia	1 (10.0)	0	1 (10.0)	0	0
Hypomagnesaemia	1 (10.0)	1 (10.0)	0	0	0
Hypophosphataemia	1 (10.0)	0	0	1 (10.0)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (30.0)	0	1 (10.0)	2 (20.0)	0
Pain in extremity	2 (20.0)	0	0	2 (20.0)	0
Arthralgia	1 (10.0)	0	0	1 (10.0)	0
Back pain	1 (10.0)	0	0	1 (10.0)	0
Pain in jaw	1 (10.0)	0	1 (10.0)	0	0
Nervous system disorders					
-Total	3 (30.0)	0	1 (10.0)	1 (10.0)	1 (10.0)
Headache	1 (10.0)	0	0	1 (10.0)	0

Response status at study entry: Relapsed disease

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyporesponsive to stimuli	1 (10.0)	0	0	1 (10.0)	0
Leukoencephalopathy	1 (10.0)	0	0	1 (10.0)	0
Seizure	1 (10.0)	0	0	0	1 (10.0)
Somnolence	1 (10.0)	0	1 (10.0)	0	0
Product issues					
-Total	1 (10.0)	0	1 (10.0)	0	0
Device occlusion	1 (10.0)	0	1 (10.0)	0	0
Psychiatric disorders					
-Total	2 (20.0)	0	0	2 (20.0)	0
Agitation	1 (10.0)	0	0	1 (10.0)	0
Delirium	1 (10.0)	0	0	1 (10.0)	0
Renal and urinary disorders					
-Total	4 (40.0)	1 (10.0)	0	2 (20.0)	1 (10.0)
Acute kidney injury	2 (20.0)	0	0	1 (10.0)	1 (10.0)
Cystitis haemorrhagic	1 (10.0)	0	0	1 (10.0)	0
Haematuria	1 (10.0)	1 (10.0)	0	0	0
Oliguria	1 (10.0)	0	0	1 (10.0)	0
Urinary retention	1 (10.0)	0	1 (10.0)	0	0

Response status at study entry: Relapsed disease

	All patients N=10				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	4 (40.0)	0	0	1 (10.0)	3 (30.0)
Hypoxia	3 (30.0)	0	0	2 (20.0)	1 (10.0)
Pulmonary oedema	2 (20.0)	0	0	0	2 (20.0)
Cough	1 (10.0)	0	0	1 (10.0)	0
Dyspnoea	1 (10.0)	0	0	1 (10.0)	0
Haemoptysis	1 (10.0)	0	0	1 (10.0)	0
Oropharyngeal pain	1 (10.0)	0	0	1 (10.0)	0
Pleural effusion	1 (10.0)	0	0	1 (10.0)	0
Pulmonary alveolar haemorrhage	1 (10.0)	0	0	0	1 (10.0)
Pulmonary hypertension	1 (10.0)	0	0	1 (10.0)	0
Respiratory distress	1 (10.0)	0	0	0	1 (10.0)
Respiratory failure	1 (10.0)	0	0	0	1 (10.0)
Tachypnoea	1 (10.0)	0	0	1 (10.0)	0
Vascular disorders					
-Total	5 (50.0)	0	0	3 (30.0)	2 (20.0)
Hypotension	5 (50.0)	0	0	3 (30.0)	2 (20.0)

Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (10.0)	0	1 (10.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177f
Adverse events by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set – non – infused patients

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (81.8)	0	1 (9.1)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Lymphopenia	1 (9.1)	0	0	0	1 (9.1)
Cardiac disorders					
-Total	2 (18.2)	0	0	0	2 (18.2)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (9.1)	0	0	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	0	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	0	0	1 (9.1)	0
Sinus tachycardia	1 (9.1)	0	0	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	0	0	1 (9.1)	0
Endocrine disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Adrenal insufficiency	1 (9.1)	0	1 (9.1)	0	0
Eye disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Photophobia	1 (9.1)	0	1 (9.1)	0	0
Gastrointestinal disorders					
-Total	6 (54.5)	0	2 (18.2)	4 (36.4)	0
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
Ascites	1 (9.1)	0	0	1 (9.1)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (9.1)	1 (9.1)	0	0	0
Diarrhoea	1 (9.1)	0	0	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	0	0	1 (9.1)	0
Haematochezia	1 (9.1)	0	0	1 (9.1)	0
Stomatitis	1 (9.1)	0	0	1 (9.1)	0
General disorders and administration site conditions					
-Total	6 (54.5)	0	1 (9.1)	2 (18.2)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	0	0	3 (27.3)
Pyrexia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Chills	1 (9.1)	1 (9.1)	0	0	0
Non-cardiac chest pain	1 (9.1)	0	0	1 (9.1)	0
Hepatobiliary disorders					
-Total	1 (9.1)	0	0	0	1 (9.1)
Hepatic failure	1 (9.1)	0	0	0	1 (9.1)
Infections and infestations					
-Total	7 (63.6)	0	0	1 (9.1)	6 (54.5)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Bronchitis	1 (9.1)	0	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	0	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	0	0	1 (9.1)	0
Escherichia infection	1 (9.1)	0	0	1 (9.1)	0
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Oral herpes	1 (9.1)	0	1 (9.1)	0	0
Pneumonia	1 (9.1)	0	0	0	1 (9.1)
Pneumonia fungal	1 (9.1)	0	0	1 (9.1)	0
Sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	0	0	1 (9.1)
Streptococcal infection	1 (9.1)	0	0	1 (9.1)	0
Investigations					
-Total	4 (36.4)	0	0	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Activated partial thromboplastin time prolonged	1 (9.1)	0	1 (9.1)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	0	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	0	0	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	0	0	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	0	0	1 (9.1)	0
International normalised ratio increased	1 (9.1)	0	1 (9.1)	0	0
Platelet count decreased	1 (9.1)	0	0	0	1 (9.1)
Weight increased	1 (9.1)	1 (9.1)	0	0	0
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					
-Total	6 (54.5)	0	2 (18.2)	1 (9.1)	3 (27.3)
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	0	0	3 (27.3)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Decreased appetite	1 (9.1)	0	0	1 (9.1)	0
Dehydration	1 (9.1)	0	0	1 (9.1)	0
Fluid overload	1 (9.1)	0	0	1 (9.1)	0
Hyperkalaemia	1 (9.1)	0	0	1 (9.1)	0
Hypocalcaemia	1 (9.1)	0	0	0	1 (9.1)
Hypoglycaemia	1 (9.1)	0	1 (9.1)	0	0
Hypomagnesaemia	1 (9.1)	1 (9.1)	0	0	0
Hypophosphataemia	1 (9.1)	0	0	1 (9.1)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Arthralgia	1 (9.1)	0	0	1 (9.1)	0
Back pain	1 (9.1)	0	0	1 (9.1)	0
Pain in jaw	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	3 (27.3)	0	1 (9.1)	1 (9.1)	1 (9.1)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (9.1)	0	0	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	0	0	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	0	0	1 (9.1)	0
Seizure	1 (9.1)	0	0	0	1 (9.1)
Somnolence	1 (9.1)	0	1 (9.1)	0	0
Product issues					
-Total	1 (9.1)	0	1 (9.1)	0	0
Device occlusion	1 (9.1)	0	1 (9.1)	0	0
Psychiatric disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Agitation	1 (9.1)	0	0	1 (9.1)	0
Confusional state	1 (9.1)	0	1 (9.1)	0	0
Delirium	1 (9.1)	0	0	1 (9.1)	0
Renal and urinary disorders					
-Total	4 (36.4)	1 (9.1)	0	2 (18.2)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Cystitis haemorrhagic	1 (9.1)	0	0	1 (9.1)	0
Haematuria	1 (9.1)	1 (9.1)	0	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oliguria	1 (9.1)	0	0	1 (9.1)	0
Urinary retention	1 (9.1)	0	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	0	0	1 (9.1)	4 (36.4)
Hypoxia	4 (36.4)	0	0	3 (27.3)	1 (9.1)
Pleural effusion	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Aspiration	1 (9.1)	0	0	0	1 (9.1)
Cough	1 (9.1)	0	0	1 (9.1)	0
Dyspnoea	1 (9.1)	0	0	1 (9.1)	0
Epistaxis	1 (9.1)	0	1 (9.1)	0	0
Haemoptysis	1 (9.1)	0	0	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	0	0	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	0	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	0	0	1 (9.1)	0
Respiratory distress	1 (9.1)	0	0	0	1 (9.1)
Respiratory failure	1 (9.1)	0	0	0	1 (9.1)

Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (9.1)	0	0	1 (9.1)	0
Vascular disorders					
-Total	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Hypotension	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Hypertension	1 (9.1)	0	1 (9.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177g
Adverse events by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set – non – infused patients

Mixed-lineage leukemia rearrangement: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (81.8)	0	1 (9.1)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Lymphopenia	1 (9.1)	0	0	0	1 (9.1)
Cardiac disorders					
-Total	2 (18.2)	0	0	0	2 (18.2)

Mixed-lineage leukemia rearrangement: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (9.1)	0	0	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	0	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	0	0	1 (9.1)	0
Sinus tachycardia	1 (9.1)	0	0	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	0	0	1 (9.1)	0
Endocrine disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Adrenal insufficiency	1 (9.1)	0	1 (9.1)	0	0
Eye disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Photophobia	1 (9.1)	0	1 (9.1)	0	0
Gastrointestinal disorders					
-Total	6 (54.5)	0	2 (18.2)	4 (36.4)	0
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
Ascites	1 (9.1)	0	0	1 (9.1)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (9.1)	1 (9.1)	0	0	0
Diarrhoea	1 (9.1)	0	0	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	0	0	1 (9.1)	0
Haematochezia	1 (9.1)	0	0	1 (9.1)	0
Stomatitis	1 (9.1)	0	0	1 (9.1)	0
General disorders and administration site conditions					
-Total	6 (54.5)	0	1 (9.1)	2 (18.2)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	0	0	3 (27.3)
Pyrexia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Chills	1 (9.1)	1 (9.1)	0	0	0
Non-cardiac chest pain	1 (9.1)	0	0	1 (9.1)	0
Hepatobiliary disorders					
-Total	1 (9.1)	0	0	0	1 (9.1)
Hepatic failure	1 (9.1)	0	0	0	1 (9.1)
Infections and infestations					
-Total	7 (63.6)	0	0	1 (9.1)	6 (54.5)

Mixed-lineage leukemia rearrangement: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Bronchitis	1 (9.1)	0	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	0	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	0	0	1 (9.1)	0
Escherichia infection	1 (9.1)	0	0	1 (9.1)	0
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Oral herpes	1 (9.1)	0	1 (9.1)	0	0
Pneumonia	1 (9.1)	0	0	0	1 (9.1)
Pneumonia fungal	1 (9.1)	0	0	1 (9.1)	0
Sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	0	0	1 (9.1)
Streptococcal infection	1 (9.1)	0	0	1 (9.1)	0
Investigations					
-Total	4 (36.4)	0	0	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Activated partial thromboplastin time prolonged	1 (9.1)	0	1 (9.1)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	0	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	0	0	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	0	0	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	0	0	1 (9.1)	0
International normalised ratio increased	1 (9.1)	0	1 (9.1)	0	0
Platelet count decreased	1 (9.1)	0	0	0	1 (9.1)
Weight increased	1 (9.1)	1 (9.1)	0	0	0
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					
-Total	6 (54.5)	0	2 (18.2)	1 (9.1)	3 (27.3)
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	0	0	3 (27.3)

Mixed-lineage leukemia rearrangement: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Decreased appetite	1 (9.1)	0	0	1 (9.1)	0
Dehydration	1 (9.1)	0	0	1 (9.1)	0
Fluid overload	1 (9.1)	0	0	1 (9.1)	0
Hyperkalaemia	1 (9.1)	0	0	1 (9.1)	0
Hypocalcaemia	1 (9.1)	0	0	0	1 (9.1)
Hypoglycaemia	1 (9.1)	0	1 (9.1)	0	0
Hypomagnesaemia	1 (9.1)	1 (9.1)	0	0	0
Hypophosphataemia	1 (9.1)	0	0	1 (9.1)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Arthralgia	1 (9.1)	0	0	1 (9.1)	0
Back pain	1 (9.1)	0	0	1 (9.1)	0
Pain in jaw	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	3 (27.3)	0	1 (9.1)	1 (9.1)	1 (9.1)

Mixed-lineage leukemia rearrangement: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (9.1)	0	0	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	0	0	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	0	0	1 (9.1)	0
Seizure	1 (9.1)	0	0	0	1 (9.1)
Somnolence	1 (9.1)	0	1 (9.1)	0	0
Product issues					
-Total	1 (9.1)	0	1 (9.1)	0	0
Device occlusion	1 (9.1)	0	1 (9.1)	0	0
Psychiatric disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Agitation	1 (9.1)	0	0	1 (9.1)	0
Confusional state	1 (9.1)	0	1 (9.1)	0	0
Delirium	1 (9.1)	0	0	1 (9.1)	0
Renal and urinary disorders					
-Total	4 (36.4)	1 (9.1)	0	2 (18.2)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Cystitis haemorrhagic	1 (9.1)	0	0	1 (9.1)	0
Haematuria	1 (9.1)	1 (9.1)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oliguria	1 (9.1)	0	0	1 (9.1)	0
Urinary retention	1 (9.1)	0	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	0	0	1 (9.1)	4 (36.4)
Hypoxia	4 (36.4)	0	0	3 (27.3)	1 (9.1)
Pleural effusion	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Aspiration	1 (9.1)	0	0	0	1 (9.1)
Cough	1 (9.1)	0	0	1 (9.1)	0
Dyspnoea	1 (9.1)	0	0	1 (9.1)	0
Epistaxis	1 (9.1)	0	1 (9.1)	0	0
Haemoptysis	1 (9.1)	0	0	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	0	0	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	0	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	0	0	1 (9.1)	0
Respiratory distress	1 (9.1)	0	0	0	1 (9.1)
Respiratory failure	1 (9.1)	0	0	0	1 (9.1)

Mixed-lineage leukemia rearrangement: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	1 (9.1)	0	0	1 (9.1)	0
Vascular disorders					
-Total	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Hypotension	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Hypertension	1 (9.1)	0	1 (9.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177h
Adverse events by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (81.8)	0	1 (9.1)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Lymphopenia	1 (9.1)	0	0	0	1 (9.1)
Cardiac disorders					
-Total	2 (18.2)	0	0	0	2 (18.2)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bradycardia	1 (9.1)	0	0	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	0	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	0	0	1 (9.1)	0
Sinus tachycardia	1 (9.1)	0	0	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	0	0	1 (9.1)	0
Endocrine disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Adrenal insufficiency	1 (9.1)	0	1 (9.1)	0	0
Eye disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Photophobia	1 (9.1)	0	1 (9.1)	0	0
Gastrointestinal disorders					
-Total	6 (54.5)	0	2 (18.2)	4 (36.4)	0
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
Ascites	1 (9.1)	0	0	1 (9.1)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Constipation	1 (9.1)	1 (9.1)	0	0	0
Diarrhoea	1 (9.1)	0	0	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	0	0	1 (9.1)	0
Haematochezia	1 (9.1)	0	0	1 (9.1)	0
Stomatitis	1 (9.1)	0	0	1 (9.1)	0
General disorders and administration site conditions					
-Total	6 (54.5)	0	1 (9.1)	2 (18.2)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	0	0	3 (27.3)
Pyrexia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Chills	1 (9.1)	1 (9.1)	0	0	0
Non-cardiac chest pain	1 (9.1)	0	0	1 (9.1)	0
Hepatobiliary disorders					
-Total	1 (9.1)	0	0	0	1 (9.1)
Hepatic failure	1 (9.1)	0	0	0	1 (9.1)
Infections and infestations					
-Total	7 (63.6)	0	0	1 (9.1)	6 (54.5)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Bronchitis	1 (9.1)	0	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	0	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	0	0	1 (9.1)	0
Escherichia infection	1 (9.1)	0	0	1 (9.1)	0
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Oral herpes	1 (9.1)	0	1 (9.1)	0	0
Pneumonia	1 (9.1)	0	0	0	1 (9.1)
Pneumonia fungal	1 (9.1)	0	0	1 (9.1)	0
Sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	0	0	1 (9.1)
Streptococcal infection	1 (9.1)	0	0	1 (9.1)	0
Investigations					
-Total	4 (36.4)	0	0	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Activated partial thromboplastin time prolonged	1 (9.1)	0	1 (9.1)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Alanine aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	0	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	0	0	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	0	0	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	0	0	1 (9.1)	0
International normalised ratio increased	1 (9.1)	0	1 (9.1)	0	0
Platelet count decreased	1 (9.1)	0	0	0	1 (9.1)
Weight increased	1 (9.1)	1 (9.1)	0	0	0
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					
-Total	6 (54.5)	0	2 (18.2)	1 (9.1)	3 (27.3)
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	0	0	3 (27.3)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoalbuminaemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Decreased appetite	1 (9.1)	0	0	1 (9.1)	0
Dehydration	1 (9.1)	0	0	1 (9.1)	0
Fluid overload	1 (9.1)	0	0	1 (9.1)	0
Hyperkalaemia	1 (9.1)	0	0	1 (9.1)	0
Hypocalcaemia	1 (9.1)	0	0	0	1 (9.1)
Hypoglycaemia	1 (9.1)	0	1 (9.1)	0	0
Hypomagnesaemia	1 (9.1)	1 (9.1)	0	0	0
Hypophosphataemia	1 (9.1)	0	0	1 (9.1)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Arthralgia	1 (9.1)	0	0	1 (9.1)	0
Back pain	1 (9.1)	0	0	1 (9.1)	0
Pain in jaw	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	3 (27.3)	0	1 (9.1)	1 (9.1)	1 (9.1)

Hypodiploidy: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (9.1)	0	0	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	0	0	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	0	0	1 (9.1)	0
Seizure	1 (9.1)	0	0	0	1 (9.1)
Somnolence	1 (9.1)	0	1 (9.1)	0	0
Product issues					
-Total	1 (9.1)	0	1 (9.1)	0	0
Device occlusion	1 (9.1)	0	1 (9.1)	0	0
Psychiatric disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Agitation	1 (9.1)	0	0	1 (9.1)	0
Confusional state	1 (9.1)	0	1 (9.1)	0	0
Delirium	1 (9.1)	0	0	1 (9.1)	0
Renal and urinary disorders					
-Total	4 (36.4)	1 (9.1)	0	2 (18.2)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Cystitis haemorrhagic	1 (9.1)	0	0	1 (9.1)	0
Haematuria	1 (9.1)	1 (9.1)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oliguria	1 (9.1)	0	0	1 (9.1)	0
Urinary retention	1 (9.1)	0	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	0	0	1 (9.1)	4 (36.4)
Hypoxia	4 (36.4)	0	0	3 (27.3)	1 (9.1)
Pleural effusion	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Aspiration	1 (9.1)	0	0	0	1 (9.1)
Cough	1 (9.1)	0	0	1 (9.1)	0
Dyspnoea	1 (9.1)	0	0	1 (9.1)	0
Epistaxis	1 (9.1)	0	1 (9.1)	0	0
Haemoptysis	1 (9.1)	0	0	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	0	0	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	0	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	0	0	1 (9.1)	0
Respiratory distress	1 (9.1)	0	0	0	1 (9.1)
Respiratory failure	1 (9.1)	0	0	0	1 (9.1)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (9.1)	0	0	1 (9.1)	0
Vascular disorders					
-Total	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Hypotension	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Hypertension	1 (9.1)	0	1 (9.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177i
Adverse events by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (81.8)	0	1 (9.1)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Lymphopenia	1 (9.1)	0	0	0	1 (9.1)
Cardiac disorders					
-Total	2 (18.2)	0	0	0	2 (18.2)

BCR-ABL1-like: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (9.1)	0	0	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	0	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	0	0	1 (9.1)	0
Sinus tachycardia	1 (9.1)	0	0	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	0	0	1 (9.1)	0
Endocrine disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Adrenal insufficiency	1 (9.1)	0	1 (9.1)	0	0
Eye disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Photophobia	1 (9.1)	0	1 (9.1)	0	0
Gastrointestinal disorders					
-Total	6 (54.5)	0	2 (18.2)	4 (36.4)	0
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
Ascites	1 (9.1)	0	0	1 (9.1)	0

BCR-ABL1-like: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (9.1)	1 (9.1)	0	0	0
Diarrhoea	1 (9.1)	0	0	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	0	0	1 (9.1)	0
Haematochezia	1 (9.1)	0	0	1 (9.1)	0
Stomatitis	1 (9.1)	0	0	1 (9.1)	0
General disorders and administration site conditions					
-Total	6 (54.5)	0	1 (9.1)	2 (18.2)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	0	0	3 (27.3)
Pyrexia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Chills	1 (9.1)	1 (9.1)	0	0	0
Non-cardiac chest pain	1 (9.1)	0	0	1 (9.1)	0
Hepatobiliary disorders					
-Total	1 (9.1)	0	0	0	1 (9.1)
Hepatic failure	1 (9.1)	0	0	0	1 (9.1)
Infections and infestations					
-Total	7 (63.6)	0	0	1 (9.1)	6 (54.5)

BCR-ABL1-like: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Bronchitis	1 (9.1)	0	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	0	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	0	0	1 (9.1)	0
Escherichia infection	1 (9.1)	0	0	1 (9.1)	0
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Oral herpes	1 (9.1)	0	1 (9.1)	0	0
Pneumonia	1 (9.1)	0	0	0	1 (9.1)
Pneumonia fungal	1 (9.1)	0	0	1 (9.1)	0
Sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	0	0	1 (9.1)
Streptococcal infection	1 (9.1)	0	0	1 (9.1)	0
Investigations					
-Total	4 (36.4)	0	0	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Activated partial thromboplastin time prolonged	1 (9.1)	0	1 (9.1)	0	0

BCR-ABL1-like: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	0	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	0	0	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	0	0	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	0	0	1 (9.1)	0
International normalised ratio increased	1 (9.1)	0	1 (9.1)	0	0
Platelet count decreased	1 (9.1)	0	0	0	1 (9.1)
Weight increased	1 (9.1)	1 (9.1)	0	0	0
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					
-Total	6 (54.5)	0	2 (18.2)	1 (9.1)	3 (27.3)
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	0	0	3 (27.3)

BCR-ABL1-like: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Decreased appetite	1 (9.1)	0	0	1 (9.1)	0
Dehydration	1 (9.1)	0	0	1 (9.1)	0
Fluid overload	1 (9.1)	0	0	1 (9.1)	0
Hyperkalaemia	1 (9.1)	0	0	1 (9.1)	0
Hypocalcaemia	1 (9.1)	0	0	0	1 (9.1)
Hypoglycaemia	1 (9.1)	0	1 (9.1)	0	0
Hypomagnesaemia	1 (9.1)	1 (9.1)	0	0	0
Hypophosphataemia	1 (9.1)	0	0	1 (9.1)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Arthralgia	1 (9.1)	0	0	1 (9.1)	0
Back pain	1 (9.1)	0	0	1 (9.1)	0
Pain in jaw	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	3 (27.3)	0	1 (9.1)	1 (9.1)	1 (9.1)

BCR-ABL1-like: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (9.1)	0	0	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	0	0	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	0	0	1 (9.1)	0
Seizure	1 (9.1)	0	0	0	1 (9.1)
Somnolence	1 (9.1)	0	1 (9.1)	0	0
Product issues					
-Total	1 (9.1)	0	1 (9.1)	0	0
Device occlusion	1 (9.1)	0	1 (9.1)	0	0
Psychiatric disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Agitation	1 (9.1)	0	0	1 (9.1)	0
Confusional state	1 (9.1)	0	1 (9.1)	0	0
Delirium	1 (9.1)	0	0	1 (9.1)	0
Renal and urinary disorders					
-Total	4 (36.4)	1 (9.1)	0	2 (18.2)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Cystitis haemorrhagic	1 (9.1)	0	0	1 (9.1)	0
Haematuria	1 (9.1)	1 (9.1)	0	0	0

BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oliguria	1 (9.1)	0	0	1 (9.1)	0
Urinary retention	1 (9.1)	0	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	0	0	1 (9.1)	4 (36.4)
Hypoxia	4 (36.4)	0	0	3 (27.3)	1 (9.1)
Pleural effusion	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Aspiration	1 (9.1)	0	0	0	1 (9.1)
Cough	1 (9.1)	0	0	1 (9.1)	0
Dyspnoea	1 (9.1)	0	0	1 (9.1)	0
Epistaxis	1 (9.1)	0	1 (9.1)	0	0
Haemoptysis	1 (9.1)	0	0	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	0	0	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	0	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	0	0	1 (9.1)	0
Respiratory distress	1 (9.1)	0	0	0	1 (9.1)
Respiratory failure	1 (9.1)	0	0	0	1 (9.1)

BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (9.1)	0	0	1 (9.1)	0
Vascular disorders					
-Total	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Hypotension	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Hypertension	1 (9.1)	0	1 (9.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177j
Adverse events by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	1 (33.3)	0	2 (66.7)
Blood and lymphatic system disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Febrile neutropenia	1 (33.3)	0	0	1 (33.3)	0
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	0	0	1 (33.3)
Endocrine disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Adrenal insufficiency	1 (33.3)	0	1 (33.3)	0	0
Gastrointestinal disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Constipation	1 (33.3)	1 (33.3)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=3		
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (33.3)	0	0	1 (33.3)	0
Nausea	1 (33.3)	0	1 (33.3)	0	0
Vomiting	1 (33.3)	0	1 (33.3)	0	0
General disorders and administration site conditions					
-Total	1 (33.3)	0	1 (33.3)	0	0
Chills	1 (33.3)	1 (33.3)	0	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Infections and infestations					
-Total	2 (66.7)	0	0	0	2 (66.7)
Candida sepsis	1 (33.3)	0	0	0	1 (33.3)
Pneumonia fungal	1 (33.3)	0	0	1 (33.3)	0
Sepsis	1 (33.3)	0	0	0	1 (33.3)
Metabolism and nutrition disorders					
-Total	2 (66.7)	0	1 (33.3)	0	1 (33.3)
Hyperglycaemia	1 (33.3)	0	1 (33.3)	0	0
Hypernatraemia	1 (33.3)	0	0	0	1 (33.3)
Hypokalaemia	1 (33.3)	0	0	0	1 (33.3)
Hypomagnesaemia	1 (33.3)	1 (33.3)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	1 (33.3)	0	0	1 (33.3)	0
Renal and urinary disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Acute kidney injury	1 (33.3)	0	0	0	1 (33.3)
Respiratory, thoracic and mediastinal disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	0	0	1 (33.3)
Respiratory failure	1 (33.3)	0	0	0	1 (33.3)
Vascular disorders					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Hypotension	2 (66.7)	0	0	1 (33.3)	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177j
Adverse events by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (75.0)	0	0	1 (12.5)	5 (62.5)
Blood and lymphatic system disorders					
-Total	4 (50.0)	0	0	2 (25.0)	2 (25.0)
Anaemia	4 (50.0)	0	0	4 (50.0)	0
Disseminated intravascular coagulation	3 (37.5)	0	0	2 (25.0)	1 (12.5)
Thrombocytopenia	3 (37.5)	0	0	1 (12.5)	2 (25.0)
Febrile neutropenia	1 (12.5)	0	0	1 (12.5)	0
Lymphopenia	1 (12.5)	0	0	0	1 (12.5)
Neutropenia	1 (12.5)	0	0	0	1 (12.5)
Cardiac disorders					
-Total	2 (25.0)	0	0	0	2 (25.0)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (12.5)	0	0	0	1 (12.5)
Cardiovascular insufficiency	1 (12.5)	0	0	0	1 (12.5)
Right ventricular dysfunction	1 (12.5)	0	0	1 (12.5)	0
Sinus tachycardia	1 (12.5)	0	0	1 (12.5)	0
Ventricular tachycardia	1 (12.5)	0	0	1 (12.5)	0
Eye disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Photophobia	1 (12.5)	0	1 (12.5)	0	0
Gastrointestinal disorders					
-Total	4 (50.0)	0	1 (12.5)	3 (37.5)	0
Abdominal pain	2 (25.0)	0	0	2 (25.0)	0
Colitis	2 (25.0)	0	0	2 (25.0)	0
Nausea	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Vomiting	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Ascites	1 (12.5)	0	0	1 (12.5)	0
Diarrhoea	1 (12.5)	0	0	1 (12.5)	0
Haematochezia	1 (12.5)	0	0	1 (12.5)	0
Stomatitis	1 (12.5)	0	0	1 (12.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	5 (62.5)	0	0	2 (25.0)	3 (37.5)
Multiple organ dysfunction syndrome	3 (37.5)	0	0	0	3 (37.5)
Pain	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Pyrexia	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Non-cardiac chest pain	1 (12.5)	0	0	1 (12.5)	0
Hepatobiliary disorders					
-Total	1 (12.5)	0	0	0	1 (12.5)
Hepatic failure	1 (12.5)	0	0	0	1 (12.5)
Infections and infestations					
-Total	5 (62.5)	0	0	1 (12.5)	4 (50.0)
Klebsiella sepsis	2 (25.0)	0	0	0	2 (25.0)
Bronchitis	1 (12.5)	0	1 (12.5)	0	0
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0
Escherichia infection	1 (12.5)	0	0	1 (12.5)	0
Klebsiella infection	1 (12.5)	0	0	1 (12.5)	0
Oral herpes	1 (12.5)	0	1 (12.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Streptococcal infection	1 (12.5)	0	0	1 (12.5)	0
Investigations					
-Total	4 (50.0)	0	0	0	4 (50.0)
Neutrophil count decreased	2 (25.0)	0	0	0	2 (25.0)
Activated partial thromboplastin time prolonged	1 (12.5)	0	1 (12.5)	0	0
Alanine aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)
Aspartate aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)
Blood bilirubin increased	1 (12.5)	0	0	0	1 (12.5)
Blood lactate dehydrogenase increased	1 (12.5)	0	0	1 (12.5)	0
Computerised tomogram thorax abnormal	1 (12.5)	0	0	1 (12.5)	0
Electrocardiogram qt prolonged	1 (12.5)	0	0	1 (12.5)	0
International normalised ratio increased	1 (12.5)	0	1 (12.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (12.5)	0	0	0	1 (12.5)
Weight increased	1 (12.5)	1 (12.5)	0	0	0
White blood cell count decreased	1 (12.5)	0	0	0	1 (12.5)
Metabolism and nutrition disorders					
-Total	4 (50.0)	0	1 (12.5)	1 (12.5)	2 (25.0)
Hyperglycaemia	2 (25.0)	0	1 (12.5)	0	1 (12.5)
Hypernatraemia	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Hypoalbuminaemia	2 (25.0)	0	1 (12.5)	0	1 (12.5)
Hypokalaemia	2 (25.0)	0	0	0	2 (25.0)
Decreased appetite	1 (12.5)	0	0	1 (12.5)	0
Dehydration	1 (12.5)	0	0	1 (12.5)	0
Fluid overload	1 (12.5)	0	0	1 (12.5)	0
Hyperkalaemia	1 (12.5)	0	0	1 (12.5)	0
Hypocalcaemia	1 (12.5)	0	0	0	1 (12.5)
Hypoglycaemia	1 (12.5)	0	1 (12.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (37.5)	0	1 (12.5)	2 (25.0)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	2 (25.0)	0	0	2 (25.0)	0
Arthralgia	1 (12.5)	0	0	1 (12.5)	0
Back pain	1 (12.5)	0	0	1 (12.5)	0
Pain in jaw	1 (12.5)	0	1 (12.5)	0	0
Nervous system disorders					
-Total	3 (37.5)	0	1 (12.5)	1 (12.5)	1 (12.5)
Headache	1 (12.5)	0	0	1 (12.5)	0
Hyporesponsive to stimuli	1 (12.5)	0	0	1 (12.5)	0
Leukoencephalopathy	1 (12.5)	0	0	1 (12.5)	0
Seizure	1 (12.5)	0	0	0	1 (12.5)
Somnolence	1 (12.5)	0	1 (12.5)	0	0
Product issues					
-Total	1 (12.5)	0	1 (12.5)	0	0
Device occlusion	1 (12.5)	0	1 (12.5)	0	0
Psychiatric disorders					
-Total	3 (37.5)	0	1 (12.5)	2 (25.0)	0
Agitation	1 (12.5)	0	0	1 (12.5)	0
Confusional state	1 (12.5)	0	1 (12.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	1 (12.5)	0	0	1 (12.5)	0
Renal and urinary disorders					
-Total	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Acute kidney injury	1 (12.5)	0	0	1 (12.5)	0
Cystitis haemorrhagic	1 (12.5)	0	0	1 (12.5)	0
Haematuria	1 (12.5)	1 (12.5)	0	0	0
Oliguria	1 (12.5)	0	0	1 (12.5)	0
Urinary retention	1 (12.5)	0	1 (12.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (50.0)	0	0	1 (12.5)	3 (37.5)
Hypoxia	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Pleural effusion	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Aspiration	1 (12.5)	0	0	0	1 (12.5)
Cough	1 (12.5)	0	0	1 (12.5)	0
Dyspnoea	1 (12.5)	0	0	1 (12.5)	0
Epistaxis	1 (12.5)	0	1 (12.5)	0	0
Haemoptysis	1 (12.5)	0	0	1 (12.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	1 (12.5)	0	0	1 (12.5)	0
Pulmonary alveolar haemorrhage	1 (12.5)	0	0	0	1 (12.5)
Pulmonary hypertension	1 (12.5)	0	0	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)
Respiratory distress	1 (12.5)	0	0	0	1 (12.5)
Tachypnoea	1 (12.5)	0	0	1 (12.5)	0
Vascular disorders					
-Total	4 (50.0)	0	0	2 (25.0)	2 (25.0)
Hypotension	4 (50.0)	0	0	2 (25.0)	2 (25.0)
Hypertension	1 (12.5)	0	1 (12.5)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177k
Adverse events by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: US

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (81.8)	0	1 (9.1)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Lymphopenia	1 (9.1)	0	0	0	1 (9.1)
Cardiac disorders					
-Total	2 (18.2)	0	0	0	2 (18.2)

Region: US

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bradycardia	1 (9.1)	0	0	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	0	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	0	0	1 (9.1)	0
Sinus tachycardia	1 (9.1)	0	0	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	0	0	1 (9.1)	0
Endocrine disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Adrenal insufficiency	1 (9.1)	0	1 (9.1)	0	0
Eye disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Photophobia	1 (9.1)	0	1 (9.1)	0	0
Gastrointestinal disorders					
-Total	6 (54.5)	0	2 (18.2)	4 (36.4)	0
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
Ascites	1 (9.1)	0	0	1 (9.1)	0

Region: US

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Constipation	1 (9.1)	1 (9.1)	0	0	0
Diarrhoea	1 (9.1)	0	0	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	0	0	1 (9.1)	0
Haematochezia	1 (9.1)	0	0	1 (9.1)	0
Stomatitis	1 (9.1)	0	0	1 (9.1)	0
General disorders and administration site conditions					
-Total	6 (54.5)	0	1 (9.1)	2 (18.2)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	0	0	3 (27.3)
Pyrexia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Chills	1 (9.1)	1 (9.1)	0	0	0
Non-cardiac chest pain	1 (9.1)	0	0	1 (9.1)	0
Hepatobiliary disorders					
-Total	1 (9.1)	0	0	0	1 (9.1)
Hepatic failure	1 (9.1)	0	0	0	1 (9.1)
Infections and infestations					
-Total	7 (63.6)	0	0	1 (9.1)	6 (54.5)

Region: US

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Bronchitis	1 (9.1)	0	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	0	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	0	0	1 (9.1)	0
Escherichia infection	1 (9.1)	0	0	1 (9.1)	0
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Oral herpes	1 (9.1)	0	1 (9.1)	0	0
Pneumonia	1 (9.1)	0	0	0	1 (9.1)
Pneumonia fungal	1 (9.1)	0	0	1 (9.1)	0
Sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	0	0	1 (9.1)
Streptococcal infection	1 (9.1)	0	0	1 (9.1)	0
Investigations					
-Total	4 (36.4)	0	0	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Activated partial thromboplastin time prolonged	1 (9.1)	0	1 (9.1)	0	0

Region: US

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Alanine aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	0	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	0	0	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	0	0	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	0	0	1 (9.1)	0
International normalised ratio increased	1 (9.1)	0	1 (9.1)	0	0
Platelet count decreased	1 (9.1)	0	0	0	1 (9.1)
Weight increased	1 (9.1)	1 (9.1)	0	0	0
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					
-Total	6 (54.5)	0	2 (18.2)	1 (9.1)	3 (27.3)
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	0	0	3 (27.3)

Region: US

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoalbuminaemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Decreased appetite	1 (9.1)	0	0	1 (9.1)	0
Dehydration	1 (9.1)	0	0	1 (9.1)	0
Fluid overload	1 (9.1)	0	0	1 (9.1)	0
Hyperkalaemia	1 (9.1)	0	0	1 (9.1)	0
Hypocalcaemia	1 (9.1)	0	0	0	1 (9.1)
Hypoglycaemia	1 (9.1)	0	1 (9.1)	0	0
Hypomagnesaemia	1 (9.1)	1 (9.1)	0	0	0
Hypophosphataemia	1 (9.1)	0	0	1 (9.1)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Arthralgia	1 (9.1)	0	0	1 (9.1)	0
Back pain	1 (9.1)	0	0	1 (9.1)	0
Pain in jaw	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	3 (27.3)	0	1 (9.1)	1 (9.1)	1 (9.1)

Region: US

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Headache	1 (9.1)	0	0	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	0	0	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	0	0	1 (9.1)	0
Seizure	1 (9.1)	0	0	0	1 (9.1)
Somnolence	1 (9.1)	0	1 (9.1)	0	0
Product issues					
-Total	1 (9.1)	0	1 (9.1)	0	0
Device occlusion	1 (9.1)	0	1 (9.1)	0	0
Psychiatric disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Agitation	1 (9.1)	0	0	1 (9.1)	0
Confusional state	1 (9.1)	0	1 (9.1)	0	0
Delirium	1 (9.1)	0	0	1 (9.1)	0
Renal and urinary disorders					
-Total	4 (36.4)	1 (9.1)	0	2 (18.2)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Cystitis haemorrhagic	1 (9.1)	0	0	1 (9.1)	0
Haematuria	1 (9.1)	1 (9.1)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oliguria	1 (9.1)	0	0	1 (9.1)	0
Urinary retention	1 (9.1)	0	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	0	0	1 (9.1)	4 (36.4)
Hypoxia	4 (36.4)	0	0	3 (27.3)	1 (9.1)
Pleural effusion	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Aspiration	1 (9.1)	0	0	0	1 (9.1)
Cough	1 (9.1)	0	0	1 (9.1)	0
Dyspnoea	1 (9.1)	0	0	1 (9.1)	0
Epistaxis	1 (9.1)	0	1 (9.1)	0	0
Haemoptysis	1 (9.1)	0	0	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	0	0	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	0	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	0	0	1 (9.1)	0
Respiratory distress	1 (9.1)	0	0	0	1 (9.1)
Respiratory failure	1 (9.1)	0	0	0	1 (9.1)

Region: US

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (9.1)	0	0	1 (9.1)	0
Vascular disorders					
-Total	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Hypotension	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Hypertension	1 (9.1)	0	1 (9.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177l
Adverse events by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	0	0	4 (100)
Blood and lymphatic system disorders					
-Total	3 (75.0)	0	0	2 (50.0)	1 (25.0)
Anaemia	3 (75.0)	0	0	3 (75.0)	0
Disseminated intravascular coagulation	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Thrombocytopenia	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Febrile neutropenia	1 (25.0)	0	0	1 (25.0)	0
Cardiac disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Cardiovascular insufficiency	1 (25.0)	0	0	0	1 (25.0)
Gastrointestinal disorders					

Prior SCT therapy: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (75.0)	0	1 (25.0)	2 (50.0)	0
Colitis	2 (50.0)	0	0	2 (50.0)	0
Abdominal pain	1 (25.0)	0	0	1 (25.0)	0
Ascites	1 (25.0)	0	0	1 (25.0)	0
Diarrhoea	1 (25.0)	0	0	1 (25.0)	0
Nausea	1 (25.0)	0	1 (25.0)	0	0
Stomatitis	1 (25.0)	0	0	1 (25.0)	0
Vomiting	1 (25.0)	0	1 (25.0)	0	0
General disorders and administration site conditions					
-Total	4 (100)	0	1 (25.0)	0	3 (75.0)
Multiple organ dysfunction syndrome	3 (75.0)	0	0	0	3 (75.0)
Pyrexia	2 (50.0)	0	2 (50.0)	0	0
Chills	1 (25.0)	1 (25.0)	0	0	0
Pain	1 (25.0)	0	1 (25.0)	0	0
Hepatobiliary disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Hepatic failure	1 (25.0)	0	0	0	1 (25.0)

Prior SCT therapy: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	4 (100)	0	0	0	4 (100)
Klebsiella sepsis	2 (50.0)	0	0	0	2 (50.0)
Bronchitis	1 (25.0)	0	1 (25.0)	0	0
Clostridium difficile colitis	1 (25.0)	0	0	1 (25.0)	0
Klebsiella infection	1 (25.0)	0	0	1 (25.0)	0
Oral herpes	1 (25.0)	0	1 (25.0)	0	0
Sepsis	1 (25.0)	0	0	0	1 (25.0)
Staphylococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Staphylococcal infection	1 (25.0)	0	0	0	1 (25.0)
Investigations					
-Total	3 (75.0)	0	0	0	3 (75.0)
Neutrophil count decreased	2 (50.0)	0	0	0	2 (50.0)
Activated partial thromboplastin time prolonged	1 (25.0)	0	1 (25.0)	0	0
Alanine aminotransferase increased	1 (25.0)	0	0	0	1 (25.0)
Aspartate aminotransferase increased	1 (25.0)	0	0	0	1 (25.0)
Blood bilirubin increased	1 (25.0)	0	0	0	1 (25.0)

Prior SCT therapy: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	1 (25.0)	0	1 (25.0)	0	0
Platelet count decreased	1 (25.0)	0	0	0	1 (25.0)
Weight increased	1 (25.0)	1 (25.0)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (75.0)	0	1 (25.0)	0	2 (50.0)
Hyperglycaemia	2 (50.0)	0	1 (25.0)	0	1 (25.0)
Hypernatraemia	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Hypoalbuminaemia	2 (50.0)	0	1 (25.0)	0	1 (25.0)
Hypokalaemia	2 (50.0)	0	0	0	2 (50.0)
Decreased appetite	1 (25.0)	0	0	1 (25.0)	0
Dehydration	1 (25.0)	0	0	1 (25.0)	0
Hypocalcaemia	1 (25.0)	0	0	0	1 (25.0)
Hypoglycaemia	1 (25.0)	0	1 (25.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Pain in extremity	1 (25.0)	0	0	1 (25.0)	0
Nervous system disorders					

Prior SCT therapy: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Leukoencephalopathy	1 (25.0)	0	0	1 (25.0)	0
Somnolence	1 (25.0)	0	1 (25.0)	0	0
Product issues					
-Total	1 (25.0)	0	1 (25.0)	0	0
Device occlusion	1 (25.0)	0	1 (25.0)	0	0
Psychiatric disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Delirium	1 (25.0)	0	0	1 (25.0)	0
Renal and urinary disorders					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Cystitis haemorrhagic	1 (25.0)	0	0	1 (25.0)	0
Haematuria	1 (25.0)	1 (25.0)	0	0	0
Urinary retention	1 (25.0)	0	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Hypoxia	2 (50.0)	0	0	1 (25.0)	1 (25.0)

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pleural effusion	1 (25.0)	0	0	1 (25.0)	0
Vascular disorders					
-Total	3 (75.0)	0	0	3 (75.0)	0
Hypotension	3 (75.0)	0	0	3 (75.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177l
Adverse events by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: No

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	0	1 (14.3)	1 (14.3)	3 (42.9)
Blood and lymphatic system disorders					
-Total	2 (28.6)	0	0	0	2 (28.6)
Neutropenia	2 (28.6)	0	0	0	2 (28.6)
Thrombocytopenia	2 (28.6)	0	0	0	2 (28.6)
Anaemia	1 (14.3)	0	0	1 (14.3)	0
Disseminated intravascular coagulation	1 (14.3)	0	0	1 (14.3)	0
Febrile neutropenia	1 (14.3)	0	0	1 (14.3)	0
Lymphopenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)

Prior SCT therapy: No

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (14.3)	0	0	0	1 (14.3)
Right ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0
Sinus tachycardia	1 (14.3)	0	0	1 (14.3)	0
Ventricular tachycardia	1 (14.3)	0	0	1 (14.3)	0
Endocrine disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Adrenal insufficiency	1 (14.3)	0	1 (14.3)	0	0
Eye disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Photophobia	1 (14.3)	0	1 (14.3)	0	0
Gastrointestinal disorders					
-Total	3 (42.9)	0	1 (14.3)	2 (28.6)	0
Nausea	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Vomiting	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Abdominal pain	1 (14.3)	0	0	1 (14.3)	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Haematochezia	1 (14.3)	0	0	1 (14.3)	0

Prior SCT therapy: No

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	2 (28.6)	0	0	2 (28.6)	0
Non-cardiac chest pain	1 (14.3)	0	0	1 (14.3)	0
Pain	1 (14.3)	0	0	1 (14.3)	0
Pyrexia	1 (14.3)	0	0	1 (14.3)	0
Infections and infestations					
-Total	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Candida sepsis	1 (14.3)	0	0	0	1 (14.3)
Escherichia infection	1 (14.3)	0	0	1 (14.3)	0
Pneumonia	1 (14.3)	0	0	0	1 (14.3)
Pneumonia fungal	1 (14.3)	0	0	1 (14.3)	0
Streptococcal infection	1 (14.3)	0	0	1 (14.3)	0
Investigations					
-Total	1 (14.3)	0	0	0	1 (14.3)
Blood lactate dehydrogenase increased	1 (14.3)	0	0	1 (14.3)	0
Computerised tomogram thorax abnormal	1 (14.3)	0	0	1 (14.3)	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Electrocardiogram qt prolonged	1 (14.3)	0	0	1 (14.3)	0
White blood cell count decreased	1 (14.3)	0	0	0	1 (14.3)
Metabolism and nutrition disorders					
-Total	3 (42.9)	0	1 (14.3)	1 (14.3)	1 (14.3)
Fluid overload	1 (14.3)	0	0	1 (14.3)	0
Hyperglycaemia	1 (14.3)	0	1 (14.3)	0	0
Hyperkalaemia	1 (14.3)	0	0	1 (14.3)	0
Hypernatraemia	1 (14.3)	0	0	0	1 (14.3)
Hypokalaemia	1 (14.3)	0	0	0	1 (14.3)
Hypomagnesaemia	1 (14.3)	1 (14.3)	0	0	0
Hypophosphataemia	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Arthralgia	1 (14.3)	0	0	1 (14.3)	0
Back pain	1 (14.3)	0	0	1 (14.3)	0
Pain in extremity	1 (14.3)	0	0	1 (14.3)	0
Pain in jaw	1 (14.3)	0	1 (14.3)	0	0

Prior SCT therapy: No

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)
Headache	1 (14.3)	0	0	1 (14.3)	0
Hyporesponsive to stimuli	1 (14.3)	0	0	1 (14.3)	0
Seizure	1 (14.3)	0	0	0	1 (14.3)
Psychiatric disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Agitation	1 (14.3)	0	0	1 (14.3)	0
Confusional state	1 (14.3)	0	1 (14.3)	0	0
Renal and urinary disorders					
-Total	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Acute kidney injury	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Oliguria	1 (14.3)	0	0	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (42.9)	0	0	0	3 (42.9)
Hypoxia	2 (28.6)	0	0	2 (28.6)	0
Pulmonary oedema	2 (28.6)	0	0	0	2 (28.6)

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspiration	1 (14.3)	0	0	0	1 (14.3)
Cough	1 (14.3)	0	0	1 (14.3)	0
Dyspnoea	1 (14.3)	0	0	1 (14.3)	0
Epistaxis	1 (14.3)	0	1 (14.3)	0	0
Haemoptysis	1 (14.3)	0	0	1 (14.3)	0
Oropharyngeal pain	1 (14.3)	0	0	1 (14.3)	0
Pleural effusion	1 (14.3)	0	1 (14.3)	0	0
Pulmonary alveolar haemorrhage	1 (14.3)	0	0	0	1 (14.3)
Pulmonary hypertension	1 (14.3)	0	0	1 (14.3)	0
Respiratory distress	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Tachypnoea	1 (14.3)	0	0	1 (14.3)	0
Vascular disorders					
-Total	3 (42.9)	0	0	0	3 (42.9)
Hypotension	3 (42.9)	0	0	0	3 (42.9)
Hypertension	1 (14.3)	0	1 (14.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177m
Adverse events by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	0	1 (25.0)	1 (25.0)	1 (25.0)
Gastrointestinal disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Constipation	1 (25.0)	1 (25.0)	0	0	0
Nausea	1 (25.0)	0	1 (25.0)	0	0
Vomiting	1 (25.0)	0	1 (25.0)	0	0
General disorders and administration site conditions					
-Total	1 (25.0)	0	0	1 (25.0)	0
Pain	1 (25.0)	0	0	1 (25.0)	0
Pyrexia	1 (25.0)	0	0	1 (25.0)	0
Infections and infestations					

Eligibility for SCT: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Escherichia infection	1 (25.0)	0	0	1 (25.0)	0
Pneumonia	1 (25.0)	0	0	0	1 (25.0)
Streptococcal infection	1 (25.0)	0	0	1 (25.0)	0
Metabolism and nutrition disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Hyperglycaemia	1 (25.0)	0	1 (25.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Pain in jaw	1 (25.0)	0	1 (25.0)	0	0
Psychiatric disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Confusional state	1 (25.0)	0	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Aspiration	1 (25.0)	0	0	0	1 (25.0)
Epistaxis	1 (25.0)	0	1 (25.0)	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	1 (25.0)	0	0	1 (25.0)	0
Pleural effusion	1 (25.0)	0	1 (25.0)	0	0
Vascular disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Hypotension	1 (25.0)	0	0	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177m
Adverse events by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: No

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	0	0	6 (85.7)
Blood and lymphatic system disorders					
-Total	5 (71.4)	0	0	2 (28.6)	3 (42.9)
Anaemia	4 (57.1)	0	0	4 (57.1)	0
Thrombocytopenia	4 (57.1)	0	0	1 (14.3)	3 (42.9)
Disseminated intravascular coagulation	3 (42.9)	0	0	2 (28.6)	1 (14.3)
Febrile neutropenia	2 (28.6)	0	0	2 (28.6)	0
Neutropenia	2 (28.6)	0	0	0	2 (28.6)
Lymphopenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					
-Total	2 (28.6)	0	0	0	2 (28.6)

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bradycardia	1 (14.3)	0	0	0	1 (14.3)
Cardiovascular insufficiency	1 (14.3)	0	0	0	1 (14.3)
Right ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0
Sinus tachycardia	1 (14.3)	0	0	1 (14.3)	0
Ventricular tachycardia	1 (14.3)	0	0	1 (14.3)	0
Endocrine disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Adrenal insufficiency	1 (14.3)	0	1 (14.3)	0	0
Eye disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Photophobia	1 (14.3)	0	1 (14.3)	0	0
Gastrointestinal disorders					
-Total	5 (71.4)	0	1 (14.3)	4 (57.1)	0
Abdominal pain	2 (28.6)	0	0	2 (28.6)	0
Colitis	2 (28.6)	0	0	2 (28.6)	0
Nausea	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Vomiting	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Ascites	1 (14.3)	0	0	1 (14.3)	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Diarrhoea	1 (14.3)	0	0	1 (14.3)	0
Gastrointestinal haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Haematochezia	1 (14.3)	0	0	1 (14.3)	0
Stomatitis	1 (14.3)	0	0	1 (14.3)	0
General disorders and administration site conditions					
-Total	5 (71.4)	0	1 (14.3)	1 (14.3)	3 (42.9)
Multiple organ dysfunction syndrome	3 (42.9)	0	0	0	3 (42.9)
Pyrexia	2 (28.6)	0	2 (28.6)	0	0
Chills	1 (14.3)	1 (14.3)	0	0	0
Non-cardiac chest pain	1 (14.3)	0	0	1 (14.3)	0
Pain	1 (14.3)	0	1 (14.3)	0	0
Hepatobiliary disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)
Hepatic failure	1 (14.3)	0	0	0	1 (14.3)
Infections and infestations					
-Total	5 (71.4)	0	0	0	5 (71.4)
Klebsiella sepsis	2 (28.6)	0	0	0	2 (28.6)

Eligibility for SCT: No

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bronchitis	1 (14.3)	0	1 (14.3)	0	0
Candida sepsis	1 (14.3)	0	0	0	1 (14.3)
Clostridium difficile colitis	1 (14.3)	0	0	1 (14.3)	0
Klebsiella infection	1 (14.3)	0	0	1 (14.3)	0
Oral herpes	1 (14.3)	0	1 (14.3)	0	0
Pneumonia fungal	1 (14.3)	0	0	1 (14.3)	0
Sepsis	1 (14.3)	0	0	0	1 (14.3)
Staphylococcal bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Staphylococcal infection	1 (14.3)	0	0	0	1 (14.3)
Investigations					
-Total	4 (57.1)	0	0	0	4 (57.1)
Neutrophil count decreased	2 (28.6)	0	0	0	2 (28.6)
Activated partial thromboplastin time prolonged	1 (14.3)	0	1 (14.3)	0	0
Alanine aminotransferase increased	1 (14.3)	0	0	0	1 (14.3)
Aspartate aminotransferase increased	1 (14.3)	0	0	0	1 (14.3)
Blood bilirubin increased	1 (14.3)	0	0	0	1 (14.3)

Eligibility for SCT: No

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	1 (14.3)	0	0	1 (14.3)	0
Computerised tomogram thorax abnormal	1 (14.3)	0	0	1 (14.3)	0
Electrocardiogram qt prolonged	1 (14.3)	0	0	1 (14.3)	0
International normalised ratio increased	1 (14.3)	0	1 (14.3)	0	0
Platelet count decreased	1 (14.3)	0	0	0	1 (14.3)
Weight increased	1 (14.3)	1 (14.3)	0	0	0
White blood cell count decreased	1 (14.3)	0	0	0	1 (14.3)
Metabolism and nutrition disorders					
-Total	5 (71.4)	0	1 (14.3)	1 (14.3)	3 (42.9)
Hypernatraemia	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Hypokalaemia	3 (42.9)	0	0	0	3 (42.9)
Hyperglycaemia	2 (28.6)	0	1 (14.3)	0	1 (14.3)
Hypoalbuminaemia	2 (28.6)	0	1 (14.3)	0	1 (14.3)
Decreased appetite	1 (14.3)	0	0	1 (14.3)	0
Dehydration	1 (14.3)	0	0	1 (14.3)	0
Fluid overload	1 (14.3)	0	0	1 (14.3)	0

Eligibility for SCT: No

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (14.3)	0	0	1 (14.3)	0
Hypocalcaemia	1 (14.3)	0	0	0	1 (14.3)
Hypoglycaemia	1 (14.3)	0	1 (14.3)	0	0
Hypomagnesaemia	1 (14.3)	1 (14.3)	0	0	0
Hypophosphataemia	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (28.6)	0	0	2 (28.6)	0
Pain in extremity	2 (28.6)	0	0	2 (28.6)	0
Arthralgia	1 (14.3)	0	0	1 (14.3)	0
Back pain	1 (14.3)	0	0	1 (14.3)	0
Nervous system disorders					
-Total	3 (42.9)	0	1 (14.3)	1 (14.3)	1 (14.3)
Headache	1 (14.3)	0	0	1 (14.3)	0
Hyporesponsive to stimuli	1 (14.3)	0	0	1 (14.3)	0
Leukoencephalopathy	1 (14.3)	0	0	1 (14.3)	0
Seizure	1 (14.3)	0	0	0	1 (14.3)
Somnolence	1 (14.3)	0	1 (14.3)	0	0

Eligibility for SCT: No

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Product issues					
-Total	1 (14.3)	0	1 (14.3)	0	0
Device occlusion	1 (14.3)	0	1 (14.3)	0	0
Psychiatric disorders					
-Total	2 (28.6)	0	0	2 (28.6)	0
Agitation	1 (14.3)	0	0	1 (14.3)	0
Delirium	1 (14.3)	0	0	1 (14.3)	0
Renal and urinary disorders					
-Total	4 (57.1)	1 (14.3)	0	2 (28.6)	1 (14.3)
Acute kidney injury	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Cystitis haemorrhagic	1 (14.3)	0	0	1 (14.3)	0
Haematuria	1 (14.3)	1 (14.3)	0	0	0
Oliguria	1 (14.3)	0	0	1 (14.3)	0
Urinary retention	1 (14.3)	0	1 (14.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (57.1)	0	0	1 (14.3)	3 (42.9)
Hypoxia	3 (42.9)	0	0	2 (28.6)	1 (14.3)

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary oedema	2 (28.6)	0	0	0	2 (28.6)
Cough	1 (14.3)	0	0	1 (14.3)	0
Dyspnoea	1 (14.3)	0	0	1 (14.3)	0
Haemoptysis	1 (14.3)	0	0	1 (14.3)	0
Oropharyngeal pain	1 (14.3)	0	0	1 (14.3)	0
Pleural effusion	1 (14.3)	0	0	1 (14.3)	0
Pulmonary alveolar haemorrhage	1 (14.3)	0	0	0	1 (14.3)
Pulmonary hypertension	1 (14.3)	0	0	1 (14.3)	0
Respiratory distress	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Tachypnoea	1 (14.3)	0	0	1 (14.3)	0
Vascular disorders					
-Total	5 (71.4)	0	0	3 (42.9)	2 (28.6)
Hypotension	5 (71.4)	0	0	3 (42.9)	2 (28.6)
Hypertension	1 (14.3)	0	1 (14.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177n
Adverse events by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: Low

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	0	2 (100)
Anaemia	2 (100)	0	0	2 (100)	0
Disseminated intravascular coagulation	2 (100)	0	0	1 (50.0)	1 (50.0)
Thrombocytopenia	2 (100)	0	0	0	2 (100)
Febrile neutropenia	1 (50.0)	0	0	1 (50.0)	0
Lymphopenia	1 (50.0)	0	0	0	1 (50.0)
Neutropenia	1 (50.0)	0	0	0	1 (50.0)
Cardiac disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)

Baseline bone marrow tumor burden: Low

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (50.0)	0	0	0	1 (50.0)
Right ventricular dysfunction	1 (50.0)	0	0	1 (50.0)	0
Sinus tachycardia	1 (50.0)	0	0	1 (50.0)	0
Ventricular tachycardia	1 (50.0)	0	0	1 (50.0)	0
Eye disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Photophobia	1 (50.0)	0	1 (50.0)	0	0
Gastrointestinal disorders					
-Total	2 (100)	0	0	2 (100)	0
Abdominal pain	2 (100)	0	0	2 (100)	0
Ascites	1 (50.0)	0	0	1 (50.0)	0
Colitis	1 (50.0)	0	0	1 (50.0)	0
Diarrhoea	1 (50.0)	0	0	1 (50.0)	0
Haematochezia	1 (50.0)	0	0	1 (50.0)	0
Nausea	1 (50.0)	0	0	1 (50.0)	0
Stomatitis	1 (50.0)	0	0	1 (50.0)	0
Vomiting	1 (50.0)	0	0	1 (50.0)	0

Baseline bone marrow tumor burden: Low

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Multiple organ dysfunction syndrome	1 (50.0)	0	0	0	1 (50.0)
Non-cardiac chest pain	1 (50.0)	0	0	1 (50.0)	0
Pyrexia	1 (50.0)	0	1 (50.0)	0	0
Hepatobiliary disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Hepatic failure	1 (50.0)	0	0	0	1 (50.0)
Infections and infestations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Bronchitis	1 (50.0)	0	1 (50.0)	0	0
Oral herpes	1 (50.0)	0	1 (50.0)	0	0
Staphylococcal bacteraemia	1 (50.0)	0	0	1 (50.0)	0
Staphylococcal infection	1 (50.0)	0	0	0	1 (50.0)
Investigations					
-Total	2 (100)	0	0	0	2 (100)
Activated partial thromboplastin time prolonged	1 (50.0)	0	1 (50.0)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (50.0)	0	0	0	1 (50.0)
Aspartate aminotransferase increased	1 (50.0)	0	0	0	1 (50.0)
Blood bilirubin increased	1 (50.0)	0	0	0	1 (50.0)
Blood lactate dehydrogenase increased	1 (50.0)	0	0	1 (50.0)	0
Computerised tomogram thorax abnormal	1 (50.0)	0	0	1 (50.0)	0
Electrocardiogram qt prolonged	1 (50.0)	0	0	1 (50.0)	0
International normalised ratio increased	1 (50.0)	0	1 (50.0)	0	0
Neutrophil count decreased	1 (50.0)	0	0	0	1 (50.0)
Weight increased	1 (50.0)	1 (50.0)	0	0	0
White blood cell count decreased	1 (50.0)	0	0	0	1 (50.0)
Metabolism and nutrition disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Decreased appetite	1 (50.0)	0	0	1 (50.0)	0
Dehydration	1 (50.0)	0	0	1 (50.0)	0
Fluid overload	1 (50.0)	0	0	1 (50.0)	0

Baseline bone marrow tumor burden: Low

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (50.0)	0	0	1 (50.0)	0
Hypernatraemia	1 (50.0)	0	0	0	1 (50.0)
Hypoalbuminaemia	1 (50.0)	0	1 (50.0)	0	0
Hypoglycaemia	1 (50.0)	0	1 (50.0)	0	0
Hypokalaemia	1 (50.0)	0	0	0	1 (50.0)
Musculoskeletal and connective tissue disorders					
-Total	2 (100)	0	0	2 (100)	0
Pain in extremity	2 (100)	0	0	2 (100)	0
Arthralgia	1 (50.0)	0	0	1 (50.0)	0
Back pain	1 (50.0)	0	0	1 (50.0)	0
Nervous system disorders					
-Total	2 (100)	0	1 (50.0)	0	1 (50.0)
Headache	1 (50.0)	0	0	1 (50.0)	0
Hyporesponsive to stimuli	1 (50.0)	0	0	1 (50.0)	0
Seizure	1 (50.0)	0	0	0	1 (50.0)
Somnolence	1 (50.0)	0	1 (50.0)	0	0
Psychiatric disorders					

Baseline bone marrow tumor burden: Low

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (100)	0	0	2 (100)	0
Agitation	1 (50.0)	0	0	1 (50.0)	0
Delirium	1 (50.0)	0	0	1 (50.0)	0
Renal and urinary disorders					
-Total	2 (100)	0	0	2 (100)	0
Acute kidney injury	1 (50.0)	0	0	1 (50.0)	0
Cystitis haemorrhagic	1 (50.0)	0	0	1 (50.0)	0
Oliguria	1 (50.0)	0	0	1 (50.0)	0
Urinary retention	1 (50.0)	0	1 (50.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Hypoxia	2 (100)	0	0	2 (100)	0
Cough	1 (50.0)	0	0	1 (50.0)	0
Dyspnoea	1 (50.0)	0	0	1 (50.0)	0
Haemoptysis	1 (50.0)	0	0	1 (50.0)	0
Oropharyngeal pain	1 (50.0)	0	0	1 (50.0)	0
Pleural effusion	1 (50.0)	0	0	1 (50.0)	0

Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary alveolar haemorrhage	1 (50.0)	0	0	0	1 (50.0)
Pulmonary hypertension	1 (50.0)	0	0	1 (50.0)	0
Pulmonary oedema	1 (50.0)	0	0	0	1 (50.0)
Respiratory distress	1 (50.0)	0	0	0	1 (50.0)
Tachypnoea	1 (50.0)	0	0	1 (50.0)	0
Vascular disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Hypotension	2 (100)	0	0	1 (50.0)	1 (50.0)
Hypertension	1 (50.0)	0	1 (50.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177n
Adverse events by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: High

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (77.8)	0	1 (11.1)	1 (11.1)	5 (55.6)
Blood and lymphatic system disorders					
-Total	3 (33.3)	0	0	2 (22.2)	1 (11.1)
Anaemia	2 (22.2)	0	0	2 (22.2)	0
Thrombocytopenia	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Disseminated intravascular coagulation	1 (11.1)	0	0	1 (11.1)	0
Febrile neutropenia	1 (11.1)	0	0	1 (11.1)	0
Neutropenia	1 (11.1)	0	0	0	1 (11.1)
Cardiac disorders					
-Total	1 (11.1)	0	0	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	0	0	1 (11.1)

Baseline bone marrow tumor burden: High

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Adrenal insufficiency	1 (11.1)	0	1 (11.1)	0	0
Gastrointestinal disorders					
-Total	4 (44.4)	0	2 (22.2)	2 (22.2)	0
Nausea	2 (22.2)	0	2 (22.2)	0	0
Vomiting	2 (22.2)	0	2 (22.2)	0	0
Colitis	1 (11.1)	0	0	1 (11.1)	0
Constipation	1 (11.1)	1 (11.1)	0	0	0
Gastrointestinal haemorrhage	1 (11.1)	0	0	1 (11.1)	0
General disorders and administration site conditions					
-Total	4 (44.4)	0	1 (11.1)	1 (11.1)	2 (22.2)
Multiple organ dysfunction syndrome	2 (22.2)	0	0	0	2 (22.2)
Pain	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Pyrexia	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Chills	1 (11.1)	1 (11.1)	0	0	0
Infections and infestations					

Baseline bone marrow tumor burden: High

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (66.7)	0	0	1 (11.1)	5 (55.6)
Klebsiella sepsis	2 (22.2)	0	0	0	2 (22.2)
Candida sepsis	1 (11.1)	0	0	0	1 (11.1)
Clostridium difficile colitis	1 (11.1)	0	0	1 (11.1)	0
Escherichia infection	1 (11.1)	0	0	1 (11.1)	0
Klebsiella infection	1 (11.1)	0	0	1 (11.1)	0
Pneumonia	1 (11.1)	0	0	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	0	1 (11.1)	0
Sepsis	1 (11.1)	0	0	0	1 (11.1)
Streptococcal infection	1 (11.1)	0	0	1 (11.1)	0
Investigations					
-Total	2 (22.2)	0	0	0	2 (22.2)
Neutrophil count decreased	1 (11.1)	0	0	0	1 (11.1)
Platelet count decreased	1 (11.1)	0	0	0	1 (11.1)
Metabolism and nutrition disorders					
-Total	4 (44.4)	0	2 (22.2)	0	2 (22.2)
Hyperglycaemia	3 (33.3)	0	2 (22.2)	0	1 (11.1)
Hypernatraemia	2 (22.2)	0	0	1 (11.1)	1 (11.1)

Baseline bone marrow tumor burden: High

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	2 (22.2)	0	0	0	2 (22.2)
Hypoalbuminaemia	1 (11.1)	0	0	0	1 (11.1)
Hypocalcaemia	1 (11.1)	0	0	0	1 (11.1)
Hypomagnesaemia	1 (11.1)	1 (11.1)	0	0	0
Hypophosphataemia	1 (11.1)	0	0	1 (11.1)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Pain in jaw	1 (11.1)	0	1 (11.1)	0	0
Nervous system disorders					
-Total	1 (11.1)	0	0	1 (11.1)	0
Leukoencephalopathy	1 (11.1)	0	0	1 (11.1)	0
Product issues					
-Total	1 (11.1)	0	1 (11.1)	0	0
Device occlusion	1 (11.1)	0	1 (11.1)	0	0
Psychiatric disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Confusional state	1 (11.1)	0	1 (11.1)	0	0

Baseline bone marrow tumor burden: High

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	2 (22.2)	1 (11.1)	0	0	1 (11.1)
Acute kidney injury	1 (11.1)	0	0	0	1 (11.1)
Haematuria	1 (11.1)	1 (11.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (33.3)	0	0	0	3 (33.3)
Hypoxia	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Aspiration	1 (11.1)	0	0	0	1 (11.1)
Epistaxis	1 (11.1)	0	1 (11.1)	0	0
Pleural effusion	1 (11.1)	0	1 (11.1)	0	0
Pulmonary oedema	1 (11.1)	0	0	0	1 (11.1)
Respiratory failure	1 (11.1)	0	0	0	1 (11.1)
Vascular disorders					
-Total	4 (44.4)	0	0	2 (22.2)	2 (22.2)
Hypotension	4 (44.4)	0	0	2 (22.2)	2 (22.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177o
Adverse events by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set – non – infused patients

Baseline extramedullary disease presence: Yes

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	0	1 (50.0)	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0
Escherichia infection	1 (50.0)	0	0	1 (50.0)	0
Streptococcal infection	1 (50.0)	0	0	1 (50.0)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Pain in jaw	1 (50.0)	0	1 (50.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177o
Adverse events by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set – non – infused patients

Baseline extramedullary disease presence: No

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (88.9)	0	1 (11.1)	0	7 (77.8)
Blood and lymphatic system disorders					
-Total	5 (55.6)	0	0	2 (22.2)	3 (33.3)
Anaemia	4 (44.4)	0	0	4 (44.4)	0
Thrombocytopenia	4 (44.4)	0	0	1 (11.1)	3 (33.3)
Disseminated intravascular coagulation	3 (33.3)	0	0	2 (22.2)	1 (11.1)
Febrile neutropenia	2 (22.2)	0	0	2 (22.2)	0
Neutropenia	2 (22.2)	0	0	0	2 (22.2)
Lymphopenia	1 (11.1)	0	0	0	1 (11.1)
Cardiac disorders					
-Total	2 (22.2)	0	0	0	2 (22.2)

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bradycardia	1 (11.1)	0	0	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	0	0	1 (11.1)
Right ventricular dysfunction	1 (11.1)	0	0	1 (11.1)	0
Sinus tachycardia	1 (11.1)	0	0	1 (11.1)	0
Ventricular tachycardia	1 (11.1)	0	0	1 (11.1)	0
Endocrine disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Adrenal insufficiency	1 (11.1)	0	1 (11.1)	0	0
Eye disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Photophobia	1 (11.1)	0	1 (11.1)	0	0
Gastrointestinal disorders					
-Total	6 (66.7)	0	2 (22.2)	4 (44.4)	0
Nausea	3 (33.3)	0	2 (22.2)	1 (11.1)	0
Vomiting	3 (33.3)	0	2 (22.2)	1 (11.1)	0
Abdominal pain	2 (22.2)	0	0	2 (22.2)	0
Colitis	2 (22.2)	0	0	2 (22.2)	0
Ascites	1 (11.1)	0	0	1 (11.1)	0

Baseline extramedullary disease presence: No

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (11.1)	1 (11.1)	0	0	0
Diarrhoea	1 (11.1)	0	0	1 (11.1)	0
Gastrointestinal haemorrhage	1 (11.1)	0	0	1 (11.1)	0
Haematochezia	1 (11.1)	0	0	1 (11.1)	0
Stomatitis	1 (11.1)	0	0	1 (11.1)	0
General disorders and administration site conditions					
-Total	6 (66.7)	0	1 (11.1)	2 (22.2)	3 (33.3)
Multiple organ dysfunction syndrome	3 (33.3)	0	0	0	3 (33.3)
Pyrexia	3 (33.3)	0	2 (22.2)	1 (11.1)	0
Pain	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Chills	1 (11.1)	1 (11.1)	0	0	0
Non-cardiac chest pain	1 (11.1)	0	0	1 (11.1)	0
Hepatobiliary disorders					
-Total	1 (11.1)	0	0	0	1 (11.1)
Hepatic failure	1 (11.1)	0	0	0	1 (11.1)
Infections and infestations					
-Total	6 (66.7)	0	0	0	6 (66.7)

Baseline extramedullary disease presence: No

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella sepsis	2 (22.2)	0	0	0	2 (22.2)
Bronchitis	1 (11.1)	0	1 (11.1)	0	0
Candida sepsis	1 (11.1)	0	0	0	1 (11.1)
Clostridium difficile colitis	1 (11.1)	0	0	1 (11.1)	0
Klebsiella infection	1 (11.1)	0	0	1 (11.1)	0
Oral herpes	1 (11.1)	0	1 (11.1)	0	0
Pneumonia	1 (11.1)	0	0	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	0	1 (11.1)	0
Sepsis	1 (11.1)	0	0	0	1 (11.1)
Staphylococcal bacteraemia	1 (11.1)	0	0	1 (11.1)	0
Staphylococcal infection	1 (11.1)	0	0	0	1 (11.1)
Investigations					
-Total	4 (44.4)	0	0	0	4 (44.4)
Neutrophil count decreased	2 (22.2)	0	0	0	2 (22.2)
Activated partial thromboplastin time prolonged	1 (11.1)	0	1 (11.1)	0	0
Alanine aminotransferase increased	1 (11.1)	0	0	0	1 (11.1)
Aspartate aminotransferase increased	1 (11.1)	0	0	0	1 (11.1)

Baseline extramedullary disease presence: No

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (11.1)	0	0	0	1 (11.1)
Blood lactate dehydrogenase increased	1 (11.1)	0	0	1 (11.1)	0
Computerised tomogram thorax abnormal	1 (11.1)	0	0	1 (11.1)	0
Electrocardiogram qt prolonged	1 (11.1)	0	0	1 (11.1)	0
International normalised ratio increased	1 (11.1)	0	1 (11.1)	0	0
Platelet count decreased	1 (11.1)	0	0	0	1 (11.1)
Weight increased	1 (11.1)	1 (11.1)	0	0	0
White blood cell count decreased	1 (11.1)	0	0	0	1 (11.1)
Metabolism and nutrition disorders					
-Total	6 (66.7)	0	2 (22.2)	1 (11.1)	3 (33.3)
Hyperglycaemia	3 (33.3)	0	2 (22.2)	0	1 (11.1)
Hypernatraemia	3 (33.3)	0	0	1 (11.1)	2 (22.2)
Hypokalaemia	3 (33.3)	0	0	0	3 (33.3)
Hypoalbuminaemia	2 (22.2)	0	1 (11.1)	0	1 (11.1)
Decreased appetite	1 (11.1)	0	0	1 (11.1)	0
Dehydration	1 (11.1)	0	0	1 (11.1)	0

Baseline extramedullary disease presence: No

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fluid overload	1 (11.1)	0	0	1 (11.1)	0
Hyperkalaemia	1 (11.1)	0	0	1 (11.1)	0
Hypocalcaemia	1 (11.1)	0	0	0	1 (11.1)
Hypoglycaemia	1 (11.1)	0	1 (11.1)	0	0
Hypomagnesaemia	1 (11.1)	1 (11.1)	0	0	0
Hypophosphataemia	1 (11.1)	0	0	1 (11.1)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (22.2)	0	0	2 (22.2)	0
Pain in extremity	2 (22.2)	0	0	2 (22.2)	0
Arthralgia	1 (11.1)	0	0	1 (11.1)	0
Back pain	1 (11.1)	0	0	1 (11.1)	0
Nervous system disorders					
-Total	3 (33.3)	0	1 (11.1)	1 (11.1)	1 (11.1)
Headache	1 (11.1)	0	0	1 (11.1)	0
Hyporesponsive to stimuli	1 (11.1)	0	0	1 (11.1)	0
Leukoencephalopathy	1 (11.1)	0	0	1 (11.1)	0
Seizure	1 (11.1)	0	0	0	1 (11.1)

Baseline extramedullary disease presence: No

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Somnolence	1 (11.1)	0	1 (11.1)	0	0
Product issues					
-Total	1 (11.1)	0	1 (11.1)	0	0
Device occlusion	1 (11.1)	0	1 (11.1)	0	0
Psychiatric disorders					
-Total	3 (33.3)	0	1 (11.1)	2 (22.2)	0
Agitation	1 (11.1)	0	0	1 (11.1)	0
Confusional state	1 (11.1)	0	1 (11.1)	0	0
Delirium	1 (11.1)	0	0	1 (11.1)	0
Renal and urinary disorders					
-Total	4 (44.4)	1 (11.1)	0	2 (22.2)	1 (11.1)
Acute kidney injury	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Cystitis haemorrhagic	1 (11.1)	0	0	1 (11.1)	0
Haematuria	1 (11.1)	1 (11.1)	0	0	0
Oliguria	1 (11.1)	0	0	1 (11.1)	0
Urinary retention	1 (11.1)	0	1 (11.1)	0	0
Respiratory, thoracic and mediastinal disorders					

Baseline extramedullary disease presence: No

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (55.6)	0	0	1 (11.1)	4 (44.4)
Hypoxia	4 (44.4)	0	0	3 (33.3)	1 (11.1)
Pleural effusion	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Pulmonary oedema	2 (22.2)	0	0	0	2 (22.2)
Aspiration	1 (11.1)	0	0	0	1 (11.1)
Cough	1 (11.1)	0	0	1 (11.1)	0
Dyspnoea	1 (11.1)	0	0	1 (11.1)	0
Epistaxis	1 (11.1)	0	1 (11.1)	0	0
Haemoptysis	1 (11.1)	0	0	1 (11.1)	0
Oropharyngeal pain	1 (11.1)	0	0	1 (11.1)	0
Pulmonary alveolar haemorrhage	1 (11.1)	0	0	0	1 (11.1)
Pulmonary hypertension	1 (11.1)	0	0	1 (11.1)	0
Respiratory distress	1 (11.1)	0	0	0	1 (11.1)
Respiratory failure	1 (11.1)	0	0	0	1 (11.1)
Tachypnoea	1 (11.1)	0	0	1 (11.1)	0
Vascular disorders					
-Total	6 (66.7)	0	0	3 (33.3)	3 (33.3)
Hypotension	6 (66.7)	0	0	3 (33.3)	3 (33.3)

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (11.1)	0	1 (11.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177p
Adverse events by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (81.8)	0	1 (9.1)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Lymphopenia	1 (9.1)	0	0	0	1 (9.1)
Cardiac disorders					
-Total	2 (18.2)	0	0	0	2 (18.2)

Down syndrome: No

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bradycardia	1 (9.1)	0	0	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	0	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	0	0	1 (9.1)	0
Sinus tachycardia	1 (9.1)	0	0	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	0	0	1 (9.1)	0
Endocrine disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Adrenal insufficiency	1 (9.1)	0	1 (9.1)	0	0
Eye disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Photophobia	1 (9.1)	0	1 (9.1)	0	0
Gastrointestinal disorders					
-Total	6 (54.5)	0	2 (18.2)	4 (36.4)	0
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
Ascites	1 (9.1)	0	0	1 (9.1)	0

Down syndrome: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (9.1)	1 (9.1)	0	0	0
Diarrhoea	1 (9.1)	0	0	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	0	0	1 (9.1)	0
Haematochezia	1 (9.1)	0	0	1 (9.1)	0
Stomatitis	1 (9.1)	0	0	1 (9.1)	0
General disorders and administration site conditions					
-Total	6 (54.5)	0	1 (9.1)	2 (18.2)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	0	0	3 (27.3)
Pyrexia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Chills	1 (9.1)	1 (9.1)	0	0	0
Non-cardiac chest pain	1 (9.1)	0	0	1 (9.1)	0
Hepatobiliary disorders					
-Total	1 (9.1)	0	0	0	1 (9.1)
Hepatic failure	1 (9.1)	0	0	0	1 (9.1)
Infections and infestations					
-Total	7 (63.6)	0	0	1 (9.1)	6 (54.5)

Down syndrome: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Bronchitis	1 (9.1)	0	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	0	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	0	0	1 (9.1)	0
Escherichia infection	1 (9.1)	0	0	1 (9.1)	0
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Oral herpes	1 (9.1)	0	1 (9.1)	0	0
Pneumonia	1 (9.1)	0	0	0	1 (9.1)
Pneumonia fungal	1 (9.1)	0	0	1 (9.1)	0
Sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	0	0	1 (9.1)
Streptococcal infection	1 (9.1)	0	0	1 (9.1)	0
Investigations					
-Total	4 (36.4)	0	0	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Activated partial thromboplastin time prolonged	1 (9.1)	0	1 (9.1)	0	0

Down syndrome: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	0	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	0	0	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	0	0	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	0	0	1 (9.1)	0
International normalised ratio increased	1 (9.1)	0	1 (9.1)	0	0
Platelet count decreased	1 (9.1)	0	0	0	1 (9.1)
Weight increased	1 (9.1)	1 (9.1)	0	0	0
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					
-Total	6 (54.5)	0	2 (18.2)	1 (9.1)	3 (27.3)
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	0	0	3 (27.3)

Down syndrome: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Decreased appetite	1 (9.1)	0	0	1 (9.1)	0
Dehydration	1 (9.1)	0	0	1 (9.1)	0
Fluid overload	1 (9.1)	0	0	1 (9.1)	0
Hyperkalaemia	1 (9.1)	0	0	1 (9.1)	0
Hypocalcaemia	1 (9.1)	0	0	0	1 (9.1)
Hypoglycaemia	1 (9.1)	0	1 (9.1)	0	0
Hypomagnesaemia	1 (9.1)	1 (9.1)	0	0	0
Hypophosphataemia	1 (9.1)	0	0	1 (9.1)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Arthralgia	1 (9.1)	0	0	1 (9.1)	0
Back pain	1 (9.1)	0	0	1 (9.1)	0
Pain in jaw	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	3 (27.3)	0	1 (9.1)	1 (9.1)	1 (9.1)

Down syndrome: No

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (9.1)	0	0	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	0	0	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	0	0	1 (9.1)	0
Seizure	1 (9.1)	0	0	0	1 (9.1)
Somnolence	1 (9.1)	0	1 (9.1)	0	0
Product issues					
-Total	1 (9.1)	0	1 (9.1)	0	0
Device occlusion	1 (9.1)	0	1 (9.1)	0	0
Psychiatric disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Agitation	1 (9.1)	0	0	1 (9.1)	0
Confusional state	1 (9.1)	0	1 (9.1)	0	0
Delirium	1 (9.1)	0	0	1 (9.1)	0
Renal and urinary disorders					
-Total	4 (36.4)	1 (9.1)	0	2 (18.2)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Cystitis haemorrhagic	1 (9.1)	0	0	1 (9.1)	0
Haematuria	1 (9.1)	1 (9.1)	0	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oliguria	1 (9.1)	0	0	1 (9.1)	0
Urinary retention	1 (9.1)	0	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	0	0	1 (9.1)	4 (36.4)
Hypoxia	4 (36.4)	0	0	3 (27.3)	1 (9.1)
Pleural effusion	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Aspiration	1 (9.1)	0	0	0	1 (9.1)
Cough	1 (9.1)	0	0	1 (9.1)	0
Dyspnoea	1 (9.1)	0	0	1 (9.1)	0
Epistaxis	1 (9.1)	0	1 (9.1)	0	0
Haemoptysis	1 (9.1)	0	0	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	0	0	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	0	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	0	0	1 (9.1)	0
Respiratory distress	1 (9.1)	0	0	0	1 (9.1)
Respiratory failure	1 (9.1)	0	0	0	1 (9.1)

Down syndrome: No

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (9.1)	0	0	1 (9.1)	0
Vascular disorders					
-Total	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Hypotension	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Hypertension	1 (9.1)	0	1 (9.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177q
Adverse events by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set – non – infused patients

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (81.8)	0	1 (9.1)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Lymphopenia	1 (9.1)	0	0	0	1 (9.1)
Cardiac disorders					
-Total	2 (18.2)	0	0	0	2 (18.2)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (9.1)	0	0	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	0	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	0	0	1 (9.1)	0
Sinus tachycardia	1 (9.1)	0	0	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	0	0	1 (9.1)	0
Endocrine disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Adrenal insufficiency	1 (9.1)	0	1 (9.1)	0	0
Eye disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Photophobia	1 (9.1)	0	1 (9.1)	0	0
Gastrointestinal disorders					
-Total	6 (54.5)	0	2 (18.2)	4 (36.4)	0
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
Ascites	1 (9.1)	0	0	1 (9.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (9.1)	1 (9.1)	0	0	0
Diarrhoea	1 (9.1)	0	0	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	0	0	1 (9.1)	0
Haematochezia	1 (9.1)	0	0	1 (9.1)	0
Stomatitis	1 (9.1)	0	0	1 (9.1)	0
General disorders and administration site conditions					
-Total	6 (54.5)	0	1 (9.1)	2 (18.2)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	0	0	3 (27.3)
Pyrexia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Chills	1 (9.1)	1 (9.1)	0	0	0
Non-cardiac chest pain	1 (9.1)	0	0	1 (9.1)	0
Hepatobiliary disorders					
-Total	1 (9.1)	0	0	0	1 (9.1)
Hepatic failure	1 (9.1)	0	0	0	1 (9.1)
Infections and infestations					
-Total	7 (63.6)	0	0	1 (9.1)	6 (54.5)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Bronchitis	1 (9.1)	0	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	0	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	0	0	1 (9.1)	0
Escherichia infection	1 (9.1)	0	0	1 (9.1)	0
Klebsiella infection	1 (9.1)	0	0	1 (9.1)	0
Oral herpes	1 (9.1)	0	1 (9.1)	0	0
Pneumonia	1 (9.1)	0	0	0	1 (9.1)
Pneumonia fungal	1 (9.1)	0	0	1 (9.1)	0
Sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	0	0	1 (9.1)
Streptococcal infection	1 (9.1)	0	0	1 (9.1)	0
Investigations					
-Total	4 (36.4)	0	0	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Activated partial thromboplastin time prolonged	1 (9.1)	0	1 (9.1)	0	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	0	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	0	0	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	0	0	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	0	0	1 (9.1)	0
International normalised ratio increased	1 (9.1)	0	1 (9.1)	0	0
Platelet count decreased	1 (9.1)	0	0	0	1 (9.1)
Weight increased	1 (9.1)	1 (9.1)	0	0	0
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					
-Total	6 (54.5)	0	2 (18.2)	1 (9.1)	3 (27.3)
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	0	0	3 (27.3)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Decreased appetite	1 (9.1)	0	0	1 (9.1)	0
Dehydration	1 (9.1)	0	0	1 (9.1)	0
Fluid overload	1 (9.1)	0	0	1 (9.1)	0
Hyperkalaemia	1 (9.1)	0	0	1 (9.1)	0
Hypocalcaemia	1 (9.1)	0	0	0	1 (9.1)
Hypoglycaemia	1 (9.1)	0	1 (9.1)	0	0
Hypomagnesaemia	1 (9.1)	1 (9.1)	0	0	0
Hypophosphataemia	1 (9.1)	0	0	1 (9.1)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Arthralgia	1 (9.1)	0	0	1 (9.1)	0
Back pain	1 (9.1)	0	0	1 (9.1)	0
Pain in jaw	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	3 (27.3)	0	1 (9.1)	1 (9.1)	1 (9.1)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (9.1)	0	0	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	0	0	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	0	0	1 (9.1)	0
Seizure	1 (9.1)	0	0	0	1 (9.1)
Somnolence	1 (9.1)	0	1 (9.1)	0	0
Product issues					
-Total	1 (9.1)	0	1 (9.1)	0	0
Device occlusion	1 (9.1)	0	1 (9.1)	0	0
Psychiatric disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Agitation	1 (9.1)	0	0	1 (9.1)	0
Confusional state	1 (9.1)	0	1 (9.1)	0	0
Delirium	1 (9.1)	0	0	1 (9.1)	0
Renal and urinary disorders					
-Total	4 (36.4)	1 (9.1)	0	2 (18.2)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Cystitis haemorrhagic	1 (9.1)	0	0	1 (9.1)	0
Haematuria	1 (9.1)	1 (9.1)	0	0	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oliguria	1 (9.1)	0	0	1 (9.1)	0
Urinary retention	1 (9.1)	0	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	0	0	1 (9.1)	4 (36.4)
Hypoxia	4 (36.4)	0	0	3 (27.3)	1 (9.1)
Pleural effusion	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Aspiration	1 (9.1)	0	0	0	1 (9.1)
Cough	1 (9.1)	0	0	1 (9.1)	0
Dyspnoea	1 (9.1)	0	0	1 (9.1)	0
Epistaxis	1 (9.1)	0	1 (9.1)	0	0
Haemoptysis	1 (9.1)	0	0	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	0	0	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	0	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	0	0	1 (9.1)	0
Respiratory distress	1 (9.1)	0	0	0	1 (9.1)
Respiratory failure	1 (9.1)	0	0	0	1 (9.1)

Time since enrollment to CTL019 infusion: Missing

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (9.1)	0	0	1 (9.1)	0
Vascular disorders					
-Total	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Hypotension	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Hypertension	1 (9.1)	0	1 (9.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177r
Adverse events by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 0

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
General disorders and administration site conditions					
-Total	1 (100)	0	0	1 (100)	0
Pain	1 (100)	0	0	1 (100)	0
Pyrexia	1 (100)	0	0	1 (100)	0
Infections and infestations					
-Total	1 (100)	0	0	0	1 (100)
Pneumonia	1 (100)	0	0	0	1 (100)
Psychiatric disorders					
-Total	1 (100)	0	1 (100)	0	0
Confusional state	1 (100)	0	1 (100)	0	0

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	0	0	0	1 (100)
Aspiration	1 (100)	0	0	0	1 (100)
Epistaxis	1 (100)	0	1 (100)	0	0
Hypoxia	1 (100)	0	0	1 (100)	0
Pleural effusion	1 (100)	0	1 (100)	0	0
Vascular disorders					
-Total	1 (100)	0	0	0	1 (100)
Hypotension	1 (100)	0	0	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177r
Adverse events by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 1

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	1 (33.3)	0	1 (33.3)
Blood and lymphatic system disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Anaemia	1 (33.3)	0	0	1 (33.3)	0
Disseminated intravascular coagulation	1 (33.3)	0	0	1 (33.3)	0
Lymphopenia	1 (33.3)	0	0	0	1 (33.3)
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	0	0	1 (33.3)
Cardiac disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Bradycardia	1 (33.3)	0	0	0	1 (33.3)

Number of previous relapses: 1

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Right ventricular dysfunction	1 (33.3)	0	0	1 (33.3)	0
Sinus tachycardia	1 (33.3)	0	0	1 (33.3)	0
Ventricular tachycardia	1 (33.3)	0	0	1 (33.3)	0
Eye disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Photophobia	1 (33.3)	0	1 (33.3)	0	0
Gastrointestinal disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Nausea	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Vomiting	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Abdominal pain	1 (33.3)	0	0	1 (33.3)	0
Constipation	1 (33.3)	1 (33.3)	0	0	0
Haematochezia	1 (33.3)	0	0	1 (33.3)	0
General disorders and administration site conditions					
-Total	1 (33.3)	0	0	1 (33.3)	0
Non-cardiac chest pain	1 (33.3)	0	0	1 (33.3)	0
Investigations					

Number of previous relapses: 1

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (33.3)	0	0	0	1 (33.3)
Blood lactate dehydrogenase increased	1 (33.3)	0	0	1 (33.3)	0
Computerised tomogram thorax abnormal	1 (33.3)	0	0	1 (33.3)	0
Electrocardiogram qt prolonged	1 (33.3)	0	0	1 (33.3)	0
White blood cell count decreased	1 (33.3)	0	0	0	1 (33.3)
Metabolism and nutrition disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Fluid overload	1 (33.3)	0	0	1 (33.3)	0
Hyperglycaemia	1 (33.3)	0	1 (33.3)	0	0
Hyperkalaemia	1 (33.3)	0	0	1 (33.3)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Arthralgia	1 (33.3)	0	0	1 (33.3)	0
Back pain	1 (33.3)	0	0	1 (33.3)	0
Pain in extremity	1 (33.3)	0	0	1 (33.3)	0
Nervous system disorders					

Number of previous relapses: 1

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (33.3)	0	0	0	1 (33.3)
Headache	1 (33.3)	0	0	1 (33.3)	0
Hyporesponsive to stimuli	1 (33.3)	0	0	1 (33.3)	0
Seizure	1 (33.3)	0	0	0	1 (33.3)
Psychiatric disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Agitation	1 (33.3)	0	0	1 (33.3)	0
Renal and urinary disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Acute kidney injury	1 (33.3)	0	0	1 (33.3)	0
Oliguria	1 (33.3)	0	0	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Cough	1 (33.3)	0	0	1 (33.3)	0
Dyspnoea	1 (33.3)	0	0	1 (33.3)	0
Haemoptysis	1 (33.3)	0	0	1 (33.3)	0
Hypoxia	1 (33.3)	0	0	1 (33.3)	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oropharyngeal pain	1 (33.3)	0	0	1 (33.3)	0
Pulmonary alveolar haemorrhage	1 (33.3)	0	0	0	1 (33.3)
Pulmonary hypertension	1 (33.3)	0	0	1 (33.3)	0
Pulmonary oedema	1 (33.3)	0	0	0	1 (33.3)
Respiratory distress	1 (33.3)	0	0	0	1 (33.3)
Tachypnoea	1 (33.3)	0	0	1 (33.3)	0
Vascular disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Hypertension	1 (33.3)	0	1 (33.3)	0	0
Hypotension	1 (33.3)	0	0	0	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177r
Adverse events by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 2

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Blood and lymphatic system disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Febrile neutropenia	1 (33.3)	0	0	1 (33.3)	0
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	0	0	1 (33.3)
Endocrine disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Adrenal insufficiency	1 (33.3)	0	1 (33.3)	0	0
Gastrointestinal disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0

Number of previous relapses: 2

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (33.3)	0	0	1 (33.3)	0
Infections and infestations					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Candida sepsis	1 (33.3)	0	0	0	1 (33.3)
Escherichia infection	1 (33.3)	0	0	1 (33.3)	0
Pneumonia fungal	1 (33.3)	0	0	1 (33.3)	0
Streptococcal infection	1 (33.3)	0	0	1 (33.3)	0
Metabolism and nutrition disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Hypernatraemia	1 (33.3)	0	0	0	1 (33.3)
Hypokalaemia	1 (33.3)	0	0	0	1 (33.3)
Hypomagnesaemia	1 (33.3)	1 (33.3)	0	0	0
Hypophosphataemia	1 (33.3)	0	0	1 (33.3)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Pain in jaw	1 (33.3)	0	1 (33.3)	0	0
Renal and urinary disorders					

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=3 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (33.3)	0	0	0	1 (33.3)
Acute kidney injury	1 (33.3)	0	0	0	1 (33.3)
Respiratory, thoracic and mediastinal disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	0	0	1 (33.3)
Respiratory failure	1 (33.3)	0	0	0	1 (33.3)
Vascular disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Hypotension	1 (33.3)	0	0	0	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 177r
Adverse events by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: >=3

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	0	0	4 (100)
Blood and lymphatic system disorders					
-Total	3 (75.0)	0	0	2 (50.0)	1 (25.0)
Anaemia	3 (75.0)	0	0	3 (75.0)	0
Disseminated intravascular coagulation	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Thrombocytopenia	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Febrile neutropenia	1 (25.0)	0	0	1 (25.0)	0
Cardiac disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Cardiovascular insufficiency	1 (25.0)	0	0	0	1 (25.0)

Number of previous relapses: >=3

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	3 (75.0)	0	1 (25.0)	2 (50.0)	0
Colitis	2 (50.0)	0	0	2 (50.0)	0
Abdominal pain	1 (25.0)	0	0	1 (25.0)	0
Ascites	1 (25.0)	0	0	1 (25.0)	0
Diarrhoea	1 (25.0)	0	0	1 (25.0)	0
Nausea	1 (25.0)	0	1 (25.0)	0	0
Stomatitis	1 (25.0)	0	0	1 (25.0)	0
Vomiting	1 (25.0)	0	1 (25.0)	0	0
General disorders and administration site conditions					
-Total	4 (100)	0	1 (25.0)	0	3 (75.0)
Multiple organ dysfunction syndrome	3 (75.0)	0	0	0	3 (75.0)
Pyrexia	2 (50.0)	0	2 (50.0)	0	0
Chills	1 (25.0)	1 (25.0)	0	0	0
Pain	1 (25.0)	0	1 (25.0)	0	0
Hepatobiliary disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)

Number of previous relapses: >=3

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic failure	1 (25.0)	0	0	0	1 (25.0)
Infections and infestations					
-Total	4 (100)	0	0	0	4 (100)
Klebsiella sepsis	2 (50.0)	0	0	0	2 (50.0)
Bronchitis	1 (25.0)	0	1 (25.0)	0	0
Clostridium difficile colitis	1 (25.0)	0	0	1 (25.0)	0
Klebsiella infection	1 (25.0)	0	0	1 (25.0)	0
Oral herpes	1 (25.0)	0	1 (25.0)	0	0
Sepsis	1 (25.0)	0	0	0	1 (25.0)
Staphylococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Staphylococcal infection	1 (25.0)	0	0	0	1 (25.0)
Investigations					
-Total	3 (75.0)	0	0	0	3 (75.0)
Neutrophil count decreased	2 (50.0)	0	0	0	2 (50.0)
Activated partial thromboplastin time prolonged	1 (25.0)	0	1 (25.0)	0	0
Alanine aminotransferase increased	1 (25.0)	0	0	0	1 (25.0)
Aspartate aminotransferase increased	1 (25.0)	0	0	0	1 (25.0)

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood bilirubin increased	1 (25.0)	0	0	0	1 (25.0)
International normalised ratio increased	1 (25.0)	0	1 (25.0)	0	0
Platelet count decreased	1 (25.0)	0	0	0	1 (25.0)
Weight increased	1 (25.0)	1 (25.0)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (75.0)	0	1 (25.0)	0	2 (50.0)
Hyperglycaemia	2 (50.0)	0	1 (25.0)	0	1 (25.0)
Hypernatraemia	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Hypoalbuminaemia	2 (50.0)	0	1 (25.0)	0	1 (25.0)
Hypokalaemia	2 (50.0)	0	0	0	2 (50.0)
Decreased appetite	1 (25.0)	0	0	1 (25.0)	0
Dehydration	1 (25.0)	0	0	1 (25.0)	0
Hypocalcaemia	1 (25.0)	0	0	0	1 (25.0)
Hypoglycaemia	1 (25.0)	0	1 (25.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Pain in extremity	1 (25.0)	0	0	1 (25.0)	0

Number of previous relapses: >=3

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Leukoencephalopathy	1 (25.0)	0	0	1 (25.0)	0
Somnolence	1 (25.0)	0	1 (25.0)	0	0
Product issues					
-Total	1 (25.0)	0	1 (25.0)	0	0
Device occlusion	1 (25.0)	0	1 (25.0)	0	0
Psychiatric disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Delirium	1 (25.0)	0	0	1 (25.0)	0
Renal and urinary disorders					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Cystitis haemorrhagic	1 (25.0)	0	0	1 (25.0)	0
Haematuria	1 (25.0)	1 (25.0)	0	0	0
Urinary retention	1 (25.0)	0	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (50.0)	0	0	1 (25.0)	1 (25.0)

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Pleural effusion	1 (25.0)	0	0	1 (25.0)	0
Vascular disorders					
-Total	3 (75.0)	0	0	3 (75.0)	0
Hypotension	3 (75.0)	0	0	3 (75.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178a
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (95.5)	0	3 (13.6)	3 (13.6)	15 (68.2)
Blood and lymphatic system disorders					
-Total	16 (72.7)	1 (4.5)	1 (4.5)	9 (40.9)	5 (22.7)
Febrile neutropenia	11 (50.0)	0	0	11 (50.0)	0
Anaemia	7 (31.8)	1 (4.5)	0	6 (27.3)	0
Thrombocytopenia	4 (18.2)	0	1 (4.5)	1 (4.5)	2 (9.1)
Neutropenia	2 (9.1)	0	0	0	2 (9.1)
Coagulopathy	1 (4.5)	1 (4.5)	0	0	0
Disseminated intravascular coagulation	1 (4.5)	0	0	1 (4.5)	0
Leukopenia	1 (4.5)	0	0	0	1 (4.5)
Lymphopenia	1 (4.5)	0	0	0	1 (4.5)

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac disorders					
-Total	8 (36.4)	5 (22.7)	3 (13.6)	0	0
Sinus tachycardia	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Tachycardia	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Atrioventricular block second degree	1 (4.5)	1 (4.5)	0	0	0
Bradycardia	1 (4.5)	0	1 (4.5)	0	0
Cardiac dysfunction	1 (4.5)	1 (4.5)	0	0	0
Palpitations	1 (4.5)	1 (4.5)	0	0	0
Pericardial effusion	1 (4.5)	0	1 (4.5)	0	0
Ear and labyrinth disorders					
-Total	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Ear pain	1 (4.5)	1 (4.5)	0	0	0
Tympanic membrane perforation	1 (4.5)	0	1 (4.5)	0	0
Endocrine disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Cushingoid	1 (4.5)	1 (4.5)	0	0	0
Eye disorders					
-Total	7 (31.8)	6 (27.3)	1 (4.5)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Conjunctival haemorrhage	2 (9.1)	2 (9.1)	0	0	0
Periorbital oedema	2 (9.1)	2 (9.1)	0	0	0
Conjunctivitis allergic	1 (4.5)	1 (4.5)	0	0	0
Dry eye	1 (4.5)	0	1 (4.5)	0	0
Photophobia	1 (4.5)	1 (4.5)	0	0	0
Retinal haemorrhage	1 (4.5)	1 (4.5)	0	0	0
Vision blurred	1 (4.5)	1 (4.5)	0	0	0
Gastrointestinal disorders					
-Total	15 (68.2)	4 (18.2)	4 (18.2)	7 (31.8)	0
Nausea	11 (50.0)	3 (13.6)	6 (27.3)	2 (9.1)	0
Diarrhoea	9 (40.9)	5 (22.7)	4 (18.2)	0	0
Vomiting	9 (40.9)	5 (22.7)	4 (18.2)	0	0
Constipation	5 (22.7)	5 (22.7)	0	0	0
Abdominal pain	4 (18.2)	2 (9.1)	2 (9.1)	0	0
Colitis	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Pancreatitis	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Abdominal distension	1 (4.5)	0	1 (4.5)	0	0
Abdominal tenderness	1 (4.5)	1 (4.5)	0	0	0

Age: <10 years

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	1 (4.5)	0	0	1 (4.5)	0
Dysphagia	1 (4.5)	0	0	1 (4.5)	0
Enterocolitis	1 (4.5)	0	0	1 (4.5)	0
Ileus	1 (4.5)	0	0	1 (4.5)	0
Perianal erythema	1 (4.5)	0	1 (4.5)	0	0
Tooth socket haemorrhage	1 (4.5)	1 (4.5)	0	0	0
General disorders and administration site conditions					
-Total	13 (59.1)	6 (27.3)	3 (13.6)	4 (18.2)	0
Pyrexia	8 (36.4)	3 (13.6)	3 (13.6)	2 (9.1)	0
Fatigue	4 (18.2)	4 (18.2)	0	0	0
Catheter site pain	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Oedema peripheral	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Acquired gene mutation	1 (4.5)	1 (4.5)	0	0	0
Chills	1 (4.5)	1 (4.5)	0	0	0
Crying	1 (4.5)	1 (4.5)	0	0	0
Cyst	1 (4.5)	0	0	1 (4.5)	0
Face oedema	1 (4.5)	0	0	1 (4.5)	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gait disturbance	1 (4.5)	1 (4.5)	0	0	0
Generalised oedema	1 (4.5)	0	1 (4.5)	0	0
Localised oedema	1 (4.5)	0	0	1 (4.5)	0
Malaise	1 (4.5)	1 (4.5)	0	0	0
Mucosal haemorrhage	1 (4.5)	0	1 (4.5)	0	0
Multiple organ dysfunction syndrome	1 (4.5)	0	0	1 (4.5)	0
Hepatobiliary disorders					
-Total	3 (13.6)	1 (4.5)	0	2 (9.1)	0
Cholecystitis	1 (4.5)	0	0	1 (4.5)	0
Hepatosplenomegaly	1 (4.5)	1 (4.5)	0	0	0
Hyperbilirubinaemia	1 (4.5)	0	0	1 (4.5)	0
Immune system disorders					
-Total	20 (90.9)	2 (9.1)	12 (54.5)	3 (13.6)	3 (13.6)
Cytokine release syndrome	16 (72.7)	2 (9.1)	8 (36.4)	3 (13.6)	3 (13.6)
Hypogammaglobulinaemia	11 (50.0)	2 (9.1)	7 (31.8)	2 (9.1)	0
Chronic graft versus host disease	1 (4.5)	0	1 (4.5)	0	0
Haemophagocytic lymphohistiocytosis	1 (4.5)	0	1 (4.5)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Seasonal allergy	1 (4.5)	1 (4.5)	0	0	0
Infections and infestations					
-Total	17 (77.3)	1 (4.5)	4 (18.2)	10 (45.5)	2 (9.1)
Upper respiratory tract infection	5 (22.7)	3 (13.6)	2 (9.1)	0	0
Clostridium difficile infection	4 (18.2)	0	3 (13.6)	1 (4.5)	0
Clostridium difficile colitis	3 (13.6)	1 (4.5)	0	2 (9.1)	0
Gastroenteritis	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Pneumonia	3 (13.6)	0	2 (9.1)	1 (4.5)	0
Rhinovirus infection	3 (13.6)	3 (13.6)	0	0	0
Sinusitis	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Ear infection	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Otitis media acute	2 (9.1)	0	2 (9.1)	0	0
Respiratory syncytial virus infection	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Urinary tract infection	2 (9.1)	0	2 (9.1)	0	0
Viral upper respiratory tract infection	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Vulvovaginal candidiasis	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Bronchopulmonary aspergillosis	1 (4.5)	0	0	1 (4.5)	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Campylobacter infection	1 (4.5)	0	0	1 (4.5)	0
Catheter site infection	1 (4.5)	0	0	1 (4.5)	0
Corona virus infection	1 (4.5)	0	0	1 (4.5)	0
Croup infectious	1 (4.5)	0	0	1 (4.5)	0
Cytomegalovirus infection	1 (4.5)	1 (4.5)	0	0	0
Device related infection	1 (4.5)	0	0	1 (4.5)	0
Enterovirus infection	1 (4.5)	0	0	1 (4.5)	0
Escherichia bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Gastroenteritis viral	1 (4.5)	1 (4.5)	0	0	0
Haemophilus infection	1 (4.5)	0	1 (4.5)	0	0
Metapneumovirus infection	1 (4.5)	0	1 (4.5)	0	0
Molluscum contagiosum	1 (4.5)	1 (4.5)	0	0	0
Oral candidiasis	1 (4.5)	1 (4.5)	0	0	0
Otitis externa	1 (4.5)	0	1 (4.5)	0	0
Otitis media	1 (4.5)	0	0	1 (4.5)	0
Parainfluenzae virus infection	1 (4.5)	0	0	1 (4.5)	0
Paronychia	1 (4.5)	1 (4.5)	0	0	0
Rash pustular	1 (4.5)	0	1 (4.5)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory tract infection	1 (4.5)	0	0	0	1 (4.5)
Respiratory tract infection viral	1 (4.5)	0	0	1 (4.5)	0
Rotavirus infection	1 (4.5)	0	0	1 (4.5)	0
Septic embolus	1 (4.5)	0	0	0	1 (4.5)
Skin infection	1 (4.5)	0	1 (4.5)	0	0
Staphylococcal infection	1 (4.5)	1 (4.5)	0	0	0
Streptococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Tinea capitis	1 (4.5)	1 (4.5)	0	0	0
Viral infection	1 (4.5)	0	1 (4.5)	0	0
Injury, poisoning and procedural complications					
-Total	9 (40.9)	6 (27.3)	3 (13.6)	0	0
Procedural pain	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Infusion related reaction	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Transfusion reaction	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Contusion	1 (4.5)	1 (4.5)	0	0	0
Procedural complication	1 (4.5)	1 (4.5)	0	0	0
Procedural site reaction	1 (4.5)	1 (4.5)	0	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Radius fracture	1 (4.5)	0	1 (4.5)	0	0
Skin abrasion	1 (4.5)	1 (4.5)	0	0	0
Stoma site irritation	1 (4.5)	1 (4.5)	0	0	0
Tibia fracture	1 (4.5)	0	1 (4.5)	0	0
Wound	1 (4.5)	1 (4.5)	0	0	0
Investigations					
-Total	16 (72.7)	0	1 (4.5)	4 (18.2)	11 (50.0)
White blood cell count decreased	10 (45.5)	2 (9.1)	0	1 (4.5)	7 (31.8)
Neutrophil count decreased	9 (40.9)	0	1 (4.5)	1 (4.5)	7 (31.8)
Alanine aminotransferase increased	7 (31.8)	0	2 (9.1)	5 (22.7)	0
Aspartate aminotransferase increased	7 (31.8)	1 (4.5)	1 (4.5)	3 (13.6)	2 (9.1)
Lymphocyte count decreased	6 (27.3)	1 (4.5)	1 (4.5)	1 (4.5)	3 (13.6)
Platelet count decreased	4 (18.2)	0	0	0	4 (18.2)
Blood bilirubin increased	3 (13.6)	0	2 (9.1)	1 (4.5)	0
International normalised ratio increased	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Blood fibrinogen decreased	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Blood lactic acid increased	2 (9.1)	0	1 (4.5)	0	1 (4.5)

Age: <10 years

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood urea increased	2 (9.1)	1 (4.5)	0	1 (4.5)	0
C-reactive protein increased	2 (9.1)	0	2 (9.1)	0	0
Lipase increased	2 (9.1)	0	0	0	2 (9.1)
Prothrombin time prolonged	2 (9.1)	2 (9.1)	0	0	0
Activated partial thromboplastin time prolonged	1 (4.5)	1 (4.5)	0	0	0
Blood creatinine increased	1 (4.5)	0	0	1 (4.5)	0
Blood immunoglobulin g decreased	1 (4.5)	0	1 (4.5)	0	0
Blood immunoglobulin m decreased	1 (4.5)	1 (4.5)	0	0	0
Blood phosphorus decreased	1 (4.5)	1 (4.5)	0	0	0
Blood phosphorus increased	1 (4.5)	1 (4.5)	0	0	0
Blood sodium increased	1 (4.5)	0	1 (4.5)	0	0
Blood uric acid increased	1 (4.5)	1 (4.5)	0	0	0
Coronavirus test positive	1 (4.5)	1 (4.5)	0	0	0
Fibrin d dimer increased	1 (4.5)	1 (4.5)	0	0	0
Oxygen saturation decreased	1 (4.5)	1 (4.5)	0	0	0
Protein total decreased	1 (4.5)	0	0	1 (4.5)	0
Pulmonary function test decreased	1 (4.5)	0	1 (4.5)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Serum ferritin increased	1 (4.5)	0	1 (4.5)	0	0
Transaminases increased	1 (4.5)	1 (4.5)	0	0	0
Weight decreased	1 (4.5)	0	1 (4.5)	0	0
Weight increased	1 (4.5)	0	1 (4.5)	0	0
Metabolism and nutrition disorders					
-Total	14 (63.6)	2 (9.1)	3 (13.6)	8 (36.4)	1 (4.5)
Decreased appetite	8 (36.4)	2 (9.1)	3 (13.6)	3 (13.6)	0
Hypokalaemia	7 (31.8)	0	1 (4.5)	6 (27.3)	0
Hypophosphataemia	6 (27.3)	3 (13.6)	0	2 (9.1)	1 (4.5)
Hypocalcaemia	4 (18.2)	2 (9.1)	1 (4.5)	0	1 (4.5)
Fluid overload	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Hypertriglyceridaemia	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Hypoalbuminaemia	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Hypomagnesaemia	2 (9.1)	2 (9.1)	0	0	0
Acidosis	1 (4.5)	0	0	1 (4.5)	0
Dehydration	1 (4.5)	0	0	1 (4.5)	0
Hyperalbuminaemia	1 (4.5)	1 (4.5)	0	0	0
Hypercalcaemia	1 (4.5)	1 (4.5)	0	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperchloraemia	1 (4.5)	1 (4.5)	0	0	0
Hyperglycaemia	1 (4.5)	0	1 (4.5)	0	0
Hyperkalaemia	1 (4.5)	1 (4.5)	0	0	0
Hypermagnesaemia	1 (4.5)	1 (4.5)	0	0	0
Hypernatraemia	1 (4.5)	0	1 (4.5)	0	0
Hyperphosphataemia	1 (4.5)	1 (4.5)	0	0	0
Hypoglycaemia	1 (4.5)	0	0	1 (4.5)	0
Hyponatraemia	1 (4.5)	0	0	1 (4.5)	0
Malnutrition	1 (4.5)	0	0	1 (4.5)	0
Metabolic alkalosis	1 (4.5)	1 (4.5)	0	0	0
Tumour lysis syndrome	1 (4.5)	0	0	1 (4.5)	0
Vitamin d deficiency	1 (4.5)	1 (4.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	13 (59.1)	6 (27.3)	5 (22.7)	2 (9.1)	0
Pain in extremity	7 (31.8)	4 (18.2)	3 (13.6)	0	0
Pain in jaw	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Bone pain	1 (4.5)	0	0	1 (4.5)	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Myalgia	1 (4.5)	0	0	1 (4.5)	0
Osteopenia	1 (4.5)	0	1 (4.5)	0	0
Toe walking	1 (4.5)	1 (4.5)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (9.1)	0	1 (4.5)	0	1 (4.5)
Glioblastoma multiforme	1 (4.5)	0	0	0	1 (4.5)
Skin papilloma	1 (4.5)	0	1 (4.5)	0	0
Nervous system disorders					
-Total	12 (54.5)	4 (18.2)	5 (22.7)	2 (9.1)	1 (4.5)
Headache	8 (36.4)	5 (22.7)	3 (13.6)	0	0
Dizziness	2 (9.1)	2 (9.1)	0	0	0
Seizure	2 (9.1)	0	0	2 (9.1)	0
Depressed level of consciousness	1 (4.5)	1 (4.5)	0	0	0
Embolic stroke	1 (4.5)	0	0	0	1 (4.5)
Hypotonia	1 (4.5)	0	1 (4.5)	0	0
Migraine	1 (4.5)	0	1 (4.5)	0	0
Neuralgia	1 (4.5)	0	1 (4.5)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Psychiatric disorders					
-Total	6 (27.3)	2 (9.1)	4 (18.2)	0	0
Anxiety	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Confusional state	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Insomnia	2 (9.1)	0	2 (9.1)	0	0
Irritability	2 (9.1)	2 (9.1)	0	0	0
Delirium	1 (4.5)	0	1 (4.5)	0	0
Renal and urinary disorders					
-Total	5 (22.7)	1 (4.5)	2 (9.1)	2 (9.1)	0
Acute kidney injury	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Dysuria	1 (4.5)	0	1 (4.5)	0	0
Pollakiuria	1 (4.5)	1 (4.5)	0	0	0
Renal impairment	1 (4.5)	0	0	1 (4.5)	0
Urinary incontinence	1 (4.5)	1 (4.5)	0	0	0
Reproductive system and breast disorders					
-Total	2 (9.1)	2 (9.1)	0	0	0
Vulvovaginal adhesion	2 (9.1)	2 (9.1)	0	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	12 (54.5)	3 (13.6)	2 (9.1)	4 (18.2)	3 (13.6)
Cough	5 (22.7)	5 (22.7)	0	0	0
Hypoxia	5 (22.7)	0	0	5 (22.7)	0
Pleural effusion	4 (18.2)	0	2 (9.1)	2 (9.1)	0
Rhinorrhoea	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Tachypnoea	3 (13.6)	0	2 (9.1)	1 (4.5)	0
Epistaxis	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Oropharyngeal pain	2 (9.1)	2 (9.1)	0	0	0
Pulmonary oedema	2 (9.1)	0	0	2 (9.1)	0
Dyspnoea	1 (4.5)	1 (4.5)	0	0	0
Idiopathic pneumonia syndrome	1 (4.5)	0	0	0	1 (4.5)
Nasal congestion	1 (4.5)	1 (4.5)	0	0	0
Respiratory distress	1 (4.5)	0	0	0	1 (4.5)
Respiratory failure	1 (4.5)	0	0	0	1 (4.5)
Rhinitis allergic	1 (4.5)	0	1 (4.5)	0	0
Wheezing	1 (4.5)	0	1 (4.5)	0	0

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	10 (45.5)	8 (36.4)	2 (9.1)	0	0
Rash	4 (18.2)	3 (13.6)	1 (4.5)	0	0
Hyperhidrosis	2 (9.1)	2 (9.1)	0	0	0
Rash maculo-papular	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Rash papular	2 (9.1)	2 (9.1)	0	0	0
Alopecia	1 (4.5)	1 (4.5)	0	0	0
Dermatitis diaper	1 (4.5)	1 (4.5)	0	0	0
Erythema	1 (4.5)	1 (4.5)	0	0	0
Macule	1 (4.5)	1 (4.5)	0	0	0
Papule	1 (4.5)	1 (4.5)	0	0	0
Petechiae	1 (4.5)	1 (4.5)	0	0	0
Pruritus	1 (4.5)	1 (4.5)	0	0	0
Rash erythematous	1 (4.5)	1 (4.5)	0	0	0
Rash follicular	1 (4.5)	1 (4.5)	0	0	0
Rash macular	1 (4.5)	1 (4.5)	0	0	0
Vascular disorders					

Age: <10 years

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	9 (40.9)	2 (9.1)	1 (4.5)	3 (13.6)	3 (13.6)
Hypertension	6 (27.3)	2 (9.1)	3 (13.6)	1 (4.5)	0
Hypotension	5 (22.7)	1 (4.5)	0	1 (4.5)	3 (13.6)
Flushing	2 (9.1)	2 (9.1)	0	0	0
Capillary leak syndrome	1 (4.5)	0	0	0	1 (4.5)
Embolism	1 (4.5)	0	0	1 (4.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178a
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (97.4)	0	0	7 (17.9)	31 (79.5)
Blood and lymphatic system disorders					
-Total	35 (89.7)	0	1 (2.6)	22 (56.4)	12 (30.8)
Anaemia	22 (56.4)	1 (2.6)	5 (12.8)	15 (38.5)	1 (2.6)
Febrile neutropenia	22 (56.4)	0	0	21 (53.8)	1 (2.6)
Neutropenia	9 (23.1)	0	0	2 (5.1)	7 (17.9)
Thrombocytopenia	7 (17.9)	0	0	4 (10.3)	3 (7.7)
Disseminated intravascular coagulation	4 (10.3)	0	2 (5.1)	1 (2.6)	1 (2.6)
Lymphopenia	3 (7.7)	0	1 (2.6)	1 (2.6)	1 (2.6)
Pancytopenia	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Coagulopathy	1 (2.6)	0	0	1 (2.6)	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eosinophilia	1 (2.6)	0	0	1 (2.6)	0
Hypofibrinogenaemia	1 (2.6)	0	0	0	1 (2.6)
Lymphadenopathy	1 (2.6)	0	1 (2.6)	0	0
Splenomegaly	1 (2.6)	1 (2.6)	0	0	0
Cardiac disorders					
-Total	13 (33.3)	5 (12.8)	5 (12.8)	3 (7.7)	0
Tachycardia	10 (25.6)	6 (15.4)	3 (7.7)	1 (2.6)	0
Sinus tachycardia	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Bradycardia	1 (2.6)	1 (2.6)	0	0	0
Left ventricular dysfunction	1 (2.6)	0	0	1 (2.6)	0
Palpitations	1 (2.6)	1 (2.6)	0	0	0
Pericardial effusion	1 (2.6)	1 (2.6)	0	0	0
Sinus bradycardia	1 (2.6)	1 (2.6)	0	0	0
Ventricular tachycardia	1 (2.6)	0	1 (2.6)	0	0
Ear and labyrinth disorders					
-Total	1 (2.6)	1 (2.6)	0	0	0
Ear pain	1 (2.6)	1 (2.6)	0	0	0
Endocrine disorders					

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (10.3)	1 (2.6)	3 (7.7)	0	0
Adrenal insufficiency	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Hyperthyroidism	1 (2.6)	0	1 (2.6)	0	0
Eye disorders					
-Total	10 (25.6)	5 (12.8)	5 (12.8)	0	0
Eye pain	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Vision blurred	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Periorbital oedema	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Conjunctival haemorrhage	1 (2.6)	1 (2.6)	0	0	0
Dry eye	1 (2.6)	1 (2.6)	0	0	0
Eye irritation	1 (2.6)	1 (2.6)	0	0	0
Ocular hyperaemia	1 (2.6)	1 (2.6)	0	0	0
Ocular hypertension	1 (2.6)	0	1 (2.6)	0	0
Photophobia	1 (2.6)	0	1 (2.6)	0	0
Retinal haemorrhage	1 (2.6)	1 (2.6)	0	0	0
Uveitis	1 (2.6)	0	1 (2.6)	0	0
Gastrointestinal disorders					
-Total	29 (74.4)	7 (17.9)	11 (28.2)	10 (25.6)	1 (2.6)

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	15 (38.5)	11 (28.2)	2 (5.1)	2 (5.1)	0
Nausea	14 (35.9)	5 (12.8)	7 (17.9)	2 (5.1)	0
Diarrhoea	12 (30.8)	7 (17.9)	4 (10.3)	1 (2.6)	0
Abdominal pain	10 (25.6)	4 (10.3)	4 (10.3)	2 (5.1)	0
Stomatitis	5 (12.8)	1 (2.6)	1 (2.6)	2 (5.1)	1 (2.6)
Constipation	4 (10.3)	3 (7.7)	1 (2.6)	0	0
Oral pain	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Abdominal pain lower	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Abdominal pain upper	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Colitis	2 (5.1)	0	0	2 (5.1)	0
Gastrointestinal haemorrhage	2 (5.1)	2 (5.1)	0	0	0
Haematemesis	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Abdominal distension	1 (2.6)	0	1 (2.6)	0	0
Anal fissure	1 (2.6)	0	1 (2.6)	0	0
Anal incontinence	1 (2.6)	1 (2.6)	0	0	0
Ascites	1 (2.6)	0	0	1 (2.6)	0
Dry mouth	1 (2.6)	1 (2.6)	0	0	0
Dysphagia	1 (2.6)	0	1 (2.6)	0	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flatulence	1 (2.6)	1 (2.6)	0	0	0
Gastrooesophageal reflux disease	1 (2.6)	1 (2.6)	0	0	0
Gingival discomfort	1 (2.6)	1 (2.6)	0	0	0
Glossodynia	1 (2.6)	1 (2.6)	0	0	0
Haematochezia	1 (2.6)	1 (2.6)	0	0	0
Lip pain	1 (2.6)	0	1 (2.6)	0	0
Mouth haemorrhage	1 (2.6)	0	0	1 (2.6)	0
Oral mucosal blistering	1 (2.6)	1 (2.6)	0	0	0
Pancreatic failure	1 (2.6)	0	1 (2.6)	0	0
Pancreatitis	1 (2.6)	0	1 (2.6)	0	0
Pigmentation lip	1 (2.6)	1 (2.6)	0	0	0
Proctalgia	1 (2.6)	0	1 (2.6)	0	0
General disorders and administration site conditions					
-Total	27 (69.2)	9 (23.1)	10 (25.6)	5 (12.8)	3 (7.7)
Pyrexia	15 (38.5)	4 (10.3)	8 (20.5)	2 (5.1)	1 (2.6)
Fatigue	11 (28.2)	9 (23.1)	0	2 (5.1)	0
Chills	7 (17.9)	5 (12.8)	2 (5.1)	0	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	4 (10.3)	1 (2.6)	1 (2.6)	2 (5.1)	0
Catheter site pain	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Generalised oedema	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Malaise	2 (5.1)	0	2 (5.1)	0	0
Multiple organ dysfunction syndrome	2 (5.1)	0	0	0	2 (5.1)
Catheter site extravasation	1 (2.6)	0	1 (2.6)	0	0
Catheter site haemorrhage	1 (2.6)	1 (2.6)	0	0	0
Device related thrombosis	1 (2.6)	0	1 (2.6)	0	0
Face oedema	1 (2.6)	0	1 (2.6)	0	0
Influenza like illness	1 (2.6)	1 (2.6)	0	0	0
Injection site haematoma	1 (2.6)	1 (2.6)	0	0	0
Non-cardiac chest pain	1 (2.6)	1 (2.6)	0	0	0
Oedema peripheral	1 (2.6)	1 (2.6)	0	0	0
Peripheral swelling	1 (2.6)	0	1 (2.6)	0	0
Physical deconditioning	1 (2.6)	0	0	1 (2.6)	0
Hepatobiliary disorders					
-Total	6 (15.4)	2 (5.1)	2 (5.1)	1 (2.6)	1 (2.6)
Hyperbilirubinaemia	3 (7.7)	0	2 (5.1)	1 (2.6)	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Gallbladder enlargement	1 (2.6)	1 (2.6)	0	0	0
Hepatic failure	1 (2.6)	0	0	0	1 (2.6)
Immune system disorders					
-Total	31 (79.5)	4 (10.3)	14 (35.9)	8 (20.5)	5 (12.8)
Cytokine release syndrome	26 (66.7)	4 (10.3)	12 (30.8)	5 (12.8)	5 (12.8)
Hypogammaglobulinaemia	19 (48.7)	2 (5.1)	14 (35.9)	3 (7.7)	0
Graft versus host disease	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Immunodeficiency common variable	2 (5.1)	0	2 (5.1)	0	0
Drug hypersensitivity	1 (2.6)	0	1 (2.6)	0	0
Graft versus host disease in gastrointestinal tract	1 (2.6)	0	1 (2.6)	0	0
Graft versus host disease in skin	1 (2.6)	1 (2.6)	0	0	0
Immunodeficiency	1 (2.6)	0	1 (2.6)	0	0
Seasonal allergy	1 (2.6)	1 (2.6)	0	0	0
Infections and infestations					
-Total	26 (66.7)	3 (7.7)	10 (25.6)	9 (23.1)	4 (10.3)
Upper respiratory tract infection	5 (12.8)	2 (5.1)	2 (5.1)	1 (2.6)	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	3 (7.7)	0	3 (7.7)	0	0
Parainfluenzae virus infection	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Urinary tract infection	3 (7.7)	0	1 (2.6)	2 (5.1)	0
Clostridium difficile colitis	2 (5.1)	0	2 (5.1)	0	0
Clostridium difficile infection	2 (5.1)	0	2 (5.1)	0	0
Device related infection	2 (5.1)	0	0	2 (5.1)	0
Escherichia urinary tract infection	2 (5.1)	0	0	2 (5.1)	0
Fungal skin infection	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Gastroenteritis	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Influenza	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Oral herpes	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Pneumonia	2 (5.1)	0	2 (5.1)	0	0
Rhinovirus infection	2 (5.1)	2 (5.1)	0	0	0
Staphylococcal bacteraemia	2 (5.1)	0	0	2 (5.1)	0
Staphylococcal infection	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Viral infection	2 (5.1)	2 (5.1)	0	0	0
Viral upper respiratory tract infection	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Acute sinusitis	1 (2.6)	0	1 (2.6)	0	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Body tinea	1 (2.6)	1 (2.6)	0	0	0
Bronchitis	1 (2.6)	0	1 (2.6)	0	0
Candida sepsis	1 (2.6)	0	0	0	1 (2.6)
Catheter site cellulitis	1 (2.6)	1 (2.6)	0	0	0
Cellulitis	1 (2.6)	0	0	1 (2.6)	0
Cellulitis of male external genital organ	1 (2.6)	0	0	1 (2.6)	0
Conjunctivitis	1 (2.6)	0	1 (2.6)	0	0
Cytomegalovirus infection	1 (2.6)	1 (2.6)	0	0	0
Enterococcal infection	1 (2.6)	1 (2.6)	0	0	0
Escherichia bacteraemia	1 (2.6)	0	0	1 (2.6)	0
Gastroenteritis norovirus	1 (2.6)	0	1 (2.6)	0	0
Gingivitis	1 (2.6)	1 (2.6)	0	0	0
Herpes simplex	1 (2.6)	1 (2.6)	0	0	0
Herpes zoster	1 (2.6)	0	0	1 (2.6)	0
Human polyomavirus infection	1 (2.6)	0	0	0	1 (2.6)
Hypopyon	1 (2.6)	0	1 (2.6)	0	0
Meningitis aseptic	1 (2.6)	0	1 (2.6)	0	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Orchitis	1 (2.6)	1 (2.6)	0	0	0
Pharyngitis	1 (2.6)	0	1 (2.6)	0	0
Respiratory syncytial virus bronchitis	1 (2.6)	0	0	1 (2.6)	0
Rhinitis	1 (2.6)	1 (2.6)	0	0	0
Sepsis	1 (2.6)	0	0	0	1 (2.6)
Sinusitis	1 (2.6)	0	1 (2.6)	0	0
Skin infection	1 (2.6)	0	1 (2.6)	0	0
Streptococcal infection	1 (2.6)	0	1 (2.6)	0	0
Subcutaneous abscess	1 (2.6)	0	1 (2.6)	0	0
Vascular device infection	1 (2.6)	0	0	1 (2.6)	0
Vulvovaginal mycotic infection	1 (2.6)	0	1 (2.6)	0	0
Injury, poisoning and procedural complications					
-Total	13 (33.3)	5 (12.8)	5 (12.8)	2 (5.1)	1 (2.6)
Infusion related reaction	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Contusion	2 (5.1)	2 (5.1)	0	0	0
Procedural pain	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Radiation skin injury	2 (5.1)	0	2 (5.1)	0	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthropod bite	1 (2.6)	1 (2.6)	0	0	0
Extradural haematoma	1 (2.6)	0	0	1 (2.6)	0
Mouth injury	1 (2.6)	1 (2.6)	0	0	0
Post procedural haemorrhage	1 (2.6)	1 (2.6)	0	0	0
Procedural headache	1 (2.6)	0	1 (2.6)	0	0
Procedural nausea	1 (2.6)	0	1 (2.6)	0	0
Skin abrasion	1 (2.6)	1 (2.6)	0	0	0
Skin laceration	1 (2.6)	0	1 (2.6)	0	0
Subdural haematoma	1 (2.6)	0	0	1 (2.6)	0
Subdural haemorrhage	1 (2.6)	1 (2.6)	0	0	0
Sunburn	1 (2.6)	1 (2.6)	0	0	0
Tongue injury	1 (2.6)	1 (2.6)	0	0	0
Transfusion reaction	1 (2.6)	1 (2.6)	0	0	0
Transfusion related complication	1 (2.6)	0	0	0	1 (2.6)
Investigations					
-Total	32 (82.1)	1 (2.6)	3 (7.7)	5 (12.8)	23 (59.0)
White blood cell count decreased	26 (66.7)	2 (5.1)	1 (2.6)	5 (12.8)	18 (46.2)
Neutrophil count decreased	21 (53.8)	1 (2.6)	1 (2.6)	2 (5.1)	17 (43.6)

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	17 (43.6)	2 (5.1)	2 (5.1)	12 (30.8)	1 (2.6)
Aspartate aminotransferase increased	14 (35.9)	3 (7.7)	4 (10.3)	5 (12.8)	2 (5.1)
Platelet count decreased	14 (35.9)	2 (5.1)	1 (2.6)	3 (7.7)	8 (20.5)
Lymphocyte count decreased	12 (30.8)	0	2 (5.1)	6 (15.4)	4 (10.3)
Blood creatinine increased	8 (20.5)	5 (12.8)	2 (5.1)	1 (2.6)	0
Blood bilirubin increased	7 (17.9)	2 (5.1)	1 (2.6)	3 (7.7)	1 (2.6)
International normalised ratio increased	7 (17.9)	6 (15.4)	1 (2.6)	0	0
Activated partial thromboplastin time prolonged	5 (12.8)	2 (5.1)	3 (7.7)	0	0
Prothrombin time prolonged	4 (10.3)	3 (7.7)	1 (2.6)	0	0
Blood immunoglobulin a decreased	3 (7.7)	3 (7.7)	0	0	0
Blood immunoglobulin m decreased	2 (5.1)	2 (5.1)	0	0	0
Blood magnesium decreased	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Haemoglobin decreased	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Weight decreased	2 (5.1)	2 (5.1)	0	0	0
Weight increased	2 (5.1)	2 (5.1)	0	0	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood alkaline phosphatase increased	1 (2.6)	1 (2.6)	0	0	0
Blood bicarbonate decreased	1 (2.6)	0	1 (2.6)	0	0
Blood lactate dehydrogenase increased	1 (2.6)	1 (2.6)	0	0	0
Blood phosphorus increased	1 (2.6)	1 (2.6)	0	0	0
Blood urea increased	1 (2.6)	0	1 (2.6)	0	0
Blood uric acid increased	1 (2.6)	1 (2.6)	0	0	0
C-reactive protein increased	1 (2.6)	1 (2.6)	0	0	0
Cardiac murmur	1 (2.6)	1 (2.6)	0	0	0
Culture stool positive	1 (2.6)	1 (2.6)	0	0	0
Electrocardiogram qt prolonged	1 (2.6)	0	0	1 (2.6)	0
Lipase increased	1 (2.6)	0	0	0	1 (2.6)
Norovirus test positive	1 (2.6)	1 (2.6)	0	0	0
Serum ferritin increased	1 (2.6)	0	1 (2.6)	0	0
Transaminases increased	1 (2.6)	1 (2.6)	0	0	0
Metabolism and nutrition disorders					
-Total	25 (64.1)	4 (10.3)	3 (7.7)	13 (33.3)	5 (12.8)
Decreased appetite	14 (35.9)	5 (12.8)	2 (5.1)	7 (17.9)	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	13 (33.3)	3 (7.7)	3 (7.7)	3 (7.7)	4 (10.3)
Hyperphosphataemia	7 (17.9)	6 (15.4)	1 (2.6)	0	0
Hypernatraemia	5 (12.8)	1 (2.6)	1 (2.6)	0	3 (7.7)
Hypophosphataemia	5 (12.8)	0	0	5 (12.8)	0
Hypoalbuminaemia	4 (10.3)	1 (2.6)	3 (7.7)	0	0
Hyperglycaemia	3 (7.7)	0	0	3 (7.7)	0
Hyperuricaemia	3 (7.7)	3 (7.7)	0	0	0
Dehydration	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Acidosis	1 (2.6)	1 (2.6)	0	0	0
Fluid overload	1 (2.6)	0	1 (2.6)	0	0
Hyperammonaemia	1 (2.6)	1 (2.6)	0	0	0
Hyperkalaemia	1 (2.6)	0	1 (2.6)	0	0
Hypocalcaemia	1 (2.6)	0	0	1 (2.6)	0
Hypoglycaemia	1 (2.6)	0	1 (2.6)	0	0
Hyponatraemia	1 (2.6)	0	0	1 (2.6)	0
Iron overload	1 (2.6)	0	0	1 (2.6)	0
Malnutrition	1 (2.6)	0	1 (2.6)	0	0
Tumour lysis syndrome	1 (2.6)	0	0	1 (2.6)	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vitamin d deficiency	1 (2.6)	1 (2.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	18 (46.2)	10 (25.6)	5 (12.8)	3 (7.7)	0
Arthralgia	5 (12.8)	4 (10.3)	0	1 (2.6)	0
Myalgia	5 (12.8)	4 (10.3)	1 (2.6)	0	0
Pain in extremity	4 (10.3)	3 (7.7)	0	1 (2.6)	0
Muscle spasms	3 (7.7)	3 (7.7)	0	0	0
Muscular weakness	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Musculoskeletal chest pain	3 (7.7)	3 (7.7)	0	0	0
Back pain	2 (5.1)	1 (2.6)	0	1 (2.6)	0
Joint range of motion decreased	2 (5.1)	2 (5.1)	0	0	0
Musculoskeletal pain	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Coccydynia	1 (2.6)	1 (2.6)	0	0	0
Flank pain	1 (2.6)	0	1 (2.6)	0	0
Neck pain	1 (2.6)	0	1 (2.6)	0	0
Osteonecrosis	1 (2.6)	0	1 (2.6)	0	0
Pain in jaw	1 (2.6)	1 (2.6)	0	0	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.6)	0	1 (2.6)	0	0
Myelodysplastic syndrome	1 (2.6)	0	1 (2.6)	0	0
Nervous system disorders					
-Total	23 (59.0)	10 (25.6)	8 (20.5)	5 (12.8)	0
Headache	17 (43.6)	9 (23.1)	4 (10.3)	4 (10.3)	0
Encephalopathy	4 (10.3)	1 (2.6)	1 (2.6)	2 (5.1)	0
Dysarthria	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Seizure	2 (5.1)	0	2 (5.1)	0	0
Somnolence	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Tremor	2 (5.1)	2 (5.1)	0	0	0
Asterixis	1 (2.6)	1 (2.6)	0	0	0
Ataxia	1 (2.6)	0	1 (2.6)	0	0
Disturbance in attention	1 (2.6)	1 (2.6)	0	0	0
Dizziness	1 (2.6)	1 (2.6)	0	0	0
Dysgeusia	1 (2.6)	1 (2.6)	0	0	0
Myoclonus	1 (2.6)	1 (2.6)	0	0	0

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Neuropathy peripheral	1 (2.6)	0	1 (2.6)	0	0
Peroneal nerve palsy	1 (2.6)	1 (2.6)	0	0	0
Pleocytosis	1 (2.6)	1 (2.6)	0	0	0
Product issues					
-Total	2 (5.1)	2 (5.1)	0	0	0
Device occlusion	2 (5.1)	2 (5.1)	0	0	0
Psychiatric disorders					
-Total	13 (33.3)	5 (12.8)	6 (15.4)	2 (5.1)	0
Anxiety	5 (12.8)	2 (5.1)	3 (7.7)	0	0
Mental status changes	4 (10.3)	3 (7.7)	0	1 (2.6)	0
Confusional state	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Delirium	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Depression	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Agitation	2 (5.1)	0	2 (5.1)	0	0
Hallucination	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Adjustment disorder	1 (2.6)	0	1 (2.6)	0	0
Insomnia	1 (2.6)	0	1 (2.6)	0	0
Irritability	1 (2.6)	1 (2.6)	0	0	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Listless	1 (2.6)	1 (2.6)	0	0	0
Sleep disorder	1 (2.6)	0	1 (2.6)	0	0
Suicidal ideation	1 (2.6)	1 (2.6)	0	0	0
Renal and urinary disorders					
-Total	10 (25.6)	2 (5.1)	1 (2.6)	4 (10.3)	3 (7.7)
Acute kidney injury	6 (15.4)	1 (2.6)	0	3 (7.7)	2 (5.1)
Haematuria	3 (7.7)	0	1 (2.6)	1 (2.6)	1 (2.6)
Oliguria	2 (5.1)	0	0	2 (5.1)	0
Calculus urinary	1 (2.6)	0	1 (2.6)	0	0
Cystitis haemorrhagic	1 (2.6)	0	0	0	1 (2.6)
Dysuria	1 (2.6)	1 (2.6)	0	0	0
Nephrolithiasis	1 (2.6)	0	0	1 (2.6)	0
Renal failure	1 (2.6)	0	0	0	1 (2.6)
Urinary retention	1 (2.6)	0	1 (2.6)	0	0
Reproductive system and breast disorders					
-Total	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Ovarian failure	1 (2.6)	0	0	1 (2.6)	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Scrotal pain	1 (2.6)	0	1 (2.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	25 (64.1)	9 (23.1)	5 (12.8)	6 (15.4)	5 (12.8)
Cough	9 (23.1)	7 (17.9)	2 (5.1)	0	0
Epistaxis	8 (20.5)	3 (7.7)	0	4 (10.3)	1 (2.6)
Hypoxia	6 (15.4)	0	3 (7.7)	2 (5.1)	1 (2.6)
Nasal congestion	5 (12.8)	5 (12.8)	0	0	0
Pulmonary oedema	5 (12.8)	1 (2.6)	0	2 (5.1)	2 (5.1)
Oropharyngeal pain	4 (10.3)	2 (5.1)	2 (5.1)	0	0
Tachypnoea	4 (10.3)	3 (7.7)	0	1 (2.6)	0
Pleural effusion	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Respiratory failure	3 (7.7)	0	0	0	3 (7.7)
Rhinitis allergic	3 (7.7)	3 (7.7)	0	0	0
Rhinorrhoea	3 (7.7)	3 (7.7)	0	0	0
Haemoptysis	2 (5.1)	1 (2.6)	0	0	1 (2.6)
Acute respiratory failure	1 (2.6)	0	0	0	1 (2.6)
Atelectasis	1 (2.6)	1 (2.6)	0	0	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphonia	1 (2.6)	1 (2.6)	0	0	0
Dyspnoea	1 (2.6)	0	0	1 (2.6)	0
Nasal discomfort	1 (2.6)	1 (2.6)	0	0	0
Oropharyngeal plaque	1 (2.6)	1 (2.6)	0	0	0
Pharyngeal erythema	1 (2.6)	1 (2.6)	0	0	0
Pharyngeal lesion	1 (2.6)	0	0	1 (2.6)	0
Pharyngeal ulceration	1 (2.6)	0	1 (2.6)	0	0
Pulmonary mass	1 (2.6)	0	1 (2.6)	0	0
Respiratory depression	1 (2.6)	0	1 (2.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	23 (59.0)	12 (30.8)	8 (20.5)	3 (7.7)	0
Dry skin	5 (12.8)	5 (12.8)	0	0	0
Rash	4 (10.3)	2 (5.1)	2 (5.1)	0	0
Erythema	3 (7.7)	3 (7.7)	0	0	0
Pruritus	3 (7.7)	3 (7.7)	0	0	0
Rash erythematous	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Alopecia	2 (5.1)	1 (2.6)	1 (2.6)	0	0

Age: >=10 years to <18 years

	All patients N=39				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dermatitis acneiform	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Ingrowing nail	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Night sweats	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Petechiae	2 (5.1)	2 (5.1)	0	0	0
Rash maculo-papular	2 (5.1)	2 (5.1)	0	0	0
Rash pruritic	2 (5.1)	2 (5.1)	0	0	0
Acne	1 (2.6)	1 (2.6)	0	0	0
Cold sweat	1 (2.6)	1 (2.6)	0	0	0
Dermatitis	1 (2.6)	1 (2.6)	0	0	0
Dermatitis atopic	1 (2.6)	1 (2.6)	0	0	0
Ecchymosis	1 (2.6)	0	0	1 (2.6)	0
Eczema	1 (2.6)	1 (2.6)	0	0	0
Hyperhidrosis	1 (2.6)	1 (2.6)	0	0	0
Keloid scar	1 (2.6)	0	1 (2.6)	0	0
Livedo reticularis	1 (2.6)	1 (2.6)	0	0	0
Macule	1 (2.6)	1 (2.6)	0	0	0
Papule	1 (2.6)	1 (2.6)	0	0	0
Pruritus generalised	1 (2.6)	1 (2.6)	0	0	0

Age: >=10 years to <18 years

Primary system organ class Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash macular	1 (2.6)	0	0	1 (2.6)	0
Rash papular	1 (2.6)	1 (2.6)	0	0	0
Rash vesicular	1 (2.6)	1 (2.6)	0	0	0
Skin exfoliation	1 (2.6)	1 (2.6)	0	0	0
Skin fissures	1 (2.6)	1 (2.6)	0	0	0
Skin irritation	1 (2.6)	1 (2.6)	0	0	0
Skin ulcer	1 (2.6)	1 (2.6)	0	0	0
Vascular disorders					
-Total	17 (43.6)	1 (2.6)	2 (5.1)	9 (23.1)	5 (12.8)
Hypotension	14 (35.9)	0	0	9 (23.1)	5 (12.8)
Hypertension	5 (12.8)	2 (5.1)	2 (5.1)	1 (2.6)	0
Haematoma	1 (2.6)	0	1 (2.6)	0	0
Hot flush	1 (2.6)	1 (2.6)	0	0	0
Orthostatic hypotension	1 (2.6)	0	1 (2.6)	0	0
Secondary hypertension	1 (2.6)	0	1 (2.6)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178a
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (92.9)	0	0	2 (14.3)	11 (78.6)
Blood and lymphatic system disorders					
-Total	10 (71.4)	0	0	4 (28.6)	6 (42.9)
Anaemia	6 (42.9)	0	1 (7.1)	5 (35.7)	0
Neutropenia	5 (35.7)	0	0	2 (14.3)	3 (21.4)
Thrombocytopenia	4 (28.6)	0	0	0	4 (28.6)
Febrile neutropenia	3 (21.4)	0	0	3 (21.4)	0
Lymphopenia	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Pancytopenia	2 (14.3)	0	0	0	2 (14.3)
Disseminated intravascular coagulation	1 (7.1)	0	0	1 (7.1)	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Leukocytosis	1 (7.1)	1 (7.1)	0	0	0
Cardiac disorders					
-Total	7 (50.0)	1 (7.1)	2 (14.3)	2 (14.3)	2 (14.3)
Tachycardia	5 (35.7)	2 (14.3)	2 (14.3)	1 (7.1)	0
Left ventricular dysfunction	2 (14.3)	0	0	2 (14.3)	0
Bradycardia	1 (7.1)	0	0	0	1 (7.1)
Cardiovascular insufficiency	1 (7.1)	0	0	0	1 (7.1)
Pericardial effusion	1 (7.1)	0	1 (7.1)	0	0
Right ventricular dysfunction	1 (7.1)	0	0	1 (7.1)	0
Sinus tachycardia	1 (7.1)	0	0	1 (7.1)	0
Ventricular tachycardia	1 (7.1)	0	0	1 (7.1)	0
Ear and labyrinth disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Deafness unilateral	1 (7.1)	0	1 (7.1)	0	0
Hypoacusis	1 (7.1)	0	1 (7.1)	0	0
Eye disorders					
-Total	3 (21.4)	0	3 (21.4)	0	0
Papilloedema	1 (7.1)	0	1 (7.1)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Photophobia	1 (7.1)	0	1 (7.1)	0	0
Retinopathy	1 (7.1)	0	1 (7.1)	0	0
Uveitis	1 (7.1)	0	1 (7.1)	0	0
Visual impairment	1 (7.1)	0	1 (7.1)	0	0
Gastrointestinal disorders					
-Total	9 (64.3)	1 (7.1)	5 (35.7)	3 (21.4)	0
Nausea	8 (57.1)	1 (7.1)	4 (28.6)	3 (21.4)	0
Vomiting	6 (42.9)	1 (7.1)	3 (21.4)	2 (14.3)	0
Diarrhoea	5 (35.7)	2 (14.3)	2 (14.3)	1 (7.1)	0
Abdominal pain	3 (21.4)	1 (7.1)	1 (7.1)	1 (7.1)	0
Constipation	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Abdominal discomfort	1 (7.1)	1 (7.1)	0	0	0
Abdominal pain upper	1 (7.1)	0	1 (7.1)	0	0
Dyspepsia	1 (7.1)	0	1 (7.1)	0	0
Haematochezia	1 (7.1)	0	0	1 (7.1)	0
Intestinal obstruction	1 (7.1)	0	0	1 (7.1)	0
General disorders and administration site conditions					

Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (85.7)	1 (7.1)	5 (35.7)	5 (35.7)	1 (7.1)
Pyrexia	9 (64.3)	2 (14.3)	4 (28.6)	3 (21.4)	0
Chills	3 (21.4)	3 (21.4)	0	0	0
Fatigue	3 (21.4)	0	3 (21.4)	0	0
Pain	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Catheter site pain	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Asthenia	1 (7.1)	1 (7.1)	0	0	0
Facial pain	1 (7.1)	0	1 (7.1)	0	0
Generalised oedema	1 (7.1)	1 (7.1)	0	0	0
Influenza like illness	1 (7.1)	1 (7.1)	0	0	0
Malaise	1 (7.1)	0	1 (7.1)	0	0
Medical device pain	1 (7.1)	0	1 (7.1)	0	0
Multiple organ dysfunction syndrome	1 (7.1)	0	0	0	1 (7.1)
Non-cardiac chest pain	1 (7.1)	0	0	1 (7.1)	0
Oedema peripheral	1 (7.1)	0	1 (7.1)	0	0
Physical deconditioning	1 (7.1)	0	0	1 (7.1)	0
Hepatobiliary disorders					
-Total	2 (14.3)	0	1 (7.1)	1 (7.1)	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatic steatosis	1 (7.1)	0	1 (7.1)	0	0
Hepatomegaly	1 (7.1)	0	1 (7.1)	0	0
Hyperbilirubinaemia	1 (7.1)	0	0	1 (7.1)	0
Immune system disorders					
-Total	8 (57.1)	0	5 (35.7)	0	3 (21.4)
Cytokine release syndrome	8 (57.1)	0	5 (35.7)	0	3 (21.4)
Hypogammaglobulinaemia	3 (21.4)	0	3 (21.4)	0	0
Infections and infestations					
-Total	9 (64.3)	0	2 (14.3)	2 (14.3)	5 (35.7)
Influenza	2 (14.3)	0	2 (14.3)	0	0
Pneumonia	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Abscess limb	1 (7.1)	0	0	1 (7.1)	0
Bacterial sepsis	1 (7.1)	0	0	0	1 (7.1)
Cholecystitis infective	1 (7.1)	0	0	1 (7.1)	0
Device related infection	1 (7.1)	0	1 (7.1)	0	0
Escherichia sepsis	1 (7.1)	0	0	0	1 (7.1)
Escherichia urinary tract infection	1 (7.1)	0	1 (7.1)	0	0
Folliculitis	1 (7.1)	0	1 (7.1)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Human herpesvirus 6 infection	1 (7.1)	0	1 (7.1)	0	0
Klebsiella sepsis	1 (7.1)	0	0	0	1 (7.1)
Necrotising fasciitis	1 (7.1)	0	0	1 (7.1)	0
Pneumonia fungal	1 (7.1)	0	1 (7.1)	0	0
Rhinovirus infection	1 (7.1)	0	1 (7.1)	0	0
Sepsis	1 (7.1)	0	0	0	1 (7.1)
Sinusitis	1 (7.1)	0	1 (7.1)	0	0
Staphylococcal scalded skin syndrome	1 (7.1)	0	1 (7.1)	0	0
Staphylococcal sepsis	1 (7.1)	0	0	0	1 (7.1)
Upper respiratory tract infection	1 (7.1)	0	1 (7.1)	0	0
Urinary tract infection enterococcal	1 (7.1)	0	0	1 (7.1)	0
Injury, poisoning and procedural complications					
-Total	4 (28.6)	1 (7.1)	2 (14.3)	1 (7.1)	0
Foot fracture	1 (7.1)	0	1 (7.1)	0	0
Incision site pain	1 (7.1)	1 (7.1)	0	0	0
Limb injury	1 (7.1)	1 (7.1)	0	0	0
Subdural haematoma	1 (7.1)	0	1 (7.1)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tracheal haemorrhage	1 (7.1)	0	0	1 (7.1)	0
Transfusion reaction	1 (7.1)	0	1 (7.1)	0	0
Investigations					
-Total	10 (71.4)	0	0	3 (21.4)	7 (50.0)
White blood cell count decreased	6 (42.9)	0	0	2 (14.3)	4 (28.6)
Aspartate aminotransferase increased	3 (21.4)	1 (7.1)	0	1 (7.1)	1 (7.1)
Platelet count decreased	3 (21.4)	1 (7.1)	1 (7.1)	0	1 (7.1)
Prothrombin time prolonged	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Alanine aminotransferase increased	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Blood fibrinogen decreased	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Neutrophil count decreased	2 (14.3)	0	0	0	2 (14.3)
Transaminases increased	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Weight decreased	2 (14.3)	0	2 (14.3)	0	0
Blood immunoglobulin m decreased	1 (7.1)	1 (7.1)	0	0	0
Blood lactate dehydrogenase increased	1 (7.1)	0	0	1 (7.1)	0
C-reactive protein increased	1 (7.1)	0	0	1 (7.1)	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Computerised tomogram thorax abnormal	1 (7.1)	0	0	1 (7.1)	0
Electrocardiogram qt prolonged	1 (7.1)	0	0	1 (7.1)	0
Haemoglobin decreased	1 (7.1)	1 (7.1)	0	0	0
Hepatic enzyme increased	1 (7.1)	0	1 (7.1)	0	0
International normalised ratio increased	1 (7.1)	1 (7.1)	0	0	0
Lymphocyte count decreased	1 (7.1)	0	0	0	1 (7.1)
Metabolism and nutrition disorders					
-Total	10 (71.4)	0	4 (28.6)	5 (35.7)	1 (7.1)
Decreased appetite	6 (42.9)	0	3 (21.4)	3 (21.4)	0
Fluid overload	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Hyperglycaemia	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Hypokalaemia	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Hypophosphataemia	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Dehydration	1 (7.1)	0	0	1 (7.1)	0
Hyperkalaemia	1 (7.1)	0	0	1 (7.1)	0
Hyperphosphataemia	1 (7.1)	1 (7.1)	0	0	0
Hyperuricaemia	1 (7.1)	0	0	0	1 (7.1)

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypocalcaemia	1 (7.1)	1 (7.1)	0	0	0
Hypomagnesaemia	1 (7.1)	0	1 (7.1)	0	0
Metabolic acidosis	1 (7.1)	0	1 (7.1)	0	0
Tumour lysis syndrome	1 (7.1)	0	0	1 (7.1)	0
Vitamin d deficiency	1 (7.1)	0	1 (7.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	6 (42.9)	1 (7.1)	2 (14.3)	3 (21.4)	0
Pain in extremity	3 (21.4)	0	1 (7.1)	2 (14.3)	0
Arthralgia	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Musculoskeletal pain	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Back pain	1 (7.1)	0	0	1 (7.1)	0
Limb discomfort	1 (7.1)	1 (7.1)	0	0	0
Myopathy	1 (7.1)	0	0	1 (7.1)	0
Myositis	1 (7.1)	0	0	1 (7.1)	0
Neck pain	1 (7.1)	0	1 (7.1)	0	0
Synovitis	1 (7.1)	0	1 (7.1)	0	0
Nervous system disorders					

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	8 (57.1)	3 (21.4)	4 (28.6)	0	1 (7.1)
Headache	4 (28.6)	1 (7.1)	2 (14.3)	1 (7.1)	0
Dizziness	3 (21.4)	3 (21.4)	0	0	0
Peroneal nerve palsy	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Hyporesponsive to stimuli	1 (7.1)	0	0	1 (7.1)	0
Idiopathic intracranial hypertension	1 (7.1)	0	1 (7.1)	0	0
Neuropathy peripheral	1 (7.1)	1 (7.1)	0	0	0
Peripheral sensory neuropathy	1 (7.1)	0	1 (7.1)	0	0
Seizure	1 (7.1)	0	0	0	1 (7.1)
Visual field defect	1 (7.1)	0	1 (7.1)	0	0
Psychiatric disorders					
-Total	7 (50.0)	1 (7.1)	4 (28.6)	2 (14.3)	0
Anxiety	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Confusional state	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Agitation	1 (7.1)	0	0	1 (7.1)	0
Delirium	1 (7.1)	1 (7.1)	0	0	0
Depression	1 (7.1)	0	1 (7.1)	0	0
Insomnia	1 (7.1)	0	1 (7.1)	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Panic attack	1 (7.1)	0	1 (7.1)	0	0
Renal and urinary disorders					
-Total	4 (28.6)	0	1 (7.1)	1 (7.1)	2 (14.3)
Acute kidney injury	4 (28.6)	1 (7.1)	0	1 (7.1)	2 (14.3)
Haematuria	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Dysuria	1 (7.1)	0	1 (7.1)	0	0
Oliguria	1 (7.1)	0	0	1 (7.1)	0
Reproductive system and breast disorders					
-Total	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Oedema genital	1 (7.1)	0	1 (7.1)	0	0
Vaginal haemorrhage	1 (7.1)	0	0	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (50.0)	1 (7.1)	2 (14.3)	0	4 (28.6)
Epistaxis	4 (28.6)	1 (7.1)	3 (21.4)	0	0
Hypoxia	4 (28.6)	0	0	2 (14.3)	2 (14.3)
Dyspnoea	3 (21.4)	0	1 (7.1)	1 (7.1)	1 (7.1)
Pleural effusion	3 (21.4)	0	3 (21.4)	0	0

Age: >=18

	All patients N=14				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Pulmonary oedema	2 (14.3)	0	0	0	2 (14.3)
Aspiration	1 (7.1)	0	0	0	1 (7.1)
Atelectasis	1 (7.1)	0	1 (7.1)	0	0
Haemoptysis	1 (7.1)	0	0	1 (7.1)	0
Interstitial lung disease	1 (7.1)	0	0	0	1 (7.1)
Oropharyngeal pain	1 (7.1)	0	0	1 (7.1)	0
Pulmonary alveolar haemorrhage	1 (7.1)	0	0	0	1 (7.1)
Pulmonary hypertension	1 (7.1)	0	0	1 (7.1)	0
Respiratory distress	1 (7.1)	0	0	0	1 (7.1)
Rhinitis allergic	1 (7.1)	1 (7.1)	0	0	0
Tachypnoea	1 (7.1)	0	0	1 (7.1)	0
Skin and subcutaneous tissue disorders					
-Total	4 (28.6)	1 (7.1)	2 (14.3)	1 (7.1)	0
Alopecia	1 (7.1)	0	1 (7.1)	0	0
Erythema	1 (7.1)	1 (7.1)	0	0	0
Hyperhidrosis	1 (7.1)	1 (7.1)	0	0	0

Age: >=18

Primary system organ class Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ingrowing nail	1 (7.1)	0	1 (7.1)	0	0
Petechiae	1 (7.1)	0	1 (7.1)	0	0
Pruritus	1 (7.1)	1 (7.1)	0	0	0
Rash	1 (7.1)	1 (7.1)	0	0	0
Rash erythematous	1 (7.1)	0	1 (7.1)	0	0
Rash maculo-papular	1 (7.1)	0	0	1 (7.1)	0
Skin haemorrhage	1 (7.1)	1 (7.1)	0	0	0
Vascular disorders					
-Total	8 (57.1)	0	3 (21.4)	2 (14.3)	3 (21.4)
Hypertension	5 (35.7)	0	5 (35.7)	0	0
Hypotension	5 (35.7)	0	0	2 (14.3)	3 (21.4)
Orthostatic hypotension	1 (7.1)	1 (7.1)	0	0	0
Phlebitis	1 (7.1)	0	1 (7.1)	0	0
Venous thrombosis limb	1 (7.1)	1 (7.1)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178b
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (95.0)	0	3 (7.5)	8 (20.0)	27 (67.5)
Blood and lymphatic system disorders					
-Total	30 (75.0)	0	0	19 (47.5)	11 (27.5)
Anaemia	18 (45.0)	2 (5.0)	3 (7.5)	13 (32.5)	0
Febrile neutropenia	18 (45.0)	0	0	18 (45.0)	0
Neutropenia	9 (22.5)	0	0	3 (7.5)	6 (15.0)
Thrombocytopenia	8 (20.0)	0	0	2 (5.0)	6 (15.0)
Disseminated intravascular coagulation	4 (10.0)	0	1 (2.5)	2 (5.0)	1 (2.5)
Lymphopenia	3 (7.5)	0	0	1 (2.5)	2 (5.0)
Eosinophilia	1 (2.5)	0	0	1 (2.5)	0
Leukopenia	1 (2.5)	0	0	0	1 (2.5)

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pancytopenia	1 (2.5)	0	0	1 (2.5)	0
Cardiac disorders					
-Total	14 (35.0)	5 (12.5)	4 (10.0)	3 (7.5)	2 (5.0)
Tachycardia	8 (20.0)	3 (7.5)	3 (7.5)	2 (5.0)	0
Bradycardia	3 (7.5)	1 (2.5)	1 (2.5)	0	1 (2.5)
Palpitations	2 (5.0)	2 (5.0)	0	0	0
Sinus tachycardia	2 (5.0)	0	0	2 (5.0)	0
Cardiovascular insufficiency	1 (2.5)	0	0	0	1 (2.5)
Left ventricular dysfunction	1 (2.5)	0	0	1 (2.5)	0
Pericardial effusion	1 (2.5)	0	1 (2.5)	0	0
Right ventricular dysfunction	1 (2.5)	0	0	1 (2.5)	0
Sinus bradycardia	1 (2.5)	1 (2.5)	0	0	0
Ventricular tachycardia	1 (2.5)	0	0	1 (2.5)	0
Ear and labyrinth disorders					
-Total	2 (5.0)	0	2 (5.0)	0	0
Hypoacusis	1 (2.5)	0	1 (2.5)	0	0
Tympanic membrane perforation	1 (2.5)	0	1 (2.5)	0	0
Endocrine disorders					

Gender: Male

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Adrenal insufficiency	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Hyperthyroidism	1 (2.5)	0	1 (2.5)	0	0
Eye disorders					
-Total	8 (20.0)	5 (12.5)	3 (7.5)	0	0
Eye pain	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Periorbital oedema	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Vision blurred	2 (5.0)	2 (5.0)	0	0	0
Conjunctival haemorrhage	1 (2.5)	1 (2.5)	0	0	0
Ocular hyperaemia	1 (2.5)	1 (2.5)	0	0	0
Photophobia	1 (2.5)	0	1 (2.5)	0	0
Retinal haemorrhage	1 (2.5)	1 (2.5)	0	0	0
Gastrointestinal disorders					
-Total	23 (57.5)	5 (12.5)	8 (20.0)	10 (25.0)	0
Vomiting	13 (32.5)	9 (22.5)	3 (7.5)	1 (2.5)	0
Nausea	11 (27.5)	4 (10.0)	5 (12.5)	2 (5.0)	0
Diarrhoea	7 (17.5)	3 (7.5)	4 (10.0)	0	0
Abdominal pain	6 (15.0)	3 (7.5)	2 (5.0)	1 (2.5)	0

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Colitis	3 (7.5)	1 (2.5)	0	2 (5.0)	0
Oral pain	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Gastrointestinal haemorrhage	2 (5.0)	2 (5.0)	0	0	0
Haematemesis	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Pancreatitis	2 (5.0)	0	2 (5.0)	0	0
Stomatitis	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Abdominal distension	1 (2.5)	0	1 (2.5)	0	0
Abdominal pain upper	1 (2.5)	1 (2.5)	0	0	0
Anal incontinence	1 (2.5)	1 (2.5)	0	0	0
Ascites	1 (2.5)	0	0	1 (2.5)	0
Constipation	1 (2.5)	1 (2.5)	0	0	0
Dry mouth	1 (2.5)	1 (2.5)	0	0	0
Dysphagia	1 (2.5)	0	0	1 (2.5)	0
Enterocolitis	1 (2.5)	0	0	1 (2.5)	0
Gingival discomfort	1 (2.5)	1 (2.5)	0	0	0
Haematochezia	1 (2.5)	0	0	1 (2.5)	0
Ileus	1 (2.5)	0	0	1 (2.5)	0
Mouth haemorrhage	1 (2.5)	0	0	1 (2.5)	0

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pancreatic failure	1 (2.5)	0	1 (2.5)	0	0
Perianal erythema	1 (2.5)	0	1 (2.5)	0	0
Pigmentation lip	1 (2.5)	1 (2.5)	0	0	0
General disorders and administration site conditions					
-Total	25 (62.5)	6 (15.0)	8 (20.0)	8 (20.0)	3 (7.5)
Pyrexia	14 (35.0)	2 (5.0)	8 (20.0)	4 (10.0)	0
Pain	6 (15.0)	1 (2.5)	2 (5.0)	3 (7.5)	0
Chills	5 (12.5)	5 (12.5)	0	0	0
Fatigue	4 (10.0)	3 (7.5)	0	1 (2.5)	0
Multiple organ dysfunction syndrome	4 (10.0)	0	0	1 (2.5)	3 (7.5)
Catheter site pain	2 (5.0)	0	2 (5.0)	0	0
Face oedema	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Generalised oedema	2 (5.0)	0	2 (5.0)	0	0
Non-cardiac chest pain	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Acquired gene mutation	1 (2.5)	1 (2.5)	0	0	0
Asthenia	1 (2.5)	1 (2.5)	0	0	0
Catheter site extravasation	1 (2.5)	0	1 (2.5)	0	0

Gender: Male

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza like illness	1 (2.5)	1 (2.5)	0	0	0
Localised oedema	1 (2.5)	0	0	1 (2.5)	0
Malaise	1 (2.5)	0	1 (2.5)	0	0
Mucosal haemorrhage	1 (2.5)	0	1 (2.5)	0	0
Oedema peripheral	1 (2.5)	0	0	1 (2.5)	0
Peripheral swelling	1 (2.5)	0	1 (2.5)	0	0
Hepatobiliary disorders					
-Total	6 (15.0)	1 (2.5)	2 (5.0)	2 (5.0)	1 (2.5)
Hepatomegaly	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Hyperbilirubinaemia	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Hepatic failure	1 (2.5)	0	0	0	1 (2.5)
Immune system disorders					
-Total	28 (70.0)	5 (12.5)	13 (32.5)	4 (10.0)	6 (15.0)
Cytokine release syndrome	23 (57.5)	4 (10.0)	10 (25.0)	3 (7.5)	6 (15.0)
Hypogammaglobulinaemia	17 (42.5)	2 (5.0)	13 (32.5)	2 (5.0)	0
Graft versus host disease	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Chronic graft versus host disease	1 (2.5)	0	1 (2.5)	0	0
Drug hypersensitivity	1 (2.5)	0	1 (2.5)	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Graft versus host disease in skin	1 (2.5)	1 (2.5)	0	0	0
Seasonal allergy	1 (2.5)	1 (2.5)	0	0	0
Infections and infestations					
-Total	25 (62.5)	2 (5.0)	10 (25.0)	8 (20.0)	5 (12.5)
Upper respiratory tract infection	6 (15.0)	2 (5.0)	4 (10.0)	0	0
Gastroenteritis	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Otitis media	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Pneumonia	3 (7.5)	0	2 (5.0)	0	1 (2.5)
Sinusitis	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Viral infection	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Influenza	2 (5.0)	0	2 (5.0)	0	0
Respiratory syncytial virus infection	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Viral upper respiratory tract infection	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Acute sinusitis	1 (2.5)	0	1 (2.5)	0	0
Body tinea	1 (2.5)	1 (2.5)	0	0	0
Bronchitis	1 (2.5)	0	1 (2.5)	0	0
Candida sepsis	1 (2.5)	0	0	0	1 (2.5)

Gender: Male

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (2.5)	0	0	1 (2.5)	0
Cholecystitis infective	1 (2.5)	0	0	1 (2.5)	0
Clostridium difficile colitis	1 (2.5)	0	0	1 (2.5)	0
Clostridium difficile infection	1 (2.5)	0	1 (2.5)	0	0
Conjunctivitis	1 (2.5)	0	1 (2.5)	0	0
Corona virus infection	1 (2.5)	0	0	1 (2.5)	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Escherichia bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Fungal skin infection	1 (2.5)	1 (2.5)	0	0	0
Gingivitis	1 (2.5)	1 (2.5)	0	0	0
Haemophilus infection	1 (2.5)	0	1 (2.5)	0	0
Herpes zoster	1 (2.5)	0	0	1 (2.5)	0
Klebsiella sepsis	1 (2.5)	0	0	0	1 (2.5)
Metapneumovirus infection	1 (2.5)	0	1 (2.5)	0	0
Orchitis	1 (2.5)	1 (2.5)	0	0	0
Otitis media acute	1 (2.5)	0	1 (2.5)	0	0
Parainfluenzae virus infection	1 (2.5)	1 (2.5)	0	0	0

Gender: Male

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis	1 (2.5)	0	1 (2.5)	0	0
Rash pustular	1 (2.5)	0	1 (2.5)	0	0
Rhinovirus infection	1 (2.5)	1 (2.5)	0	0	0
Sepsis	1 (2.5)	0	0	0	1 (2.5)
Skin infection	1 (2.5)	0	1 (2.5)	0	0
Staphylococcal bacteraemia	1 (2.5)	0	0	1 (2.5)	0
Staphylococcal infection	1 (2.5)	0	0	0	1 (2.5)
Streptococcal infection	1 (2.5)	0	1 (2.5)	0	0
Subcutaneous abscess	1 (2.5)	0	1 (2.5)	0	0
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0
Injury, poisoning and procedural complications					
-Total	10 (25.0)	3 (7.5)	5 (12.5)	2 (5.0)	0
Infusion related reaction	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Radiation skin injury	2 (5.0)	0	2 (5.0)	0	0
Contusion	1 (2.5)	1 (2.5)	0	0	0
Extradural haematoma	1 (2.5)	0	0	1 (2.5)	0
Foot fracture	1 (2.5)	0	1 (2.5)	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Mouth injury	1 (2.5)	1 (2.5)	0	0	0
Procedural complication	1 (2.5)	1 (2.5)	0	0	0
Procedural headache	1 (2.5)	0	1 (2.5)	0	0
Procedural nausea	1 (2.5)	0	1 (2.5)	0	0
Skin abrasion	1 (2.5)	1 (2.5)	0	0	0
Skin laceration	1 (2.5)	0	1 (2.5)	0	0
Subdural haematoma	1 (2.5)	0	0	1 (2.5)	0
Sunburn	1 (2.5)	1 (2.5)	0	0	0
Tongue injury	1 (2.5)	1 (2.5)	0	0	0
Tracheal haemorrhage	1 (2.5)	0	0	1 (2.5)	0
Investigations					
-Total	27 (67.5)	1 (2.5)	3 (7.5)	5 (12.5)	18 (45.0)
White blood cell count decreased	19 (47.5)	3 (7.5)	0	3 (7.5)	13 (32.5)
Neutrophil count decreased	14 (35.0)	1 (2.5)	1 (2.5)	2 (5.0)	10 (25.0)
Aspartate aminotransferase increased	10 (25.0)	0	2 (5.0)	4 (10.0)	4 (10.0)
Alanine aminotransferase increased	9 (22.5)	1 (2.5)	1 (2.5)	6 (15.0)	1 (2.5)
Platelet count decreased	8 (20.0)	2 (5.0)	1 (2.5)	1 (2.5)	4 (10.0)

Gender: Male

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	7 (17.5)	1 (2.5)	2 (5.0)	2 (5.0)	2 (5.0)
Blood bilirubin increased	6 (15.0)	2 (5.0)	0	3 (7.5)	1 (2.5)
International normalised ratio increased	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Activated partial thromboplastin time prolonged	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Blood creatinine increased	4 (10.0)	2 (5.0)	0	2 (5.0)	0
Blood fibrinogen decreased	2 (5.0)	0	1 (2.5)	0	1 (2.5)
Blood immunoglobulin m decreased	2 (5.0)	2 (5.0)	0	0	0
Blood phosphorus increased	2 (5.0)	2 (5.0)	0	0	0
Blood urea increased	2 (5.0)	0	1 (2.5)	1 (2.5)	0
C-reactive protein increased	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Electrocardiogram qt prolonged	2 (5.0)	0	0	2 (5.0)	0
Prothrombin time prolonged	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Blood bicarbonate decreased	1 (2.5)	0	1 (2.5)	0	0
Blood immunoglobulin a decreased	1 (2.5)	1 (2.5)	0	0	0
Blood lactate dehydrogenase increased	1 (2.5)	0	0	1 (2.5)	0
Blood lactic acid increased	1 (2.5)	0	1 (2.5)	0	0

Gender: Male

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood magnesium decreased	1 (2.5)	1 (2.5)	0	0	0
Blood phosphorus decreased	1 (2.5)	1 (2.5)	0	0	0
Blood uric acid increased	1 (2.5)	1 (2.5)	0	0	0
Cardiac murmur	1 (2.5)	1 (2.5)	0	0	0
Computerised tomogram thorax abnormal	1 (2.5)	0	0	1 (2.5)	0
Fibrin d dimer increased	1 (2.5)	1 (2.5)	0	0	0
Lipase increased	1 (2.5)	0	0	0	1 (2.5)
Norovirus test positive	1 (2.5)	1 (2.5)	0	0	0
Protein total decreased	1 (2.5)	0	0	1 (2.5)	0
Serum ferritin increased	1 (2.5)	0	1 (2.5)	0	0
Transaminases increased	1 (2.5)	1 (2.5)	0	0	0
Weight decreased	1 (2.5)	1 (2.5)	0	0	0
Weight increased	1 (2.5)	1 (2.5)	0	0	0
Metabolism and nutrition disorders					
-Total	21 (52.5)	4 (10.0)	3 (7.5)	11 (27.5)	3 (7.5)
Decreased appetite	11 (27.5)	2 (5.0)	3 (7.5)	6 (15.0)	0
Hypokalaemia	10 (25.0)	4 (10.0)	1 (2.5)	3 (7.5)	2 (5.0)

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypophosphataemia	7 (17.5)	2 (5.0)	0	5 (12.5)	0
Fluid overload	4 (10.0)	0	3 (7.5)	1 (2.5)	0
Hyperglycaemia	3 (7.5)	0	2 (5.0)	1 (2.5)	0
Hypernatraemia	3 (7.5)	0	1 (2.5)	0	2 (5.0)
Hyperphosphataemia	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Hypoalbuminaemia	3 (7.5)	0	3 (7.5)	0	0
Hyperkalaemia	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Hyperuricaemia	2 (5.0)	1 (2.5)	0	0	1 (2.5)
Hypocalcaemia	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Vitamin d deficiency	2 (5.0)	2 (5.0)	0	0	0
Acidosis	1 (2.5)	0	0	1 (2.5)	0
Dehydration	1 (2.5)	0	0	1 (2.5)	0
Hyperalbuminaemia	1 (2.5)	1 (2.5)	0	0	0
Hypercalcaemia	1 (2.5)	1 (2.5)	0	0	0
Hyperchloraemia	1 (2.5)	1 (2.5)	0	0	0
Hypermagnesaemia	1 (2.5)	1 (2.5)	0	0	0
Hypertriglyceridaemia	1 (2.5)	0	0	1 (2.5)	0
Hypoglycaemia	1 (2.5)	0	1 (2.5)	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypomagnesaemia	1 (2.5)	0	1 (2.5)	0	0
Hyponatraemia	1 (2.5)	0	0	1 (2.5)	0
Iron overload	1 (2.5)	0	0	1 (2.5)	0
Malnutrition	1 (2.5)	0	1 (2.5)	0	0
Metabolic alkalosis	1 (2.5)	1 (2.5)	0	0	0
Tumour lysis syndrome	1 (2.5)	0	0	1 (2.5)	0
Musculoskeletal and connective tissue disorders					
-Total	15 (37.5)	6 (15.0)	6 (15.0)	3 (7.5)	0
Arthralgia	4 (10.0)	2 (5.0)	0	2 (5.0)	0
Muscle spasms	3 (7.5)	3 (7.5)	0	0	0
Pain in extremity	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Back pain	2 (5.0)	1 (2.5)	0	1 (2.5)	0
Muscular weakness	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Myalgia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Neck pain	2 (5.0)	0	2 (5.0)	0	0
Pain in jaw	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Bone pain	1 (2.5)	0	0	1 (2.5)	0

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Joint range of motion decreased	1 (2.5)	1 (2.5)	0	0	0
Musculoskeletal chest pain	1 (2.5)	1 (2.5)	0	0	0
Musculoskeletal pain	1 (2.5)	1 (2.5)	0	0	0
Osteonecrosis	1 (2.5)	0	1 (2.5)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.5)	0	0	0	1 (2.5)
Glioblastoma multiforme	1 (2.5)	0	0	0	1 (2.5)
Nervous system disorders					
-Total	20 (50.0)	8 (20.0)	8 (20.0)	3 (7.5)	1 (2.5)
Headache	12 (30.0)	7 (17.5)	2 (5.0)	3 (7.5)	0
Seizure	3 (7.5)	0	1 (2.5)	1 (2.5)	1 (2.5)
Encephalopathy	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Peroneal nerve palsy	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Somnolence	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Disturbance in attention	1 (2.5)	1 (2.5)	0	0	0
Dizziness	1 (2.5)	1 (2.5)	0	0	0
Dysarthria	1 (2.5)	0	1 (2.5)	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyporesponsive to stimuli	1 (2.5)	0	0	1 (2.5)	0
Hypotonia	1 (2.5)	0	1 (2.5)	0	0
Psychiatric disorders					
-Total	13 (32.5)	3 (7.5)	7 (17.5)	3 (7.5)	0
Confusional state	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Anxiety	3 (7.5)	1 (2.5)	2 (5.0)	0	0
Delirium	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Insomnia	3 (7.5)	0	3 (7.5)	0	0
Mental status changes	3 (7.5)	2 (5.0)	0	1 (2.5)	0
Agitation	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Depression	2 (5.0)	2 (5.0)	0	0	0
Irritability	2 (5.0)	2 (5.0)	0	0	0
Hallucination	1 (2.5)	0	1 (2.5)	0	0
Listless	1 (2.5)	1 (2.5)	0	0	0
Sleep disorder	1 (2.5)	0	1 (2.5)	0	0
Renal and urinary disorders					
-Total	8 (20.0)	1 (2.5)	2 (5.0)	2 (5.0)	3 (7.5)
Acute kidney injury	5 (12.5)	0	1 (2.5)	1 (2.5)	3 (7.5)

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haematuria	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Oliguria	2 (5.0)	0	0	2 (5.0)	0
Dysuria	1 (2.5)	1 (2.5)	0	0	0
Renal impairment	1 (2.5)	0	0	1 (2.5)	0
Urinary retention	1 (2.5)	0	1 (2.5)	0	0
Reproductive system and breast disorders					
-Total	1 (2.5)	0	1 (2.5)	0	0
Scrotal pain	1 (2.5)	0	1 (2.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	22 (55.0)	5 (12.5)	6 (15.0)	5 (12.5)	6 (15.0)
Hypoxia	9 (22.5)	0	2 (5.0)	5 (12.5)	2 (5.0)
Epistaxis	8 (20.0)	1 (2.5)	3 (7.5)	4 (10.0)	0
Cough	7 (17.5)	4 (10.0)	2 (5.0)	1 (2.5)	0
Pleural effusion	7 (17.5)	1 (2.5)	4 (10.0)	2 (5.0)	0
Pulmonary oedema	6 (15.0)	0	0	3 (7.5)	3 (7.5)
Tachypnoea	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Dyspnoea	3 (7.5)	0	0	2 (5.0)	1 (2.5)

Gender: Male

	All patients N=40				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	3 (7.5)	3 (7.5)	0	0	0
Oropharyngeal pain	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Respiratory distress	2 (5.0)	0	0	0	2 (5.0)
Rhinorrhoea	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Aspiration	1 (2.5)	0	0	0	1 (2.5)
Atelectasis	1 (2.5)	1 (2.5)	0	0	0
Dysphonia	1 (2.5)	1 (2.5)	0	0	0
Haemoptysis	1 (2.5)	0	0	1 (2.5)	0
Interstitial lung disease	1 (2.5)	0	0	0	1 (2.5)
Oropharyngeal plaque	1 (2.5)	1 (2.5)	0	0	0
Pharyngeal erythema	1 (2.5)	1 (2.5)	0	0	0
Pharyngeal lesion	1 (2.5)	0	0	1 (2.5)	0
Pharyngeal ulceration	1 (2.5)	0	1 (2.5)	0	0
Pulmonary alveolar haemorrhage	1 (2.5)	0	0	0	1 (2.5)
Pulmonary hypertension	1 (2.5)	0	0	1 (2.5)	0
Respiratory depression	1 (2.5)	0	1 (2.5)	0	0
Respiratory failure	1 (2.5)	0	0	0	1 (2.5)
Rhinitis allergic	1 (2.5)	1 (2.5)	0	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	20 (50.0)	11 (27.5)	6 (15.0)	3 (7.5)	0
Erythema	4 (10.0)	4 (10.0)	0	0	0
Rash maculo-papular	4 (10.0)	3 (7.5)	0	1 (2.5)	0
Rash	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Alopecia	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Dermatitis acneiform	2 (5.0)	0	1 (2.5)	1 (2.5)	0
Hyperhidrosis	2 (5.0)	2 (5.0)	0	0	0
Ingrowing nail	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Papule	2 (5.0)	2 (5.0)	0	0	0
Rash erythematous	2 (5.0)	0	2 (5.0)	0	0
Rash papular	2 (5.0)	2 (5.0)	0	0	0
Acne	1 (2.5)	1 (2.5)	0	0	0
Dermatitis diaper	1 (2.5)	1 (2.5)	0	0	0
Dry skin	1 (2.5)	1 (2.5)	0	0	0
Keloid scar	1 (2.5)	0	1 (2.5)	0	0
Livedo reticularis	1 (2.5)	1 (2.5)	0	0	0

Gender: Male

Primary system organ class Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Macule	1 (2.5)	1 (2.5)	0	0	0
Night sweats	1 (2.5)	0	1 (2.5)	0	0
Pruritus	1 (2.5)	1 (2.5)	0	0	0
Pruritus generalised	1 (2.5)	1 (2.5)	0	0	0
Rash macular	1 (2.5)	0	0	1 (2.5)	0
Skin irritation	1 (2.5)	1 (2.5)	0	0	0
Vascular disorders					
-Total	18 (45.0)	1 (2.5)	2 (5.0)	8 (20.0)	7 (17.5)
Hypotension	15 (37.5)	0	0	8 (20.0)	7 (17.5)
Hypertension	10 (25.0)	3 (7.5)	6 (15.0)	1 (2.5)	0
Capillary leak syndrome	1 (2.5)	0	0	0	1 (2.5)
Flushing	1 (2.5)	1 (2.5)	0	0	0
Hot flush	1 (2.5)	1 (2.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178b
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (97.1)	0	0	4 (11.4)	30 (85.7)
Blood and lymphatic system disorders					
-Total	31 (88.6)	1 (2.9)	2 (5.7)	16 (45.7)	12 (34.3)
Febrile neutropenia	18 (51.4)	0	0	17 (48.6)	1 (2.9)
Anaemia	17 (48.6)	0	3 (8.6)	13 (37.1)	1 (2.9)
Neutropenia	7 (20.0)	0	0	1 (2.9)	6 (17.1)
Thrombocytopenia	7 (20.0)	0	1 (2.9)	3 (8.6)	3 (8.6)
Lymphopenia	3 (8.6)	0	2 (5.7)	0	1 (2.9)
Pancytopenia	3 (8.6)	0	0	0	3 (8.6)
Coagulopathy	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Disseminated intravascular coagulation	2 (5.7)	0	1 (2.9)	1 (2.9)	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypofibrinogenaemia	1 (2.9)	0	0	0	1 (2.9)
Leukocytosis	1 (2.9)	1 (2.9)	0	0	0
Lymphadenopathy	1 (2.9)	0	1 (2.9)	0	0
Splenomegaly	1 (2.9)	1 (2.9)	0	0	0
Cardiac disorders					
-Total	14 (40.0)	6 (17.1)	6 (17.1)	2 (5.7)	0
Tachycardia	9 (25.7)	6 (17.1)	3 (8.6)	0	0
Sinus tachycardia	5 (14.3)	3 (8.6)	2 (5.7)	0	0
Left ventricular dysfunction	2 (5.7)	0	0	2 (5.7)	0
Pericardial effusion	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Atrioventricular block second degree	1 (2.9)	1 (2.9)	0	0	0
Cardiac dysfunction	1 (2.9)	1 (2.9)	0	0	0
Ventricular tachycardia	1 (2.9)	0	1 (2.9)	0	0
Ear and labyrinth disorders					
-Total	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Ear pain	2 (5.7)	2 (5.7)	0	0	0
Deafness unilateral	1 (2.9)	0	1 (2.9)	0	0
Endocrine disorders					

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Adrenal insufficiency	1 (2.9)	0	1 (2.9)	0	0
Cushingoid	1 (2.9)	1 (2.9)	0	0	0
Eye disorders					
-Total	12 (34.3)	6 (17.1)	6 (17.1)	0	0
Conjunctival haemorrhage	2 (5.7)	2 (5.7)	0	0	0
Dry eye	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Periorbital oedema	2 (5.7)	2 (5.7)	0	0	0
Photophobia	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Uveitis	2 (5.7)	0	2 (5.7)	0	0
Vision blurred	2 (5.7)	0	2 (5.7)	0	0
Conjunctivitis allergic	1 (2.9)	1 (2.9)	0	0	0
Eye irritation	1 (2.9)	1 (2.9)	0	0	0
Eye pain	1 (2.9)	0	1 (2.9)	0	0
Ocular hypertension	1 (2.9)	0	1 (2.9)	0	0
Papilloedema	1 (2.9)	0	1 (2.9)	0	0
Retinal haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Retinopathy	1 (2.9)	0	1 (2.9)	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Visual impairment	1 (2.9)	0	1 (2.9)	0	0
Gastrointestinal disorders					
-Total	30 (85.7)	7 (20.0)	12 (34.3)	10 (28.6)	1 (2.9)
Nausea	22 (62.9)	5 (14.3)	12 (34.3)	5 (14.3)	0
Diarrhoea	19 (54.3)	11 (31.4)	6 (17.1)	2 (5.7)	0
Vomiting	17 (48.6)	8 (22.9)	6 (17.1)	3 (8.6)	0
Abdominal pain	11 (31.4)	4 (11.4)	5 (14.3)	2 (5.7)	0
Constipation	10 (28.6)	8 (22.9)	2 (5.7)	0	0
Stomatitis	3 (8.6)	1 (2.9)	0	1 (2.9)	1 (2.9)
Abdominal pain lower	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Abdominal pain upper	2 (5.7)	0	2 (5.7)	0	0
Abdominal discomfort	1 (2.9)	1 (2.9)	0	0	0
Abdominal distension	1 (2.9)	0	1 (2.9)	0	0
Abdominal tenderness	1 (2.9)	1 (2.9)	0	0	0
Anal fissure	1 (2.9)	0	1 (2.9)	0	0
Ascites	1 (2.9)	0	0	1 (2.9)	0
Colitis	1 (2.9)	0	0	1 (2.9)	0
Dyspepsia	1 (2.9)	0	1 (2.9)	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysphagia	1 (2.9)	0	1 (2.9)	0	0
Flatulence	1 (2.9)	1 (2.9)	0	0	0
Gastrooesophageal reflux disease	1 (2.9)	1 (2.9)	0	0	0
Glossodynia	1 (2.9)	1 (2.9)	0	0	0
Haematochezia	1 (2.9)	1 (2.9)	0	0	0
Intestinal obstruction	1 (2.9)	0	0	1 (2.9)	0
Lip pain	1 (2.9)	0	1 (2.9)	0	0
Oral mucosal blistering	1 (2.9)	1 (2.9)	0	0	0
Pancreatitis	1 (2.9)	0	0	1 (2.9)	0
Proctalgia	1 (2.9)	0	1 (2.9)	0	0
Tooth socket haemorrhage	1 (2.9)	1 (2.9)	0	0	0
General disorders and administration site conditions					
-Total	27 (77.1)	10 (28.6)	10 (28.6)	6 (17.1)	1 (2.9)
Pyrexia	18 (51.4)	7 (20.0)	7 (20.0)	3 (8.6)	1 (2.9)
Fatigue	14 (40.0)	10 (28.6)	3 (8.6)	1 (2.9)	0
Chills	6 (17.1)	4 (11.4)	2 (5.7)	0	0
Catheter site pain	5 (14.3)	3 (8.6)	2 (5.7)	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oedema peripheral	4 (11.4)	3 (8.6)	1 (2.9)	0	0
Malaise	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Generalised oedema	2 (5.7)	2 (5.7)	0	0	0
Physical deconditioning	2 (5.7)	0	0	2 (5.7)	0
Catheter site haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Crying	1 (2.9)	1 (2.9)	0	0	0
Cyst	1 (2.9)	0	0	1 (2.9)	0
Device related thrombosis	1 (2.9)	0	1 (2.9)	0	0
Facial pain	1 (2.9)	0	1 (2.9)	0	0
Gait disturbance	1 (2.9)	1 (2.9)	0	0	0
Influenza like illness	1 (2.9)	1 (2.9)	0	0	0
Injection site haematoma	1 (2.9)	1 (2.9)	0	0	0
Medical device pain	1 (2.9)	0	1 (2.9)	0	0
Pain	1 (2.9)	0	1 (2.9)	0	0
Hepatobiliary disorders					
-Total	5 (14.3)	2 (5.7)	1 (2.9)	2 (5.7)	0
Hyperbilirubinaemia	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Cholecystitis	1 (2.9)	0	0	1 (2.9)	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gallbladder enlargement	1 (2.9)	1 (2.9)	0	0	0
Hepatic steatosis	1 (2.9)	0	1 (2.9)	0	0
Hepatosplenomegaly	1 (2.9)	1 (2.9)	0	0	0
Immune system disorders					
-Total	31 (88.6)	1 (2.9)	18 (51.4)	7 (20.0)	5 (14.3)
Cytokine release syndrome	27 (77.1)	2 (5.7)	15 (42.9)	5 (14.3)	5 (14.3)
Hypogammaglobulinaemia	16 (45.7)	2 (5.7)	11 (31.4)	3 (8.6)	0
Immunodeficiency common variable	2 (5.7)	0	2 (5.7)	0	0
Graft versus host disease in gastrointestinal tract	1 (2.9)	0	1 (2.9)	0	0
Haemophagocytic lymphohistiocytosis	1 (2.9)	0	1 (2.9)	0	0
Immunodeficiency	1 (2.9)	0	1 (2.9)	0	0
Seasonal allergy	1 (2.9)	1 (2.9)	0	0	0
Infections and infestations					
-Total	27 (77.1)	2 (5.7)	6 (17.1)	13 (37.1)	6 (17.1)
Clostridium difficile infection	5 (14.3)	0	4 (11.4)	1 (2.9)	0
Rhinovirus infection	5 (14.3)	4 (11.4)	1 (2.9)	0	0
Upper respiratory tract infection	5 (14.3)	3 (8.6)	1 (2.9)	1 (2.9)	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile colitis	4 (11.4)	1 (2.9)	2 (5.7)	1 (2.9)	0
Pneumonia	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Urinary tract infection	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Device related infection	3 (8.6)	0	1 (2.9)	2 (5.7)	0
Escherichia urinary tract infection	3 (8.6)	0	1 (2.9)	2 (5.7)	0
Parainfluenzae virus infection	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Cytomegalovirus infection	2 (5.7)	2 (5.7)	0	0	0
Ear infection	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Gastroenteritis	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Influenza	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Oral herpes	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Sinusitis	2 (5.7)	0	2 (5.7)	0	0
Staphylococcal infection	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Viral upper respiratory tract infection	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Vulvovaginal candidiasis	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Abscess limb	1 (2.9)	0	0	1 (2.9)	0
Bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Bacterial sepsis	1 (2.9)	0	0	0	1 (2.9)

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchopulmonary aspergillosis	1 (2.9)	0	0	1 (2.9)	0
Campylobacter infection	1 (2.9)	0	0	1 (2.9)	0
Catheter site cellulitis	1 (2.9)	1 (2.9)	0	0	0
Catheter site infection	1 (2.9)	0	0	1 (2.9)	0
Cellulitis	1 (2.9)	0	0	1 (2.9)	0
Croup infectious	1 (2.9)	0	0	1 (2.9)	0
Enterococcal infection	1 (2.9)	1 (2.9)	0	0	0
Enterovirus infection	1 (2.9)	0	0	1 (2.9)	0
Escherichia bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Escherichia sepsis	1 (2.9)	0	0	0	1 (2.9)
Folliculitis	1 (2.9)	0	1 (2.9)	0	0
Fungal skin infection	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis norovirus	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis viral	1 (2.9)	1 (2.9)	0	0	0
Herpes simplex	1 (2.9)	1 (2.9)	0	0	0
Human herpesvirus 6 infection	1 (2.9)	0	1 (2.9)	0	0
Human polyomavirus infection	1 (2.9)	0	0	0	1 (2.9)
Hypopyon	1 (2.9)	0	1 (2.9)	0	0

Gender: Female

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Meningitis aseptic	1 (2.9)	0	1 (2.9)	0	0
Molluscum contagiosum	1 (2.9)	1 (2.9)	0	0	0
Necrotising fasciitis	1 (2.9)	0	0	1 (2.9)	0
Oral candidiasis	1 (2.9)	1 (2.9)	0	0	0
Otitis externa	1 (2.9)	0	1 (2.9)	0	0
Otitis media	1 (2.9)	0	1 (2.9)	0	0
Otitis media acute	1 (2.9)	0	1 (2.9)	0	0
Paronychia	1 (2.9)	1 (2.9)	0	0	0
Pneumonia fungal	1 (2.9)	0	1 (2.9)	0	0
Respiratory syncytial virus bronchitis	1 (2.9)	0	0	1 (2.9)	0
Respiratory tract infection	1 (2.9)	0	0	0	1 (2.9)
Respiratory tract infection viral	1 (2.9)	0	0	1 (2.9)	0
Rhinitis	1 (2.9)	1 (2.9)	0	0	0
Rotavirus infection	1 (2.9)	0	0	1 (2.9)	0
Sepsis	1 (2.9)	0	0	0	1 (2.9)
Septic embolus	1 (2.9)	0	0	0	1 (2.9)
Skin infection	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal bacteraemia	1 (2.9)	0	0	1 (2.9)	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal scalded skin syndrome	1 (2.9)	0	1 (2.9)	0	0
Staphylococcal sepsis	1 (2.9)	0	0	0	1 (2.9)
Streptococcal bacteraemia	1 (2.9)	0	0	1 (2.9)	0
Tinea capitis	1 (2.9)	1 (2.9)	0	0	0
Urinary tract infection enterococcal	1 (2.9)	0	0	1 (2.9)	0
Vascular device infection	1 (2.9)	0	0	1 (2.9)	0
Vulvovaginal mycotic infection	1 (2.9)	0	1 (2.9)	0	0
Injury, poisoning and procedural complications					
-Total	16 (45.7)	9 (25.7)	5 (14.3)	1 (2.9)	1 (2.9)
Procedural pain	5 (14.3)	2 (5.7)	2 (5.7)	1 (2.9)	0
Transfusion reaction	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Contusion	2 (5.7)	2 (5.7)	0	0	0
Infusion related reaction	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Arthropod bite	1 (2.9)	1 (2.9)	0	0	0
Incision site pain	1 (2.9)	1 (2.9)	0	0	0
Limb injury	1 (2.9)	1 (2.9)	0	0	0
Post procedural haemorrhage	1 (2.9)	1 (2.9)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Procedural site reaction	1 (2.9)	1 (2.9)	0	0	0
Radius fracture	1 (2.9)	0	1 (2.9)	0	0
Skin abrasion	1 (2.9)	1 (2.9)	0	0	0
Stoma site irritation	1 (2.9)	1 (2.9)	0	0	0
Subdural haematoma	1 (2.9)	0	1 (2.9)	0	0
Subdural haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Tibia fracture	1 (2.9)	0	1 (2.9)	0	0
Transfusion related complication	1 (2.9)	0	0	0	1 (2.9)
Wound	1 (2.9)	1 (2.9)	0	0	0
Investigations					
-Total	31 (88.6)	0	1 (2.9)	7 (20.0)	23 (65.7)
White blood cell count decreased	23 (65.7)	1 (2.9)	1 (2.9)	5 (14.3)	16 (45.7)
Neutrophil count decreased	18 (51.4)	0	1 (2.9)	1 (2.9)	16 (45.7)
Alanine aminotransferase increased	17 (48.6)	2 (5.7)	3 (8.6)	12 (34.3)	0
Aspartate aminotransferase increased	14 (40.0)	5 (14.3)	3 (8.6)	5 (14.3)	1 (2.9)
Platelet count decreased	13 (37.1)	1 (2.9)	1 (2.9)	2 (5.7)	9 (25.7)
Lymphocyte count decreased	12 (34.3)	0	1 (2.9)	5 (14.3)	6 (17.1)

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prothrombin time prolonged	7 (20.0)	4 (11.4)	2 (5.7)	1 (2.9)	0
International normalised ratio increased	6 (17.1)	5 (14.3)	0	1 (2.9)	0
Blood creatinine increased	5 (14.3)	3 (8.6)	2 (5.7)	0	0
Blood bilirubin increased	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Weight decreased	4 (11.4)	1 (2.9)	3 (8.6)	0	0
Haemoglobin decreased	3 (8.6)	2 (5.7)	0	1 (2.9)	0
Transaminases increased	3 (8.6)	2 (5.7)	0	1 (2.9)	0
Activated partial thromboplastin time prolonged	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Blood fibrinogen decreased	2 (5.7)	0	0	2 (5.7)	0
Blood immunoglobulin a decreased	2 (5.7)	2 (5.7)	0	0	0
Blood immunoglobulin m decreased	2 (5.7)	2 (5.7)	0	0	0
C-reactive protein increased	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Lipase increased	2 (5.7)	0	0	0	2 (5.7)
Weight increased	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Blood alkaline phosphatase increased	1 (2.9)	1 (2.9)	0	0	0
Blood immunoglobulin g decreased	1 (2.9)	0	1 (2.9)	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood lactate dehydrogenase increased	1 (2.9)	1 (2.9)	0	0	0
Blood lactic acid increased	1 (2.9)	0	0	0	1 (2.9)
Blood magnesium decreased	1 (2.9)	0	0	1 (2.9)	0
Blood sodium increased	1 (2.9)	0	1 (2.9)	0	0
Blood urea increased	1 (2.9)	1 (2.9)	0	0	0
Blood uric acid increased	1 (2.9)	1 (2.9)	0	0	0
Coronavirus test positive	1 (2.9)	1 (2.9)	0	0	0
Culture stool positive	1 (2.9)	1 (2.9)	0	0	0
Hepatic enzyme increased	1 (2.9)	0	1 (2.9)	0	0
Oxygen saturation decreased	1 (2.9)	1 (2.9)	0	0	0
Pulmonary function test decreased	1 (2.9)	0	1 (2.9)	0	0
Serum ferritin increased	1 (2.9)	0	1 (2.9)	0	0
Metabolism and nutrition disorders					
-Total	28 (80.0)	2 (5.7)	7 (20.0)	15 (42.9)	4 (11.4)
Decreased appetite	17 (48.6)	5 (14.3)	5 (14.3)	7 (20.0)	0
Hypokalaemia	13 (37.1)	1 (2.9)	4 (11.4)	6 (17.1)	2 (5.7)
Hyperphosphataemia	6 (17.1)	6 (17.1)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypophosphataemia	6 (17.1)	2 (5.7)	0	3 (8.6)	1 (2.9)
Hyperglycaemia	4 (11.4)	0	1 (2.9)	3 (8.6)	0
Hypocalcaemia	4 (11.4)	2 (5.7)	1 (2.9)	0	1 (2.9)
Dehydration	3 (8.6)	1 (2.9)	0	2 (5.7)	0
Hypernatraemia	3 (8.6)	1 (2.9)	1 (2.9)	0	1 (2.9)
Hypoalbuminaemia	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Fluid overload	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Hyperuricaemia	2 (5.7)	2 (5.7)	0	0	0
Hypomagnesaemia	2 (5.7)	2 (5.7)	0	0	0
Tumour lysis syndrome	2 (5.7)	0	0	2 (5.7)	0
Acidosis	1 (2.9)	1 (2.9)	0	0	0
Hyperammonaemia	1 (2.9)	1 (2.9)	0	0	0
Hyperkalaemia	1 (2.9)	1 (2.9)	0	0	0
Hypertriglyceridaemia	1 (2.9)	1 (2.9)	0	0	0
Hypoglycaemia	1 (2.9)	0	0	1 (2.9)	0
Hyponatraemia	1 (2.9)	0	0	1 (2.9)	0
Malnutrition	1 (2.9)	0	0	1 (2.9)	0
Metabolic acidosis	1 (2.9)	0	1 (2.9)	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vitamin d deficiency	1 (2.9)	0	1 (2.9)	0	0
Musculoskeletal and connective tissue disorders					
-Total	22 (62.9)	11 (31.4)	6 (17.1)	5 (14.3)	0
Pain in extremity	11 (31.4)	6 (17.1)	3 (8.6)	2 (5.7)	0
Myalgia	4 (11.4)	3 (8.6)	0	1 (2.9)	0
Arthralgia	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Musculoskeletal pain	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Musculoskeletal chest pain	2 (5.7)	2 (5.7)	0	0	0
Pain in jaw	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Back pain	1 (2.9)	0	0	1 (2.9)	0
Coccydynia	1 (2.9)	1 (2.9)	0	0	0
Flank pain	1 (2.9)	0	1 (2.9)	0	0
Joint range of motion decreased	1 (2.9)	1 (2.9)	0	0	0
Limb discomfort	1 (2.9)	1 (2.9)	0	0	0
Muscular weakness	1 (2.9)	1 (2.9)	0	0	0
Myopathy	1 (2.9)	0	0	1 (2.9)	0
Myositis	1 (2.9)	0	0	1 (2.9)	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Osteopenia	1 (2.9)	0	1 (2.9)	0	0
Synovitis	1 (2.9)	0	1 (2.9)	0	0
Toe walking	1 (2.9)	1 (2.9)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (5.7)	0	2 (5.7)	0	0
Myelodysplastic syndrome	1 (2.9)	0	1 (2.9)	0	0
Skin papilloma	1 (2.9)	0	1 (2.9)	0	0
Nervous system disorders					
-Total	23 (65.7)	9 (25.7)	9 (25.7)	4 (11.4)	1 (2.9)
Headache	17 (48.6)	8 (22.9)	7 (20.0)	2 (5.7)	0
Dizziness	5 (14.3)	5 (14.3)	0	0	0
Encephalopathy	2 (5.7)	1 (2.9)	0	1 (2.9)	0
Neuropathy peripheral	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Seizure	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Tremor	2 (5.7)	2 (5.7)	0	0	0
Asterixis	1 (2.9)	1 (2.9)	0	0	0
Ataxia	1 (2.9)	0	1 (2.9)	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Depressed level of consciousness	1 (2.9)	1 (2.9)	0	0	0
Dysarthria	1 (2.9)	1 (2.9)	0	0	0
Dysgeusia	1 (2.9)	1 (2.9)	0	0	0
Embolic stroke	1 (2.9)	0	0	0	1 (2.9)
Idiopathic intracranial hypertension	1 (2.9)	0	1 (2.9)	0	0
Migraine	1 (2.9)	0	1 (2.9)	0	0
Myoclonus	1 (2.9)	1 (2.9)	0	0	0
Neuralgia	1 (2.9)	0	1 (2.9)	0	0
Peripheral sensory neuropathy	1 (2.9)	0	1 (2.9)	0	0
Peroneal nerve palsy	1 (2.9)	1 (2.9)	0	0	0
Pleocytosis	1 (2.9)	1 (2.9)	0	0	0
Visual field defect	1 (2.9)	0	1 (2.9)	0	0
Product issues					
-Total	2 (5.7)	2 (5.7)	0	0	0
Device occlusion	2 (5.7)	2 (5.7)	0	0	0
Psychiatric disorders					
-Total	13 (37.1)	5 (14.3)	7 (20.0)	1 (2.9)	0
Anxiety	6 (17.1)	2 (5.7)	3 (8.6)	1 (2.9)	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Confusional state	2 (5.7)	0	2 (5.7)	0	0
Delirium	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Depression	2 (5.7)	0	2 (5.7)	0	0
Adjustment disorder	1 (2.9)	0	1 (2.9)	0	0
Agitation	1 (2.9)	0	1 (2.9)	0	0
Hallucination	1 (2.9)	1 (2.9)	0	0	0
Insomnia	1 (2.9)	0	1 (2.9)	0	0
Irritability	1 (2.9)	1 (2.9)	0	0	0
Mental status changes	1 (2.9)	1 (2.9)	0	0	0
Panic attack	1 (2.9)	0	1 (2.9)	0	0
Suicidal ideation	1 (2.9)	1 (2.9)	0	0	0
Renal and urinary disorders					
-Total	11 (31.4)	2 (5.7)	2 (5.7)	5 (14.3)	2 (5.7)
Acute kidney injury	7 (20.0)	2 (5.7)	0	4 (11.4)	1 (2.9)
Haematuria	3 (8.6)	0	1 (2.9)	1 (2.9)	1 (2.9)
Dysuria	2 (5.7)	0	2 (5.7)	0	0
Calculus urinary	1 (2.9)	0	1 (2.9)	0	0
Cystitis haemorrhagic	1 (2.9)	0	0	0	1 (2.9)

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nephrolithiasis	1 (2.9)	0	0	1 (2.9)	0
Oliguria	1 (2.9)	0	0	1 (2.9)	0
Pollakiuria	1 (2.9)	1 (2.9)	0	0	0
Renal failure	1 (2.9)	0	0	0	1 (2.9)
Urinary incontinence	1 (2.9)	1 (2.9)	0	0	0
Reproductive system and breast disorders					
-Total	5 (14.3)	2 (5.7)	1 (2.9)	2 (5.7)	0
Vulvovaginal adhesion	2 (5.7)	2 (5.7)	0	0	0
Oedema genital	1 (2.9)	0	1 (2.9)	0	0
Ovarian failure	1 (2.9)	0	0	1 (2.9)	0
Vaginal haemorrhage	1 (2.9)	0	0	1 (2.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	22 (62.9)	8 (22.9)	3 (8.6)	5 (14.3)	6 (17.1)
Cough	9 (25.7)	9 (25.7)	0	0	0
Epistaxis	6 (17.1)	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)
Hypoxia	6 (17.1)	0	1 (2.9)	4 (11.4)	1 (2.9)
Oropharyngeal pain	5 (14.3)	4 (11.4)	1 (2.9)	0	0

Gender: Female

	All patients N=35				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis allergic	4 (11.4)	3 (8.6)	1 (2.9)	0	0
Rhinorrhoea	4 (11.4)	4 (11.4)	0	0	0
Tachypnoea	4 (11.4)	2 (5.7)	1 (2.9)	1 (2.9)	0
Nasal congestion	3 (8.6)	3 (8.6)	0	0	0
Pleural effusion	3 (8.6)	0	2 (5.7)	1 (2.9)	0
Pulmonary oedema	3 (8.6)	1 (2.9)	0	1 (2.9)	1 (2.9)
Respiratory failure	3 (8.6)	0	0	0	3 (8.6)
Dyspnoea	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Haemoptysis	2 (5.7)	1 (2.9)	0	0	1 (2.9)
Acute respiratory failure	1 (2.9)	0	0	0	1 (2.9)
Atelectasis	1 (2.9)	0	1 (2.9)	0	0
Idiopathic pneumonia syndrome	1 (2.9)	0	0	0	1 (2.9)
Nasal discomfort	1 (2.9)	1 (2.9)	0	0	0
Pulmonary mass	1 (2.9)	0	1 (2.9)	0	0
Wheezing	1 (2.9)	0	1 (2.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	17 (48.6)	10 (28.6)	6 (17.1)	1 (2.9)	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	6 (17.1)	4 (11.4)	2 (5.7)	0	0
Dry skin	4 (11.4)	4 (11.4)	0	0	0
Petechiae	4 (11.4)	3 (8.6)	1 (2.9)	0	0
Pruritus	4 (11.4)	4 (11.4)	0	0	0
Rash erythematous	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Alopecia	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Hyperhidrosis	2 (5.7)	2 (5.7)	0	0	0
Rash pruritic	2 (5.7)	2 (5.7)	0	0	0
Cold sweat	1 (2.9)	1 (2.9)	0	0	0
Dermatitis	1 (2.9)	1 (2.9)	0	0	0
Dermatitis atopic	1 (2.9)	1 (2.9)	0	0	0
Ecchymosis	1 (2.9)	0	0	1 (2.9)	0
Eczema	1 (2.9)	1 (2.9)	0	0	0
Erythema	1 (2.9)	1 (2.9)	0	0	0
Ingrowing nail	1 (2.9)	0	1 (2.9)	0	0
Macule	1 (2.9)	1 (2.9)	0	0	0
Night sweats	1 (2.9)	1 (2.9)	0	0	0
Rash follicular	1 (2.9)	1 (2.9)	0	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash macular	1 (2.9)	1 (2.9)	0	0	0
Rash maculo-papular	1 (2.9)	0	1 (2.9)	0	0
Rash papular	1 (2.9)	1 (2.9)	0	0	0
Rash vesicular	1 (2.9)	1 (2.9)	0	0	0
Skin exfoliation	1 (2.9)	1 (2.9)	0	0	0
Skin fissures	1 (2.9)	1 (2.9)	0	0	0
Skin haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Skin ulcer	1 (2.9)	1 (2.9)	0	0	0
Vascular disorders					
-Total	16 (45.7)	2 (5.7)	4 (11.4)	6 (17.1)	4 (11.4)
Hypotension	9 (25.7)	1 (2.9)	0	4 (11.4)	4 (11.4)
Hypertension	6 (17.1)	1 (2.9)	4 (11.4)	1 (2.9)	0
Orthostatic hypotension	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Embolism	1 (2.9)	0	0	1 (2.9)	0
Flushing	1 (2.9)	1 (2.9)	0	0	0
Haematoma	1 (2.9)	0	1 (2.9)	0	0
Phlebitis	1 (2.9)	0	1 (2.9)	0	0
Secondary hypertension	1 (2.9)	0	1 (2.9)	0	0

Gender: Female

Primary system organ class Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Venous thrombosis limb	1 (2.9)	1 (2.9)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178c
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	57 (95.0)	0	2 (3.3)	10 (16.7)	45 (75.0)
Blood and lymphatic system disorders					
-Total	50 (83.3)	1 (1.7)	1 (1.7)	31 (51.7)	17 (28.3)
Febrile neutropenia	29 (48.3)	0	0	29 (48.3)	0
Anaemia	28 (46.7)	2 (3.3)	5 (8.3)	20 (33.3)	1 (1.7)
Neutropenia	14 (23.3)	0	0	4 (6.7)	10 (16.7)
Thrombocytopenia	14 (23.3)	0	1 (1.7)	5 (8.3)	8 (13.3)
Disseminated intravascular coagulation	4 (6.7)	0	1 (1.7)	2 (3.3)	1 (1.7)
Lymphopenia	3 (5.0)	0	1 (1.7)	1 (1.7)	1 (1.7)
Pancytopenia	2 (3.3)	0	0	1 (1.7)	1 (1.7)
Coagulopathy	1 (1.7)	1 (1.7)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eosinophilia	1 (1.7)	0	0	1 (1.7)	0
Leukopenia	1 (1.7)	0	0	0	1 (1.7)
Splenomegaly	1 (1.7)	1 (1.7)	0	0	0
Cardiac disorders					
-Total	21 (35.0)	8 (13.3)	8 (13.3)	5 (8.3)	0
Tachycardia	13 (21.7)	5 (8.3)	6 (10.0)	2 (3.3)	0
Sinus tachycardia	6 (10.0)	3 (5.0)	2 (3.3)	1 (1.7)	0
Left ventricular dysfunction	3 (5.0)	0	0	3 (5.0)	0
Bradycardia	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Palpitations	2 (3.3)	2 (3.3)	0	0	0
Pericardial effusion	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Cardiac dysfunction	1 (1.7)	1 (1.7)	0	0	0
Sinus bradycardia	1 (1.7)	1 (1.7)	0	0	0
Ear and labyrinth disorders					
-Total	5 (8.3)	2 (3.3)	3 (5.0)	0	0
Ear pain	2 (3.3)	2 (3.3)	0	0	0
Deafness unilateral	1 (1.7)	0	1 (1.7)	0	0
Hypoacusis	1 (1.7)	0	1 (1.7)	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tympanic membrane perforation	1 (1.7)	0	1 (1.7)	0	0
Endocrine disorders					
-Total	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Adrenal insufficiency	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Cushingoid	1 (1.7)	1 (1.7)	0	0	0
Hyperthyroidism	1 (1.7)	0	1 (1.7)	0	0
Eye disorders					
-Total	16 (26.7)	10 (16.7)	6 (10.0)	0	0
Eye pain	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Periorbital oedema	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Vision blurred	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Conjunctival haemorrhage	2 (3.3)	2 (3.3)	0	0	0
Photophobia	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Retinal haemorrhage	2 (3.3)	2 (3.3)	0	0	0
Conjunctivitis allergic	1 (1.7)	1 (1.7)	0	0	0
Dry eye	1 (1.7)	0	1 (1.7)	0	0
Eye irritation	1 (1.7)	1 (1.7)	0	0	0
Ocular hyperaemia	1 (1.7)	1 (1.7)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ocular hypertension	1 (1.7)	0	1 (1.7)	0	0
Papilloedema	1 (1.7)	0	1 (1.7)	0	0
Uveitis	1 (1.7)	0	1 (1.7)	0	0
Visual impairment	1 (1.7)	0	1 (1.7)	0	0
Gastrointestinal disorders					
-Total	43 (71.7)	11 (18.3)	14 (23.3)	17 (28.3)	1 (1.7)
Nausea	24 (40.0)	5 (8.3)	13 (21.7)	6 (10.0)	0
Vomiting	24 (40.0)	12 (20.0)	9 (15.0)	3 (5.0)	0
Diarrhoea	22 (36.7)	12 (20.0)	8 (13.3)	2 (3.3)	0
Abdominal pain	14 (23.3)	6 (10.0)	6 (10.0)	2 (3.3)	0
Constipation	9 (15.0)	7 (11.7)	2 (3.3)	0	0
Colitis	4 (6.7)	1 (1.7)	0	3 (5.0)	0
Stomatitis	4 (6.7)	1 (1.7)	1 (1.7)	1 (1.7)	1 (1.7)
Oral pain	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Pancreatitis	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Abdominal distension	2 (3.3)	0	2 (3.3)	0	0
Abdominal pain upper	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Ascites	2 (3.3)	0	0	2 (3.3)	0

Race: White

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	2 (3.3)	2 (3.3)	0	0	0
Haematemesis	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Abdominal discomfort	1 (1.7)	1 (1.7)	0	0	0
Abdominal pain lower	1 (1.7)	0	1 (1.7)	0	0
Abdominal tenderness	1 (1.7)	1 (1.7)	0	0	0
Anal fissure	1 (1.7)	0	1 (1.7)	0	0
Anal incontinence	1 (1.7)	1 (1.7)	0	0	0
Dyspepsia	1 (1.7)	0	1 (1.7)	0	0
Dysphagia	1 (1.7)	0	0	1 (1.7)	0
Enterocolitis	1 (1.7)	0	0	1 (1.7)	0
Gastrooesophageal reflux disease	1 (1.7)	1 (1.7)	0	0	0
Gingival discomfort	1 (1.7)	1 (1.7)	0	0	0
Glossodynia	1 (1.7)	1 (1.7)	0	0	0
Ileus	1 (1.7)	0	0	1 (1.7)	0
Intestinal obstruction	1 (1.7)	0	0	1 (1.7)	0
Mouth haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Oral mucosal blistering	1 (1.7)	1 (1.7)	0	0	0
Pancreatic failure	1 (1.7)	0	1 (1.7)	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Perianal erythema	1 (1.7)	0	1 (1.7)	0	0
Pigmentation lip	1 (1.7)	1 (1.7)	0	0	0
Proctalgia	1 (1.7)	0	1 (1.7)	0	0
Tooth socket haemorrhage	1 (1.7)	1 (1.7)	0	0	0
General disorders and administration site conditions					
-Total	39 (65.0)	12 (20.0)	13 (21.7)	11 (18.3)	3 (5.0)
Pyrexia	26 (43.3)	6 (10.0)	12 (20.0)	7 (11.7)	1 (1.7)
Fatigue	14 (23.3)	9 (15.0)	3 (5.0)	2 (3.3)	0
Chills	9 (15.0)	9 (15.0)	0	0	0
Catheter site pain	5 (8.3)	1 (1.7)	4 (6.7)	0	0
Pain	5 (8.3)	1 (1.7)	1 (1.7)	3 (5.0)	0
Generalised oedema	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Malaise	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Multiple organ dysfunction syndrome	3 (5.0)	0	0	1 (1.7)	2 (3.3)
Oedema peripheral	3 (5.0)	2 (3.3)	0	1 (1.7)	0
Face oedema	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Influenza like illness	2 (3.3)	2 (3.3)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acquired gene mutation	1 (1.7)	1 (1.7)	0	0	0
Asthenia	1 (1.7)	1 (1.7)	0	0	0
Catheter site extravasation	1 (1.7)	0	1 (1.7)	0	0
Crying	1 (1.7)	1 (1.7)	0	0	0
Cyst	1 (1.7)	0	0	1 (1.7)	0
Facial pain	1 (1.7)	0	1 (1.7)	0	0
Gait disturbance	1 (1.7)	1 (1.7)	0	0	0
Localised oedema	1 (1.7)	0	0	1 (1.7)	0
Medical device pain	1 (1.7)	0	1 (1.7)	0	0
Mucosal haemorrhage	1 (1.7)	0	1 (1.7)	0	0
Non-cardiac chest pain	1 (1.7)	1 (1.7)	0	0	0
Peripheral swelling	1 (1.7)	0	1 (1.7)	0	0
Hepatobiliary disorders					
-Total	8 (13.3)	2 (3.3)	2 (3.3)	3 (5.0)	1 (1.7)
Hepatomegaly	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Hyperbilirubinaemia	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Cholecystitis	1 (1.7)	0	0	1 (1.7)	0
Hepatic failure	1 (1.7)	0	0	0	1 (1.7)

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatosplenomegaly	1 (1.7)	1 (1.7)	0	0	0
Immune system disorders					
-Total	48 (80.0)	5 (8.3)	23 (38.3)	10 (16.7)	10 (16.7)
Cytokine release syndrome	40 (66.7)	4 (6.7)	19 (31.7)	7 (11.7)	10 (16.7)
Hypogammaglobulinaemia	27 (45.0)	2 (3.3)	20 (33.3)	5 (8.3)	0
Graft versus host disease	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Chronic graft versus host disease	1 (1.7)	0	1 (1.7)	0	0
Drug hypersensitivity	1 (1.7)	0	1 (1.7)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.7)	0	1 (1.7)	0	0
Graft versus host disease in skin	1 (1.7)	1 (1.7)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.7)	0	1 (1.7)	0	0
Seasonal allergy	1 (1.7)	1 (1.7)	0	0	0
Infections and infestations					
-Total	43 (71.7)	4 (6.7)	14 (23.3)	17 (28.3)	8 (13.3)
Upper respiratory tract infection	10 (16.7)	4 (6.7)	5 (8.3)	1 (1.7)	0
Pneumonia	7 (11.7)	0	5 (8.3)	1 (1.7)	1 (1.7)
Clostridium difficile infection	5 (8.3)	0	4 (6.7)	1 (1.7)	0

Race: White

	All patients N=60				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	5 (8.3)	5 (8.3)	0	0	0
Sinusitis	5 (8.3)	1 (1.7)	4 (6.7)	0	0
Clostridium difficile colitis	4 (6.7)	1 (1.7)	1 (1.7)	2 (3.3)	0
Gastroenteritis	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Influenza	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Parainfluenzae virus infection	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Urinary tract infection	4 (6.7)	0	2 (3.3)	2 (3.3)	0
Device related infection	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Otitis media	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Staphylococcal infection	3 (5.0)	1 (1.7)	0	1 (1.7)	1 (1.7)
Viral upper respiratory tract infection	3 (5.0)	2 (3.3)	0	1 (1.7)	0
Ear infection	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Escherichia bacteraemia	2 (3.3)	0	0	2 (3.3)	0
Escherichia urinary tract infection	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Fungal skin infection	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Otitis media acute	2 (3.3)	0	2 (3.3)	0	0
Respiratory syncytial virus infection	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Skin infection	2 (3.3)	0	2 (3.3)	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	2 (3.3)	0	0	2 (3.3)	0
Viral infection	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Vulvovaginal candidiasis	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Acute sinusitis	1 (1.7)	0	1 (1.7)	0	0
Bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Bacterial sepsis	1 (1.7)	0	0	0	1 (1.7)
Body tinea	1 (1.7)	1 (1.7)	0	0	0
Bronchitis	1 (1.7)	0	1 (1.7)	0	0
Bronchopulmonary aspergillosis	1 (1.7)	0	0	1 (1.7)	0
Campylobacter infection	1 (1.7)	0	0	1 (1.7)	0
Candida sepsis	1 (1.7)	0	0	0	1 (1.7)
Catheter site infection	1 (1.7)	0	0	1 (1.7)	0
Cellulitis	1 (1.7)	0	0	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	0	0	1 (1.7)	0
Cholecystitis infective	1 (1.7)	0	0	1 (1.7)	0
Conjunctivitis	1 (1.7)	0	1 (1.7)	0	0
Corona virus infection	1 (1.7)	0	0	1 (1.7)	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Croup infectious	1 (1.7)	0	0	1 (1.7)	0
Cytomegalovirus infection	1 (1.7)	1 (1.7)	0	0	0
Enterococcal infection	1 (1.7)	1 (1.7)	0	0	0
Enterovirus infection	1 (1.7)	0	0	1 (1.7)	0
Escherichia sepsis	1 (1.7)	0	0	0	1 (1.7)
Folliculitis	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis norovirus	1 (1.7)	0	1 (1.7)	0	0
Gastroenteritis viral	1 (1.7)	1 (1.7)	0	0	0
Haemophilus infection	1 (1.7)	0	1 (1.7)	0	0
Human herpesvirus 6 infection	1 (1.7)	0	1 (1.7)	0	0
Human polyomavirus infection	1 (1.7)	0	0	0	1 (1.7)
Hypopyon	1 (1.7)	0	1 (1.7)	0	0
Metapneumovirus infection	1 (1.7)	0	1 (1.7)	0	0
Necrotising fasciitis	1 (1.7)	0	0	1 (1.7)	0
Oral candidiasis	1 (1.7)	1 (1.7)	0	0	0
Oral herpes	1 (1.7)	0	0	1 (1.7)	0
Orchitis	1 (1.7)	1 (1.7)	0	0	0
Otitis externa	1 (1.7)	0	1 (1.7)	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Paronychia	1 (1.7)	1 (1.7)	0	0	0
Rash pustular	1 (1.7)	0	1 (1.7)	0	0
Respiratory syncytial virus bronchitis	1 (1.7)	0	0	1 (1.7)	0
Respiratory tract infection viral	1 (1.7)	0	0	1 (1.7)	0
Rotavirus infection	1 (1.7)	0	0	1 (1.7)	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)
Septic embolus	1 (1.7)	0	0	0	1 (1.7)
Streptococcal bacteraemia	1 (1.7)	0	0	1 (1.7)	0
Subcutaneous abscess	1 (1.7)	0	1 (1.7)	0	0
Tinea capitis	1 (1.7)	1 (1.7)	0	0	0
Urinary tract infection enterococcal	1 (1.7)	0	0	1 (1.7)	0
Injury, poisoning and procedural complications					
-Total	21 (35.0)	11 (18.3)	9 (15.0)	1 (1.7)	0
Infusion related reaction	5 (8.3)	2 (3.3)	3 (5.0)	0	0
Contusion	3 (5.0)	3 (5.0)	0	0	0
Procedural pain	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Transfusion reaction	3 (5.0)	1 (1.7)	2 (3.3)	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Radiation skin injury	2 (3.3)	0	2 (3.3)	0	0
Skin abrasion	2 (3.3)	2 (3.3)	0	0	0
Foot fracture	1 (1.7)	0	1 (1.7)	0	0
Incision site pain	1 (1.7)	1 (1.7)	0	0	0
Limb injury	1 (1.7)	1 (1.7)	0	0	0
Mouth injury	1 (1.7)	1 (1.7)	0	0	0
Procedural complication	1 (1.7)	1 (1.7)	0	0	0
Procedural headache	1 (1.7)	0	1 (1.7)	0	0
Procedural nausea	1 (1.7)	0	1 (1.7)	0	0
Procedural site reaction	1 (1.7)	1 (1.7)	0	0	0
Radius fracture	1 (1.7)	0	1 (1.7)	0	0
Skin laceration	1 (1.7)	0	1 (1.7)	0	0
Stoma site irritation	1 (1.7)	1 (1.7)	0	0	0
Subdural haematoma	1 (1.7)	0	1 (1.7)	0	0
Subdural haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Sunburn	1 (1.7)	1 (1.7)	0	0	0
Tibia fracture	1 (1.7)	0	1 (1.7)	0	0
Tongue injury	1 (1.7)	1 (1.7)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tracheal haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Wound	1 (1.7)	1 (1.7)	0	0	0
Investigations					
-Total	47 (78.3)	1 (1.7)	3 (5.0)	10 (16.7)	33 (55.0)
White blood cell count decreased	32 (53.3)	4 (6.7)	0	6 (10.0)	22 (36.7)
Neutrophil count decreased	26 (43.3)	1 (1.7)	1 (1.7)	3 (5.0)	21 (35.0)
Alanine aminotransferase increased	21 (35.0)	2 (3.3)	2 (3.3)	16 (26.7)	1 (1.7)
Aspartate aminotransferase increased	18 (30.0)	3 (5.0)	3 (5.0)	7 (11.7)	5 (8.3)
Platelet count decreased	17 (28.3)	3 (5.0)	2 (3.3)	2 (3.3)	10 (16.7)
Lymphocyte count decreased	16 (26.7)	1 (1.7)	2 (3.3)	6 (10.0)	7 (11.7)
Blood bilirubin increased	10 (16.7)	2 (3.3)	3 (5.0)	4 (6.7)	1 (1.7)
International normalised ratio increased	9 (15.0)	7 (11.7)	1 (1.7)	1 (1.7)	0
Blood creatinine increased	7 (11.7)	4 (6.7)	1 (1.7)	2 (3.3)	0
Prothrombin time prolonged	7 (11.7)	4 (6.7)	2 (3.3)	1 (1.7)	0
Activated partial thromboplastin time prolonged	5 (8.3)	2 (3.3)	3 (5.0)	0	0
Blood fibrinogen decreased	4 (6.7)	0	1 (1.7)	2 (3.3)	1 (1.7)

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Weight decreased	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Blood immunoglobulin m decreased	3 (5.0)	3 (5.0)	0	0	0
Blood urea increased	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
C-reactive protein increased	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Transaminases increased	3 (5.0)	3 (5.0)	0	0	0
Weight increased	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Blood lactic acid increased	2 (3.3)	0	1 (1.7)	0	1 (1.7)
Blood magnesium decreased	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Blood phosphorus increased	2 (3.3)	2 (3.3)	0	0	0
Lipase increased	2 (3.3)	0	0	0	2 (3.3)
Serum ferritin increased	2 (3.3)	0	2 (3.3)	0	0
Blood bicarbonate decreased	1 (1.7)	0	1 (1.7)	0	0
Blood immunoglobulin a decreased	1 (1.7)	1 (1.7)	0	0	0
Blood immunoglobulin g decreased	1 (1.7)	0	1 (1.7)	0	0
Blood phosphorus decreased	1 (1.7)	1 (1.7)	0	0	0
Blood sodium increased	1 (1.7)	0	1 (1.7)	0	0
Blood uric acid increased	1 (1.7)	1 (1.7)	0	0	0
Cardiac murmur	1 (1.7)	1 (1.7)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Coronavirus test positive	1 (1.7)	1 (1.7)	0	0	0
Electrocardiogram qt prolonged	1 (1.7)	0	0	1 (1.7)	0
Fibrin d dimer increased	1 (1.7)	1 (1.7)	0	0	0
Haemoglobin decreased	1 (1.7)	1 (1.7)	0	0	0
Norovirus test positive	1 (1.7)	1 (1.7)	0	0	0
Oxygen saturation decreased	1 (1.7)	1 (1.7)	0	0	0
Protein total decreased	1 (1.7)	0	0	1 (1.7)	0
Pulmonary function test decreased	1 (1.7)	0	1 (1.7)	0	0
Metabolism and nutrition disorders					
-Total	39 (65.0)	4 (6.7)	8 (13.3)	21 (35.0)	6 (10.0)
Decreased appetite	23 (38.3)	3 (5.0)	8 (13.3)	12 (20.0)	0
Hypokalaemia	21 (35.0)	4 (6.7)	5 (8.3)	9 (15.0)	3 (5.0)
Hypophosphataemia	13 (21.7)	4 (6.7)	0	8 (13.3)	1 (1.7)
Hyperphosphataemia	7 (11.7)	6 (10.0)	1 (1.7)	0	0
Hypoalbuminaemia	6 (10.0)	1 (1.7)	4 (6.7)	1 (1.7)	0
Fluid overload	5 (8.3)	1 (1.7)	4 (6.7)	0	0
Hypernatraemia	5 (8.3)	0	2 (3.3)	0	3 (5.0)
Hypocalcaemia	5 (8.3)	2 (3.3)	1 (1.7)	1 (1.7)	1 (1.7)

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperglycaemia	4 (6.7)	0	1 (1.7)	3 (5.0)	0
Dehydration	3 (5.0)	1 (1.7)	0	2 (3.3)	0
Hyperuricaemia	3 (5.0)	2 (3.3)	0	0	1 (1.7)
Hypomagnesaemia	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Hyperkalaemia	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Hypertriglyceridaemia	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Hypoglycaemia	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Hyponatraemia	2 (3.3)	0	0	2 (3.3)	0
Malnutrition	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Tumour lysis syndrome	2 (3.3)	0	0	2 (3.3)	0
Vitamin d deficiency	2 (3.3)	2 (3.3)	0	0	0
Acidosis	1 (1.7)	0	0	1 (1.7)	0
Hyperalbuminaemia	1 (1.7)	1 (1.7)	0	0	0
Hyperammonaemia	1 (1.7)	1 (1.7)	0	0	0
Hypercalcaemia	1 (1.7)	1 (1.7)	0	0	0
Hyperchloraemia	1 (1.7)	1 (1.7)	0	0	0
Hypermagnesaemia	1 (1.7)	1 (1.7)	0	0	0
Iron overload	1 (1.7)	0	0	1 (1.7)	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolic acidosis	1 (1.7)	0	1 (1.7)	0	0
Metabolic alkalosis	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	25 (41.7)	11 (18.3)	9 (15.0)	5 (8.3)	0
Pain in extremity	8 (13.3)	3 (5.0)	3 (5.0)	2 (3.3)	0
Arthralgia	5 (8.3)	3 (5.0)	1 (1.7)	1 (1.7)	0
Musculoskeletal pain	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Myalgia	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Pain in jaw	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Muscle spasms	2 (3.3)	2 (3.3)	0	0	0
Muscular weakness	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Musculoskeletal chest pain	2 (3.3)	2 (3.3)	0	0	0
Neck pain	2 (3.3)	0	2 (3.3)	0	0
Back pain	1 (1.7)	1 (1.7)	0	0	0
Bone pain	1 (1.7)	0	0	1 (1.7)	0
Flank pain	1 (1.7)	0	1 (1.7)	0	0
Joint range of motion decreased	1 (1.7)	1 (1.7)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Limb discomfort	1 (1.7)	1 (1.7)	0	0	0
Osteopenia	1 (1.7)	0	1 (1.7)	0	0
Toe walking	1 (1.7)	1 (1.7)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (3.3)	0	1 (1.7)	0	1 (1.7)
Glioblastoma multiforme	1 (1.7)	0	0	0	1 (1.7)
Skin papilloma	1 (1.7)	0	1 (1.7)	0	0
Nervous system disorders					
-Total	35 (58.3)	14 (23.3)	14 (23.3)	6 (10.0)	1 (1.7)
Headache	22 (36.7)	13 (21.7)	6 (10.0)	3 (5.0)	0
Dizziness	6 (10.0)	6 (10.0)	0	0	0
Encephalopathy	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Peroneal nerve palsy	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Seizure	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Somnolence	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Depressed level of consciousness	1 (1.7)	1 (1.7)	0	0	0
Disturbance in attention	1 (1.7)	1 (1.7)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysarthria	1 (1.7)	0	1 (1.7)	0	0
Dysgeusia	1 (1.7)	1 (1.7)	0	0	0
Embolic stroke	1 (1.7)	0	0	0	1 (1.7)
Hypotonia	1 (1.7)	0	1 (1.7)	0	0
Idiopathic intracranial hypertension	1 (1.7)	0	1 (1.7)	0	0
Migraine	1 (1.7)	0	1 (1.7)	0	0
Neuralgia	1 (1.7)	0	1 (1.7)	0	0
Neuropathy peripheral	1 (1.7)	1 (1.7)	0	0	0
Peripheral sensory neuropathy	1 (1.7)	0	1 (1.7)	0	0
Tremor	1 (1.7)	1 (1.7)	0	0	0
Visual field defect	1 (1.7)	0	1 (1.7)	0	0
Product issues					
-Total	1 (1.7)	1 (1.7)	0	0	0
Device occlusion	1 (1.7)	1 (1.7)	0	0	0
Psychiatric disorders					
-Total	22 (36.7)	8 (13.3)	12 (20.0)	2 (3.3)	0
Anxiety	7 (11.7)	3 (5.0)	3 (5.0)	1 (1.7)	0
Confusional state	7 (11.7)	3 (5.0)	4 (6.7)	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Delirium	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Insomnia	4 (6.7)	0	4 (6.7)	0	0
Depression	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Irritability	3 (5.0)	3 (5.0)	0	0	0
Mental status changes	3 (5.0)	3 (5.0)	0	0	0
Hallucination	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Agitation	1 (1.7)	0	1 (1.7)	0	0
Listless	1 (1.7)	1 (1.7)	0	0	0
Panic attack	1 (1.7)	0	1 (1.7)	0	0
Sleep disorder	1 (1.7)	0	1 (1.7)	0	0
Renal and urinary disorders					
-Total	14 (23.3)	2 (3.3)	2 (3.3)	5 (8.3)	5 (8.3)
Acute kidney injury	8 (13.3)	0	1 (1.7)	3 (5.0)	4 (6.7)
Haematuria	5 (8.3)	0	2 (3.3)	2 (3.3)	1 (1.7)
Oliguria	2 (3.3)	0	0	2 (3.3)	0
Calculus urinary	1 (1.7)	0	1 (1.7)	0	0
Cystitis haemorrhagic	1 (1.7)	0	0	0	1 (1.7)
Dysuria	1 (1.7)	1 (1.7)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nephrolithiasis	1 (1.7)	0	0	1 (1.7)	0
Renal failure	1 (1.7)	0	0	0	1 (1.7)
Renal impairment	1 (1.7)	0	0	1 (1.7)	0
Urinary incontinence	1 (1.7)	1 (1.7)	0	0	0
Urinary retention	1 (1.7)	0	1 (1.7)	0	0
Reproductive system and breast disorders					
-Total	5 (8.3)	2 (3.3)	2 (3.3)	1 (1.7)	0
Vulvovaginal adhesion	2 (3.3)	2 (3.3)	0	0	0
Oedema genital	1 (1.7)	0	1 (1.7)	0	0
Scrotal pain	1 (1.7)	0	1 (1.7)	0	0
Vaginal haemorrhage	1 (1.7)	0	0	1 (1.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	36 (60.0)	10 (16.7)	9 (15.0)	7 (11.7)	10 (16.7)
Hypoxia	14 (23.3)	0	3 (5.0)	8 (13.3)	3 (5.0)
Cough	12 (20.0)	10 (16.7)	2 (3.3)	0	0
Epistaxis	11 (18.3)	3 (5.0)	4 (6.7)	3 (5.0)	1 (1.7)
Pleural effusion	10 (16.7)	1 (1.7)	6 (10.0)	3 (5.0)	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	7 (11.7)	3 (5.0)	2 (3.3)	2 (3.3)	0
Pulmonary oedema	6 (10.0)	1 (1.7)	0	3 (5.0)	2 (3.3)
Nasal congestion	5 (8.3)	5 (8.3)	0	0	0
Oropharyngeal pain	5 (8.3)	4 (6.7)	1 (1.7)	0	0
Rhinorrhoea	5 (8.3)	4 (6.7)	1 (1.7)	0	0
Dyspnoea	4 (6.7)	1 (1.7)	1 (1.7)	1 (1.7)	1 (1.7)
Rhinitis allergic	4 (6.7)	3 (5.0)	1 (1.7)	0	0
Respiratory failure	3 (5.0)	0	0	0	3 (5.0)
Atelectasis	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Acute respiratory failure	1 (1.7)	0	0	0	1 (1.7)
Aspiration	1 (1.7)	0	0	0	1 (1.7)
Dysphonia	1 (1.7)	1 (1.7)	0	0	0
Haemoptysis	1 (1.7)	0	0	0	1 (1.7)
Idiopathic pneumonia syndrome	1 (1.7)	0	0	0	1 (1.7)
Interstitial lung disease	1 (1.7)	0	0	0	1 (1.7)
Oropharyngeal plaque	1 (1.7)	1 (1.7)	0	0	0
Pharyngeal erythema	1 (1.7)	1 (1.7)	0	0	0
Pharyngeal lesion	1 (1.7)	0	0	1 (1.7)	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pharyngeal ulceration	1 (1.7)	0	1 (1.7)	0	0
Pulmonary mass	1 (1.7)	0	1 (1.7)	0	0
Respiratory depression	1 (1.7)	0	1 (1.7)	0	0
Respiratory distress	1 (1.7)	0	0	0	1 (1.7)
Wheezing	1 (1.7)	0	1 (1.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	31 (51.7)	18 (30.0)	10 (16.7)	3 (5.0)	0
Rash	6 (10.0)	5 (8.3)	1 (1.7)	0	0
Rash maculo-papular	5 (8.3)	3 (5.0)	1 (1.7)	1 (1.7)	0
Alopecia	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Erythema	4 (6.7)	4 (6.7)	0	0	0
Petechiae	4 (6.7)	3 (5.0)	1 (1.7)	0	0
Rash erythematous	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Hyperhidrosis	3 (5.0)	3 (5.0)	0	0	0
Ingrowing nail	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Pruritus	3 (5.0)	3 (5.0)	0	0	0
Rash papular	3 (5.0)	3 (5.0)	0	0	0

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dermatitis acneiform	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Dry skin	2 (3.3)	2 (3.3)	0	0	0
Macule	2 (3.3)	2 (3.3)	0	0	0
Papule	2 (3.3)	2 (3.3)	0	0	0
Rash macular	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Acne	1 (1.7)	1 (1.7)	0	0	0
Dermatitis diaper	1 (1.7)	1 (1.7)	0	0	0
Keloid scar	1 (1.7)	0	1 (1.7)	0	0
Livedo reticularis	1 (1.7)	1 (1.7)	0	0	0
Night sweats	1 (1.7)	0	1 (1.7)	0	0
Rash follicular	1 (1.7)	1 (1.7)	0	0	0
Rash pruritic	1 (1.7)	1 (1.7)	0	0	0
Skin haemorrhage	1 (1.7)	1 (1.7)	0	0	0
Skin irritation	1 (1.7)	1 (1.7)	0	0	0
Skin ulcer	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					
-Total	28 (46.7)	3 (5.0)	4 (6.7)	12 (20.0)	9 (15.0)
Hypotension	21 (35.0)	1 (1.7)	0	11 (18.3)	9 (15.0)

Race: White

Primary system organ class Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	13 (21.7)	4 (6.7)	7 (11.7)	2 (3.3)	0
Flushing	2 (3.3)	2 (3.3)	0	0	0
Capillary leak syndrome	1 (1.7)	0	0	0	1 (1.7)
Haematoma	1 (1.7)	0	1 (1.7)	0	0
Hot flush	1 (1.7)	1 (1.7)	0	0	0
Orthostatic hypotension	1 (1.7)	1 (1.7)	0	0	0
Phlebitis	1 (1.7)	0	1 (1.7)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178c
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	1 (16.7)	2 (33.3)	3 (50.0)
Blood and lymphatic system disorders					
-Total	3 (50.0)	0	1 (16.7)	1 (16.7)	1 (16.7)
Anaemia	3 (50.0)	0	1 (16.7)	2 (33.3)	0
Febrile neutropenia	1 (16.7)	0	0	1 (16.7)	0
Lymphopenia	1 (16.7)	0	1 (16.7)	0	0
Neutropenia	1 (16.7)	0	0	0	1 (16.7)
Cardiac disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Atrioventricular block second degree	1 (16.7)	1 (16.7)	0	0	0
Gastrointestinal disorders					
-Total	2 (33.3)	1 (16.7)	1 (16.7)	0	0

Race: Asian

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Diarrhoea	1 (16.7)	0	1 (16.7)	0	0
Dry mouth	1 (16.7)	1 (16.7)	0	0	0
Nausea	1 (16.7)	1 (16.7)	0	0	0
Vomiting	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	5 (83.3)	3 (50.0)	2 (33.3)	0	0
Fatigue	3 (50.0)	3 (50.0)	0	0	0
Pyrexia	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Oedema peripheral	1 (16.7)	1 (16.7)	0	0	0
Pain	1 (16.7)	0	1 (16.7)	0	0
Immune system disorders					
-Total	5 (83.3)	0	5 (83.3)	0	0
Cytokine release syndrome	4 (66.7)	0	4 (66.7)	0	0
Hypogammaglobulinaemia	3 (50.0)	1 (16.7)	2 (33.3)	0	0
Infections and infestations					
-Total	3 (50.0)	0	1 (16.7)	1 (16.7)	1 (16.7)
Gastroenteritis	1 (16.7)	0	0	1 (16.7)	0

Race: Asian

	All patients N=6				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gingivitis	1 (16.7)	1 (16.7)	0	0	0
Herpes zoster	1 (16.7)	0	0	1 (16.7)	0
Molluscum contagiosum	1 (16.7)	1 (16.7)	0	0	0
Pharyngitis	1 (16.7)	0	1 (16.7)	0	0
Respiratory tract infection	1 (16.7)	0	0	0	1 (16.7)
Streptococcal infection	1 (16.7)	0	1 (16.7)	0	0
Viral infection	1 (16.7)	1 (16.7)	0	0	0
Viral upper respiratory tract infection	1 (16.7)	0	1 (16.7)	0	0
Investigations					
-Total	4 (66.7)	0	1 (16.7)	1 (16.7)	2 (33.3)
Neutrophil count decreased	3 (50.0)	0	1 (16.7)	0	2 (33.3)
White blood cell count decreased	3 (50.0)	0	1 (16.7)	0	2 (33.3)
Aspartate aminotransferase increased	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Alanine aminotransferase increased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin a decreased	1 (16.7)	1 (16.7)	0	0	0
Blood uric acid increased	1 (16.7)	1 (16.7)	0	0	0
International normalised ratio increased	1 (16.7)	1 (16.7)	0	0	0

Race: Asian

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Lymphocyte count decreased	1 (16.7)	0	1 (16.7)	0	0
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)
Metabolism and nutrition disorders					
-Total	3 (50.0)	1 (16.7)	0	2 (33.3)	0
Decreased appetite	1 (16.7)	1 (16.7)	0	0	0
Dehydration	1 (16.7)	0	0	1 (16.7)	0
Hyperglycaemia	1 (16.7)	0	0	1 (16.7)	0
Hyperphosphataemia	1 (16.7)	1 (16.7)	0	0	0
Hyperuricaemia	1 (16.7)	1 (16.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (83.3)	2 (33.3)	3 (50.0)	0	0
Pain in extremity	3 (50.0)	2 (33.3)	1 (16.7)	0	0
Arthralgia	1 (16.7)	1 (16.7)	0	0	0
Joint range of motion decreased	1 (16.7)	1 (16.7)	0	0	0
Myalgia	1 (16.7)	1 (16.7)	0	0	0
Osteonecrosis	1 (16.7)	0	1 (16.7)	0	0
Pain in jaw	1 (16.7)	0	1 (16.7)	0	0

Race: Asian

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nervous system disorders					
-Total	2 (33.3)	2 (33.3)	0	0	0
Headache	2 (33.3)	2 (33.3)	0	0	0
Renal and urinary disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Dysuria	1 (16.7)	0	1 (16.7)	0	0
Pollakiuria	1 (16.7)	1 (16.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Pulmonary oedema	1 (16.7)	0	0	1 (16.7)	0
Skin and subcutaneous tissue disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Pruritus generalised	1 (16.7)	1 (16.7)	0	0	0
Rash	1 (16.7)	0	1 (16.7)	0	0
Vascular disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Embolism	1 (16.7)	0	0	1 (16.7)	0

Race: Asian

Primary system organ class Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (16.7)	0	1 (16.7)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178c
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (100)	0	0	0	9 (100)
Blood and lymphatic system disorders					
-Total	8 (88.9)	0	0	3 (33.3)	5 (55.6)
Febrile neutropenia	6 (66.7)	0	0	5 (55.6)	1 (11.1)
Anaemia	4 (44.4)	0	0	4 (44.4)	0
Disseminated intravascular coagulation	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Lymphopenia	2 (22.2)	0	0	0	2 (22.2)
Pancytopenia	2 (22.2)	0	0	0	2 (22.2)
Coagulopathy	1 (11.1)	0	0	1 (11.1)	0
Hypofibrinogenaemia	1 (11.1)	0	0	0	1 (11.1)

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Leukocytosis	1 (11.1)	1 (11.1)	0	0	0
Lymphadenopathy	1 (11.1)	0	1 (11.1)	0	0
Neutropenia	1 (11.1)	0	0	0	1 (11.1)
Thrombocytopenia	1 (11.1)	0	0	0	1 (11.1)
Cardiac disorders					
-Total	6 (66.7)	2 (22.2)	2 (22.2)	0	2 (22.2)
Tachycardia	4 (44.4)	4 (44.4)	0	0	0
Ventricular tachycardia	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Bradycardia	1 (11.1)	0	0	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	0	0	1 (11.1)
Pericardial effusion	1 (11.1)	0	1 (11.1)	0	0
Right ventricular dysfunction	1 (11.1)	0	0	1 (11.1)	0
Sinus tachycardia	1 (11.1)	0	0	1 (11.1)	0
Endocrine disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Adrenal insufficiency	1 (11.1)	0	1 (11.1)	0	0
Eye disorders					
-Total	4 (44.4)	1 (11.1)	3 (33.3)	0	0

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Conjunctival haemorrhage	1 (11.1)	1 (11.1)	0	0	0
Dry eye	1 (11.1)	1 (11.1)	0	0	0
Periorbital oedema	1 (11.1)	1 (11.1)	0	0	0
Photophobia	1 (11.1)	0	1 (11.1)	0	0
Retinopathy	1 (11.1)	0	1 (11.1)	0	0
Uveitis	1 (11.1)	0	1 (11.1)	0	0
Vision blurred	1 (11.1)	0	1 (11.1)	0	0
Gastrointestinal disorders					
-Total	8 (88.9)	0	5 (55.6)	3 (33.3)	0
Nausea	8 (88.9)	3 (33.3)	4 (44.4)	1 (11.1)	0
Vomiting	5 (55.6)	4 (44.4)	0	1 (11.1)	0
Abdominal pain	3 (33.3)	1 (11.1)	1 (11.1)	1 (11.1)	0
Diarrhoea	3 (33.3)	2 (22.2)	1 (11.1)	0	0
Constipation	2 (22.2)	2 (22.2)	0	0	0
Haematochezia	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Abdominal pain lower	1 (11.1)	1 (11.1)	0	0	0
Abdominal pain upper	1 (11.1)	0	1 (11.1)	0	0
Dysphagia	1 (11.1)	0	1 (11.1)	0	0

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Flatulence	1 (11.1)	1 (11.1)	0	0	0
Lip pain	1 (11.1)	0	1 (11.1)	0	0
Stomatitis	1 (11.1)	0	0	1 (11.1)	0
General disorders and administration site conditions					
-Total	8 (88.9)	1 (11.1)	3 (33.3)	3 (33.3)	1 (11.1)
Pyrexia	4 (44.4)	2 (22.2)	2 (22.2)	0	0
Catheter site pain	2 (22.2)	2 (22.2)	0	0	0
Chills	2 (22.2)	0	2 (22.2)	0	0
Physical deconditioning	2 (22.2)	0	0	2 (22.2)	0
Catheter site haemorrhage	1 (11.1)	1 (11.1)	0	0	0
Device related thrombosis	1 (11.1)	0	1 (11.1)	0	0
Fatigue	1 (11.1)	1 (11.1)	0	0	0
Injection site haematoma	1 (11.1)	1 (11.1)	0	0	0
Malaise	1 (11.1)	0	1 (11.1)	0	0
Multiple organ dysfunction syndrome	1 (11.1)	0	0	0	1 (11.1)
Non-cardiac chest pain	1 (11.1)	0	0	1 (11.1)	0
Oedema peripheral	1 (11.1)	0	1 (11.1)	0	0

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain	1 (11.1)	0	1 (11.1)	0	0
Hepatobiliary disorders					
-Total	3 (33.3)	1 (11.1)	1 (11.1)	1 (11.1)	0
Hyperbilirubinaemia	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Gallbladder enlargement	1 (11.1)	1 (11.1)	0	0	0
Hepatic steatosis	1 (11.1)	0	1 (11.1)	0	0
Immune system disorders					
-Total	6 (66.7)	1 (11.1)	3 (33.3)	1 (11.1)	1 (11.1)
Cytokine release syndrome	6 (66.7)	2 (22.2)	2 (22.2)	1 (11.1)	1 (11.1)
Hypogammaglobulinaemia	3 (33.3)	1 (11.1)	2 (22.2)	0	0
Immunodeficiency common variable	2 (22.2)	0	2 (22.2)	0	0
Immunodeficiency	1 (11.1)	0	1 (11.1)	0	0
Seasonal allergy	1 (11.1)	1 (11.1)	0	0	0
Infections and infestations					
-Total	6 (66.7)	0	1 (11.1)	3 (33.3)	2 (22.2)
Abscess limb	1 (11.1)	0	0	1 (11.1)	0
Catheter site cellulitis	1 (11.1)	1 (11.1)	0	0	0
Clostridium difficile colitis	1 (11.1)	0	1 (11.1)	0	0

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile infection	1 (11.1)	0	1 (11.1)	0	0
Cytomegalovirus infection	1 (11.1)	1 (11.1)	0	0	0
Device related infection	1 (11.1)	0	0	1 (11.1)	0
Escherichia urinary tract infection	1 (11.1)	0	0	1 (11.1)	0
Herpes simplex	1 (11.1)	1 (11.1)	0	0	0
Klebsiella sepsis	1 (11.1)	0	0	0	1 (11.1)
Meningitis aseptic	1 (11.1)	0	1 (11.1)	0	0
Oral herpes	1 (11.1)	0	1 (11.1)	0	0
Otitis media	1 (11.1)	0	1 (11.1)	0	0
Pneumonia fungal	1 (11.1)	0	1 (11.1)	0	0
Rhinitis	1 (11.1)	1 (11.1)	0	0	0
Rhinovirus infection	1 (11.1)	0	1 (11.1)	0	0
Sepsis	1 (11.1)	0	0	0	1 (11.1)
Staphylococcal scalded skin syndrome	1 (11.1)	0	1 (11.1)	0	0
Staphylococcal sepsis	1 (11.1)	0	0	0	1 (11.1)
Upper respiratory tract infection	1 (11.1)	1 (11.1)	0	0	0
Urinary tract infection	1 (11.1)	0	1 (11.1)	0	0

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular device infection	1 (11.1)	0	0	1 (11.1)	0
Vulvovaginal mycotic infection	1 (11.1)	0	1 (11.1)	0	0
Injury, poisoning and procedural complications					
-Total	5 (55.6)	1 (11.1)	1 (11.1)	2 (22.2)	1 (11.1)
Procedural pain	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Arthropod bite	1 (11.1)	1 (11.1)	0	0	0
Extradural haematoma	1 (11.1)	0	0	1 (11.1)	0
Post procedural haemorrhage	1 (11.1)	1 (11.1)	0	0	0
Subdural haematoma	1 (11.1)	0	0	1 (11.1)	0
Transfusion reaction	1 (11.1)	1 (11.1)	0	0	0
Transfusion related complication	1 (11.1)	0	0	0	1 (11.1)
Investigations					
-Total	7 (77.8)	0	0	1 (11.1)	6 (66.7)
White blood cell count decreased	7 (77.8)	0	0	2 (22.2)	5 (55.6)
Alanine aminotransferase increased	4 (44.4)	1 (11.1)	1 (11.1)	2 (22.2)	0
Aspartate aminotransferase increased	4 (44.4)	1 (11.1)	2 (22.2)	1 (11.1)	0
Neutrophil count decreased	3 (33.3)	0	0	0	3 (33.3)

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Platelet count decreased	3 (33.3)	0	0	1 (11.1)	2 (22.2)
Blood creatinine increased	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Blood lactate dehydrogenase increased	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Haemoglobin decreased	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Lymphocyte count decreased	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Prothrombin time prolonged	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Activated partial thromboplastin time prolonged	1 (11.1)	1 (11.1)	0	0	0
Blood alkaline phosphatase increased	1 (11.1)	1 (11.1)	0	0	0
Blood immunoglobulin a decreased	1 (11.1)	1 (11.1)	0	0	0
Blood immunoglobulin m decreased	1 (11.1)	1 (11.1)	0	0	0
C-reactive protein increased	1 (11.1)	1 (11.1)	0	0	0
Computerised tomogram thorax abnormal	1 (11.1)	0	0	1 (11.1)	0
Culture stool positive	1 (11.1)	1 (11.1)	0	0	0
Electrocardiogram qt prolonged	1 (11.1)	0	0	1 (11.1)	0
Hepatic enzyme increased	1 (11.1)	0	1 (11.1)	0	0

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
International normalised ratio increased	1 (11.1)	1 (11.1)	0	0	0
Lipase increased	1 (11.1)	0	0	0	1 (11.1)
Transaminases increased	1 (11.1)	0	0	1 (11.1)	0
Weight decreased	1 (11.1)	1 (11.1)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (77.8)	1 (11.1)	2 (22.2)	3 (33.3)	1 (11.1)
Decreased appetite	4 (44.4)	3 (33.3)	0	1 (11.1)	0
Hyperglycaemia	2 (22.2)	0	2 (22.2)	0	0
Hypokalaemia	2 (22.2)	1 (11.1)	0	0	1 (11.1)
Acidosis	1 (11.1)	1 (11.1)	0	0	0
Fluid overload	1 (11.1)	0	0	1 (11.1)	0
Hyperkalaemia	1 (11.1)	0	0	1 (11.1)	0
Hypernatraemia	1 (11.1)	1 (11.1)	0	0	0
Hyperphosphataemia	1 (11.1)	1 (11.1)	0	0	0
Hypocalcaemia	1 (11.1)	1 (11.1)	0	0	0
Tumour lysis syndrome	1 (11.1)	0	0	1 (11.1)	0
Vitamin d deficiency	1 (11.1)	0	1 (11.1)	0	0

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal and connective tissue disorders					
-Total	7 (77.8)	4 (44.4)	0	3 (33.3)	0
Pain in extremity	3 (33.3)	2 (22.2)	0	1 (11.1)	0
Back pain	2 (22.2)	0	0	2 (22.2)	0
Arthralgia	1 (11.1)	0	0	1 (11.1)	0
Coccydynia	1 (11.1)	1 (11.1)	0	0	0
Muscle spasms	1 (11.1)	1 (11.1)	0	0	0
Muscular weakness	1 (11.1)	1 (11.1)	0	0	0
Musculoskeletal chest pain	1 (11.1)	1 (11.1)	0	0	0
Myalgia	1 (11.1)	1 (11.1)	0	0	0
Myopathy	1 (11.1)	0	0	1 (11.1)	0
Myositis	1 (11.1)	0	0	1 (11.1)	0
Synovitis	1 (11.1)	0	1 (11.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (11.1)	0	1 (11.1)	0	0
Myelodysplastic syndrome	1 (11.1)	0	1 (11.1)	0	0
Nervous system disorders					

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	6 (66.7)	1 (11.1)	3 (33.3)	1 (11.1)	1 (11.1)
Headache	5 (55.6)	0	3 (33.3)	2 (22.2)	0
Seizure	2 (22.2)	0	1 (11.1)	0	1 (11.1)
Asterixis	1 (11.1)	1 (11.1)	0	0	0
Ataxia	1 (11.1)	0	1 (11.1)	0	0
Dysarthria	1 (11.1)	1 (11.1)	0	0	0
Encephalopathy	1 (11.1)	1 (11.1)	0	0	0
Hyporesponsive to stimuli	1 (11.1)	0	0	1 (11.1)	0
Myoclonus	1 (11.1)	1 (11.1)	0	0	0
Neuropathy peripheral	1 (11.1)	0	1 (11.1)	0	0
Pleocytosis	1 (11.1)	1 (11.1)	0	0	0
Tremor	1 (11.1)	1 (11.1)	0	0	0
Product issues					
-Total	1 (11.1)	1 (11.1)	0	0	0
Device occlusion	1 (11.1)	1 (11.1)	0	0	0
Psychiatric disorders					
-Total	4 (44.4)	0	2 (22.2)	2 (22.2)	0
Agitation	2 (22.2)	0	1 (11.1)	1 (11.1)	0

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Anxiety	2 (22.2)	0	2 (22.2)	0	0
Adjustment disorder	1 (11.1)	0	1 (11.1)	0	0
Delirium	1 (11.1)	0	1 (11.1)	0	0
Depression	1 (11.1)	0	1 (11.1)	0	0
Mental status changes	1 (11.1)	0	0	1 (11.1)	0
Suicidal ideation	1 (11.1)	1 (11.1)	0	0	0
Renal and urinary disorders					
-Total	4 (44.4)	1 (11.1)	1 (11.1)	2 (22.2)	0
Acute kidney injury	4 (44.4)	2 (22.2)	0	2 (22.2)	0
Dysuria	1 (11.1)	0	1 (11.1)	0	0
Oliguria	1 (11.1)	0	0	1 (11.1)	0
Reproductive system and breast disorders					
-Total	1 (11.1)	0	0	1 (11.1)	0
Ovarian failure	1 (11.1)	0	0	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (77.8)	3 (33.3)	0	2 (22.2)	2 (22.2)
Cough	4 (44.4)	3 (33.3)	0	1 (11.1)	0

Race: Other

	All patients N=9				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	3 (33.3)	1 (11.1)	0	2 (22.2)	0
Haemoptysis	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Oropharyngeal pain	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Pulmonary oedema	2 (22.2)	0	0	0	2 (22.2)
Dyspnoea	1 (11.1)	0	0	1 (11.1)	0
Hypoxia	1 (11.1)	0	0	1 (11.1)	0
Nasal congestion	1 (11.1)	1 (11.1)	0	0	0
Nasal discomfort	1 (11.1)	1 (11.1)	0	0	0
Pulmonary alveolar haemorrhage	1 (11.1)	0	0	0	1 (11.1)
Pulmonary hypertension	1 (11.1)	0	0	1 (11.1)	0
Respiratory distress	1 (11.1)	0	0	0	1 (11.1)
Respiratory failure	1 (11.1)	0	0	0	1 (11.1)
Rhinitis allergic	1 (11.1)	1 (11.1)	0	0	0
Rhinorrhoea	1 (11.1)	1 (11.1)	0	0	0
Tachypnoea	1 (11.1)	0	0	1 (11.1)	0
Skin and subcutaneous tissue disorders					
-Total	5 (55.6)	3 (33.3)	1 (11.1)	1 (11.1)	0

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dry skin	3 (33.3)	3 (33.3)	0	0	0
Pruritus	2 (22.2)	2 (22.2)	0	0	0
Rash	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Cold sweat	1 (11.1)	1 (11.1)	0	0	0
Dermatitis	1 (11.1)	1 (11.1)	0	0	0
Dermatitis atopic	1 (11.1)	1 (11.1)	0	0	0
Ecchymosis	1 (11.1)	0	0	1 (11.1)	0
Eczema	1 (11.1)	1 (11.1)	0	0	0
Erythema	1 (11.1)	1 (11.1)	0	0	0
Hyperhidrosis	1 (11.1)	1 (11.1)	0	0	0
Night sweats	1 (11.1)	1 (11.1)	0	0	0
Rash erythematous	1 (11.1)	1 (11.1)	0	0	0
Rash pruritic	1 (11.1)	1 (11.1)	0	0	0
Rash vesicular	1 (11.1)	1 (11.1)	0	0	0
Skin exfoliation	1 (11.1)	1 (11.1)	0	0	0
Skin fissures	1 (11.1)	1 (11.1)	0	0	0
Vascular disorders					
-Total	5 (55.6)	0	2 (22.2)	1 (11.1)	2 (22.2)

Race: Other

Primary system organ class Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	3 (33.3)	0	0	1 (11.1)	2 (22.2)
Hypertension	2 (22.2)	0	2 (22.2)	0	0
Orthostatic hypotension	1 (11.1)	0	1 (11.1)	0	0
Secondary hypertension	1 (11.1)	0	1 (11.1)	0	0
Venous thrombosis limb	1 (11.1)	1 (11.1)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178d
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (93.3)	0	0	4 (13.3)	24 (80.0)
Blood and lymphatic system disorders					
-Total	26 (86.7)	0	0	19 (63.3)	7 (23.3)
Febrile neutropenia	21 (70.0)	0	0	20 (66.7)	1 (3.3)
Anaemia	14 (46.7)	1 (3.3)	3 (10.0)	10 (33.3)	0
Neutropenia	5 (16.7)	0	0	2 (6.7)	3 (10.0)
Disseminated intravascular coagulation	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Lymphopenia	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Thrombocytopenia	2 (6.7)	0	0	0	2 (6.7)
Eosinophilia	1 (3.3)	0	0	1 (3.3)	0
Lymphadenopathy	1 (3.3)	0	1 (3.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	1 (3.3)	0	0	0	1 (3.3)
Splenomegaly	1 (3.3)	1 (3.3)	0	0	0
Cardiac disorders					
-Total	11 (36.7)	6 (20.0)	2 (6.7)	2 (6.7)	1 (3.3)
Tachycardia	7 (23.3)	6 (20.0)	1 (3.3)	0	0
Sinus tachycardia	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Bradycardia	1 (3.3)	1 (3.3)	0	0	0
Cardiac dysfunction	1 (3.3)	1 (3.3)	0	0	0
Cardiovascular insufficiency	1 (3.3)	0	0	0	1 (3.3)
Left ventricular dysfunction	1 (3.3)	0	0	1 (3.3)	0
Ventricular tachycardia	1 (3.3)	0	1 (3.3)	0	0
Endocrine disorders					
-Total	4 (13.3)	1 (3.3)	3 (10.0)	0	0
Adrenal insufficiency	2 (6.7)	0	2 (6.7)	0	0
Cushingoid	1 (3.3)	1 (3.3)	0	0	0
Hyperthyroidism	1 (3.3)	0	1 (3.3)	0	0
Eye disorders					
-Total	7 (23.3)	5 (16.7)	2 (6.7)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry eye	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Conjunctival haemorrhage	1 (3.3)	1 (3.3)	0	0	0
Conjunctivitis allergic	1 (3.3)	1 (3.3)	0	0	0
Eye irritation	1 (3.3)	1 (3.3)	0	0	0
Eye pain	1 (3.3)	1 (3.3)	0	0	0
Ocular hyperaemia	1 (3.3)	1 (3.3)	0	0	0
Periorbital oedema	1 (3.3)	1 (3.3)	0	0	0
Vision blurred	1 (3.3)	0	1 (3.3)	0	0
Gastrointestinal disorders					
-Total	20 (66.7)	4 (13.3)	9 (30.0)	7 (23.3)	0
Nausea	12 (40.0)	1 (3.3)	10 (33.3)	1 (3.3)	0
Vomiting	12 (40.0)	8 (26.7)	3 (10.0)	1 (3.3)	0
Diarrhoea	10 (33.3)	5 (16.7)	4 (13.3)	1 (3.3)	0
Abdominal pain	5 (16.7)	3 (10.0)	1 (3.3)	1 (3.3)	0
Constipation	3 (10.0)	3 (10.0)	0	0	0
Abdominal distension	1 (3.3)	0	1 (3.3)	0	0
Abdominal pain lower	1 (3.3)	1 (3.3)	0	0	0
Abdominal pain upper	1 (3.3)	0	1 (3.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal tenderness	1 (3.3)	1 (3.3)	0	0	0
Ascites	1 (3.3)	0	0	1 (3.3)	0
Colitis	1 (3.3)	0	0	1 (3.3)	0
Dysphagia	1 (3.3)	0	1 (3.3)	0	0
Enterocolitis	1 (3.3)	0	0	1 (3.3)	0
Flatulence	1 (3.3)	1 (3.3)	0	0	0
Gastrointestinal haemorrhage	1 (3.3)	1 (3.3)	0	0	0
Gastrooesophageal reflux disease	1 (3.3)	1 (3.3)	0	0	0
Glossodynia	1 (3.3)	1 (3.3)	0	0	0
Haematochezia	1 (3.3)	1 (3.3)	0	0	0
Oral mucosal blistering	1 (3.3)	1 (3.3)	0	0	0
Oral pain	1 (3.3)	1 (3.3)	0	0	0
Pancreatic failure	1 (3.3)	0	1 (3.3)	0	0
Pancreatitis	1 (3.3)	0	0	1 (3.3)	0
Pigmentation lip	1 (3.3)	1 (3.3)	0	0	0
Stomatitis	1 (3.3)	0	0	1 (3.3)	0
General disorders and administration site conditions					

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	17 (56.7)	5 (16.7)	7 (23.3)	4 (13.3)	1 (3.3)
Pyrexia	9 (30.0)	3 (10.0)	4 (13.3)	2 (6.7)	0
Chills	5 (16.7)	3 (10.0)	2 (6.7)	0	0
Fatigue	3 (10.0)	3 (10.0)	0	0	0
Pain	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Influenza like illness	2 (6.7)	2 (6.7)	0	0	0
Catheter site pain	1 (3.3)	0	1 (3.3)	0	0
Cyst	1 (3.3)	0	0	1 (3.3)	0
Generalised oedema	1 (3.3)	1 (3.3)	0	0	0
Malaise	1 (3.3)	0	1 (3.3)	0	0
Multiple organ dysfunction syndrome	1 (3.3)	0	0	0	1 (3.3)
Oedema peripheral	1 (3.3)	1 (3.3)	0	0	0
Physical deconditioning	1 (3.3)	0	0	1 (3.3)	0
Hepatobiliary disorders					
-Total	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Cholecystitis	1 (3.3)	0	0	1 (3.3)	0
Gallbladder enlargement	1 (3.3)	1 (3.3)	0	0	0
Hyperbilirubinaemia	1 (3.3)	0	1 (3.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	24 (80.0)	2 (6.7)	15 (50.0)	4 (13.3)	3 (10.0)
Cytokine release syndrome	20 (66.7)	2 (6.7)	12 (40.0)	3 (10.0)	3 (10.0)
Hypogammaglobulinaemia	15 (50.0)	0	14 (46.7)	1 (3.3)	0
Immunodeficiency common variable	2 (6.7)	0	2 (6.7)	0	0
Drug hypersensitivity	1 (3.3)	0	1 (3.3)	0	0
Graft versus host disease	1 (3.3)	1 (3.3)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (3.3)	0	1 (3.3)	0	0
Graft versus host disease in skin	1 (3.3)	1 (3.3)	0	0	0
Immunodeficiency	1 (3.3)	0	1 (3.3)	0	0
Seasonal allergy	1 (3.3)	1 (3.3)	0	0	0
Infections and infestations					
-Total	21 (70.0)	1 (3.3)	8 (26.7)	8 (26.7)	4 (13.3)
Influenza	4 (13.3)	1 (3.3)	3 (10.0)	0	0
Upper respiratory tract infection	4 (13.3)	2 (6.7)	2 (6.7)	0	0
Urinary tract infection	4 (13.3)	0	2 (6.7)	2 (6.7)	0
Otitis media	3 (10.0)	0	3 (10.0)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Clostridium difficile infection	2 (6.7)	0	2 (6.7)	0	0
Cytomegalovirus infection	2 (6.7)	2 (6.7)	0	0	0
Escherichia urinary tract infection	2 (6.7)	0	0	2 (6.7)	0
Gastroenteritis	2 (6.7)	0	2 (6.7)	0	0
Skin infection	2 (6.7)	0	2 (6.7)	0	0
Viral upper respiratory tract infection	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Candida sepsis	1 (3.3)	0	0	0	1 (3.3)
Cellulitis of male external genital organ	1 (3.3)	0	0	1 (3.3)	0
Clostridium difficile colitis	1 (3.3)	0	0	1 (3.3)	0
Conjunctivitis	1 (3.3)	0	1 (3.3)	0	0
Corona virus infection	1 (3.3)	0	0	1 (3.3)	0
Device related infection	1 (3.3)	0	0	1 (3.3)	0
Ear infection	1 (3.3)	1 (3.3)	0	0	0
Enterococcal infection	1 (3.3)	1 (3.3)	0	0	0
Escherichia bacteraemia	1 (3.3)	0	0	1 (3.3)	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia sepsis	1 (3.3)	0	0	0	1 (3.3)
Fungal skin infection	1 (3.3)	1 (3.3)	0	0	0
Gastroenteritis norovirus	1 (3.3)	0	1 (3.3)	0	0
Klebsiella sepsis	1 (3.3)	0	0	0	1 (3.3)
Meningitis aseptic	1 (3.3)	0	1 (3.3)	0	0
Otitis externa	1 (3.3)	0	1 (3.3)	0	0
Otitis media acute	1 (3.3)	0	1 (3.3)	0	0
Paronychia	1 (3.3)	1 (3.3)	0	0	0
Pneumonia	1 (3.3)	0	1 (3.3)	0	0
Respiratory syncytial virus bronchitis	1 (3.3)	0	0	1 (3.3)	0
Respiratory syncytial virus infection	1 (3.3)	0	0	1 (3.3)	0
Rhinovirus infection	1 (3.3)	1 (3.3)	0	0	0
Sepsis	1 (3.3)	0	0	0	1 (3.3)
Sinusitis	1 (3.3)	0	1 (3.3)	0	0
Staphylococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Staphylococcal infection	1 (3.3)	0	0	1 (3.3)	0
Streptococcal bacteraemia	1 (3.3)	0	0	1 (3.3)	0
Subcutaneous abscess	1 (3.3)	0	1 (3.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tinea capitis	1 (3.3)	1 (3.3)	0	0	0
Viral infection	1 (3.3)	0	1 (3.3)	0	0
Vulvovaginal mycotic infection	1 (3.3)	0	1 (3.3)	0	0
Injury, poisoning and procedural complications					
-Total	12 (40.0)	6 (20.0)	4 (13.3)	2 (6.7)	0
Procedural pain	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Radiation skin injury	2 (6.7)	0	2 (6.7)	0	0
Skin abrasion	2 (6.7)	2 (6.7)	0	0	0
Arthropod bite	1 (3.3)	1 (3.3)	0	0	0
Contusion	1 (3.3)	1 (3.3)	0	0	0
Extradural haematoma	1 (3.3)	0	0	1 (3.3)	0
Infusion related reaction	1 (3.3)	0	1 (3.3)	0	0
Post procedural haemorrhage	1 (3.3)	1 (3.3)	0	0	0
Procedural site reaction	1 (3.3)	1 (3.3)	0	0	0
Skin laceration	1 (3.3)	0	1 (3.3)	0	0
Subdural haematoma	1 (3.3)	0	0	1 (3.3)	0
Subdural haemorrhage	1 (3.3)	1 (3.3)	0	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion reaction	1 (3.3)	0	1 (3.3)	0	0
Wound	1 (3.3)	1 (3.3)	0	0	0
Investigations					
-Total	22 (73.3)	0	1 (3.3)	2 (6.7)	19 (63.3)
White blood cell count decreased	20 (66.7)	1 (3.3)	0	6 (20.0)	13 (43.3)
Neutrophil count decreased	16 (53.3)	1 (3.3)	0	2 (6.7)	13 (43.3)
Platelet count decreased	10 (33.3)	3 (10.0)	2 (6.7)	1 (3.3)	4 (13.3)
Alanine aminotransferase increased	9 (30.0)	1 (3.3)	0	8 (26.7)	0
Lymphocyte count decreased	9 (30.0)	1 (3.3)	1 (3.3)	4 (13.3)	3 (10.0)
Aspartate aminotransferase increased	5 (16.7)	1 (3.3)	1 (3.3)	3 (10.0)	0
Blood creatinine increased	4 (13.3)	4 (13.3)	0	0	0
Activated partial thromboplastin time prolonged	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Blood bilirubin increased	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Blood immunoglobulin m decreased	2 (6.7)	2 (6.7)	0	0	0
C-reactive protein increased	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Prothrombin time prolonged	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Weight decreased	2 (6.7)	1 (3.3)	1 (3.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood alkaline phosphatase increased	1 (3.3)	1 (3.3)	0	0	0
Blood fibrinogen decreased	1 (3.3)	0	0	1 (3.3)	0
Blood immunoglobulin a decreased	1 (3.3)	1 (3.3)	0	0	0
Blood immunoglobulin g decreased	1 (3.3)	0	1 (3.3)	0	0
Blood lactate dehydrogenase increased	1 (3.3)	1 (3.3)	0	0	0
Blood magnesium decreased	1 (3.3)	1 (3.3)	0	0	0
Blood sodium increased	1 (3.3)	0	1 (3.3)	0	0
Blood urea increased	1 (3.3)	1 (3.3)	0	0	0
Coronavirus test positive	1 (3.3)	1 (3.3)	0	0	0
Electrocardiogram qt prolonged	1 (3.3)	0	0	1 (3.3)	0
Fibrin d dimer increased	1 (3.3)	1 (3.3)	0	0	0
Haemoglobin decreased	1 (3.3)	1 (3.3)	0	0	0
International normalised ratio increased	1 (3.3)	1 (3.3)	0	0	0
Lipase increased	1 (3.3)	0	0	0	1 (3.3)
Pulmonary function test decreased	1 (3.3)	0	1 (3.3)	0	0
Serum ferritin increased	1 (3.3)	0	1 (3.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight increased	1 (3.3)	1 (3.3)	0	0	0
Metabolism and nutrition disorders					
-Total	20 (66.7)	4 (13.3)	5 (16.7)	6 (20.0)	5 (16.7)
Decreased appetite	12 (40.0)	3 (10.0)	5 (16.7)	4 (13.3)	0
Hypokalaemia	10 (33.3)	3 (10.0)	2 (6.7)	3 (10.0)	2 (6.7)
Hyperphosphataemia	5 (16.7)	4 (13.3)	1 (3.3)	0	0
Hypophosphataemia	4 (13.3)	1 (3.3)	0	2 (6.7)	1 (3.3)
Hyperglycaemia	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Hypernatraemia	3 (10.0)	1 (3.3)	0	0	2 (6.7)
Hyperuricaemia	3 (10.0)	2 (6.7)	0	0	1 (3.3)
Tumour lysis syndrome	3 (10.0)	0	0	3 (10.0)	0
Hypomagnesaemia	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Acidosis	1 (3.3)	1 (3.3)	0	0	0
Dehydration	1 (3.3)	1 (3.3)	0	0	0
Fluid overload	1 (3.3)	0	1 (3.3)	0	0
Hyperammonaemia	1 (3.3)	1 (3.3)	0	0	0
Hyperkalaemia	1 (3.3)	0	1 (3.3)	0	0
Hypertriglyceridaemia	1 (3.3)	1 (3.3)	0	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	1 (3.3)	0	0	1 (3.3)	0
Hypocalcaemia	1 (3.3)	0	0	0	1 (3.3)
Iron overload	1 (3.3)	0	0	1 (3.3)	0
Malnutrition	1 (3.3)	0	1 (3.3)	0	0
Vitamin d deficiency	1 (3.3)	1 (3.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	13 (43.3)	9 (30.0)	3 (10.0)	1 (3.3)	0
Arthralgia	3 (10.0)	3 (10.0)	0	0	0
Pain in extremity	3 (10.0)	3 (10.0)	0	0	0
Back pain	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Muscle spasms	2 (6.7)	2 (6.7)	0	0	0
Muscular weakness	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Musculoskeletal chest pain	2 (6.7)	2 (6.7)	0	0	0
Flank pain	1 (3.3)	0	1 (3.3)	0	0
Joint range of motion decreased	1 (3.3)	1 (3.3)	0	0	0
Musculoskeletal pain	1 (3.3)	0	1 (3.3)	0	0
Pain in jaw	1 (3.3)	1 (3.3)	0	0	0

Ethnicity: Hispanic or Latino

Primary system organ class Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Toe walking	1 (3.3)	1 (3.3)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (6.7)	0	2 (6.7)	0	0
Myelodysplastic syndrome	1 (3.3)	0	1 (3.3)	0	0
Skin papilloma	1 (3.3)	0	1 (3.3)	0	0
Nervous system disorders					
-Total	13 (43.3)	4 (13.3)	6 (20.0)	3 (10.0)	0
Headache	11 (36.7)	6 (20.0)	3 (10.0)	2 (6.7)	0
Dizziness	2 (6.7)	2 (6.7)	0	0	0
Dysarthria	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Seizure	2 (6.7)	0	2 (6.7)	0	0
Asterixis	1 (3.3)	1 (3.3)	0	0	0
Ataxia	1 (3.3)	0	1 (3.3)	0	0
Encephalopathy	1 (3.3)	0	0	1 (3.3)	0
Neuralgia	1 (3.3)	0	1 (3.3)	0	0
Neuropathy peripheral	1 (3.3)	0	1 (3.3)	0	0
Peripheral sensory neuropathy	1 (3.3)	0	1 (3.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleocytosis	1 (3.3)	1 (3.3)	0	0	0
Somnolence	1 (3.3)	1 (3.3)	0	0	0
Tremor	1 (3.3)	1 (3.3)	0	0	0
Product issues					
-Total	2 (6.7)	2 (6.7)	0	0	0
Device occlusion	2 (6.7)	2 (6.7)	0	0	0
Psychiatric disorders					
-Total	7 (23.3)	4 (13.3)	2 (6.7)	1 (3.3)	0
Mental status changes	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Adjustment disorder	1 (3.3)	0	1 (3.3)	0	0
Agitation	1 (3.3)	0	1 (3.3)	0	0
Anxiety	1 (3.3)	0	1 (3.3)	0	0
Confusional state	1 (3.3)	1 (3.3)	0	0	0
Delirium	1 (3.3)	0	1 (3.3)	0	0
Depression	1 (3.3)	1 (3.3)	0	0	0
Hallucination	1 (3.3)	1 (3.3)	0	0	0
Insomnia	1 (3.3)	0	1 (3.3)	0	0
Suicidal ideation	1 (3.3)	1 (3.3)	0	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	6 (20.0)	1 (3.3)	0	4 (13.3)	1 (3.3)
Acute kidney injury	4 (13.3)	0	0	3 (10.0)	1 (3.3)
Calculus urinary	1 (3.3)	0	1 (3.3)	0	0
Dysuria	1 (3.3)	1 (3.3)	0	0	0
Haematuria	1 (3.3)	0	0	1 (3.3)	0
Nephrolithiasis	1 (3.3)	0	0	1 (3.3)	0
Reproductive system and breast disorders					
-Total	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Ovarian failure	1 (3.3)	0	0	1 (3.3)	0
Scrotal pain	1 (3.3)	0	1 (3.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	22 (73.3)	10 (33.3)	6 (20.0)	1 (3.3)	5 (16.7)
Cough	6 (20.0)	4 (13.3)	2 (6.7)	0	0
Epistaxis	5 (16.7)	3 (10.0)	1 (3.3)	1 (3.3)	0
Nasal congestion	5 (16.7)	5 (16.7)	0	0	0
Rhinorrhoea	5 (16.7)	4 (13.3)	1 (3.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	4 (13.3)	1 (3.3)	0	1 (3.3)	2 (6.7)
Oropharyngeal pain	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Respiratory failure	3 (10.0)	0	0	0	3 (10.0)
Tachypnoea	3 (10.0)	3 (10.0)	0	0	0
Hypoxia	2 (6.7)	0	2 (6.7)	0	0
Rhinitis allergic	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Acute respiratory failure	1 (3.3)	0	0	0	1 (3.3)
Haemoptysis	1 (3.3)	1 (3.3)	0	0	0
Idiopathic pneumonia syndrome	1 (3.3)	0	0	0	1 (3.3)
Nasal discomfort	1 (3.3)	1 (3.3)	0	0	0
Oropharyngeal plaque	1 (3.3)	1 (3.3)	0	0	0
Pleural effusion	1 (3.3)	0	0	1 (3.3)	0
Pulmonary mass	1 (3.3)	0	1 (3.3)	0	0
Wheezing	1 (3.3)	0	1 (3.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	15 (50.0)	10 (33.3)	3 (10.0)	2 (6.7)	0
Dry skin	3 (10.0)	3 (10.0)	0	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	3 (10.0)	3 (10.0)	0	0	0
Ingrowing nail	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Petechiae	2 (6.7)	2 (6.7)	0	0	0
Rash	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Rash maculo-papular	2 (6.7)	2 (6.7)	0	0	0
Rash papular	2 (6.7)	2 (6.7)	0	0	0
Rash pruritic	2 (6.7)	2 (6.7)	0	0	0
Cold sweat	1 (3.3)	1 (3.3)	0	0	0
Dermatitis	1 (3.3)	1 (3.3)	0	0	0
Dermatitis acneiform	1 (3.3)	0	0	1 (3.3)	0
Dermatitis diaper	1 (3.3)	1 (3.3)	0	0	0
Ecchymosis	1 (3.3)	0	0	1 (3.3)	0
Eczema	1 (3.3)	1 (3.3)	0	0	0
Erythema	1 (3.3)	1 (3.3)	0	0	0
Keloid scar	1 (3.3)	0	1 (3.3)	0	0
Macule	1 (3.3)	1 (3.3)	0	0	0
Night sweats	1 (3.3)	1 (3.3)	0	0	0
Papule	1 (3.3)	1 (3.3)	0	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash erythematous	1 (3.3)	1 (3.3)	0	0	0
Rash follicular	1 (3.3)	1 (3.3)	0	0	0
Skin exfoliation	1 (3.3)	1 (3.3)	0	0	0
Skin fissures	1 (3.3)	1 (3.3)	0	0	0
Skin irritation	1 (3.3)	1 (3.3)	0	0	0
Vascular disorders					
-Total	15 (50.0)	1 (3.3)	5 (16.7)	7 (23.3)	2 (6.7)
Hypotension	9 (30.0)	0	0	7 (23.3)	2 (6.7)
Hypertension	4 (13.3)	1 (3.3)	3 (10.0)	0	0
Orthostatic hypotension	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Phlebitis	1 (3.3)	0	1 (3.3)	0	0
Secondary hypertension	1 (3.3)	0	1 (3.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178d
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	44 (97.8)	0	3 (6.7)	8 (17.8)	33 (73.3)
Blood and lymphatic system disorders					
-Total	35 (77.8)	1 (2.2)	2 (4.4)	16 (35.6)	16 (35.6)
Anaemia	21 (46.7)	1 (2.2)	3 (6.7)	16 (35.6)	1 (2.2)
Febrile neutropenia	15 (33.3)	0	0	15 (33.3)	0
Thrombocytopenia	13 (28.9)	0	1 (2.2)	5 (11.1)	7 (15.6)
Neutropenia	11 (24.4)	0	0	2 (4.4)	9 (20.0)
Disseminated intravascular coagulation	4 (8.9)	0	1 (2.2)	2 (4.4)	1 (2.2)
Lymphopenia	4 (8.9)	0	1 (2.2)	0	3 (6.7)
Pancytopenia	3 (6.7)	0	0	1 (2.2)	2 (4.4)
Coagulopathy	2 (4.4)	1 (2.2)	0	1 (2.2)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypofibrinogenaemia	1 (2.2)	0	0	0	1 (2.2)
Leukocytosis	1 (2.2)	1 (2.2)	0	0	0
Leukopenia	1 (2.2)	0	0	0	1 (2.2)
Cardiac disorders					
-Total	17 (37.8)	5 (11.1)	8 (17.8)	3 (6.7)	1 (2.2)
Tachycardia	10 (22.2)	3 (6.7)	5 (11.1)	2 (4.4)	0
Sinus tachycardia	5 (11.1)	3 (6.7)	1 (2.2)	1 (2.2)	0
Pericardial effusion	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Bradycardia	2 (4.4)	0	1 (2.2)	0	1 (2.2)
Left ventricular dysfunction	2 (4.4)	0	0	2 (4.4)	0
Palpitations	2 (4.4)	2 (4.4)	0	0	0
Atrioventricular block second degree	1 (2.2)	1 (2.2)	0	0	0
Right ventricular dysfunction	1 (2.2)	0	0	1 (2.2)	0
Sinus bradycardia	1 (2.2)	1 (2.2)	0	0	0
Ventricular tachycardia	1 (2.2)	0	0	1 (2.2)	0
Ear and labyrinth disorders					
-Total	5 (11.1)	2 (4.4)	3 (6.7)	0	0
Ear pain	2 (4.4)	2 (4.4)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Deafness unilateral	1 (2.2)	0	1 (2.2)	0	0
Hypoacusis	1 (2.2)	0	1 (2.2)	0	0
Tympanic membrane perforation	1 (2.2)	0	1 (2.2)	0	0
Endocrine disorders					
-Total	1 (2.2)	1 (2.2)	0	0	0
Adrenal insufficiency	1 (2.2)	1 (2.2)	0	0	0
Eye disorders					
-Total	13 (28.9)	6 (13.3)	7 (15.6)	0	0
Periorbital oedema	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Photophobia	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Vision blurred	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Conjunctival haemorrhage	2 (4.4)	2 (4.4)	0	0	0
Eye pain	2 (4.4)	0	2 (4.4)	0	0
Retinal haemorrhage	2 (4.4)	2 (4.4)	0	0	0
Uveitis	2 (4.4)	0	2 (4.4)	0	0
Ocular hypertension	1 (2.2)	0	1 (2.2)	0	0
Papilloedema	1 (2.2)	0	1 (2.2)	0	0
Retinopathy	1 (2.2)	0	1 (2.2)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Visual impairment	1 (2.2)	0	1 (2.2)	0	0
Gastrointestinal disorders					
-Total	33 (73.3)	8 (17.8)	11 (24.4)	13 (28.9)	1 (2.2)
Nausea	21 (46.7)	8 (17.8)	7 (15.6)	6 (13.3)	0
Vomiting	18 (40.0)	9 (20.0)	6 (13.3)	3 (6.7)	0
Diarrhoea	16 (35.6)	9 (20.0)	6 (13.3)	1 (2.2)	0
Abdominal pain	12 (26.7)	4 (8.9)	6 (13.3)	2 (4.4)	0
Constipation	8 (17.8)	6 (13.3)	2 (4.4)	0	0
Stomatitis	4 (8.9)	1 (2.2)	1 (2.2)	1 (2.2)	1 (2.2)
Colitis	3 (6.7)	1 (2.2)	0	2 (4.4)	0
Abdominal pain upper	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Haematemesis	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Oral pain	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Pancreatitis	2 (4.4)	0	2 (4.4)	0	0
Abdominal discomfort	1 (2.2)	1 (2.2)	0	0	0
Abdominal distension	1 (2.2)	0	1 (2.2)	0	0
Abdominal pain lower	1 (2.2)	0	1 (2.2)	0	0
Anal fissure	1 (2.2)	0	1 (2.2)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Anal incontinence	1 (2.2)	1 (2.2)	0	0	0
Ascites	1 (2.2)	0	0	1 (2.2)	0
Dry mouth	1 (2.2)	1 (2.2)	0	0	0
Dyspepsia	1 (2.2)	0	1 (2.2)	0	0
Dysphagia	1 (2.2)	0	0	1 (2.2)	0
Gastrointestinal haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Gingival discomfort	1 (2.2)	1 (2.2)	0	0	0
Haematochezia	1 (2.2)	0	0	1 (2.2)	0
Ileus	1 (2.2)	0	0	1 (2.2)	0
Intestinal obstruction	1 (2.2)	0	0	1 (2.2)	0
Lip pain	1 (2.2)	0	1 (2.2)	0	0
Mouth haemorrhage	1 (2.2)	0	0	1 (2.2)	0
Perianal erythema	1 (2.2)	0	1 (2.2)	0	0
Proctalgia	1 (2.2)	0	1 (2.2)	0	0
Tooth socket haemorrhage	1 (2.2)	1 (2.2)	0	0	0
General disorders and administration site conditions					
-Total	35 (77.8)	11 (24.4)	11 (24.4)	10 (22.2)	3 (6.7)

Ethnicity: Other

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	23 (51.1)	6 (13.3)	11 (24.4)	5 (11.1)	1 (2.2)
Fatigue	15 (33.3)	10 (22.2)	3 (6.7)	2 (4.4)	0
Catheter site pain	6 (13.3)	3 (6.7)	3 (6.7)	0	0
Chills	6 (13.3)	6 (13.3)	0	0	0
Oedema peripheral	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Pain	4 (8.9)	0	1 (2.2)	3 (6.7)	0
Generalised oedema	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Malaise	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Multiple organ dysfunction syndrome	3 (6.7)	0	0	1 (2.2)	2 (4.4)
Face oedema	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Non-cardiac chest pain	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Acquired gene mutation	1 (2.2)	1 (2.2)	0	0	0
Asthenia	1 (2.2)	1 (2.2)	0	0	0
Catheter site extravasation	1 (2.2)	0	1 (2.2)	0	0
Catheter site haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Crying	1 (2.2)	1 (2.2)	0	0	0
Device related thrombosis	1 (2.2)	0	1 (2.2)	0	0
Facial pain	1 (2.2)	0	1 (2.2)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gait disturbance	1 (2.2)	1 (2.2)	0	0	0
Injection site haematoma	1 (2.2)	1 (2.2)	0	0	0
Localised oedema	1 (2.2)	0	0	1 (2.2)	0
Medical device pain	1 (2.2)	0	1 (2.2)	0	0
Mucosal haemorrhage	1 (2.2)	0	1 (2.2)	0	0
Peripheral swelling	1 (2.2)	0	1 (2.2)	0	0
Physical deconditioning	1 (2.2)	0	0	1 (2.2)	0
Hepatobiliary disorders					
-Total	8 (17.8)	2 (4.4)	2 (4.4)	3 (6.7)	1 (2.2)
Hyperbilirubinaemia	4 (8.9)	0	1 (2.2)	3 (6.7)	0
Hepatomegaly	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Hepatic failure	1 (2.2)	0	0	0	1 (2.2)
Hepatic steatosis	1 (2.2)	0	1 (2.2)	0	0
Hepatosplenomegaly	1 (2.2)	1 (2.2)	0	0	0
Immune system disorders					
-Total	35 (77.8)	4 (8.9)	16 (35.6)	7 (15.6)	8 (17.8)
Cytokine release syndrome	30 (66.7)	4 (8.9)	13 (28.9)	5 (11.1)	8 (17.8)
Hypogammaglobulinaemia	18 (40.0)	4 (8.9)	10 (22.2)	4 (8.9)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Chronic graft versus host disease	1 (2.2)	0	1 (2.2)	0	0
Graft versus host disease	1 (2.2)	0	1 (2.2)	0	0
Haemophagocytic lymphohistiocytosis	1 (2.2)	0	1 (2.2)	0	0
Seasonal allergy	1 (2.2)	1 (2.2)	0	0	0
Infections and infestations					
-Total	31 (68.9)	3 (6.7)	8 (17.8)	13 (28.9)	7 (15.6)
Upper respiratory tract infection	7 (15.6)	3 (6.7)	3 (6.7)	1 (2.2)	0
Pneumonia	6 (13.3)	0	4 (8.9)	1 (2.2)	1 (2.2)
Rhinovirus infection	5 (11.1)	4 (8.9)	1 (2.2)	0	0
Clostridium difficile colitis	4 (8.9)	1 (2.2)	2 (4.4)	1 (2.2)	0
Clostridium difficile infection	4 (8.9)	0	3 (6.7)	1 (2.2)	0
Sinusitis	4 (8.9)	1 (2.2)	3 (6.7)	0	0
Device related infection	3 (6.7)	0	1 (2.2)	2 (4.4)	0
Gastroenteritis	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Oral herpes	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Staphylococcal infection	2 (4.4)	1 (2.2)	0	0	1 (2.2)
Viral infection	2 (4.4)	2 (4.4)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Viral upper respiratory tract infection	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Vulvovaginal candidiasis	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Abscess limb	1 (2.2)	0	0	1 (2.2)	0
Acute sinusitis	1 (2.2)	0	1 (2.2)	0	0
Bacterial sepsis	1 (2.2)	0	0	0	1 (2.2)
Body tinea	1 (2.2)	1 (2.2)	0	0	0
Bronchitis	1 (2.2)	0	1 (2.2)	0	0
Bronchopulmonary aspergillosis	1 (2.2)	0	0	1 (2.2)	0
Campylobacter infection	1 (2.2)	0	0	1 (2.2)	0
Catheter site cellulitis	1 (2.2)	1 (2.2)	0	0	0
Catheter site infection	1 (2.2)	0	0	1 (2.2)	0
Cellulitis	1 (2.2)	0	0	1 (2.2)	0
Cholecystitis infective	1 (2.2)	0	0	1 (2.2)	0
Croup infectious	1 (2.2)	0	0	1 (2.2)	0
Ear infection	1 (2.2)	0	1 (2.2)	0	0
Enterovirus infection	1 (2.2)	0	0	1 (2.2)	0
Escherichia bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Escherichia urinary tract infection	1 (2.2)	0	1 (2.2)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Folliculitis	1 (2.2)	0	1 (2.2)	0	0
Fungal skin infection	1 (2.2)	0	1 (2.2)	0	0
Gastroenteritis viral	1 (2.2)	1 (2.2)	0	0	0
Gingivitis	1 (2.2)	1 (2.2)	0	0	0
Haemophilus infection	1 (2.2)	0	1 (2.2)	0	0
Herpes simplex	1 (2.2)	1 (2.2)	0	0	0
Herpes zoster	1 (2.2)	0	0	1 (2.2)	0
Human herpesvirus 6 infection	1 (2.2)	0	1 (2.2)	0	0
Human polyomavirus infection	1 (2.2)	0	0	0	1 (2.2)
Hypopyon	1 (2.2)	0	1 (2.2)	0	0
Metapneumovirus infection	1 (2.2)	0	1 (2.2)	0	0
Molluscum contagiosum	1 (2.2)	1 (2.2)	0	0	0
Necrotising fasciitis	1 (2.2)	0	0	1 (2.2)	0
Oral candidiasis	1 (2.2)	1 (2.2)	0	0	0
Orchitis	1 (2.2)	1 (2.2)	0	0	0
Otitis media	1 (2.2)	0	0	1 (2.2)	0
Otitis media acute	1 (2.2)	0	1 (2.2)	0	0
Parainfluenzae virus infection	1 (2.2)	0	0	1 (2.2)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pharyngitis	1 (2.2)	0	1 (2.2)	0	0
Pneumonia fungal	1 (2.2)	0	1 (2.2)	0	0
Rash pustular	1 (2.2)	0	1 (2.2)	0	0
Respiratory syncytial virus infection	1 (2.2)	0	1 (2.2)	0	0
Respiratory tract infection	1 (2.2)	0	0	0	1 (2.2)
Respiratory tract infection viral	1 (2.2)	0	0	1 (2.2)	0
Rhinitis	1 (2.2)	1 (2.2)	0	0	0
Rotavirus infection	1 (2.2)	0	0	1 (2.2)	0
Sepsis	1 (2.2)	0	0	0	1 (2.2)
Septic embolus	1 (2.2)	0	0	0	1 (2.2)
Staphylococcal bacteraemia	1 (2.2)	0	0	1 (2.2)	0
Staphylococcal scalded skin syndrome	1 (2.2)	0	1 (2.2)	0	0
Staphylococcal sepsis	1 (2.2)	0	0	0	1 (2.2)
Streptococcal infection	1 (2.2)	0	1 (2.2)	0	0
Urinary tract infection	1 (2.2)	0	1 (2.2)	0	0
Urinary tract infection enterococcal	1 (2.2)	0	0	1 (2.2)	0
Vascular device infection	1 (2.2)	0	0	1 (2.2)	0

Ethnicity: Other

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	14 (31.1)	6 (13.3)	6 (13.3)	1 (2.2)	1 (2.2)
Infusion related reaction	4 (8.9)	2 (4.4)	2 (4.4)	0	0
Transfusion reaction	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Contusion	2 (4.4)	2 (4.4)	0	0	0
Procedural pain	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Foot fracture	1 (2.2)	0	1 (2.2)	0	0
Incision site pain	1 (2.2)	1 (2.2)	0	0	0
Limb injury	1 (2.2)	1 (2.2)	0	0	0
Mouth injury	1 (2.2)	1 (2.2)	0	0	0
Procedural complication	1 (2.2)	1 (2.2)	0	0	0
Procedural headache	1 (2.2)	0	1 (2.2)	0	0
Procedural nausea	1 (2.2)	0	1 (2.2)	0	0
Radius fracture	1 (2.2)	0	1 (2.2)	0	0
Stoma site irritation	1 (2.2)	1 (2.2)	0	0	0
Subdural haematoma	1 (2.2)	0	1 (2.2)	0	0
Sunburn	1 (2.2)	1 (2.2)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tibia fracture	1 (2.2)	0	1 (2.2)	0	0
Tongue injury	1 (2.2)	1 (2.2)	0	0	0
Tracheal haemorrhage	1 (2.2)	0	0	1 (2.2)	0
Transfusion related complication	1 (2.2)	0	0	0	1 (2.2)
Investigations					
-Total	36 (80.0)	1 (2.2)	3 (6.7)	10 (22.2)	22 (48.9)
White blood cell count decreased	22 (48.9)	3 (6.7)	1 (2.2)	2 (4.4)	16 (35.6)
Aspartate aminotransferase increased	19 (42.2)	4 (8.9)	4 (8.9)	6 (13.3)	5 (11.1)
Alanine aminotransferase increased	17 (37.8)	2 (4.4)	4 (8.9)	10 (22.2)	1 (2.2)
Neutrophil count decreased	16 (35.6)	0	2 (4.4)	1 (2.2)	13 (28.9)
Platelet count decreased	11 (24.4)	0	0	2 (4.4)	9 (20.0)
International normalised ratio increased	10 (22.2)	8 (17.8)	1 (2.2)	1 (2.2)	0
Lymphocyte count decreased	10 (22.2)	0	2 (4.4)	3 (6.7)	5 (11.1)
Blood bilirubin increased	7 (15.6)	1 (2.2)	2 (4.4)	3 (6.7)	1 (2.2)
Prothrombin time prolonged	7 (15.6)	4 (8.9)	2 (4.4)	1 (2.2)	0
Blood creatinine increased	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Transaminases increased	4 (8.9)	3 (6.7)	0	1 (2.2)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Activated partial thromboplastin time prolonged	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Blood fibrinogen decreased	3 (6.7)	0	1 (2.2)	1 (2.2)	1 (2.2)
Weight decreased	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Blood immunoglobulin a decreased	2 (4.4)	2 (4.4)	0	0	0
Blood immunoglobulin m decreased	2 (4.4)	2 (4.4)	0	0	0
Blood lactic acid increased	2 (4.4)	0	1 (2.2)	0	1 (2.2)
Blood phosphorus increased	2 (4.4)	2 (4.4)	0	0	0
Blood urea increased	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Blood uric acid increased	2 (4.4)	2 (4.4)	0	0	0
C-reactive protein increased	2 (4.4)	0	2 (4.4)	0	0
Haemoglobin decreased	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Lipase increased	2 (4.4)	0	0	0	2 (4.4)
Weight increased	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Blood bicarbonate decreased	1 (2.2)	0	1 (2.2)	0	0
Blood lactate dehydrogenase increased	1 (2.2)	0	0	1 (2.2)	0
Blood magnesium decreased	1 (2.2)	0	0	1 (2.2)	0
Blood phosphorus decreased	1 (2.2)	1 (2.2)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac murmur	1 (2.2)	1 (2.2)	0	0	0
Computerised tomogram thorax abnormal	1 (2.2)	0	0	1 (2.2)	0
Culture stool positive	1 (2.2)	1 (2.2)	0	0	0
Electrocardiogram qt prolonged	1 (2.2)	0	0	1 (2.2)	0
Hepatic enzyme increased	1 (2.2)	0	1 (2.2)	0	0
Norovirus test positive	1 (2.2)	1 (2.2)	0	0	0
Oxygen saturation decreased	1 (2.2)	1 (2.2)	0	0	0
Protein total decreased	1 (2.2)	0	0	1 (2.2)	0
Serum ferritin increased	1 (2.2)	0	1 (2.2)	0	0
Metabolism and nutrition disorders					
-Total	29 (64.4)	2 (4.4)	5 (11.1)	20 (44.4)	2 (4.4)
Decreased appetite	16 (35.6)	4 (8.9)	3 (6.7)	9 (20.0)	0
Hypokalaemia	13 (28.9)	2 (4.4)	3 (6.7)	6 (13.3)	2 (4.4)
Hypophosphataemia	9 (20.0)	3 (6.7)	0	6 (13.3)	0
Fluid overload	5 (11.1)	1 (2.2)	3 (6.7)	1 (2.2)	0
Hypoalbuminaemia	5 (11.1)	1 (2.2)	4 (8.9)	0	0
Hypocalcaemia	5 (11.1)	3 (6.7)	1 (2.2)	1 (2.2)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperglycaemia	4 (8.9)	0	2 (4.4)	2 (4.4)	0
Hyperphosphataemia	4 (8.9)	4 (8.9)	0	0	0
Dehydration	3 (6.7)	0	0	3 (6.7)	0
Hypernatraemia	3 (6.7)	0	2 (4.4)	0	1 (2.2)
Hyperkalaemia	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Hypoglycaemia	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Hyponatraemia	2 (4.4)	0	0	2 (4.4)	0
Vitamin d deficiency	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Acidosis	1 (2.2)	0	0	1 (2.2)	0
Hyperalbuminaemia	1 (2.2)	1 (2.2)	0	0	0
Hypercalcaemia	1 (2.2)	1 (2.2)	0	0	0
Hyperchloraemia	1 (2.2)	1 (2.2)	0	0	0
Hypermagnesaemia	1 (2.2)	1 (2.2)	0	0	0
Hypertriglyceridaemia	1 (2.2)	0	0	1 (2.2)	0
Hyperuricaemia	1 (2.2)	1 (2.2)	0	0	0
Hypomagnesaemia	1 (2.2)	1 (2.2)	0	0	0
Malnutrition	1 (2.2)	0	0	1 (2.2)	0
Metabolic acidosis	1 (2.2)	0	1 (2.2)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolic alkalosis	1 (2.2)	1 (2.2)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	24 (53.3)	8 (17.8)	9 (20.0)	7 (15.6)	0
Pain in extremity	11 (24.4)	4 (8.9)	4 (8.9)	3 (6.7)	0
Myalgia	6 (13.3)	4 (8.9)	1 (2.2)	1 (2.2)	0
Arthralgia	4 (8.9)	1 (2.2)	1 (2.2)	2 (4.4)	0
Musculoskeletal pain	3 (6.7)	2 (4.4)	0	1 (2.2)	0
Pain in jaw	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Neck pain	2 (4.4)	0	2 (4.4)	0	0
Back pain	1 (2.2)	0	0	1 (2.2)	0
Bone pain	1 (2.2)	0	0	1 (2.2)	0
Coccydynia	1 (2.2)	1 (2.2)	0	0	0
Joint range of motion decreased	1 (2.2)	1 (2.2)	0	0	0
Limb discomfort	1 (2.2)	1 (2.2)	0	0	0
Muscle spasms	1 (2.2)	1 (2.2)	0	0	0
Muscular weakness	1 (2.2)	1 (2.2)	0	0	0
Musculoskeletal chest pain	1 (2.2)	1 (2.2)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Myopathy	1 (2.2)	0	0	1 (2.2)	0
Myositis	1 (2.2)	0	0	1 (2.2)	0
Osteonecrosis	1 (2.2)	0	1 (2.2)	0	0
Osteopenia	1 (2.2)	0	1 (2.2)	0	0
Synovitis	1 (2.2)	0	1 (2.2)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (2.2)	0	0	0	1 (2.2)
Glioblastoma multiforme	1 (2.2)	0	0	0	1 (2.2)
Nervous system disorders					
-Total	30 (66.7)	13 (28.9)	11 (24.4)	4 (8.9)	2 (4.4)
Headache	18 (40.0)	9 (20.0)	6 (13.3)	3 (6.7)	0
Dizziness	4 (8.9)	4 (8.9)	0	0	0
Encephalopathy	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Peroneal nerve palsy	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Seizure	3 (6.7)	0	0	2 (4.4)	1 (2.2)
Depressed level of consciousness	1 (2.2)	1 (2.2)	0	0	0
Disturbance in attention	1 (2.2)	1 (2.2)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dysgeusia	1 (2.2)	1 (2.2)	0	0	0
Embolic stroke	1 (2.2)	0	0	0	1 (2.2)
Hyporesponsive to stimuli	1 (2.2)	0	0	1 (2.2)	0
Hypotonia	1 (2.2)	0	1 (2.2)	0	0
Idiopathic intracranial hypertension	1 (2.2)	0	1 (2.2)	0	0
Migraine	1 (2.2)	0	1 (2.2)	0	0
Myoclonus	1 (2.2)	1 (2.2)	0	0	0
Neuropathy peripheral	1 (2.2)	1 (2.2)	0	0	0
Somnolence	1 (2.2)	0	1 (2.2)	0	0
Tremor	1 (2.2)	1 (2.2)	0	0	0
Visual field defect	1 (2.2)	0	1 (2.2)	0	0
Psychiatric disorders					
-Total	19 (42.2)	4 (8.9)	12 (26.7)	3 (6.7)	0
Anxiety	8 (17.8)	3 (6.7)	4 (8.9)	1 (2.2)	0
Confusional state	6 (13.3)	2 (4.4)	4 (8.9)	0	0
Delirium	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Depression	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Insomnia	3 (6.7)	0	3 (6.7)	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Irritability	3 (6.7)	3 (6.7)	0	0	0
Agitation	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Mental status changes	2 (4.4)	2 (4.4)	0	0	0
Hallucination	1 (2.2)	0	1 (2.2)	0	0
Listless	1 (2.2)	1 (2.2)	0	0	0
Panic attack	1 (2.2)	0	1 (2.2)	0	0
Sleep disorder	1 (2.2)	0	1 (2.2)	0	0
Renal and urinary disorders					
-Total	13 (28.9)	2 (4.4)	4 (8.9)	3 (6.7)	4 (8.9)
Acute kidney injury	8 (17.8)	2 (4.4)	1 (2.2)	2 (4.4)	3 (6.7)
Haematuria	4 (8.9)	0	2 (4.4)	1 (2.2)	1 (2.2)
Oliguria	3 (6.7)	0	0	3 (6.7)	0
Dysuria	2 (4.4)	0	2 (4.4)	0	0
Cystitis haemorrhagic	1 (2.2)	0	0	0	1 (2.2)
Pollakiuria	1 (2.2)	1 (2.2)	0	0	0
Renal failure	1 (2.2)	0	0	0	1 (2.2)
Renal impairment	1 (2.2)	0	0	1 (2.2)	0
Urinary incontinence	1 (2.2)	1 (2.2)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urinary retention	1 (2.2)	0	1 (2.2)	0	0
Reproductive system and breast disorders					
-Total	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Vulvovaginal adhesion	2 (4.4)	2 (4.4)	0	0	0
Oedema genital	1 (2.2)	0	1 (2.2)	0	0
Vaginal haemorrhage	1 (2.2)	0	0	1 (2.2)	0
Respiratory, thoracic and mediastinal disorders					
-Total	22 (48.9)	3 (6.7)	3 (6.7)	9 (20.0)	7 (15.6)
Hypoxia	13 (28.9)	0	1 (2.2)	9 (20.0)	3 (6.7)
Cough	10 (22.2)	9 (20.0)	0	1 (2.2)	0
Epistaxis	9 (20.0)	1 (2.2)	3 (6.7)	4 (8.9)	1 (2.2)
Pleural effusion	9 (20.0)	1 (2.2)	6 (13.3)	2 (4.4)	0
Dyspnoea	5 (11.1)	1 (2.2)	1 (2.2)	2 (4.4)	1 (2.2)
Pulmonary oedema	5 (11.1)	0	0	3 (6.7)	2 (4.4)
Tachypnoea	5 (11.1)	0	2 (4.4)	3 (6.7)	0
Oropharyngeal pain	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Rhinitis allergic	3 (6.7)	3 (6.7)	0	0	0

Ethnicity: Other

	All patients N=45				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atelectasis	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Haemoptysis	2 (4.4)	0	0	1 (2.2)	1 (2.2)
Respiratory distress	2 (4.4)	0	0	0	2 (4.4)
Aspiration	1 (2.2)	0	0	0	1 (2.2)
Dysphonia	1 (2.2)	1 (2.2)	0	0	0
Interstitial lung disease	1 (2.2)	0	0	0	1 (2.2)
Nasal congestion	1 (2.2)	1 (2.2)	0	0	0
Pharyngeal erythema	1 (2.2)	1 (2.2)	0	0	0
Pharyngeal lesion	1 (2.2)	0	0	1 (2.2)	0
Pharyngeal ulceration	1 (2.2)	0	1 (2.2)	0	0
Pulmonary alveolar haemorrhage	1 (2.2)	0	0	0	1 (2.2)
Pulmonary hypertension	1 (2.2)	0	0	1 (2.2)	0
Respiratory depression	1 (2.2)	0	1 (2.2)	0	0
Respiratory failure	1 (2.2)	0	0	0	1 (2.2)
Rhinorrhoea	1 (2.2)	1 (2.2)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	22 (48.9)	11 (24.4)	9 (20.0)	2 (4.4)	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	7 (15.6)	5 (11.1)	2 (4.4)	0	0
Alopecia	4 (8.9)	2 (4.4)	2 (4.4)	0	0
Erythema	4 (8.9)	4 (8.9)	0	0	0
Hyperhidrosis	4 (8.9)	4 (8.9)	0	0	0
Rash erythematous	4 (8.9)	1 (2.2)	3 (6.7)	0	0
Rash maculo-papular	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Dry skin	2 (4.4)	2 (4.4)	0	0	0
Petechiae	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Pruritus	2 (4.4)	2 (4.4)	0	0	0
Rash macular	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Acne	1 (2.2)	1 (2.2)	0	0	0
Dermatitis acneiform	1 (2.2)	0	1 (2.2)	0	0
Dermatitis atopic	1 (2.2)	1 (2.2)	0	0	0
Ingrowing nail	1 (2.2)	0	1 (2.2)	0	0
Livedo reticularis	1 (2.2)	1 (2.2)	0	0	0
Macule	1 (2.2)	1 (2.2)	0	0	0
Night sweats	1 (2.2)	0	1 (2.2)	0	0
Papule	1 (2.2)	1 (2.2)	0	0	0

Ethnicity: Other

Primary system organ class Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pruritus generalised	1 (2.2)	1 (2.2)	0	0	0
Rash papular	1 (2.2)	1 (2.2)	0	0	0
Rash vesicular	1 (2.2)	1 (2.2)	0	0	0
Skin haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Skin ulcer	1 (2.2)	1 (2.2)	0	0	0
Vascular disorders					
-Total	19 (42.2)	2 (4.4)	1 (2.2)	7 (15.6)	9 (20.0)
Hypotension	15 (33.3)	1 (2.2)	0	5 (11.1)	9 (20.0)
Hypertension	12 (26.7)	3 (6.7)	7 (15.6)	2 (4.4)	0
Flushing	2 (4.4)	2 (4.4)	0	0	0
Capillary leak syndrome	1 (2.2)	0	0	0	1 (2.2)
Embolism	1 (2.2)	0	0	1 (2.2)	0
Haematoma	1 (2.2)	0	1 (2.2)	0	0
Hot flush	1 (2.2)	1 (2.2)	0	0	0
Venous thrombosis limb	1 (2.2)	1 (2.2)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178e
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	0	1 (12.5)	7 (87.5)
Blood and lymphatic system disorders					
-Total	6 (75.0)	0	0	4 (50.0)	2 (25.0)
Anaemia	5 (62.5)	1 (12.5)	0	3 (37.5)	1 (12.5)
Febrile neutropenia	4 (50.0)	0	0	4 (50.0)	0
Neutropenia	2 (25.0)	0	0	0	2 (25.0)
Thrombocytopenia	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Cardiac disorders					
-Total	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Left ventricular dysfunction	2 (25.0)	0	0	2 (25.0)	0
Tachycardia	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Palpitations	1 (12.5)	1 (12.5)	0	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pericardial effusion	1 (12.5)	1 (12.5)	0	0	0
Endocrine disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Adrenal insufficiency	1 (12.5)	1 (12.5)	0	0	0
Eye disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Eye pain	1 (12.5)	1 (12.5)	0	0	0
Gastrointestinal disorders					
-Total	7 (87.5)	2 (25.0)	1 (12.5)	3 (37.5)	1 (12.5)
Nausea	5 (62.5)	1 (12.5)	2 (25.0)	2 (25.0)	0
Vomiting	5 (62.5)	3 (37.5)	2 (25.0)	0	0
Diarrhoea	4 (50.0)	3 (37.5)	1 (12.5)	0	0
Abdominal pain	3 (37.5)	2 (25.0)	1 (12.5)	0	0
Oral pain	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Constipation	1 (12.5)	1 (12.5)	0	0	0
Enterocolitis	1 (12.5)	0	0	1 (12.5)	0
Stomatitis	1 (12.5)	0	0	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	6 (75.0)	1 (12.5)	1 (12.5)	3 (37.5)	1 (12.5)
Pyrexia	5 (62.5)	1 (12.5)	1 (12.5)	2 (25.0)	1 (12.5)
Fatigue	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Pain	2 (25.0)	0	0	2 (25.0)	0
Asthenia	1 (12.5)	1 (12.5)	0	0	0
Catheter site pain	1 (12.5)	0	1 (12.5)	0	0
Chills	1 (12.5)	1 (12.5)	0	0	0
Hepatobiliary disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hepatomegaly	1 (12.5)	0	1 (12.5)	0	0
Immune system disorders					
-Total	7 (87.5)	0	4 (50.0)	0	3 (37.5)
Cytokine release syndrome	5 (62.5)	0	2 (25.0)	0	3 (37.5)
Hypogammaglobulinaemia	4 (50.0)	0	4 (50.0)	0	0
Graft versus host disease	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (75.0)	1 (12.5)	2 (25.0)	1 (12.5)	2 (25.0)
Upper respiratory tract infection	2 (25.0)	0	2 (25.0)	0	0
Viral infection	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Cellulitis	1 (12.5)	0	0	1 (12.5)	0
Clostridium difficile infection	1 (12.5)	0	1 (12.5)	0	0
Corona virus infection	1 (12.5)	0	0	1 (12.5)	0
Ear infection	1 (12.5)	1 (12.5)	0	0	0
Gastroenteritis	1 (12.5)	0	1 (12.5)	0	0
Human polyomavirus infection	1 (12.5)	0	0	0	1 (12.5)
Oral herpes	1 (12.5)	0	0	1 (12.5)	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Respiratory syncytial virus infection	1 (12.5)	0	0	1 (12.5)	0
Rhinovirus infection	1 (12.5)	1 (12.5)	0	0	0
Skin infection	1 (12.5)	0	1 (12.5)	0	0
Tinea capitis	1 (12.5)	1 (12.5)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Contusion	1 (12.5)	1 (12.5)	0	0	0
Infusion related reaction	1 (12.5)	0	1 (12.5)	0	0
Procedural nausea	1 (12.5)	0	1 (12.5)	0	0
Sunburn	1 (12.5)	1 (12.5)	0	0	0
Tracheal haemorrhage	1 (12.5)	0	0	1 (12.5)	0
Wound	1 (12.5)	1 (12.5)	0	0	0
Investigations					
-Total	7 (87.5)	0	1 (12.5)	2 (25.0)	4 (50.0)
Neutrophil count decreased	4 (50.0)	0	1 (12.5)	0	3 (37.5)
White blood cell count decreased	4 (50.0)	1 (12.5)	0	0	3 (37.5)
Blood magnesium decreased	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Lymphocyte count decreased	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Activated partial thromboplastin time prolonged	1 (12.5)	1 (12.5)	0	0	0
Aspartate aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)
Blood bilirubin increased	1 (12.5)	0	0	1 (12.5)	0
Blood creatinine increased	1 (12.5)	0	1 (12.5)	0	0
Blood fibrinogen decreased	1 (12.5)	0	1 (12.5)	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (12.5)	1 (12.5)	0	0	0
Blood phosphorus increased	1 (12.5)	1 (12.5)	0	0	0
Blood uric acid increased	1 (12.5)	1 (12.5)	0	0	0
Cardiac murmur	1 (12.5)	1 (12.5)	0	0	0
Fibrin d dimer increased	1 (12.5)	1 (12.5)	0	0	0
International normalised ratio increased	1 (12.5)	1 (12.5)	0	0	0
Prothrombin time prolonged	1 (12.5)	0	1 (12.5)	0	0
Weight decreased	1 (12.5)	1 (12.5)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (62.5)	2 (25.0)	2 (25.0)	1 (12.5)	0
Decreased appetite	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Hypokalaemia	3 (37.5)	2 (25.0)	1 (12.5)	0	0
Hypernatraemia	1 (12.5)	0	1 (12.5)	0	0
Hypoalbuminaemia	1 (12.5)	1 (12.5)	0	0	0
Hypophosphataemia	1 (12.5)	0	0	1 (12.5)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (62.5)	2 (25.0)	1 (12.5)	2 (25.0)	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	3 (37.5)	2 (25.0)	0	1 (12.5)	0
Arthralgia	1 (12.5)	0	0	1 (12.5)	0
Muscular weakness	1 (12.5)	1 (12.5)	0	0	0
Neck pain	1 (12.5)	0	1 (12.5)	0	0
Pain in jaw	1 (12.5)	1 (12.5)	0	0	0
Nervous system disorders					
-Total	5 (62.5)	5 (62.5)	0	0	0
Headache	3 (37.5)	3 (37.5)	0	0	0
Dizziness	1 (12.5)	1 (12.5)	0	0	0
Dysgeusia	1 (12.5)	1 (12.5)	0	0	0
Peroneal nerve palsy	1 (12.5)	1 (12.5)	0	0	0
Psychiatric disorders					
-Total	4 (50.0)	0	4 (50.0)	0	0
Confusional state	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Depression	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Anxiety	1 (12.5)	1 (12.5)	0	0	0
Delirium	1 (12.5)	1 (12.5)	0	0	0
Insomnia	1 (12.5)	0	1 (12.5)	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sleep disorder	1 (12.5)	0	1 (12.5)	0	0
Renal and urinary disorders					
-Total	2 (25.0)	0	0	0	2 (25.0)
Haematuria	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Acute kidney injury	1 (12.5)	0	0	0	1 (12.5)
Cystitis haemorrhagic	1 (12.5)	0	0	0	1 (12.5)
Oliguria	1 (12.5)	0	0	1 (12.5)	0
Renal failure	1 (12.5)	0	0	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders					
-Total	7 (87.5)	2 (25.0)	1 (12.5)	1 (12.5)	3 (37.5)
Cough	3 (37.5)	3 (37.5)	0	0	0
Epistaxis	3 (37.5)	0	1 (12.5)	1 (12.5)	1 (12.5)
Hypoxia	3 (37.5)	0	0	2 (25.0)	1 (12.5)
Pleural effusion	2 (25.0)	0	2 (25.0)	0	0
Rhinorrhoea	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Aspiration	1 (12.5)	0	0	0	1 (12.5)
Dyspnoea	1 (12.5)	0	0	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoptysis	1 (12.5)	0	0	0	1 (12.5)
Interstitial lung disease	1 (12.5)	0	0	0	1 (12.5)
Nasal congestion	1 (12.5)	1 (12.5)	0	0	0
Oropharyngeal pain	1 (12.5)	0	1 (12.5)	0	0
Pharyngeal erythema	1 (12.5)	1 (12.5)	0	0	0
Pharyngeal lesion	1 (12.5)	0	0	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)
Respiratory failure	1 (12.5)	0	0	0	1 (12.5)
Skin and subcutaneous tissue disorders					
-Total	4 (50.0)	3 (37.5)	1 (12.5)	0	0
Erythema	2 (25.0)	2 (25.0)	0	0	0
Alopecia	1 (12.5)	0	1 (12.5)	0	0
Dermatitis diaper	1 (12.5)	1 (12.5)	0	0	0
Dry skin	1 (12.5)	1 (12.5)	0	0	0
Livedo reticularis	1 (12.5)	1 (12.5)	0	0	0
Rash erythematous	1 (12.5)	0	1 (12.5)	0	0
Rash maculo-papular	1 (12.5)	1 (12.5)	0	0	0

Response status at study entry: Primary refractory

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	6 (75.0)	0	1 (12.5)	2 (25.0)	3 (37.5)
Hypotension	5 (62.5)	0	0	2 (25.0)	3 (37.5)
Hypertension	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Haematoma	1 (12.5)	0	1 (12.5)	0	0
Hot flush	1 (12.5)	1 (12.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178e
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	64 (95.5)	0	3 (4.5)	11 (16.4)	50 (74.6)
Blood and lymphatic system disorders					
-Total	55 (82.1)	1 (1.5)	2 (3.0)	31 (46.3)	21 (31.3)
Febrile neutropenia	32 (47.8)	0	0	31 (46.3)	1 (1.5)
Anaemia	30 (44.8)	1 (1.5)	6 (9.0)	23 (34.3)	0
Neutropenia	14 (20.9)	0	0	4 (6.0)	10 (14.9)
Thrombocytopenia	13 (19.4)	0	1 (1.5)	4 (6.0)	8 (11.9)
Disseminated intravascular coagulation	6 (9.0)	0	2 (3.0)	3 (4.5)	1 (1.5)
Lymphopenia	6 (9.0)	0	2 (3.0)	1 (1.5)	3 (4.5)
Pancytopenia	4 (6.0)	0	0	1 (1.5)	3 (4.5)
Coagulopathy	2 (3.0)	1 (1.5)	0	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eosinophilia	1 (1.5)	0	0	1 (1.5)	0
Hypofibrinogenaemia	1 (1.5)	0	0	0	1 (1.5)
Leukocytosis	1 (1.5)	1 (1.5)	0	0	0
Leukopenia	1 (1.5)	0	0	0	1 (1.5)
Lymphadenopathy	1 (1.5)	0	1 (1.5)	0	0
Splenomegaly	1 (1.5)	1 (1.5)	0	0	0
Cardiac disorders					
-Total	25 (37.3)	10 (14.9)	10 (14.9)	3 (4.5)	2 (3.0)
Tachycardia	15 (22.4)	8 (11.9)	6 (9.0)	1 (1.5)	0
Sinus tachycardia	7 (10.4)	3 (4.5)	2 (3.0)	2 (3.0)	0
Bradycardia	3 (4.5)	1 (1.5)	1 (1.5)	0	1 (1.5)
Pericardial effusion	2 (3.0)	0	2 (3.0)	0	0
Ventricular tachycardia	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Atrioventricular block second degree	1 (1.5)	1 (1.5)	0	0	0
Cardiac dysfunction	1 (1.5)	1 (1.5)	0	0	0
Cardiovascular insufficiency	1 (1.5)	0	0	0	1 (1.5)
Left ventricular dysfunction	1 (1.5)	0	0	1 (1.5)	0
Palpitations	1 (1.5)	1 (1.5)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Right ventricular dysfunction	1 (1.5)	0	0	1 (1.5)	0
Sinus bradycardia	1 (1.5)	1 (1.5)	0	0	0
Ear and labyrinth disorders					
-Total	5 (7.5)	2 (3.0)	3 (4.5)	0	0
Ear pain	2 (3.0)	2 (3.0)	0	0	0
Deafness unilateral	1 (1.5)	0	1 (1.5)	0	0
Hypoacusis	1 (1.5)	0	1 (1.5)	0	0
Tympanic membrane perforation	1 (1.5)	0	1 (1.5)	0	0
Endocrine disorders					
-Total	4 (6.0)	1 (1.5)	3 (4.5)	0	0
Adrenal insufficiency	2 (3.0)	0	2 (3.0)	0	0
Cushingoid	1 (1.5)	1 (1.5)	0	0	0
Hyperthyroidism	1 (1.5)	0	1 (1.5)	0	0
Eye disorders					
-Total	19 (28.4)	10 (14.9)	9 (13.4)	0	0
Periorbital oedema	4 (6.0)	3 (4.5)	1 (1.5)	0	0
Vision blurred	4 (6.0)	2 (3.0)	2 (3.0)	0	0
Conjunctival haemorrhage	3 (4.5)	3 (4.5)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Photophobia	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Dry eye	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Eye pain	2 (3.0)	0	2 (3.0)	0	0
Retinal haemorrhage	2 (3.0)	2 (3.0)	0	0	0
Uveitis	2 (3.0)	0	2 (3.0)	0	0
Conjunctivitis allergic	1 (1.5)	1 (1.5)	0	0	0
Eye irritation	1 (1.5)	1 (1.5)	0	0	0
Ocular hyperaemia	1 (1.5)	1 (1.5)	0	0	0
Ocular hypertension	1 (1.5)	0	1 (1.5)	0	0
Papilloedema	1 (1.5)	0	1 (1.5)	0	0
Retinopathy	1 (1.5)	0	1 (1.5)	0	0
Visual impairment	1 (1.5)	0	1 (1.5)	0	0
Gastrointestinal disorders					
-Total	46 (68.7)	10 (14.9)	19 (28.4)	17 (25.4)	0
Nausea	28 (41.8)	8 (11.9)	15 (22.4)	5 (7.5)	0
Vomiting	25 (37.3)	14 (20.9)	7 (10.4)	4 (6.0)	0
Diarrhoea	22 (32.8)	11 (16.4)	9 (13.4)	2 (3.0)	0
Abdominal pain	14 (20.9)	5 (7.5)	6 (9.0)	3 (4.5)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	10 (14.9)	8 (11.9)	2 (3.0)	0	0
Colitis	4 (6.0)	1 (1.5)	0	3 (4.5)	0
Stomatitis	4 (6.0)	1 (1.5)	1 (1.5)	2 (3.0)	0
Abdominal pain upper	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Pancreatitis	3 (4.5)	0	2 (3.0)	1 (1.5)	0
Abdominal distension	2 (3.0)	0	2 (3.0)	0	0
Abdominal pain lower	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Ascites	2 (3.0)	0	0	2 (3.0)	0
Dysphagia	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Gastrointestinal haemorrhage	2 (3.0)	2 (3.0)	0	0	0
Haematemesis	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Haematochezia	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Abdominal discomfort	1 (1.5)	1 (1.5)	0	0	0
Abdominal tenderness	1 (1.5)	1 (1.5)	0	0	0
Anal fissure	1 (1.5)	0	1 (1.5)	0	0
Anal incontinence	1 (1.5)	1 (1.5)	0	0	0
Dry mouth	1 (1.5)	1 (1.5)	0	0	0
Dyspepsia	1 (1.5)	0	1 (1.5)	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flatulence	1 (1.5)	1 (1.5)	0	0	0
Gastrooesophageal reflux disease	1 (1.5)	1 (1.5)	0	0	0
Gingival discomfort	1 (1.5)	1 (1.5)	0	0	0
Glossodynia	1 (1.5)	1 (1.5)	0	0	0
Ileus	1 (1.5)	0	0	1 (1.5)	0
Intestinal obstruction	1 (1.5)	0	0	1 (1.5)	0
Lip pain	1 (1.5)	0	1 (1.5)	0	0
Mouth haemorrhage	1 (1.5)	0	0	1 (1.5)	0
Oral mucosal blistering	1 (1.5)	1 (1.5)	0	0	0
Oral pain	1 (1.5)	0	1 (1.5)	0	0
Pancreatic failure	1 (1.5)	0	1 (1.5)	0	0
Perianal erythema	1 (1.5)	0	1 (1.5)	0	0
Pigmentation lip	1 (1.5)	1 (1.5)	0	0	0
Proctalgia	1 (1.5)	0	1 (1.5)	0	0
Tooth socket haemorrhage	1 (1.5)	1 (1.5)	0	0	0
General disorders and administration site conditions					
-Total	46 (68.7)	15 (22.4)	17 (25.4)	11 (16.4)	3 (4.5)

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	27 (40.3)	8 (11.9)	14 (20.9)	5 (7.5)	0
Fatigue	16 (23.9)	12 (17.9)	3 (4.5)	1 (1.5)	0
Chills	10 (14.9)	8 (11.9)	2 (3.0)	0	0
Catheter site pain	6 (9.0)	3 (4.5)	3 (4.5)	0	0
Oedema peripheral	5 (7.5)	3 (4.5)	1 (1.5)	1 (1.5)	0
Pain	5 (7.5)	1 (1.5)	3 (4.5)	1 (1.5)	0
Generalised oedema	4 (6.0)	2 (3.0)	2 (3.0)	0	0
Malaise	4 (6.0)	1 (1.5)	3 (4.5)	0	0
Multiple organ dysfunction syndrome	4 (6.0)	0	0	1 (1.5)	3 (4.5)
Face oedema	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Influenza like illness	2 (3.0)	2 (3.0)	0	0	0
Non-cardiac chest pain	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Physical deconditioning	2 (3.0)	0	0	2 (3.0)	0
Acquired gene mutation	1 (1.5)	1 (1.5)	0	0	0
Catheter site extravasation	1 (1.5)	0	1 (1.5)	0	0
Catheter site haemorrhage	1 (1.5)	1 (1.5)	0	0	0
Crying	1 (1.5)	1 (1.5)	0	0	0
Cyst	1 (1.5)	0	0	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related thrombosis	1 (1.5)	0	1 (1.5)	0	0
Facial pain	1 (1.5)	0	1 (1.5)	0	0
Gait disturbance	1 (1.5)	1 (1.5)	0	0	0
Injection site haematoma	1 (1.5)	1 (1.5)	0	0	0
Localised oedema	1 (1.5)	0	0	1 (1.5)	0
Medical device pain	1 (1.5)	0	1 (1.5)	0	0
Mucosal haemorrhage	1 (1.5)	0	1 (1.5)	0	0
Peripheral swelling	1 (1.5)	0	1 (1.5)	0	0
Hepatobiliary disorders					
-Total	10 (14.9)	3 (4.5)	2 (3.0)	4 (6.0)	1 (1.5)
Hyperbilirubinaemia	5 (7.5)	0	2 (3.0)	3 (4.5)	0
Hepatomegaly	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Cholecystitis	1 (1.5)	0	0	1 (1.5)	0
Gallbladder enlargement	1 (1.5)	1 (1.5)	0	0	0
Hepatic failure	1 (1.5)	0	0	0	1 (1.5)
Hepatic steatosis	1 (1.5)	0	1 (1.5)	0	0
Hepatosplenomegaly	1 (1.5)	1 (1.5)	0	0	0
Immune system disorders					

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	52 (77.6)	6 (9.0)	27 (40.3)	11 (16.4)	8 (11.9)
Cytokine release syndrome	45 (67.2)	6 (9.0)	23 (34.3)	8 (11.9)	8 (11.9)
Hypogammaglobulinaemia	29 (43.3)	4 (6.0)	20 (29.9)	5 (7.5)	0
Immunodeficiency common variable	2 (3.0)	0	2 (3.0)	0	0
Seasonal allergy	2 (3.0)	2 (3.0)	0	0	0
Chronic graft versus host disease	1 (1.5)	0	1 (1.5)	0	0
Drug hypersensitivity	1 (1.5)	0	1 (1.5)	0	0
Graft versus host disease	1 (1.5)	1 (1.5)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (1.5)	0	1 (1.5)	0	0
Graft versus host disease in skin	1 (1.5)	1 (1.5)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.5)	0	1 (1.5)	0	0
Immunodeficiency	1 (1.5)	0	1 (1.5)	0	0
Infections and infestations					
-Total	46 (68.7)	3 (4.5)	14 (20.9)	20 (29.9)	9 (13.4)
Upper respiratory tract infection	9 (13.4)	5 (7.5)	3 (4.5)	1 (1.5)	0
Pneumonia	6 (9.0)	0	5 (7.5)	1 (1.5)	0
Clostridium difficile colitis	5 (7.5)	1 (1.5)	2 (3.0)	2 (3.0)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	5 (7.5)	0	4 (6.0)	1 (1.5)	0
Rhinovirus infection	5 (7.5)	4 (6.0)	1 (1.5)	0	0
Sinusitis	5 (7.5)	1 (1.5)	4 (6.0)	0	0
Urinary tract infection	5 (7.5)	0	3 (4.5)	2 (3.0)	0
Device related infection	4 (6.0)	0	1 (1.5)	3 (4.5)	0
Gastroenteritis	4 (6.0)	1 (1.5)	2 (3.0)	1 (1.5)	0
Influenza	4 (6.0)	1 (1.5)	3 (4.5)	0	0
Otitis media	4 (6.0)	0	3 (4.5)	1 (1.5)	0
Parainfluenzae virus infection	4 (6.0)	2 (3.0)	1 (1.5)	1 (1.5)	0
Viral upper respiratory tract infection	4 (6.0)	2 (3.0)	1 (1.5)	1 (1.5)	0
Escherichia urinary tract infection	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Staphylococcal infection	3 (4.5)	1 (1.5)	0	1 (1.5)	1 (1.5)
Cytomegalovirus infection	2 (3.0)	2 (3.0)	0	0	0
Escherichia bacteraemia	2 (3.0)	0	0	2 (3.0)	0
Fungal skin infection	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Otitis media acute	2 (3.0)	0	2 (3.0)	0	0
Sepsis	2 (3.0)	0	0	0	2 (3.0)
Staphylococcal bacteraemia	2 (3.0)	0	0	2 (3.0)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal candidiasis	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Abscess limb	1 (1.5)	0	0	1 (1.5)	0
Acute sinusitis	1 (1.5)	0	1 (1.5)	0	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Bacterial sepsis	1 (1.5)	0	0	0	1 (1.5)
Body tinea	1 (1.5)	1 (1.5)	0	0	0
Bronchitis	1 (1.5)	0	1 (1.5)	0	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Campylobacter infection	1 (1.5)	0	0	1 (1.5)	0
Candida sepsis	1 (1.5)	0	0	0	1 (1.5)
Catheter site cellulitis	1 (1.5)	1 (1.5)	0	0	0
Catheter site infection	1 (1.5)	0	0	1 (1.5)	0
Cellulitis of male external genital organ	1 (1.5)	0	0	1 (1.5)	0
Cholecystitis infective	1 (1.5)	0	0	1 (1.5)	0
Conjunctivitis	1 (1.5)	0	1 (1.5)	0	0
Croup infectious	1 (1.5)	0	0	1 (1.5)	0
Ear infection	1 (1.5)	0	1 (1.5)	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterococcal infection	1 (1.5)	1 (1.5)	0	0	0
Enterovirus infection	1 (1.5)	0	0	1 (1.5)	0
Escherichia sepsis	1 (1.5)	0	0	0	1 (1.5)
Folliculitis	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis norovirus	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis viral	1 (1.5)	1 (1.5)	0	0	0
Gingivitis	1 (1.5)	1 (1.5)	0	0	0
Haemophilus infection	1 (1.5)	0	1 (1.5)	0	0
Herpes simplex	1 (1.5)	1 (1.5)	0	0	0
Herpes zoster	1 (1.5)	0	0	1 (1.5)	0
Human herpesvirus 6 infection	1 (1.5)	0	1 (1.5)	0	0
Hypopyon	1 (1.5)	0	1 (1.5)	0	0
Klebsiella sepsis	1 (1.5)	0	0	0	1 (1.5)
Meningitis aseptic	1 (1.5)	0	1 (1.5)	0	0
Metapneumovirus infection	1 (1.5)	0	1 (1.5)	0	0
Molluscum contagiosum	1 (1.5)	1 (1.5)	0	0	0
Necrotising fasciitis	1 (1.5)	0	0	1 (1.5)	0
Oral candidiasis	1 (1.5)	1 (1.5)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (1.5)	0	1 (1.5)	0	0
Orchitis	1 (1.5)	1 (1.5)	0	0	0
Otitis externa	1 (1.5)	0	1 (1.5)	0	0
Paronychia	1 (1.5)	1 (1.5)	0	0	0
Pharyngitis	1 (1.5)	0	1 (1.5)	0	0
Pneumonia fungal	1 (1.5)	0	1 (1.5)	0	0
Rash pustular	1 (1.5)	0	1 (1.5)	0	0
Respiratory syncytial virus bronchitis	1 (1.5)	0	0	1 (1.5)	0
Respiratory syncytial virus infection	1 (1.5)	0	1 (1.5)	0	0
Respiratory tract infection	1 (1.5)	0	0	0	1 (1.5)
Respiratory tract infection viral	1 (1.5)	0	0	1 (1.5)	0
Rhinitis	1 (1.5)	1 (1.5)	0	0	0
Rotavirus infection	1 (1.5)	0	0	1 (1.5)	0
Septic embolus	1 (1.5)	0	0	0	1 (1.5)
Skin infection	1 (1.5)	0	1 (1.5)	0	0
Staphylococcal scalded skin syndrome	1 (1.5)	0	1 (1.5)	0	0
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Streptococcal infection	1 (1.5)	0	1 (1.5)	0	0
Subcutaneous abscess	1 (1.5)	0	1 (1.5)	0	0
Urinary tract infection enterococcal	1 (1.5)	0	0	1 (1.5)	0
Vascular device infection	1 (1.5)	0	0	1 (1.5)	0
Viral infection	1 (1.5)	1 (1.5)	0	0	0
Vulvovaginal mycotic infection	1 (1.5)	0	1 (1.5)	0	0
Injury, poisoning and procedural complications					
-Total	23 (34.3)	11 (16.4)	9 (13.4)	2 (3.0)	1 (1.5)
Procedural pain	5 (7.5)	2 (3.0)	2 (3.0)	1 (1.5)	0
Infusion related reaction	4 (6.0)	2 (3.0)	2 (3.0)	0	0
Transfusion reaction	4 (6.0)	2 (3.0)	2 (3.0)	0	0
Contusion	2 (3.0)	2 (3.0)	0	0	0
Radiation skin injury	2 (3.0)	0	2 (3.0)	0	0
Skin abrasion	2 (3.0)	2 (3.0)	0	0	0
Subdural haematoma	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Arthropod bite	1 (1.5)	1 (1.5)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Extradural haematoma	1 (1.5)	0	0	1 (1.5)	0
Foot fracture	1 (1.5)	0	1 (1.5)	0	0
Incision site pain	1 (1.5)	1 (1.5)	0	0	0
Limb injury	1 (1.5)	1 (1.5)	0	0	0
Mouth injury	1 (1.5)	1 (1.5)	0	0	0
Post procedural haemorrhage	1 (1.5)	1 (1.5)	0	0	0
Procedural complication	1 (1.5)	1 (1.5)	0	0	0
Procedural headache	1 (1.5)	0	1 (1.5)	0	0
Procedural site reaction	1 (1.5)	1 (1.5)	0	0	0
Radius fracture	1 (1.5)	0	1 (1.5)	0	0
Skin laceration	1 (1.5)	0	1 (1.5)	0	0
Stoma site irritation	1 (1.5)	1 (1.5)	0	0	0
Subdural haemorrhage	1 (1.5)	1 (1.5)	0	0	0
Tibia fracture	1 (1.5)	0	1 (1.5)	0	0
Tongue injury	1 (1.5)	1 (1.5)	0	0	0
Transfusion related complication	1 (1.5)	0	0	0	1 (1.5)
Investigations					
-Total	51 (76.1)	1 (1.5)	3 (4.5)	10 (14.9)	37 (55.2)

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	38 (56.7)	3 (4.5)	1 (1.5)	8 (11.9)	26 (38.8)
Neutrophil count decreased	28 (41.8)	1 (1.5)	1 (1.5)	3 (4.5)	23 (34.3)
Alanine aminotransferase increased	26 (38.8)	3 (4.5)	4 (6.0)	18 (26.9)	1 (1.5)
Aspartate aminotransferase increased	23 (34.3)	5 (7.5)	5 (7.5)	9 (13.4)	4 (6.0)
Platelet count decreased	21 (31.3)	3 (4.5)	2 (3.0)	3 (4.5)	13 (19.4)
Lymphocyte count decreased	17 (25.4)	0	2 (3.0)	7 (10.4)	8 (11.9)
International normalised ratio increased	10 (14.9)	8 (11.9)	1 (1.5)	1 (1.5)	0
Blood bilirubin increased	9 (13.4)	2 (3.0)	3 (4.5)	3 (4.5)	1 (1.5)
Blood creatinine increased	8 (11.9)	5 (7.5)	1 (1.5)	2 (3.0)	0
Prothrombin time prolonged	8 (11.9)	5 (7.5)	2 (3.0)	1 (1.5)	0
Activated partial thromboplastin time prolonged	5 (7.5)	2 (3.0)	3 (4.5)	0	0
C-reactive protein increased	4 (6.0)	1 (1.5)	2 (3.0)	1 (1.5)	0
Transaminases increased	4 (6.0)	3 (4.5)	0	1 (1.5)	0
Weight decreased	4 (6.0)	1 (1.5)	3 (4.5)	0	0
Blood fibrinogen decreased	3 (4.5)	0	0	2 (3.0)	1 (1.5)
Blood immunoglobulin a decreased	3 (4.5)	3 (4.5)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	3 (4.5)	3 (4.5)	0	0	0
Blood urea increased	3 (4.5)	1 (1.5)	1 (1.5)	1 (1.5)	0
Haemoglobin decreased	3 (4.5)	2 (3.0)	0	1 (1.5)	0
Lipase increased	3 (4.5)	0	0	0	3 (4.5)
Weight increased	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Blood lactate dehydrogenase increased	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Blood lactic acid increased	2 (3.0)	0	1 (1.5)	0	1 (1.5)
Electrocardiogram qt prolonged	2 (3.0)	0	0	2 (3.0)	0
Serum ferritin increased	2 (3.0)	0	2 (3.0)	0	0
Blood alkaline phosphatase increased	1 (1.5)	1 (1.5)	0	0	0
Blood bicarbonate decreased	1 (1.5)	0	1 (1.5)	0	0
Blood immunoglobulin g decreased	1 (1.5)	0	1 (1.5)	0	0
Blood phosphorus decreased	1 (1.5)	1 (1.5)	0	0	0
Blood phosphorus increased	1 (1.5)	1 (1.5)	0	0	0
Blood sodium increased	1 (1.5)	0	1 (1.5)	0	0
Blood uric acid increased	1 (1.5)	1 (1.5)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Computerised tomogram thorax abnormal	1 (1.5)	0	0	1 (1.5)	0
Coronavirus test positive	1 (1.5)	1 (1.5)	0	0	0
Culture stool positive	1 (1.5)	1 (1.5)	0	0	0
Hepatic enzyme increased	1 (1.5)	0	1 (1.5)	0	0
Norovirus test positive	1 (1.5)	1 (1.5)	0	0	0
Oxygen saturation decreased	1 (1.5)	1 (1.5)	0	0	0
Protein total decreased	1 (1.5)	0	0	1 (1.5)	0
Pulmonary function test decreased	1 (1.5)	0	1 (1.5)	0	0
Metabolism and nutrition disorders					
-Total	44 (65.7)	4 (6.0)	8 (11.9)	25 (37.3)	7 (10.4)
Decreased appetite	25 (37.3)	6 (9.0)	7 (10.4)	12 (17.9)	0
Hypokalaemia	20 (29.9)	3 (4.5)	4 (6.0)	9 (13.4)	4 (6.0)
Hypophosphataemia	12 (17.9)	4 (6.0)	0	7 (10.4)	1 (1.5)
Hyperphosphataemia	9 (13.4)	8 (11.9)	1 (1.5)	0	0
Hyperglycaemia	7 (10.4)	0	3 (4.5)	4 (6.0)	0
Fluid overload	6 (9.0)	1 (1.5)	4 (6.0)	1 (1.5)	0
Hypocalcaemia	6 (9.0)	3 (4.5)	1 (1.5)	1 (1.5)	1 (1.5)

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	5 (7.5)	1 (1.5)	1 (1.5)	0	3 (4.5)
Hypoalbuminaemia	5 (7.5)	0	4 (6.0)	1 (1.5)	0
Dehydration	4 (6.0)	1 (1.5)	0	3 (4.5)	0
Hyperuricaemia	4 (6.0)	3 (4.5)	0	0	1 (1.5)
Hyperkalaemia	3 (4.5)	1 (1.5)	1 (1.5)	1 (1.5)	0
Hypomagnesaemia	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Tumour lysis syndrome	3 (4.5)	0	0	3 (4.5)	0
Vitamin d deficiency	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Acidosis	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Hypertriglyceridaemia	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Hypoglycaemia	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Hyponatraemia	2 (3.0)	0	0	2 (3.0)	0
Malnutrition	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Hyperalbuminaemia	1 (1.5)	1 (1.5)	0	0	0
Hyperammonaemia	1 (1.5)	1 (1.5)	0	0	0
Hypercalcaemia	1 (1.5)	1 (1.5)	0	0	0
Hyperchloraemia	1 (1.5)	1 (1.5)	0	0	0
Hypermagnesaemia	1 (1.5)	1 (1.5)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Iron overload	1 (1.5)	0	0	1 (1.5)	0
Metabolic acidosis	1 (1.5)	0	1 (1.5)	0	0
Metabolic alkalosis	1 (1.5)	1 (1.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	32 (47.8)	15 (22.4)	11 (16.4)	6 (9.0)	0
Pain in extremity	11 (16.4)	5 (7.5)	4 (6.0)	2 (3.0)	0
Arthralgia	6 (9.0)	4 (6.0)	1 (1.5)	1 (1.5)	0
Myalgia	6 (9.0)	4 (6.0)	1 (1.5)	1 (1.5)	0
Musculoskeletal pain	4 (6.0)	2 (3.0)	1 (1.5)	1 (1.5)	0
Back pain	3 (4.5)	1 (1.5)	0	2 (3.0)	0
Muscle spasms	3 (4.5)	3 (4.5)	0	0	0
Musculoskeletal chest pain	3 (4.5)	3 (4.5)	0	0	0
Pain in jaw	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Joint range of motion decreased	2 (3.0)	2 (3.0)	0	0	0
Muscular weakness	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Bone pain	1 (1.5)	0	0	1 (1.5)	0
Coccydynia	1 (1.5)	1 (1.5)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flank pain	1 (1.5)	0	1 (1.5)	0	0
Limb discomfort	1 (1.5)	1 (1.5)	0	0	0
Myopathy	1 (1.5)	0	0	1 (1.5)	0
Myositis	1 (1.5)	0	0	1 (1.5)	0
Neck pain	1 (1.5)	0	1 (1.5)	0	0
Osteonecrosis	1 (1.5)	0	1 (1.5)	0	0
Osteopenia	1 (1.5)	0	1 (1.5)	0	0
Synovitis	1 (1.5)	0	1 (1.5)	0	0
Toe walking	1 (1.5)	1 (1.5)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (4.5)	0	2 (3.0)	0	1 (1.5)
Glioblastoma multiforme	1 (1.5)	0	0	0	1 (1.5)
Myelodysplastic syndrome	1 (1.5)	0	1 (1.5)	0	0
Skin papilloma	1 (1.5)	0	1 (1.5)	0	0
Nervous system disorders					
-Total	38 (56.7)	12 (17.9)	17 (25.4)	7 (10.4)	2 (3.0)
Headache	26 (38.8)	12 (17.9)	9 (13.4)	5 (7.5)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dizziness	5 (7.5)	5 (7.5)	0	0	0
Seizure	5 (7.5)	0	2 (3.0)	2 (3.0)	1 (1.5)
Encephalopathy	4 (6.0)	1 (1.5)	1 (1.5)	2 (3.0)	0
Dysarthria	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Neuropathy peripheral	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Peroneal nerve palsy	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Somnolence	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Tremor	2 (3.0)	2 (3.0)	0	0	0
Asterixis	1 (1.5)	1 (1.5)	0	0	0
Ataxia	1 (1.5)	0	1 (1.5)	0	0
Depressed level of consciousness	1 (1.5)	1 (1.5)	0	0	0
Disturbance in attention	1 (1.5)	1 (1.5)	0	0	0
Embolic stroke	1 (1.5)	0	0	0	1 (1.5)
Hyporesponsive to stimuli	1 (1.5)	0	0	1 (1.5)	0
Hypotonia	1 (1.5)	0	1 (1.5)	0	0
Idiopathic intracranial hypertension	1 (1.5)	0	1 (1.5)	0	0
Migraine	1 (1.5)	0	1 (1.5)	0	0
Myoclonus	1 (1.5)	1 (1.5)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neuralgia	1 (1.5)	0	1 (1.5)	0	0
Peripheral sensory neuropathy	1 (1.5)	0	1 (1.5)	0	0
Pleocytosis	1 (1.5)	1 (1.5)	0	0	0
Visual field defect	1 (1.5)	0	1 (1.5)	0	0
Product issues					
-Total	2 (3.0)	2 (3.0)	0	0	0
Device occlusion	2 (3.0)	2 (3.0)	0	0	0
Psychiatric disorders					
-Total	22 (32.8)	8 (11.9)	10 (14.9)	4 (6.0)	0
Anxiety	8 (11.9)	2 (3.0)	5 (7.5)	1 (1.5)	0
Confusional state	4 (6.0)	2 (3.0)	2 (3.0)	0	0
Delirium	4 (6.0)	1 (1.5)	2 (3.0)	1 (1.5)	0
Mental status changes	4 (6.0)	3 (4.5)	0	1 (1.5)	0
Agitation	3 (4.5)	0	2 (3.0)	1 (1.5)	0
Insomnia	3 (4.5)	0	3 (4.5)	0	0
Irritability	3 (4.5)	3 (4.5)	0	0	0
Depression	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Hallucination	2 (3.0)	1 (1.5)	1 (1.5)	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adjustment disorder	1 (1.5)	0	1 (1.5)	0	0
Listless	1 (1.5)	1 (1.5)	0	0	0
Panic attack	1 (1.5)	0	1 (1.5)	0	0
Suicidal ideation	1 (1.5)	1 (1.5)	0	0	0
Renal and urinary disorders					
-Total	17 (25.4)	3 (4.5)	4 (6.0)	7 (10.4)	3 (4.5)
Acute kidney injury	11 (16.4)	2 (3.0)	1 (1.5)	5 (7.5)	3 (4.5)
Dysuria	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Haematuria	3 (4.5)	0	2 (3.0)	1 (1.5)	0
Oliguria	2 (3.0)	0	0	2 (3.0)	0
Calculus urinary	1 (1.5)	0	1 (1.5)	0	0
Nephrolithiasis	1 (1.5)	0	0	1 (1.5)	0
Pollakiuria	1 (1.5)	1 (1.5)	0	0	0
Renal impairment	1 (1.5)	0	0	1 (1.5)	0
Urinary incontinence	1 (1.5)	1 (1.5)	0	0	0
Urinary retention	1 (1.5)	0	1 (1.5)	0	0
Reproductive system and breast disorders					

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (9.0)	2 (3.0)	2 (3.0)	2 (3.0)	0
Vulvovaginal adhesion	2 (3.0)	2 (3.0)	0	0	0
Oedema genital	1 (1.5)	0	1 (1.5)	0	0
Ovarian failure	1 (1.5)	0	0	1 (1.5)	0
Scrotal pain	1 (1.5)	0	1 (1.5)	0	0
Vaginal haemorrhage	1 (1.5)	0	0	1 (1.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	37 (55.2)	11 (16.4)	8 (11.9)	9 (13.4)	9 (13.4)
Cough	13 (19.4)	10 (14.9)	2 (3.0)	1 (1.5)	0
Hypoxia	12 (17.9)	0	3 (4.5)	7 (10.4)	2 (3.0)
Epistaxis	11 (16.4)	4 (6.0)	3 (4.5)	4 (6.0)	0
Pleural effusion	8 (11.9)	1 (1.5)	4 (6.0)	3 (4.5)	0
Pulmonary oedema	8 (11.9)	1 (1.5)	0	4 (6.0)	3 (4.5)
Tachypnoea	8 (11.9)	3 (4.5)	2 (3.0)	3 (4.5)	0
Oropharyngeal pain	6 (9.0)	4 (6.0)	1 (1.5)	1 (1.5)	0
Nasal congestion	5 (7.5)	5 (7.5)	0	0	0
Rhinitis allergic	5 (7.5)	4 (6.0)	1 (1.5)	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	4 (6.0)	1 (1.5)	1 (1.5)	2 (3.0)	0
Rhinorrhoea	4 (6.0)	4 (6.0)	0	0	0
Respiratory failure	3 (4.5)	0	0	0	3 (4.5)
Atelectasis	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Haemoptysis	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Respiratory distress	2 (3.0)	0	0	0	2 (3.0)
Acute respiratory failure	1 (1.5)	0	0	0	1 (1.5)
Dysphonia	1 (1.5)	1 (1.5)	0	0	0
Idiopathic pneumonia syndrome	1 (1.5)	0	0	0	1 (1.5)
Nasal discomfort	1 (1.5)	1 (1.5)	0	0	0
Oropharyngeal plaque	1 (1.5)	1 (1.5)	0	0	0
Pharyngeal ulceration	1 (1.5)	0	1 (1.5)	0	0
Pulmonary alveolar haemorrhage	1 (1.5)	0	0	0	1 (1.5)
Pulmonary hypertension	1 (1.5)	0	0	1 (1.5)	0
Pulmonary mass	1 (1.5)	0	1 (1.5)	0	0
Respiratory depression	1 (1.5)	0	1 (1.5)	0	0
Wheezing	1 (1.5)	0	1 (1.5)	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	33 (49.3)	18 (26.9)	11 (16.4)	4 (6.0)	0
Rash	9 (13.4)	6 (9.0)	3 (4.5)	0	0
Pruritus	5 (7.5)	5 (7.5)	0	0	0
Dry skin	4 (6.0)	4 (6.0)	0	0	0
Hyperhidrosis	4 (6.0)	4 (6.0)	0	0	0
Petechiae	4 (6.0)	3 (4.5)	1 (1.5)	0	0
Rash erythematous	4 (6.0)	2 (3.0)	2 (3.0)	0	0
Rash maculo-papular	4 (6.0)	2 (3.0)	1 (1.5)	1 (1.5)	0
Alopecia	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Erythema	3 (4.5)	3 (4.5)	0	0	0
Ingrowing nail	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Rash papular	3 (4.5)	3 (4.5)	0	0	0
Dermatitis acneiform	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Macule	2 (3.0)	2 (3.0)	0	0	0
Night sweats	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Papule	2 (3.0)	2 (3.0)	0	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash macular	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Rash pruritic	2 (3.0)	2 (3.0)	0	0	0
Acne	1 (1.5)	1 (1.5)	0	0	0
Cold sweat	1 (1.5)	1 (1.5)	0	0	0
Dermatitis	1 (1.5)	1 (1.5)	0	0	0
Dermatitis atopic	1 (1.5)	1 (1.5)	0	0	0
Ecchymosis	1 (1.5)	0	0	1 (1.5)	0
Eczema	1 (1.5)	1 (1.5)	0	0	0
Keloid scar	1 (1.5)	0	1 (1.5)	0	0
Pruritus generalised	1 (1.5)	1 (1.5)	0	0	0
Rash follicular	1 (1.5)	1 (1.5)	0	0	0
Rash vesicular	1 (1.5)	1 (1.5)	0	0	0
Skin exfoliation	1 (1.5)	1 (1.5)	0	0	0
Skin fissures	1 (1.5)	1 (1.5)	0	0	0
Skin haemorrhage	1 (1.5)	1 (1.5)	0	0	0
Skin irritation	1 (1.5)	1 (1.5)	0	0	0
Skin ulcer	1 (1.5)	1 (1.5)	0	0	0
Vascular disorders					

Response status at study entry: Relapsed disease

Primary system organ class Preferred term	All patients N=67 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	28 (41.8)	3 (4.5)	5 (7.5)	12 (17.9)	8 (11.9)
Hypotension	19 (28.4)	1 (1.5)	0	10 (14.9)	8 (11.9)
Hypertension	13 (19.4)	3 (4.5)	8 (11.9)	2 (3.0)	0
Flushing	2 (3.0)	2 (3.0)	0	0	0
Orthostatic hypotension	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Capillary leak syndrome	1 (1.5)	0	0	0	1 (1.5)
Embolism	1 (1.5)	0	0	1 (1.5)	0
Phlebitis	1 (1.5)	0	1 (1.5)	0	0
Secondary hypertension	1 (1.5)	0	1 (1.5)	0	0
Venous thrombosis limb	1 (1.5)	1 (1.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178f
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders					
-Total	2 (100)	0	1 (50.0)	0	1 (50.0)
Anaemia	1 (50.0)	0	1 (50.0)	0	0
Eosinophilia	1 (50.0)	0	0	1 (50.0)	0
Lymphopenia	1 (50.0)	0	1 (50.0)	0	0
Neutropenia	1 (50.0)	0	0	0	1 (50.0)
Cardiac disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Sinus tachycardia	1 (50.0)	0	0	1 (50.0)	0
Gastrointestinal disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (50.0)	0	1 (50.0)	0	0
Pigmentation lip	1 (50.0)	1 (50.0)	0	0	0
General disorders and administration site conditions					
-Total	2 (100)	1 (50.0)	1 (50.0)	0	0
Chills	1 (50.0)	1 (50.0)	0	0	0
Fatigue	1 (50.0)	1 (50.0)	0	0	0
Pain	1 (50.0)	1 (50.0)	0	0	0
Pyrexia	1 (50.0)	0	1 (50.0)	0	0
Immune system disorders					
-Total	2 (100)	1 (50.0)	1 (50.0)	0	0
Graft versus host disease	1 (50.0)	1 (50.0)	0	0	0
Graft versus host disease in skin	1 (50.0)	1 (50.0)	0	0	0
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	0	0	1 (50.0)	0
Otitis media	1 (50.0)	0	1 (50.0)	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (50.0)	0	0	1 (50.0)	0
Injury, poisoning and procedural complications					
-Total	1 (50.0)	1 (50.0)	0	0	0
Skin abrasion	1 (50.0)	1 (50.0)	0	0	0
Investigations					
-Total	1 (50.0)	0	1 (50.0)	0	0
Alanine aminotransferase increased	1 (50.0)	0	1 (50.0)	0	0
Aspartate aminotransferase increased	1 (50.0)	1 (50.0)	0	0	0
Blood immunoglobulin a decreased	1 (50.0)	1 (50.0)	0	0	0
Blood uric acid increased	1 (50.0)	1 (50.0)	0	0	0
International normalised ratio increased	1 (50.0)	1 (50.0)	0	0	0
Lymphocyte count decreased	1 (50.0)	0	1 (50.0)	0	0
Neutrophil count decreased	1 (50.0)	0	1 (50.0)	0	0
White blood cell count decreased	1 (50.0)	0	1 (50.0)	0	0
Metabolism and nutrition disorders					
-Total	2 (100)	1 (50.0)	0	1 (50.0)	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	1 (50.0)	0	0	1 (50.0)	0
Hyperphosphataemia	1 (50.0)	1 (50.0)	0	0	0
Hyperuricaemia	1 (50.0)	1 (50.0)	0	0	0
Vitamin d deficiency	1 (50.0)	1 (50.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (100)	2 (100)	0	0	0
Joint range of motion decreased	2 (100)	2 (100)	0	0	0
Arthralgia	1 (50.0)	1 (50.0)	0	0	0
Back pain	1 (50.0)	1 (50.0)	0	0	0
Muscle spasms	1 (50.0)	1 (50.0)	0	0	0
Myalgia	1 (50.0)	1 (50.0)	0	0	0
Pain in extremity	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					
-Total	2 (100)	2 (100)	0	0	0
Headache	2 (100)	2 (100)	0	0	0
Reproductive system and breast disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Scrotal pain	1 (50.0)	0	1 (50.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Cough	1 (50.0)	1 (50.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Macule	1 (50.0)	1 (50.0)	0	0	0
Rash maculo-papular	1 (50.0)	1 (50.0)	0	0	0
Skin irritation	1 (50.0)	1 (50.0)	0	0	0
Vascular disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Hypotension	1 (50.0)	0	0	1 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178f
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	70 (95.9)	0	3 (4.1)	11 (15.1)	56 (76.7)
Blood and lymphatic system disorders					
-Total	59 (80.8)	1 (1.4)	1 (1.4)	35 (47.9)	22 (30.1)
Febrile neutropenia	36 (49.3)	0	0	35 (47.9)	1 (1.4)
Anaemia	34 (46.6)	2 (2.7)	5 (6.8)	26 (35.6)	1 (1.4)
Neutropenia	15 (20.5)	0	0	4 (5.5)	11 (15.1)
Thrombocytopenia	15 (20.5)	0	1 (1.4)	5 (6.8)	9 (12.3)
Disseminated intravascular coagulation	6 (8.2)	0	2 (2.7)	3 (4.1)	1 (1.4)
Lymphopenia	5 (6.8)	0	1 (1.4)	1 (1.4)	3 (4.1)
Pancytopenia	4 (5.5)	0	0	1 (1.4)	3 (4.1)
Coagulopathy	2 (2.7)	1 (1.4)	0	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypofibrinogenaemia	1 (1.4)	0	0	0	1 (1.4)
Leukocytosis	1 (1.4)	1 (1.4)	0	0	0
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Lymphadenopathy	1 (1.4)	0	1 (1.4)	0	0
Splenomegaly	1 (1.4)	1 (1.4)	0	0	0
Cardiac disorders					
-Total	27 (37.0)	11 (15.1)	10 (13.7)	4 (5.5)	2 (2.7)
Tachycardia	17 (23.3)	9 (12.3)	6 (8.2)	2 (2.7)	0
Sinus tachycardia	6 (8.2)	3 (4.1)	2 (2.7)	1 (1.4)	0
Bradycardia	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Left ventricular dysfunction	3 (4.1)	0	0	3 (4.1)	0
Pericardial effusion	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Palpitations	2 (2.7)	2 (2.7)	0	0	0
Ventricular tachycardia	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Atrioventricular block second degree	1 (1.4)	1 (1.4)	0	0	0
Cardiac dysfunction	1 (1.4)	1 (1.4)	0	0	0
Cardiovascular insufficiency	1 (1.4)	0	0	0	1 (1.4)
Right ventricular dysfunction	1 (1.4)	0	0	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus bradycardia	1 (1.4)	1 (1.4)	0	0	0
Ear and labyrinth disorders					
-Total	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Ear pain	2 (2.7)	2 (2.7)	0	0	0
Deafness unilateral	1 (1.4)	0	1 (1.4)	0	0
Hypoacusis	1 (1.4)	0	1 (1.4)	0	0
Tympanic membrane perforation	1 (1.4)	0	1 (1.4)	0	0
Endocrine disorders					
-Total	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Adrenal insufficiency	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Cushingoid	1 (1.4)	1 (1.4)	0	0	0
Hyperthyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	20 (27.4)	11 (15.1)	9 (12.3)	0	0
Periorbital oedema	4 (5.5)	3 (4.1)	1 (1.4)	0	0
Vision blurred	4 (5.5)	2 (2.7)	2 (2.7)	0	0
Conjunctival haemorrhage	3 (4.1)	3 (4.1)	0	0	0
Eye pain	3 (4.1)	1 (1.4)	2 (2.7)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Photophobia	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Dry eye	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Retinal haemorrhage	2 (2.7)	2 (2.7)	0	0	0
Uveitis	2 (2.7)	0	2 (2.7)	0	0
Conjunctivitis allergic	1 (1.4)	1 (1.4)	0	0	0
Eye irritation	1 (1.4)	1 (1.4)	0	0	0
Ocular hyperaemia	1 (1.4)	1 (1.4)	0	0	0
Ocular hypertension	1 (1.4)	0	1 (1.4)	0	0
Papilloedema	1 (1.4)	0	1 (1.4)	0	0
Retinopathy	1 (1.4)	0	1 (1.4)	0	0
Visual impairment	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	52 (71.2)	12 (16.4)	19 (26.0)	20 (27.4)	1 (1.4)
Nausea	33 (45.2)	9 (12.3)	17 (23.3)	7 (9.6)	0
Vomiting	30 (41.1)	17 (23.3)	9 (12.3)	4 (5.5)	0
Diarrhoea	25 (34.2)	14 (19.2)	9 (12.3)	2 (2.7)	0
Abdominal pain	17 (23.3)	7 (9.6)	7 (9.6)	3 (4.1)	0
Constipation	11 (15.1)	9 (12.3)	2 (2.7)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	5 (6.8)	1 (1.4)	1 (1.4)	2 (2.7)	1 (1.4)
Colitis	4 (5.5)	1 (1.4)	0	3 (4.1)	0
Abdominal pain upper	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Oral pain	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Pancreatitis	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Abdominal distension	2 (2.7)	0	2 (2.7)	0	0
Abdominal pain lower	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Ascites	2 (2.7)	0	0	2 (2.7)	0
Dysphagia	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Gastrointestinal haemorrhage	2 (2.7)	2 (2.7)	0	0	0
Haematemesis	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Haematochezia	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Abdominal discomfort	1 (1.4)	1 (1.4)	0	0	0
Abdominal tenderness	1 (1.4)	1 (1.4)	0	0	0
Anal fissure	1 (1.4)	0	1 (1.4)	0	0
Anal incontinence	1 (1.4)	1 (1.4)	0	0	0
Dry mouth	1 (1.4)	1 (1.4)	0	0	0
Dyspepsia	1 (1.4)	0	1 (1.4)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterocolitis	1 (1.4)	0	0	1 (1.4)	0
Flatulence	1 (1.4)	1 (1.4)	0	0	0
Gastrooesophageal reflux disease	1 (1.4)	1 (1.4)	0	0	0
Gingival discomfort	1 (1.4)	1 (1.4)	0	0	0
Glossodynia	1 (1.4)	1 (1.4)	0	0	0
Ileus	1 (1.4)	0	0	1 (1.4)	0
Intestinal obstruction	1 (1.4)	0	0	1 (1.4)	0
Lip pain	1 (1.4)	0	1 (1.4)	0	0
Mouth haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Oral mucosal blistering	1 (1.4)	1 (1.4)	0	0	0
Pancreatic failure	1 (1.4)	0	1 (1.4)	0	0
Perianal erythema	1 (1.4)	0	1 (1.4)	0	0
Proctalgia	1 (1.4)	0	1 (1.4)	0	0
Tooth socket haemorrhage	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	50 (68.5)	15 (20.5)	17 (23.3)	14 (19.2)	4 (5.5)
Pyrexia	31 (42.5)	9 (12.3)	14 (19.2)	7 (9.6)	1 (1.4)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	17 (23.3)	12 (16.4)	3 (4.1)	2 (2.7)	0
Chills	10 (13.7)	8 (11.0)	2 (2.7)	0	0
Catheter site pain	7 (9.6)	3 (4.1)	4 (5.5)	0	0
Pain	6 (8.2)	0	3 (4.1)	3 (4.1)	0
Oedema peripheral	5 (6.8)	3 (4.1)	1 (1.4)	1 (1.4)	0
Generalised oedema	4 (5.5)	2 (2.7)	2 (2.7)	0	0
Malaise	4 (5.5)	1 (1.4)	3 (4.1)	0	0
Multiple organ dysfunction syndrome	4 (5.5)	0	0	1 (1.4)	3 (4.1)
Face oedema	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Influenza like illness	2 (2.7)	2 (2.7)	0	0	0
Non-cardiac chest pain	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Physical deconditioning	2 (2.7)	0	0	2 (2.7)	0
Acquired gene mutation	1 (1.4)	1 (1.4)	0	0	0
Asthenia	1 (1.4)	1 (1.4)	0	0	0
Catheter site extravasation	1 (1.4)	0	1 (1.4)	0	0
Catheter site haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Crying	1 (1.4)	1 (1.4)	0	0	0
Cyst	1 (1.4)	0	0	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related thrombosis	1 (1.4)	0	1 (1.4)	0	0
Facial pain	1 (1.4)	0	1 (1.4)	0	0
Gait disturbance	1 (1.4)	1 (1.4)	0	0	0
Injection site haematoma	1 (1.4)	1 (1.4)	0	0	0
Localised oedema	1 (1.4)	0	0	1 (1.4)	0
Medical device pain	1 (1.4)	0	1 (1.4)	0	0
Mucosal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Peripheral swelling	1 (1.4)	0	1 (1.4)	0	0
Hepatobiliary disorders					
-Total	11 (15.1)	3 (4.1)	3 (4.1)	4 (5.5)	1 (1.4)
Hyperbilirubinaemia	5 (6.8)	0	2 (2.7)	3 (4.1)	0
Hepatomegaly	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Cholecystitis	1 (1.4)	0	0	1 (1.4)	0
Gallbladder enlargement	1 (1.4)	1 (1.4)	0	0	0
Hepatic failure	1 (1.4)	0	0	0	1 (1.4)
Hepatic steatosis	1 (1.4)	0	1 (1.4)	0	0
Hepatosplenomegaly	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	57 (78.1)	5 (6.8)	30 (41.1)	11 (15.1)	11 (15.1)
Cytokine release syndrome	50 (68.5)	6 (8.2)	25 (34.2)	8 (11.0)	11 (15.1)
Hypogammaglobulinaemia	32 (43.8)	4 (5.5)	23 (31.5)	5 (6.8)	0
Immunodeficiency common variable	2 (2.7)	0	2 (2.7)	0	0
Seasonal allergy	2 (2.7)	2 (2.7)	0	0	0
Chronic graft versus host disease	1 (1.4)	0	1 (1.4)	0	0
Drug hypersensitivity	1 (1.4)	0	1 (1.4)	0	0
Graft versus host disease	1 (1.4)	0	1 (1.4)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.4)	0	1 (1.4)	0	0
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	1 (1.4)	0	0
Immunodeficiency	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	51 (69.9)	4 (5.5)	16 (21.9)	20 (27.4)	11 (15.1)
Upper respiratory tract infection	11 (15.1)	5 (6.8)	5 (6.8)	1 (1.4)	0
Pneumonia	7 (9.6)	0	5 (6.8)	1 (1.4)	1 (1.4)
Clostridium difficile infection	6 (8.2)	0	5 (6.8)	1 (1.4)	0
Rhinovirus infection	6 (8.2)	5 (6.8)	1 (1.4)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	5 (6.8)	1 (1.4)	2 (2.7)	2 (2.7)	0
Gastroenteritis	5 (6.8)	1 (1.4)	3 (4.1)	1 (1.4)	0
Sinusitis	5 (6.8)	1 (1.4)	4 (5.5)	0	0
Device related infection	4 (5.5)	0	1 (1.4)	3 (4.1)	0
Influenza	4 (5.5)	1 (1.4)	3 (4.1)	0	0
Parainfluenzae virus infection	4 (5.5)	2 (2.7)	1 (1.4)	1 (1.4)	0
Urinary tract infection	4 (5.5)	0	3 (4.1)	1 (1.4)	0
Viral upper respiratory tract infection	4 (5.5)	2 (2.7)	1 (1.4)	1 (1.4)	0
Escherichia urinary tract infection	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Otitis media	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Staphylococcal infection	3 (4.1)	1 (1.4)	0	1 (1.4)	1 (1.4)
Viral infection	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Cytomegalovirus infection	2 (2.7)	2 (2.7)	0	0	0
Ear infection	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Escherichia bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Fungal skin infection	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Oral herpes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Otitis media acute	2 (2.7)	0	2 (2.7)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Sepsis	2 (2.7)	0	0	0	2 (2.7)
Skin infection	2 (2.7)	0	2 (2.7)	0	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Vulvovaginal candidiasis	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Body tinea	1 (1.4)	1 (1.4)	0	0	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Campylobacter infection	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Catheter site cellulitis	1 (1.4)	1 (1.4)	0	0	0
Catheter site infection	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	0	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Corona virus infection	1 (1.4)	0	0	1 (1.4)	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Enterococcal infection	1 (1.4)	1 (1.4)	0	0	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis norovirus	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Haemophilus infection	1 (1.4)	0	1 (1.4)	0	0
Herpes simplex	1 (1.4)	1 (1.4)	0	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	1 (1.4)	0	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Hypopyon	1 (1.4)	0	1 (1.4)	0	0
Klebsiella sepsis	1 (1.4)	0	0	0	1 (1.4)
Meningitis aseptic	1 (1.4)	0	1 (1.4)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metapneumovirus infection	1 (1.4)	0	1 (1.4)	0	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Necrotising fasciitis	1 (1.4)	0	0	1 (1.4)	0
Oral candidiasis	1 (1.4)	1 (1.4)	0	0	0
Orchitis	1 (1.4)	1 (1.4)	0	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	1 (1.4)	0	0	0
Pharyngitis	1 (1.4)	0	1 (1.4)	0	0
Pneumonia fungal	1 (1.4)	0	1 (1.4)	0	0
Rash pustular	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	0	0	1 (1.4)	0
Rhinitis	1 (1.4)	1 (1.4)	0	0	0
Rotavirus infection	1 (1.4)	0	0	1 (1.4)	0
Septic embolus	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Streptococcal infection	1 (1.4)	0	1 (1.4)	0	0
Subcutaneous abscess	1 (1.4)	0	1 (1.4)	0	0
Tinea capitis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection enterococcal	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Vulvovaginal mycotic infection	1 (1.4)	0	1 (1.4)	0	0
Injury, poisoning and procedural complications					
-Total	25 (34.2)	11 (15.1)	10 (13.7)	3 (4.1)	1 (1.4)
Infusion related reaction	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Procedural pain	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Transfusion reaction	4 (5.5)	2 (2.7)	2 (2.7)	0	0
Contusion	3 (4.1)	3 (4.1)	0	0	0
Radiation skin injury	2 (2.7)	0	2 (2.7)	0	0
Subdural haematoma	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Arthropod bite	1 (1.4)	1 (1.4)	0	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Extradural haematoma	1 (1.4)	0	0	1 (1.4)	0
Foot fracture	1 (1.4)	0	1 (1.4)	0	0
Incision site pain	1 (1.4)	1 (1.4)	0	0	0
Limb injury	1 (1.4)	1 (1.4)	0	0	0
Mouth injury	1 (1.4)	1 (1.4)	0	0	0
Post procedural haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Procedural complication	1 (1.4)	1 (1.4)	0	0	0
Procedural headache	1 (1.4)	0	1 (1.4)	0	0
Procedural nausea	1 (1.4)	0	1 (1.4)	0	0
Procedural site reaction	1 (1.4)	1 (1.4)	0	0	0
Radius fracture	1 (1.4)	0	1 (1.4)	0	0
Skin abrasion	1 (1.4)	1 (1.4)	0	0	0
Skin laceration	1 (1.4)	0	1 (1.4)	0	0
Stoma site irritation	1 (1.4)	1 (1.4)	0	0	0
Subdural haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Sunburn	1 (1.4)	1 (1.4)	0	0	0
Tibia fracture	1 (1.4)	0	1 (1.4)	0	0
Tongue injury	1 (1.4)	1 (1.4)	0	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tracheal haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Transfusion related complication	1 (1.4)	0	0	0	1 (1.4)
Wound	1 (1.4)	1 (1.4)	0	0	0
Investigations					
-Total	57 (78.1)	1 (1.4)	3 (4.1)	12 (16.4)	41 (56.2)
White blood cell count decreased	41 (56.2)	4 (5.5)	0	8 (11.0)	29 (39.7)
Neutrophil count decreased	31 (42.5)	1 (1.4)	1 (1.4)	3 (4.1)	26 (35.6)
Alanine aminotransferase increased	25 (34.2)	3 (4.1)	3 (4.1)	18 (24.7)	1 (1.4)
Aspartate aminotransferase increased	23 (31.5)	4 (5.5)	5 (6.8)	9 (12.3)	5 (6.8)
Platelet count decreased	21 (28.8)	3 (4.1)	2 (2.7)	3 (4.1)	13 (17.8)
Lymphocyte count decreased	18 (24.7)	1 (1.4)	2 (2.7)	7 (9.6)	8 (11.0)
Blood bilirubin increased	10 (13.7)	2 (2.7)	3 (4.1)	4 (5.5)	1 (1.4)
International normalised ratio increased	10 (13.7)	8 (11.0)	1 (1.4)	1 (1.4)	0
Blood creatinine increased	9 (12.3)	5 (6.8)	2 (2.7)	2 (2.7)	0
Prothrombin time prolonged	9 (12.3)	5 (6.8)	3 (4.1)	1 (1.4)	0
Activated partial thromboplastin time prolonged	6 (8.2)	3 (4.1)	3 (4.1)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Weight decreased	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Blood fibrinogen decreased	4 (5.5)	0	1 (1.4)	2 (2.7)	1 (1.4)
Blood immunoglobulin m decreased	4 (5.5)	4 (5.5)	0	0	0
C-reactive protein increased	4 (5.5)	1 (1.4)	2 (2.7)	1 (1.4)	0
Transaminases increased	4 (5.5)	3 (4.1)	0	1 (1.4)	0
Blood urea increased	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Haemoglobin decreased	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Lipase increased	3 (4.1)	0	0	0	3 (4.1)
Weight increased	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Blood immunoglobulin a decreased	2 (2.7)	2 (2.7)	0	0	0
Blood lactate dehydrogenase increased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood lactic acid increased	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Blood magnesium decreased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood phosphorus increased	2 (2.7)	2 (2.7)	0	0	0
Electrocardiogram qt prolonged	2 (2.7)	0	0	2 (2.7)	0
Serum ferritin increased	2 (2.7)	0	2 (2.7)	0	0
Blood alkaline phosphatase increased	1 (1.4)	1 (1.4)	0	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bicarbonate decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood phosphorus decreased	1 (1.4)	1 (1.4)	0	0	0
Blood sodium increased	1 (1.4)	0	1 (1.4)	0	0
Blood uric acid increased	1 (1.4)	1 (1.4)	0	0	0
Cardiac murmur	1 (1.4)	1 (1.4)	0	0	0
Computerised tomogram thorax abnormal	1 (1.4)	0	0	1 (1.4)	0
Coronavirus test positive	1 (1.4)	1 (1.4)	0	0	0
Culture stool positive	1 (1.4)	1 (1.4)	0	0	0
Fibrin d dimer increased	1 (1.4)	1 (1.4)	0	0	0
Hepatic enzyme increased	1 (1.4)	0	1 (1.4)	0	0
Norovirus test positive	1 (1.4)	1 (1.4)	0	0	0
Oxygen saturation decreased	1 (1.4)	1 (1.4)	0	0	0
Protein total decreased	1 (1.4)	0	0	1 (1.4)	0
Pulmonary function test decreased	1 (1.4)	0	1 (1.4)	0	0
Metabolism and nutrition disorders					
-Total	47 (64.4)	5 (6.8)	10 (13.7)	25 (34.2)	7 (9.6)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	28 (38.4)	7 (9.6)	8 (11.0)	13 (17.8)	0
Hypokalaemia	23 (31.5)	5 (6.8)	5 (6.8)	9 (12.3)	4 (5.5)
Hypophosphataemia	13 (17.8)	4 (5.5)	0	8 (11.0)	1 (1.4)
Hyperphosphataemia	8 (11.0)	7 (9.6)	1 (1.4)	0	0
Fluid overload	6 (8.2)	1 (1.4)	4 (5.5)	1 (1.4)	0
Hyperglycaemia	6 (8.2)	0	3 (4.1)	3 (4.1)	0
Hypernatraemia	6 (8.2)	1 (1.4)	2 (2.7)	0	3 (4.1)
Hypoalbuminaemia	6 (8.2)	1 (1.4)	4 (5.5)	1 (1.4)	0
Hypocalcaemia	6 (8.2)	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)
Dehydration	4 (5.5)	1 (1.4)	0	3 (4.1)	0
Hyperkalaemia	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Hyperuricaemia	3 (4.1)	2 (2.7)	0	0	1 (1.4)
Hypomagnesaemia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Tumour lysis syndrome	3 (4.1)	0	0	3 (4.1)	0
Acidosis	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Hypertriglyceridaemia	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Hypoglycaemia	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Hyponatraemia	2 (2.7)	0	0	2 (2.7)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malnutrition	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Vitamin d deficiency	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Hyperalbuminaemia	1 (1.4)	1 (1.4)	0	0	0
Hyperammonaemia	1 (1.4)	1 (1.4)	0	0	0
Hypercalcaemia	1 (1.4)	1 (1.4)	0	0	0
Hyperchloraemia	1 (1.4)	1 (1.4)	0	0	0
Hypermagnesaemia	1 (1.4)	1 (1.4)	0	0	0
Iron overload	1 (1.4)	0	0	1 (1.4)	0
Metabolic acidosis	1 (1.4)	0	1 (1.4)	0	0
Metabolic alkalosis	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	35 (47.9)	15 (20.5)	12 (16.4)	8 (11.0)	0
Pain in extremity	13 (17.8)	6 (8.2)	4 (5.5)	3 (4.1)	0
Arthralgia	6 (8.2)	3 (4.1)	1 (1.4)	2 (2.7)	0
Myalgia	5 (6.8)	3 (4.1)	1 (1.4)	1 (1.4)	0
Musculoskeletal pain	4 (5.5)	2 (2.7)	1 (1.4)	1 (1.4)	0
Pain in jaw	4 (5.5)	2 (2.7)	2 (2.7)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Musculoskeletal chest pain	3 (4.1)	3 (4.1)	0	0	0
Back pain	2 (2.7)	0	0	2 (2.7)	0
Muscle spasms	2 (2.7)	2 (2.7)	0	0	0
Neck pain	2 (2.7)	0	2 (2.7)	0	0
Bone pain	1 (1.4)	0	0	1 (1.4)	0
Coccydynia	1 (1.4)	1 (1.4)	0	0	0
Flank pain	1 (1.4)	0	1 (1.4)	0	0
Limb discomfort	1 (1.4)	1 (1.4)	0	0	0
Myopathy	1 (1.4)	0	0	1 (1.4)	0
Myositis	1 (1.4)	0	0	1 (1.4)	0
Osteonecrosis	1 (1.4)	0	1 (1.4)	0	0
Osteopenia	1 (1.4)	0	1 (1.4)	0	0
Synovitis	1 (1.4)	0	1 (1.4)	0	0
Toe walking	1 (1.4)	1 (1.4)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (4.1)	0	2 (2.7)	0	1 (1.4)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Glioblastoma multiforme	1 (1.4)	0	0	0	1 (1.4)
Myelodysplastic syndrome	1 (1.4)	0	1 (1.4)	0	0
Skin papilloma	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	41 (56.2)	15 (20.5)	17 (23.3)	7 (9.6)	2 (2.7)
Headache	27 (37.0)	13 (17.8)	9 (12.3)	5 (6.8)	0
Dizziness	6 (8.2)	6 (8.2)	0	0	0
Seizure	5 (6.8)	0	2 (2.7)	2 (2.7)	1 (1.4)
Encephalopathy	4 (5.5)	1 (1.4)	1 (1.4)	2 (2.7)	0
Peroneal nerve palsy	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Dysarthria	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Neuropathy peripheral	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Somnolence	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Tremor	2 (2.7)	2 (2.7)	0	0	0
Asterixis	1 (1.4)	1 (1.4)	0	0	0
Ataxia	1 (1.4)	0	1 (1.4)	0	0
Depressed level of consciousness	1 (1.4)	1 (1.4)	0	0	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysgeusia	1 (1.4)	1 (1.4)	0	0	0
Embolic stroke	1 (1.4)	0	0	0	1 (1.4)
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Hypotonia	1 (1.4)	0	1 (1.4)	0	0
Idiopathic intracranial hypertension	1 (1.4)	0	1 (1.4)	0	0
Migraine	1 (1.4)	0	1 (1.4)	0	0
Myoclonus	1 (1.4)	1 (1.4)	0	0	0
Neuralgia	1 (1.4)	0	1 (1.4)	0	0
Peripheral sensory neuropathy	1 (1.4)	0	1 (1.4)	0	0
Pleocytosis	1 (1.4)	1 (1.4)	0	0	0
Visual field defect	1 (1.4)	0	1 (1.4)	0	0
Product issues					
-Total	2 (2.7)	2 (2.7)	0	0	0
Device occlusion	2 (2.7)	2 (2.7)	0	0	0
Psychiatric disorders					
-Total	26 (35.6)	8 (11.0)	14 (19.2)	4 (5.5)	0
Anxiety	9 (12.3)	3 (4.1)	5 (6.8)	1 (1.4)	0
Confusional state	7 (9.6)	3 (4.1)	4 (5.5)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Depression	4 (5.5)	2 (2.7)	2 (2.7)	0	0
Insomnia	4 (5.5)	0	4 (5.5)	0	0
Mental status changes	4 (5.5)	3 (4.1)	0	1 (1.4)	0
Agitation	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Irritability	3 (4.1)	3 (4.1)	0	0	0
Hallucination	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Adjustment disorder	1 (1.4)	0	1 (1.4)	0	0
Listless	1 (1.4)	1 (1.4)	0	0	0
Panic attack	1 (1.4)	0	1 (1.4)	0	0
Sleep disorder	1 (1.4)	0	1 (1.4)	0	0
Suicidal ideation	1 (1.4)	1 (1.4)	0	0	0
Renal and urinary disorders					
-Total	19 (26.0)	3 (4.1)	4 (5.5)	7 (9.6)	5 (6.8)
Acute kidney injury	12 (16.4)	2 (2.7)	1 (1.4)	5 (6.8)	4 (5.5)
Haematuria	5 (6.8)	0	2 (2.7)	2 (2.7)	1 (1.4)
Dysuria	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Oliguria	3 (4.1)	0	0	3 (4.1)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Calculus urinary	1 (1.4)	0	1 (1.4)	0	0
Cystitis haemorrhagic	1 (1.4)	0	0	0	1 (1.4)
Nephrolithiasis	1 (1.4)	0	0	1 (1.4)	0
Pollakiuria	1 (1.4)	1 (1.4)	0	0	0
Renal failure	1 (1.4)	0	0	0	1 (1.4)
Renal impairment	1 (1.4)	0	0	1 (1.4)	0
Urinary incontinence	1 (1.4)	1 (1.4)	0	0	0
Urinary retention	1 (1.4)	0	1 (1.4)	0	0
Reproductive system and breast disorders					
-Total	5 (6.8)	2 (2.7)	1 (1.4)	2 (2.7)	0
Vulvovaginal adhesion	2 (2.7)	2 (2.7)	0	0	0
Oedema genital	1 (1.4)	0	1 (1.4)	0	0
Ovarian failure	1 (1.4)	0	0	1 (1.4)	0
Vaginal haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	43 (58.9)	12 (16.4)	9 (12.3)	10 (13.7)	12 (16.4)
Cough	15 (20.5)	12 (16.4)	2 (2.7)	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	15 (20.5)	0	3 (4.1)	9 (12.3)	3 (4.1)
Epistaxis	14 (19.2)	4 (5.5)	4 (5.5)	5 (6.8)	1 (1.4)
Pleural effusion	10 (13.7)	1 (1.4)	6 (8.2)	3 (4.1)	0
Pulmonary oedema	9 (12.3)	1 (1.4)	0	4 (5.5)	4 (5.5)
Tachypnoea	8 (11.0)	3 (4.1)	2 (2.7)	3 (4.1)	0
Oropharyngeal pain	7 (9.6)	4 (5.5)	2 (2.7)	1 (1.4)	0
Nasal congestion	6 (8.2)	6 (8.2)	0	0	0
Rhinorrhoea	6 (8.2)	5 (6.8)	1 (1.4)	0	0
Dyspnoea	5 (6.8)	1 (1.4)	1 (1.4)	2 (2.7)	1 (1.4)
Rhinitis allergic	5 (6.8)	4 (5.5)	1 (1.4)	0	0
Respiratory failure	4 (5.5)	0	0	0	4 (5.5)
Haemoptysis	3 (4.1)	1 (1.4)	0	1 (1.4)	1 (1.4)
Atelectasis	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Respiratory distress	2 (2.7)	0	0	0	2 (2.7)
Acute respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Aspiration	1 (1.4)	0	0	0	1 (1.4)
Dysphonia	1 (1.4)	1 (1.4)	0	0	0
Idiopathic pneumonia syndrome	1 (1.4)	0	0	0	1 (1.4)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Interstitial lung disease	1 (1.4)	0	0	0	1 (1.4)
Nasal discomfort	1 (1.4)	1 (1.4)	0	0	0
Oropharyngeal plaque	1 (1.4)	1 (1.4)	0	0	0
Pharyngeal erythema	1 (1.4)	1 (1.4)	0	0	0
Pharyngeal lesion	1 (1.4)	0	0	1 (1.4)	0
Pharyngeal ulceration	1 (1.4)	0	1 (1.4)	0	0
Pulmonary alveolar haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Pulmonary hypertension	1 (1.4)	0	0	1 (1.4)	0
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory depression	1 (1.4)	0	1 (1.4)	0	0
Wheezing	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	36 (49.3)	20 (27.4)	12 (16.4)	4 (5.5)	0
Rash	9 (12.3)	6 (8.2)	3 (4.1)	0	0
Dry skin	5 (6.8)	5 (6.8)	0	0	0
Erythema	5 (6.8)	5 (6.8)	0	0	0
Pruritus	5 (6.8)	5 (6.8)	0	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash erythematous	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Alopecia	4 (5.5)	2 (2.7)	2 (2.7)	0	0
Hyperhidrosis	4 (5.5)	4 (5.5)	0	0	0
Petechiae	4 (5.5)	3 (4.1)	1 (1.4)	0	0
Rash maculo-papular	4 (5.5)	2 (2.7)	1 (1.4)	1 (1.4)	0
Ingrowing nail	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Rash papular	3 (4.1)	3 (4.1)	0	0	0
Dermatitis acneiform	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Night sweats	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Papule	2 (2.7)	2 (2.7)	0	0	0
Rash macular	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Rash pruritic	2 (2.7)	2 (2.7)	0	0	0
Acne	1 (1.4)	1 (1.4)	0	0	0
Cold sweat	1 (1.4)	1 (1.4)	0	0	0
Dermatitis	1 (1.4)	1 (1.4)	0	0	0
Dermatitis atopic	1 (1.4)	1 (1.4)	0	0	0
Dermatitis diaper	1 (1.4)	1 (1.4)	0	0	0
Ecchymosis	1 (1.4)	0	0	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eczema	1 (1.4)	1 (1.4)	0	0	0
Keloid scar	1 (1.4)	0	1 (1.4)	0	0
Livedo reticularis	1 (1.4)	1 (1.4)	0	0	0
Macule	1 (1.4)	1 (1.4)	0	0	0
Pruritus generalised	1 (1.4)	1 (1.4)	0	0	0
Rash follicular	1 (1.4)	1 (1.4)	0	0	0
Rash vesicular	1 (1.4)	1 (1.4)	0	0	0
Skin exfoliation	1 (1.4)	1 (1.4)	0	0	0
Skin fissures	1 (1.4)	1 (1.4)	0	0	0
Skin haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Skin ulcer	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	33 (45.2)	3 (4.1)	6 (8.2)	13 (17.8)	11 (15.1)
Hypotension	23 (31.5)	1 (1.4)	0	11 (15.1)	11 (15.1)
Hypertension	16 (21.9)	4 (5.5)	10 (13.7)	2 (2.7)	0
Flushing	2 (2.7)	2 (2.7)	0	0	0
Orthostatic hypotension	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Capillary leak syndrome	1 (1.4)	0	0	0	1 (1.4)

Philadelphia chromosome/BCR-ABL: Negative

Primary system organ class Preferred term	All patients N=73 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Embolism	1 (1.4)	0	0	1 (1.4)	0
Haematoma	1 (1.4)	0	1 (1.4)	0	0
Hot flush	1 (1.4)	1 (1.4)	0	0	0
Phlebitis	1 (1.4)	0	1 (1.4)	0	0
Secondary hypertension	1 (1.4)	0	1 (1.4)	0	0
Venous thrombosis limb	1 (1.4)	1 (1.4)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178g
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	0	3 (100)
Blood and lymphatic system disorders					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Anaemia	2 (66.7)	0	0	2 (66.7)	0
Febrile neutropenia	2 (66.7)	0	0	2 (66.7)	0
Leukopenia	1 (33.3)	0	0	0	1 (33.3)
Lymphopenia	1 (33.3)	0	0	0	1 (33.3)
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	0	0	1 (33.3)
Cardiac disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Bradycardia	1 (33.3)	0	1 (33.3)	0	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (33.3)	0	0	1 (33.3)	0
Pericardial effusion	1 (33.3)	0	1 (33.3)	0	0
Tachycardia	1 (33.3)	0	0	1 (33.3)	0
Eye disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Conjunctival haemorrhage	1 (33.3)	1 (33.3)	0	0	0
Periorbital oedema	1 (33.3)	1 (33.3)	0	0	0
Gastrointestinal disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Nausea	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Abdominal pain	1 (33.3)	1 (33.3)	0	0	0
Colitis	1 (33.3)	1 (33.3)	0	0	0
Diarrhoea	1 (33.3)	0	1 (33.3)	0	0
Dysphagia	1 (33.3)	0	0	1 (33.3)	0
Perianal erythema	1 (33.3)	0	1 (33.3)	0	0
Vomiting	1 (33.3)	0	1 (33.3)	0	0
General disorders and administration site conditions					

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (66.7)	0	0	2 (66.7)	0
Pyrexia	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Asthenia	1 (33.3)	1 (33.3)	0	0	0
Chills	1 (33.3)	1 (33.3)	0	0	0
Face oedema	1 (33.3)	0	0	1 (33.3)	0
Localised oedema	1 (33.3)	0	0	1 (33.3)	0
Mucosal haemorrhage	1 (33.3)	0	1 (33.3)	0	0
Multiple organ dysfunction syndrome	1 (33.3)	0	0	1 (33.3)	0
Oedema peripheral	1 (33.3)	0	0	1 (33.3)	0
Hepatobiliary disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Hepatomegaly	1 (33.3)	0	1 (33.3)	0	0
Hyperbilirubinaemia	1 (33.3)	0	0	1 (33.3)	0
Immune system disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	0	0	2 (66.7)
Hypogammaglobulinaemia	1 (33.3)	0	0	1 (33.3)	0
Infections and infestations					

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (33.3)	0	0	1 (33.3)	0
Escherichia bacteraemia	1 (33.3)	0	0	1 (33.3)	0
Pneumonia	1 (33.3)	0	1 (33.3)	0	0
Sinusitis	1 (33.3)	1 (33.3)	0	0	0
Upper respiratory tract infection	1 (33.3)	1 (33.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Procedural complication	1 (33.3)	1 (33.3)	0	0	0
Tracheal haemorrhage	1 (33.3)	0	0	1 (33.3)	0
Investigations					
-Total	3 (100)	0	0	0	3 (100)
Aspartate aminotransferase increased	3 (100)	1 (33.3)	0	0	2 (66.7)
Alanine aminotransferase increased	2 (66.7)	0	0	2 (66.7)	0
Blood fibrinogen decreased	2 (66.7)	0	1 (33.3)	0	1 (33.3)
Blood creatinine increased	1 (33.3)	0	0	1 (33.3)	0
Blood lactic acid increased	1 (33.3)	0	1 (33.3)	0	0
Blood phosphorus decreased	1 (33.3)	1 (33.3)	0	0	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood urea increased	1 (33.3)	0	0	1 (33.3)	0
C-reactive protein increased	1 (33.3)	0	1 (33.3)	0	0
International normalised ratio increased	1 (33.3)	1 (33.3)	0	0	0
Neutrophil count decreased	1 (33.3)	0	0	0	1 (33.3)
Platelet count decreased	1 (33.3)	0	0	1 (33.3)	0
Protein total decreased	1 (33.3)	0	0	1 (33.3)	0
Prothrombin time prolonged	1 (33.3)	0	1 (33.3)	0	0
White blood cell count decreased	1 (33.3)	0	0	0	1 (33.3)
Metabolism and nutrition disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Hypokalaemia	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Hypophosphataemia	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Acidosis	1 (33.3)	0	0	1 (33.3)	0
Decreased appetite	1 (33.3)	0	0	1 (33.3)	0
Fluid overload	1 (33.3)	0	1 (33.3)	0	0
Hyperalbuminaemia	1 (33.3)	1 (33.3)	0	0	0
Hypercalcaemia	1 (33.3)	1 (33.3)	0	0	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperchloraemia	1 (33.3)	1 (33.3)	0	0	0
Hypermagnesaemia	1 (33.3)	1 (33.3)	0	0	0
Hypernatraemia	1 (33.3)	0	1 (33.3)	0	0
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)	0	0
Metabolic alkalosis	1 (33.3)	1 (33.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Bone pain	1 (33.3)	0	0	1 (33.3)	0
Neck pain	1 (33.3)	0	1 (33.3)	0	0
Nervous system disorders					
-Total	3 (100)	2 (66.7)	1 (33.3)	0	0
Dizziness	1 (33.3)	1 (33.3)	0	0	0
Headache	1 (33.3)	1 (33.3)	0	0	0
Hypotonia	1 (33.3)	0	1 (33.3)	0	0
Psychiatric disorders					
-Total	2 (66.7)	0	2 (66.7)	0	0
Insomnia	2 (66.7)	0	2 (66.7)	0	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	1 (33.3)	1 (33.3)	0	0	0
Delirium	1 (33.3)	0	1 (33.3)	0	0
Irritability	1 (33.3)	1 (33.3)	0	0	0
Renal and urinary disorders					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Acute kidney injury	1 (33.3)	0	0	0	1 (33.3)
Haematuria	1 (33.3)	0	0	1 (33.3)	0
Renal impairment	1 (33.3)	0	0	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Hypoxia	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Pleural effusion	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Pulmonary oedema	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Cough	1 (33.3)	1 (33.3)	0	0	0
Dyspnoea	1 (33.3)	0	0	0	1 (33.3)
Epistaxis	1 (33.3)	0	1 (33.3)	0	0
Interstitial lung disease	1 (33.3)	0	0	0	1 (33.3)

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	1 (33.3)	0	0	0	1 (33.3)
Tachypnoea	1 (33.3)	0	0	1 (33.3)	0
Skin and subcutaneous tissue disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Hyperhidrosis	1 (33.3)	1 (33.3)	0	0	0
Papule	1 (33.3)	1 (33.3)	0	0	0
Rash papular	1 (33.3)	1 (33.3)	0	0	0
Vascular disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Hypertension	2 (66.7)	0	2 (66.7)	0	0
Hypotension	2 (66.7)	0	0	0	2 (66.7)
Capillary leak syndrome	1 (33.3)	0	0	0	1 (33.3)
Flushing	1 (33.3)	1 (33.3)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178g
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	69 (95.8)	0	3 (4.2)	12 (16.7)	54 (75.0)
Blood and lymphatic system disorders					
-Total	58 (80.6)	1 (1.4)	2 (2.8)	34 (47.2)	21 (29.2)
Febrile neutropenia	34 (47.2)	0	0	33 (45.8)	1 (1.4)
Anaemia	33 (45.8)	2 (2.8)	6 (8.3)	24 (33.3)	1 (1.4)
Neutropenia	15 (20.8)	0	0	4 (5.6)	11 (15.3)
Thrombocytopenia	14 (19.4)	0	1 (1.4)	5 (6.9)	8 (11.1)
Disseminated intravascular coagulation	6 (8.3)	0	2 (2.8)	3 (4.2)	1 (1.4)
Lymphopenia	5 (6.9)	0	2 (2.8)	1 (1.4)	2 (2.8)
Pancytopenia	4 (5.6)	0	0	1 (1.4)	3 (4.2)
Coagulopathy	2 (2.8)	1 (1.4)	0	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eosinophilia	1 (1.4)	0	0	1 (1.4)	0
Hypofibrinogenaemia	1 (1.4)	0	0	0	1 (1.4)
Leukocytosis	1 (1.4)	1 (1.4)	0	0	0
Lymphadenopathy	1 (1.4)	0	1 (1.4)	0	0
Splenomegaly	1 (1.4)	1 (1.4)	0	0	0
Cardiac disorders					
-Total	26 (36.1)	11 (15.3)	9 (12.5)	4 (5.6)	2 (2.8)
Tachycardia	16 (22.2)	9 (12.5)	6 (8.3)	1 (1.4)	0
Sinus tachycardia	7 (9.7)	3 (4.2)	2 (2.8)	2 (2.8)	0
Bradycardia	2 (2.8)	1 (1.4)	0	0	1 (1.4)
Left ventricular dysfunction	2 (2.8)	0	0	2 (2.8)	0
Palpitations	2 (2.8)	2 (2.8)	0	0	0
Pericardial effusion	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Ventricular tachycardia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Atrioventricular block second degree	1 (1.4)	1 (1.4)	0	0	0
Cardiac dysfunction	1 (1.4)	1 (1.4)	0	0	0
Cardiovascular insufficiency	1 (1.4)	0	0	0	1 (1.4)
Right ventricular dysfunction	1 (1.4)	0	0	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus bradycardia	1 (1.4)	1 (1.4)	0	0	0
Ear and labyrinth disorders					
-Total	5 (6.9)	2 (2.8)	3 (4.2)	0	0
Ear pain	2 (2.8)	2 (2.8)	0	0	0
Deafness unilateral	1 (1.4)	0	1 (1.4)	0	0
Hypoacusis	1 (1.4)	0	1 (1.4)	0	0
Tympanic membrane perforation	1 (1.4)	0	1 (1.4)	0	0
Endocrine disorders					
-Total	5 (6.9)	2 (2.8)	3 (4.2)	0	0
Adrenal insufficiency	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Cushingoid	1 (1.4)	1 (1.4)	0	0	0
Hyperthyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	19 (26.4)	10 (13.9)	9 (12.5)	0	0
Vision blurred	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Eye pain	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Periorbital oedema	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Photophobia	3 (4.2)	1 (1.4)	2 (2.8)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctival haemorrhage	2 (2.8)	2 (2.8)	0	0	0
Dry eye	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Retinal haemorrhage	2 (2.8)	2 (2.8)	0	0	0
Uveitis	2 (2.8)	0	2 (2.8)	0	0
Conjunctivitis allergic	1 (1.4)	1 (1.4)	0	0	0
Eye irritation	1 (1.4)	1 (1.4)	0	0	0
Ocular hyperaemia	1 (1.4)	1 (1.4)	0	0	0
Ocular hypertension	1 (1.4)	0	1 (1.4)	0	0
Papilloedema	1 (1.4)	0	1 (1.4)	0	0
Retinopathy	1 (1.4)	0	1 (1.4)	0	0
Visual impairment	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	51 (70.8)	12 (16.7)	20 (27.8)	18 (25.0)	1 (1.4)
Nausea	31 (43.1)	8 (11.1)	17 (23.6)	6 (8.3)	0
Vomiting	29 (40.3)	17 (23.6)	8 (11.1)	4 (5.6)	0
Diarrhoea	25 (34.7)	14 (19.4)	9 (12.5)	2 (2.8)	0
Abdominal pain	16 (22.2)	6 (8.3)	7 (9.7)	3 (4.2)	0
Constipation	11 (15.3)	9 (12.5)	2 (2.8)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	5 (6.9)	1 (1.4)	1 (1.4)	2 (2.8)	1 (1.4)
Abdominal pain upper	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Colitis	3 (4.2)	0	0	3 (4.2)	0
Oral pain	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Pancreatitis	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Abdominal distension	2 (2.8)	0	2 (2.8)	0	0
Abdominal pain lower	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Ascites	2 (2.8)	0	0	2 (2.8)	0
Gastrointestinal haemorrhage	2 (2.8)	2 (2.8)	0	0	0
Haematemesis	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Haematochezia	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Abdominal discomfort	1 (1.4)	1 (1.4)	0	0	0
Abdominal tenderness	1 (1.4)	1 (1.4)	0	0	0
Anal fissure	1 (1.4)	0	1 (1.4)	0	0
Anal incontinence	1 (1.4)	1 (1.4)	0	0	0
Dry mouth	1 (1.4)	1 (1.4)	0	0	0
Dyspepsia	1 (1.4)	0	1 (1.4)	0	0
Dysphagia	1 (1.4)	0	1 (1.4)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterocolitis	1 (1.4)	0	0	1 (1.4)	0
Flatulence	1 (1.4)	1 (1.4)	0	0	0
Gastrooesophageal reflux disease	1 (1.4)	1 (1.4)	0	0	0
Gingival discomfort	1 (1.4)	1 (1.4)	0	0	0
Glossodynia	1 (1.4)	1 (1.4)	0	0	0
Ileus	1 (1.4)	0	0	1 (1.4)	0
Intestinal obstruction	1 (1.4)	0	0	1 (1.4)	0
Lip pain	1 (1.4)	0	1 (1.4)	0	0
Mouth haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Oral mucosal blistering	1 (1.4)	1 (1.4)	0	0	0
Pancreatic failure	1 (1.4)	0	1 (1.4)	0	0
Pigmentation lip	1 (1.4)	1 (1.4)	0	0	0
Proctalgia	1 (1.4)	0	1 (1.4)	0	0
Tooth socket haemorrhage	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	50 (69.4)	16 (22.2)	18 (25.0)	12 (16.7)	4 (5.6)
Pyrexia	30 (41.7)	9 (12.5)	14 (19.4)	6 (8.3)	1 (1.4)

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	18 (25.0)	13 (18.1)	3 (4.2)	2 (2.8)	0
Chills	10 (13.9)	8 (11.1)	2 (2.8)	0	0
Catheter site pain	7 (9.7)	3 (4.2)	4 (5.6)	0	0
Pain	7 (9.7)	1 (1.4)	3 (4.2)	3 (4.2)	0
Generalised oedema	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Malaise	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Oedema peripheral	4 (5.6)	3 (4.2)	1 (1.4)	0	0
Multiple organ dysfunction syndrome	3 (4.2)	0	0	0	3 (4.2)
Influenza like illness	2 (2.8)	2 (2.8)	0	0	0
Non-cardiac chest pain	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Physical deconditioning	2 (2.8)	0	0	2 (2.8)	0
Acquired gene mutation	1 (1.4)	1 (1.4)	0	0	0
Catheter site extravasation	1 (1.4)	0	1 (1.4)	0	0
Catheter site haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Crying	1 (1.4)	1 (1.4)	0	0	0
Cyst	1 (1.4)	0	0	1 (1.4)	0
Device related thrombosis	1 (1.4)	0	1 (1.4)	0	0
Face oedema	1 (1.4)	0	1 (1.4)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Facial pain	1 (1.4)	0	1 (1.4)	0	0
Gait disturbance	1 (1.4)	1 (1.4)	0	0	0
Injection site haematoma	1 (1.4)	1 (1.4)	0	0	0
Medical device pain	1 (1.4)	0	1 (1.4)	0	0
Peripheral swelling	1 (1.4)	0	1 (1.4)	0	0
Hepatobiliary disorders					
-Total	9 (12.5)	3 (4.2)	2 (2.8)	3 (4.2)	1 (1.4)
Hyperbilirubinaemia	4 (5.6)	0	2 (2.8)	2 (2.8)	0
Hepatomegaly	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Cholecystitis	1 (1.4)	0	0	1 (1.4)	0
Gallbladder enlargement	1 (1.4)	1 (1.4)	0	0	0
Hepatic failure	1 (1.4)	0	0	0	1 (1.4)
Hepatic steatosis	1 (1.4)	0	1 (1.4)	0	0
Hepatosplenomegaly	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	57 (79.2)	6 (8.3)	31 (43.1)	11 (15.3)	9 (12.5)
Cytokine release syndrome	48 (66.7)	6 (8.3)	25 (34.7)	8 (11.1)	9 (12.5)
Hypogammaglobulinaemia	32 (44.4)	4 (5.6)	24 (33.3)	4 (5.6)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Immunodeficiency common variable	2 (2.8)	0	2 (2.8)	0	0
Seasonal allergy	2 (2.8)	2 (2.8)	0	0	0
Chronic graft versus host disease	1 (1.4)	0	1 (1.4)	0	0
Drug hypersensitivity	1 (1.4)	0	1 (1.4)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.4)	0	1 (1.4)	0	0
Graft versus host disease in skin	1 (1.4)	1 (1.4)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	1 (1.4)	0	0
Immunodeficiency	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	51 (70.8)	4 (5.6)	16 (22.2)	20 (27.8)	11 (15.3)
Upper respiratory tract infection	10 (13.9)	4 (5.6)	5 (6.9)	1 (1.4)	0
Clostridium difficile infection	6 (8.3)	0	5 (6.9)	1 (1.4)	0
Pneumonia	6 (8.3)	0	4 (5.6)	1 (1.4)	1 (1.4)
Rhinovirus infection	6 (8.3)	5 (6.9)	1 (1.4)	0	0
Clostridium difficile colitis	5 (6.9)	1 (1.4)	2 (2.8)	2 (2.8)	0
Gastroenteritis	5 (6.9)	1 (1.4)	3 (4.2)	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	5 (6.9)	0	3 (4.2)	2 (2.8)	0
Device related infection	4 (5.6)	0	1 (1.4)	3 (4.2)	0
Influenza	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Otitis media	4 (5.6)	0	3 (4.2)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Sinusitis	4 (5.6)	0	4 (5.6)	0	0
Viral upper respiratory tract infection	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Escherichia urinary tract infection	3 (4.2)	0	1 (1.4)	2 (2.8)	0
Staphylococcal infection	3 (4.2)	1 (1.4)	0	1 (1.4)	1 (1.4)
Viral infection	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Cytomegalovirus infection	2 (2.8)	2 (2.8)	0	0	0
Ear infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Fungal skin infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Oral herpes	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Otitis media acute	2 (2.8)	0	2 (2.8)	0	0
Respiratory syncytial virus infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Sepsis	2 (2.8)	0	0	0	2 (2.8)
Skin infection	2 (2.8)	0	2 (2.8)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Vulvovaginal candidiasis	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Body tinea	1 (1.4)	1 (1.4)	0	0	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Campylobacter infection	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Catheter site cellulitis	1 (1.4)	1 (1.4)	0	0	0
Catheter site infection	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis of male external genital organ	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	0	1 (1.4)	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	1 (1.4)	0	0	1 (1.4)	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Enterococcal infection	1 (1.4)	1 (1.4)	0	0	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis norovirus	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Haemophilus infection	1 (1.4)	0	1 (1.4)	0	0
Herpes simplex	1 (1.4)	1 (1.4)	0	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	1 (1.4)	0	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Hypopyon	1 (1.4)	0	1 (1.4)	0	0
Klebsiella sepsis	1 (1.4)	0	0	0	1 (1.4)
Meningitis aseptic	1 (1.4)	0	1 (1.4)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metapneumovirus infection	1 (1.4)	0	1 (1.4)	0	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Necrotising fasciitis	1 (1.4)	0	0	1 (1.4)	0
Oral candidiasis	1 (1.4)	1 (1.4)	0	0	0
Orchitis	1 (1.4)	1 (1.4)	0	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	1 (1.4)	0	0	0
Pharyngitis	1 (1.4)	0	1 (1.4)	0	0
Pneumonia fungal	1 (1.4)	0	1 (1.4)	0	0
Rash pustular	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	0	0	1 (1.4)	0
Rhinitis	1 (1.4)	1 (1.4)	0	0	0
Rotavirus infection	1 (1.4)	0	0	1 (1.4)	0
Septic embolus	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Streptococcal infection	1 (1.4)	0	1 (1.4)	0	0
Subcutaneous abscess	1 (1.4)	0	1 (1.4)	0	0
Tinea capitis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection enterococcal	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Vulvovaginal mycotic infection	1 (1.4)	0	1 (1.4)	0	0
Injury, poisoning and procedural complications					
-Total	24 (33.3)	11 (15.3)	10 (13.9)	2 (2.8)	1 (1.4)
Infusion related reaction	5 (6.9)	2 (2.8)	3 (4.2)	0	0
Procedural pain	5 (6.9)	2 (2.8)	2 (2.8)	1 (1.4)	0
Transfusion reaction	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Contusion	3 (4.2)	3 (4.2)	0	0	0
Radiation skin injury	2 (2.8)	0	2 (2.8)	0	0
Skin abrasion	2 (2.8)	2 (2.8)	0	0	0
Subdural haematoma	2 (2.8)	0	1 (1.4)	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthropod bite	1 (1.4)	1 (1.4)	0	0	0
Extradural haematoma	1 (1.4)	0	0	1 (1.4)	0
Foot fracture	1 (1.4)	0	1 (1.4)	0	0
Incision site pain	1 (1.4)	1 (1.4)	0	0	0
Limb injury	1 (1.4)	1 (1.4)	0	0	0
Mouth injury	1 (1.4)	1 (1.4)	0	0	0
Post procedural haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Procedural headache	1 (1.4)	0	1 (1.4)	0	0
Procedural nausea	1 (1.4)	0	1 (1.4)	0	0
Procedural site reaction	1 (1.4)	1 (1.4)	0	0	0
Radius fracture	1 (1.4)	0	1 (1.4)	0	0
Skin laceration	1 (1.4)	0	1 (1.4)	0	0
Stoma site irritation	1 (1.4)	1 (1.4)	0	0	0
Subdural haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Sunburn	1 (1.4)	1 (1.4)	0	0	0
Tibia fracture	1 (1.4)	0	1 (1.4)	0	0
Tongue injury	1 (1.4)	1 (1.4)	0	0	0
Transfusion related complication	1 (1.4)	0	0	0	1 (1.4)

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wound	1 (1.4)	1 (1.4)	0	0	0
Investigations					
-Total	55 (76.4)	1 (1.4)	4 (5.6)	12 (16.7)	38 (52.8)
White blood cell count decreased	41 (56.9)	4 (5.6)	1 (1.4)	8 (11.1)	28 (38.9)
Neutrophil count decreased	31 (43.1)	1 (1.4)	2 (2.8)	3 (4.2)	25 (34.7)
Alanine aminotransferase increased	24 (33.3)	3 (4.2)	4 (5.6)	16 (22.2)	1 (1.4)
Aspartate aminotransferase increased	21 (29.2)	4 (5.6)	5 (6.9)	9 (12.5)	3 (4.2)
Platelet count decreased	20 (27.8)	3 (4.2)	2 (2.8)	2 (2.8)	13 (18.1)
Lymphocyte count decreased	19 (26.4)	1 (1.4)	3 (4.2)	7 (9.7)	8 (11.1)
Blood bilirubin increased	10 (13.9)	2 (2.8)	3 (4.2)	4 (5.6)	1 (1.4)
International normalised ratio increased	10 (13.9)	8 (11.1)	1 (1.4)	1 (1.4)	0
Blood creatinine increased	8 (11.1)	5 (6.9)	2 (2.8)	1 (1.4)	0
Prothrombin time prolonged	8 (11.1)	5 (6.9)	2 (2.8)	1 (1.4)	0
Activated partial thromboplastin time prolonged	6 (8.3)	3 (4.2)	3 (4.2)	0	0
Weight decreased	5 (6.9)	2 (2.8)	3 (4.2)	0	0
Blood immunoglobulin m decreased	4 (5.6)	4 (5.6)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transaminases increased	4 (5.6)	3 (4.2)	0	1 (1.4)	0
Blood immunoglobulin a decreased	3 (4.2)	3 (4.2)	0	0	0
C-reactive protein increased	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Haemoglobin decreased	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Lipase increased	3 (4.2)	0	0	0	3 (4.2)
Weight increased	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Blood fibrinogen decreased	2 (2.8)	0	0	2 (2.8)	0
Blood lactate dehydrogenase increased	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Blood magnesium decreased	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Blood phosphorus increased	2 (2.8)	2 (2.8)	0	0	0
Blood urea increased	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Blood uric acid increased	2 (2.8)	2 (2.8)	0	0	0
Electrocardiogram qt prolonged	2 (2.8)	0	0	2 (2.8)	0
Serum ferritin increased	2 (2.8)	0	2 (2.8)	0	0
Blood alkaline phosphatase increased	1 (1.4)	1 (1.4)	0	0	0
Blood bicarbonate decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactic acid increased	1 (1.4)	0	0	0	1 (1.4)
Blood sodium increased	1 (1.4)	0	1 (1.4)	0	0
Cardiac murmur	1 (1.4)	1 (1.4)	0	0	0
Computerised tomogram thorax abnormal	1 (1.4)	0	0	1 (1.4)	0
Coronavirus test positive	1 (1.4)	1 (1.4)	0	0	0
Culture stool positive	1 (1.4)	1 (1.4)	0	0	0
Fibrin d dimer increased	1 (1.4)	1 (1.4)	0	0	0
Hepatic enzyme increased	1 (1.4)	0	1 (1.4)	0	0
Norovirus test positive	1 (1.4)	1 (1.4)	0	0	0
Oxygen saturation decreased	1 (1.4)	1 (1.4)	0	0	0
Pulmonary function test decreased	1 (1.4)	0	1 (1.4)	0	0
Metabolism and nutrition disorders					
-Total	47 (65.3)	6 (8.3)	10 (13.9)	24 (33.3)	7 (9.7)
Decreased appetite	27 (37.5)	7 (9.7)	8 (11.1)	12 (16.7)	0
Hypokalaemia	21 (29.2)	4 (5.6)	5 (6.9)	8 (11.1)	4 (5.6)
Hypophosphataemia	11 (15.3)	3 (4.2)	0	7 (9.7)	1 (1.4)
Hyperphosphataemia	9 (12.5)	8 (11.1)	1 (1.4)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	7 (9.7)	0	3 (4.2)	4 (5.6)	0
Hypocalcaemia	6 (8.3)	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)
Fluid overload	5 (6.9)	1 (1.4)	3 (4.2)	1 (1.4)	0
Hypernatraemia	5 (6.9)	1 (1.4)	1 (1.4)	0	3 (4.2)
Hypoalbuminaemia	5 (6.9)	1 (1.4)	3 (4.2)	1 (1.4)	0
Dehydration	4 (5.6)	1 (1.4)	0	3 (4.2)	0
Hyperuricaemia	4 (5.6)	3 (4.2)	0	0	1 (1.4)
Hyperkalaemia	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Hypomagnesaemia	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Tumour lysis syndrome	3 (4.2)	0	0	3 (4.2)	0
Vitamin d deficiency	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Hypertriglyceridaemia	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Hypoglycaemia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Hyponatraemia	2 (2.8)	0	0	2 (2.8)	0
Malnutrition	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Acidosis	1 (1.4)	1 (1.4)	0	0	0
Hyperammonaemia	1 (1.4)	1 (1.4)	0	0	0
Iron overload	1 (1.4)	0	0	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	1 (1.4)	0	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders					
-Total	35 (48.6)	17 (23.6)	11 (15.3)	7 (9.7)	0
Pain in extremity	14 (19.4)	7 (9.7)	4 (5.6)	3 (4.2)	0
Arthralgia	7 (9.7)	4 (5.6)	1 (1.4)	2 (2.8)	0
Myalgia	6 (8.3)	4 (5.6)	1 (1.4)	1 (1.4)	0
Musculoskeletal pain	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Pain in jaw	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Back pain	3 (4.2)	1 (1.4)	0	2 (2.8)	0
Muscle spasms	3 (4.2)	3 (4.2)	0	0	0
Muscular weakness	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Musculoskeletal chest pain	3 (4.2)	3 (4.2)	0	0	0
Joint range of motion decreased	2 (2.8)	2 (2.8)	0	0	0
Coccydynia	1 (1.4)	1 (1.4)	0	0	0
Flank pain	1 (1.4)	0	1 (1.4)	0	0
Limb discomfort	1 (1.4)	1 (1.4)	0	0	0
Myopathy	1 (1.4)	0	0	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myositis	1 (1.4)	0	0	1 (1.4)	0
Neck pain	1 (1.4)	0	1 (1.4)	0	0
Osteonecrosis	1 (1.4)	0	1 (1.4)	0	0
Osteopenia	1 (1.4)	0	1 (1.4)	0	0
Synovitis	1 (1.4)	0	1 (1.4)	0	0
Toe walking	1 (1.4)	1 (1.4)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (4.2)	0	2 (2.8)	0	1 (1.4)
Glioblastoma multiforme	1 (1.4)	0	0	0	1 (1.4)
Myelodysplastic syndrome	1 (1.4)	0	1 (1.4)	0	0
Skin papilloma	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	40 (55.6)	15 (20.8)	16 (22.2)	7 (9.7)	2 (2.8)
Headache	28 (38.9)	14 (19.4)	9 (12.5)	5 (6.9)	0
Dizziness	5 (6.9)	5 (6.9)	0	0	0
Seizure	5 (6.9)	0	2 (2.8)	2 (2.8)	1 (1.4)
Encephalopathy	4 (5.6)	1 (1.4)	1 (1.4)	2 (2.8)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Peroneal nerve palsy	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Dysarthria	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Neuropathy peripheral	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Somnolence	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Tremor	2 (2.8)	2 (2.8)	0	0	0
Asterixis	1 (1.4)	1 (1.4)	0	0	0
Ataxia	1 (1.4)	0	1 (1.4)	0	0
Depressed level of consciousness	1 (1.4)	1 (1.4)	0	0	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Dysgeusia	1 (1.4)	1 (1.4)	0	0	0
Embolic stroke	1 (1.4)	0	0	0	1 (1.4)
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Idiopathic intracranial hypertension	1 (1.4)	0	1 (1.4)	0	0
Migraine	1 (1.4)	0	1 (1.4)	0	0
Myoclonus	1 (1.4)	1 (1.4)	0	0	0
Neuralgia	1 (1.4)	0	1 (1.4)	0	0
Peripheral sensory neuropathy	1 (1.4)	0	1 (1.4)	0	0
Pleocytosis	1 (1.4)	1 (1.4)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Visual field defect	1 (1.4)	0	1 (1.4)	0	0
Product issues					
-Total	2 (2.8)	2 (2.8)	0	0	0
Device occlusion	2 (2.8)	2 (2.8)	0	0	0
Psychiatric disorders					
-Total	24 (33.3)	8 (11.1)	12 (16.7)	4 (5.6)	0
Anxiety	9 (12.5)	3 (4.2)	5 (6.9)	1 (1.4)	0
Confusional state	6 (8.3)	2 (2.8)	4 (5.6)	0	0
Delirium	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Depression	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Mental status changes	4 (5.6)	3 (4.2)	0	1 (1.4)	0
Agitation	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Hallucination	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Insomnia	2 (2.8)	0	2 (2.8)	0	0
Irritability	2 (2.8)	2 (2.8)	0	0	0
Adjustment disorder	1 (1.4)	0	1 (1.4)	0	0
Listless	1 (1.4)	1 (1.4)	0	0	0
Panic attack	1 (1.4)	0	1 (1.4)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sleep disorder	1 (1.4)	0	1 (1.4)	0	0
Suicidal ideation	1 (1.4)	1 (1.4)	0	0	0
Renal and urinary disorders					
-Total	17 (23.6)	3 (4.2)	4 (5.6)	6 (8.3)	4 (5.6)
Acute kidney injury	11 (15.3)	2 (2.8)	1 (1.4)	5 (6.9)	3 (4.2)
Haematuria	4 (5.6)	0	2 (2.8)	1 (1.4)	1 (1.4)
Dysuria	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Oliguria	3 (4.2)	0	0	3 (4.2)	0
Calculus urinary	1 (1.4)	0	1 (1.4)	0	0
Cystitis haemorrhagic	1 (1.4)	0	0	0	1 (1.4)
Nephrolithiasis	1 (1.4)	0	0	1 (1.4)	0
Pollakiuria	1 (1.4)	1 (1.4)	0	0	0
Renal failure	1 (1.4)	0	0	0	1 (1.4)
Urinary incontinence	1 (1.4)	1 (1.4)	0	0	0
Urinary retention	1 (1.4)	0	1 (1.4)	0	0
Reproductive system and breast disorders					
-Total	6 (8.3)	2 (2.8)	2 (2.8)	2 (2.8)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal adhesion	2 (2.8)	2 (2.8)	0	0	0
Oedema genital	1 (1.4)	0	1 (1.4)	0	0
Ovarian failure	1 (1.4)	0	0	1 (1.4)	0
Scrotal pain	1 (1.4)	0	1 (1.4)	0	0
Vaginal haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	42 (58.3)	13 (18.1)	9 (12.5)	10 (13.9)	10 (13.9)
Cough	15 (20.8)	12 (16.7)	2 (2.8)	1 (1.4)	0
Epistaxis	13 (18.1)	4 (5.6)	3 (4.2)	5 (6.9)	1 (1.4)
Hypoxia	13 (18.1)	0	3 (4.2)	8 (11.1)	2 (2.8)
Pleural effusion	8 (11.1)	1 (1.4)	5 (6.9)	2 (2.8)	0
Oropharyngeal pain	7 (9.7)	4 (5.6)	2 (2.8)	1 (1.4)	0
Pulmonary oedema	7 (9.7)	1 (1.4)	0	3 (4.2)	3 (4.2)
Tachypnoea	7 (9.7)	3 (4.2)	2 (2.8)	2 (2.8)	0
Nasal congestion	6 (8.3)	6 (8.3)	0	0	0
Rhinorrhoea	6 (8.3)	5 (6.9)	1 (1.4)	0	0
Rhinitis allergic	5 (6.9)	4 (5.6)	1 (1.4)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	4 (5.6)	1 (1.4)	1 (1.4)	2 (2.8)	0
Respiratory failure	4 (5.6)	0	0	0	4 (5.6)
Haemoptysis	3 (4.2)	1 (1.4)	0	1 (1.4)	1 (1.4)
Atelectasis	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Acute respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Aspiration	1 (1.4)	0	0	0	1 (1.4)
Dysphonia	1 (1.4)	1 (1.4)	0	0	0
Idiopathic pneumonia syndrome	1 (1.4)	0	0	0	1 (1.4)
Nasal discomfort	1 (1.4)	1 (1.4)	0	0	0
Oropharyngeal plaque	1 (1.4)	1 (1.4)	0	0	0
Pharyngeal erythema	1 (1.4)	1 (1.4)	0	0	0
Pharyngeal lesion	1 (1.4)	0	0	1 (1.4)	0
Pharyngeal ulceration	1 (1.4)	0	1 (1.4)	0	0
Pulmonary alveolar haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Pulmonary hypertension	1 (1.4)	0	0	1 (1.4)	0
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory depression	1 (1.4)	0	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	0	0	1 (1.4)

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wheezing	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	36 (50.0)	20 (27.8)	12 (16.7)	4 (5.6)	0
Rash	9 (12.5)	6 (8.3)	3 (4.2)	0	0
Dry skin	5 (6.9)	5 (6.9)	0	0	0
Erythema	5 (6.9)	5 (6.9)	0	0	0
Pruritus	5 (6.9)	5 (6.9)	0	0	0
Rash erythematous	5 (6.9)	2 (2.8)	3 (4.2)	0	0
Rash maculo-papular	5 (6.9)	3 (4.2)	1 (1.4)	1 (1.4)	0
Alopecia	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Petechiae	4 (5.6)	3 (4.2)	1 (1.4)	0	0
Hyperhidrosis	3 (4.2)	3 (4.2)	0	0	0
Ingrowing nail	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Dermatitis acneiform	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Macule	2 (2.8)	2 (2.8)	0	0	0
Night sweats	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Rash macular	2 (2.8)	1 (1.4)	0	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash papular	2 (2.8)	2 (2.8)	0	0	0
Rash pruritic	2 (2.8)	2 (2.8)	0	0	0
Acne	1 (1.4)	1 (1.4)	0	0	0
Cold sweat	1 (1.4)	1 (1.4)	0	0	0
Dermatitis	1 (1.4)	1 (1.4)	0	0	0
Dermatitis atopic	1 (1.4)	1 (1.4)	0	0	0
Dermatitis diaper	1 (1.4)	1 (1.4)	0	0	0
Ecchymosis	1 (1.4)	0	0	1 (1.4)	0
Eczema	1 (1.4)	1 (1.4)	0	0	0
Keloid scar	1 (1.4)	0	1 (1.4)	0	0
Livedo reticularis	1 (1.4)	1 (1.4)	0	0	0
Papule	1 (1.4)	1 (1.4)	0	0	0
Pruritus generalised	1 (1.4)	1 (1.4)	0	0	0
Rash follicular	1 (1.4)	1 (1.4)	0	0	0
Rash vesicular	1 (1.4)	1 (1.4)	0	0	0
Skin exfoliation	1 (1.4)	1 (1.4)	0	0	0
Skin fissures	1 (1.4)	1 (1.4)	0	0	0
Skin haemorrhage	1 (1.4)	1 (1.4)	0	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin irritation	1 (1.4)	1 (1.4)	0	0	0
Skin ulcer	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	32 (44.4)	3 (4.2)	6 (8.3)	14 (19.4)	9 (12.5)
Hypotension	22 (30.6)	1 (1.4)	0	12 (16.7)	9 (12.5)
Hypertension	14 (19.4)	4 (5.6)	8 (11.1)	2 (2.8)	0
Orthostatic hypotension	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Embolism	1 (1.4)	0	0	1 (1.4)	0
Flushing	1 (1.4)	1 (1.4)	0	0	0
Haematoma	1 (1.4)	0	1 (1.4)	0	0
Hot flush	1 (1.4)	1 (1.4)	0	0	0
Phlebitis	1 (1.4)	0	1 (1.4)	0	0
Secondary hypertension	1 (1.4)	0	1 (1.4)	0	0
Venous thrombosis limb	1 (1.4)	1 (1.4)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178h
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Blood and lymphatic system disorders					
-Total	1 (100)	0	0	1 (100)	0
Anaemia	1 (100)	0	0	1 (100)	0
Febrile neutropenia	1 (100)	0	0	1 (100)	0
Cardiac disorders					
-Total	1 (100)	0	1 (100)	0	0
Tachycardia	1 (100)	0	1 (100)	0	0
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Haematemesis	1 (100)	0	1 (100)	0	0
Nausea	1 (100)	0	1 (100)	0	0

Hypodiploidy: Yes

	All patients N=1				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (100)	0	1 (100)	0	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0
Cytokine release syndrome	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	0	0	1 (100)	0
Activated partial thromboplastin time prolonged	1 (100)	0	1 (100)	0	0
Aspartate aminotransferase increased	1 (100)	0	1 (100)	0	0
Blood phosphorus increased	1 (100)	1 (100)	0	0	0
International normalised ratio increased	1 (100)	1 (100)	0	0	0
Neutrophil count decreased	1 (100)	0	0	1 (100)	0
Platelet count decreased	1 (100)	0	0	1 (100)	0
White blood cell count decreased	1 (100)	1 (100)	0	0	0
Nervous system disorders					
-Total	1 (100)	0	1 (100)	0	0
Encephalopathy	1 (100)	0	1 (100)	0	0

Hypodiploidy: Yes

Primary system organ class Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Psychiatric disorders					
-Total	1 (100)	0	1 (100)	0	0
Insomnia	1 (100)	0	1 (100)	0	0
Mental status changes	1 (100)	1 (100)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	0	1 (100)	0	0
Rash erythematous	1 (100)	0	1 (100)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178h
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	71 (95.9)	0	3 (4.1)	11 (14.9)	57 (77.0)
Blood and lymphatic system disorders					
-Total	60 (81.1)	1 (1.4)	2 (2.7)	34 (45.9)	23 (31.1)
Febrile neutropenia	35 (47.3)	0	0	34 (45.9)	1 (1.4)
Anaemia	34 (45.9)	2 (2.7)	6 (8.1)	25 (33.8)	1 (1.4)
Neutropenia	16 (21.6)	0	0	4 (5.4)	12 (16.2)
Thrombocytopenia	15 (20.3)	0	1 (1.4)	5 (6.8)	9 (12.2)
Disseminated intravascular coagulation	6 (8.1)	0	2 (2.7)	3 (4.1)	1 (1.4)
Lymphopenia	6 (8.1)	0	2 (2.7)	1 (1.4)	3 (4.1)
Pancytopenia	4 (5.4)	0	0	1 (1.4)	3 (4.1)
Coagulopathy	2 (2.7)	1 (1.4)	0	1 (1.4)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eosinophilia	1 (1.4)	0	0	1 (1.4)	0
Hypofibrinogenaemia	1 (1.4)	0	0	0	1 (1.4)
Leukocytosis	1 (1.4)	1 (1.4)	0	0	0
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Lymphadenopathy	1 (1.4)	0	1 (1.4)	0	0
Splenomegaly	1 (1.4)	1 (1.4)	0	0	0
Cardiac disorders					
-Total	27 (36.5)	11 (14.9)	9 (12.2)	5 (6.8)	2 (2.7)
Tachycardia	16 (21.6)	9 (12.2)	5 (6.8)	2 (2.7)	0
Sinus tachycardia	7 (9.5)	3 (4.1)	2 (2.7)	2 (2.7)	0
Bradycardia	3 (4.1)	1 (1.4)	1 (1.4)	0	1 (1.4)
Left ventricular dysfunction	3 (4.1)	0	0	3 (4.1)	0
Pericardial effusion	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Palpitations	2 (2.7)	2 (2.7)	0	0	0
Ventricular tachycardia	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Atrioventricular block second degree	1 (1.4)	1 (1.4)	0	0	0
Cardiac dysfunction	1 (1.4)	1 (1.4)	0	0	0
Cardiovascular insufficiency	1 (1.4)	0	0	0	1 (1.4)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Right ventricular dysfunction	1 (1.4)	0	0	1 (1.4)	0
Sinus bradycardia	1 (1.4)	1 (1.4)	0	0	0
Ear and labyrinth disorders					
-Total	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Ear pain	2 (2.7)	2 (2.7)	0	0	0
Deafness unilateral	1 (1.4)	0	1 (1.4)	0	0
Hypoacusis	1 (1.4)	0	1 (1.4)	0	0
Tympanic membrane perforation	1 (1.4)	0	1 (1.4)	0	0
Endocrine disorders					
-Total	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Adrenal insufficiency	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Cushingoid	1 (1.4)	1 (1.4)	0	0	0
Hyperthyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	20 (27.0)	11 (14.9)	9 (12.2)	0	0
Periorbital oedema	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Vision blurred	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Conjunctival haemorrhage	3 (4.1)	3 (4.1)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eye pain	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Photophobia	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Dry eye	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Retinal haemorrhage	2 (2.7)	2 (2.7)	0	0	0
Uveitis	2 (2.7)	0	2 (2.7)	0	0
Conjunctivitis allergic	1 (1.4)	1 (1.4)	0	0	0
Eye irritation	1 (1.4)	1 (1.4)	0	0	0
Ocular hyperaemia	1 (1.4)	1 (1.4)	0	0	0
Ocular hypertension	1 (1.4)	0	1 (1.4)	0	0
Papilloedema	1 (1.4)	0	1 (1.4)	0	0
Retinopathy	1 (1.4)	0	1 (1.4)	0	0
Visual impairment	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	52 (70.3)	12 (16.2)	19 (25.7)	20 (27.0)	1 (1.4)
Nausea	32 (43.2)	9 (12.2)	16 (21.6)	7 (9.5)	0
Vomiting	29 (39.2)	17 (23.0)	8 (10.8)	4 (5.4)	0
Diarrhoea	26 (35.1)	14 (18.9)	10 (13.5)	2 (2.7)	0
Abdominal pain	17 (23.0)	7 (9.5)	7 (9.5)	3 (4.1)	0

Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	11 (14.9)	9 (12.2)	2 (2.7)	0	0
Stomatitis	5 (6.8)	1 (1.4)	1 (1.4)	2 (2.7)	1 (1.4)
Colitis	4 (5.4)	1 (1.4)	0	3 (4.1)	0
Abdominal pain upper	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Oral pain	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Pancreatitis	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Abdominal distension	2 (2.7)	0	2 (2.7)	0	0
Abdominal pain lower	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Ascites	2 (2.7)	0	0	2 (2.7)	0
Dysphagia	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Gastrointestinal haemorrhage	2 (2.7)	2 (2.7)	0	0	0
Haematochezia	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Abdominal discomfort	1 (1.4)	1 (1.4)	0	0	0
Abdominal tenderness	1 (1.4)	1 (1.4)	0	0	0
Anal fissure	1 (1.4)	0	1 (1.4)	0	0
Anal incontinence	1 (1.4)	1 (1.4)	0	0	0
Dry mouth	1 (1.4)	1 (1.4)	0	0	0
Dyspepsia	1 (1.4)	0	1 (1.4)	0	0

Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterocolitis	1 (1.4)	0	0	1 (1.4)	0
Flatulence	1 (1.4)	1 (1.4)	0	0	0
Gastrooesophageal reflux disease	1 (1.4)	1 (1.4)	0	0	0
Gingival discomfort	1 (1.4)	1 (1.4)	0	0	0
Glossodynia	1 (1.4)	1 (1.4)	0	0	0
Haematemesis	1 (1.4)	1 (1.4)	0	0	0
Ileus	1 (1.4)	0	0	1 (1.4)	0
Intestinal obstruction	1 (1.4)	0	0	1 (1.4)	0
Lip pain	1 (1.4)	0	1 (1.4)	0	0
Mouth haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Oral mucosal blistering	1 (1.4)	1 (1.4)	0	0	0
Pancreatic failure	1 (1.4)	0	1 (1.4)	0	0
Perianal erythema	1 (1.4)	0	1 (1.4)	0	0
Pigmentation lip	1 (1.4)	1 (1.4)	0	0	0
Proctalgia	1 (1.4)	0	1 (1.4)	0	0
Tooth socket haemorrhage	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	52 (70.3)	16 (21.6)	18 (24.3)	14 (18.9)	4 (5.4)
Pyrexia	32 (43.2)	9 (12.2)	15 (20.3)	7 (9.5)	1 (1.4)
Fatigue	18 (24.3)	13 (17.6)	3 (4.1)	2 (2.7)	0
Chills	11 (14.9)	9 (12.2)	2 (2.7)	0	0
Catheter site pain	7 (9.5)	3 (4.1)	4 (5.4)	0	0
Pain	7 (9.5)	1 (1.4)	3 (4.1)	3 (4.1)	0
Oedema peripheral	5 (6.8)	3 (4.1)	1 (1.4)	1 (1.4)	0
Generalised oedema	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Malaise	4 (5.4)	1 (1.4)	3 (4.1)	0	0
Multiple organ dysfunction syndrome	4 (5.4)	0	0	1 (1.4)	3 (4.1)
Face oedema	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Influenza like illness	2 (2.7)	2 (2.7)	0	0	0
Non-cardiac chest pain	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Physical deconditioning	2 (2.7)	0	0	2 (2.7)	0
Acquired gene mutation	1 (1.4)	1 (1.4)	0	0	0
Asthenia	1 (1.4)	1 (1.4)	0	0	0
Catheter site extravasation	1 (1.4)	0	1 (1.4)	0	0
Catheter site haemorrhage	1 (1.4)	1 (1.4)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Crying	1 (1.4)	1 (1.4)	0	0	0
Cyst	1 (1.4)	0	0	1 (1.4)	0
Device related thrombosis	1 (1.4)	0	1 (1.4)	0	0
Facial pain	1 (1.4)	0	1 (1.4)	0	0
Gait disturbance	1 (1.4)	1 (1.4)	0	0	0
Injection site haematoma	1 (1.4)	1 (1.4)	0	0	0
Localised oedema	1 (1.4)	0	0	1 (1.4)	0
Medical device pain	1 (1.4)	0	1 (1.4)	0	0
Mucosal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Peripheral swelling	1 (1.4)	0	1 (1.4)	0	0
Hepatobiliary disorders					
-Total	11 (14.9)	3 (4.1)	3 (4.1)	4 (5.4)	1 (1.4)
Hyperbilirubinaemia	5 (6.8)	0	2 (2.7)	3 (4.1)	0
Hepatomegaly	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Cholecystitis	1 (1.4)	0	0	1 (1.4)	0
Gallbladder enlargement	1 (1.4)	1 (1.4)	0	0	0
Hepatic failure	1 (1.4)	0	0	0	1 (1.4)
Hepatic steatosis	1 (1.4)	0	1 (1.4)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatosplenomegaly	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	58 (78.4)	6 (8.1)	30 (40.5)	11 (14.9)	11 (14.9)
Cytokine release syndrome	49 (66.2)	6 (8.1)	24 (32.4)	8 (10.8)	11 (14.9)
Hypogammaglobulinaemia	33 (44.6)	4 (5.4)	24 (32.4)	5 (6.8)	0
Graft versus host disease	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Immunodeficiency common variable	2 (2.7)	0	2 (2.7)	0	0
Seasonal allergy	2 (2.7)	2 (2.7)	0	0	0
Chronic graft versus host disease	1 (1.4)	0	1 (1.4)	0	0
Drug hypersensitivity	1 (1.4)	0	1 (1.4)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.4)	0	1 (1.4)	0	0
Graft versus host disease in skin	1 (1.4)	1 (1.4)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	1 (1.4)	0	0
Immunodeficiency	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	52 (70.3)	4 (5.4)	16 (21.6)	21 (28.4)	11 (14.9)
Upper respiratory tract infection	11 (14.9)	5 (6.8)	5 (6.8)	1 (1.4)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	7 (9.5)	0	5 (6.8)	1 (1.4)	1 (1.4)
Clostridium difficile infection	6 (8.1)	0	5 (6.8)	1 (1.4)	0
Rhinovirus infection	6 (8.1)	5 (6.8)	1 (1.4)	0	0
Clostridium difficile colitis	5 (6.8)	1 (1.4)	2 (2.7)	2 (2.7)	0
Gastroenteritis	5 (6.8)	1 (1.4)	3 (4.1)	1 (1.4)	0
Sinusitis	5 (6.8)	1 (1.4)	4 (5.4)	0	0
Urinary tract infection	5 (6.8)	0	3 (4.1)	2 (2.7)	0
Device related infection	4 (5.4)	0	1 (1.4)	3 (4.1)	0
Influenza	4 (5.4)	1 (1.4)	3 (4.1)	0	0
Otitis media	4 (5.4)	0	3 (4.1)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.4)	2 (2.7)	1 (1.4)	1 (1.4)	0
Viral upper respiratory tract infection	4 (5.4)	2 (2.7)	1 (1.4)	1 (1.4)	0
Escherichia urinary tract infection	3 (4.1)	0	1 (1.4)	2 (2.7)	0
Staphylococcal infection	3 (4.1)	1 (1.4)	0	1 (1.4)	1 (1.4)
Viral infection	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Cytomegalovirus infection	2 (2.7)	2 (2.7)	0	0	0
Ear infection	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Escherichia bacteraemia	2 (2.7)	0	0	2 (2.7)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal skin infection	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Oral herpes	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Otitis media acute	2 (2.7)	0	2 (2.7)	0	0
Respiratory syncytial virus infection	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Sepsis	2 (2.7)	0	0	0	2 (2.7)
Skin infection	2 (2.7)	0	2 (2.7)	0	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Vulvovaginal candidiasis	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Body tinea	1 (1.4)	1 (1.4)	0	0	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Campylobacter infection	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Catheter site cellulitis	1 (1.4)	1 (1.4)	0	0	0

Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis of male external genital organ	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	0	1 (1.4)	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Corona virus infection	1 (1.4)	0	0	1 (1.4)	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Enterococcal infection	1 (1.4)	1 (1.4)	0	0	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis norovirus	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Haemophilus infection	1 (1.4)	0	1 (1.4)	0	0
Herpes simplex	1 (1.4)	1 (1.4)	0	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Human herpesvirus 6 infection	1 (1.4)	0	1 (1.4)	0	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Hypopyon	1 (1.4)	0	1 (1.4)	0	0
Klebsiella sepsis	1 (1.4)	0	0	0	1 (1.4)
Meningitis aseptic	1 (1.4)	0	1 (1.4)	0	0
Metapneumovirus infection	1 (1.4)	0	1 (1.4)	0	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Necrotising fasciitis	1 (1.4)	0	0	1 (1.4)	0
Oral candidiasis	1 (1.4)	1 (1.4)	0	0	0
Orchitis	1 (1.4)	1 (1.4)	0	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	1 (1.4)	0	0	0
Pharyngitis	1 (1.4)	0	1 (1.4)	0	0
Pneumonia fungal	1 (1.4)	0	1 (1.4)	0	0
Rash pustular	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	0	0	1 (1.4)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinitis	1 (1.4)	1 (1.4)	0	0	0
Rotavirus infection	1 (1.4)	0	0	1 (1.4)	0
Septic embolus	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Streptococcal infection	1 (1.4)	0	1 (1.4)	0	0
Subcutaneous abscess	1 (1.4)	0	1 (1.4)	0	0
Tinea capitis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection enterococcal	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Vulvovaginal mycotic infection	1 (1.4)	0	1 (1.4)	0	0
Injury, poisoning and procedural complications					
-Total	26 (35.1)	12 (16.2)	10 (13.5)	3 (4.1)	1 (1.4)
Infusion related reaction	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Procedural pain	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Transfusion reaction	4 (5.4)	2 (2.7)	2 (2.7)	0	0

Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Contusion	3 (4.1)	3 (4.1)	0	0	0
Radiation skin injury	2 (2.7)	0	2 (2.7)	0	0
Skin abrasion	2 (2.7)	2 (2.7)	0	0	0
Subdural haematoma	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Arthropod bite	1 (1.4)	1 (1.4)	0	0	0
Extradural haematoma	1 (1.4)	0	0	1 (1.4)	0
Foot fracture	1 (1.4)	0	1 (1.4)	0	0
Incision site pain	1 (1.4)	1 (1.4)	0	0	0
Limb injury	1 (1.4)	1 (1.4)	0	0	0
Mouth injury	1 (1.4)	1 (1.4)	0	0	0
Post procedural haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Procedural complication	1 (1.4)	1 (1.4)	0	0	0
Procedural headache	1 (1.4)	0	1 (1.4)	0	0
Procedural nausea	1 (1.4)	0	1 (1.4)	0	0
Procedural site reaction	1 (1.4)	1 (1.4)	0	0	0
Radius fracture	1 (1.4)	0	1 (1.4)	0	0
Skin laceration	1 (1.4)	0	1 (1.4)	0	0
Stoma site irritation	1 (1.4)	1 (1.4)	0	0	0

Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Subdural haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Sunburn	1 (1.4)	1 (1.4)	0	0	0
Tibia fracture	1 (1.4)	0	1 (1.4)	0	0
Tongue injury	1 (1.4)	1 (1.4)	0	0	0
Tracheal haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Transfusion related complication	1 (1.4)	0	0	0	1 (1.4)
Wound	1 (1.4)	1 (1.4)	0	0	0
Investigations					
-Total	57 (77.0)	1 (1.4)	4 (5.4)	11 (14.9)	41 (55.4)
White blood cell count decreased	41 (55.4)	3 (4.1)	1 (1.4)	8 (10.8)	29 (39.2)
Neutrophil count decreased	31 (41.9)	1 (1.4)	2 (2.7)	2 (2.7)	26 (35.1)
Alanine aminotransferase increased	26 (35.1)	3 (4.1)	4 (5.4)	18 (24.3)	1 (1.4)
Aspartate aminotransferase increased	23 (31.1)	5 (6.8)	4 (5.4)	9 (12.2)	5 (6.8)
Platelet count decreased	20 (27.0)	3 (4.1)	2 (2.7)	2 (2.7)	13 (17.6)
Lymphocyte count decreased	19 (25.7)	1 (1.4)	3 (4.1)	7 (9.5)	8 (10.8)
Blood bilirubin increased	10 (13.5)	2 (2.7)	3 (4.1)	4 (5.4)	1 (1.4)
International normalised ratio increased	10 (13.5)	8 (10.8)	1 (1.4)	1 (1.4)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood creatinine increased	9 (12.2)	5 (6.8)	2 (2.7)	2 (2.7)	0
Prothrombin time prolonged	9 (12.2)	5 (6.8)	3 (4.1)	1 (1.4)	0
Activated partial thromboplastin time prolonged	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Weight decreased	5 (6.8)	2 (2.7)	3 (4.1)	0	0
Blood fibrinogen decreased	4 (5.4)	0	1 (1.4)	2 (2.7)	1 (1.4)
Blood immunoglobulin m decreased	4 (5.4)	4 (5.4)	0	0	0
C-reactive protein increased	4 (5.4)	1 (1.4)	2 (2.7)	1 (1.4)	0
Transaminases increased	4 (5.4)	3 (4.1)	0	1 (1.4)	0
Blood immunoglobulin a decreased	3 (4.1)	3 (4.1)	0	0	0
Blood urea increased	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Haemoglobin decreased	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Lipase increased	3 (4.1)	0	0	0	3 (4.1)
Weight increased	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Blood lactate dehydrogenase increased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood lactic acid increased	2 (2.7)	0	1 (1.4)	0	1 (1.4)
Blood magnesium decreased	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Blood uric acid increased	2 (2.7)	2 (2.7)	0	0	0

Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	2 (2.7)	0	0	2 (2.7)	0
Serum ferritin increased	2 (2.7)	0	2 (2.7)	0	0
Blood alkaline phosphatase increased	1 (1.4)	1 (1.4)	0	0	0
Blood bicarbonate decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood phosphorus decreased	1 (1.4)	1 (1.4)	0	0	0
Blood phosphorus increased	1 (1.4)	1 (1.4)	0	0	0
Blood sodium increased	1 (1.4)	0	1 (1.4)	0	0
Cardiac murmur	1 (1.4)	1 (1.4)	0	0	0
Computerised tomogram thorax abnormal	1 (1.4)	0	0	1 (1.4)	0
Coronavirus test positive	1 (1.4)	1 (1.4)	0	0	0
Culture stool positive	1 (1.4)	1 (1.4)	0	0	0
Fibrin d dimer increased	1 (1.4)	1 (1.4)	0	0	0
Hepatic enzyme increased	1 (1.4)	0	1 (1.4)	0	0
Norovirus test positive	1 (1.4)	1 (1.4)	0	0	0
Oxygen saturation decreased	1 (1.4)	1 (1.4)	0	0	0
Protein total decreased	1 (1.4)	0	0	1 (1.4)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary function test decreased	1 (1.4)	0	1 (1.4)	0	0
Metabolism and nutrition disorders					
-Total	49 (66.2)	6 (8.1)	10 (13.5)	26 (35.1)	7 (9.5)
Decreased appetite	28 (37.8)	7 (9.5)	8 (10.8)	13 (17.6)	0
Hypokalaemia	23 (31.1)	5 (6.8)	5 (6.8)	9 (12.2)	4 (5.4)
Hypophosphataemia	13 (17.6)	4 (5.4)	0	8 (10.8)	1 (1.4)
Hyperphosphataemia	9 (12.2)	8 (10.8)	1 (1.4)	0	0
Hyperglycaemia	7 (9.5)	0	3 (4.1)	4 (5.4)	0
Fluid overload	6 (8.1)	1 (1.4)	4 (5.4)	1 (1.4)	0
Hypernatraemia	6 (8.1)	1 (1.4)	2 (2.7)	0	3 (4.1)
Hypoalbuminaemia	6 (8.1)	1 (1.4)	4 (5.4)	1 (1.4)	0
Hypocalcaemia	6 (8.1)	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)
Dehydration	4 (5.4)	1 (1.4)	0	3 (4.1)	0
Hyperuricaemia	4 (5.4)	3 (4.1)	0	0	1 (1.4)
Hyperkalaemia	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Hypomagnesaemia	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Tumour lysis syndrome	3 (4.1)	0	0	3 (4.1)	0
Vitamin d deficiency	3 (4.1)	2 (2.7)	1 (1.4)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acidosis	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Hypertriglyceridaemia	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Hypoglycaemia	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Hyponatraemia	2 (2.7)	0	0	2 (2.7)	0
Malnutrition	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Hyperalbuminaemia	1 (1.4)	1 (1.4)	0	0	0
Hyperammonaemia	1 (1.4)	1 (1.4)	0	0	0
Hypercalcaemia	1 (1.4)	1 (1.4)	0	0	0
Hyperchloraemia	1 (1.4)	1 (1.4)	0	0	0
Hypermagnesaemia	1 (1.4)	1 (1.4)	0	0	0
Iron overload	1 (1.4)	0	0	1 (1.4)	0
Metabolic acidosis	1 (1.4)	0	1 (1.4)	0	0
Metabolic alkalosis	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	37 (50.0)	17 (23.0)	12 (16.2)	8 (10.8)	0
Pain in extremity	14 (18.9)	7 (9.5)	4 (5.4)	3 (4.1)	0
Arthralgia	7 (9.5)	4 (5.4)	1 (1.4)	2 (2.7)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Myalgia	6 (8.1)	4 (5.4)	1 (1.4)	1 (1.4)	0
Musculoskeletal pain	4 (5.4)	2 (2.7)	1 (1.4)	1 (1.4)	0
Pain in jaw	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Back pain	3 (4.1)	1 (1.4)	0	2 (2.7)	0
Muscle spasms	3 (4.1)	3 (4.1)	0	0	0
Muscular weakness	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Musculoskeletal chest pain	3 (4.1)	3 (4.1)	0	0	0
Joint range of motion decreased	2 (2.7)	2 (2.7)	0	0	0
Neck pain	2 (2.7)	0	2 (2.7)	0	0
Bone pain	1 (1.4)	0	0	1 (1.4)	0
Coccydynia	1 (1.4)	1 (1.4)	0	0	0
Flank pain	1 (1.4)	0	1 (1.4)	0	0
Limb discomfort	1 (1.4)	1 (1.4)	0	0	0
Myopathy	1 (1.4)	0	0	1 (1.4)	0
Myositis	1 (1.4)	0	0	1 (1.4)	0
Osteonecrosis	1 (1.4)	0	1 (1.4)	0	0
Osteopenia	1 (1.4)	0	1 (1.4)	0	0
Synovitis	1 (1.4)	0	1 (1.4)	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Toe walking	1 (1.4)	1 (1.4)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (4.1)	0	2 (2.7)	0	1 (1.4)
Glioblastoma multiforme	1 (1.4)	0	0	0	1 (1.4)
Myelodysplastic syndrome	1 (1.4)	0	1 (1.4)	0	0
Skin papilloma	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	42 (56.8)	17 (23.0)	16 (21.6)	7 (9.5)	2 (2.7)
Headache	29 (39.2)	15 (20.3)	9 (12.2)	5 (6.8)	0
Dizziness	6 (8.1)	6 (8.1)	0	0	0
Seizure	5 (6.8)	0	2 (2.7)	2 (2.7)	1 (1.4)
Encephalopathy	3 (4.1)	1 (1.4)	0	2 (2.7)	0
Peroneal nerve palsy	3 (4.1)	2 (2.7)	1 (1.4)	0	0
Dysarthria	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Neuropathy peripheral	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Somnolence	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Tremor	2 (2.7)	2 (2.7)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Asterixis	1 (1.4)	1 (1.4)	0	0	0
Ataxia	1 (1.4)	0	1 (1.4)	0	0
Depressed level of consciousness	1 (1.4)	1 (1.4)	0	0	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Dysgeusia	1 (1.4)	1 (1.4)	0	0	0
Embolic stroke	1 (1.4)	0	0	0	1 (1.4)
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Hypotonia	1 (1.4)	0	1 (1.4)	0	0
Idiopathic intracranial hypertension	1 (1.4)	0	1 (1.4)	0	0
Migraine	1 (1.4)	0	1 (1.4)	0	0
Myoclonus	1 (1.4)	1 (1.4)	0	0	0
Neuralgia	1 (1.4)	0	1 (1.4)	0	0
Peripheral sensory neuropathy	1 (1.4)	0	1 (1.4)	0	0
Pleocytosis	1 (1.4)	1 (1.4)	0	0	0
Visual field defect	1 (1.4)	0	1 (1.4)	0	0
Product issues					
-Total	2 (2.7)	2 (2.7)	0	0	0
Device occlusion	2 (2.7)	2 (2.7)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Psychiatric disorders					
-Total	25 (33.8)	8 (10.8)	13 (17.6)	4 (5.4)	0
Anxiety	9 (12.2)	3 (4.1)	5 (6.8)	1 (1.4)	0
Confusional state	7 (9.5)	3 (4.1)	4 (5.4)	0	0
Delirium	5 (6.8)	2 (2.7)	2 (2.7)	1 (1.4)	0
Depression	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Agitation	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Insomnia	3 (4.1)	0	3 (4.1)	0	0
Irritability	3 (4.1)	3 (4.1)	0	0	0
Mental status changes	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Hallucination	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Adjustment disorder	1 (1.4)	0	1 (1.4)	0	0
Listless	1 (1.4)	1 (1.4)	0	0	0
Panic attack	1 (1.4)	0	1 (1.4)	0	0
Sleep disorder	1 (1.4)	0	1 (1.4)	0	0
Suicidal ideation	1 (1.4)	1 (1.4)	0	0	0
Renal and urinary disorders					
-Total	19 (25.7)	3 (4.1)	4 (5.4)	7 (9.5)	5 (6.8)

Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	12 (16.2)	2 (2.7)	1 (1.4)	5 (6.8)	4 (5.4)
Haematuria	5 (6.8)	0	2 (2.7)	2 (2.7)	1 (1.4)
Dysuria	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Oliguria	3 (4.1)	0	0	3 (4.1)	0
Calculus urinary	1 (1.4)	0	1 (1.4)	0	0
Cystitis haemorrhagic	1 (1.4)	0	0	0	1 (1.4)
Nephrolithiasis	1 (1.4)	0	0	1 (1.4)	0
Pollakiuria	1 (1.4)	1 (1.4)	0	0	0
Renal failure	1 (1.4)	0	0	0	1 (1.4)
Renal impairment	1 (1.4)	0	0	1 (1.4)	0
Urinary incontinence	1 (1.4)	1 (1.4)	0	0	0
Urinary retention	1 (1.4)	0	1 (1.4)	0	0
Reproductive system and breast disorders					
-Total	6 (8.1)	2 (2.7)	2 (2.7)	2 (2.7)	0
Vulvovaginal adhesion	2 (2.7)	2 (2.7)	0	0	0
Oedema genital	1 (1.4)	0	1 (1.4)	0	0
Ovarian failure	1 (1.4)	0	0	1 (1.4)	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Scrotal pain	1 (1.4)	0	1 (1.4)	0	0
Vaginal haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	44 (59.5)	13 (17.6)	9 (12.2)	10 (13.5)	12 (16.2)
Cough	16 (21.6)	13 (17.6)	2 (2.7)	1 (1.4)	0
Hypoxia	15 (20.3)	0	3 (4.1)	9 (12.2)	3 (4.1)
Epistaxis	14 (18.9)	4 (5.4)	4 (5.4)	5 (6.8)	1 (1.4)
Pleural effusion	10 (13.5)	1 (1.4)	6 (8.1)	3 (4.1)	0
Pulmonary oedema	9 (12.2)	1 (1.4)	0	4 (5.4)	4 (5.4)
Tachypnoea	8 (10.8)	3 (4.1)	2 (2.7)	3 (4.1)	0
Oropharyngeal pain	7 (9.5)	4 (5.4)	2 (2.7)	1 (1.4)	0
Nasal congestion	6 (8.1)	6 (8.1)	0	0	0
Rhinorrhoea	6 (8.1)	5 (6.8)	1 (1.4)	0	0
Dyspnoea	5 (6.8)	1 (1.4)	1 (1.4)	2 (2.7)	1 (1.4)
Rhinitis allergic	5 (6.8)	4 (5.4)	1 (1.4)	0	0
Respiratory failure	4 (5.4)	0	0	0	4 (5.4)
Haemoptysis	3 (4.1)	1 (1.4)	0	1 (1.4)	1 (1.4)

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Atelectasis	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Respiratory distress	2 (2.7)	0	0	0	2 (2.7)
Acute respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Aspiration	1 (1.4)	0	0	0	1 (1.4)
Dysphonia	1 (1.4)	1 (1.4)	0	0	0
Idiopathic pneumonia syndrome	1 (1.4)	0	0	0	1 (1.4)
Interstitial lung disease	1 (1.4)	0	0	0	1 (1.4)
Nasal discomfort	1 (1.4)	1 (1.4)	0	0	0
Oropharyngeal plaque	1 (1.4)	1 (1.4)	0	0	0
Pharyngeal erythema	1 (1.4)	1 (1.4)	0	0	0
Pharyngeal lesion	1 (1.4)	0	0	1 (1.4)	0
Pharyngeal ulceration	1 (1.4)	0	1 (1.4)	0	0
Pulmonary alveolar haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Pulmonary hypertension	1 (1.4)	0	0	1 (1.4)	0
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory depression	1 (1.4)	0	1 (1.4)	0	0
Wheezing	1 (1.4)	0	1 (1.4)	0	0

Hypodiploidy: No

	All patients N=74				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	36 (48.6)	21 (28.4)	11 (14.9)	4 (5.4)	0
Rash	9 (12.2)	6 (8.1)	3 (4.1)	0	0
Dry skin	5 (6.8)	5 (6.8)	0	0	0
Erythema	5 (6.8)	5 (6.8)	0	0	0
Pruritus	5 (6.8)	5 (6.8)	0	0	0
Rash maculo-papular	5 (6.8)	3 (4.1)	1 (1.4)	1 (1.4)	0
Alopecia	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Hyperhidrosis	4 (5.4)	4 (5.4)	0	0	0
Petechiae	4 (5.4)	3 (4.1)	1 (1.4)	0	0
Rash erythematous	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Ingrowing nail	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Rash papular	3 (4.1)	3 (4.1)	0	0	0
Dermatitis acneiform	2 (2.7)	0	1 (1.4)	1 (1.4)	0
Macule	2 (2.7)	2 (2.7)	0	0	0
Night sweats	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Papule	2 (2.7)	2 (2.7)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash macular	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Rash pruritic	2 (2.7)	2 (2.7)	0	0	0
Acne	1 (1.4)	1 (1.4)	0	0	0
Cold sweat	1 (1.4)	1 (1.4)	0	0	0
Dermatitis	1 (1.4)	1 (1.4)	0	0	0
Dermatitis atopic	1 (1.4)	1 (1.4)	0	0	0
Dermatitis diaper	1 (1.4)	1 (1.4)	0	0	0
Ecchymosis	1 (1.4)	0	0	1 (1.4)	0
Eczema	1 (1.4)	1 (1.4)	0	0	0
Keloid scar	1 (1.4)	0	1 (1.4)	0	0
Livedo reticularis	1 (1.4)	1 (1.4)	0	0	0
Pruritus generalised	1 (1.4)	1 (1.4)	0	0	0
Rash follicular	1 (1.4)	1 (1.4)	0	0	0
Rash vesicular	1 (1.4)	1 (1.4)	0	0	0
Skin exfoliation	1 (1.4)	1 (1.4)	0	0	0
Skin fissures	1 (1.4)	1 (1.4)	0	0	0
Skin haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Skin irritation	1 (1.4)	1 (1.4)	0	0	0

Hypodiploidy: No

Primary system organ class Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin ulcer	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	34 (45.9)	3 (4.1)	6 (8.1)	14 (18.9)	11 (14.9)
Hypotension	24 (32.4)	1 (1.4)	0	12 (16.2)	11 (14.9)
Hypertension	16 (21.6)	4 (5.4)	10 (13.5)	2 (2.7)	0
Flushing	2 (2.7)	2 (2.7)	0	0	0
Orthostatic hypotension	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Capillary leak syndrome	1 (1.4)	0	0	0	1 (1.4)
Embolism	1 (1.4)	0	0	1 (1.4)	0
Haematoma	1 (1.4)	0	1 (1.4)	0	0
Hot flush	1 (1.4)	1 (1.4)	0	0	0
Phlebitis	1 (1.4)	0	1 (1.4)	0	0
Secondary hypertension	1 (1.4)	0	1 (1.4)	0	0
Venous thrombosis limb	1 (1.4)	1 (1.4)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178i
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	0	1 (25.0)	3 (75.0)
Blood and lymphatic system disorders					
-Total	4 (100)	0	1 (25.0)	1 (25.0)	2 (50.0)
Anaemia	3 (75.0)	0	2 (50.0)	1 (25.0)	0
Febrile neutropenia	3 (75.0)	0	0	3 (75.0)	0
Neutropenia	2 (50.0)	0	0	0	2 (50.0)
Lymphopenia	1 (25.0)	0	1 (25.0)	0	0
Cardiac disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Cardiac dysfunction	1 (25.0)	1 (25.0)	0	0	0
Sinus tachycardia	1 (25.0)	0	1 (25.0)	0	0
Tachycardia	1 (25.0)	1 (25.0)	0	0	0

BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Cushingoid	1 (25.0)	1 (25.0)	0	0	0
Eye disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Dry eye	1 (25.0)	0	1 (25.0)	0	0
Eye irritation	1 (25.0)	1 (25.0)	0	0	0
Gastrointestinal disorders					
-Total	3 (75.0)	1 (25.0)	1 (25.0)	1 (25.0)	0
Diarrhoea	3 (75.0)	2 (50.0)	1 (25.0)	0	0
Abdominal pain	2 (50.0)	2 (50.0)	0	0	0
Nausea	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Vomiting	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Abdominal distension	1 (25.0)	0	1 (25.0)	0	0
Abdominal tenderness	1 (25.0)	1 (25.0)	0	0	0
Colitis	1 (25.0)	0	0	1 (25.0)	0
Constipation	1 (25.0)	1 (25.0)	0	0	0
Dry mouth	1 (25.0)	1 (25.0)	0	0	0

BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrooesophageal reflux disease	1 (25.0)	1 (25.0)	0	0	0
General disorders and administration site conditions					
-Total	4 (100)	2 (50.0)	1 (25.0)	1 (25.0)	0
Fatigue	4 (100)	4 (100)	0	0	0
Cyst	1 (25.0)	0	0	1 (25.0)	0
Pain	1 (25.0)	0	1 (25.0)	0	0
Pyrexia	1 (25.0)	1 (25.0)	0	0	0
Hepatobiliary disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Cholecystitis	1 (25.0)	0	0	1 (25.0)	0
Immune system disorders					
-Total	4 (100)	0	3 (75.0)	1 (25.0)	0
Hypogammaglobulinaemia	4 (100)	0	4 (100)	0	0
Cytokine release syndrome	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Infections and infestations					
-Total	3 (75.0)	1 (25.0)	0	2 (50.0)	0
Bacteraemia	1 (25.0)	0	0	1 (25.0)	0

BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (25.0)	0	1 (25.0)	0	0
Cytomegalovirus infection	1 (25.0)	1 (25.0)	0	0	0
Gastroenteritis	1 (25.0)	0	0	1 (25.0)	0
Gingivitis	1 (25.0)	1 (25.0)	0	0	0
Herpes zoster	1 (25.0)	0	0	1 (25.0)	0
Otitis media acute	1 (25.0)	0	1 (25.0)	0	0
Parainfluenzae virus infection	1 (25.0)	1 (25.0)	0	0	0
Pharyngitis	1 (25.0)	0	1 (25.0)	0	0
Sinusitis	1 (25.0)	0	1 (25.0)	0	0
Streptococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Streptococcal infection	1 (25.0)	0	1 (25.0)	0	0
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0
Viral infection	1 (25.0)	1 (25.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Contusion	1 (25.0)	1 (25.0)	0	0	0
Infusion related reaction	1 (25.0)	0	1 (25.0)	0	0

BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural pain	1 (25.0)	0	1 (25.0)	0	0
Procedural site reaction	1 (25.0)	1 (25.0)	0	0	0
Investigations					
-Total	4 (100)	0	1 (25.0)	0	3 (75.0)
Alanine aminotransferase increased	3 (75.0)	0	1 (25.0)	2 (50.0)	0
Lymphocyte count decreased	3 (75.0)	0	1 (25.0)	1 (25.0)	1 (25.0)
Neutrophil count decreased	3 (75.0)	0	1 (25.0)	0	2 (50.0)
White blood cell count decreased	3 (75.0)	0	1 (25.0)	1 (25.0)	1 (25.0)
Aspartate aminotransferase increased	2 (50.0)	1 (25.0)	0	1 (25.0)	0
International normalised ratio increased	2 (50.0)	2 (50.0)	0	0	0
Activated partial thromboplastin time prolonged	1 (25.0)	1 (25.0)	0	0	0
Blood bilirubin increased	1 (25.0)	0	1 (25.0)	0	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0
Blood uric acid increased	1 (25.0)	1 (25.0)	0	0	0
Coronavirus test positive	1 (25.0)	1 (25.0)	0	0	0

BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (25.0)	0	1 (25.0)	0	0
Pulmonary function test decreased	1 (25.0)	0	1 (25.0)	0	0
Metabolism and nutrition disorders					
-Total	4 (100)	0	0	4 (100)	0
Decreased appetite	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Hyperphosphataemia	2 (50.0)	2 (50.0)	0	0	0
Dehydration	1 (25.0)	0	0	1 (25.0)	0
Hyperglycaemia	1 (25.0)	0	0	1 (25.0)	0
Hyperuricaemia	1 (25.0)	1 (25.0)	0	0	0
Hypokalaemia	1 (25.0)	0	0	1 (25.0)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (100)	2 (50.0)	2 (50.0)	0	0
Arthralgia	2 (50.0)	2 (50.0)	0	0	0
Joint range of motion decreased	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal chest pain	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal pain	1 (25.0)	0	1 (25.0)	0	0
Myalgia	1 (25.0)	1 (25.0)	0	0	0

BCR-ABL1-like: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Osteonecrosis	1 (25.0)	0	1 (25.0)	0	0
Pain in extremity	1 (25.0)	1 (25.0)	0	0	0
Pain in jaw	1 (25.0)	1 (25.0)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (25.0)	0	1 (25.0)	0	0
Skin papilloma	1 (25.0)	0	1 (25.0)	0	0
Nervous system disorders					
-Total	3 (75.0)	2 (50.0)	1 (25.0)	0	0
Headache	3 (75.0)	3 (75.0)	0	0	0
Dizziness	1 (25.0)	1 (25.0)	0	0	0
Neuralgia	1 (25.0)	0	1 (25.0)	0	0
Psychiatric disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Insomnia	1 (25.0)	0	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (75.0)	1 (25.0)	0	1 (25.0)	1 (25.0)
Idiopathic pneumonia syndrome	1 (25.0)	0	0	0	1 (25.0)

BCR-ABL1-like: Yes

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary oedema	1 (25.0)	0	0	1 (25.0)	0
Rhinorrhoea	1 (25.0)	1 (25.0)	0	0	0
Tachypnoea	1 (25.0)	1 (25.0)	0	0	0
Wheezing	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (75.0)	2 (50.0)	1 (25.0)	0	0
Petechiae	1 (25.0)	1 (25.0)	0	0	0
Pruritus generalised	1 (25.0)	1 (25.0)	0	0	0
Rash	1 (25.0)	0	1 (25.0)	0	0
Rash follicular	1 (25.0)	1 (25.0)	0	0	0
Rash papular	1 (25.0)	1 (25.0)	0	0	0
Vascular disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Hypotension	1 (25.0)	0	0	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178i
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	68 (95.8)	0	3 (4.2)	11 (15.5)	54 (76.1)
Blood and lymphatic system disorders					
-Total	57 (80.3)	1 (1.4)	1 (1.4)	34 (47.9)	21 (29.6)
Febrile neutropenia	33 (46.5)	0	0	32 (45.1)	1 (1.4)
Anaemia	32 (45.1)	2 (2.8)	4 (5.6)	25 (35.2)	1 (1.4)
Thrombocytopenia	15 (21.1)	0	1 (1.4)	5 (7.0)	9 (12.7)
Neutropenia	14 (19.7)	0	0	4 (5.6)	10 (14.1)
Disseminated intravascular coagulation	6 (8.5)	0	2 (2.8)	3 (4.2)	1 (1.4)
Lymphopenia	5 (7.0)	0	1 (1.4)	1 (1.4)	3 (4.2)
Pancytopenia	4 (5.6)	0	0	1 (1.4)	3 (4.2)
Coagulopathy	2 (2.8)	1 (1.4)	0	1 (1.4)	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eosinophilia	1 (1.4)	0	0	1 (1.4)	0
Hypofibrinogenaemia	1 (1.4)	0	0	0	1 (1.4)
Leukocytosis	1 (1.4)	1 (1.4)	0	0	0
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Lymphadenopathy	1 (1.4)	0	1 (1.4)	0	0
Splenomegaly	1 (1.4)	1 (1.4)	0	0	0
Cardiac disorders					
-Total	26 (36.6)	10 (14.1)	9 (12.7)	5 (7.0)	2 (2.8)
Tachycardia	16 (22.5)	8 (11.3)	6 (8.5)	2 (2.8)	0
Sinus tachycardia	6 (8.5)	3 (4.2)	1 (1.4)	2 (2.8)	0
Bradycardia	3 (4.2)	1 (1.4)	1 (1.4)	0	1 (1.4)
Left ventricular dysfunction	3 (4.2)	0	0	3 (4.2)	0
Pericardial effusion	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Palpitations	2 (2.8)	2 (2.8)	0	0	0
Ventricular tachycardia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Atrioventricular block second degree	1 (1.4)	1 (1.4)	0	0	0
Cardiovascular insufficiency	1 (1.4)	0	0	0	1 (1.4)
Right ventricular dysfunction	1 (1.4)	0	0	1 (1.4)	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus bradycardia	1 (1.4)	1 (1.4)	0	0	0
Ear and labyrinth disorders					
-Total	5 (7.0)	2 (2.8)	3 (4.2)	0	0
Ear pain	2 (2.8)	2 (2.8)	0	0	0
Deafness unilateral	1 (1.4)	0	1 (1.4)	0	0
Hypoacusis	1 (1.4)	0	1 (1.4)	0	0
Tympanic membrane perforation	1 (1.4)	0	1 (1.4)	0	0
Endocrine disorders					
-Total	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Adrenal insufficiency	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Hyperthyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	18 (25.4)	10 (14.1)	8 (11.3)	0	0
Periorbital oedema	4 (5.6)	3 (4.2)	1 (1.4)	0	0
Vision blurred	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Conjunctival haemorrhage	3 (4.2)	3 (4.2)	0	0	0
Eye pain	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Photophobia	3 (4.2)	1 (1.4)	2 (2.8)	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Retinal haemorrhage	2 (2.8)	2 (2.8)	0	0	0
Uveitis	2 (2.8)	0	2 (2.8)	0	0
Conjunctivitis allergic	1 (1.4)	1 (1.4)	0	0	0
Dry eye	1 (1.4)	1 (1.4)	0	0	0
Ocular hyperaemia	1 (1.4)	1 (1.4)	0	0	0
Ocular hypertension	1 (1.4)	0	1 (1.4)	0	0
Papilloedema	1 (1.4)	0	1 (1.4)	0	0
Retinopathy	1 (1.4)	0	1 (1.4)	0	0
Visual impairment	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	50 (70.4)	11 (15.5)	19 (26.8)	19 (26.8)	1 (1.4)
Nausea	31 (43.7)	8 (11.3)	16 (22.5)	7 (9.9)	0
Vomiting	28 (39.4)	16 (22.5)	8 (11.3)	4 (5.6)	0
Diarrhoea	23 (32.4)	12 (16.9)	9 (12.7)	2 (2.8)	0
Abdominal pain	15 (21.1)	5 (7.0)	7 (9.9)	3 (4.2)	0
Constipation	10 (14.1)	8 (11.3)	2 (2.8)	0	0
Stomatitis	5 (7.0)	1 (1.4)	1 (1.4)	2 (2.8)	1 (1.4)
Abdominal pain upper	3 (4.2)	1 (1.4)	2 (2.8)	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	3 (4.2)	1 (1.4)	0	2 (2.8)	0
Oral pain	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Pancreatitis	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Abdominal pain lower	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Ascites	2 (2.8)	0	0	2 (2.8)	0
Dysphagia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Gastrointestinal haemorrhage	2 (2.8)	2 (2.8)	0	0	0
Haematemesis	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Haematochezia	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Abdominal discomfort	1 (1.4)	1 (1.4)	0	0	0
Abdominal distension	1 (1.4)	0	1 (1.4)	0	0
Anal fissure	1 (1.4)	0	1 (1.4)	0	0
Anal incontinence	1 (1.4)	1 (1.4)	0	0	0
Dyspepsia	1 (1.4)	0	1 (1.4)	0	0
Enterocolitis	1 (1.4)	0	0	1 (1.4)	0
Flatulence	1 (1.4)	1 (1.4)	0	0	0
Gingival discomfort	1 (1.4)	1 (1.4)	0	0	0
Glossodynia	1 (1.4)	1 (1.4)	0	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ileus	1 (1.4)	0	0	1 (1.4)	0
Intestinal obstruction	1 (1.4)	0	0	1 (1.4)	0
Lip pain	1 (1.4)	0	1 (1.4)	0	0
Mouth haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Oral mucosal blistering	1 (1.4)	1 (1.4)	0	0	0
Pancreatic failure	1 (1.4)	0	1 (1.4)	0	0
Perianal erythema	1 (1.4)	0	1 (1.4)	0	0
Pigmentation lip	1 (1.4)	1 (1.4)	0	0	0
Proctalgia	1 (1.4)	0	1 (1.4)	0	0
Tooth socket haemorrhage	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	48 (67.6)	14 (19.7)	17 (23.9)	13 (18.3)	4 (5.6)
Pyrexia	31 (43.7)	8 (11.3)	15 (21.1)	7 (9.9)	1 (1.4)
Fatigue	14 (19.7)	9 (12.7)	3 (4.2)	2 (2.8)	0
Chills	11 (15.5)	9 (12.7)	2 (2.8)	0	0
Catheter site pain	7 (9.9)	3 (4.2)	4 (5.6)	0	0
Pain	6 (8.5)	1 (1.4)	2 (2.8)	3 (4.2)	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	5 (7.0)	3 (4.2)	1 (1.4)	1 (1.4)	0
Generalised oedema	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Malaise	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Multiple organ dysfunction syndrome	4 (5.6)	0	0	1 (1.4)	3 (4.2)
Face oedema	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Influenza like illness	2 (2.8)	2 (2.8)	0	0	0
Non-cardiac chest pain	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Physical deconditioning	2 (2.8)	0	0	2 (2.8)	0
Acquired gene mutation	1 (1.4)	1 (1.4)	0	0	0
Asthenia	1 (1.4)	1 (1.4)	0	0	0
Catheter site extravasation	1 (1.4)	0	1 (1.4)	0	0
Catheter site haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Crying	1 (1.4)	1 (1.4)	0	0	0
Device related thrombosis	1 (1.4)	0	1 (1.4)	0	0
Facial pain	1 (1.4)	0	1 (1.4)	0	0
Gait disturbance	1 (1.4)	1 (1.4)	0	0	0
Injection site haematoma	1 (1.4)	1 (1.4)	0	0	0
Localised oedema	1 (1.4)	0	0	1 (1.4)	0

BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Medical device pain	1 (1.4)	0	1 (1.4)	0	0
Mucosal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Peripheral swelling	1 (1.4)	0	1 (1.4)	0	0
Hepatobiliary disorders					
-Total	10 (14.1)	3 (4.2)	3 (4.2)	3 (4.2)	1 (1.4)
Hyperbilirubinaemia	5 (7.0)	0	2 (2.8)	3 (4.2)	0
Hepatomegaly	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Gallbladder enlargement	1 (1.4)	1 (1.4)	0	0	0
Hepatic failure	1 (1.4)	0	0	0	1 (1.4)
Hepatic steatosis	1 (1.4)	0	1 (1.4)	0	0
Hepatosplenomegaly	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					
-Total	55 (77.5)	6 (8.5)	28 (39.4)	10 (14.1)	11 (15.5)
Cytokine release syndrome	48 (67.6)	6 (8.5)	24 (33.8)	7 (9.9)	11 (15.5)
Hypogammaglobulinaemia	29 (40.8)	4 (5.6)	20 (28.2)	5 (7.0)	0
Graft versus host disease	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Immunodeficiency common variable	2 (2.8)	0	2 (2.8)	0	0
Seasonal allergy	2 (2.8)	2 (2.8)	0	0	0

BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Chronic graft versus host disease	1 (1.4)	0	1 (1.4)	0	0
Drug hypersensitivity	1 (1.4)	0	1 (1.4)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.4)	0	1 (1.4)	0	0
Graft versus host disease in skin	1 (1.4)	1 (1.4)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	1 (1.4)	0	0
Immunodeficiency	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	49 (69.0)	3 (4.2)	16 (22.5)	19 (26.8)	11 (15.5)
Upper respiratory tract infection	10 (14.1)	4 (5.6)	5 (7.0)	1 (1.4)	0
Pneumonia	7 (9.9)	0	5 (7.0)	1 (1.4)	1 (1.4)
Rhinovirus infection	6 (8.5)	5 (7.0)	1 (1.4)	0	0
Clostridium difficile colitis	5 (7.0)	1 (1.4)	2 (2.8)	2 (2.8)	0
Clostridium difficile infection	5 (7.0)	0	4 (5.6)	1 (1.4)	0
Urinary tract infection	5 (7.0)	0	3 (4.2)	2 (2.8)	0
Device related infection	4 (5.6)	0	1 (1.4)	3 (4.2)	0
Gastroenteritis	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Influenza	4 (5.6)	1 (1.4)	3 (4.2)	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	4 (5.6)	0	3 (4.2)	1 (1.4)	0
Sinusitis	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Viral upper respiratory tract infection	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Escherichia urinary tract infection	3 (4.2)	0	1 (1.4)	2 (2.8)	0
Parainfluenzae virus infection	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Staphylococcal infection	3 (4.2)	1 (1.4)	0	1 (1.4)	1 (1.4)
Ear infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Escherichia bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Fungal skin infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Oral herpes	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Respiratory syncytial virus infection	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Sepsis	2 (2.8)	0	0	0	2 (2.8)
Skin infection	2 (2.8)	0	2 (2.8)	0	0
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Viral infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Vulvovaginal candidiasis	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Body tinea	1 (1.4)	1 (1.4)	0	0	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Campylobacter infection	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Catheter site cellulitis	1 (1.4)	1 (1.4)	0	0	0
Catheter site infection	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis of male external genital organ	1 (1.4)	0	0	1 (1.4)	0
Cholecystitis infective	1 (1.4)	0	0	1 (1.4)	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Corona virus infection	1 (1.4)	0	0	1 (1.4)	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus infection	1 (1.4)	1 (1.4)	0	0	0
Enterococcal infection	1 (1.4)	1 (1.4)	0	0	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis norovirus	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Haemophilus infection	1 (1.4)	0	1 (1.4)	0	0
Herpes simplex	1 (1.4)	1 (1.4)	0	0	0
Human herpesvirus 6 infection	1 (1.4)	0	1 (1.4)	0	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Hypopyon	1 (1.4)	0	1 (1.4)	0	0
Klebsiella sepsis	1 (1.4)	0	0	0	1 (1.4)
Meningitis aseptic	1 (1.4)	0	1 (1.4)	0	0
Metapneumovirus infection	1 (1.4)	0	1 (1.4)	0	0
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Necrotising fasciitis	1 (1.4)	0	0	1 (1.4)	0
Oral candidiasis	1 (1.4)	1 (1.4)	0	0	0
Orchitis	1 (1.4)	1 (1.4)	0	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Otitis media acute	1 (1.4)	0	1 (1.4)	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Paronychia	1 (1.4)	1 (1.4)	0	0	0
Pneumonia fungal	1 (1.4)	0	1 (1.4)	0	0
Rash pustular	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	0	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	0	0	1 (1.4)	0
Rhinitis	1 (1.4)	1 (1.4)	0	0	0
Rotavirus infection	1 (1.4)	0	0	1 (1.4)	0
Septic embolus	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)
Subcutaneous abscess	1 (1.4)	0	1 (1.4)	0	0
Tinea capitis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection enterococcal	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Vulvovaginal mycotic infection	1 (1.4)	0	1 (1.4)	0	0
Injury, poisoning and procedural complications					

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	24 (33.8)	11 (15.5)	9 (12.7)	3 (4.2)	1 (1.4)
Infusion related reaction	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Procedural pain	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Transfusion reaction	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Contusion	2 (2.8)	2 (2.8)	0	0	0
Radiation skin injury	2 (2.8)	0	2 (2.8)	0	0
Skin abrasion	2 (2.8)	2 (2.8)	0	0	0
Subdural haematoma	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Arthropod bite	1 (1.4)	1 (1.4)	0	0	0
Extradural haematoma	1 (1.4)	0	0	1 (1.4)	0
Foot fracture	1 (1.4)	0	1 (1.4)	0	0
Incision site pain	1 (1.4)	1 (1.4)	0	0	0
Limb injury	1 (1.4)	1 (1.4)	0	0	0
Mouth injury	1 (1.4)	1 (1.4)	0	0	0
Post procedural haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Procedural complication	1 (1.4)	1 (1.4)	0	0	0
Procedural headache	1 (1.4)	0	1 (1.4)	0	0
Procedural nausea	1 (1.4)	0	1 (1.4)	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Radius fracture	1 (1.4)	0	1 (1.4)	0	0
Skin laceration	1 (1.4)	0	1 (1.4)	0	0
Stoma site irritation	1 (1.4)	1 (1.4)	0	0	0
Subdural haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Sunburn	1 (1.4)	1 (1.4)	0	0	0
Tibia fracture	1 (1.4)	0	1 (1.4)	0	0
Tongue injury	1 (1.4)	1 (1.4)	0	0	0
Tracheal haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Transfusion related complication	1 (1.4)	0	0	0	1 (1.4)
Wound	1 (1.4)	1 (1.4)	0	0	0
Investigations					
-Total	54 (76.1)	1 (1.4)	3 (4.2)	12 (16.9)	38 (53.5)
White blood cell count decreased	39 (54.9)	4 (5.6)	0	7 (9.9)	28 (39.4)
Neutrophil count decreased	29 (40.8)	1 (1.4)	1 (1.4)	3 (4.2)	24 (33.8)
Alanine aminotransferase increased	23 (32.4)	3 (4.2)	3 (4.2)	16 (22.5)	1 (1.4)
Aspartate aminotransferase increased	22 (31.0)	4 (5.6)	5 (7.0)	8 (11.3)	5 (7.0)
Platelet count decreased	20 (28.2)	3 (4.2)	1 (1.4)	3 (4.2)	13 (18.3)

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	16 (22.5)	1 (1.4)	2 (2.8)	6 (8.5)	7 (9.9)
Blood bilirubin increased	9 (12.7)	2 (2.8)	2 (2.8)	4 (5.6)	1 (1.4)
International normalised ratio increased	9 (12.7)	7 (9.9)	1 (1.4)	1 (1.4)	0
Prothrombin time prolonged	9 (12.7)	5 (7.0)	3 (4.2)	1 (1.4)	0
Blood creatinine increased	8 (11.3)	4 (5.6)	2 (2.8)	2 (2.8)	0
Activated partial thromboplastin time prolonged	5 (7.0)	2 (2.8)	3 (4.2)	0	0
Weight decreased	5 (7.0)	2 (2.8)	3 (4.2)	0	0
Blood fibrinogen decreased	4 (5.6)	0	1 (1.4)	2 (2.8)	1 (1.4)
Blood immunoglobulin m decreased	4 (5.6)	4 (5.6)	0	0	0
C-reactive protein increased	4 (5.6)	1 (1.4)	2 (2.8)	1 (1.4)	0
Transaminases increased	4 (5.6)	3 (4.2)	0	1 (1.4)	0
Blood urea increased	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Haemoglobin decreased	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Lipase increased	3 (4.2)	0	0	0	3 (4.2)
Weight increased	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Blood immunoglobulin a decreased	2 (2.8)	2 (2.8)	0	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Blood lactic acid increased	2 (2.8)	0	1 (1.4)	0	1 (1.4)
Blood magnesium decreased	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Blood phosphorus increased	2 (2.8)	2 (2.8)	0	0	0
Electrocardiogram qt prolonged	2 (2.8)	0	0	2 (2.8)	0
Serum ferritin increased	2 (2.8)	0	2 (2.8)	0	0
Blood alkaline phosphatase increased	1 (1.4)	1 (1.4)	0	0	0
Blood bicarbonate decreased	1 (1.4)	0	1 (1.4)	0	0
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood phosphorus decreased	1 (1.4)	1 (1.4)	0	0	0
Blood sodium increased	1 (1.4)	0	1 (1.4)	0	0
Blood uric acid increased	1 (1.4)	1 (1.4)	0	0	0
Cardiac murmur	1 (1.4)	1 (1.4)	0	0	0
Computerised tomogram thorax abnormal	1 (1.4)	0	0	1 (1.4)	0
Culture stool positive	1 (1.4)	1 (1.4)	0	0	0
Fibrin d dimer increased	1 (1.4)	1 (1.4)	0	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic enzyme increased	1 (1.4)	0	1 (1.4)	0	0
Norovirus test positive	1 (1.4)	1 (1.4)	0	0	0
Oxygen saturation decreased	1 (1.4)	1 (1.4)	0	0	0
Protein total decreased	1 (1.4)	0	0	1 (1.4)	0
Metabolism and nutrition disorders					
-Total	45 (63.4)	6 (8.5)	10 (14.1)	22 (31.0)	7 (9.9)
Decreased appetite	26 (36.6)	7 (9.9)	7 (9.9)	12 (16.9)	0
Hypokalaemia	22 (31.0)	5 (7.0)	5 (7.0)	8 (11.3)	4 (5.6)
Hypophosphataemia	13 (18.3)	4 (5.6)	0	8 (11.3)	1 (1.4)
Hyperphosphataemia	7 (9.9)	6 (8.5)	1 (1.4)	0	0
Fluid overload	6 (8.5)	1 (1.4)	4 (5.6)	1 (1.4)	0
Hyperglycaemia	6 (8.5)	0	3 (4.2)	3 (4.2)	0
Hypernatraemia	6 (8.5)	1 (1.4)	2 (2.8)	0	3 (4.2)
Hypoalbuminaemia	6 (8.5)	1 (1.4)	4 (5.6)	1 (1.4)	0
Hypocalcaemia	6 (8.5)	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)
Dehydration	3 (4.2)	1 (1.4)	0	2 (2.8)	0
Hyperkalaemia	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Hyperuricaemia	3 (4.2)	2 (2.8)	0	0	1 (1.4)

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypomagnesaemia	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Tumour lysis syndrome	3 (4.2)	0	0	3 (4.2)	0
Vitamin d deficiency	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Acidosis	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Hypertriglyceridaemia	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Hypoglycaemia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Hyponatraemia	2 (2.8)	0	0	2 (2.8)	0
Malnutrition	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Hyperalbuminaemia	1 (1.4)	1 (1.4)	0	0	0
Hyperammonaemia	1 (1.4)	1 (1.4)	0	0	0
Hypercalcaemia	1 (1.4)	1 (1.4)	0	0	0
Hyperchloraemia	1 (1.4)	1 (1.4)	0	0	0
Hypermagnesaemia	1 (1.4)	1 (1.4)	0	0	0
Iron overload	1 (1.4)	0	0	1 (1.4)	0
Metabolic acidosis	1 (1.4)	0	1 (1.4)	0	0
Metabolic alkalosis	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal and connective tissue disorders					

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	33 (46.5)	15 (21.1)	10 (14.1)	8 (11.3)	0
Pain in extremity	13 (18.3)	6 (8.5)	4 (5.6)	3 (4.2)	0
Arthralgia	5 (7.0)	2 (2.8)	1 (1.4)	2 (2.8)	0
Myalgia	5 (7.0)	3 (4.2)	1 (1.4)	1 (1.4)	0
Back pain	3 (4.2)	1 (1.4)	0	2 (2.8)	0
Muscle spasms	3 (4.2)	3 (4.2)	0	0	0
Muscular weakness	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Musculoskeletal pain	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Pain in jaw	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Musculoskeletal chest pain	2 (2.8)	2 (2.8)	0	0	0
Neck pain	2 (2.8)	0	2 (2.8)	0	0
Bone pain	1 (1.4)	0	0	1 (1.4)	0
Coccydynia	1 (1.4)	1 (1.4)	0	0	0
Flank pain	1 (1.4)	0	1 (1.4)	0	0
Joint range of motion decreased	1 (1.4)	1 (1.4)	0	0	0
Limb discomfort	1 (1.4)	1 (1.4)	0	0	0
Myopathy	1 (1.4)	0	0	1 (1.4)	0
Myositis	1 (1.4)	0	0	1 (1.4)	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Osteopenia	1 (1.4)	0	1 (1.4)	0	0
Synovitis	1 (1.4)	0	1 (1.4)	0	0
Toe walking	1 (1.4)	1 (1.4)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (2.8)	0	1 (1.4)	0	1 (1.4)
Glioblastoma multiforme	1 (1.4)	0	0	0	1 (1.4)
Myelodysplastic syndrome	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	40 (56.3)	15 (21.1)	16 (22.5)	7 (9.9)	2 (2.8)
Headache	26 (36.6)	12 (16.9)	9 (12.7)	5 (7.0)	0
Dizziness	5 (7.0)	5 (7.0)	0	0	0
Seizure	5 (7.0)	0	2 (2.8)	2 (2.8)	1 (1.4)
Encephalopathy	4 (5.6)	1 (1.4)	1 (1.4)	2 (2.8)	0
Peroneal nerve palsy	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Dysarthria	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Neuropathy peripheral	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Somnolence	2 (2.8)	1 (1.4)	1 (1.4)	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tremor	2 (2.8)	2 (2.8)	0	0	0
Asterixis	1 (1.4)	1 (1.4)	0	0	0
Ataxia	1 (1.4)	0	1 (1.4)	0	0
Depressed level of consciousness	1 (1.4)	1 (1.4)	0	0	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Dysgeusia	1 (1.4)	1 (1.4)	0	0	0
Embolic stroke	1 (1.4)	0	0	0	1 (1.4)
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0
Hypotonia	1 (1.4)	0	1 (1.4)	0	0
Idiopathic intracranial hypertension	1 (1.4)	0	1 (1.4)	0	0
Migraine	1 (1.4)	0	1 (1.4)	0	0
Myoclonus	1 (1.4)	1 (1.4)	0	0	0
Peripheral sensory neuropathy	1 (1.4)	0	1 (1.4)	0	0
Pleocytosis	1 (1.4)	1 (1.4)	0	0	0
Visual field defect	1 (1.4)	0	1 (1.4)	0	0
Product issues					
-Total	2 (2.8)	2 (2.8)	0	0	0
Device occlusion	2 (2.8)	2 (2.8)	0	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	25 (35.2)	8 (11.3)	13 (18.3)	4 (5.6)	0
Anxiety	9 (12.7)	3 (4.2)	5 (7.0)	1 (1.4)	0
Confusional state	7 (9.9)	3 (4.2)	4 (5.6)	0	0
Delirium	5 (7.0)	2 (2.8)	2 (2.8)	1 (1.4)	0
Depression	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Mental status changes	4 (5.6)	3 (4.2)	0	1 (1.4)	0
Agitation	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Insomnia	3 (4.2)	0	3 (4.2)	0	0
Irritability	3 (4.2)	3 (4.2)	0	0	0
Hallucination	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Adjustment disorder	1 (1.4)	0	1 (1.4)	0	0
Listless	1 (1.4)	1 (1.4)	0	0	0
Panic attack	1 (1.4)	0	1 (1.4)	0	0
Sleep disorder	1 (1.4)	0	1 (1.4)	0	0
Suicidal ideation	1 (1.4)	1 (1.4)	0	0	0
Renal and urinary disorders					
-Total	19 (26.8)	3 (4.2)	4 (5.6)	7 (9.9)	5 (7.0)

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	12 (16.9)	2 (2.8)	1 (1.4)	5 (7.0)	4 (5.6)
Haematuria	5 (7.0)	0	2 (2.8)	2 (2.8)	1 (1.4)
Dysuria	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Oliguria	3 (4.2)	0	0	3 (4.2)	0
Calculus urinary	1 (1.4)	0	1 (1.4)	0	0
Cystitis haemorrhagic	1 (1.4)	0	0	0	1 (1.4)
Nephrolithiasis	1 (1.4)	0	0	1 (1.4)	0
Pollakiuria	1 (1.4)	1 (1.4)	0	0	0
Renal failure	1 (1.4)	0	0	0	1 (1.4)
Renal impairment	1 (1.4)	0	0	1 (1.4)	0
Urinary incontinence	1 (1.4)	1 (1.4)	0	0	0
Urinary retention	1 (1.4)	0	1 (1.4)	0	0
Reproductive system and breast disorders					
-Total	6 (8.5)	2 (2.8)	2 (2.8)	2 (2.8)	0
Vulvovaginal adhesion	2 (2.8)	2 (2.8)	0	0	0
Oedema genital	1 (1.4)	0	1 (1.4)	0	0
Ovarian failure	1 (1.4)	0	0	1 (1.4)	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Scrotal pain	1 (1.4)	0	1 (1.4)	0	0
Vaginal haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	41 (57.7)	12 (16.9)	9 (12.7)	9 (12.7)	11 (15.5)
Cough	16 (22.5)	13 (18.3)	2 (2.8)	1 (1.4)	0
Hypoxia	15 (21.1)	0	3 (4.2)	9 (12.7)	3 (4.2)
Epistaxis	14 (19.7)	4 (5.6)	4 (5.6)	5 (7.0)	1 (1.4)
Pleural effusion	10 (14.1)	1 (1.4)	6 (8.5)	3 (4.2)	0
Pulmonary oedema	8 (11.3)	1 (1.4)	0	3 (4.2)	4 (5.6)
Oropharyngeal pain	7 (9.9)	4 (5.6)	2 (2.8)	1 (1.4)	0
Tachypnoea	7 (9.9)	2 (2.8)	2 (2.8)	3 (4.2)	0
Nasal congestion	6 (8.5)	6 (8.5)	0	0	0
Dyspnoea	5 (7.0)	1 (1.4)	1 (1.4)	2 (2.8)	1 (1.4)
Rhinitis allergic	5 (7.0)	4 (5.6)	1 (1.4)	0	0
Rhinorrhoea	5 (7.0)	4 (5.6)	1 (1.4)	0	0
Respiratory failure	4 (5.6)	0	0	0	4 (5.6)
Haemoptysis	3 (4.2)	1 (1.4)	0	1 (1.4)	1 (1.4)

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Atelectasis	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Respiratory distress	2 (2.8)	0	0	0	2 (2.8)
Acute respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Aspiration	1 (1.4)	0	0	0	1 (1.4)
Dysphonia	1 (1.4)	1 (1.4)	0	0	0
Interstitial lung disease	1 (1.4)	0	0	0	1 (1.4)
Nasal discomfort	1 (1.4)	1 (1.4)	0	0	0
Oropharyngeal plaque	1 (1.4)	1 (1.4)	0	0	0
Pharyngeal erythema	1 (1.4)	1 (1.4)	0	0	0
Pharyngeal lesion	1 (1.4)	0	0	1 (1.4)	0
Pharyngeal ulceration	1 (1.4)	0	1 (1.4)	0	0
Pulmonary alveolar haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Pulmonary hypertension	1 (1.4)	0	0	1 (1.4)	0
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory depression	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	34 (47.9)	19 (26.8)	11 (15.5)	4 (5.6)	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	8 (11.3)	6 (8.5)	2 (2.8)	0	0
Dry skin	5 (7.0)	5 (7.0)	0	0	0
Erythema	5 (7.0)	5 (7.0)	0	0	0
Pruritus	5 (7.0)	5 (7.0)	0	0	0
Rash erythematous	5 (7.0)	2 (2.8)	3 (4.2)	0	0
Rash maculo-papular	5 (7.0)	3 (4.2)	1 (1.4)	1 (1.4)	0
Alopecia	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Hyperhidrosis	4 (5.6)	4 (5.6)	0	0	0
Ingrowing nail	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Petechiae	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Dermatitis acneiform	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Macule	2 (2.8)	2 (2.8)	0	0	0
Night sweats	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Papule	2 (2.8)	2 (2.8)	0	0	0
Rash macular	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Rash papular	2 (2.8)	2 (2.8)	0	0	0
Rash pruritic	2 (2.8)	2 (2.8)	0	0	0
Acne	1 (1.4)	1 (1.4)	0	0	0

BCR-ABL1-like: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cold sweat	1 (1.4)	1 (1.4)	0	0	0
Dermatitis	1 (1.4)	1 (1.4)	0	0	0
Dermatitis atopic	1 (1.4)	1 (1.4)	0	0	0
Dermatitis diaper	1 (1.4)	1 (1.4)	0	0	0
Ecchymosis	1 (1.4)	0	0	1 (1.4)	0
Eczema	1 (1.4)	1 (1.4)	0	0	0
Keloid scar	1 (1.4)	0	1 (1.4)	0	0
Livedo reticularis	1 (1.4)	1 (1.4)	0	0	0
Rash vesicular	1 (1.4)	1 (1.4)	0	0	0
Skin exfoliation	1 (1.4)	1 (1.4)	0	0	0
Skin fissures	1 (1.4)	1 (1.4)	0	0	0
Skin haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Skin irritation	1 (1.4)	1 (1.4)	0	0	0
Skin ulcer	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	33 (46.5)	3 (4.2)	6 (8.5)	14 (19.7)	10 (14.1)
Hypotension	23 (32.4)	1 (1.4)	0	12 (16.9)	10 (14.1)
Hypertension	16 (22.5)	4 (5.6)	10 (14.1)	2 (2.8)	0

BCR-ABL1-like: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Flushing	2 (2.8)	2 (2.8)	0	0	0
Orthostatic hypotension	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Capillary leak syndrome	1 (1.4)	0	0	0	1 (1.4)
Embolism	1 (1.4)	0	0	1 (1.4)	0
Haematoma	1 (1.4)	0	1 (1.4)	0	0
Hot flush	1 (1.4)	1 (1.4)	0	0	0
Phlebitis	1 (1.4)	0	1 (1.4)	0	0
Secondary hypertension	1 (1.4)	0	1 (1.4)	0	0
Venous thrombosis limb	1 (1.4)	1 (1.4)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178j
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (95.5)	0	1 (4.5)	1 (4.5)	19 (86.4)
Blood and lymphatic system disorders					
-Total	18 (81.8)	1 (4.5)	0	8 (36.4)	9 (40.9)
Febrile neutropenia	11 (50.0)	0	0	11 (50.0)	0
Anaemia	7 (31.8)	1 (4.5)	0	6 (27.3)	0
Neutropenia	7 (31.8)	0	0	2 (9.1)	5 (22.7)
Coagulopathy	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Lymphopenia	2 (9.1)	0	0	0	2 (9.1)
Pancytopenia	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Thrombocytopenia	2 (9.1)	0	0	0	2 (9.1)
Disseminated intravascular coagulation	1 (4.5)	0	0	1 (4.5)	0
Eosinophilia	1 (4.5)	0	0	1 (4.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypofibrinogenaemia	1 (4.5)	0	0	0	1 (4.5)
Leukopenia	1 (4.5)	0	0	0	1 (4.5)
Cardiac disorders					
-Total	10 (45.5)	5 (22.7)	3 (13.6)	2 (9.1)	0
Tachycardia	4 (18.2)	2 (9.1)	1 (4.5)	1 (4.5)	0
Sinus tachycardia	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Bradycardia	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Atrioventricular block second degree	1 (4.5)	1 (4.5)	0	0	0
Pericardial effusion	1 (4.5)	0	1 (4.5)	0	0
Ear and labyrinth disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Ear pain	1 (4.5)	1 (4.5)	0	0	0
Endocrine disorders					
-Total	1 (4.5)	0	1 (4.5)	0	0
Adrenal insufficiency	1 (4.5)	0	1 (4.5)	0	0
Eye disorders					
-Total	9 (40.9)	7 (31.8)	2 (9.1)	0	0
Periorbital oedema	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Vision blurred	3 (13.6)	2 (9.1)	1 (4.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctival haemorrhage	2 (9.1)	2 (9.1)	0	0	0
Photophobia	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Conjunctivitis allergic	1 (4.5)	1 (4.5)	0	0	0
Eye pain	1 (4.5)	0	1 (4.5)	0	0
Ocular hyperaemia	1 (4.5)	1 (4.5)	0	0	0
Retinal haemorrhage	1 (4.5)	1 (4.5)	0	0	0
Gastrointestinal disorders					
-Total	17 (77.3)	3 (13.6)	6 (27.3)	8 (36.4)	0
Diarrhoea	12 (54.5)	5 (22.7)	5 (22.7)	2 (9.1)	0
Vomiting	12 (54.5)	7 (31.8)	3 (13.6)	2 (9.1)	0
Nausea	10 (45.5)	4 (18.2)	4 (18.2)	2 (9.1)	0
Abdominal pain	5 (22.7)	2 (9.1)	2 (9.1)	1 (4.5)	0
Constipation	4 (18.2)	3 (13.6)	1 (4.5)	0	0
Stomatitis	2 (9.1)	0	0	2 (9.1)	0
Abdominal discomfort	1 (4.5)	1 (4.5)	0	0	0
Abdominal distension	1 (4.5)	0	1 (4.5)	0	0
Abdominal pain upper	1 (4.5)	0	1 (4.5)	0	0
Colitis	1 (4.5)	1 (4.5)	0	0	0
Dry mouth	1 (4.5)	1 (4.5)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspepsia	1 (4.5)	0	1 (4.5)	0	0
Dysphagia	1 (4.5)	0	0	1 (4.5)	0
Gastrointestinal haemorrhage	1 (4.5)	1 (4.5)	0	0	0
Haematemesis	1 (4.5)	1 (4.5)	0	0	0
Intestinal obstruction	1 (4.5)	0	0	1 (4.5)	0
Lip pain	1 (4.5)	0	1 (4.5)	0	0
Mouth haemorrhage	1 (4.5)	0	0	1 (4.5)	0
Perianal erythema	1 (4.5)	0	1 (4.5)	0	0
Pigmentation lip	1 (4.5)	1 (4.5)	0	0	0
General disorders and administration site conditions					
-Total	17 (77.3)	4 (18.2)	9 (40.9)	4 (18.2)	0
Pyrexia	13 (59.1)	3 (13.6)	8 (36.4)	2 (9.1)	0
Fatigue	6 (27.3)	3 (13.6)	2 (9.1)	1 (4.5)	0
Catheter site pain	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Chills	3 (13.6)	3 (13.6)	0	0	0
Pain	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Face oedema	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Malaise	2 (9.1)	0	2 (9.1)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Catheter site extravasation	1 (4.5)	0	1 (4.5)	0	0
Catheter site haemorrhage	1 (4.5)	1 (4.5)	0	0	0
Crying	1 (4.5)	1 (4.5)	0	0	0
Device related thrombosis	1 (4.5)	0	1 (4.5)	0	0
Gait disturbance	1 (4.5)	1 (4.5)	0	0	0
Generalised oedema	1 (4.5)	0	1 (4.5)	0	0
Influenza like illness	1 (4.5)	1 (4.5)	0	0	0
Injection site haematoma	1 (4.5)	1 (4.5)	0	0	0
Localised oedema	1 (4.5)	0	0	1 (4.5)	0
Mucosal haemorrhage	1 (4.5)	0	1 (4.5)	0	0
Multiple organ dysfunction syndrome	1 (4.5)	0	0	1 (4.5)	0
Peripheral swelling	1 (4.5)	0	1 (4.5)	0	0
Hepatobiliary disorders					
-Total	3 (13.6)	0	1 (4.5)	2 (9.1)	0
Hyperbilirubinaemia	3 (13.6)	0	1 (4.5)	2 (9.1)	0
Hepatomegaly	1 (4.5)	0	1 (4.5)	0	0
Immune system disorders					
-Total	19 (86.4)	1 (4.5)	9 (40.9)	4 (18.2)	5 (22.7)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	18 (81.8)	1 (4.5)	9 (40.9)	3 (13.6)	5 (22.7)
Hypogammaglobulinaemia	12 (54.5)	2 (9.1)	7 (31.8)	3 (13.6)	0
Chronic graft versus host disease	1 (4.5)	0	1 (4.5)	0	0
Graft versus host disease	1 (4.5)	1 (4.5)	0	0	0
Graft versus host disease in skin	1 (4.5)	1 (4.5)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (4.5)	0	1 (4.5)	0	0
Seasonal allergy	1 (4.5)	1 (4.5)	0	0	0
Infections and infestations					
-Total	18 (81.8)	1 (4.5)	5 (22.7)	7 (31.8)	5 (22.7)
Upper respiratory tract infection	6 (27.3)	3 (13.6)	3 (13.6)	0	0
Gastroenteritis	4 (18.2)	1 (4.5)	2 (9.1)	1 (4.5)	0
Rhinovirus infection	3 (13.6)	3 (13.6)	0	0	0
Clostridium difficile colitis	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Clostridium difficile infection	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Ear infection	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Pneumonia	2 (9.1)	0	2 (9.1)	0	0
Urinary tract infection	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Bacterial sepsis	1 (4.5)	0	0	0	1 (4.5)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (4.5)	0	0	1 (4.5)	0
Candida sepsis	1 (4.5)	0	0	0	1 (4.5)
Catheter site cellulitis	1 (4.5)	1 (4.5)	0	0	0
Cellulitis of male external genital organ	1 (4.5)	0	0	1 (4.5)	0
Conjunctivitis	1 (4.5)	0	1 (4.5)	0	0
Device related infection	1 (4.5)	0	0	1 (4.5)	0
Enterovirus infection	1 (4.5)	0	0	1 (4.5)	0
Escherichia bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Escherichia urinary tract infection	1 (4.5)	0	1 (4.5)	0	0
Folliculitis	1 (4.5)	0	1 (4.5)	0	0
Fungal skin infection	1 (4.5)	1 (4.5)	0	0	0
Gingivitis	1 (4.5)	1 (4.5)	0	0	0
Herpes simplex	1 (4.5)	1 (4.5)	0	0	0
Herpes zoster	1 (4.5)	0	0	1 (4.5)	0
Molluscum contagiosum	1 (4.5)	1 (4.5)	0	0	0
Oral herpes	1 (4.5)	0	1 (4.5)	0	0
Orchitis	1 (4.5)	1 (4.5)	0	0	0
Otitis media	1 (4.5)	0	1 (4.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (4.5)	0	1 (4.5)	0	0
Pharyngitis	1 (4.5)	0	1 (4.5)	0	0
Respiratory tract infection	1 (4.5)	0	0	0	1 (4.5)
Respiratory tract infection viral	1 (4.5)	0	0	1 (4.5)	0
Rhinitis	1 (4.5)	1 (4.5)	0	0	0
Rotavirus infection	1 (4.5)	0	0	1 (4.5)	0
Sepsis	1 (4.5)	0	0	0	1 (4.5)
Septic embolus	1 (4.5)	0	0	0	1 (4.5)
Sinusitis	1 (4.5)	1 (4.5)	0	0	0
Skin infection	1 (4.5)	0	1 (4.5)	0	0
Staphylococcal infection	1 (4.5)	0	0	1 (4.5)	0
Streptococcal infection	1 (4.5)	0	1 (4.5)	0	0
Tinea capitis	1 (4.5)	1 (4.5)	0	0	0
Urinary tract infection enterococcal	1 (4.5)	0	0	1 (4.5)	0
Vascular device infection	1 (4.5)	0	0	1 (4.5)	0
Viral infection	1 (4.5)	1 (4.5)	0	0	0
Viral upper respiratory tract infection	1 (4.5)	1 (4.5)	0	0	0
Vulvovaginal candidiasis	1 (4.5)	0	1 (4.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	13 (59.1)	8 (36.4)	4 (18.2)	0	1 (4.5)
Skin abrasion	2 (9.1)	2 (9.1)	0	0	0
Transfusion reaction	2 (9.1)	2 (9.1)	0	0	0
Contusion	1 (4.5)	1 (4.5)	0	0	0
Incision site pain	1 (4.5)	1 (4.5)	0	0	0
Infusion related reaction	1 (4.5)	0	1 (4.5)	0	0
Mouth injury	1 (4.5)	1 (4.5)	0	0	0
Procedural complication	1 (4.5)	1 (4.5)	0	0	0
Procedural headache	1 (4.5)	0	1 (4.5)	0	0
Procedural pain	1 (4.5)	0	1 (4.5)	0	0
Radiation skin injury	1 (4.5)	0	1 (4.5)	0	0
Radius fracture	1 (4.5)	0	1 (4.5)	0	0
Skin laceration	1 (4.5)	0	1 (4.5)	0	0
Stoma site irritation	1 (4.5)	1 (4.5)	0	0	0
Subdural haemorrhage	1 (4.5)	1 (4.5)	0	0	0
Tibia fracture	1 (4.5)	0	1 (4.5)	0	0
Tongue injury	1 (4.5)	1 (4.5)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion related complication	1 (4.5)	0	0	0	1 (4.5)
Wound	1 (4.5)	1 (4.5)	0	0	0
Investigations					
-Total	16 (72.7)	0	1 (4.5)	3 (13.6)	12 (54.5)
White blood cell count decreased	12 (54.5)	1 (4.5)	0	0	11 (50.0)
Neutrophil count decreased	9 (40.9)	1 (4.5)	0	1 (4.5)	7 (31.8)
Alanine aminotransferase increased	8 (36.4)	1 (4.5)	1 (4.5)	6 (27.3)	0
Aspartate aminotransferase increased	6 (27.3)	2 (9.1)	1 (4.5)	1 (4.5)	2 (9.1)
Platelet count decreased	6 (27.3)	1 (4.5)	0	0	5 (22.7)
Blood creatinine increased	5 (22.7)	2 (9.1)	1 (4.5)	2 (9.1)	0
Lymphocyte count decreased	5 (22.7)	0	1 (4.5)	3 (13.6)	1 (4.5)
Prothrombin time prolonged	4 (18.2)	2 (9.1)	1 (4.5)	1 (4.5)	0
Blood bilirubin increased	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
International normalised ratio increased	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Blood fibrinogen decreased	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Blood immunoglobulin a decreased	2 (9.1)	2 (9.1)	0	0	0
Blood immunoglobulin m decreased	2 (9.1)	2 (9.1)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood urea increased	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Haemoglobin decreased	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Weight decreased	2 (9.1)	0	2 (9.1)	0	0
Activated partial thromboplastin time prolonged	1 (4.5)	0	1 (4.5)	0	0
Blood bicarbonate decreased	1 (4.5)	0	1 (4.5)	0	0
Blood lactic acid increased	1 (4.5)	0	1 (4.5)	0	0
Blood phosphorus decreased	1 (4.5)	1 (4.5)	0	0	0
C-reactive protein increased	1 (4.5)	0	1 (4.5)	0	0
Culture stool positive	1 (4.5)	1 (4.5)	0	0	0
Lipase increased	1 (4.5)	0	0	0	1 (4.5)
Protein total decreased	1 (4.5)	0	0	1 (4.5)	0
Transaminases increased	1 (4.5)	1 (4.5)	0	0	0
Weight increased	1 (4.5)	0	1 (4.5)	0	0
Metabolism and nutrition disorders					
-Total	19 (86.4)	2 (9.1)	4 (18.2)	10 (45.5)	3 (13.6)
Decreased appetite	10 (45.5)	2 (9.1)	4 (18.2)	4 (18.2)	0
Hypokalaemia	6 (27.3)	1 (4.5)	1 (4.5)	2 (9.1)	2 (9.1)
Hypophosphataemia	5 (22.7)	2 (9.1)	0	3 (13.6)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	3 (13.6)	0	0	3 (13.6)	0
Fluid overload	3 (13.6)	0	3 (13.6)	0	0
Hypernatraemia	3 (13.6)	0	1 (4.5)	0	2 (9.1)
Hyperphosphataemia	2 (9.1)	2 (9.1)	0	0	0
Hypoalbuminaemia	2 (9.1)	0	2 (9.1)	0	0
Hypocalcaemia	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Vitamin d deficiency	2 (9.1)	2 (9.1)	0	0	0
Acidosis	1 (4.5)	0	0	1 (4.5)	0
Hyperalbuminaemia	1 (4.5)	1 (4.5)	0	0	0
Hypercalcaemia	1 (4.5)	1 (4.5)	0	0	0
Hyperchloraemia	1 (4.5)	1 (4.5)	0	0	0
Hyperglycaemia	1 (4.5)	0	0	1 (4.5)	0
Hypermagnesaemia	1 (4.5)	1 (4.5)	0	0	0
Hyponatraemia	1 (4.5)	0	0	1 (4.5)	0
Malnutrition	1 (4.5)	0	0	1 (4.5)	0
Metabolic acidosis	1 (4.5)	0	1 (4.5)	0	0
Metabolic alkalosis	1 (4.5)	1 (4.5)	0	0	0
Musculoskeletal and connective tissue disorders					

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (68.2)	8 (36.4)	6 (27.3)	1 (4.5)	0
Pain in extremity	7 (31.8)	4 (18.2)	3 (13.6)	0	0
Arthralgia	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Muscle spasms	2 (9.1)	2 (9.1)	0	0	0
Myalgia	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Back pain	1 (4.5)	1 (4.5)	0	0	0
Bone pain	1 (4.5)	0	0	1 (4.5)	0
Coccydynia	1 (4.5)	1 (4.5)	0	0	0
Joint range of motion decreased	1 (4.5)	1 (4.5)	0	0	0
Limb discomfort	1 (4.5)	1 (4.5)	0	0	0
Musculoskeletal chest pain	1 (4.5)	1 (4.5)	0	0	0
Musculoskeletal pain	1 (4.5)	1 (4.5)	0	0	0
Neck pain	1 (4.5)	0	1 (4.5)	0	0
Osteonecrosis	1 (4.5)	0	1 (4.5)	0	0
Osteopenia	1 (4.5)	0	1 (4.5)	0	0
Pain in jaw	1 (4.5)	0	1 (4.5)	0	0
Toe walking	1 (4.5)	1 (4.5)	0	0	0
Nervous system disorders					
-Total	12 (54.5)	5 (22.7)	3 (13.6)	3 (13.6)	1 (4.5)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	8 (36.4)	4 (18.2)	3 (13.6)	1 (4.5)	0
Encephalopathy	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Disturbance in attention	1 (4.5)	1 (4.5)	0	0	0
Dizziness	1 (4.5)	1 (4.5)	0	0	0
Embolic stroke	1 (4.5)	0	0	0	1 (4.5)
Hypotonia	1 (4.5)	0	1 (4.5)	0	0
Myoclonus	1 (4.5)	1 (4.5)	0	0	0
Neuropathy peripheral	1 (4.5)	1 (4.5)	0	0	0
Peroneal nerve palsy	1 (4.5)	1 (4.5)	0	0	0
Seizure	1 (4.5)	0	0	1 (4.5)	0
Psychiatric disorders					
-Total	8 (36.4)	3 (13.6)	5 (22.7)	0	0
Anxiety	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Irritability	3 (13.6)	3 (13.6)	0	0	0
Confusional state	2 (9.1)	0	2 (9.1)	0	0
Delirium	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Hallucination	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Agitation	1 (4.5)	0	1 (4.5)	0	0
Insomnia	1 (4.5)	0	1 (4.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Listless	1 (4.5)	1 (4.5)	0	0	0
Mental status changes	1 (4.5)	1 (4.5)	0	0	0
Panic attack	1 (4.5)	0	1 (4.5)	0	0
Renal and urinary disorders					
-Total	6 (27.3)	1 (4.5)	0	2 (9.1)	3 (13.6)
Acute kidney injury	5 (22.7)	1 (4.5)	0	1 (4.5)	3 (13.6)
Haematuria	2 (9.1)	0	2 (9.1)	0	0
Oliguria	1 (4.5)	0	0	1 (4.5)	0
Renal impairment	1 (4.5)	0	0	1 (4.5)	0
Reproductive system and breast disorders					
-Total	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Scrotal pain	1 (4.5)	0	1 (4.5)	0	0
Vaginal haemorrhage	1 (4.5)	0	0	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	16 (72.7)	5 (22.7)	3 (13.6)	3 (13.6)	5 (22.7)
Cough	8 (36.4)	7 (31.8)	1 (4.5)	0	0
Hypoxia	5 (22.7)	0	1 (4.5)	2 (9.1)	2 (9.1)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	5 (22.7)	1 (4.5)	0	3 (13.6)	1 (4.5)
Epistaxis	4 (18.2)	1 (4.5)	1 (4.5)	2 (9.1)	0
Pleural effusion	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Rhinitis allergic	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Rhinorrhoea	2 (9.1)	2 (9.1)	0	0	0
Tachypnoea	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Acute respiratory failure	1 (4.5)	0	0	0	1 (4.5)
Dysphonia	1 (4.5)	1 (4.5)	0	0	0
Dyspnoea	1 (4.5)	0	0	1 (4.5)	0
Nasal congestion	1 (4.5)	1 (4.5)	0	0	0
Oropharyngeal pain	1 (4.5)	1 (4.5)	0	0	0
Pharyngeal ulceration	1 (4.5)	0	1 (4.5)	0	0
Respiratory depression	1 (4.5)	0	1 (4.5)	0	0
Respiratory distress	1 (4.5)	0	0	0	1 (4.5)
Respiratory failure	1 (4.5)	0	0	0	1 (4.5)
Skin and subcutaneous tissue disorders					
-Total	11 (50.0)	6 (27.3)	5 (22.7)	0	0
Rash	4 (18.2)	2 (9.1)	2 (9.1)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash maculo-papular	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Alopecia	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Erythema	2 (9.1)	2 (9.1)	0	0	0
Hyperhidrosis	2 (9.1)	2 (9.1)	0	0	0
Pruritus	2 (9.1)	2 (9.1)	0	0	0
Rash papular	2 (9.1)	2 (9.1)	0	0	0
Acne	1 (4.5)	1 (4.5)	0	0	0
Dermatitis atopic	1 (4.5)	1 (4.5)	0	0	0
Dry skin	1 (4.5)	1 (4.5)	0	0	0
Macule	1 (4.5)	1 (4.5)	0	0	0
Night sweats	1 (4.5)	0	1 (4.5)	0	0
Papule	1 (4.5)	1 (4.5)	0	0	0
Pruritus generalised	1 (4.5)	1 (4.5)	0	0	0
Rash vesicular	1 (4.5)	1 (4.5)	0	0	0
Skin irritation	1 (4.5)	1 (4.5)	0	0	0
Vascular disorders					
-Total	12 (54.5)	3 (13.6)	0	4 (18.2)	5 (22.7)
Hypotension	10 (45.5)	1 (4.5)	0	4 (18.2)	5 (22.7)
Hypertension	4 (18.2)	2 (9.1)	1 (4.5)	1 (4.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Flushing	2 (9.1)	2 (9.1)	0	0	0
Capillary leak syndrome	1 (4.5)	0	0	0	1 (4.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178j
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (96.2)	0	2 (3.8)	11 (20.8)	38 (71.7)
Blood and lymphatic system disorders					
-Total	43 (81.1)	0	2 (3.8)	27 (50.9)	14 (26.4)
Anaemia	28 (52.8)	1 (1.9)	6 (11.3)	20 (37.7)	1 (1.9)
Febrile neutropenia	25 (47.2)	0	0	24 (45.3)	1 (1.9)
Thrombocytopenia	13 (24.5)	0	1 (1.9)	5 (9.4)	7 (13.2)
Neutropenia	9 (17.0)	0	0	2 (3.8)	7 (13.2)
Disseminated intravascular coagulation	5 (9.4)	0	2 (3.8)	2 (3.8)	1 (1.9)
Lymphopenia	4 (7.5)	0	2 (3.8)	1 (1.9)	1 (1.9)
Pancytopenia	2 (3.8)	0	0	0	2 (3.8)
Leukocytosis	1 (1.9)	1 (1.9)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphadenopathy	1 (1.9)	0	1 (1.9)	0	0
Splenomegaly	1 (1.9)	1 (1.9)	0	0	0
Cardiac disorders					
-Total	18 (34.0)	6 (11.3)	7 (13.2)	3 (5.7)	2 (3.8)
Tachycardia	13 (24.5)	7 (13.2)	5 (9.4)	1 (1.9)	0
Sinus tachycardia	4 (7.5)	2 (3.8)	1 (1.9)	1 (1.9)	0
Left ventricular dysfunction	3 (5.7)	0	0	3 (5.7)	0
Palpitations	2 (3.8)	2 (3.8)	0	0	0
Pericardial effusion	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Ventricular tachycardia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Bradycardia	1 (1.9)	0	0	0	1 (1.9)
Cardiac dysfunction	1 (1.9)	1 (1.9)	0	0	0
Cardiovascular insufficiency	1 (1.9)	0	0	0	1 (1.9)
Right ventricular dysfunction	1 (1.9)	0	0	1 (1.9)	0
Sinus bradycardia	1 (1.9)	1 (1.9)	0	0	0
Ear and labyrinth disorders					
-Total	4 (7.5)	1 (1.9)	3 (5.7)	0	0
Deafness unilateral	1 (1.9)	0	1 (1.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear pain	1 (1.9)	1 (1.9)	0	0	0
Hypoacusis	1 (1.9)	0	1 (1.9)	0	0
Tympanic membrane perforation	1 (1.9)	0	1 (1.9)	0	0
Endocrine disorders					
-Total	4 (7.5)	2 (3.8)	2 (3.8)	0	0
Adrenal insufficiency	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Cushingoid	1 (1.9)	1 (1.9)	0	0	0
Hyperthyroidism	1 (1.9)	0	1 (1.9)	0	0
Eye disorders					
-Total	11 (20.8)	4 (7.5)	7 (13.2)	0	0
Dry eye	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Eye pain	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Uveitis	2 (3.8)	0	2 (3.8)	0	0
Conjunctival haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Eye irritation	1 (1.9)	1 (1.9)	0	0	0
Ocular hypertension	1 (1.9)	0	1 (1.9)	0	0
Papilloedema	1 (1.9)	0	1 (1.9)	0	0
Periorbital oedema	1 (1.9)	1 (1.9)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Photophobia	1 (1.9)	0	1 (1.9)	0	0
Retinal haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Retinopathy	1 (1.9)	0	1 (1.9)	0	0
Vision blurred	1 (1.9)	0	1 (1.9)	0	0
Visual impairment	1 (1.9)	0	1 (1.9)	0	0
Gastrointestinal disorders					
-Total	36 (67.9)	9 (17.0)	14 (26.4)	12 (22.6)	1 (1.9)
Nausea	23 (43.4)	5 (9.4)	13 (24.5)	5 (9.4)	0
Vomiting	18 (34.0)	10 (18.9)	6 (11.3)	2 (3.8)	0
Diarrhoea	14 (26.4)	9 (17.0)	5 (9.4)	0	0
Abdominal pain	12 (22.6)	5 (9.4)	5 (9.4)	2 (3.8)	0
Constipation	7 (13.2)	6 (11.3)	1 (1.9)	0	0
Colitis	3 (5.7)	0	0	3 (5.7)	0
Oral pain	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Pancreatitis	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Stomatitis	3 (5.7)	1 (1.9)	1 (1.9)	0	1 (1.9)
Abdominal pain lower	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Abdominal pain upper	2 (3.8)	1 (1.9)	1 (1.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	2 (3.8)	0	0	2 (3.8)	0
Haematochezia	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Abdominal distension	1 (1.9)	0	1 (1.9)	0	0
Abdominal tenderness	1 (1.9)	1 (1.9)	0	0	0
Anal fissure	1 (1.9)	0	1 (1.9)	0	0
Anal incontinence	1 (1.9)	1 (1.9)	0	0	0
Dysphagia	1 (1.9)	0	1 (1.9)	0	0
Enterocolitis	1 (1.9)	0	0	1 (1.9)	0
Flatulence	1 (1.9)	1 (1.9)	0	0	0
Gastrointestinal haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Gastrooesophageal reflux disease	1 (1.9)	1 (1.9)	0	0	0
Gingival discomfort	1 (1.9)	1 (1.9)	0	0	0
Glossodynia	1 (1.9)	1 (1.9)	0	0	0
Haematemesis	1 (1.9)	0	1 (1.9)	0	0
Ileus	1 (1.9)	0	0	1 (1.9)	0
Oral mucosal blistering	1 (1.9)	1 (1.9)	0	0	0
Pancreatic failure	1 (1.9)	0	1 (1.9)	0	0
Proctalgia	1 (1.9)	0	1 (1.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tooth socket haemorrhage	1 (1.9)	1 (1.9)	0	0	0
General disorders and administration site conditions					
-Total	35 (66.0)	12 (22.6)	9 (17.0)	10 (18.9)	4 (7.5)
Pyrexia	19 (35.8)	6 (11.3)	7 (13.2)	5 (9.4)	1 (1.9)
Fatigue	12 (22.6)	10 (18.9)	1 (1.9)	1 (1.9)	0
Chills	8 (15.1)	6 (11.3)	2 (3.8)	0	0
Catheter site pain	4 (7.5)	1 (1.9)	3 (5.7)	0	0
Pain	4 (7.5)	0	2 (3.8)	2 (3.8)	0
Generalised oedema	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Multiple organ dysfunction syndrome	3 (5.7)	0	0	0	3 (5.7)
Oedema peripheral	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Malaise	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Non-cardiac chest pain	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Physical deconditioning	2 (3.8)	0	0	2 (3.8)	0
Acquired gene mutation	1 (1.9)	1 (1.9)	0	0	0
Asthenia	1 (1.9)	1 (1.9)	0	0	0
Cyst	1 (1.9)	0	0	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All patients N=53 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Facial pain	1 (1.9)	0	1 (1.9)	0	0
Influenza like illness	1 (1.9)	1 (1.9)	0	0	0
Medical device pain	1 (1.9)	0	1 (1.9)	0	0
Hepatobiliary disorders					
-Total	8 (15.1)	3 (5.7)	2 (3.8)	2 (3.8)	1 (1.9)
Hepatomegaly	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Hyperbilirubinaemia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Cholecystitis	1 (1.9)	0	0	1 (1.9)	0
Gallbladder enlargement	1 (1.9)	1 (1.9)	0	0	0
Hepatic failure	1 (1.9)	0	0	0	1 (1.9)
Hepatic steatosis	1 (1.9)	0	1 (1.9)	0	0
Hepatosplenomegaly	1 (1.9)	1 (1.9)	0	0	0
Immune system disorders					
-Total	40 (75.5)	5 (9.4)	22 (41.5)	7 (13.2)	6 (11.3)
Cytokine release syndrome	32 (60.4)	5 (9.4)	16 (30.2)	5 (9.4)	6 (11.3)
Hypogammaglobulinaemia	21 (39.6)	2 (3.8)	17 (32.1)	2 (3.8)	0
Immunodeficiency common variable	2 (3.8)	0	2 (3.8)	0	0
Drug hypersensitivity	1 (1.9)	0	1 (1.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease	1 (1.9)	0	1 (1.9)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.9)	0	1 (1.9)	0	0
Immunodeficiency	1 (1.9)	0	1 (1.9)	0	0
Seasonal allergy	1 (1.9)	1 (1.9)	0	0	0
Infections and infestations					
-Total	34 (64.2)	3 (5.7)	11 (20.8)	14 (26.4)	6 (11.3)
Pneumonia	5 (9.4)	0	3 (5.7)	1 (1.9)	1 (1.9)
Upper respiratory tract infection	5 (9.4)	2 (3.8)	2 (3.8)	1 (1.9)	0
Clostridium difficile infection	4 (7.5)	0	4 (7.5)	0	0
Influenza	4 (7.5)	1 (1.9)	3 (5.7)	0	0
Sinusitis	4 (7.5)	0	4 (7.5)	0	0
Clostridium difficile colitis	3 (5.7)	0	1 (1.9)	2 (3.8)	0
Device related infection	3 (5.7)	0	1 (1.9)	2 (3.8)	0
Otitis media	3 (5.7)	0	2 (3.8)	1 (1.9)	0
Parainfluenzae virus infection	3 (5.7)	2 (3.8)	0	1 (1.9)	0
Rhinovirus infection	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Urinary tract infection	3 (5.7)	0	2 (3.8)	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Cytomegalovirus infection	2 (3.8)	2 (3.8)	0	0	0
Escherichia urinary tract infection	2 (3.8)	0	0	2 (3.8)	0
Otitis media acute	2 (3.8)	0	2 (3.8)	0	0
Respiratory syncytial virus infection	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Staphylococcal bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Staphylococcal infection	2 (3.8)	1 (1.9)	0	0	1 (1.9)
Viral infection	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Abscess limb	1 (1.9)	0	0	1 (1.9)	0
Acute sinusitis	1 (1.9)	0	1 (1.9)	0	0
Bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Body tinea	1 (1.9)	1 (1.9)	0	0	0
Bronchitis	1 (1.9)	0	1 (1.9)	0	0
Bronchopulmonary aspergillosis	1 (1.9)	0	0	1 (1.9)	0
Catheter site infection	1 (1.9)	0	0	1 (1.9)	0
Cellulitis	1 (1.9)	0	0	1 (1.9)	0
Cholecystitis infective	1 (1.9)	0	0	1 (1.9)	0
Corona virus infection	1 (1.9)	0	0	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Croup infectious	1 (1.9)	0	0	1 (1.9)	0
Enterococcal infection	1 (1.9)	1 (1.9)	0	0	0
Escherichia bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Escherichia sepsis	1 (1.9)	0	0	0	1 (1.9)
Fungal skin infection	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis viral	1 (1.9)	1 (1.9)	0	0	0
Haemophilus infection	1 (1.9)	0	1 (1.9)	0	0
Human herpesvirus 6 infection	1 (1.9)	0	1 (1.9)	0	0
Human polyomavirus infection	1 (1.9)	0	0	0	1 (1.9)
Hypopyon	1 (1.9)	0	1 (1.9)	0	0
Klebsiella sepsis	1 (1.9)	0	0	0	1 (1.9)
Meningitis aseptic	1 (1.9)	0	1 (1.9)	0	0
Metapneumovirus infection	1 (1.9)	0	1 (1.9)	0	0
Necrotising fasciitis	1 (1.9)	0	0	1 (1.9)	0
Oral candidiasis	1 (1.9)	1 (1.9)	0	0	0
Oral herpes	1 (1.9)	0	0	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (1.9)	0	1 (1.9)	0	0
Paronychia	1 (1.9)	1 (1.9)	0	0	0
Pneumonia fungal	1 (1.9)	0	1 (1.9)	0	0
Rash pustular	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus bronchitis	1 (1.9)	0	0	1 (1.9)	0
Sepsis	1 (1.9)	0	0	0	1 (1.9)
Skin infection	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal scalded skin syndrome	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal sepsis	1 (1.9)	0	0	0	1 (1.9)
Streptococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Subcutaneous abscess	1 (1.9)	0	1 (1.9)	0	0
Vulvovaginal candidiasis	1 (1.9)	1 (1.9)	0	0	0
Vulvovaginal mycotic infection	1 (1.9)	0	1 (1.9)	0	0
Injury, poisoning and procedural complications					
-Total	13 (24.5)	4 (7.5)	6 (11.3)	3 (5.7)	0
Infusion related reaction	4 (7.5)	2 (3.8)	2 (3.8)	0	0
Procedural pain	4 (7.5)	2 (3.8)	1 (1.9)	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Contusion	2 (3.8)	2 (3.8)	0	0	0
Subdural haematoma	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Transfusion reaction	2 (3.8)	0	2 (3.8)	0	0
Arthropod bite	1 (1.9)	1 (1.9)	0	0	0
Extradural haematoma	1 (1.9)	0	0	1 (1.9)	0
Foot fracture	1 (1.9)	0	1 (1.9)	0	0
Limb injury	1 (1.9)	1 (1.9)	0	0	0
Post procedural haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Procedural nausea	1 (1.9)	0	1 (1.9)	0	0
Procedural site reaction	1 (1.9)	1 (1.9)	0	0	0
Radiation skin injury	1 (1.9)	0	1 (1.9)	0	0
Sunburn	1 (1.9)	1 (1.9)	0	0	0
Tracheal haemorrhage	1 (1.9)	0	0	1 (1.9)	0
Investigations					
-Total	42 (79.2)	1 (1.9)	3 (5.7)	9 (17.0)	29 (54.7)
White blood cell count decreased	30 (56.6)	3 (5.7)	1 (1.9)	8 (15.1)	18 (34.0)
Neutrophil count decreased	23 (43.4)	0	2 (3.8)	2 (3.8)	19 (35.8)
Alanine aminotransferase increased	18 (34.0)	2 (3.8)	3 (5.7)	12 (22.6)	1 (1.9)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	18 (34.0)	3 (5.7)	4 (7.5)	8 (15.1)	3 (5.7)
Platelet count decreased	15 (28.3)	2 (3.8)	2 (3.8)	3 (5.7)	8 (15.1)
Lymphocyte count decreased	14 (26.4)	1 (1.9)	2 (3.8)	4 (7.5)	7 (13.2)
International normalised ratio increased	8 (15.1)	7 (13.2)	1 (1.9)	0	0
Blood bilirubin increased	7 (13.2)	1 (1.9)	2 (3.8)	3 (5.7)	1 (1.9)
Activated partial thromboplastin time prolonged	5 (9.4)	3 (5.7)	2 (3.8)	0	0
Prothrombin time prolonged	5 (9.4)	3 (5.7)	2 (3.8)	0	0
Blood creatinine increased	4 (7.5)	3 (5.7)	1 (1.9)	0	0
C-reactive protein increased	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Transaminases increased	3 (5.7)	2 (3.8)	0	1 (1.9)	0
Weight decreased	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Blood fibrinogen decreased	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Blood immunoglobulin m decreased	2 (3.8)	2 (3.8)	0	0	0
Blood lactate dehydrogenase increased	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Blood magnesium decreased	2 (3.8)	1 (1.9)	0	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood phosphorus increased	2 (3.8)	2 (3.8)	0	0	0
Blood uric acid increased	2 (3.8)	2 (3.8)	0	0	0
Electrocardiogram qt prolonged	2 (3.8)	0	0	2 (3.8)	0
Lipase increased	2 (3.8)	0	0	0	2 (3.8)
Serum ferritin increased	2 (3.8)	0	2 (3.8)	0	0
Weight increased	2 (3.8)	2 (3.8)	0	0	0
Blood alkaline phosphatase increased	1 (1.9)	1 (1.9)	0	0	0
Blood immunoglobulin a decreased	1 (1.9)	1 (1.9)	0	0	0
Blood immunoglobulin g decreased	1 (1.9)	0	1 (1.9)	0	0
Blood lactic acid increased	1 (1.9)	0	0	0	1 (1.9)
Blood sodium increased	1 (1.9)	0	1 (1.9)	0	0
Blood urea increased	1 (1.9)	1 (1.9)	0	0	0
Cardiac murmur	1 (1.9)	1 (1.9)	0	0	0
Computerised tomogram thorax abnormal	1 (1.9)	0	0	1 (1.9)	0
Coronavirus test positive	1 (1.9)	1 (1.9)	0	0	0
Fibrin d dimer increased	1 (1.9)	1 (1.9)	0	0	0
Haemoglobin decreased	1 (1.9)	1 (1.9)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic enzyme increased	1 (1.9)	0	1 (1.9)	0	0
Norovirus test positive	1 (1.9)	1 (1.9)	0	0	0
Oxygen saturation decreased	1 (1.9)	1 (1.9)	0	0	0
Pulmonary function test decreased	1 (1.9)	0	1 (1.9)	0	0
Metabolism and nutrition disorders					
-Total	30 (56.6)	4 (7.5)	6 (11.3)	16 (30.2)	4 (7.5)
Decreased appetite	18 (34.0)	5 (9.4)	4 (7.5)	9 (17.0)	0
Hypokalaemia	17 (32.1)	4 (7.5)	4 (7.5)	7 (13.2)	2 (3.8)
Hypophosphataemia	8 (15.1)	2 (3.8)	0	5 (9.4)	1 (1.9)
Hyperphosphataemia	7 (13.2)	6 (11.3)	1 (1.9)	0	0
Hyperglycaemia	6 (11.3)	0	3 (5.7)	3 (5.7)	0
Hyperuricaemia	4 (7.5)	3 (5.7)	0	0	1 (1.9)
Hypoalbuminaemia	4 (7.5)	1 (1.9)	2 (3.8)	1 (1.9)	0
Hypocalcaemia	4 (7.5)	3 (5.7)	0	0	1 (1.9)
Fluid overload	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Hyperkalaemia	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Hypernatraemia	3 (5.7)	1 (1.9)	1 (1.9)	0	1 (1.9)
Hypomagnesaemia	3 (5.7)	2 (3.8)	1 (1.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	3 (5.7)	0	0	3 (5.7)	0
Hypertriglyceridaemia	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Hypoglycaemia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Acidosis	1 (1.9)	1 (1.9)	0	0	0
Dehydration	1 (1.9)	1 (1.9)	0	0	0
Hyperammonaemia	1 (1.9)	1 (1.9)	0	0	0
Hyponatraemia	1 (1.9)	0	0	1 (1.9)	0
Iron overload	1 (1.9)	0	0	1 (1.9)	0
Malnutrition	1 (1.9)	0	1 (1.9)	0	0
Vitamin d deficiency	1 (1.9)	0	1 (1.9)	0	0
Musculoskeletal and connective tissue disorders					
-Total	22 (41.5)	9 (17.0)	6 (11.3)	7 (13.2)	0
Pain in extremity	7 (13.2)	3 (5.7)	1 (1.9)	3 (5.7)	0
Arthralgia	5 (9.4)	3 (5.7)	0	2 (3.8)	0
Myalgia	4 (7.5)	3 (5.7)	0	1 (1.9)	0
Muscular weakness	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Musculoskeletal pain	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in jaw	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Back pain	2 (3.8)	0	0	2 (3.8)	0
Musculoskeletal chest pain	2 (3.8)	2 (3.8)	0	0	0
Flank pain	1 (1.9)	0	1 (1.9)	0	0
Joint range of motion decreased	1 (1.9)	1 (1.9)	0	0	0
Muscle spasms	1 (1.9)	1 (1.9)	0	0	0
Myopathy	1 (1.9)	0	0	1 (1.9)	0
Myositis	1 (1.9)	0	0	1 (1.9)	0
Neck pain	1 (1.9)	0	1 (1.9)	0	0
Synovitis	1 (1.9)	0	1 (1.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (5.7)	0	2 (3.8)	0	1 (1.9)
Glioblastoma multiforme	1 (1.9)	0	0	0	1 (1.9)
Myelodysplastic syndrome	1 (1.9)	0	1 (1.9)	0	0
Skin papilloma	1 (1.9)	0	1 (1.9)	0	0
Nervous system disorders					
-Total	31 (58.5)	12 (22.6)	14 (26.4)	4 (7.5)	1 (1.9)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	21 (39.6)	11 (20.8)	6 (11.3)	4 (7.5)	0
Dizziness	5 (9.4)	5 (9.4)	0	0	0
Seizure	4 (7.5)	0	2 (3.8)	1 (1.9)	1 (1.9)
Dysarthria	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Encephalopathy	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Peroneal nerve palsy	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Somnolence	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Tremor	2 (3.8)	2 (3.8)	0	0	0
Asterixis	1 (1.9)	1 (1.9)	0	0	0
Ataxia	1 (1.9)	0	1 (1.9)	0	0
Depressed level of consciousness	1 (1.9)	1 (1.9)	0	0	0
Dysgeusia	1 (1.9)	1 (1.9)	0	0	0
Hyporesponsive to stimuli	1 (1.9)	0	0	1 (1.9)	0
Idiopathic intracranial hypertension	1 (1.9)	0	1 (1.9)	0	0
Migraine	1 (1.9)	0	1 (1.9)	0	0
Neuralgia	1 (1.9)	0	1 (1.9)	0	0
Neuropathy peripheral	1 (1.9)	0	1 (1.9)	0	0
Peripheral sensory neuropathy	1 (1.9)	0	1 (1.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleocytosis	1 (1.9)	1 (1.9)	0	0	0
Visual field defect	1 (1.9)	0	1 (1.9)	0	0
Product issues					
-Total	2 (3.8)	2 (3.8)	0	0	0
Device occlusion	2 (3.8)	2 (3.8)	0	0	0
Psychiatric disorders					
-Total	18 (34.0)	5 (9.4)	9 (17.0)	4 (7.5)	0
Anxiety	6 (11.3)	2 (3.8)	3 (5.7)	1 (1.9)	0
Confusional state	5 (9.4)	3 (5.7)	2 (3.8)	0	0
Depression	4 (7.5)	2 (3.8)	2 (3.8)	0	0
Delirium	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Insomnia	3 (5.7)	0	3 (5.7)	0	0
Mental status changes	3 (5.7)	2 (3.8)	0	1 (1.9)	0
Agitation	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Adjustment disorder	1 (1.9)	0	1 (1.9)	0	0
Sleep disorder	1 (1.9)	0	1 (1.9)	0	0
Suicidal ideation	1 (1.9)	1 (1.9)	0	0	0
Renal and urinary disorders					

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (24.5)	2 (3.8)	4 (7.5)	5 (9.4)	2 (3.8)
Acute kidney injury	7 (13.2)	1 (1.9)	1 (1.9)	4 (7.5)	1 (1.9)
Dysuria	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Haematuria	3 (5.7)	0	0	2 (3.8)	1 (1.9)
Oliguria	2 (3.8)	0	0	2 (3.8)	0
Calculus urinary	1 (1.9)	0	1 (1.9)	0	0
Cystitis haemorrhagic	1 (1.9)	0	0	0	1 (1.9)
Nephrolithiasis	1 (1.9)	0	0	1 (1.9)	0
Pollakiuria	1 (1.9)	1 (1.9)	0	0	0
Renal failure	1 (1.9)	0	0	0	1 (1.9)
Urinary incontinence	1 (1.9)	1 (1.9)	0	0	0
Urinary retention	1 (1.9)	0	1 (1.9)	0	0
Reproductive system and breast disorders					
-Total	4 (7.5)	2 (3.8)	1 (1.9)	1 (1.9)	0
Vulvovaginal adhesion	2 (3.8)	2 (3.8)	0	0	0
Oedema genital	1 (1.9)	0	1 (1.9)	0	0
Ovarian failure	1 (1.9)	0	0	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	28 (52.8)	8 (15.1)	6 (11.3)	7 (13.2)	7 (13.2)
Epistaxis	10 (18.9)	3 (5.7)	3 (5.7)	3 (5.7)	1 (1.9)
Hypoxia	10 (18.9)	0	2 (3.8)	7 (13.2)	1 (1.9)
Cough	8 (15.1)	6 (11.3)	1 (1.9)	1 (1.9)	0
Pleural effusion	8 (15.1)	1 (1.9)	5 (9.4)	2 (3.8)	0
Oropharyngeal pain	6 (11.3)	3 (5.7)	2 (3.8)	1 (1.9)	0
Tachypnoea	6 (11.3)	2 (3.8)	2 (3.8)	2 (3.8)	0
Nasal congestion	5 (9.4)	5 (9.4)	0	0	0
Dyspnoea	4 (7.5)	1 (1.9)	1 (1.9)	1 (1.9)	1 (1.9)
Pulmonary oedema	4 (7.5)	0	0	1 (1.9)	3 (5.7)
Rhinorrhoea	4 (7.5)	3 (5.7)	1 (1.9)	0	0
Haemoptysis	3 (5.7)	1 (1.9)	0	1 (1.9)	1 (1.9)
Respiratory failure	3 (5.7)	0	0	0	3 (5.7)
Rhinitis allergic	3 (5.7)	3 (5.7)	0	0	0
Atelectasis	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Aspiration	1 (1.9)	0	0	0	1 (1.9)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Idiopathic pneumonia syndrome	1 (1.9)	0	0	0	1 (1.9)
Interstitial lung disease	1 (1.9)	0	0	0	1 (1.9)
Nasal discomfort	1 (1.9)	1 (1.9)	0	0	0
Oropharyngeal plaque	1 (1.9)	1 (1.9)	0	0	0
Pharyngeal erythema	1 (1.9)	1 (1.9)	0	0	0
Pharyngeal lesion	1 (1.9)	0	0	1 (1.9)	0
Pulmonary alveolar haemorrhage	1 (1.9)	0	0	0	1 (1.9)
Pulmonary hypertension	1 (1.9)	0	0	1 (1.9)	0
Pulmonary mass	1 (1.9)	0	1 (1.9)	0	0
Respiratory distress	1 (1.9)	0	0	0	1 (1.9)
Wheezing	1 (1.9)	0	1 (1.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	26 (49.1)	15 (28.3)	7 (13.2)	4 (7.5)	0
Rash	5 (9.4)	4 (7.5)	1 (1.9)	0	0
Rash erythematous	5 (9.4)	2 (3.8)	3 (5.7)	0	0
Dry skin	4 (7.5)	4 (7.5)	0	0	0
Petechiae	4 (7.5)	3 (5.7)	1 (1.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

Primary system organ class Preferred term	All patients N=53 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Erythema	3 (5.7)	3 (5.7)	0	0	0
Ingrowing nail	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Pruritus	3 (5.7)	3 (5.7)	0	0	0
Alopecia	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Dermatitis acneiform	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Hyperhidrosis	2 (3.8)	2 (3.8)	0	0	0
Rash macular	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Rash maculo-papular	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Rash pruritic	2 (3.8)	2 (3.8)	0	0	0
Cold sweat	1 (1.9)	1 (1.9)	0	0	0
Dermatitis	1 (1.9)	1 (1.9)	0	0	0
Dermatitis diaper	1 (1.9)	1 (1.9)	0	0	0
Ecchymosis	1 (1.9)	0	0	1 (1.9)	0
Eczema	1 (1.9)	1 (1.9)	0	0	0
Keloid scar	1 (1.9)	0	1 (1.9)	0	0
Livedo reticularis	1 (1.9)	1 (1.9)	0	0	0
Macule	1 (1.9)	1 (1.9)	0	0	0
Night sweats	1 (1.9)	1 (1.9)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Papule	1 (1.9)	1 (1.9)	0	0	0
Rash follicular	1 (1.9)	1 (1.9)	0	0	0
Rash papular	1 (1.9)	1 (1.9)	0	0	0
Skin exfoliation	1 (1.9)	1 (1.9)	0	0	0
Skin fissures	1 (1.9)	1 (1.9)	0	0	0
Skin haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Skin ulcer	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					
-Total	22 (41.5)	0	6 (11.3)	10 (18.9)	6 (11.3)
Hypotension	14 (26.4)	0	0	8 (15.1)	6 (11.3)
Hypertension	12 (22.6)	2 (3.8)	9 (17.0)	1 (1.9)	0
Orthostatic hypotension	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Embolism	1 (1.9)	0	0	1 (1.9)	0
Haematoma	1 (1.9)	0	1 (1.9)	0	0
Hot flush	1 (1.9)	1 (1.9)	0	0	0
Phlebitis	1 (1.9)	0	1 (1.9)	0	0
Secondary hypertension	1 (1.9)	0	1 (1.9)	0	0
Venous thrombosis limb	1 (1.9)	1 (1.9)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178k
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=75				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	72 (96.0)	0	3 (4.0)	12 (16.0)	57 (76.0)
Blood and lymphatic system disorders					
-Total	61 (81.3)	1 (1.3)	2 (2.7)	35 (46.7)	23 (30.7)
Febrile neutropenia	36 (48.0)	0	0	35 (46.7)	1 (1.3)
Anaemia	35 (46.7)	2 (2.7)	6 (8.0)	26 (34.7)	1 (1.3)
Neutropenia	16 (21.3)	0	0	4 (5.3)	12 (16.0)
Thrombocytopenia	15 (20.0)	0	1 (1.3)	5 (6.7)	9 (12.0)
Disseminated intravascular coagulation	6 (8.0)	0	2 (2.7)	3 (4.0)	1 (1.3)
Lymphopenia	6 (8.0)	0	2 (2.7)	1 (1.3)	3 (4.0)
Pancytopenia	4 (5.3)	0	0	1 (1.3)	3 (4.0)
Coagulopathy	2 (2.7)	1 (1.3)	0	1 (1.3)	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eosinophilia	1 (1.3)	0	0	1 (1.3)	0
Hypofibrinogenaemia	1 (1.3)	0	0	0	1 (1.3)
Leukocytosis	1 (1.3)	1 (1.3)	0	0	0
Leukopenia	1 (1.3)	0	0	0	1 (1.3)
Lymphadenopathy	1 (1.3)	0	1 (1.3)	0	0
Splenomegaly	1 (1.3)	1 (1.3)	0	0	0
Cardiac disorders					
-Total	28 (37.3)	11 (14.7)	10 (13.3)	5 (6.7)	2 (2.7)
Tachycardia	17 (22.7)	9 (12.0)	6 (8.0)	2 (2.7)	0
Sinus tachycardia	7 (9.3)	3 (4.0)	2 (2.7)	2 (2.7)	0
Bradycardia	3 (4.0)	1 (1.3)	1 (1.3)	0	1 (1.3)
Left ventricular dysfunction	3 (4.0)	0	0	3 (4.0)	0
Pericardial effusion	3 (4.0)	1 (1.3)	2 (2.7)	0	0
Palpitations	2 (2.7)	2 (2.7)	0	0	0
Ventricular tachycardia	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Atrioventricular block second degree	1 (1.3)	1 (1.3)	0	0	0
Cardiac dysfunction	1 (1.3)	1 (1.3)	0	0	0
Cardiovascular insufficiency	1 (1.3)	0	0	0	1 (1.3)

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Right ventricular dysfunction	1 (1.3)	0	0	1 (1.3)	0
Sinus bradycardia	1 (1.3)	1 (1.3)	0	0	0
Ear and labyrinth disorders					
-Total	5 (6.7)	2 (2.7)	3 (4.0)	0	0
Ear pain	2 (2.7)	2 (2.7)	0	0	0
Deafness unilateral	1 (1.3)	0	1 (1.3)	0	0
Hypoacusis	1 (1.3)	0	1 (1.3)	0	0
Tympanic membrane perforation	1 (1.3)	0	1 (1.3)	0	0
Endocrine disorders					
-Total	5 (6.7)	2 (2.7)	3 (4.0)	0	0
Adrenal insufficiency	3 (4.0)	1 (1.3)	2 (2.7)	0	0
Cushingoid	1 (1.3)	1 (1.3)	0	0	0
Hyperthyroidism	1 (1.3)	0	1 (1.3)	0	0
Eye disorders					
-Total	20 (26.7)	11 (14.7)	9 (12.0)	0	0
Periorbital oedema	4 (5.3)	3 (4.0)	1 (1.3)	0	0
Vision blurred	4 (5.3)	2 (2.7)	2 (2.7)	0	0
Conjunctival haemorrhage	3 (4.0)	3 (4.0)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eye pain	3 (4.0)	1 (1.3)	2 (2.7)	0	0
Photophobia	3 (4.0)	1 (1.3)	2 (2.7)	0	0
Dry eye	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Retinal haemorrhage	2 (2.7)	2 (2.7)	0	0	0
Uveitis	2 (2.7)	0	2 (2.7)	0	0
Conjunctivitis allergic	1 (1.3)	1 (1.3)	0	0	0
Eye irritation	1 (1.3)	1 (1.3)	0	0	0
Ocular hyperaemia	1 (1.3)	1 (1.3)	0	0	0
Ocular hypertension	1 (1.3)	0	1 (1.3)	0	0
Papilloedema	1 (1.3)	0	1 (1.3)	0	0
Retinopathy	1 (1.3)	0	1 (1.3)	0	0
Visual impairment	1 (1.3)	0	1 (1.3)	0	0
Gastrointestinal disorders					
-Total	53 (70.7)	12 (16.0)	20 (26.7)	20 (26.7)	1 (1.3)
Nausea	33 (44.0)	9 (12.0)	17 (22.7)	7 (9.3)	0
Vomiting	30 (40.0)	17 (22.7)	9 (12.0)	4 (5.3)	0
Diarrhoea	26 (34.7)	14 (18.7)	10 (13.3)	2 (2.7)	0
Abdominal pain	17 (22.7)	7 (9.3)	7 (9.3)	3 (4.0)	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Constipation	11 (14.7)	9 (12.0)	2 (2.7)	0	0
Stomatitis	5 (6.7)	1 (1.3)	1 (1.3)	2 (2.7)	1 (1.3)
Colitis	4 (5.3)	1 (1.3)	0	3 (4.0)	0
Abdominal pain upper	3 (4.0)	1 (1.3)	2 (2.7)	0	0
Oral pain	3 (4.0)	1 (1.3)	1 (1.3)	1 (1.3)	0
Pancreatitis	3 (4.0)	0	2 (2.7)	1 (1.3)	0
Abdominal distension	2 (2.7)	0	2 (2.7)	0	0
Abdominal pain lower	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Ascites	2 (2.7)	0	0	2 (2.7)	0
Dysphagia	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Gastrointestinal haemorrhage	2 (2.7)	2 (2.7)	0	0	0
Haematemesis	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Haematochezia	2 (2.7)	1 (1.3)	0	1 (1.3)	0
Abdominal discomfort	1 (1.3)	1 (1.3)	0	0	0
Abdominal tenderness	1 (1.3)	1 (1.3)	0	0	0
Anal fissure	1 (1.3)	0	1 (1.3)	0	0
Anal incontinence	1 (1.3)	1 (1.3)	0	0	0
Dry mouth	1 (1.3)	1 (1.3)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dyspepsia	1 (1.3)	0	1 (1.3)	0	0
Enterocolitis	1 (1.3)	0	0	1 (1.3)	0
Flatulence	1 (1.3)	1 (1.3)	0	0	0
Gastrooesophageal reflux disease	1 (1.3)	1 (1.3)	0	0	0
Gingival discomfort	1 (1.3)	1 (1.3)	0	0	0
Glossodynia	1 (1.3)	1 (1.3)	0	0	0
Ileus	1 (1.3)	0	0	1 (1.3)	0
Intestinal obstruction	1 (1.3)	0	0	1 (1.3)	0
Lip pain	1 (1.3)	0	1 (1.3)	0	0
Mouth haemorrhage	1 (1.3)	0	0	1 (1.3)	0
Oral mucosal blistering	1 (1.3)	1 (1.3)	0	0	0
Pancreatic failure	1 (1.3)	0	1 (1.3)	0	0
Perianal erythema	1 (1.3)	0	1 (1.3)	0	0
Pigmentation lip	1 (1.3)	1 (1.3)	0	0	0
Proctalgia	1 (1.3)	0	1 (1.3)	0	0
Tooth socket haemorrhage	1 (1.3)	1 (1.3)	0	0	0
General disorders and administration site conditions					

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	52 (69.3)	16 (21.3)	18 (24.0)	14 (18.7)	4 (5.3)
Pyrexia	32 (42.7)	9 (12.0)	15 (20.0)	7 (9.3)	1 (1.3)
Fatigue	18 (24.0)	13 (17.3)	3 (4.0)	2 (2.7)	0
Chills	11 (14.7)	9 (12.0)	2 (2.7)	0	0
Catheter site pain	7 (9.3)	3 (4.0)	4 (5.3)	0	0
Pain	7 (9.3)	1 (1.3)	3 (4.0)	3 (4.0)	0
Oedema peripheral	5 (6.7)	3 (4.0)	1 (1.3)	1 (1.3)	0
Generalised oedema	4 (5.3)	2 (2.7)	2 (2.7)	0	0
Malaise	4 (5.3)	1 (1.3)	3 (4.0)	0	0
Multiple organ dysfunction syndrome	4 (5.3)	0	0	1 (1.3)	3 (4.0)
Face oedema	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Influenza like illness	2 (2.7)	2 (2.7)	0	0	0
Non-cardiac chest pain	2 (2.7)	1 (1.3)	0	1 (1.3)	0
Physical deconditioning	2 (2.7)	0	0	2 (2.7)	0
Acquired gene mutation	1 (1.3)	1 (1.3)	0	0	0
Asthenia	1 (1.3)	1 (1.3)	0	0	0
Catheter site extravasation	1 (1.3)	0	1 (1.3)	0	0
Catheter site haemorrhage	1 (1.3)	1 (1.3)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Crying	1 (1.3)	1 (1.3)	0	0	0
Cyst	1 (1.3)	0	0	1 (1.3)	0
Device related thrombosis	1 (1.3)	0	1 (1.3)	0	0
Facial pain	1 (1.3)	0	1 (1.3)	0	0
Gait disturbance	1 (1.3)	1 (1.3)	0	0	0
Injection site haematoma	1 (1.3)	1 (1.3)	0	0	0
Localised oedema	1 (1.3)	0	0	1 (1.3)	0
Medical device pain	1 (1.3)	0	1 (1.3)	0	0
Mucosal haemorrhage	1 (1.3)	0	1 (1.3)	0	0
Peripheral swelling	1 (1.3)	0	1 (1.3)	0	0
Hepatobiliary disorders					
-Total	11 (14.7)	3 (4.0)	3 (4.0)	4 (5.3)	1 (1.3)
Hyperbilirubinaemia	5 (6.7)	0	2 (2.7)	3 (4.0)	0
Hepatomegaly	3 (4.0)	1 (1.3)	2 (2.7)	0	0
Cholecystitis	1 (1.3)	0	0	1 (1.3)	0
Gallbladder enlargement	1 (1.3)	1 (1.3)	0	0	0
Hepatic failure	1 (1.3)	0	0	0	1 (1.3)
Hepatic steatosis	1 (1.3)	0	1 (1.3)	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatosplenomegaly	1 (1.3)	1 (1.3)	0	0	0
Immune system disorders					
-Total	59 (78.7)	6 (8.0)	31 (41.3)	11 (14.7)	11 (14.7)
Cytokine release syndrome	50 (66.7)	6 (8.0)	25 (33.3)	8 (10.7)	11 (14.7)
Hypogammaglobulinaemia	33 (44.0)	4 (5.3)	24 (32.0)	5 (6.7)	0
Graft versus host disease	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Immunodeficiency common variable	2 (2.7)	0	2 (2.7)	0	0
Seasonal allergy	2 (2.7)	2 (2.7)	0	0	0
Chronic graft versus host disease	1 (1.3)	0	1 (1.3)	0	0
Drug hypersensitivity	1 (1.3)	0	1 (1.3)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.3)	0	1 (1.3)	0	0
Graft versus host disease in skin	1 (1.3)	1 (1.3)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.3)	0	1 (1.3)	0	0
Immunodeficiency	1 (1.3)	0	1 (1.3)	0	0
Infections and infestations					
-Total	52 (69.3)	4 (5.3)	16 (21.3)	21 (28.0)	11 (14.7)
Upper respiratory tract infection	11 (14.7)	5 (6.7)	5 (6.7)	1 (1.3)	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	7 (9.3)	0	5 (6.7)	1 (1.3)	1 (1.3)
Clostridium difficile infection	6 (8.0)	0	5 (6.7)	1 (1.3)	0
Rhinovirus infection	6 (8.0)	5 (6.7)	1 (1.3)	0	0
Clostridium difficile colitis	5 (6.7)	1 (1.3)	2 (2.7)	2 (2.7)	0
Gastroenteritis	5 (6.7)	1 (1.3)	3 (4.0)	1 (1.3)	0
Sinusitis	5 (6.7)	1 (1.3)	4 (5.3)	0	0
Urinary tract infection	5 (6.7)	0	3 (4.0)	2 (2.7)	0
Device related infection	4 (5.3)	0	1 (1.3)	3 (4.0)	0
Influenza	4 (5.3)	1 (1.3)	3 (4.0)	0	0
Otitis media	4 (5.3)	0	3 (4.0)	1 (1.3)	0
Parainfluenzae virus infection	4 (5.3)	2 (2.7)	1 (1.3)	1 (1.3)	0
Viral upper respiratory tract infection	4 (5.3)	2 (2.7)	1 (1.3)	1 (1.3)	0
Escherichia urinary tract infection	3 (4.0)	0	1 (1.3)	2 (2.7)	0
Staphylococcal infection	3 (4.0)	1 (1.3)	0	1 (1.3)	1 (1.3)
Viral infection	3 (4.0)	2 (2.7)	1 (1.3)	0	0
Cytomegalovirus infection	2 (2.7)	2 (2.7)	0	0	0
Ear infection	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Escherichia bacteraemia	2 (2.7)	0	0	2 (2.7)	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fungal skin infection	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Oral herpes	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Otitis media acute	2 (2.7)	0	2 (2.7)	0	0
Respiratory syncytial virus infection	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Sepsis	2 (2.7)	0	0	0	2 (2.7)
Skin infection	2 (2.7)	0	2 (2.7)	0	0
Staphylococcal bacteraemia	2 (2.7)	0	0	2 (2.7)	0
Vulvovaginal candidiasis	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Abscess limb	1 (1.3)	0	0	1 (1.3)	0
Acute sinusitis	1 (1.3)	0	1 (1.3)	0	0
Bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Bacterial sepsis	1 (1.3)	0	0	0	1 (1.3)
Body tinea	1 (1.3)	1 (1.3)	0	0	0
Bronchitis	1 (1.3)	0	1 (1.3)	0	0
Bronchopulmonary aspergillosis	1 (1.3)	0	0	1 (1.3)	0
Campylobacter infection	1 (1.3)	0	0	1 (1.3)	0
Candida sepsis	1 (1.3)	0	0	0	1 (1.3)
Catheter site cellulitis	1 (1.3)	1 (1.3)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Catheter site infection	1 (1.3)	0	0	1 (1.3)	0
Cellulitis	1 (1.3)	0	0	1 (1.3)	0
Cellulitis of male external genital organ	1 (1.3)	0	0	1 (1.3)	0
Cholecystitis infective	1 (1.3)	0	0	1 (1.3)	0
Conjunctivitis	1 (1.3)	0	1 (1.3)	0	0
Corona virus infection	1 (1.3)	0	0	1 (1.3)	0
Croup infectious	1 (1.3)	0	0	1 (1.3)	0
Enterococcal infection	1 (1.3)	1 (1.3)	0	0	0
Enterovirus infection	1 (1.3)	0	0	1 (1.3)	0
Escherichia sepsis	1 (1.3)	0	0	0	1 (1.3)
Folliculitis	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis norovirus	1 (1.3)	0	1 (1.3)	0	0
Gastroenteritis viral	1 (1.3)	1 (1.3)	0	0	0
Gingivitis	1 (1.3)	1 (1.3)	0	0	0
Haemophilus infection	1 (1.3)	0	1 (1.3)	0	0
Herpes simplex	1 (1.3)	1 (1.3)	0	0	0
Herpes zoster	1 (1.3)	0	0	1 (1.3)	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Human herpesvirus 6 infection	1 (1.3)	0	1 (1.3)	0	0
Human polyomavirus infection	1 (1.3)	0	0	0	1 (1.3)
Hypopyon	1 (1.3)	0	1 (1.3)	0	0
Klebsiella sepsis	1 (1.3)	0	0	0	1 (1.3)
Meningitis aseptic	1 (1.3)	0	1 (1.3)	0	0
Metapneumovirus infection	1 (1.3)	0	1 (1.3)	0	0
Molluscum contagiosum	1 (1.3)	1 (1.3)	0	0	0
Necrotising fasciitis	1 (1.3)	0	0	1 (1.3)	0
Oral candidiasis	1 (1.3)	1 (1.3)	0	0	0
Orchitis	1 (1.3)	1 (1.3)	0	0	0
Otitis externa	1 (1.3)	0	1 (1.3)	0	0
Paronychia	1 (1.3)	1 (1.3)	0	0	0
Pharyngitis	1 (1.3)	0	1 (1.3)	0	0
Pneumonia fungal	1 (1.3)	0	1 (1.3)	0	0
Rash pustular	1 (1.3)	0	1 (1.3)	0	0
Respiratory syncytial virus bronchitis	1 (1.3)	0	0	1 (1.3)	0
Respiratory tract infection	1 (1.3)	0	0	0	1 (1.3)
Respiratory tract infection viral	1 (1.3)	0	0	1 (1.3)	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinitis	1 (1.3)	1 (1.3)	0	0	0
Rotavirus infection	1 (1.3)	0	0	1 (1.3)	0
Septic embolus	1 (1.3)	0	0	0	1 (1.3)
Staphylococcal scalded skin syndrome	1 (1.3)	0	1 (1.3)	0	0
Staphylococcal sepsis	1 (1.3)	0	0	0	1 (1.3)
Streptococcal bacteraemia	1 (1.3)	0	0	1 (1.3)	0
Streptococcal infection	1 (1.3)	0	1 (1.3)	0	0
Subcutaneous abscess	1 (1.3)	0	1 (1.3)	0	0
Tinea capitis	1 (1.3)	1 (1.3)	0	0	0
Urinary tract infection enterococcal	1 (1.3)	0	0	1 (1.3)	0
Vascular device infection	1 (1.3)	0	0	1 (1.3)	0
Vulvovaginal mycotic infection	1 (1.3)	0	1 (1.3)	0	0
Injury, poisoning and procedural complications					
-Total	26 (34.7)	12 (16.0)	10 (13.3)	3 (4.0)	1 (1.3)
Infusion related reaction	5 (6.7)	2 (2.7)	3 (4.0)	0	0
Procedural pain	5 (6.7)	2 (2.7)	2 (2.7)	1 (1.3)	0
Transfusion reaction	4 (5.3)	2 (2.7)	2 (2.7)	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Contusion	3 (4.0)	3 (4.0)	0	0	0
Radiation skin injury	2 (2.7)	0	2 (2.7)	0	0
Skin abrasion	2 (2.7)	2 (2.7)	0	0	0
Subdural haematoma	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Arthropod bite	1 (1.3)	1 (1.3)	0	0	0
Extradural haematoma	1 (1.3)	0	0	1 (1.3)	0
Foot fracture	1 (1.3)	0	1 (1.3)	0	0
Incision site pain	1 (1.3)	1 (1.3)	0	0	0
Limb injury	1 (1.3)	1 (1.3)	0	0	0
Mouth injury	1 (1.3)	1 (1.3)	0	0	0
Post procedural haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Procedural complication	1 (1.3)	1 (1.3)	0	0	0
Procedural headache	1 (1.3)	0	1 (1.3)	0	0
Procedural nausea	1 (1.3)	0	1 (1.3)	0	0
Procedural site reaction	1 (1.3)	1 (1.3)	0	0	0
Radius fracture	1 (1.3)	0	1 (1.3)	0	0
Skin laceration	1 (1.3)	0	1 (1.3)	0	0
Stoma site irritation	1 (1.3)	1 (1.3)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Subdural haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Sunburn	1 (1.3)	1 (1.3)	0	0	0
Tibia fracture	1 (1.3)	0	1 (1.3)	0	0
Tongue injury	1 (1.3)	1 (1.3)	0	0	0
Tracheal haemorrhage	1 (1.3)	0	0	1 (1.3)	0
Transfusion related complication	1 (1.3)	0	0	0	1 (1.3)
Wound	1 (1.3)	1 (1.3)	0	0	0
Investigations					
-Total	58 (77.3)	1 (1.3)	4 (5.3)	12 (16.0)	41 (54.7)
White blood cell count decreased	42 (56.0)	4 (5.3)	1 (1.3)	8 (10.7)	29 (38.7)
Neutrophil count decreased	32 (42.7)	1 (1.3)	2 (2.7)	3 (4.0)	26 (34.7)
Alanine aminotransferase increased	26 (34.7)	3 (4.0)	4 (5.3)	18 (24.0)	1 (1.3)
Aspartate aminotransferase increased	24 (32.0)	5 (6.7)	5 (6.7)	9 (12.0)	5 (6.7)
Platelet count decreased	21 (28.0)	3 (4.0)	2 (2.7)	3 (4.0)	13 (17.3)
Lymphocyte count decreased	19 (25.3)	1 (1.3)	3 (4.0)	7 (9.3)	8 (10.7)
International normalised ratio increased	11 (14.7)	9 (12.0)	1 (1.3)	1 (1.3)	0
Blood bilirubin increased	10 (13.3)	2 (2.7)	3 (4.0)	4 (5.3)	1 (1.3)

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood creatinine increased	9 (12.0)	5 (6.7)	2 (2.7)	2 (2.7)	0
Prothrombin time prolonged	9 (12.0)	5 (6.7)	3 (4.0)	1 (1.3)	0
Activated partial thromboplastin time prolonged	6 (8.0)	3 (4.0)	3 (4.0)	0	0
Weight decreased	5 (6.7)	2 (2.7)	3 (4.0)	0	0
Blood fibrinogen decreased	4 (5.3)	0	1 (1.3)	2 (2.7)	1 (1.3)
Blood immunoglobulin m decreased	4 (5.3)	4 (5.3)	0	0	0
C-reactive protein increased	4 (5.3)	1 (1.3)	2 (2.7)	1 (1.3)	0
Transaminases increased	4 (5.3)	3 (4.0)	0	1 (1.3)	0
Blood immunoglobulin a decreased	3 (4.0)	3 (4.0)	0	0	0
Blood urea increased	3 (4.0)	1 (1.3)	1 (1.3)	1 (1.3)	0
Haemoglobin decreased	3 (4.0)	2 (2.7)	0	1 (1.3)	0
Lipase increased	3 (4.0)	0	0	0	3 (4.0)
Weight increased	3 (4.0)	2 (2.7)	1 (1.3)	0	0
Blood lactate dehydrogenase increased	2 (2.7)	1 (1.3)	0	1 (1.3)	0
Blood lactic acid increased	2 (2.7)	0	1 (1.3)	0	1 (1.3)
Blood magnesium decreased	2 (2.7)	1 (1.3)	0	1 (1.3)	0
Blood phosphorus increased	2 (2.7)	2 (2.7)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood uric acid increased	2 (2.7)	2 (2.7)	0	0	0
Electrocardiogram qt prolonged	2 (2.7)	0	0	2 (2.7)	0
Serum ferritin increased	2 (2.7)	0	2 (2.7)	0	0
Blood alkaline phosphatase increased	1 (1.3)	1 (1.3)	0	0	0
Blood bicarbonate decreased	1 (1.3)	0	1 (1.3)	0	0
Blood immunoglobulin g decreased	1 (1.3)	0	1 (1.3)	0	0
Blood phosphorus decreased	1 (1.3)	1 (1.3)	0	0	0
Blood sodium increased	1 (1.3)	0	1 (1.3)	0	0
Cardiac murmur	1 (1.3)	1 (1.3)	0	0	0
Computerised tomogram thorax abnormal	1 (1.3)	0	0	1 (1.3)	0
Coronavirus test positive	1 (1.3)	1 (1.3)	0	0	0
Culture stool positive	1 (1.3)	1 (1.3)	0	0	0
Fibrin d dimer increased	1 (1.3)	1 (1.3)	0	0	0
Hepatic enzyme increased	1 (1.3)	0	1 (1.3)	0	0
Norovirus test positive	1 (1.3)	1 (1.3)	0	0	0
Oxygen saturation decreased	1 (1.3)	1 (1.3)	0	0	0
Protein total decreased	1 (1.3)	0	0	1 (1.3)	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary function test decreased	1 (1.3)	0	1 (1.3)	0	0
Metabolism and nutrition disorders					
-Total	49 (65.3)	6 (8.0)	10 (13.3)	26 (34.7)	7 (9.3)
Decreased appetite	28 (37.3)	7 (9.3)	8 (10.7)	13 (17.3)	0
Hypokalaemia	23 (30.7)	5 (6.7)	5 (6.7)	9 (12.0)	4 (5.3)
Hypophosphataemia	13 (17.3)	4 (5.3)	0	8 (10.7)	1 (1.3)
Hyperphosphataemia	9 (12.0)	8 (10.7)	1 (1.3)	0	0
Hyperglycaemia	7 (9.3)	0	3 (4.0)	4 (5.3)	0
Fluid overload	6 (8.0)	1 (1.3)	4 (5.3)	1 (1.3)	0
Hypernatraemia	6 (8.0)	1 (1.3)	2 (2.7)	0	3 (4.0)
Hypoalbuminaemia	6 (8.0)	1 (1.3)	4 (5.3)	1 (1.3)	0
Hypocalcaemia	6 (8.0)	3 (4.0)	1 (1.3)	1 (1.3)	1 (1.3)
Dehydration	4 (5.3)	1 (1.3)	0	3 (4.0)	0
Hyperuricaemia	4 (5.3)	3 (4.0)	0	0	1 (1.3)
Hyperkalaemia	3 (4.0)	1 (1.3)	1 (1.3)	1 (1.3)	0
Hypomagnesaemia	3 (4.0)	2 (2.7)	1 (1.3)	0	0
Tumour lysis syndrome	3 (4.0)	0	0	3 (4.0)	0
Vitamin d deficiency	3 (4.0)	2 (2.7)	1 (1.3)	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acidosis	2 (2.7)	1 (1.3)	0	1 (1.3)	0
Hypertriglyceridaemia	2 (2.7)	1 (1.3)	0	1 (1.3)	0
Hypoglycaemia	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Hyponatraemia	2 (2.7)	0	0	2 (2.7)	0
Malnutrition	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Hyperalbuminaemia	1 (1.3)	1 (1.3)	0	0	0
Hyperammonaemia	1 (1.3)	1 (1.3)	0	0	0
Hypercalcaemia	1 (1.3)	1 (1.3)	0	0	0
Hyperchloraemia	1 (1.3)	1 (1.3)	0	0	0
Hypermagnesaemia	1 (1.3)	1 (1.3)	0	0	0
Iron overload	1 (1.3)	0	0	1 (1.3)	0
Metabolic acidosis	1 (1.3)	0	1 (1.3)	0	0
Metabolic alkalosis	1 (1.3)	1 (1.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	37 (49.3)	17 (22.7)	12 (16.0)	8 (10.7)	0
Pain in extremity	14 (18.7)	7 (9.3)	4 (5.3)	3 (4.0)	0
Arthralgia	7 (9.3)	4 (5.3)	1 (1.3)	2 (2.7)	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Myalgia	6 (8.0)	4 (5.3)	1 (1.3)	1 (1.3)	0
Musculoskeletal pain	4 (5.3)	2 (2.7)	1 (1.3)	1 (1.3)	0
Pain in jaw	4 (5.3)	2 (2.7)	2 (2.7)	0	0
Back pain	3 (4.0)	1 (1.3)	0	2 (2.7)	0
Muscle spasms	3 (4.0)	3 (4.0)	0	0	0
Muscular weakness	3 (4.0)	2 (2.7)	1 (1.3)	0	0
Musculoskeletal chest pain	3 (4.0)	3 (4.0)	0	0	0
Joint range of motion decreased	2 (2.7)	2 (2.7)	0	0	0
Neck pain	2 (2.7)	0	2 (2.7)	0	0
Bone pain	1 (1.3)	0	0	1 (1.3)	0
Coccydynia	1 (1.3)	1 (1.3)	0	0	0
Flank pain	1 (1.3)	0	1 (1.3)	0	0
Limb discomfort	1 (1.3)	1 (1.3)	0	0	0
Myopathy	1 (1.3)	0	0	1 (1.3)	0
Myositis	1 (1.3)	0	0	1 (1.3)	0
Osteonecrosis	1 (1.3)	0	1 (1.3)	0	0
Osteopenia	1 (1.3)	0	1 (1.3)	0	0
Synovitis	1 (1.3)	0	1 (1.3)	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Toe walking	1 (1.3)	1 (1.3)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (4.0)	0	2 (2.7)	0	1 (1.3)
Glioblastoma multiforme	1 (1.3)	0	0	0	1 (1.3)
Myelodysplastic syndrome	1 (1.3)	0	1 (1.3)	0	0
Skin papilloma	1 (1.3)	0	1 (1.3)	0	0
Nervous system disorders					
-Total	43 (57.3)	17 (22.7)	17 (22.7)	7 (9.3)	2 (2.7)
Headache	29 (38.7)	15 (20.0)	9 (12.0)	5 (6.7)	0
Dizziness	6 (8.0)	6 (8.0)	0	0	0
Seizure	5 (6.7)	0	2 (2.7)	2 (2.7)	1 (1.3)
Encephalopathy	4 (5.3)	1 (1.3)	1 (1.3)	2 (2.7)	0
Peroneal nerve palsy	3 (4.0)	2 (2.7)	1 (1.3)	0	0
Dysarthria	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Neuropathy peripheral	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Somnolence	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Tremor	2 (2.7)	2 (2.7)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Asterixis	1 (1.3)	1 (1.3)	0	0	0
Ataxia	1 (1.3)	0	1 (1.3)	0	0
Depressed level of consciousness	1 (1.3)	1 (1.3)	0	0	0
Disturbance in attention	1 (1.3)	1 (1.3)	0	0	0
Dysgeusia	1 (1.3)	1 (1.3)	0	0	0
Embolic stroke	1 (1.3)	0	0	0	1 (1.3)
Hyporesponsive to stimuli	1 (1.3)	0	0	1 (1.3)	0
Hypotonia	1 (1.3)	0	1 (1.3)	0	0
Idiopathic intracranial hypertension	1 (1.3)	0	1 (1.3)	0	0
Migraine	1 (1.3)	0	1 (1.3)	0	0
Myoclonus	1 (1.3)	1 (1.3)	0	0	0
Neuralgia	1 (1.3)	0	1 (1.3)	0	0
Peripheral sensory neuropathy	1 (1.3)	0	1 (1.3)	0	0
Pleocytosis	1 (1.3)	1 (1.3)	0	0	0
Visual field defect	1 (1.3)	0	1 (1.3)	0	0
Product issues					
-Total	2 (2.7)	2 (2.7)	0	0	0
Device occlusion	2 (2.7)	2 (2.7)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Psychiatric disorders					
-Total	26 (34.7)	8 (10.7)	14 (18.7)	4 (5.3)	0
Anxiety	9 (12.0)	3 (4.0)	5 (6.7)	1 (1.3)	0
Confusional state	7 (9.3)	3 (4.0)	4 (5.3)	0	0
Delirium	5 (6.7)	2 (2.7)	2 (2.7)	1 (1.3)	0
Depression	4 (5.3)	2 (2.7)	2 (2.7)	0	0
Insomnia	4 (5.3)	0	4 (5.3)	0	0
Mental status changes	4 (5.3)	3 (4.0)	0	1 (1.3)	0
Agitation	3 (4.0)	0	2 (2.7)	1 (1.3)	0
Irritability	3 (4.0)	3 (4.0)	0	0	0
Hallucination	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Adjustment disorder	1 (1.3)	0	1 (1.3)	0	0
Listless	1 (1.3)	1 (1.3)	0	0	0
Panic attack	1 (1.3)	0	1 (1.3)	0	0
Sleep disorder	1 (1.3)	0	1 (1.3)	0	0
Suicidal ideation	1 (1.3)	1 (1.3)	0	0	0
Renal and urinary disorders					
-Total	19 (25.3)	3 (4.0)	4 (5.3)	7 (9.3)	5 (6.7)

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	12 (16.0)	2 (2.7)	1 (1.3)	5 (6.7)	4 (5.3)
Haematuria	5 (6.7)	0	2 (2.7)	2 (2.7)	1 (1.3)
Dysuria	3 (4.0)	1 (1.3)	2 (2.7)	0	0
Oliguria	3 (4.0)	0	0	3 (4.0)	0
Calculus urinary	1 (1.3)	0	1 (1.3)	0	0
Cystitis haemorrhagic	1 (1.3)	0	0	0	1 (1.3)
Nephrolithiasis	1 (1.3)	0	0	1 (1.3)	0
Pollakiuria	1 (1.3)	1 (1.3)	0	0	0
Renal failure	1 (1.3)	0	0	0	1 (1.3)
Renal impairment	1 (1.3)	0	0	1 (1.3)	0
Urinary incontinence	1 (1.3)	1 (1.3)	0	0	0
Urinary retention	1 (1.3)	0	1 (1.3)	0	0
Reproductive system and breast disorders					
-Total	6 (8.0)	2 (2.7)	2 (2.7)	2 (2.7)	0
Vulvovaginal adhesion	2 (2.7)	2 (2.7)	0	0	0
Oedema genital	1 (1.3)	0	1 (1.3)	0	0
Ovarian failure	1 (1.3)	0	0	1 (1.3)	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Scrotal pain	1 (1.3)	0	1 (1.3)	0	0
Vaginal haemorrhage	1 (1.3)	0	0	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	44 (58.7)	13 (17.3)	9 (12.0)	10 (13.3)	12 (16.0)
Cough	16 (21.3)	13 (17.3)	2 (2.7)	1 (1.3)	0
Hypoxia	15 (20.0)	0	3 (4.0)	9 (12.0)	3 (4.0)
Epistaxis	14 (18.7)	4 (5.3)	4 (5.3)	5 (6.7)	1 (1.3)
Pleural effusion	10 (13.3)	1 (1.3)	6 (8.0)	3 (4.0)	0
Pulmonary oedema	9 (12.0)	1 (1.3)	0	4 (5.3)	4 (5.3)
Tachypnoea	8 (10.7)	3 (4.0)	2 (2.7)	3 (4.0)	0
Oropharyngeal pain	7 (9.3)	4 (5.3)	2 (2.7)	1 (1.3)	0
Nasal congestion	6 (8.0)	6 (8.0)	0	0	0
Rhinorrhoea	6 (8.0)	5 (6.7)	1 (1.3)	0	0
Dyspnoea	5 (6.7)	1 (1.3)	1 (1.3)	2 (2.7)	1 (1.3)
Rhinitis allergic	5 (6.7)	4 (5.3)	1 (1.3)	0	0
Respiratory failure	4 (5.3)	0	0	0	4 (5.3)
Haemoptysis	3 (4.0)	1 (1.3)	0	1 (1.3)	1 (1.3)

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Atelectasis	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Respiratory distress	2 (2.7)	0	0	0	2 (2.7)
Acute respiratory failure	1 (1.3)	0	0	0	1 (1.3)
Aspiration	1 (1.3)	0	0	0	1 (1.3)
Dysphonia	1 (1.3)	1 (1.3)	0	0	0
Idiopathic pneumonia syndrome	1 (1.3)	0	0	0	1 (1.3)
Interstitial lung disease	1 (1.3)	0	0	0	1 (1.3)
Nasal discomfort	1 (1.3)	1 (1.3)	0	0	0
Oropharyngeal plaque	1 (1.3)	1 (1.3)	0	0	0
Pharyngeal erythema	1 (1.3)	1 (1.3)	0	0	0
Pharyngeal lesion	1 (1.3)	0	0	1 (1.3)	0
Pharyngeal ulceration	1 (1.3)	0	1 (1.3)	0	0
Pulmonary alveolar haemorrhage	1 (1.3)	0	0	0	1 (1.3)
Pulmonary hypertension	1 (1.3)	0	0	1 (1.3)	0
Pulmonary mass	1 (1.3)	0	1 (1.3)	0	0
Respiratory depression	1 (1.3)	0	1 (1.3)	0	0
Wheezing	1 (1.3)	0	1 (1.3)	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	37 (49.3)	21 (28.0)	12 (16.0)	4 (5.3)	0
Rash	9 (12.0)	6 (8.0)	3 (4.0)	0	0
Dry skin	5 (6.7)	5 (6.7)	0	0	0
Erythema	5 (6.7)	5 (6.7)	0	0	0
Pruritus	5 (6.7)	5 (6.7)	0	0	0
Rash erythematous	5 (6.7)	2 (2.7)	3 (4.0)	0	0
Rash maculo-papular	5 (6.7)	3 (4.0)	1 (1.3)	1 (1.3)	0
Alopecia	4 (5.3)	2 (2.7)	2 (2.7)	0	0
Hyperhidrosis	4 (5.3)	4 (5.3)	0	0	0
Petechiae	4 (5.3)	3 (4.0)	1 (1.3)	0	0
Ingrowing nail	3 (4.0)	1 (1.3)	2 (2.7)	0	0
Rash papular	3 (4.0)	3 (4.0)	0	0	0
Dermatitis acneiform	2 (2.7)	0	1 (1.3)	1 (1.3)	0
Macule	2 (2.7)	2 (2.7)	0	0	0
Night sweats	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Papule	2 (2.7)	2 (2.7)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash macular	2 (2.7)	1 (1.3)	0	1 (1.3)	0
Rash pruritic	2 (2.7)	2 (2.7)	0	0	0
Acne	1 (1.3)	1 (1.3)	0	0	0
Cold sweat	1 (1.3)	1 (1.3)	0	0	0
Dermatitis	1 (1.3)	1 (1.3)	0	0	0
Dermatitis atopic	1 (1.3)	1 (1.3)	0	0	0
Dermatitis diaper	1 (1.3)	1 (1.3)	0	0	0
Ecchymosis	1 (1.3)	0	0	1 (1.3)	0
Eczema	1 (1.3)	1 (1.3)	0	0	0
Keloid scar	1 (1.3)	0	1 (1.3)	0	0
Livedo reticularis	1 (1.3)	1 (1.3)	0	0	0
Pruritus generalised	1 (1.3)	1 (1.3)	0	0	0
Rash follicular	1 (1.3)	1 (1.3)	0	0	0
Rash vesicular	1 (1.3)	1 (1.3)	0	0	0
Skin exfoliation	1 (1.3)	1 (1.3)	0	0	0
Skin fissures	1 (1.3)	1 (1.3)	0	0	0
Skin haemorrhage	1 (1.3)	1 (1.3)	0	0	0
Skin irritation	1 (1.3)	1 (1.3)	0	0	0

Region: US

Primary system organ class Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin ulcer	1 (1.3)	1 (1.3)	0	0	0
Vascular disorders					
-Total	34 (45.3)	3 (4.0)	6 (8.0)	14 (18.7)	11 (14.7)
Hypotension	24 (32.0)	1 (1.3)	0	12 (16.0)	11 (14.7)
Hypertension	16 (21.3)	4 (5.3)	10 (13.3)	2 (2.7)	0
Flushing	2 (2.7)	2 (2.7)	0	0	0
Orthostatic hypotension	2 (2.7)	1 (1.3)	1 (1.3)	0	0
Capillary leak syndrome	1 (1.3)	0	0	0	1 (1.3)
Embolism	1 (1.3)	0	0	1 (1.3)	0
Haematoma	1 (1.3)	0	1 (1.3)	0	0
Hot flush	1 (1.3)	1 (1.3)	0	0	0
Phlebitis	1 (1.3)	0	1 (1.3)	0	0
Secondary hypertension	1 (1.3)	0	1 (1.3)	0	0
Venous thrombosis limb	1 (1.3)	1 (1.3)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178l
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	0	6 (18.8)	26 (81.3)
Blood and lymphatic system disorders					
-Total	28 (87.5)	0	1 (3.1)	19 (59.4)	8 (25.0)
Anaemia	16 (50.0)	1 (3.1)	3 (9.4)	12 (37.5)	0
Febrile neutropenia	16 (50.0)	0	0	16 (50.0)	0
Thrombocytopenia	6 (18.8)	0	0	3 (9.4)	3 (9.4)
Neutropenia	4 (12.5)	0	0	1 (3.1)	3 (9.4)
Lymphopenia	3 (9.4)	0	2 (6.3)	0	1 (3.1)
Disseminated intravascular coagulation	2 (6.3)	0	1 (3.1)	0	1 (3.1)
Coagulopathy	1 (3.1)	0	0	1 (3.1)	0
Eosinophilia	1 (3.1)	0	0	1 (3.1)	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypofibrinogenaemia	1 (3.1)	0	0	0	1 (3.1)
Leukocytosis	1 (3.1)	1 (3.1)	0	0	0
Pancytopenia	1 (3.1)	0	0	0	1 (3.1)
Splenomegaly	1 (3.1)	1 (3.1)	0	0	0
Cardiac disorders					
-Total	14 (43.8)	5 (15.6)	5 (15.6)	3 (9.4)	1 (3.1)
Tachycardia	8 (25.0)	4 (12.5)	3 (9.4)	1 (3.1)	0
Sinus tachycardia	5 (15.6)	2 (6.3)	2 (6.3)	1 (3.1)	0
Bradycardia	1 (3.1)	1 (3.1)	0	0	0
Cardiac dysfunction	1 (3.1)	1 (3.1)	0	0	0
Cardiovascular insufficiency	1 (3.1)	0	0	0	1 (3.1)
Left ventricular dysfunction	1 (3.1)	0	0	1 (3.1)	0
Palpitations	1 (3.1)	1 (3.1)	0	0	0
Pericardial effusion	1 (3.1)	0	1 (3.1)	0	0
Sinus bradycardia	1 (3.1)	1 (3.1)	0	0	0
Ear and labyrinth disorders					
-Total	5 (15.6)	2 (6.3)	3 (9.4)	0	0
Ear pain	2 (6.3)	2 (6.3)	0	0	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Deafness unilateral	1 (3.1)	0	1 (3.1)	0	0
Hypoacusis	1 (3.1)	0	1 (3.1)	0	0
Tympanic membrane perforation	1 (3.1)	0	1 (3.1)	0	0
Endocrine disorders					
-Total	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Cushingoid	1 (3.1)	1 (3.1)	0	0	0
Hyperthyroidism	1 (3.1)	0	1 (3.1)	0	0
Eye disorders					
-Total	11 (34.4)	4 (12.5)	7 (21.9)	0	0
Dry eye	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Eye pain	2 (6.3)	0	2 (6.3)	0	0
Photophobia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Uveitis	2 (6.3)	0	2 (6.3)	0	0
Eye irritation	1 (3.1)	1 (3.1)	0	0	0
Ocular hyperaemia	1 (3.1)	1 (3.1)	0	0	0
Ocular hypertension	1 (3.1)	0	1 (3.1)	0	0
Papilloedema	1 (3.1)	0	1 (3.1)	0	0
Periorbital oedema	1 (3.1)	0	1 (3.1)	0	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Retinopathy	1 (3.1)	0	1 (3.1)	0	0
Vision blurred	1 (3.1)	0	1 (3.1)	0	0
Visual impairment	1 (3.1)	0	1 (3.1)	0	0
Gastrointestinal disorders					
-Total	23 (71.9)	4 (12.5)	10 (31.3)	9 (28.1)	0
Nausea	15 (46.9)	6 (18.8)	7 (21.9)	2 (6.3)	0
Vomiting	13 (40.6)	9 (28.1)	2 (6.3)	2 (6.3)	0
Diarrhoea	12 (37.5)	6 (18.8)	6 (18.8)	0	0
Abdominal pain	11 (34.4)	4 (12.5)	6 (18.8)	1 (3.1)	0
Constipation	4 (12.5)	4 (12.5)	0	0	0
Stomatitis	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0
Colitis	3 (9.4)	0	0	3 (9.4)	0
Abdominal distension	2 (6.3)	0	2 (6.3)	0	0
Gastrointestinal haemorrhage	2 (6.3)	2 (6.3)	0	0	0
Abdominal pain lower	1 (3.1)	0	1 (3.1)	0	0
Abdominal pain upper	1 (3.1)	1 (3.1)	0	0	0
Abdominal tenderness	1 (3.1)	1 (3.1)	0	0	0
Anal incontinence	1 (3.1)	1 (3.1)	0	0	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	1 (3.1)	0	0	1 (3.1)	0
Gastrooesophageal reflux disease	1 (3.1)	1 (3.1)	0	0	0
Gingival discomfort	1 (3.1)	1 (3.1)	0	0	0
Glossodynia	1 (3.1)	1 (3.1)	0	0	0
Haematemesis	1 (3.1)	1 (3.1)	0	0	0
Lip pain	1 (3.1)	0	1 (3.1)	0	0
Mouth haemorrhage	1 (3.1)	0	0	1 (3.1)	0
Oral mucosal blistering	1 (3.1)	1 (3.1)	0	0	0
Oral pain	1 (3.1)	0	1 (3.1)	0	0
Pancreatitis	1 (3.1)	0	1 (3.1)	0	0
Pigmentation lip	1 (3.1)	1 (3.1)	0	0	0
General disorders and administration site conditions					
-Total	26 (81.3)	11 (34.4)	8 (25.0)	4 (12.5)	3 (9.4)
Pyrexia	15 (46.9)	8 (25.0)	6 (18.8)	1 (3.1)	0
Fatigue	9 (28.1)	7 (21.9)	1 (3.1)	1 (3.1)	0
Chills	4 (12.5)	4 (12.5)	0	0	0
Oedema peripheral	4 (12.5)	3 (9.4)	1 (3.1)	0	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Generalised oedema	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Multiple organ dysfunction syndrome	3 (9.4)	0	0	0	3 (9.4)
Catheter site pain	2 (6.3)	2 (6.3)	0	0	0
Influenza like illness	2 (6.3)	2 (6.3)	0	0	0
Malaise	2 (6.3)	0	2 (6.3)	0	0
Acquired gene mutation	1 (3.1)	1 (3.1)	0	0	0
Catheter site extravasation	1 (3.1)	0	1 (3.1)	0	0
Catheter site haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Crying	1 (3.1)	1 (3.1)	0	0	0
Cyst	1 (3.1)	0	0	1 (3.1)	0
Device related thrombosis	1 (3.1)	0	1 (3.1)	0	0
Face oedema	1 (3.1)	0	1 (3.1)	0	0
Facial pain	1 (3.1)	0	1 (3.1)	0	0
Gait disturbance	1 (3.1)	1 (3.1)	0	0	0
Injection site haematoma	1 (3.1)	1 (3.1)	0	0	0
Medical device pain	1 (3.1)	0	1 (3.1)	0	0
Non-cardiac chest pain	1 (3.1)	1 (3.1)	0	0	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Peripheral swelling	1 (3.1)	0	1 (3.1)	0	0
Physical deconditioning	1 (3.1)	0	0	1 (3.1)	0
Hepatobiliary disorders					
-Total	5 (15.6)	1 (3.1)	0	3 (9.4)	1 (3.1)
Hepatomegaly	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Hyperbilirubinaemia	2 (6.3)	0	0	2 (6.3)	0
Cholecystitis	1 (3.1)	0	0	1 (3.1)	0
Hepatic failure	1 (3.1)	0	0	0	1 (3.1)
Hepatic steatosis	1 (3.1)	0	1 (3.1)	0	0
Immune system disorders					
-Total	25 (78.1)	5 (15.6)	13 (40.6)	5 (15.6)	2 (6.3)
Cytokine release syndrome	20 (62.5)	3 (9.4)	11 (34.4)	4 (12.5)	2 (6.3)
Hypogammaglobulinaemia	14 (43.8)	3 (9.4)	10 (31.3)	1 (3.1)	0
Graft versus host disease	1 (3.1)	1 (3.1)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (3.1)	0	1 (3.1)	0	0
Graft versus host disease in skin	1 (3.1)	1 (3.1)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (3.1)	0	1 (3.1)	0	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Immunodeficiency common variable	1 (3.1)	0	1 (3.1)	0	0
Infections and infestations					
-Total	24 (75.0)	2 (6.3)	4 (12.5)	12 (37.5)	6 (18.8)
Upper respiratory tract infection	6 (18.8)	4 (12.5)	1 (3.1)	1 (3.1)	0
Clostridium difficile infection	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Urinary tract infection	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Device related infection	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Otitis media	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Sinusitis	3 (9.4)	0	3 (9.4)	0	0
Cytomegalovirus infection	2 (6.3)	2 (6.3)	0	0	0
Escherichia urinary tract infection	2 (6.3)	0	0	2 (6.3)	0
Fungal skin infection	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Influenza	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Otitis media acute	2 (6.3)	0	2 (6.3)	0	0
Parainfluenzae virus infection	2 (6.3)	2 (6.3)	0	0	0
Pneumonia	2 (6.3)	0	2 (6.3)	0	0
Rhinovirus infection	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Sepsis	2 (6.3)	0	0	0	2 (6.3)

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	2 (6.3)	0	0	2 (6.3)	0
Vulvovaginal candidiasis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Abscess limb	1 (3.1)	0	0	1 (3.1)	0
Acute sinusitis	1 (3.1)	0	1 (3.1)	0	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Body tinea	1 (3.1)	1 (3.1)	0	0	0
Bronchitis	1 (3.1)	0	1 (3.1)	0	0
Campylobacter infection	1 (3.1)	0	0	1 (3.1)	0
Catheter site cellulitis	1 (3.1)	1 (3.1)	0	0	0
Cellulitis of male external genital organ	1 (3.1)	0	0	1 (3.1)	0
Cholecystitis infective	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile colitis	1 (3.1)	0	1 (3.1)	0	0
Conjunctivitis	1 (3.1)	0	1 (3.1)	0	0
Croup infectious	1 (3.1)	0	0	1 (3.1)	0
Ear infection	1 (3.1)	0	1 (3.1)	0	0
Enterococcal infection	1 (3.1)	1 (3.1)	0	0	0
Enterovirus infection	1 (3.1)	0	0	1 (3.1)	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Escherichia sepsis	1 (3.1)	0	0	0	1 (3.1)
Gastroenteritis norovirus	1 (3.1)	0	1 (3.1)	0	0
Haemophilus infection	1 (3.1)	0	1 (3.1)	0	0
Herpes simplex	1 (3.1)	1 (3.1)	0	0	0
Human herpesvirus 6 infection	1 (3.1)	0	1 (3.1)	0	0
Hypopyon	1 (3.1)	0	1 (3.1)	0	0
Klebsiella sepsis	1 (3.1)	0	0	0	1 (3.1)
Necrotising fasciitis	1 (3.1)	0	0	1 (3.1)	0
Oral candidiasis	1 (3.1)	1 (3.1)	0	0	0
Oral herpes	1 (3.1)	0	1 (3.1)	0	0
Pneumonia fungal	1 (3.1)	0	1 (3.1)	0	0
Respiratory syncytial virus bronchitis	1 (3.1)	0	0	1 (3.1)	0
Respiratory tract infection viral	1 (3.1)	0	0	1 (3.1)	0
Rhinitis	1 (3.1)	1 (3.1)	0	0	0
Rotavirus infection	1 (3.1)	0	0	1 (3.1)	0
Septic embolus	1 (3.1)	0	0	0	1 (3.1)
Skin infection	1 (3.1)	0	1 (3.1)	0	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (3.1)	0	0	0	1 (3.1)
Staphylococcal scalded skin syndrome	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal sepsis	1 (3.1)	0	0	0	1 (3.1)
Streptococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Vascular device infection	1 (3.1)	0	0	1 (3.1)	0
Viral upper respiratory tract infection	1 (3.1)	1 (3.1)	0	0	0
Injury, poisoning and procedural complications					
-Total	13 (40.6)	5 (15.6)	6 (18.8)	1 (3.1)	1 (3.1)
Infusion related reaction	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Transfusion reaction	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Contusion	2 (6.3)	2 (6.3)	0	0	0
Procedural pain	2 (6.3)	0	2 (6.3)	0	0
Subdural haematoma	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Extradural haematoma	1 (3.1)	0	0	1 (3.1)	0
Foot fracture	1 (3.1)	0	1 (3.1)	0	0
Limb injury	1 (3.1)	1 (3.1)	0	0	0
Mouth injury	1 (3.1)	1 (3.1)	0	0	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural headache	1 (3.1)	0	1 (3.1)	0	0
Procedural site reaction	1 (3.1)	1 (3.1)	0	0	0
Radiation skin injury	1 (3.1)	0	1 (3.1)	0	0
Skin abrasion	1 (3.1)	1 (3.1)	0	0	0
Skin laceration	1 (3.1)	0	1 (3.1)	0	0
Tongue injury	1 (3.1)	1 (3.1)	0	0	0
Transfusion related complication	1 (3.1)	0	0	0	1 (3.1)
Investigations					
-Total	25 (78.1)	1 (3.1)	3 (9.4)	3 (9.4)	18 (56.3)
White blood cell count decreased	18 (56.3)	1 (3.1)	1 (3.1)	4 (12.5)	12 (37.5)
Alanine aminotransferase increased	17 (53.1)	3 (9.4)	2 (6.3)	11 (34.4)	1 (3.1)
Neutrophil count decreased	17 (53.1)	1 (3.1)	1 (3.1)	0	15 (46.9)
Aspartate aminotransferase increased	16 (50.0)	5 (15.6)	2 (6.3)	6 (18.8)	3 (9.4)
Platelet count decreased	12 (37.5)	2 (6.3)	1 (3.1)	1 (3.1)	8 (25.0)
Lymphocyte count decreased	9 (28.1)	0	2 (6.3)	3 (9.4)	4 (12.5)
Blood bilirubin increased	7 (21.9)	2 (6.3)	2 (6.3)	2 (6.3)	1 (3.1)
International normalised ratio increased	7 (21.9)	6 (18.8)	1 (3.1)	0	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	6 (18.8)	4 (12.5)	1 (3.1)	1 (3.1)	0
Prothrombin time prolonged	6 (18.8)	4 (12.5)	2 (6.3)	0	0
Activated partial thromboplastin time prolonged	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Blood immunoglobulin a decreased	3 (9.4)	3 (9.4)	0	0	0
Blood immunoglobulin m decreased	3 (9.4)	3 (9.4)	0	0	0
Haemoglobin decreased	3 (9.4)	2 (6.3)	0	1 (3.1)	0
Weight increased	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Transaminases increased	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Weight decreased	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Blood bicarbonate decreased	1 (3.1)	0	1 (3.1)	0	0
Blood lactic acid increased	1 (3.1)	0	0	0	1 (3.1)
Blood urea increased	1 (3.1)	0	1 (3.1)	0	0
Blood uric acid increased	1 (3.1)	1 (3.1)	0	0	0
C-reactive protein increased	1 (3.1)	0	1 (3.1)	0	0
Coronavirus test positive	1 (3.1)	1 (3.1)	0	0	0
Culture stool positive	1 (3.1)	1 (3.1)	0	0	0
Electrocardiogram qt prolonged	1 (3.1)	0	0	1 (3.1)	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatic enzyme increased	1 (3.1)	0	1 (3.1)	0	0
Lipase increased	1 (3.1)	0	0	0	1 (3.1)
Norovirus test positive	1 (3.1)	1 (3.1)	0	0	0
Pulmonary function test decreased	1 (3.1)	0	1 (3.1)	0	0
Serum ferritin increased	1 (3.1)	0	1 (3.1)	0	0
Metabolism and nutrition disorders					
-Total	22 (68.8)	3 (9.4)	6 (18.8)	10 (31.3)	3 (9.4)
Decreased appetite	13 (40.6)	4 (12.5)	3 (9.4)	6 (18.8)	0
Hypokalaemia	11 (34.4)	2 (6.3)	2 (6.3)	4 (12.5)	3 (9.4)
Hyperphosphataemia	8 (25.0)	7 (21.9)	1 (3.1)	0	0
Hypophosphataemia	6 (18.8)	2 (6.3)	0	4 (12.5)	0
Hyperglycaemia	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Hypocalcaemia	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Hyperuricaemia	3 (9.4)	3 (9.4)	0	0	0
Hypoalbuminaemia	3 (9.4)	0	3 (9.4)	0	0
Dehydration	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Fluid overload	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Hypoglycaemia	2 (6.3)	0	1 (3.1)	1 (3.1)	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyponatraemia	2 (6.3)	0	0	2 (6.3)	0
Vitamin d deficiency	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Hyperammonaemia	1 (3.1)	1 (3.1)	0	0	0
Hyperkalaemia	1 (3.1)	1 (3.1)	0	0	0
Hypernatraemia	1 (3.1)	0	0	0	1 (3.1)
Hypomagnesaemia	1 (3.1)	1 (3.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	19 (59.4)	11 (34.4)	5 (15.6)	3 (9.4)	0
Myalgia	6 (18.8)	4 (12.5)	1 (3.1)	1 (3.1)	0
Pain in extremity	6 (18.8)	3 (9.4)	2 (6.3)	1 (3.1)	0
Arthralgia	3 (9.4)	3 (9.4)	0	0	0
Muscle spasms	3 (9.4)	3 (9.4)	0	0	0
Musculoskeletal pain	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Joint range of motion decreased	2 (6.3)	2 (6.3)	0	0	0
Musculoskeletal chest pain	2 (6.3)	2 (6.3)	0	0	0
Pain in jaw	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Back pain	1 (3.1)	1 (3.1)	0	0	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Coccydynia	1 (3.1)	1 (3.1)	0	0	0
Flank pain	1 (3.1)	0	1 (3.1)	0	0
Muscular weakness	1 (3.1)	1 (3.1)	0	0	0
Myopathy	1 (3.1)	0	0	1 (3.1)	0
Myositis	1 (3.1)	0	0	1 (3.1)	0
Neck pain	1 (3.1)	0	1 (3.1)	0	0
Synovitis	1 (3.1)	0	1 (3.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (9.4)	0	2 (6.3)	0	1 (3.1)
Glioblastoma multiforme	1 (3.1)	0	0	0	1 (3.1)
Myelodysplastic syndrome	1 (3.1)	0	1 (3.1)	0	0
Skin papilloma	1 (3.1)	0	1 (3.1)	0	0
Nervous system disorders					
-Total	21 (65.6)	5 (15.6)	9 (28.1)	6 (18.8)	1 (3.1)
Headache	15 (46.9)	5 (15.6)	6 (18.8)	4 (12.5)	0
Dizziness	4 (12.5)	4 (12.5)	0	0	0
Encephalopathy	2 (6.3)	1 (3.1)	0	1 (3.1)	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	2 (6.3)	0	0	2 (6.3)	0
Embolic stroke	1 (3.1)	0	0	0	1 (3.1)
Idiopathic intracranial hypertension	1 (3.1)	0	1 (3.1)	0	0
Myoclonus	1 (3.1)	1 (3.1)	0	0	0
Neuralgia	1 (3.1)	0	1 (3.1)	0	0
Peripheral sensory neuropathy	1 (3.1)	0	1 (3.1)	0	0
Peroneal nerve palsy	1 (3.1)	0	1 (3.1)	0	0
Somnolence	1 (3.1)	0	1 (3.1)	0	0
Visual field defect	1 (3.1)	0	1 (3.1)	0	0
Product issues					
-Total	1 (3.1)	1 (3.1)	0	0	0
Device occlusion	1 (3.1)	1 (3.1)	0	0	0
Psychiatric disorders					
-Total	10 (31.3)	2 (6.3)	5 (15.6)	3 (9.4)	0
Anxiety	5 (15.6)	1 (3.1)	3 (9.4)	1 (3.1)	0
Confusional state	2 (6.3)	0	2 (6.3)	0	0
Irritability	2 (6.3)	2 (6.3)	0	0	0
Mental status changes	2 (6.3)	1 (3.1)	0	1 (3.1)	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	1 (3.1)	0	1 (3.1)	0	0
Delirium	1 (3.1)	0	0	1 (3.1)	0
Depression	1 (3.1)	0	1 (3.1)	0	0
Hallucination	1 (3.1)	0	1 (3.1)	0	0
Insomnia	1 (3.1)	0	1 (3.1)	0	0
Listless	1 (3.1)	1 (3.1)	0	0	0
Renal and urinary disorders					
-Total	6 (18.8)	2 (6.3)	2 (6.3)	1 (3.1)	1 (3.1)
Acute kidney injury	3 (9.4)	2 (6.3)	0	0	1 (3.1)
Haematuria	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Calculus urinary	1 (3.1)	0	1 (3.1)	0	0
Dysuria	1 (3.1)	0	1 (3.1)	0	0
Nephrolithiasis	1 (3.1)	0	0	1 (3.1)	0
Oliguria	1 (3.1)	0	0	1 (3.1)	0
Urinary incontinence	1 (3.1)	1 (3.1)	0	0	0
Urinary retention	1 (3.1)	0	1 (3.1)	0	0
Reproductive system and breast disorders					

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Oedema genital	1 (3.1)	0	1 (3.1)	0	0
Ovarian failure	1 (3.1)	0	0	1 (3.1)	0
Scrotal pain	1 (3.1)	0	1 (3.1)	0	0
Vulvovaginal adhesion	1 (3.1)	1 (3.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	19 (59.4)	7 (21.9)	4 (12.5)	6 (18.8)	2 (6.3)
Cough	8 (25.0)	7 (21.9)	1 (3.1)	0	0
Epistaxis	7 (21.9)	3 (9.4)	1 (3.1)	3 (9.4)	0
Hypoxia	7 (21.9)	0	3 (9.4)	3 (9.4)	1 (3.1)
Pleural effusion	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Rhinitis allergic	4 (12.5)	4 (12.5)	0	0	0
Dyspnoea	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Oropharyngeal pain	3 (9.4)	3 (9.4)	0	0	0
Tachypnoea	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Atelectasis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Nasal congestion	2 (6.3)	2 (6.3)	0	0	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinorrhoea	2 (6.3)	2 (6.3)	0	0	0
Idiopathic pneumonia syndrome	1 (3.1)	0	0	0	1 (3.1)
Pulmonary mass	1 (3.1)	0	1 (3.1)	0	0
Pulmonary oedema	1 (3.1)	0	0	1 (3.1)	0
Wheezing	1 (3.1)	0	1 (3.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	16 (50.0)	9 (28.1)	5 (15.6)	2 (6.3)	0
Rash	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Petechiae	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Pruritus	3 (9.4)	3 (9.4)	0	0	0
Rash maculo-papular	3 (9.4)	2 (6.3)	0	1 (3.1)	0
Dry skin	2 (6.3)	2 (6.3)	0	0	0
Erythema	2 (6.3)	2 (6.3)	0	0	0
Hyperhidrosis	2 (6.3)	2 (6.3)	0	0	0
Ingrowing nail	2 (6.3)	0	2 (6.3)	0	0
Rash erythematous	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Rash papular	2 (6.3)	2 (6.3)	0	0	0

Prior SCT therapy: Yes

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash pruritic	2 (6.3)	2 (6.3)	0	0	0
Alopecia	1 (3.1)	1 (3.1)	0	0	0
Dermatitis acneiform	1 (3.1)	0	1 (3.1)	0	0
Dermatitis atopic	1 (3.1)	1 (3.1)	0	0	0
Macule	1 (3.1)	1 (3.1)	0	0	0
Night sweats	1 (3.1)	0	1 (3.1)	0	0
Rash follicular	1 (3.1)	1 (3.1)	0	0	0
Rash macular	1 (3.1)	0	0	1 (3.1)	0
Rash vesicular	1 (3.1)	1 (3.1)	0	0	0
Skin haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Skin irritation	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	17 (53.1)	3 (9.4)	3 (9.4)	8 (25.0)	3 (9.4)
Hypotension	10 (31.3)	1 (3.1)	0	6 (18.8)	3 (9.4)
Hypertension	8 (25.0)	2 (6.3)	4 (12.5)	2 (6.3)	0
Orthostatic hypotension	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Embolism	1 (3.1)	0	0	1 (3.1)	0
Flushing	1 (3.1)	1 (3.1)	0	0	0

Prior SCT therapy: Yes

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Phlebitis	1 (3.1)	0	1 (3.1)	0	0
Venous thrombosis limb	1 (3.1)	1 (3.1)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178l
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (93.0)	0	3 (7.0)	6 (14.0)	31 (72.1)
Blood and lymphatic system disorders					
-Total	33 (76.7)	1 (2.3)	1 (2.3)	16 (37.2)	15 (34.9)
Febrile neutropenia	20 (46.5)	0	0	19 (44.2)	1 (2.3)
Anaemia	19 (44.2)	1 (2.3)	3 (7.0)	14 (32.6)	1 (2.3)
Neutropenia	12 (27.9)	0	0	3 (7.0)	9 (20.9)
Thrombocytopenia	9 (20.9)	0	1 (2.3)	2 (4.7)	6 (14.0)
Disseminated intravascular coagulation	4 (9.3)	0	1 (2.3)	3 (7.0)	0
Lymphopenia	3 (7.0)	0	0	1 (2.3)	2 (4.7)
Pancytopenia	3 (7.0)	0	0	1 (2.3)	2 (4.7)
Coagulopathy	1 (2.3)	1 (2.3)	0	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Leukopenia	1 (2.3)	0	0	0	1 (2.3)
Lymphadenopathy	1 (2.3)	0	1 (2.3)	0	0
Cardiac disorders					
-Total	14 (32.6)	6 (14.0)	5 (11.6)	2 (4.7)	1 (2.3)
Tachycardia	9 (20.9)	5 (11.6)	3 (7.0)	1 (2.3)	0
Bradycardia	2 (4.7)	0	1 (2.3)	0	1 (2.3)
Left ventricular dysfunction	2 (4.7)	0	0	2 (4.7)	0
Pericardial effusion	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Sinus tachycardia	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Ventricular tachycardia	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Atrioventricular block second degree	1 (2.3)	1 (2.3)	0	0	0
Palpitations	1 (2.3)	1 (2.3)	0	0	0
Right ventricular dysfunction	1 (2.3)	0	0	1 (2.3)	0
Endocrine disorders					
-Total	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Adrenal insufficiency	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Eye disorders					
-Total	9 (20.9)	7 (16.3)	2 (4.7)	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Conjunctival haemorrhage	3 (7.0)	3 (7.0)	0	0	0
Periorbital oedema	3 (7.0)	3 (7.0)	0	0	0
Vision blurred	3 (7.0)	2 (4.7)	1 (2.3)	0	0
Retinal haemorrhage	2 (4.7)	2 (4.7)	0	0	0
Conjunctivitis allergic	1 (2.3)	1 (2.3)	0	0	0
Eye pain	1 (2.3)	1 (2.3)	0	0	0
Photophobia	1 (2.3)	0	1 (2.3)	0	0
Gastrointestinal disorders					
-Total	30 (69.8)	8 (18.6)	10 (23.3)	11 (25.6)	1 (2.3)
Nausea	18 (41.9)	3 (7.0)	10 (23.3)	5 (11.6)	0
Vomiting	17 (39.5)	8 (18.6)	7 (16.3)	2 (4.7)	0
Diarrhoea	14 (32.6)	8 (18.6)	4 (9.3)	2 (4.7)	0
Constipation	7 (16.3)	5 (11.6)	2 (4.7)	0	0
Abdominal pain	6 (14.0)	3 (7.0)	1 (2.3)	2 (4.7)	0
Abdominal pain upper	2 (4.7)	0	2 (4.7)	0	0
Dysphagia	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Haematochezia	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Oral pain	2 (4.7)	1 (2.3)	0	1 (2.3)	0

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancreatitis	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Abdominal discomfort	1 (2.3)	1 (2.3)	0	0	0
Abdominal pain lower	1 (2.3)	1 (2.3)	0	0	0
Anal fissure	1 (2.3)	0	1 (2.3)	0	0
Ascites	1 (2.3)	0	0	1 (2.3)	0
Colitis	1 (2.3)	1 (2.3)	0	0	0
Dry mouth	1 (2.3)	1 (2.3)	0	0	0
Dyspepsia	1 (2.3)	0	1 (2.3)	0	0
Enterocolitis	1 (2.3)	0	0	1 (2.3)	0
Flatulence	1 (2.3)	1 (2.3)	0	0	0
Haematemesis	1 (2.3)	0	1 (2.3)	0	0
Ileus	1 (2.3)	0	0	1 (2.3)	0
Intestinal obstruction	1 (2.3)	0	0	1 (2.3)	0
Pancreatic failure	1 (2.3)	0	1 (2.3)	0	0
Perianal erythema	1 (2.3)	0	1 (2.3)	0	0
Proctalgia	1 (2.3)	0	1 (2.3)	0	0
Stomatitis	1 (2.3)	0	0	0	1 (2.3)
Tooth socket haemorrhage	1 (2.3)	1 (2.3)	0	0	0

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	26 (60.5)	5 (11.6)	10 (23.3)	10 (23.3)	1 (2.3)
Pyrexia	17 (39.5)	1 (2.3)	9 (20.9)	6 (14.0)	1 (2.3)
Fatigue	9 (20.9)	6 (14.0)	2 (4.7)	1 (2.3)	0
Chills	7 (16.3)	5 (11.6)	2 (4.7)	0	0
Catheter site pain	5 (11.6)	1 (2.3)	4 (9.3)	0	0
Pain	3 (7.0)	0	1 (2.3)	2 (4.7)	0
Malaise	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Asthenia	1 (2.3)	1 (2.3)	0	0	0
Face oedema	1 (2.3)	0	0	1 (2.3)	0
Generalised oedema	1 (2.3)	0	1 (2.3)	0	0
Localised oedema	1 (2.3)	0	0	1 (2.3)	0
Mucosal haemorrhage	1 (2.3)	0	1 (2.3)	0	0
Multiple organ dysfunction syndrome	1 (2.3)	0	0	1 (2.3)	0
Non-cardiac chest pain	1 (2.3)	0	0	1 (2.3)	0
Oedema peripheral	1 (2.3)	0	0	1 (2.3)	0
Physical deconditioning	1 (2.3)	0	0	1 (2.3)	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatobiliary disorders					
-Total	6 (14.0)	2 (4.7)	3 (7.0)	1 (2.3)	0
Hyperbilirubinaemia	3 (7.0)	0	2 (4.7)	1 (2.3)	0
Gallbladder enlargement	1 (2.3)	1 (2.3)	0	0	0
Hepatomegaly	1 (2.3)	0	1 (2.3)	0	0
Hepatosplenomegaly	1 (2.3)	1 (2.3)	0	0	0
Immune system disorders					
-Total	34 (79.1)	1 (2.3)	18 (41.9)	6 (14.0)	9 (20.9)
Cytokine release syndrome	30 (69.8)	3 (7.0)	14 (32.6)	4 (9.3)	9 (20.9)
Hypogammaglobulinaemia	19 (44.2)	1 (2.3)	14 (32.6)	4 (9.3)	0
Seasonal allergy	2 (4.7)	2 (4.7)	0	0	0
Chronic graft versus host disease	1 (2.3)	0	1 (2.3)	0	0
Drug hypersensitivity	1 (2.3)	0	1 (2.3)	0	0
Graft versus host disease	1 (2.3)	0	1 (2.3)	0	0
Immunodeficiency	1 (2.3)	0	1 (2.3)	0	0
Immunodeficiency common variable	1 (2.3)	0	1 (2.3)	0	0
Infections and infestations					
-Total	28 (65.1)	2 (4.7)	12 (27.9)	9 (20.9)	5 (11.6)

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastroenteritis	5 (11.6)	1 (2.3)	3 (7.0)	1 (2.3)	0
Pneumonia	5 (11.6)	0	3 (7.0)	1 (2.3)	1 (2.3)
Upper respiratory tract infection	5 (11.6)	1 (2.3)	4 (9.3)	0	0
Clostridium difficile colitis	4 (9.3)	1 (2.3)	1 (2.3)	2 (4.7)	0
Rhinovirus infection	4 (9.3)	4 (9.3)	0	0	0
Viral infection	3 (7.0)	2 (4.7)	1 (2.3)	0	0
Viral upper respiratory tract infection	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)	0
Clostridium difficile infection	2 (4.7)	0	2 (4.7)	0	0
Influenza	2 (4.7)	0	2 (4.7)	0	0
Parainfluenzae virus infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Respiratory syncytial virus infection	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Sinusitis	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Staphylococcal infection	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Bacterial sepsis	1 (2.3)	0	0	0	1 (2.3)
Bronchopulmonary aspergillosis	1 (2.3)	0	0	1 (2.3)	0
Candida sepsis	1 (2.3)	0	0	0	1 (2.3)
Catheter site infection	1 (2.3)	0	0	1 (2.3)	0
Cellulitis	1 (2.3)	0	0	1 (2.3)	0

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	1 (2.3)	0	0	1 (2.3)	0
Device related infection	1 (2.3)	0	0	1 (2.3)	0
Ear infection	1 (2.3)	1 (2.3)	0	0	0
Escherichia bacteraemia	1 (2.3)	0	0	1 (2.3)	0
Escherichia urinary tract infection	1 (2.3)	0	1 (2.3)	0	0
Folliculitis	1 (2.3)	0	1 (2.3)	0	0
Gastroenteritis viral	1 (2.3)	1 (2.3)	0	0	0
Gingivitis	1 (2.3)	1 (2.3)	0	0	0
Herpes zoster	1 (2.3)	0	0	1 (2.3)	0
Human polyomavirus infection	1 (2.3)	0	0	0	1 (2.3)
Meningitis aseptic	1 (2.3)	0	1 (2.3)	0	0
Metapneumovirus infection	1 (2.3)	0	1 (2.3)	0	0
Molluscum contagiosum	1 (2.3)	1 (2.3)	0	0	0
Oral herpes	1 (2.3)	0	0	1 (2.3)	0
Orchitis	1 (2.3)	1 (2.3)	0	0	0
Otitis externa	1 (2.3)	0	1 (2.3)	0	0
Otitis media	1 (2.3)	0	1 (2.3)	0	0
Paronychia	1 (2.3)	1 (2.3)	0	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pharyngitis	1 (2.3)	0	1 (2.3)	0	0
Rash pustular	1 (2.3)	0	1 (2.3)	0	0
Respiratory tract infection	1 (2.3)	0	0	0	1 (2.3)
Skin infection	1 (2.3)	0	1 (2.3)	0	0
Streptococcal infection	1 (2.3)	0	1 (2.3)	0	0
Subcutaneous abscess	1 (2.3)	0	1 (2.3)	0	0
Tinea capitis	1 (2.3)	1 (2.3)	0	0	0
Urinary tract infection	1 (2.3)	0	1 (2.3)	0	0
Urinary tract infection enterococcal	1 (2.3)	0	0	1 (2.3)	0
Vulvovaginal mycotic infection	1 (2.3)	0	1 (2.3)	0	0
Injury, poisoning and procedural complications					
-Total	13 (30.2)	7 (16.3)	4 (9.3)	2 (4.7)	0
Procedural pain	3 (7.0)	2 (4.7)	0	1 (2.3)	0
Infusion related reaction	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Arthropod bite	1 (2.3)	1 (2.3)	0	0	0
Contusion	1 (2.3)	1 (2.3)	0	0	0
Incision site pain	1 (2.3)	1 (2.3)	0	0	0

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Post procedural haemorrhage	1 (2.3)	1 (2.3)	0	0	0
Procedural complication	1 (2.3)	1 (2.3)	0	0	0
Procedural nausea	1 (2.3)	0	1 (2.3)	0	0
Radiation skin injury	1 (2.3)	0	1 (2.3)	0	0
Radius fracture	1 (2.3)	0	1 (2.3)	0	0
Skin abrasion	1 (2.3)	1 (2.3)	0	0	0
Stoma site irritation	1 (2.3)	1 (2.3)	0	0	0
Subdural haemorrhage	1 (2.3)	1 (2.3)	0	0	0
Sunburn	1 (2.3)	1 (2.3)	0	0	0
Tibia fracture	1 (2.3)	0	1 (2.3)	0	0
Tracheal haemorrhage	1 (2.3)	0	0	1 (2.3)	0
Transfusion reaction	1 (2.3)	0	1 (2.3)	0	0
Wound	1 (2.3)	1 (2.3)	0	0	0
Investigations					
-Total	33 (76.7)	0	1 (2.3)	9 (20.9)	23 (53.5)
White blood cell count decreased	24 (55.8)	3 (7.0)	0	4 (9.3)	17 (39.5)
Neutrophil count decreased	15 (34.9)	0	1 (2.3)	3 (7.0)	11 (25.6)
Lymphocyte count decreased	10 (23.3)	1 (2.3)	1 (2.3)	4 (9.3)	4 (9.3)

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	9 (20.9)	0	2 (4.7)	7 (16.3)	0
Platelet count decreased	9 (20.9)	1 (2.3)	1 (2.3)	2 (4.7)	5 (11.6)
Aspartate aminotransferase increased	8 (18.6)	0	3 (7.0)	3 (7.0)	2 (4.7)
Blood fibrinogen decreased	4 (9.3)	0	1 (2.3)	2 (4.7)	1 (2.3)
International normalised ratio increased	4 (9.3)	3 (7.0)	0	1 (2.3)	0
Activated partial thromboplastin time prolonged	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Blood bilirubin increased	3 (7.0)	0	1 (2.3)	2 (4.7)	0
Blood creatinine increased	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)	0
C-reactive protein increased	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)	0
Prothrombin time prolonged	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)	0
Weight decreased	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Blood lactate dehydrogenase increased	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Blood magnesium decreased	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Blood phosphorus increased	2 (4.7)	2 (4.7)	0	0	0
Blood urea increased	2 (4.7)	1 (2.3)	0	1 (2.3)	0

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lipase increased	2 (4.7)	0	0	0	2 (4.7)
Transaminases increased	2 (4.7)	2 (4.7)	0	0	0
Blood alkaline phosphatase increased	1 (2.3)	1 (2.3)	0	0	0
Blood immunoglobulin g decreased	1 (2.3)	0	1 (2.3)	0	0
Blood immunoglobulin m decreased	1 (2.3)	1 (2.3)	0	0	0
Blood lactic acid increased	1 (2.3)	0	1 (2.3)	0	0
Blood phosphorus decreased	1 (2.3)	1 (2.3)	0	0	0
Blood sodium increased	1 (2.3)	0	1 (2.3)	0	0
Blood uric acid increased	1 (2.3)	1 (2.3)	0	0	0
Cardiac murmur	1 (2.3)	1 (2.3)	0	0	0
Computerised tomogram thorax abnormal	1 (2.3)	0	0	1 (2.3)	0
Electrocardiogram qt prolonged	1 (2.3)	0	0	1 (2.3)	0
Fibrin d dimer increased	1 (2.3)	1 (2.3)	0	0	0
Oxygen saturation decreased	1 (2.3)	1 (2.3)	0	0	0
Protein total decreased	1 (2.3)	0	0	1 (2.3)	0
Serum ferritin increased	1 (2.3)	0	1 (2.3)	0	0
Metabolism and nutrition disorders					

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	27 (62.8)	3 (7.0)	4 (9.3)	16 (37.2)	4 (9.3)
Decreased appetite	15 (34.9)	3 (7.0)	5 (11.6)	7 (16.3)	0
Hypokalaemia	12 (27.9)	3 (7.0)	3 (7.0)	5 (11.6)	1 (2.3)
Hypophosphataemia	7 (16.3)	2 (4.7)	0	4 (9.3)	1 (2.3)
Hypernatraemia	5 (11.6)	1 (2.3)	2 (4.7)	0	2 (4.7)
Fluid overload	4 (9.3)	0	3 (7.0)	1 (2.3)	0
Hyperglycaemia	3 (7.0)	0	1 (2.3)	2 (4.7)	0
Hypoalbuminaemia	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)	0
Tumour lysis syndrome	3 (7.0)	0	0	3 (7.0)	0
Acidosis	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Dehydration	2 (4.7)	0	0	2 (4.7)	0
Hyperkalaemia	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Hypertriglyceridaemia	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Hypocalcaemia	2 (4.7)	1 (2.3)	0	0	1 (2.3)
Hypomagnesaemia	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Malnutrition	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Hyperalbuminaemia	1 (2.3)	1 (2.3)	0	0	0
Hypercalcaemia	1 (2.3)	1 (2.3)	0	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperchloraemia	1 (2.3)	1 (2.3)	0	0	0
Hypermagnesaemia	1 (2.3)	1 (2.3)	0	0	0
Hyperphosphataemia	1 (2.3)	1 (2.3)	0	0	0
Hyperuricaemia	1 (2.3)	0	0	0	1 (2.3)
Iron overload	1 (2.3)	0	0	1 (2.3)	0
Metabolic acidosis	1 (2.3)	0	1 (2.3)	0	0
Metabolic alkalosis	1 (2.3)	1 (2.3)	0	0	0
Vitamin d deficiency	1 (2.3)	1 (2.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	18 (41.9)	6 (14.0)	7 (16.3)	5 (11.6)	0
Pain in extremity	8 (18.6)	4 (9.3)	2 (4.7)	2 (4.7)	0
Arthralgia	4 (9.3)	1 (2.3)	1 (2.3)	2 (4.7)	0
Back pain	2 (4.7)	0	0	2 (4.7)	0
Muscular weakness	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Pain in jaw	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Bone pain	1 (2.3)	0	0	1 (2.3)	0
Limb discomfort	1 (2.3)	1 (2.3)	0	0	0

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal chest pain	1 (2.3)	1 (2.3)	0	0	0
Musculoskeletal pain	1 (2.3)	1 (2.3)	0	0	0
Neck pain	1 (2.3)	0	1 (2.3)	0	0
Osteonecrosis	1 (2.3)	0	1 (2.3)	0	0
Osteopenia	1 (2.3)	0	1 (2.3)	0	0
Toe walking	1 (2.3)	1 (2.3)	0	0	0
Nervous system disorders					
-Total	22 (51.2)	12 (27.9)	8 (18.6)	1 (2.3)	1 (2.3)
Headache	14 (32.6)	10 (23.3)	3 (7.0)	1 (2.3)	0
Seizure	3 (7.0)	0	2 (4.7)	0	1 (2.3)
Dizziness	2 (4.7)	2 (4.7)	0	0	0
Dysarthria	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Encephalopathy	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Neuropathy peripheral	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Peroneal nerve palsy	2 (4.7)	2 (4.7)	0	0	0
Tremor	2 (4.7)	2 (4.7)	0	0	0
Asterixis	1 (2.3)	1 (2.3)	0	0	0
Ataxia	1 (2.3)	0	1 (2.3)	0	0

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Depressed level of consciousness	1 (2.3)	1 (2.3)	0	0	0
Disturbance in attention	1 (2.3)	1 (2.3)	0	0	0
Dysgeusia	1 (2.3)	1 (2.3)	0	0	0
Hyporesponsive to stimuli	1 (2.3)	0	0	1 (2.3)	0
Hypotonia	1 (2.3)	0	1 (2.3)	0	0
Migraine	1 (2.3)	0	1 (2.3)	0	0
Pleocytosis	1 (2.3)	1 (2.3)	0	0	0
Somnolence	1 (2.3)	1 (2.3)	0	0	0
Product issues					
-Total	1 (2.3)	1 (2.3)	0	0	0
Device occlusion	1 (2.3)	1 (2.3)	0	0	0
Psychiatric disorders					
-Total	16 (37.2)	6 (14.0)	9 (20.9)	1 (2.3)	0
Confusional state	5 (11.6)	3 (7.0)	2 (4.7)	0	0
Anxiety	4 (9.3)	2 (4.7)	2 (4.7)	0	0
Delirium	4 (9.3)	2 (4.7)	2 (4.7)	0	0
Depression	3 (7.0)	2 (4.7)	1 (2.3)	0	0
Insomnia	3 (7.0)	0	3 (7.0)	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Agitation	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Mental status changes	2 (4.7)	2 (4.7)	0	0	0
Adjustment disorder	1 (2.3)	0	1 (2.3)	0	0
Hallucination	1 (2.3)	1 (2.3)	0	0	0
Irritability	1 (2.3)	1 (2.3)	0	0	0
Panic attack	1 (2.3)	0	1 (2.3)	0	0
Sleep disorder	1 (2.3)	0	1 (2.3)	0	0
Suicidal ideation	1 (2.3)	1 (2.3)	0	0	0
Renal and urinary disorders					
-Total	13 (30.2)	1 (2.3)	2 (4.7)	6 (14.0)	4 (9.3)
Acute kidney injury	9 (20.9)	0	1 (2.3)	5 (11.6)	3 (7.0)
Haematuria	3 (7.0)	0	1 (2.3)	1 (2.3)	1 (2.3)
Dysuria	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Oliguria	2 (4.7)	0	0	2 (4.7)	0
Cystitis haemorrhagic	1 (2.3)	0	0	0	1 (2.3)
Pollakiuria	1 (2.3)	1 (2.3)	0	0	0
Renal failure	1 (2.3)	0	0	0	1 (2.3)
Renal impairment	1 (2.3)	0	0	1 (2.3)	0

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	2 (4.7)	1 (2.3)	0	1 (2.3)	0
Vaginal haemorrhage	1 (2.3)	0	0	1 (2.3)	0
Vulvovaginal adhesion	1 (2.3)	1 (2.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	25 (58.1)	6 (14.0)	5 (11.6)	4 (9.3)	10 (23.3)
Cough	8 (18.6)	6 (14.0)	1 (2.3)	1 (2.3)	0
Hypoxia	8 (18.6)	0	0	6 (14.0)	2 (4.7)
Pulmonary oedema	8 (18.6)	1 (2.3)	0	3 (7.0)	4 (9.3)
Epistaxis	7 (16.3)	1 (2.3)	3 (7.0)	2 (4.7)	1 (2.3)
Pleural effusion	6 (14.0)	0	4 (9.3)	2 (4.7)	0
Tachypnoea	5 (11.6)	2 (4.7)	1 (2.3)	2 (4.7)	0
Nasal congestion	4 (9.3)	4 (9.3)	0	0	0
Oropharyngeal pain	4 (9.3)	1 (2.3)	2 (4.7)	1 (2.3)	0
Respiratory failure	4 (9.3)	0	0	0	4 (9.3)
Rhinorrhoea	4 (9.3)	3 (7.0)	1 (2.3)	0	0
Haemoptysis	3 (7.0)	1 (2.3)	0	1 (2.3)	1 (2.3)

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	2 (4.7)	0	0	1 (2.3)	1 (2.3)
Respiratory distress	2 (4.7)	0	0	0	2 (4.7)
Acute respiratory failure	1 (2.3)	0	0	0	1 (2.3)
Aspiration	1 (2.3)	0	0	0	1 (2.3)
Dysphonia	1 (2.3)	1 (2.3)	0	0	0
Interstitial lung disease	1 (2.3)	0	0	0	1 (2.3)
Nasal discomfort	1 (2.3)	1 (2.3)	0	0	0
Oropharyngeal plaque	1 (2.3)	1 (2.3)	0	0	0
Pharyngeal erythema	1 (2.3)	1 (2.3)	0	0	0
Pharyngeal lesion	1 (2.3)	0	0	1 (2.3)	0
Pharyngeal ulceration	1 (2.3)	0	1 (2.3)	0	0
Pulmonary alveolar haemorrhage	1 (2.3)	0	0	0	1 (2.3)
Pulmonary hypertension	1 (2.3)	0	0	1 (2.3)	0
Respiratory depression	1 (2.3)	0	1 (2.3)	0	0
Rhinitis allergic	1 (2.3)	0	1 (2.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	21 (48.8)	12 (27.9)	7 (16.3)	2 (4.7)	0

Prior SCT therapy: No

	All patients N=43				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	4 (9.3)	2 (4.7)	2 (4.7)	0	0
Alopecia	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Dry skin	3 (7.0)	3 (7.0)	0	0	0
Erythema	3 (7.0)	3 (7.0)	0	0	0
Rash erythematous	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Hyperhidrosis	2 (4.7)	2 (4.7)	0	0	0
Papule	2 (4.7)	2 (4.7)	0	0	0
Pruritus	2 (4.7)	2 (4.7)	0	0	0
Rash maculo-papular	2 (4.7)	1 (2.3)	1 (2.3)	0	0
Acne	1 (2.3)	1 (2.3)	0	0	0
Cold sweat	1 (2.3)	1 (2.3)	0	0	0
Dermatitis	1 (2.3)	1 (2.3)	0	0	0
Dermatitis acneiform	1 (2.3)	0	0	1 (2.3)	0
Dermatitis diaper	1 (2.3)	1 (2.3)	0	0	0
Ecchymosis	1 (2.3)	0	0	1 (2.3)	0
Eczema	1 (2.3)	1 (2.3)	0	0	0
Ingrowing nail	1 (2.3)	1 (2.3)	0	0	0
Keloid scar	1 (2.3)	0	1 (2.3)	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Livedo reticularis	1 (2.3)	1 (2.3)	0	0	0
Macule	1 (2.3)	1 (2.3)	0	0	0
Night sweats	1 (2.3)	1 (2.3)	0	0	0
Petechiae	1 (2.3)	1 (2.3)	0	0	0
Pruritus generalised	1 (2.3)	1 (2.3)	0	0	0
Rash macular	1 (2.3)	1 (2.3)	0	0	0
Rash papular	1 (2.3)	1 (2.3)	0	0	0
Skin exfoliation	1 (2.3)	1 (2.3)	0	0	0
Skin fissures	1 (2.3)	1 (2.3)	0	0	0
Skin ulcer	1 (2.3)	1 (2.3)	0	0	0
Vascular disorders					
-Total	17 (39.5)	0	3 (7.0)	6 (14.0)	8 (18.6)
Hypotension	14 (32.6)	0	0	6 (14.0)	8 (18.6)
Hypertension	8 (18.6)	2 (4.7)	6 (14.0)	0	0
Capillary leak syndrome	1 (2.3)	0	0	0	1 (2.3)
Flushing	1 (2.3)	1 (2.3)	0	0	0
Haematoma	1 (2.3)	0	1 (2.3)	0	0
Hot flush	1 (2.3)	1 (2.3)	0	0	0

Prior SCT therapy: No

Primary system organ class Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Secondary hypertension	1 (2.3)	0	1 (2.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178m
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (88.9)	0	1 (5.6)	3 (16.7)	12 (66.7)
Blood and lymphatic system disorders					
-Total	13 (72.2)	0	1 (5.6)	8 (44.4)	4 (22.2)
Febrile neutropenia	10 (55.6)	0	0	10 (55.6)	0
Anaemia	6 (33.3)	1 (5.6)	1 (5.6)	4 (22.2)	0
Neutropenia	3 (16.7)	0	0	1 (5.6)	2 (11.1)
Thrombocytopenia	3 (16.7)	0	1 (5.6)	0	2 (11.1)
Pancytopenia	1 (5.6)	0	0	0	1 (5.6)
Cardiac disorders					
-Total	5 (27.8)	5 (27.8)	0	0	0
Tachycardia	2 (11.1)	2 (11.1)	0	0	0
Atrioventricular block second degree	1 (5.6)	1 (5.6)	0	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bradycardia	1 (5.6)	1 (5.6)	0	0	0
Sinus tachycardia	1 (5.6)	1 (5.6)	0	0	0
Eye disorders					
-Total	4 (22.2)	4 (22.2)	0	0	0
Conjunctivitis allergic	1 (5.6)	1 (5.6)	0	0	0
Dry eye	1 (5.6)	1 (5.6)	0	0	0
Ocular hyperaemia	1 (5.6)	1 (5.6)	0	0	0
Retinal haemorrhage	1 (5.6)	1 (5.6)	0	0	0
Gastrointestinal disorders					
-Total	11 (61.1)	1 (5.6)	5 (27.8)	5 (27.8)	0
Nausea	7 (38.9)	0	5 (27.8)	2 (11.1)	0
Vomiting	5 (27.8)	2 (11.1)	2 (11.1)	1 (5.6)	0
Diarrhoea	4 (22.2)	2 (11.1)	1 (5.6)	1 (5.6)	0
Constipation	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Abdominal pain	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Abdominal pain upper	1 (5.6)	0	1 (5.6)	0	0
Ascites	1 (5.6)	0	0	1 (5.6)	0
Dyspepsia	1 (5.6)	0	1 (5.6)	0	0

Eligibility for SCT: Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterocolitis	1 (5.6)	0	0	1 (5.6)	0
Gastrointestinal haemorrhage	1 (5.6)	1 (5.6)	0	0	0
Intestinal obstruction	1 (5.6)	0	0	1 (5.6)	0
Pancreatic failure	1 (5.6)	0	1 (5.6)	0	0
Pancreatitis	1 (5.6)	0	0	1 (5.6)	0
Stomatitis	1 (5.6)	0	0	1 (5.6)	0
Tooth socket haemorrhage	1 (5.6)	1 (5.6)	0	0	0
General disorders and administration site conditions					
-Total	7 (38.9)	2 (11.1)	3 (16.7)	2 (11.1)	0
Pyrexia	4 (22.2)	0	2 (11.1)	2 (11.1)	0
Catheter site pain	2 (11.1)	0	2 (11.1)	0	0
Fatigue	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Chills	1 (5.6)	1 (5.6)	0	0	0
Influenza like illness	1 (5.6)	1 (5.6)	0	0	0
Malaise	1 (5.6)	1 (5.6)	0	0	0
Pain	1 (5.6)	0	0	1 (5.6)	0
Hepatobiliary disorders					

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (5.6)	1 (5.6)	0	0	0
Hepatosplenomegaly	1 (5.6)	1 (5.6)	0	0	0
Immune system disorders					
-Total	14 (77.8)	0	10 (55.6)	3 (16.7)	1 (5.6)
Cytokine release syndrome	13 (72.2)	0	10 (55.6)	2 (11.1)	1 (5.6)
Hypogammaglobulinaemia	8 (44.4)	1 (5.6)	6 (33.3)	1 (5.6)	0
Immunodeficiency common variable	1 (5.6)	0	1 (5.6)	0	0
Infections and infestations					
-Total	12 (66.7)	0	3 (16.7)	6 (33.3)	3 (16.7)
Viral upper respiratory tract infection	3 (16.7)	2 (11.1)	0	1 (5.6)	0
Escherichia urinary tract infection	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Influenza	2 (11.1)	0	2 (11.1)	0	0
Pneumonia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Urinary tract infection	2 (11.1)	0	2 (11.1)	0	0
Bacterial sepsis	1 (5.6)	0	0	0	1 (5.6)
Bronchopulmonary aspergillosis	1 (5.6)	0	0	1 (5.6)	0
Catheter site infection	1 (5.6)	0	0	1 (5.6)	0
Clostridium difficile colitis	1 (5.6)	0	0	1 (5.6)	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile infection	1 (5.6)	0	1 (5.6)	0	0
Conjunctivitis	1 (5.6)	0	1 (5.6)	0	0
Corona virus infection	1 (5.6)	0	0	1 (5.6)	0
Cytomegalovirus infection	1 (5.6)	1 (5.6)	0	0	0
Device related infection	1 (5.6)	0	0	1 (5.6)	0
Folliculitis	1 (5.6)	0	1 (5.6)	0	0
Fungal skin infection	1 (5.6)	1 (5.6)	0	0	0
Gastroenteritis	1 (5.6)	0	1 (5.6)	0	0
Gastroenteritis viral	1 (5.6)	1 (5.6)	0	0	0
Molluscum contagiosum	1 (5.6)	1 (5.6)	0	0	0
Otitis externa	1 (5.6)	0	1 (5.6)	0	0
Parainfluenzae virus infection	1 (5.6)	0	0	1 (5.6)	0
Paronychia	1 (5.6)	1 (5.6)	0	0	0
Respiratory syncytial virus infection	1 (5.6)	0	0	1 (5.6)	0
Respiratory tract infection	1 (5.6)	0	0	0	1 (5.6)
Rhinovirus infection	1 (5.6)	1 (5.6)	0	0	0
Staphylococcal infection	1 (5.6)	1 (5.6)	0	0	0
Subcutaneous abscess	1 (5.6)	0	1 (5.6)	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urinary tract infection enterococcal	1 (5.6)	0	0	1 (5.6)	0
Viral infection	1 (5.6)	0	1 (5.6)	0	0
Injury, poisoning and procedural complications					
-Total	5 (27.8)	2 (11.1)	3 (16.7)	0	0
Procedural pain	2 (11.1)	2 (11.1)	0	0	0
Radiation skin injury	2 (11.1)	0	2 (11.1)	0	0
Infusion related reaction	1 (5.6)	1 (5.6)	0	0	0
Skin abrasion	1 (5.6)	1 (5.6)	0	0	0
Skin laceration	1 (5.6)	0	1 (5.6)	0	0
Transfusion reaction	1 (5.6)	0	1 (5.6)	0	0
Investigations					
-Total	13 (72.2)	0	1 (5.6)	2 (11.1)	10 (55.6)
White blood cell count decreased	12 (66.7)	2 (11.1)	0	2 (11.1)	8 (44.4)
Neutrophil count decreased	8 (44.4)	1 (5.6)	0	2 (11.1)	5 (27.8)
Lymphocyte count decreased	6 (33.3)	1 (5.6)	1 (5.6)	2 (11.1)	2 (11.1)
Platelet count decreased	4 (22.2)	1 (5.6)	0	0	3 (16.7)
Blood bilirubin increased	3 (16.7)	1 (5.6)	1 (5.6)	1 (5.6)	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Alanine aminotransferase increased	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Aspartate aminotransferase increased	1 (5.6)	0	1 (5.6)	0	0
Blood creatinine increased	1 (5.6)	1 (5.6)	0	0	0
Blood fibrinogen decreased	1 (5.6)	0	0	1 (5.6)	0
Blood immunoglobulin a decreased	1 (5.6)	1 (5.6)	0	0	0
Blood immunoglobulin g decreased	1 (5.6)	0	1 (5.6)	0	0
Blood immunoglobulin m decreased	1 (5.6)	1 (5.6)	0	0	0
Blood sodium increased	1 (5.6)	0	1 (5.6)	0	0
Blood urea increased	1 (5.6)	1 (5.6)	0	0	0
C-reactive protein increased	1 (5.6)	0	0	1 (5.6)	0
Fibrin d dimer increased	1 (5.6)	1 (5.6)	0	0	0
International normalised ratio increased	1 (5.6)	1 (5.6)	0	0	0
Lipase increased	1 (5.6)	0	0	0	1 (5.6)
Oxygen saturation decreased	1 (5.6)	1 (5.6)	0	0	0
Prothrombin time prolonged	1 (5.6)	1 (5.6)	0	0	0
Serum ferritin increased	1 (5.6)	0	1 (5.6)	0	0
Weight decreased	1 (5.6)	1 (5.6)	0	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders					
-Total	9 (50.0)	2 (11.1)	1 (5.6)	4 (22.2)	2 (11.1)
Decreased appetite	7 (38.9)	2 (11.1)	3 (16.7)	2 (11.1)	0
Hypokalaemia	5 (27.8)	2 (11.1)	1 (5.6)	2 (11.1)	0
Hyperphosphataemia	2 (11.1)	2 (11.1)	0	0	0
Hypomagnesaemia	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Hypophosphataemia	2 (11.1)	1 (5.6)	0	0	1 (5.6)
Tumour lysis syndrome	2 (11.1)	0	0	2 (11.1)	0
Dehydration	1 (5.6)	0	0	1 (5.6)	0
Fluid overload	1 (5.6)	0	1 (5.6)	0	0
Hyperglycaemia	1 (5.6)	0	0	1 (5.6)	0
Hyperkalaemia	1 (5.6)	0	1 (5.6)	0	0
Hypertriglyceridaemia	1 (5.6)	1 (5.6)	0	0	0
Hyperuricaemia	1 (5.6)	0	0	0	1 (5.6)
Hypoalbuminaemia	1 (5.6)	0	0	1 (5.6)	0
Hypocalcaemia	1 (5.6)	0	0	0	1 (5.6)
Iron overload	1 (5.6)	0	0	1 (5.6)	0
Malnutrition	1 (5.6)	0	1 (5.6)	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal and connective tissue disorders					
-Total	9 (50.0)	6 (33.3)	3 (16.7)	0	0
Pain in extremity	4 (22.2)	3 (16.7)	1 (5.6)	0	0
Arthralgia	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Muscular weakness	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Musculoskeletal chest pain	1 (5.6)	1 (5.6)	0	0	0
Pain in jaw	1 (5.6)	0	1 (5.6)	0	0
Toe walking	1 (5.6)	1 (5.6)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (5.6)	0	1 (5.6)	0	0
Myelodysplastic syndrome	1 (5.6)	0	1 (5.6)	0	0
Nervous system disorders					
-Total	6 (33.3)	3 (16.7)	3 (16.7)	0	0
Headache	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Depressed level of consciousness	1 (5.6)	1 (5.6)	0	0	0
Dizziness	1 (5.6)	1 (5.6)	0	0	0
Dysarthria	1 (5.6)	0	1 (5.6)	0	0

Eligibility for SCT: Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Migraine	1 (5.6)	0	1 (5.6)	0	0
Neuropathy peripheral	1 (5.6)	1 (5.6)	0	0	0
Peroneal nerve palsy	1 (5.6)	1 (5.6)	0	0	0
Somnolence	1 (5.6)	1 (5.6)	0	0	0
Psychiatric disorders					
-Total	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Confusional state	1 (5.6)	0	1 (5.6)	0	0
Depression	1 (5.6)	1 (5.6)	0	0	0
Panic attack	1 (5.6)	0	1 (5.6)	0	0
Renal and urinary disorders					
-Total	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Acute kidney injury	1 (5.6)	0	0	1 (5.6)	0
Dysuria	1 (5.6)	1 (5.6)	0	0	0
Reproductive system and breast disorders					
-Total	3 (16.7)	1 (5.6)	0	2 (11.1)	0
Ovarian failure	1 (5.6)	0	0	1 (5.6)	0
Vaginal haemorrhage	1 (5.6)	0	0	1 (5.6)	0

Eligibility for SCT: Yes

	All patients N=18				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal adhesion	1 (5.6)	1 (5.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (61.1)	3 (16.7)	5 (27.8)	1 (5.6)	2 (11.1)
Cough	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Epistaxis	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Hypoxia	3 (16.7)	0	1 (5.6)	2 (11.1)	0
Nasal congestion	3 (16.7)	3 (16.7)	0	0	0
Pleural effusion	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Rhinorrhoea	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Aspiration	1 (5.6)	0	0	0	1 (5.6)
Oropharyngeal pain	1 (5.6)	1 (5.6)	0	0	0
Oropharyngeal plaque	1 (5.6)	1 (5.6)	0	0	0
Pulmonary oedema	1 (5.6)	0	0	1 (5.6)	0
Respiratory failure	1 (5.6)	0	0	0	1 (5.6)
Rhinitis allergic	1 (5.6)	0	1 (5.6)	0	0
Tachypnoea	1 (5.6)	1 (5.6)	0	0	0
Skin and subcutaneous tissue disorders					

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	9 (50.0)	6 (33.3)	2 (11.1)	1 (5.6)	0
Rash erythematous	2 (11.1)	2 (11.1)	0	0	0
Alopecia	1 (5.6)	0	1 (5.6)	0	0
Dermatitis acneiform	1 (5.6)	0	0	1 (5.6)	0
Dermatitis diaper	1 (5.6)	1 (5.6)	0	0	0
Dry skin	1 (5.6)	1 (5.6)	0	0	0
Erythema	1 (5.6)	1 (5.6)	0	0	0
Hyperhidrosis	1 (5.6)	1 (5.6)	0	0	0
Keloid scar	1 (5.6)	0	1 (5.6)	0	0
Macule	1 (5.6)	1 (5.6)	0	0	0
Papule	1 (5.6)	1 (5.6)	0	0	0
Petechiae	1 (5.6)	1 (5.6)	0	0	0
Pruritus	1 (5.6)	1 (5.6)	0	0	0
Rash	1 (5.6)	1 (5.6)	0	0	0
Rash macular	1 (5.6)	1 (5.6)	0	0	0
Rash maculo-papular	1 (5.6)	1 (5.6)	0	0	0
Rash papular	1 (5.6)	1 (5.6)	0	0	0
Rash pruritic	1 (5.6)	1 (5.6)	0	0	0

Eligibility for SCT: Yes

Primary system organ class Preferred term	All patients N=18 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	7 (38.9)	1 (5.6)	3 (16.7)	2 (11.1)	1 (5.6)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Hypotension	3 (16.7)	0	0	2 (11.1)	1 (5.6)
Orthostatic hypotension	1 (5.6)	0	1 (5.6)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178m
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (98.2)	0	2 (3.5)	9 (15.8)	45 (78.9)
Blood and lymphatic system disorders					
-Total	48 (84.2)	1 (1.8)	1 (1.8)	27 (47.4)	19 (33.3)
Anaemia	29 (50.9)	1 (1.8)	5 (8.8)	22 (38.6)	1 (1.8)
Febrile neutropenia	26 (45.6)	0	0	25 (43.9)	1 (1.8)
Neutropenia	13 (22.8)	0	0	3 (5.3)	10 (17.5)
Thrombocytopenia	12 (21.1)	0	0	5 (8.8)	7 (12.3)
Disseminated intravascular coagulation	6 (10.5)	0	2 (3.5)	3 (5.3)	1 (1.8)
Lymphopenia	6 (10.5)	0	2 (3.5)	1 (1.8)	3 (5.3)
Pancytopenia	3 (5.3)	0	0	1 (1.8)	2 (3.5)
Coagulopathy	2 (3.5)	1 (1.8)	0	1 (1.8)	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eosinophilia	1 (1.8)	0	0	1 (1.8)	0
Hypofibrinogenaemia	1 (1.8)	0	0	0	1 (1.8)
Leukocytosis	1 (1.8)	1 (1.8)	0	0	0
Leukopenia	1 (1.8)	0	0	0	1 (1.8)
Lymphadenopathy	1 (1.8)	0	1 (1.8)	0	0
Splenomegaly	1 (1.8)	1 (1.8)	0	0	0
Cardiac disorders					
-Total	23 (40.4)	6 (10.5)	10 (17.5)	5 (8.8)	2 (3.5)
Tachycardia	15 (26.3)	7 (12.3)	6 (10.5)	2 (3.5)	0
Sinus tachycardia	6 (10.5)	2 (3.5)	2 (3.5)	2 (3.5)	0
Left ventricular dysfunction	3 (5.3)	0	0	3 (5.3)	0
Pericardial effusion	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Bradycardia	2 (3.5)	0	1 (1.8)	0	1 (1.8)
Palpitations	2 (3.5)	2 (3.5)	0	0	0
Ventricular tachycardia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Cardiac dysfunction	1 (1.8)	1 (1.8)	0	0	0
Cardiovascular insufficiency	1 (1.8)	0	0	0	1 (1.8)
Right ventricular dysfunction	1 (1.8)	0	0	1 (1.8)	0

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Sinus bradycardia	1 (1.8)	1 (1.8)	0	0	0
Ear and labyrinth disorders					
-Total	5 (8.8)	2 (3.5)	3 (5.3)	0	0
Ear pain	2 (3.5)	2 (3.5)	0	0	0
Deafness unilateral	1 (1.8)	0	1 (1.8)	0	0
Hypoacusis	1 (1.8)	0	1 (1.8)	0	0
Tympanic membrane perforation	1 (1.8)	0	1 (1.8)	0	0
Endocrine disorders					
-Total	5 (8.8)	2 (3.5)	3 (5.3)	0	0
Adrenal insufficiency	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Cushingoid	1 (1.8)	1 (1.8)	0	0	0
Hyperthyroidism	1 (1.8)	0	1 (1.8)	0	0
Eye disorders					
-Total	16 (28.1)	7 (12.3)	9 (15.8)	0	0
Periorbital oedema	4 (7.0)	3 (5.3)	1 (1.8)	0	0
Vision blurred	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Conjunctival haemorrhage	3 (5.3)	3 (5.3)	0	0	0
Eye pain	3 (5.3)	1 (1.8)	2 (3.5)	0	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Photophobia	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Uveitis	2 (3.5)	0	2 (3.5)	0	0
Dry eye	1 (1.8)	0	1 (1.8)	0	0
Eye irritation	1 (1.8)	1 (1.8)	0	0	0
Ocular hypertension	1 (1.8)	0	1 (1.8)	0	0
Papilloedema	1 (1.8)	0	1 (1.8)	0	0
Retinal haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Retinopathy	1 (1.8)	0	1 (1.8)	0	0
Visual impairment	1 (1.8)	0	1 (1.8)	0	0
Gastrointestinal disorders					
-Total	42 (73.7)	11 (19.3)	15 (26.3)	15 (26.3)	1 (1.8)
Nausea	26 (45.6)	9 (15.8)	12 (21.1)	5 (8.8)	0
Vomiting	25 (43.9)	15 (26.3)	7 (12.3)	3 (5.3)	0
Diarrhoea	22 (38.6)	12 (21.1)	9 (15.8)	1 (1.8)	0
Abdominal pain	15 (26.3)	6 (10.5)	7 (12.3)	2 (3.5)	0
Constipation	8 (14.0)	7 (12.3)	1 (1.8)	0	0
Colitis	4 (7.0)	1 (1.8)	0	3 (5.3)	0
Stomatitis	4 (7.0)	1 (1.8)	1 (1.8)	1 (1.8)	1 (1.8)

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral pain	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Abdominal distension	2 (3.5)	0	2 (3.5)	0	0
Abdominal pain lower	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Abdominal pain upper	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Dysphagia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Haematemesis	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Haematochezia	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Pancreatitis	2 (3.5)	0	2 (3.5)	0	0
Abdominal discomfort	1 (1.8)	1 (1.8)	0	0	0
Abdominal tenderness	1 (1.8)	1 (1.8)	0	0	0
Anal fissure	1 (1.8)	0	1 (1.8)	0	0
Anal incontinence	1 (1.8)	1 (1.8)	0	0	0
Ascites	1 (1.8)	0	0	1 (1.8)	0
Dry mouth	1 (1.8)	1 (1.8)	0	0	0
Flatulence	1 (1.8)	1 (1.8)	0	0	0
Gastrointestinal haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Gastrooesophageal reflux disease	1 (1.8)	1 (1.8)	0	0	0
Gingival discomfort	1 (1.8)	1 (1.8)	0	0	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Glossodynia	1 (1.8)	1 (1.8)	0	0	0
Ileus	1 (1.8)	0	0	1 (1.8)	0
Lip pain	1 (1.8)	0	1 (1.8)	0	0
Mouth haemorrhage	1 (1.8)	0	0	1 (1.8)	0
Oral mucosal blistering	1 (1.8)	1 (1.8)	0	0	0
Perianal erythema	1 (1.8)	0	1 (1.8)	0	0
Pigmentation lip	1 (1.8)	1 (1.8)	0	0	0
Proctalgia	1 (1.8)	0	1 (1.8)	0	0
General disorders and administration site conditions					
-Total	45 (78.9)	14 (24.6)	15 (26.3)	12 (21.1)	4 (7.0)
Pyrexia	28 (49.1)	9 (15.8)	13 (22.8)	5 (8.8)	1 (1.8)
Fatigue	16 (28.1)	12 (21.1)	2 (3.5)	2 (3.5)	0
Chills	10 (17.5)	8 (14.0)	2 (3.5)	0	0
Pain	6 (10.5)	1 (1.8)	3 (5.3)	2 (3.5)	0
Catheter site pain	5 (8.8)	3 (5.3)	2 (3.5)	0	0
Oedema peripheral	5 (8.8)	3 (5.3)	1 (1.8)	1 (1.8)	0
Generalised oedema	4 (7.0)	2 (3.5)	2 (3.5)	0	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	4 (7.0)	0	0	1 (1.8)	3 (5.3)
Malaise	3 (5.3)	0	3 (5.3)	0	0
Face oedema	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Non-cardiac chest pain	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Physical deconditioning	2 (3.5)	0	0	2 (3.5)	0
Acquired gene mutation	1 (1.8)	1 (1.8)	0	0	0
Asthenia	1 (1.8)	1 (1.8)	0	0	0
Catheter site extravasation	1 (1.8)	0	1 (1.8)	0	0
Catheter site haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Crying	1 (1.8)	1 (1.8)	0	0	0
Cyst	1 (1.8)	0	0	1 (1.8)	0
Device related thrombosis	1 (1.8)	0	1 (1.8)	0	0
Facial pain	1 (1.8)	0	1 (1.8)	0	0
Gait disturbance	1 (1.8)	1 (1.8)	0	0	0
Influenza like illness	1 (1.8)	1 (1.8)	0	0	0
Injection site haematoma	1 (1.8)	1 (1.8)	0	0	0
Localised oedema	1 (1.8)	0	0	1 (1.8)	0
Medical device pain	1 (1.8)	0	1 (1.8)	0	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mucosal haemorrhage	1 (1.8)	0	1 (1.8)	0	0
Peripheral swelling	1 (1.8)	0	1 (1.8)	0	0
Hepatobiliary disorders					
-Total	10 (17.5)	2 (3.5)	3 (5.3)	4 (7.0)	1 (1.8)
Hyperbilirubinaemia	5 (8.8)	0	2 (3.5)	3 (5.3)	0
Hepatomegaly	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Cholecystitis	1 (1.8)	0	0	1 (1.8)	0
Gallbladder enlargement	1 (1.8)	1 (1.8)	0	0	0
Hepatic failure	1 (1.8)	0	0	0	1 (1.8)
Hepatic steatosis	1 (1.8)	0	1 (1.8)	0	0
Immune system disorders					
-Total	45 (78.9)	6 (10.5)	21 (36.8)	8 (14.0)	10 (17.5)
Cytokine release syndrome	37 (64.9)	6 (10.5)	15 (26.3)	6 (10.5)	10 (17.5)
Hypogammaglobulinaemia	25 (43.9)	3 (5.3)	18 (31.6)	4 (7.0)	0
Graft versus host disease	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Seasonal allergy	2 (3.5)	2 (3.5)	0	0	0
Chronic graft versus host disease	1 (1.8)	0	1 (1.8)	0	0
Drug hypersensitivity	1 (1.8)	0	1 (1.8)	0	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease in gastrointestinal tract	1 (1.8)	0	1 (1.8)	0	0
Graft versus host disease in skin	1 (1.8)	1 (1.8)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.8)	0	1 (1.8)	0	0
Immunodeficiency	1 (1.8)	0	1 (1.8)	0	0
Immunodeficiency common variable	1 (1.8)	0	1 (1.8)	0	0
Infections and infestations					
-Total	40 (70.2)	4 (7.0)	13 (22.8)	15 (26.3)	8 (14.0)
Upper respiratory tract infection	11 (19.3)	5 (8.8)	5 (8.8)	1 (1.8)	0
Clostridium difficile infection	5 (8.8)	0	4 (7.0)	1 (1.8)	0
Pneumonia	5 (8.8)	0	5 (8.8)	0	0
Rhinovirus infection	5 (8.8)	4 (7.0)	1 (1.8)	0	0
Sinusitis	5 (8.8)	1 (1.8)	4 (7.0)	0	0
Clostridium difficile colitis	4 (7.0)	1 (1.8)	2 (3.5)	1 (1.8)	0
Gastroenteritis	4 (7.0)	1 (1.8)	2 (3.5)	1 (1.8)	0
Otitis media	4 (7.0)	0	3 (5.3)	1 (1.8)	0
Device related infection	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Parainfluenzae virus infection	3 (5.3)	2 (3.5)	1 (1.8)	0	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Ear infection	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Escherichia bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Influenza	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Oral herpes	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Otitis media acute	2 (3.5)	0	2 (3.5)	0	0
Sepsis	2 (3.5)	0	0	0	2 (3.5)
Skin infection	2 (3.5)	0	2 (3.5)	0	0
Staphylococcal bacteraemia	2 (3.5)	0	0	2 (3.5)	0
Staphylococcal infection	2 (3.5)	0	0	1 (1.8)	1 (1.8)
Viral infection	2 (3.5)	2 (3.5)	0	0	0
Vulvovaginal candidiasis	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Abscess limb	1 (1.8)	0	0	1 (1.8)	0
Acute sinusitis	1 (1.8)	0	1 (1.8)	0	0
Bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Body tinea	1 (1.8)	1 (1.8)	0	0	0
Bronchitis	1 (1.8)	0	1 (1.8)	0	0
Campylobacter infection	1 (1.8)	0	0	1 (1.8)	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida sepsis	1 (1.8)	0	0	0	1 (1.8)
Catheter site cellulitis	1 (1.8)	1 (1.8)	0	0	0
Cellulitis	1 (1.8)	0	0	1 (1.8)	0
Cellulitis of male external genital organ	1 (1.8)	0	0	1 (1.8)	0
Cholecystitis infective	1 (1.8)	0	0	1 (1.8)	0
Croup infectious	1 (1.8)	0	0	1 (1.8)	0
Cytomegalovirus infection	1 (1.8)	1 (1.8)	0	0	0
Enterococcal infection	1 (1.8)	1 (1.8)	0	0	0
Enterovirus infection	1 (1.8)	0	0	1 (1.8)	0
Escherichia sepsis	1 (1.8)	0	0	0	1 (1.8)
Escherichia urinary tract infection	1 (1.8)	0	0	1 (1.8)	0
Fungal skin infection	1 (1.8)	0	1 (1.8)	0	0
Gastroenteritis norovirus	1 (1.8)	0	1 (1.8)	0	0
Gingivitis	1 (1.8)	1 (1.8)	0	0	0
Haemophilus infection	1 (1.8)	0	1 (1.8)	0	0
Herpes simplex	1 (1.8)	1 (1.8)	0	0	0
Herpes zoster	1 (1.8)	0	0	1 (1.8)	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (1.8)	0	1 (1.8)	0	0
Human polyomavirus infection	1 (1.8)	0	0	0	1 (1.8)
Hypopyon	1 (1.8)	0	1 (1.8)	0	0
Klebsiella sepsis	1 (1.8)	0	0	0	1 (1.8)
Meningitis aseptic	1 (1.8)	0	1 (1.8)	0	0
Metapneumovirus infection	1 (1.8)	0	1 (1.8)	0	0
Necrotising fasciitis	1 (1.8)	0	0	1 (1.8)	0
Oral candidiasis	1 (1.8)	1 (1.8)	0	0	0
Orchitis	1 (1.8)	1 (1.8)	0	0	0
Pharyngitis	1 (1.8)	0	1 (1.8)	0	0
Pneumonia fungal	1 (1.8)	0	1 (1.8)	0	0
Rash pustular	1 (1.8)	0	1 (1.8)	0	0
Respiratory syncytial virus bronchitis	1 (1.8)	0	0	1 (1.8)	0
Respiratory syncytial virus infection	1 (1.8)	0	1 (1.8)	0	0
Respiratory tract infection viral	1 (1.8)	0	0	1 (1.8)	0
Rhinitis	1 (1.8)	1 (1.8)	0	0	0
Rotavirus infection	1 (1.8)	0	0	1 (1.8)	0
Septic embolus	1 (1.8)	0	0	0	1 (1.8)

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal scalded skin syndrome	1 (1.8)	0	1 (1.8)	0	0
Staphylococcal sepsis	1 (1.8)	0	0	0	1 (1.8)
Streptococcal bacteraemia	1 (1.8)	0	0	1 (1.8)	0
Streptococcal infection	1 (1.8)	0	1 (1.8)	0	0
Tinea capitis	1 (1.8)	1 (1.8)	0	0	0
Vascular device infection	1 (1.8)	0	0	1 (1.8)	0
Viral upper respiratory tract infection	1 (1.8)	0	1 (1.8)	0	0
Vulvovaginal mycotic infection	1 (1.8)	0	1 (1.8)	0	0
Injury, poisoning and procedural complications					
-Total	21 (36.8)	10 (17.5)	7 (12.3)	3 (5.3)	1 (1.8)
Infusion related reaction	4 (7.0)	1 (1.8)	3 (5.3)	0	0
Contusion	3 (5.3)	3 (5.3)	0	0	0
Procedural pain	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Transfusion reaction	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Subdural haematoma	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Arthropod bite	1 (1.8)	1 (1.8)	0	0	0
Extradural haematoma	1 (1.8)	0	0	1 (1.8)	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Foot fracture	1 (1.8)	0	1 (1.8)	0	0
Incision site pain	1 (1.8)	1 (1.8)	0	0	0
Limb injury	1 (1.8)	1 (1.8)	0	0	0
Mouth injury	1 (1.8)	1 (1.8)	0	0	0
Post procedural haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Procedural complication	1 (1.8)	1 (1.8)	0	0	0
Procedural headache	1 (1.8)	0	1 (1.8)	0	0
Procedural nausea	1 (1.8)	0	1 (1.8)	0	0
Procedural site reaction	1 (1.8)	1 (1.8)	0	0	0
Radius fracture	1 (1.8)	0	1 (1.8)	0	0
Skin abrasion	1 (1.8)	1 (1.8)	0	0	0
Stoma site irritation	1 (1.8)	1 (1.8)	0	0	0
Subdural haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Sunburn	1 (1.8)	1 (1.8)	0	0	0
Tibia fracture	1 (1.8)	0	1 (1.8)	0	0
Tongue injury	1 (1.8)	1 (1.8)	0	0	0
Tracheal haemorrhage	1 (1.8)	0	0	1 (1.8)	0
Transfusion related complication	1 (1.8)	0	0	0	1 (1.8)

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wound	1 (1.8)	1 (1.8)	0	0	0
Investigations					
-Total	45 (78.9)	1 (1.8)	3 (5.3)	10 (17.5)	31 (54.4)
White blood cell count decreased	30 (52.6)	2 (3.5)	1 (1.8)	6 (10.5)	21 (36.8)
Alanine aminotransferase increased	24 (42.1)	3 (5.3)	3 (5.3)	17 (29.8)	1 (1.8)
Neutrophil count decreased	24 (42.1)	0	2 (3.5)	1 (1.8)	21 (36.8)
Aspartate aminotransferase increased	23 (40.4)	5 (8.8)	4 (7.0)	9 (15.8)	5 (8.8)
Platelet count decreased	17 (29.8)	2 (3.5)	2 (3.5)	3 (5.3)	10 (17.5)
Lymphocyte count decreased	13 (22.8)	0	2 (3.5)	5 (8.8)	6 (10.5)
International normalised ratio increased	10 (17.5)	8 (14.0)	1 (1.8)	1 (1.8)	0
Blood creatinine increased	8 (14.0)	4 (7.0)	2 (3.5)	2 (3.5)	0
Prothrombin time prolonged	8 (14.0)	4 (7.0)	3 (5.3)	1 (1.8)	0
Blood bilirubin increased	7 (12.3)	1 (1.8)	2 (3.5)	3 (5.3)	1 (1.8)
Activated partial thromboplastin time prolonged	6 (10.5)	3 (5.3)	3 (5.3)	0	0
Transaminases increased	4 (7.0)	3 (5.3)	0	1 (1.8)	0
Weight decreased	4 (7.0)	1 (1.8)	3 (5.3)	0	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	3 (5.3)	0	1 (1.8)	1 (1.8)	1 (1.8)
Blood immunoglobulin m decreased	3 (5.3)	3 (5.3)	0	0	0
C-reactive protein increased	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Haemoglobin decreased	3 (5.3)	2 (3.5)	0	1 (1.8)	0
Weight increased	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Blood immunoglobulin a decreased	2 (3.5)	2 (3.5)	0	0	0
Blood lactate dehydrogenase increased	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Blood lactic acid increased	2 (3.5)	0	1 (1.8)	0	1 (1.8)
Blood magnesium decreased	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Blood phosphorus increased	2 (3.5)	2 (3.5)	0	0	0
Blood urea increased	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Blood uric acid increased	2 (3.5)	2 (3.5)	0	0	0
Electrocardiogram qt prolonged	2 (3.5)	0	0	2 (3.5)	0
Lipase increased	2 (3.5)	0	0	0	2 (3.5)
Blood alkaline phosphatase increased	1 (1.8)	1 (1.8)	0	0	0
Blood bicarbonate decreased	1 (1.8)	0	1 (1.8)	0	0
Blood phosphorus decreased	1 (1.8)	1 (1.8)	0	0	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac murmur	1 (1.8)	1 (1.8)	0	0	0
Computerised tomogram thorax abnormal	1 (1.8)	0	0	1 (1.8)	0
Coronavirus test positive	1 (1.8)	1 (1.8)	0	0	0
Culture stool positive	1 (1.8)	1 (1.8)	0	0	0
Hepatic enzyme increased	1 (1.8)	0	1 (1.8)	0	0
Norovirus test positive	1 (1.8)	1 (1.8)	0	0	0
Protein total decreased	1 (1.8)	0	0	1 (1.8)	0
Pulmonary function test decreased	1 (1.8)	0	1 (1.8)	0	0
Serum ferritin increased	1 (1.8)	0	1 (1.8)	0	0
Metabolism and nutrition disorders					
-Total	40 (70.2)	4 (7.0)	9 (15.8)	22 (38.6)	5 (8.8)
Decreased appetite	21 (36.8)	5 (8.8)	5 (8.8)	11 (19.3)	0
Hypokalaemia	18 (31.6)	3 (5.3)	4 (7.0)	7 (12.3)	4 (7.0)
Hypophosphataemia	11 (19.3)	3 (5.3)	0	8 (14.0)	0
Hyperphosphataemia	7 (12.3)	6 (10.5)	1 (1.8)	0	0
Hyperglycaemia	6 (10.5)	0	3 (5.3)	3 (5.3)	0
Hypernatraemia	6 (10.5)	1 (1.8)	2 (3.5)	0	3 (5.3)

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fluid overload	5 (8.8)	1 (1.8)	3 (5.3)	1 (1.8)	0
Hypoalbuminaemia	5 (8.8)	1 (1.8)	4 (7.0)	0	0
Hypocalcaemia	5 (8.8)	3 (5.3)	1 (1.8)	1 (1.8)	0
Dehydration	3 (5.3)	1 (1.8)	0	2 (3.5)	0
Hyperuricaemia	3 (5.3)	3 (5.3)	0	0	0
Vitamin d deficiency	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Acidosis	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Hyperkalaemia	2 (3.5)	1 (1.8)	0	1 (1.8)	0
Hypoglycaemia	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Hyponatraemia	2 (3.5)	0	0	2 (3.5)	0
Hyperalbuminaemia	1 (1.8)	1 (1.8)	0	0	0
Hyperammonaemia	1 (1.8)	1 (1.8)	0	0	0
Hypercalcaemia	1 (1.8)	1 (1.8)	0	0	0
Hyperchloraemia	1 (1.8)	1 (1.8)	0	0	0
Hypermagnesaemia	1 (1.8)	1 (1.8)	0	0	0
Hypertriglyceridaemia	1 (1.8)	0	0	1 (1.8)	0
Hypomagnesaemia	1 (1.8)	1 (1.8)	0	0	0
Malnutrition	1 (1.8)	0	0	1 (1.8)	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic acidosis	1 (1.8)	0	1 (1.8)	0	0
Metabolic alkalosis	1 (1.8)	1 (1.8)	0	0	0
Tumour lysis syndrome	1 (1.8)	0	0	1 (1.8)	0
Musculoskeletal and connective tissue disorders					
-Total	28 (49.1)	11 (19.3)	9 (15.8)	8 (14.0)	0
Pain in extremity	10 (17.5)	4 (7.0)	3 (5.3)	3 (5.3)	0
Myalgia	6 (10.5)	4 (7.0)	1 (1.8)	1 (1.8)	0
Arthralgia	4 (7.0)	2 (3.5)	0	2 (3.5)	0
Musculoskeletal pain	4 (7.0)	2 (3.5)	1 (1.8)	1 (1.8)	0
Back pain	3 (5.3)	1 (1.8)	0	2 (3.5)	0
Muscle spasms	3 (5.3)	3 (5.3)	0	0	0
Pain in jaw	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Joint range of motion decreased	2 (3.5)	2 (3.5)	0	0	0
Musculoskeletal chest pain	2 (3.5)	2 (3.5)	0	0	0
Neck pain	2 (3.5)	0	2 (3.5)	0	0
Bone pain	1 (1.8)	0	0	1 (1.8)	0
Coccydynia	1 (1.8)	1 (1.8)	0	0	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flank pain	1 (1.8)	0	1 (1.8)	0	0
Limb discomfort	1 (1.8)	1 (1.8)	0	0	0
Muscular weakness	1 (1.8)	1 (1.8)	0	0	0
Myopathy	1 (1.8)	0	0	1 (1.8)	0
Myositis	1 (1.8)	0	0	1 (1.8)	0
Osteonecrosis	1 (1.8)	0	1 (1.8)	0	0
Osteopenia	1 (1.8)	0	1 (1.8)	0	0
Synovitis	1 (1.8)	0	1 (1.8)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (3.5)	0	1 (1.8)	0	1 (1.8)
Glioblastoma multiforme	1 (1.8)	0	0	0	1 (1.8)
Skin papilloma	1 (1.8)	0	1 (1.8)	0	0
Nervous system disorders					
-Total	37 (64.9)	14 (24.6)	14 (24.6)	7 (12.3)	2 (3.5)
Headache	26 (45.6)	13 (22.8)	8 (14.0)	5 (8.8)	0
Dizziness	5 (8.8)	5 (8.8)	0	0	0
Seizure	5 (8.8)	0	2 (3.5)	2 (3.5)	1 (1.8)

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	4 (7.0)	1 (1.8)	1 (1.8)	2 (3.5)	0
Peroneal nerve palsy	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Tremor	2 (3.5)	2 (3.5)	0	0	0
Asterixis	1 (1.8)	1 (1.8)	0	0	0
Ataxia	1 (1.8)	0	1 (1.8)	0	0
Disturbance in attention	1 (1.8)	1 (1.8)	0	0	0
Dysarthria	1 (1.8)	1 (1.8)	0	0	0
Dysgeusia	1 (1.8)	1 (1.8)	0	0	0
Embolic stroke	1 (1.8)	0	0	0	1 (1.8)
Hyporesponsive to stimuli	1 (1.8)	0	0	1 (1.8)	0
Hypotonia	1 (1.8)	0	1 (1.8)	0	0
Idiopathic intracranial hypertension	1 (1.8)	0	1 (1.8)	0	0
Myoclonus	1 (1.8)	1 (1.8)	0	0	0
Neuralgia	1 (1.8)	0	1 (1.8)	0	0
Neuropathy peripheral	1 (1.8)	0	1 (1.8)	0	0
Peripheral sensory neuropathy	1 (1.8)	0	1 (1.8)	0	0
Pleocytosis	1 (1.8)	1 (1.8)	0	0	0
Somnolence	1 (1.8)	0	1 (1.8)	0	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Visual field defect	1 (1.8)	0	1 (1.8)	0	0
Product issues					
-Total	2 (3.5)	2 (3.5)	0	0	0
Device occlusion	2 (3.5)	2 (3.5)	0	0	0
Psychiatric disorders					
-Total	23 (40.4)	7 (12.3)	12 (21.1)	4 (7.0)	0
Anxiety	9 (15.8)	3 (5.3)	5 (8.8)	1 (1.8)	0
Confusional state	6 (10.5)	3 (5.3)	3 (5.3)	0	0
Delirium	5 (8.8)	2 (3.5)	2 (3.5)	1 (1.8)	0
Insomnia	4 (7.0)	0	4 (7.0)	0	0
Mental status changes	4 (7.0)	3 (5.3)	0	1 (1.8)	0
Agitation	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Depression	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Irritability	3 (5.3)	3 (5.3)	0	0	0
Hallucination	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Adjustment disorder	1 (1.8)	0	1 (1.8)	0	0
Listless	1 (1.8)	1 (1.8)	0	0	0
Sleep disorder	1 (1.8)	0	1 (1.8)	0	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Suicidal ideation	1 (1.8)	1 (1.8)	0	0	0
Renal and urinary disorders					
-Total	17 (29.8)	2 (3.5)	4 (7.0)	6 (10.5)	5 (8.8)
Acute kidney injury	11 (19.3)	2 (3.5)	1 (1.8)	4 (7.0)	4 (7.0)
Haematuria	5 (8.8)	0	2 (3.5)	2 (3.5)	1 (1.8)
Oliguria	3 (5.3)	0	0	3 (5.3)	0
Dysuria	2 (3.5)	0	2 (3.5)	0	0
Calculus urinary	1 (1.8)	0	1 (1.8)	0	0
Cystitis haemorrhagic	1 (1.8)	0	0	0	1 (1.8)
Nephrolithiasis	1 (1.8)	0	0	1 (1.8)	0
Pollakiuria	1 (1.8)	1 (1.8)	0	0	0
Renal failure	1 (1.8)	0	0	0	1 (1.8)
Renal impairment	1 (1.8)	0	0	1 (1.8)	0
Urinary incontinence	1 (1.8)	1 (1.8)	0	0	0
Urinary retention	1 (1.8)	0	1 (1.8)	0	0
Reproductive system and breast disorders					
-Total	3 (5.3)	1 (1.8)	2 (3.5)	0	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema genital	1 (1.8)	0	1 (1.8)	0	0
Scrotal pain	1 (1.8)	0	1 (1.8)	0	0
Vulvovaginal adhesion	1 (1.8)	1 (1.8)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	33 (57.9)	10 (17.5)	4 (7.0)	9 (15.8)	10 (17.5)
Cough	13 (22.8)	12 (21.1)	0	1 (1.8)	0
Hypoxia	12 (21.1)	0	2 (3.5)	7 (12.3)	3 (5.3)
Epistaxis	11 (19.3)	3 (5.3)	2 (3.5)	5 (8.8)	1 (1.8)
Pulmonary oedema	8 (14.0)	1 (1.8)	0	3 (5.3)	4 (7.0)
Pleural effusion	7 (12.3)	1 (1.8)	4 (7.0)	2 (3.5)	0
Tachypnoea	7 (12.3)	2 (3.5)	2 (3.5)	3 (5.3)	0
Oropharyngeal pain	6 (10.5)	3 (5.3)	2 (3.5)	1 (1.8)	0
Dyspnoea	5 (8.8)	1 (1.8)	1 (1.8)	2 (3.5)	1 (1.8)
Rhinitis allergic	4 (7.0)	4 (7.0)	0	0	0
Rhinorrhoea	4 (7.0)	4 (7.0)	0	0	0
Haemoptysis	3 (5.3)	1 (1.8)	0	1 (1.8)	1 (1.8)
Nasal congestion	3 (5.3)	3 (5.3)	0	0	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	3 (5.3)	0	0	0	3 (5.3)
Atelectasis	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Respiratory distress	2 (3.5)	0	0	0	2 (3.5)
Acute respiratory failure	1 (1.8)	0	0	0	1 (1.8)
Dysphonia	1 (1.8)	1 (1.8)	0	0	0
Idiopathic pneumonia syndrome	1 (1.8)	0	0	0	1 (1.8)
Interstitial lung disease	1 (1.8)	0	0	0	1 (1.8)
Nasal discomfort	1 (1.8)	1 (1.8)	0	0	0
Pharyngeal erythema	1 (1.8)	1 (1.8)	0	0	0
Pharyngeal lesion	1 (1.8)	0	0	1 (1.8)	0
Pharyngeal ulceration	1 (1.8)	0	1 (1.8)	0	0
Pulmonary alveolar haemorrhage	1 (1.8)	0	0	0	1 (1.8)
Pulmonary hypertension	1 (1.8)	0	0	1 (1.8)	0
Pulmonary mass	1 (1.8)	0	1 (1.8)	0	0
Respiratory depression	1 (1.8)	0	1 (1.8)	0	0
Wheezing	1 (1.8)	0	1 (1.8)	0	0
Skin and subcutaneous tissue disorders					

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	28 (49.1)	15 (26.3)	10 (17.5)	3 (5.3)	0
Rash	8 (14.0)	5 (8.8)	3 (5.3)	0	0
Dry skin	4 (7.0)	4 (7.0)	0	0	0
Erythema	4 (7.0)	4 (7.0)	0	0	0
Pruritus	4 (7.0)	4 (7.0)	0	0	0
Rash maculo-papular	4 (7.0)	2 (3.5)	1 (1.8)	1 (1.8)	0
Alopecia	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Hyperhidrosis	3 (5.3)	3 (5.3)	0	0	0
Ingrowing nail	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Petechiae	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Rash erythematous	3 (5.3)	0	3 (5.3)	0	0
Night sweats	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Rash papular	2 (3.5)	2 (3.5)	0	0	0
Acne	1 (1.8)	1 (1.8)	0	0	0
Cold sweat	1 (1.8)	1 (1.8)	0	0	0
Dermatitis	1 (1.8)	1 (1.8)	0	0	0
Dermatitis acneiform	1 (1.8)	0	1 (1.8)	0	0
Dermatitis atopic	1 (1.8)	1 (1.8)	0	0	0

Eligibility for SCT: No

	All patients N=57				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ecchymosis	1 (1.8)	0	0	1 (1.8)	0
Eczema	1 (1.8)	1 (1.8)	0	0	0
Livedo reticularis	1 (1.8)	1 (1.8)	0	0	0
Macule	1 (1.8)	1 (1.8)	0	0	0
Papule	1 (1.8)	1 (1.8)	0	0	0
Pruritus generalised	1 (1.8)	1 (1.8)	0	0	0
Rash follicular	1 (1.8)	1 (1.8)	0	0	0
Rash macular	1 (1.8)	0	0	1 (1.8)	0
Rash pruritic	1 (1.8)	1 (1.8)	0	0	0
Rash vesicular	1 (1.8)	1 (1.8)	0	0	0
Skin exfoliation	1 (1.8)	1 (1.8)	0	0	0
Skin fissures	1 (1.8)	1 (1.8)	0	0	0
Skin haemorrhage	1 (1.8)	1 (1.8)	0	0	0
Skin irritation	1 (1.8)	1 (1.8)	0	0	0
Skin ulcer	1 (1.8)	1 (1.8)	0	0	0
Vascular disorders					
-Total	27 (47.4)	2 (3.5)	3 (5.3)	12 (21.1)	10 (17.5)
Hypotension	21 (36.8)	1 (1.8)	0	10 (17.5)	10 (17.5)

Eligibility for SCT: No

Primary system organ class Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	13 (22.8)	3 (5.3)	8 (14.0)	2 (3.5)	0
Flushing	2 (3.5)	2 (3.5)	0	0	0
Capillary leak syndrome	1 (1.8)	0	0	0	1 (1.8)
Embolism	1 (1.8)	0	0	1 (1.8)	0
Haematoma	1 (1.8)	0	1 (1.8)	0	0
Hot flush	1 (1.8)	1 (1.8)	0	0	0
Orthostatic hypotension	1 (1.8)	1 (1.8)	0	0	0
Phlebitis	1 (1.8)	0	1 (1.8)	0	0
Secondary hypertension	1 (1.8)	0	1 (1.8)	0	0
Venous thrombosis limb	1 (1.8)	1 (1.8)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178n
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (100)	0	0	6 (27.3)	16 (72.7)
Blood and lymphatic system disorders					
-Total	21 (95.5)	0	0	14 (63.6)	7 (31.8)
Anaemia	13 (59.1)	1 (4.5)	2 (9.1)	10 (45.5)	0
Febrile neutropenia	11 (50.0)	0	0	11 (50.0)	0
Neutropenia	7 (31.8)	0	0	2 (9.1)	5 (22.7)
Thrombocytopenia	6 (27.3)	0	0	3 (13.6)	3 (13.6)
Disseminated intravascular coagulation	3 (13.6)	0	1 (4.5)	1 (4.5)	1 (4.5)
Lymphopenia	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Pancytopenia	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Cardiac disorders					

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (22.7)	2 (9.1)	2 (9.1)	0	1 (4.5)
Tachycardia	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Bradycardia	2 (9.1)	1 (4.5)	0	0	1 (4.5)
Palpitations	1 (4.5)	1 (4.5)	0	0	0
Right ventricular dysfunction	1 (4.5)	0	0	1 (4.5)	0
Sinus bradycardia	1 (4.5)	1 (4.5)	0	0	0
Sinus tachycardia	1 (4.5)	0	0	1 (4.5)	0
Ventricular tachycardia	1 (4.5)	0	0	1 (4.5)	0
Ear and labyrinth disorders					
-Total	2 (9.1)	0	2 (9.1)	0	0
Hypoacusis	1 (4.5)	0	1 (4.5)	0	0
Tympanic membrane perforation	1 (4.5)	0	1 (4.5)	0	0
Endocrine disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Adrenal insufficiency	1 (4.5)	1 (4.5)	0	0	0
Eye disorders					
-Total	5 (22.7)	3 (13.6)	2 (9.1)	0	0
Eye pain	2 (9.1)	1 (4.5)	1 (4.5)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ocular hyperaemia	1 (4.5)	1 (4.5)	0	0	0
Photophobia	1 (4.5)	0	1 (4.5)	0	0
Retinal haemorrhage	1 (4.5)	1 (4.5)	0	0	0
Vision blurred	1 (4.5)	1 (4.5)	0	0	0
Gastrointestinal disorders					
-Total	19 (86.4)	6 (27.3)	7 (31.8)	6 (27.3)	0
Vomiting	13 (59.1)	8 (36.4)	3 (13.6)	2 (9.1)	0
Nausea	11 (50.0)	4 (18.2)	5 (22.7)	2 (9.1)	0
Abdominal pain	6 (27.3)	2 (9.1)	2 (9.1)	2 (9.1)	0
Diarrhoea	5 (22.7)	2 (9.1)	2 (9.1)	1 (4.5)	0
Constipation	4 (18.2)	3 (13.6)	1 (4.5)	0	0
Oral pain	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Abdominal pain upper	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Gastrointestinal haemorrhage	2 (9.1)	2 (9.1)	0	0	0
Stomatitis	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Anal incontinence	1 (4.5)	1 (4.5)	0	0	0
Ascites	1 (4.5)	0	0	1 (4.5)	0
Colitis	1 (4.5)	0	0	1 (4.5)	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry mouth	1 (4.5)	1 (4.5)	0	0	0
Dyspepsia	1 (4.5)	0	1 (4.5)	0	0
Enterocolitis	1 (4.5)	0	0	1 (4.5)	0
Gingival discomfort	1 (4.5)	1 (4.5)	0	0	0
Haematemesis	1 (4.5)	0	1 (4.5)	0	0
Haematochezia	1 (4.5)	0	0	1 (4.5)	0
Intestinal obstruction	1 (4.5)	0	0	1 (4.5)	0
Lip pain	1 (4.5)	0	1 (4.5)	0	0
Pancreatitis	1 (4.5)	0	1 (4.5)	0	0
General disorders and administration site conditions					
-Total	17 (77.3)	9 (40.9)	3 (13.6)	4 (18.2)	1 (4.5)
Pyrexia	10 (45.5)	5 (22.7)	3 (13.6)	2 (9.1)	0
Fatigue	6 (27.3)	5 (22.7)	1 (4.5)	0	0
Catheter site pain	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Chills	2 (9.1)	2 (9.1)	0	0	0
Non-cardiac chest pain	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Pain	2 (9.1)	0	1 (4.5)	1 (4.5)	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acquired gene mutation	1 (4.5)	1 (4.5)	0	0	0
Influenza like illness	1 (4.5)	1 (4.5)	0	0	0
Multiple organ dysfunction syndrome	1 (4.5)	0	0	0	1 (4.5)
Oedema peripheral	1 (4.5)	1 (4.5)	0	0	0
Hepatobiliary disorders					
-Total	3 (13.6)	1 (4.5)	1 (4.5)	0	1 (4.5)
Hepatic failure	1 (4.5)	0	0	0	1 (4.5)
Hepatomegaly	1 (4.5)	1 (4.5)	0	0	0
Hyperbilirubinaemia	1 (4.5)	0	1 (4.5)	0	0
Immune system disorders					
-Total	18 (81.8)	1 (4.5)	11 (50.0)	4 (18.2)	2 (9.1)
Cytokine release syndrome	16 (72.7)	0	11 (50.0)	3 (13.6)	2 (9.1)
Hypogammaglobulinaemia	13 (59.1)	2 (9.1)	10 (45.5)	1 (4.5)	0
Drug hypersensitivity	1 (4.5)	0	1 (4.5)	0	0
Graft versus host disease	1 (4.5)	0	1 (4.5)	0	0
Infections and infestations					
-Total	16 (72.7)	1 (4.5)	7 (31.8)	6 (27.3)	2 (9.1)
Upper respiratory tract infection	5 (22.7)	1 (4.5)	4 (18.2)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Gastroenteritis	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Influenza	2 (9.1)	0	2 (9.1)	0	0
Sinusitis	2 (9.1)	0	2 (9.1)	0	0
Acute sinusitis	1 (4.5)	0	1 (4.5)	0	0
Bacterial sepsis	1 (4.5)	0	0	0	1 (4.5)
Bronchitis	1 (4.5)	0	1 (4.5)	0	0
Cholecystitis infective	1 (4.5)	0	0	1 (4.5)	0
Clostridium difficile colitis	1 (4.5)	0	1 (4.5)	0	0
Conjunctivitis	1 (4.5)	0	1 (4.5)	0	0
Corona virus infection	1 (4.5)	0	0	1 (4.5)	0
Croup infectious	1 (4.5)	0	0	1 (4.5)	0
Device related infection	1 (4.5)	0	0	1 (4.5)	0
Ear infection	1 (4.5)	1 (4.5)	0	0	0
Escherichia urinary tract infection	1 (4.5)	0	1 (4.5)	0	0
Folliculitis	1 (4.5)	0	1 (4.5)	0	0
Fungal skin infection	1 (4.5)	1 (4.5)	0	0	0
Gingivitis	1 (4.5)	1 (4.5)	0	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemophilus infection	1 (4.5)	0	1 (4.5)	0	0
Herpes simplex	1 (4.5)	1 (4.5)	0	0	0
Herpes zoster	1 (4.5)	0	0	1 (4.5)	0
Oral candidiasis	1 (4.5)	1 (4.5)	0	0	0
Orchitis	1 (4.5)	1 (4.5)	0	0	0
Otitis media	1 (4.5)	0	0	1 (4.5)	0
Otitis media acute	1 (4.5)	0	1 (4.5)	0	0
Pharyngitis	1 (4.5)	0	1 (4.5)	0	0
Pneumonia	1 (4.5)	0	1 (4.5)	0	0
Respiratory syncytial virus infection	1 (4.5)	0	0	1 (4.5)	0
Rhinovirus infection	1 (4.5)	1 (4.5)	0	0	0
Skin infection	1 (4.5)	0	1 (4.5)	0	0
Staphylococcal bacteraemia	1 (4.5)	0	0	1 (4.5)	0
Staphylococcal infection	1 (4.5)	0	0	0	1 (4.5)
Streptococcal infection	1 (4.5)	0	1 (4.5)	0	0
Tinea capitis	1 (4.5)	1 (4.5)	0	0	0
Urinary tract infection enterococcal	1 (4.5)	0	0	1 (4.5)	0
Vascular device infection	1 (4.5)	0	0	1 (4.5)	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (4.5)	1 (4.5)	0	0	0
Vulvovaginal candidiasis	1 (4.5)	1 (4.5)	0	0	0
Injury, poisoning and procedural complications					
-Total	6 (27.3)	2 (9.1)	4 (18.2)	0	0
Infusion related reaction	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Contusion	1 (4.5)	1 (4.5)	0	0	0
Foot fracture	1 (4.5)	0	1 (4.5)	0	0
Procedural nausea	1 (4.5)	0	1 (4.5)	0	0
Procedural pain	1 (4.5)	0	1 (4.5)	0	0
Radiation skin injury	1 (4.5)	0	1 (4.5)	0	0
Skin laceration	1 (4.5)	0	1 (4.5)	0	0
Sunburn	1 (4.5)	1 (4.5)	0	0	0
Wound	1 (4.5)	1 (4.5)	0	0	0
Investigations					
-Total	21 (95.5)	0	2 (9.1)	5 (22.7)	14 (63.6)
White blood cell count decreased	14 (63.6)	2 (9.1)	0	2 (9.1)	10 (45.5)
Neutrophil count decreased	12 (54.5)	1 (4.5)	0	2 (9.1)	9 (40.9)

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	8 (36.4)	1 (4.5)	1 (4.5)	3 (13.6)	3 (13.6)
Aspartate aminotransferase increased	7 (31.8)	0	3 (13.6)	2 (9.1)	2 (9.1)
Platelet count decreased	7 (31.8)	2 (9.1)	0	1 (4.5)	4 (18.2)
Alanine aminotransferase increased	6 (27.3)	1 (4.5)	1 (4.5)	3 (13.6)	1 (4.5)
Blood bilirubin increased	5 (22.7)	2 (9.1)	0	2 (9.1)	1 (4.5)
International normalised ratio increased	5 (22.7)	4 (18.2)	1 (4.5)	0	0
Blood creatinine increased	3 (13.6)	3 (13.6)	0	0	0
Activated partial thromboplastin time prolonged	2 (9.1)	0	2 (9.1)	0	0
Prothrombin time prolonged	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Blood immunoglobulin a decreased	1 (4.5)	1 (4.5)	0	0	0
Blood immunoglobulin m decreased	1 (4.5)	1 (4.5)	0	0	0
Blood lactate dehydrogenase increased	1 (4.5)	0	0	1 (4.5)	0
Blood lactic acid increased	1 (4.5)	0	0	0	1 (4.5)
Blood magnesium decreased	1 (4.5)	1 (4.5)	0	0	0
Blood phosphorus increased	1 (4.5)	1 (4.5)	0	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	1 (4.5)	0	1 (4.5)	0	0
Cardiac murmur	1 (4.5)	1 (4.5)	0	0	0
Computerised tomogram thorax abnormal	1 (4.5)	0	0	1 (4.5)	0
Culture stool positive	1 (4.5)	1 (4.5)	0	0	0
Electrocardiogram qt prolonged	1 (4.5)	0	0	1 (4.5)	0
Fibrin d dimer increased	1 (4.5)	1 (4.5)	0	0	0
Haemoglobin decreased	1 (4.5)	1 (4.5)	0	0	0
Serum ferritin increased	1 (4.5)	0	1 (4.5)	0	0
Transaminases increased	1 (4.5)	1 (4.5)	0	0	0
Weight decreased	1 (4.5)	1 (4.5)	0	0	0
Weight increased	1 (4.5)	1 (4.5)	0	0	0
Metabolism and nutrition disorders					
-Total	13 (59.1)	2 (9.1)	1 (4.5)	8 (36.4)	2 (9.1)
Decreased appetite	7 (31.8)	1 (4.5)	3 (13.6)	3 (13.6)	0
Hypokalaemia	3 (13.6)	1 (4.5)	0	1 (4.5)	1 (4.5)
Hypophosphataemia	3 (13.6)	1 (4.5)	0	2 (9.1)	0
Dehydration	2 (9.1)	0	0	2 (9.1)	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fluid overload	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Hyperkalaemia	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Hyperphosphataemia	2 (9.1)	2 (9.1)	0	0	0
Hypoglycaemia	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Hypernatraemia	1 (4.5)	0	0	0	1 (4.5)
Hyperuricaemia	1 (4.5)	0	0	0	1 (4.5)
Hypoalbuminaemia	1 (4.5)	0	1 (4.5)	0	0
Hypocalcaemia	1 (4.5)	1 (4.5)	0	0	0
Hypomagnesaemia	1 (4.5)	1 (4.5)	0	0	0
Hyponatraemia	1 (4.5)	0	0	1 (4.5)	0
Musculoskeletal and connective tissue disorders					
-Total	11 (50.0)	5 (22.7)	3 (13.6)	3 (13.6)	0
Pain in extremity	6 (27.3)	3 (13.6)	2 (9.1)	1 (4.5)	0
Arthralgia	4 (18.2)	1 (4.5)	1 (4.5)	2 (9.1)	0
Myalgia	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Back pain	1 (4.5)	0	0	1 (4.5)	0
Muscular weakness	1 (4.5)	1 (4.5)	0	0	0

Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Osteonecrosis	1 (4.5)	0	1 (4.5)	0	0
Pain in jaw	1 (4.5)	1 (4.5)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (4.5)	0	0	0	1 (4.5)
Glioblastoma multiforme	1 (4.5)	0	0	0	1 (4.5)
Nervous system disorders					
-Total	15 (68.2)	6 (27.3)	6 (27.3)	2 (9.1)	1 (4.5)
Headache	8 (36.4)	4 (18.2)	2 (9.1)	2 (9.1)	0
Encephalopathy	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Peroneal nerve palsy	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Seizure	3 (13.6)	0	1 (4.5)	1 (4.5)	1 (4.5)
Disturbance in attention	1 (4.5)	1 (4.5)	0	0	0
Hyporesponsive to stimuli	1 (4.5)	0	0	1 (4.5)	0
Myoclonus	1 (4.5)	1 (4.5)	0	0	0
Neuropathy peripheral	1 (4.5)	1 (4.5)	0	0	0
Somnolence	1 (4.5)	0	1 (4.5)	0	0
Tremor	1 (4.5)	1 (4.5)	0	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	9 (40.9)	2 (9.1)	5 (22.7)	2 (9.1)	0
Anxiety	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Delirium	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Depression	2 (9.1)	2 (9.1)	0	0	0
Mental status changes	2 (9.1)	2 (9.1)	0	0	0
Agitation	1 (4.5)	0	0	1 (4.5)	0
Confusional state	1 (4.5)	1 (4.5)	0	0	0
Insomnia	1 (4.5)	0	1 (4.5)	0	0
Panic attack	1 (4.5)	0	1 (4.5)	0	0
Sleep disorder	1 (4.5)	0	1 (4.5)	0	0
Renal and urinary disorders					
-Total	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Acute kidney injury	1 (4.5)	0	0	1 (4.5)	0
Oliguria	1 (4.5)	0	0	1 (4.5)	0
Urinary incontinence	1 (4.5)	1 (4.5)	0	0	0
Urinary retention	1 (4.5)	0	1 (4.5)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Vaginal haemorrhage	1 (4.5)	0	0	1 (4.5)	0
Vulvovaginal adhesion	1 (4.5)	1 (4.5)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	13 (59.1)	4 (18.2)	4 (18.2)	4 (18.2)	1 (4.5)
Cough	6 (27.3)	4 (18.2)	1 (4.5)	1 (4.5)	0
Hypoxia	5 (22.7)	0	2 (9.1)	3 (13.6)	0
Nasal congestion	3 (13.6)	3 (13.6)	0	0	0
Dyspnoea	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Oropharyngeal pain	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Pleural effusion	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Pulmonary oedema	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Rhinitis allergic	2 (9.1)	2 (9.1)	0	0	0
Rhinorrhoea	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Tachypnoea	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Atelectasis	1 (4.5)	1 (4.5)	0	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphonia	1 (4.5)	1 (4.5)	0	0	0
Epistaxis	1 (4.5)	0	0	1 (4.5)	0
Haemoptysis	1 (4.5)	0	0	1 (4.5)	0
Pharyngeal erythema	1 (4.5)	1 (4.5)	0	0	0
Pharyngeal lesion	1 (4.5)	0	0	1 (4.5)	0
Pharyngeal ulceration	1 (4.5)	0	1 (4.5)	0	0
Pulmonary alveolar haemorrhage	1 (4.5)	0	0	0	1 (4.5)
Pulmonary hypertension	1 (4.5)	0	0	1 (4.5)	0
Respiratory depression	1 (4.5)	0	1 (4.5)	0	0
Respiratory distress	1 (4.5)	0	0	0	1 (4.5)
Skin and subcutaneous tissue disorders					
-Total	16 (72.7)	9 (40.9)	5 (22.7)	2 (9.1)	0
Erythema	4 (18.2)	4 (18.2)	0	0	0
Alopecia	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Dry skin	2 (9.1)	2 (9.1)	0	0	0
Ingrowing nail	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Rash	2 (9.1)	1 (4.5)	1 (4.5)	0	0

Baseline bone marrow tumor burden: Low

Primary system organ class Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash erythematous	2 (9.1)	0	2 (9.1)	0	0
Rash maculo-papular	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Acne	1 (4.5)	1 (4.5)	0	0	0
Dermatitis atopic	1 (4.5)	1 (4.5)	0	0	0
Dermatitis diaper	1 (4.5)	1 (4.5)	0	0	0
Hyperhidrosis	1 (4.5)	1 (4.5)	0	0	0
Keloid scar	1 (4.5)	0	1 (4.5)	0	0
Livedo reticularis	1 (4.5)	1 (4.5)	0	0	0
Papule	1 (4.5)	1 (4.5)	0	0	0
Pruritus generalised	1 (4.5)	1 (4.5)	0	0	0
Rash macular	1 (4.5)	0	0	1 (4.5)	0
Rash papular	1 (4.5)	1 (4.5)	0	0	0
Vascular disorders					
-Total	10 (45.5)	1 (4.5)	1 (4.5)	6 (27.3)	2 (9.1)
Hypertension	7 (31.8)	2 (9.1)	4 (18.2)	1 (4.5)	0
Hypotension	6 (27.3)	0	0	4 (18.2)	2 (9.1)
Embolism	1 (4.5)	0	0	1 (4.5)	0
Hot flush	1 (4.5)	1 (4.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178n
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (94.3)	0	3 (5.7)	6 (11.3)	41 (77.4)
Blood and lymphatic system disorders					
-Total	40 (75.5)	1 (1.9)	2 (3.8)	21 (39.6)	16 (30.2)
Febrile neutropenia	25 (47.2)	0	0	24 (45.3)	1 (1.9)
Anaemia	22 (41.5)	1 (1.9)	4 (7.5)	16 (30.2)	1 (1.9)
Neutropenia	9 (17.0)	0	0	2 (3.8)	7 (13.2)
Thrombocytopenia	9 (17.0)	0	1 (1.9)	2 (3.8)	6 (11.3)
Lymphopenia	4 (7.5)	0	2 (3.8)	0	2 (3.8)
Disseminated intravascular coagulation	3 (5.7)	0	1 (1.9)	2 (3.8)	0
Coagulopathy	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Pancytopenia	2 (3.8)	0	0	0	2 (3.8)

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eosinophilia	1 (1.9)	0	0	1 (1.9)	0
Hypofibrinogenaemia	1 (1.9)	0	0	0	1 (1.9)
Leukocytosis	1 (1.9)	1 (1.9)	0	0	0
Leukopenia	1 (1.9)	0	0	0	1 (1.9)
Lymphadenopathy	1 (1.9)	0	1 (1.9)	0	0
Splenomegaly	1 (1.9)	1 (1.9)	0	0	0
Cardiac disorders					
-Total	23 (43.4)	9 (17.0)	8 (15.1)	5 (9.4)	1 (1.9)
Tachycardia	14 (26.4)	8 (15.1)	4 (7.5)	2 (3.8)	0
Sinus tachycardia	6 (11.3)	3 (5.7)	2 (3.8)	1 (1.9)	0
Left ventricular dysfunction	3 (5.7)	0	0	3 (5.7)	0
Pericardial effusion	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Atrioventricular block second degree	1 (1.9)	1 (1.9)	0	0	0
Bradycardia	1 (1.9)	0	1 (1.9)	0	0
Cardiac dysfunction	1 (1.9)	1 (1.9)	0	0	0
Cardiovascular insufficiency	1 (1.9)	0	0	0	1 (1.9)
Palpitations	1 (1.9)	1 (1.9)	0	0	0
Ventricular tachycardia	1 (1.9)	0	1 (1.9)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear and labyrinth disorders					
-Total	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Ear pain	2 (3.8)	2 (3.8)	0	0	0
Deafness unilateral	1 (1.9)	0	1 (1.9)	0	0
Endocrine disorders					
-Total	4 (7.5)	1 (1.9)	3 (5.7)	0	0
Adrenal insufficiency	2 (3.8)	0	2 (3.8)	0	0
Cushingoid	1 (1.9)	1 (1.9)	0	0	0
Hyperthyroidism	1 (1.9)	0	1 (1.9)	0	0
Eye disorders					
-Total	15 (28.3)	8 (15.1)	7 (13.2)	0	0
Periorbital oedema	4 (7.5)	3 (5.7)	1 (1.9)	0	0
Conjunctival haemorrhage	3 (5.7)	3 (5.7)	0	0	0
Vision blurred	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Dry eye	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Photophobia	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Uveitis	2 (3.8)	0	2 (3.8)	0	0
Conjunctivitis allergic	1 (1.9)	1 (1.9)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye irritation	1 (1.9)	1 (1.9)	0	0	0
Eye pain	1 (1.9)	0	1 (1.9)	0	0
Ocular hypertension	1 (1.9)	0	1 (1.9)	0	0
Papilloedema	1 (1.9)	0	1 (1.9)	0	0
Retinal haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Retinopathy	1 (1.9)	0	1 (1.9)	0	0
Visual impairment	1 (1.9)	0	1 (1.9)	0	0
Gastrointestinal disorders					
-Total	34 (64.2)	6 (11.3)	13 (24.5)	14 (26.4)	1 (1.9)
Nausea	22 (41.5)	5 (9.4)	12 (22.6)	5 (9.4)	0
Diarrhoea	21 (39.6)	12 (22.6)	8 (15.1)	1 (1.9)	0
Vomiting	17 (32.1)	9 (17.0)	6 (11.3)	2 (3.8)	0
Abdominal pain	11 (20.8)	5 (9.4)	5 (9.4)	1 (1.9)	0
Constipation	7 (13.2)	6 (11.3)	1 (1.9)	0	0
Colitis	3 (5.7)	1 (1.9)	0	2 (3.8)	0
Stomatitis	3 (5.7)	1 (1.9)	0	1 (1.9)	1 (1.9)
Abdominal distension	2 (3.8)	0	2 (3.8)	0	0
Abdominal pain lower	2 (3.8)	1 (1.9)	1 (1.9)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphagia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Pancreatitis	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Abdominal discomfort	1 (1.9)	1 (1.9)	0	0	0
Abdominal pain upper	1 (1.9)	0	1 (1.9)	0	0
Abdominal tenderness	1 (1.9)	1 (1.9)	0	0	0
Anal fissure	1 (1.9)	0	1 (1.9)	0	0
Ascites	1 (1.9)	0	0	1 (1.9)	0
Flatulence	1 (1.9)	1 (1.9)	0	0	0
Gastrooesophageal reflux disease	1 (1.9)	1 (1.9)	0	0	0
Glossodynia	1 (1.9)	1 (1.9)	0	0	0
Haematemesis	1 (1.9)	1 (1.9)	0	0	0
Haematochezia	1 (1.9)	1 (1.9)	0	0	0
Ileus	1 (1.9)	0	0	1 (1.9)	0
Mouth haemorrhage	1 (1.9)	0	0	1 (1.9)	0
Oral mucosal blistering	1 (1.9)	1 (1.9)	0	0	0
Pancreatic failure	1 (1.9)	0	1 (1.9)	0	0
Perianal erythema	1 (1.9)	0	1 (1.9)	0	0
Pigmentation lip	1 (1.9)	1 (1.9)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Proctalgia	1 (1.9)	0	1 (1.9)	0	0
Tooth socket haemorrhage	1 (1.9)	1 (1.9)	0	0	0
General disorders and administration site conditions					
-Total	35 (66.0)	7 (13.2)	15 (28.3)	10 (18.9)	3 (5.7)
Pyrexia	22 (41.5)	4 (7.5)	12 (22.6)	5 (9.4)	1 (1.9)
Fatigue	12 (22.6)	8 (15.1)	2 (3.8)	2 (3.8)	0
Chills	9 (17.0)	7 (13.2)	2 (3.8)	0	0
Pain	5 (9.4)	1 (1.9)	2 (3.8)	2 (3.8)	0
Catheter site pain	4 (7.5)	2 (3.8)	2 (3.8)	0	0
Generalised oedema	4 (7.5)	2 (3.8)	2 (3.8)	0	0
Malaise	4 (7.5)	1 (1.9)	3 (5.7)	0	0
Oedema peripheral	4 (7.5)	2 (3.8)	1 (1.9)	1 (1.9)	0
Multiple organ dysfunction syndrome	3 (5.7)	0	0	1 (1.9)	2 (3.8)
Face oedema	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Physical deconditioning	2 (3.8)	0	0	2 (3.8)	0
Asthenia	1 (1.9)	1 (1.9)	0	0	0
Catheter site extravasation	1 (1.9)	0	1 (1.9)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Crying	1 (1.9)	1 (1.9)	0	0	0
Cyst	1 (1.9)	0	0	1 (1.9)	0
Device related thrombosis	1 (1.9)	0	1 (1.9)	0	0
Facial pain	1 (1.9)	0	1 (1.9)	0	0
Gait disturbance	1 (1.9)	1 (1.9)	0	0	0
Influenza like illness	1 (1.9)	1 (1.9)	0	0	0
Injection site haematoma	1 (1.9)	1 (1.9)	0	0	0
Localised oedema	1 (1.9)	0	0	1 (1.9)	0
Medical device pain	1 (1.9)	0	1 (1.9)	0	0
Mucosal haemorrhage	1 (1.9)	0	1 (1.9)	0	0
Peripheral swelling	1 (1.9)	0	1 (1.9)	0	0
Hepatobiliary disorders					
-Total	8 (15.1)	2 (3.8)	2 (3.8)	4 (7.5)	0
Hyperbilirubinaemia	4 (7.5)	0	1 (1.9)	3 (5.7)	0
Hepatomegaly	2 (3.8)	0	2 (3.8)	0	0
Cholecystitis	1 (1.9)	0	0	1 (1.9)	0
Gallbladder enlargement	1 (1.9)	1 (1.9)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic steatosis	1 (1.9)	0	1 (1.9)	0	0
Hepatosplenomegaly	1 (1.9)	1 (1.9)	0	0	0
Immune system disorders					
-Total	41 (77.4)	5 (9.4)	20 (37.7)	7 (13.2)	9 (17.0)
Cytokine release syndrome	34 (64.2)	6 (11.3)	14 (26.4)	5 (9.4)	9 (17.0)
Hypogammaglobulinaemia	20 (37.7)	2 (3.8)	14 (26.4)	4 (7.5)	0
Immunodeficiency common variable	2 (3.8)	0	2 (3.8)	0	0
Seasonal allergy	2 (3.8)	2 (3.8)	0	0	0
Chronic graft versus host disease	1 (1.9)	0	1 (1.9)	0	0
Graft versus host disease	1 (1.9)	1 (1.9)	0	0	0
Graft versus host disease in gastrointestinal tract	1 (1.9)	0	1 (1.9)	0	0
Graft versus host disease in skin	1 (1.9)	1 (1.9)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.9)	0	1 (1.9)	0	0
Immunodeficiency	1 (1.9)	0	1 (1.9)	0	0
Infections and infestations					
-Total	36 (67.9)	3 (5.7)	9 (17.0)	15 (28.3)	9 (17.0)
Clostridium difficile infection	6 (11.3)	0	5 (9.4)	1 (1.9)	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	6 (11.3)	0	4 (7.5)	1 (1.9)	1 (1.9)
Upper respiratory tract infection	6 (11.3)	4 (7.5)	1 (1.9)	1 (1.9)	0
Rhinovirus infection	5 (9.4)	4 (7.5)	1 (1.9)	0	0
Urinary tract infection	5 (9.4)	0	3 (5.7)	2 (3.8)	0
Clostridium difficile colitis	4 (7.5)	1 (1.9)	1 (1.9)	2 (3.8)	0
Parainfluenzae virus infection	4 (7.5)	2 (3.8)	1 (1.9)	1 (1.9)	0
Device related infection	3 (5.7)	0	1 (1.9)	2 (3.8)	0
Gastroenteritis	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Otitis media	3 (5.7)	0	3 (5.7)	0	0
Sinusitis	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Viral upper respiratory tract infection	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Cytomegalovirus infection	2 (3.8)	2 (3.8)	0	0	0
Escherichia bacteraemia	2 (3.8)	0	0	2 (3.8)	0
Escherichia urinary tract infection	2 (3.8)	0	0	2 (3.8)	0
Influenza	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Oral herpes	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Sepsis	2 (3.8)	0	0	0	2 (3.8)
Staphylococcal infection	2 (3.8)	1 (1.9)	0	1 (1.9)	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (1.9)	0	0	1 (1.9)	0
Bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Body tinea	1 (1.9)	1 (1.9)	0	0	0
Bronchopulmonary aspergillosis	1 (1.9)	0	0	1 (1.9)	0
Campylobacter infection	1 (1.9)	0	0	1 (1.9)	0
Candida sepsis	1 (1.9)	0	0	0	1 (1.9)
Catheter site cellulitis	1 (1.9)	1 (1.9)	0	0	0
Catheter site infection	1 (1.9)	0	0	1 (1.9)	0
Cellulitis	1 (1.9)	0	0	1 (1.9)	0
Cellulitis of male external genital organ	1 (1.9)	0	0	1 (1.9)	0
Ear infection	1 (1.9)	0	1 (1.9)	0	0
Enterococcal infection	1 (1.9)	1 (1.9)	0	0	0
Enterovirus infection	1 (1.9)	0	0	1 (1.9)	0
Escherichia sepsis	1 (1.9)	0	0	0	1 (1.9)
Fungal skin infection	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis norovirus	1 (1.9)	0	1 (1.9)	0	0
Gastroenteritis viral	1 (1.9)	1 (1.9)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (1.9)	0	1 (1.9)	0	0
Human polyomavirus infection	1 (1.9)	0	0	0	1 (1.9)
Hypopyon	1 (1.9)	0	1 (1.9)	0	0
Klebsiella sepsis	1 (1.9)	0	0	0	1 (1.9)
Meningitis aseptic	1 (1.9)	0	1 (1.9)	0	0
Metapneumovirus infection	1 (1.9)	0	1 (1.9)	0	0
Molluscum contagiosum	1 (1.9)	1 (1.9)	0	0	0
Necrotising fasciitis	1 (1.9)	0	0	1 (1.9)	0
Otitis externa	1 (1.9)	0	1 (1.9)	0	0
Otitis media acute	1 (1.9)	0	1 (1.9)	0	0
Paronychia	1 (1.9)	1 (1.9)	0	0	0
Pneumonia fungal	1 (1.9)	0	1 (1.9)	0	0
Rash pustular	1 (1.9)	0	1 (1.9)	0	0
Respiratory syncytial virus bronchitis	1 (1.9)	0	0	1 (1.9)	0
Respiratory syncytial virus infection	1 (1.9)	0	1 (1.9)	0	0
Respiratory tract infection	1 (1.9)	0	0	0	1 (1.9)
Respiratory tract infection viral	1 (1.9)	0	0	1 (1.9)	0
Rhinitis	1 (1.9)	1 (1.9)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rotavirus infection	1 (1.9)	0	0	1 (1.9)	0
Septic embolus	1 (1.9)	0	0	0	1 (1.9)
Skin infection	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Staphylococcal scalded skin syndrome	1 (1.9)	0	1 (1.9)	0	0
Staphylococcal sepsis	1 (1.9)	0	0	0	1 (1.9)
Streptococcal bacteraemia	1 (1.9)	0	0	1 (1.9)	0
Subcutaneous abscess	1 (1.9)	0	1 (1.9)	0	0
Vulvovaginal candidiasis	1 (1.9)	0	1 (1.9)	0	0
Vulvovaginal mycotic infection	1 (1.9)	0	1 (1.9)	0	0
Injury, poisoning and procedural complications					
-Total	20 (37.7)	10 (18.9)	6 (11.3)	3 (5.7)	1 (1.9)
Procedural pain	4 (7.5)	2 (3.8)	1 (1.9)	1 (1.9)	0
Transfusion reaction	4 (7.5)	2 (3.8)	2 (3.8)	0	0
Infusion related reaction	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Contusion	2 (3.8)	2 (3.8)	0	0	0
Skin abrasion	2 (3.8)	2 (3.8)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Subdural haematoma	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Arthropod bite	1 (1.9)	1 (1.9)	0	0	0
Extradural haematoma	1 (1.9)	0	0	1 (1.9)	0
Incision site pain	1 (1.9)	1 (1.9)	0	0	0
Limb injury	1 (1.9)	1 (1.9)	0	0	0
Mouth injury	1 (1.9)	1 (1.9)	0	0	0
Post procedural haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Procedural complication	1 (1.9)	1 (1.9)	0	0	0
Procedural headache	1 (1.9)	0	1 (1.9)	0	0
Procedural site reaction	1 (1.9)	1 (1.9)	0	0	0
Radiation skin injury	1 (1.9)	0	1 (1.9)	0	0
Radius fracture	1 (1.9)	0	1 (1.9)	0	0
Stoma site irritation	1 (1.9)	1 (1.9)	0	0	0
Subdural haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Tibia fracture	1 (1.9)	0	1 (1.9)	0	0
Tongue injury	1 (1.9)	1 (1.9)	0	0	0
Tracheal haemorrhage	1 (1.9)	0	0	1 (1.9)	0
Transfusion related complication	1 (1.9)	0	0	0	1 (1.9)

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	37 (69.8)	1 (1.9)	2 (3.8)	7 (13.2)	27 (50.9)
White blood cell count decreased	28 (52.8)	2 (3.8)	1 (1.9)	6 (11.3)	19 (35.8)
Alanine aminotransferase increased	20 (37.7)	2 (3.8)	3 (5.7)	15 (28.3)	0
Neutrophil count decreased	20 (37.7)	0	2 (3.8)	1 (1.9)	17 (32.1)
Aspartate aminotransferase increased	17 (32.1)	5 (9.4)	2 (3.8)	7 (13.2)	3 (5.7)
Platelet count decreased	14 (26.4)	1 (1.9)	2 (3.8)	2 (3.8)	9 (17.0)
Lymphocyte count decreased	11 (20.8)	0	2 (3.8)	4 (7.5)	5 (9.4)
Prothrombin time prolonged	7 (13.2)	4 (7.5)	2 (3.8)	1 (1.9)	0
Blood creatinine increased	6 (11.3)	2 (3.8)	2 (3.8)	2 (3.8)	0
International normalised ratio increased	6 (11.3)	5 (9.4)	0	1 (1.9)	0
Blood bilirubin increased	5 (9.4)	0	3 (5.7)	2 (3.8)	0
Activated partial thromboplastin time prolonged	4 (7.5)	3 (5.7)	1 (1.9)	0	0
Blood fibrinogen decreased	4 (7.5)	0	1 (1.9)	2 (3.8)	1 (1.9)
Weight decreased	4 (7.5)	1 (1.9)	3 (5.7)	0	0
Blood immunoglobulin m decreased	3 (5.7)	3 (5.7)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood urea increased	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
C-reactive protein increased	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Lipase increased	3 (5.7)	0	0	0	3 (5.7)
Transaminases increased	3 (5.7)	2 (3.8)	0	1 (1.9)	0
Blood immunoglobulin a decreased	2 (3.8)	2 (3.8)	0	0	0
Blood uric acid increased	2 (3.8)	2 (3.8)	0	0	0
Haemoglobin decreased	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Weight increased	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Blood alkaline phosphatase increased	1 (1.9)	1 (1.9)	0	0	0
Blood bicarbonate decreased	1 (1.9)	0	1 (1.9)	0	0
Blood immunoglobulin g decreased	1 (1.9)	0	1 (1.9)	0	0
Blood lactate dehydrogenase increased	1 (1.9)	1 (1.9)	0	0	0
Blood lactic acid increased	1 (1.9)	0	1 (1.9)	0	0
Blood magnesium decreased	1 (1.9)	0	0	1 (1.9)	0
Blood phosphorus decreased	1 (1.9)	1 (1.9)	0	0	0
Blood phosphorus increased	1 (1.9)	1 (1.9)	0	0	0
Blood sodium increased	1 (1.9)	0	1 (1.9)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Coronavirus test positive	1 (1.9)	1 (1.9)	0	0	0
Electrocardiogram qt prolonged	1 (1.9)	0	0	1 (1.9)	0
Hepatic enzyme increased	1 (1.9)	0	1 (1.9)	0	0
Norovirus test positive	1 (1.9)	1 (1.9)	0	0	0
Oxygen saturation decreased	1 (1.9)	1 (1.9)	0	0	0
Protein total decreased	1 (1.9)	0	0	1 (1.9)	0
Pulmonary function test decreased	1 (1.9)	0	1 (1.9)	0	0
Serum ferritin increased	1 (1.9)	0	1 (1.9)	0	0
Metabolism and nutrition disorders					
-Total	36 (67.9)	4 (7.5)	9 (17.0)	18 (34.0)	5 (9.4)
Decreased appetite	21 (39.6)	6 (11.3)	5 (9.4)	10 (18.9)	0
Hypokalaemia	20 (37.7)	4 (7.5)	5 (9.4)	8 (15.1)	3 (5.7)
Hypophosphataemia	10 (18.9)	3 (5.7)	0	6 (11.3)	1 (1.9)
Hyperglycaemia	7 (13.2)	0	3 (5.7)	4 (7.5)	0
Hyperphosphataemia	7 (13.2)	6 (11.3)	1 (1.9)	0	0
Hypernatraemia	5 (9.4)	1 (1.9)	2 (3.8)	0	2 (3.8)
Hypoalbuminaemia	5 (9.4)	1 (1.9)	3 (5.7)	1 (1.9)	0
Hypocalcaemia	5 (9.4)	2 (3.8)	1 (1.9)	1 (1.9)	1 (1.9)

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fluid overload	4 (7.5)	0	4 (7.5)	0	0
Hyperuricaemia	3 (5.7)	3 (5.7)	0	0	0
Tumour lysis syndrome	3 (5.7)	0	0	3 (5.7)	0
Vitamin d deficiency	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Acidosis	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Dehydration	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Hypertriglyceridaemia	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Hypomagnesaemia	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Malnutrition	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Hyperalbuminaemia	1 (1.9)	1 (1.9)	0	0	0
Hyperammonaemia	1 (1.9)	1 (1.9)	0	0	0
Hypercalcaemia	1 (1.9)	1 (1.9)	0	0	0
Hyperchloraemia	1 (1.9)	1 (1.9)	0	0	0
Hyperkalaemia	1 (1.9)	0	1 (1.9)	0	0
Hypermagnesaemia	1 (1.9)	1 (1.9)	0	0	0
Hyponatraemia	1 (1.9)	0	0	1 (1.9)	0
Iron overload	1 (1.9)	0	0	1 (1.9)	0
Metabolic acidosis	1 (1.9)	0	1 (1.9)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic alkalosis	1 (1.9)	1 (1.9)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	26 (49.1)	12 (22.6)	9 (17.0)	5 (9.4)	0
Pain in extremity	8 (15.1)	4 (7.5)	2 (3.8)	2 (3.8)	0
Musculoskeletal pain	4 (7.5)	2 (3.8)	1 (1.9)	1 (1.9)	0
Arthralgia	3 (5.7)	3 (5.7)	0	0	0
Muscle spasms	3 (5.7)	3 (5.7)	0	0	0
Musculoskeletal chest pain	3 (5.7)	3 (5.7)	0	0	0
Myalgia	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Pain in jaw	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Back pain	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Joint range of motion decreased	2 (3.8)	2 (3.8)	0	0	0
Muscular weakness	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Neck pain	2 (3.8)	0	2 (3.8)	0	0
Bone pain	1 (1.9)	0	0	1 (1.9)	0
Coccydynia	1 (1.9)	1 (1.9)	0	0	0
Flank pain	1 (1.9)	0	1 (1.9)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Limb discomfort	1 (1.9)	1 (1.9)	0	0	0
Myopathy	1 (1.9)	0	0	1 (1.9)	0
Myositis	1 (1.9)	0	0	1 (1.9)	0
Osteopenia	1 (1.9)	0	1 (1.9)	0	0
Synovitis	1 (1.9)	0	1 (1.9)	0	0
Toe walking	1 (1.9)	1 (1.9)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (3.8)	0	2 (3.8)	0	0
Myelodysplastic syndrome	1 (1.9)	0	1 (1.9)	0	0
Skin papilloma	1 (1.9)	0	1 (1.9)	0	0
Nervous system disorders					
-Total	28 (52.8)	11 (20.8)	11 (20.8)	5 (9.4)	1 (1.9)
Headache	21 (39.6)	11 (20.8)	7 (13.2)	3 (5.7)	0
Dizziness	6 (11.3)	6 (11.3)	0	0	0
Dysarthria	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Seizure	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Asterixis	1 (1.9)	1 (1.9)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ataxia	1 (1.9)	0	1 (1.9)	0	0
Depressed level of consciousness	1 (1.9)	1 (1.9)	0	0	0
Dysgeusia	1 (1.9)	1 (1.9)	0	0	0
Embolic stroke	1 (1.9)	0	0	0	1 (1.9)
Encephalopathy	1 (1.9)	0	0	1 (1.9)	0
Hypotonia	1 (1.9)	0	1 (1.9)	0	0
Idiopathic intracranial hypertension	1 (1.9)	0	1 (1.9)	0	0
Migraine	1 (1.9)	0	1 (1.9)	0	0
Neuralgia	1 (1.9)	0	1 (1.9)	0	0
Neuropathy peripheral	1 (1.9)	0	1 (1.9)	0	0
Peripheral sensory neuropathy	1 (1.9)	0	1 (1.9)	0	0
Pleocytosis	1 (1.9)	1 (1.9)	0	0	0
Somnolence	1 (1.9)	1 (1.9)	0	0	0
Tremor	1 (1.9)	1 (1.9)	0	0	0
Visual field defect	1 (1.9)	0	1 (1.9)	0	0
Product issues					
-Total	2 (3.8)	2 (3.8)	0	0	0
Device occlusion	2 (3.8)	2 (3.8)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	17 (32.1)	6 (11.3)	9 (17.0)	2 (3.8)	0
Anxiety	6 (11.3)	2 (3.8)	3 (5.7)	1 (1.9)	0
Confusional state	6 (11.3)	2 (3.8)	4 (7.5)	0	0
Delirium	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Insomnia	3 (5.7)	0	3 (5.7)	0	0
Irritability	3 (5.7)	3 (5.7)	0	0	0
Agitation	2 (3.8)	0	2 (3.8)	0	0
Depression	2 (3.8)	0	2 (3.8)	0	0
Hallucination	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Mental status changes	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Adjustment disorder	1 (1.9)	0	1 (1.9)	0	0
Listless	1 (1.9)	1 (1.9)	0	0	0
Suicidal ideation	1 (1.9)	1 (1.9)	0	0	0
Renal and urinary disorders					
-Total	16 (30.2)	2 (3.8)	3 (5.7)	6 (11.3)	5 (9.4)
Acute kidney injury	11 (20.8)	2 (3.8)	1 (1.9)	4 (7.5)	4 (7.5)
Haematuria	5 (9.4)	0	2 (3.8)	2 (3.8)	1 (1.9)

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysuria	3 (5.7)	1 (1.9)	2 (3.8)	0	0
Oliguria	2 (3.8)	0	0	2 (3.8)	0
Calculus urinary	1 (1.9)	0	1 (1.9)	0	0
Cystitis haemorrhagic	1 (1.9)	0	0	0	1 (1.9)
Nephrolithiasis	1 (1.9)	0	0	1 (1.9)	0
Pollakiuria	1 (1.9)	1 (1.9)	0	0	0
Renal failure	1 (1.9)	0	0	0	1 (1.9)
Renal impairment	1 (1.9)	0	0	1 (1.9)	0
Reproductive system and breast disorders					
-Total	4 (7.5)	1 (1.9)	2 (3.8)	1 (1.9)	0
Oedema genital	1 (1.9)	0	1 (1.9)	0	0
Ovarian failure	1 (1.9)	0	0	1 (1.9)	0
Scrotal pain	1 (1.9)	0	1 (1.9)	0	0
Vulvovaginal adhesion	1 (1.9)	1 (1.9)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	31 (58.5)	9 (17.0)	5 (9.4)	6 (11.3)	11 (20.8)
Epistaxis	13 (24.5)	4 (7.5)	4 (7.5)	4 (7.5)	1 (1.9)

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	10 (18.9)	9 (17.0)	1 (1.9)	0	0
Hypoxia	10 (18.9)	0	1 (1.9)	6 (11.3)	3 (5.7)
Pleural effusion	8 (15.1)	0	6 (11.3)	2 (3.8)	0
Pulmonary oedema	7 (13.2)	1 (1.9)	0	3 (5.7)	3 (5.7)
Tachypnoea	6 (11.3)	3 (5.7)	1 (1.9)	2 (3.8)	0
Oropharyngeal pain	5 (9.4)	4 (7.5)	1 (1.9)	0	0
Respiratory failure	4 (7.5)	0	0	0	4 (7.5)
Rhinorrhoea	4 (7.5)	4 (7.5)	0	0	0
Dyspnoea	3 (5.7)	0	1 (1.9)	1 (1.9)	1 (1.9)
Nasal congestion	3 (5.7)	3 (5.7)	0	0	0
Rhinitis allergic	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Haemoptysis	2 (3.8)	1 (1.9)	0	0	1 (1.9)
Acute respiratory failure	1 (1.9)	0	0	0	1 (1.9)
Aspiration	1 (1.9)	0	0	0	1 (1.9)
Atelectasis	1 (1.9)	0	1 (1.9)	0	0
Idiopathic pneumonia syndrome	1 (1.9)	0	0	0	1 (1.9)
Interstitial lung disease	1 (1.9)	0	0	0	1 (1.9)
Nasal discomfort	1 (1.9)	1 (1.9)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal plaque	1 (1.9)	1 (1.9)	0	0	0
Pulmonary mass	1 (1.9)	0	1 (1.9)	0	0
Respiratory distress	1 (1.9)	0	0	0	1 (1.9)
Wheezing	1 (1.9)	0	1 (1.9)	0	0
Skin and subcutaneous tissue disorders					
-Total	21 (39.6)	12 (22.6)	7 (13.2)	2 (3.8)	0
Rash	7 (13.2)	5 (9.4)	2 (3.8)	0	0
Pruritus	5 (9.4)	5 (9.4)	0	0	0
Petechiae	4 (7.5)	3 (5.7)	1 (1.9)	0	0
Dry skin	3 (5.7)	3 (5.7)	0	0	0
Hyperhidrosis	3 (5.7)	3 (5.7)	0	0	0
Rash erythematous	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Rash maculo-papular	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Dermatitis acneiform	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Macule	2 (3.8)	2 (3.8)	0	0	0
Night sweats	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Rash papular	2 (3.8)	2 (3.8)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash pruritic	2 (3.8)	2 (3.8)	0	0	0
Alopecia	1 (1.9)	1 (1.9)	0	0	0
Cold sweat	1 (1.9)	1 (1.9)	0	0	0
Dermatitis	1 (1.9)	1 (1.9)	0	0	0
Ecchymosis	1 (1.9)	0	0	1 (1.9)	0
Eczema	1 (1.9)	1 (1.9)	0	0	0
Erythema	1 (1.9)	1 (1.9)	0	0	0
Ingrowing nail	1 (1.9)	0	1 (1.9)	0	0
Papule	1 (1.9)	1 (1.9)	0	0	0
Rash follicular	1 (1.9)	1 (1.9)	0	0	0
Rash macular	1 (1.9)	1 (1.9)	0	0	0
Rash vesicular	1 (1.9)	1 (1.9)	0	0	0
Skin exfoliation	1 (1.9)	1 (1.9)	0	0	0
Skin fissures	1 (1.9)	1 (1.9)	0	0	0
Skin haemorrhage	1 (1.9)	1 (1.9)	0	0	0
Skin irritation	1 (1.9)	1 (1.9)	0	0	0
Skin ulcer	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					

Baseline bone marrow tumor burden: High

Primary system organ class Preferred term	All patients N=53 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	24 (45.3)	2 (3.8)	5 (9.4)	8 (15.1)	9 (17.0)
Hypotension	18 (34.0)	1 (1.9)	0	8 (15.1)	9 (17.0)
Hypertension	9 (17.0)	2 (3.8)	6 (11.3)	1 (1.9)	0
Flushing	2 (3.8)	2 (3.8)	0	0	0
Orthostatic hypotension	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Capillary leak syndrome	1 (1.9)	0	0	0	1 (1.9)
Haematoma	1 (1.9)	0	1 (1.9)	0	0
Phlebitis	1 (1.9)	0	1 (1.9)	0	0
Secondary hypertension	1 (1.9)	0	1 (1.9)	0	0
Venous thrombosis limb	1 (1.9)	1 (1.9)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178o
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	1 (14.3)	0	5 (71.4)
Blood and lymphatic system disorders					
-Total	5 (71.4)	0	0	2 (28.6)	3 (42.9)
Febrile neutropenia	4 (57.1)	0	0	3 (42.9)	1 (14.3)
Anaemia	2 (28.6)	0	0	2 (28.6)	0
Leukopenia	1 (14.3)	0	0	0	1 (14.3)
Lymphadenopathy	1 (14.3)	0	1 (14.3)	0	0
Lymphopenia	1 (14.3)	0	0	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					
-Total	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Bradycardia	1 (14.3)	0	1 (14.3)	0	0

Baseline extramedullary disease presence: Yes

Primary system organ class Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pericardial effusion	1 (14.3)	0	1 (14.3)	0	0
Tachycardia	1 (14.3)	1 (14.3)	0	0	0
Ear and labyrinth disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Tympanic membrane perforation	1 (14.3)	0	1 (14.3)	0	0
Eye disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Conjunctival haemorrhage	1 (14.3)	1 (14.3)	0	0	0
Periorbital oedema	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal disorders					
-Total	4 (57.1)	0	3 (42.9)	1 (14.3)	0
Nausea	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Abdominal pain	1 (14.3)	1 (14.3)	0	0	0
Colitis	1 (14.3)	1 (14.3)	0	0	0
Dysphagia	1 (14.3)	0	0	1 (14.3)	0
Pancreatic failure	1 (14.3)	0	1 (14.3)	0	0
Perianal erythema	1 (14.3)	0	1 (14.3)	0	0
Vomiting	1 (14.3)	1 (14.3)	0	0	0

Baseline extramedullary disease presence: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Pyrexia	2 (28.6)	0	2 (28.6)	0	0
Acquired gene mutation	1 (14.3)	1 (14.3)	0	0	0
Chills	1 (14.3)	0	1 (14.3)	0	0
Face oedema	1 (14.3)	0	0	1 (14.3)	0
Localised oedema	1 (14.3)	0	0	1 (14.3)	0
Malaise	1 (14.3)	0	1 (14.3)	0	0
Mucosal haemorrhage	1 (14.3)	0	1 (14.3)	0	0
Multiple organ dysfunction syndrome	1 (14.3)	0	0	1 (14.3)	0
Oedema peripheral	1 (14.3)	0	0	1 (14.3)	0
Hepatobiliary disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Hyperbilirubinaemia	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Immune system disorders					
-Total	5 (71.4)	2 (28.6)	2 (28.6)	0	1 (14.3)
Cytokine release syndrome	4 (57.1)	2 (28.6)	1 (14.3)	0	1 (14.3)

Baseline extramedullary disease presence: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Immunodeficiency	1 (14.3)	0	1 (14.3)	0	0
Seasonal allergy	1 (14.3)	1 (14.3)	0	0	0
Infections and infestations					
-Total	3 (42.9)	0	0	3 (42.9)	0
Pneumonia	2 (28.6)	0	2 (28.6)	0	0
Sinusitis	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Device related infection	1 (14.3)	0	0	1 (14.3)	0
Escherichia bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Gastroenteritis	1 (14.3)	0	1 (14.3)	0	0
Haemophilus infection	1 (14.3)	0	1 (14.3)	0	0
Otitis media	1 (14.3)	0	0	1 (14.3)	0
Otitis media acute	1 (14.3)	0	1 (14.3)	0	0
Subcutaneous abscess	1 (14.3)	0	1 (14.3)	0	0
Upper respiratory tract infection	1 (14.3)	1 (14.3)	0	0	0
Viral upper respiratory tract infection	1 (14.3)	0	0	1 (14.3)	0
Injury, poisoning and procedural complications					

Baseline extramedullary disease presence: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (57.1)	1 (14.3)	1 (14.3)	2 (28.6)	0
Arthropod bite	1 (14.3)	1 (14.3)	0	0	0
Extradural haematoma	1 (14.3)	0	0	1 (14.3)	0
Procedural complication	1 (14.3)	1 (14.3)	0	0	0
Procedural pain	1 (14.3)	0	0	1 (14.3)	0
Radiation skin injury	1 (14.3)	0	1 (14.3)	0	0
Subdural haematoma	1 (14.3)	0	0	1 (14.3)	0
Investigations					
-Total	4 (57.1)	0	0	0	4 (57.1)
Alanine aminotransferase increased	3 (42.9)	0	0	3 (42.9)	0
Aspartate aminotransferase increased	3 (42.9)	0	1 (14.3)	1 (14.3)	1 (14.3)
White blood cell count decreased	3 (42.9)	0	0	1 (14.3)	2 (28.6)
C-reactive protein increased	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Neutrophil count decreased	2 (28.6)	0	0	0	2 (28.6)
Platelet count decreased	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0	0	0

Baseline extramedullary disease presence: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood alkaline phosphatase increased	1 (14.3)	1 (14.3)	0	0	0
Blood bilirubin increased	1 (14.3)	0	0	1 (14.3)	0
Blood creatinine increased	1 (14.3)	0	0	1 (14.3)	0
Blood fibrinogen decreased	1 (14.3)	0	0	0	1 (14.3)
Blood lactate dehydrogenase increased	1 (14.3)	1 (14.3)	0	0	0
Blood lactic acid increased	1 (14.3)	0	1 (14.3)	0	0
Blood phosphorus decreased	1 (14.3)	1 (14.3)	0	0	0
Blood urea increased	1 (14.3)	0	0	1 (14.3)	0
Lymphocyte count decreased	1 (14.3)	0	0	0	1 (14.3)
Protein total decreased	1 (14.3)	0	0	1 (14.3)	0
Serum ferritin increased	1 (14.3)	0	1 (14.3)	0	0
Metabolism and nutrition disorders					
-Total	2 (28.6)	0	0	2 (28.6)	0
Hypokalaemia	2 (28.6)	0	0	2 (28.6)	0
Acidosis	1 (14.3)	0	0	1 (14.3)	0
Decreased appetite	1 (14.3)	0	1 (14.3)	0	0
Fluid overload	1 (14.3)	0	1 (14.3)	0	0

Baseline extramedullary disease presence: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperalbuminaemia	1 (14.3)	1 (14.3)	0	0	0
Hypercalcaemia	1 (14.3)	1 (14.3)	0	0	0
Hyperchloraemia	1 (14.3)	1 (14.3)	0	0	0
Hyperglycaemia	1 (14.3)	0	0	1 (14.3)	0
Hyperkalaemia	1 (14.3)	0	1 (14.3)	0	0
Hypermagnesaemia	1 (14.3)	1 (14.3)	0	0	0
Hypernatraemia	1 (14.3)	0	1 (14.3)	0	0
Hypoalbuminaemia	1 (14.3)	0	1 (14.3)	0	0
Hypophosphataemia	1 (14.3)	1 (14.3)	0	0	0
Iron overload	1 (14.3)	0	0	1 (14.3)	0
Malnutrition	1 (14.3)	0	1 (14.3)	0	0
Metabolic alkalosis	1 (14.3)	1 (14.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Arthralgia	1 (14.3)	1 (14.3)	0	0	0
Bone pain	1 (14.3)	0	0	1 (14.3)	0
Muscle spasms	1 (14.3)	1 (14.3)	0	0	0

Baseline extramedullary disease presence: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	1 (14.3)	0	1 (14.3)	0	0
Musculoskeletal chest pain	1 (14.3)	1 (14.3)	0	0	0
Pain in jaw	1 (14.3)	0	1 (14.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (14.3)	0	0	0	1 (14.3)
Glioblastoma multiforme	1 (14.3)	0	0	0	1 (14.3)
Nervous system disorders					
-Total	4 (57.1)	0	2 (28.6)	2 (28.6)	0
Dysarthria	1 (14.3)	0	1 (14.3)	0	0
Headache	1 (14.3)	0	0	1 (14.3)	0
Hypotonia	1 (14.3)	0	1 (14.3)	0	0
Seizure	1 (14.3)	0	0	1 (14.3)	0
Somnolence	1 (14.3)	1 (14.3)	0	0	0
Product issues					
-Total	1 (14.3)	1 (14.3)	0	0	0
Device occlusion	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					

Baseline extramedullary disease presence: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Delirium	1 (14.3)	0	1 (14.3)	0	0
Insomnia	1 (14.3)	0	1 (14.3)	0	0
Irritability	1 (14.3)	1 (14.3)	0	0	0
Mental status changes	1 (14.3)	0	0	1 (14.3)	0
Renal and urinary disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Renal impairment	1 (14.3)	0	0	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (57.1)	2 (28.6)	0	1 (14.3)	1 (14.3)
Epistaxis	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Cough	1 (14.3)	1 (14.3)	0	0	0
Hypoxia	1 (14.3)	0	0	1 (14.3)	0
Oropharyngeal plaque	1 (14.3)	1 (14.3)	0	0	0
Pleural effusion	1 (14.3)	0	0	1 (14.3)	0
Pulmonary oedema	1 (14.3)	0	0	1 (14.3)	0
Respiratory distress	1 (14.3)	0	0	0	1 (14.3)

Baseline extramedullary disease presence: Yes

	All patients N=7				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	1 (14.3)	1 (14.3)	0	0	0
Tachypnoea	1 (14.3)	0	0	1 (14.3)	0
Skin and subcutaneous tissue disorders					
-Total	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Dermatitis	1 (14.3)	1 (14.3)	0	0	0
Hyperhidrosis	1 (14.3)	1 (14.3)	0	0	0
Papule	1 (14.3)	1 (14.3)	0	0	0
Pruritus	1 (14.3)	1 (14.3)	0	0	0
Rash	1 (14.3)	0	1 (14.3)	0	0
Rash papular	1 (14.3)	1 (14.3)	0	0	0
Vascular disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)
Capillary leak syndrome	1 (14.3)	0	0	0	1 (14.3)
Flushing	1 (14.3)	1 (14.3)	0	0	0
Hypertension	1 (14.3)	0	1 (14.3)	0	0
Hypotension	1 (14.3)	0	0	0	1 (14.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178o
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	66 (97.1)	0	2 (2.9)	12 (17.6)	52 (76.5)
Blood and lymphatic system disorders					
-Total	56 (82.4)	1 (1.5)	2 (2.9)	33 (48.5)	20 (29.4)
Anaemia	33 (48.5)	2 (2.9)	6 (8.8)	24 (35.3)	1 (1.5)
Febrile neutropenia	32 (47.1)	0	0	32 (47.1)	0
Neutropenia	16 (23.5)	0	0	4 (5.9)	12 (17.6)
Thrombocytopenia	14 (20.6)	0	1 (1.5)	5 (7.4)	8 (11.8)
Disseminated intravascular coagulation	6 (8.8)	0	2 (2.9)	3 (4.4)	1 (1.5)
Lymphopenia	5 (7.4)	0	2 (2.9)	1 (1.5)	2 (2.9)
Pancytopenia	4 (5.9)	0	0	1 (1.5)	3 (4.4)
Coagulopathy	2 (2.9)	1 (1.5)	0	1 (1.5)	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eosinophilia	1 (1.5)	0	0	1 (1.5)	0
Hypofibrinogenaemia	1 (1.5)	0	0	0	1 (1.5)
Leukocytosis	1 (1.5)	1 (1.5)	0	0	0
Splenomegaly	1 (1.5)	1 (1.5)	0	0	0
Cardiac disorders					
-Total	26 (38.2)	10 (14.7)	9 (13.2)	5 (7.4)	2 (2.9)
Tachycardia	16 (23.5)	8 (11.8)	6 (8.8)	2 (2.9)	0
Sinus tachycardia	7 (10.3)	3 (4.4)	2 (2.9)	2 (2.9)	0
Left ventricular dysfunction	3 (4.4)	0	0	3 (4.4)	0
Bradycardia	2 (2.9)	1 (1.5)	0	0	1 (1.5)
Palpitations	2 (2.9)	2 (2.9)	0	0	0
Pericardial effusion	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Ventricular tachycardia	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Atrioventricular block second degree	1 (1.5)	1 (1.5)	0	0	0
Cardiac dysfunction	1 (1.5)	1 (1.5)	0	0	0
Cardiovascular insufficiency	1 (1.5)	0	0	0	1 (1.5)
Right ventricular dysfunction	1 (1.5)	0	0	1 (1.5)	0
Sinus bradycardia	1 (1.5)	1 (1.5)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ear and labyrinth disorders					
-Total	4 (5.9)	2 (2.9)	2 (2.9)	0	0
Ear pain	2 (2.9)	2 (2.9)	0	0	0
Deafness unilateral	1 (1.5)	0	1 (1.5)	0	0
Hypoacusis	1 (1.5)	0	1 (1.5)	0	0
Endocrine disorders					
-Total	5 (7.4)	2 (2.9)	3 (4.4)	0	0
Adrenal insufficiency	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Cushingoid	1 (1.5)	1 (1.5)	0	0	0
Hyperthyroidism	1 (1.5)	0	1 (1.5)	0	0
Eye disorders					
-Total	19 (27.9)	10 (14.7)	9 (13.2)	0	0
Vision blurred	4 (5.9)	2 (2.9)	2 (2.9)	0	0
Eye pain	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Periorbital oedema	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Photophobia	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Conjunctival haemorrhage	2 (2.9)	2 (2.9)	0	0	0
Dry eye	2 (2.9)	1 (1.5)	1 (1.5)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Retinal haemorrhage	2 (2.9)	2 (2.9)	0	0	0
Uveitis	2 (2.9)	0	2 (2.9)	0	0
Conjunctivitis allergic	1 (1.5)	1 (1.5)	0	0	0
Eye irritation	1 (1.5)	1 (1.5)	0	0	0
Ocular hyperaemia	1 (1.5)	1 (1.5)	0	0	0
Ocular hypertension	1 (1.5)	0	1 (1.5)	0	0
Papilloedema	1 (1.5)	0	1 (1.5)	0	0
Retinopathy	1 (1.5)	0	1 (1.5)	0	0
Visual impairment	1 (1.5)	0	1 (1.5)	0	0
Gastrointestinal disorders					
-Total	49 (72.1)	12 (17.6)	17 (25.0)	19 (27.9)	1 (1.5)
Nausea	30 (44.1)	8 (11.8)	15 (22.1)	7 (10.3)	0
Vomiting	29 (42.6)	16 (23.5)	9 (13.2)	4 (5.9)	0
Diarrhoea	26 (38.2)	14 (20.6)	10 (14.7)	2 (2.9)	0
Abdominal pain	16 (23.5)	6 (8.8)	7 (10.3)	3 (4.4)	0
Constipation	11 (16.2)	9 (13.2)	2 (2.9)	0	0
Stomatitis	5 (7.4)	1 (1.5)	1 (1.5)	2 (2.9)	1 (1.5)
Abdominal pain upper	3 (4.4)	1 (1.5)	2 (2.9)	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	3 (4.4)	0	0	3 (4.4)	0
Oral pain	3 (4.4)	1 (1.5)	1 (1.5)	1 (1.5)	0
Pancreatitis	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Abdominal distension	2 (2.9)	0	2 (2.9)	0	0
Abdominal pain lower	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Ascites	2 (2.9)	0	0	2 (2.9)	0
Gastrointestinal haemorrhage	2 (2.9)	2 (2.9)	0	0	0
Haematemesis	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Haematochezia	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Abdominal discomfort	1 (1.5)	1 (1.5)	0	0	0
Abdominal tenderness	1 (1.5)	1 (1.5)	0	0	0
Anal fissure	1 (1.5)	0	1 (1.5)	0	0
Anal incontinence	1 (1.5)	1 (1.5)	0	0	0
Dry mouth	1 (1.5)	1 (1.5)	0	0	0
Dyspepsia	1 (1.5)	0	1 (1.5)	0	0
Dysphagia	1 (1.5)	0	1 (1.5)	0	0
Enterocolitis	1 (1.5)	0	0	1 (1.5)	0
Flatulence	1 (1.5)	1 (1.5)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastrooesophageal reflux disease	1 (1.5)	1 (1.5)	0	0	0
Gingival discomfort	1 (1.5)	1 (1.5)	0	0	0
Glossodynia	1 (1.5)	1 (1.5)	0	0	0
Ileus	1 (1.5)	0	0	1 (1.5)	0
Intestinal obstruction	1 (1.5)	0	0	1 (1.5)	0
Lip pain	1 (1.5)	0	1 (1.5)	0	0
Mouth haemorrhage	1 (1.5)	0	0	1 (1.5)	0
Oral mucosal blistering	1 (1.5)	1 (1.5)	0	0	0
Pigmentation lip	1 (1.5)	1 (1.5)	0	0	0
Proctalgia	1 (1.5)	0	1 (1.5)	0	0
Tooth socket haemorrhage	1 (1.5)	1 (1.5)	0	0	0
General disorders and administration site conditions					
-Total	48 (70.6)	15 (22.1)	16 (23.5)	13 (19.1)	4 (5.9)
Pyrexia	30 (44.1)	9 (13.2)	13 (19.1)	7 (10.3)	1 (1.5)
Fatigue	18 (26.5)	13 (19.1)	3 (4.4)	2 (2.9)	0
Chills	10 (14.7)	9 (13.2)	1 (1.5)	0	0
Catheter site pain	7 (10.3)	3 (4.4)	4 (5.9)	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	7 (10.3)	1 (1.5)	3 (4.4)	3 (4.4)	0
Generalised oedema	4 (5.9)	2 (2.9)	2 (2.9)	0	0
Oedema peripheral	4 (5.9)	3 (4.4)	1 (1.5)	0	0
Malaise	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Multiple organ dysfunction syndrome	3 (4.4)	0	0	0	3 (4.4)
Influenza like illness	2 (2.9)	2 (2.9)	0	0	0
Non-cardiac chest pain	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Physical deconditioning	2 (2.9)	0	0	2 (2.9)	0
Asthenia	1 (1.5)	1 (1.5)	0	0	0
Catheter site extravasation	1 (1.5)	0	1 (1.5)	0	0
Catheter site haemorrhage	1 (1.5)	1 (1.5)	0	0	0
Crying	1 (1.5)	1 (1.5)	0	0	0
Cyst	1 (1.5)	0	0	1 (1.5)	0
Device related thrombosis	1 (1.5)	0	1 (1.5)	0	0
Face oedema	1 (1.5)	0	1 (1.5)	0	0
Facial pain	1 (1.5)	0	1 (1.5)	0	0
Gait disturbance	1 (1.5)	1 (1.5)	0	0	0
Injection site haematoma	1 (1.5)	1 (1.5)	0	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Medical device pain	1 (1.5)	0	1 (1.5)	0	0
Peripheral swelling	1 (1.5)	0	1 (1.5)	0	0
Hepatobiliary disorders					
-Total	9 (13.2)	3 (4.4)	2 (2.9)	3 (4.4)	1 (1.5)
Hepatomegaly	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Hyperbilirubinaemia	3 (4.4)	0	1 (1.5)	2 (2.9)	0
Cholecystitis	1 (1.5)	0	0	1 (1.5)	0
Gallbladder enlargement	1 (1.5)	1 (1.5)	0	0	0
Hepatic failure	1 (1.5)	0	0	0	1 (1.5)
Hepatic steatosis	1 (1.5)	0	1 (1.5)	0	0
Hepatosplenomegaly	1 (1.5)	1 (1.5)	0	0	0
Immune system disorders					
-Total	54 (79.4)	4 (5.9)	29 (42.6)	11 (16.2)	10 (14.7)
Cytokine release syndrome	46 (67.6)	4 (5.9)	24 (35.3)	8 (11.8)	10 (14.7)
Hypogammaglobulinaemia	29 (42.6)	3 (4.4)	22 (32.4)	4 (5.9)	0
Graft versus host disease	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Immunodeficiency common variable	2 (2.9)	0	2 (2.9)	0	0
Chronic graft versus host disease	1 (1.5)	0	1 (1.5)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Drug hypersensitivity	1 (1.5)	0	1 (1.5)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.5)	0	1 (1.5)	0	0
Graft versus host disease in skin	1 (1.5)	1 (1.5)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.5)	0	1 (1.5)	0	0
Seasonal allergy	1 (1.5)	1 (1.5)	0	0	0
Infections and infestations					
-Total	49 (72.1)	4 (5.9)	16 (23.5)	18 (26.5)	11 (16.2)
Upper respiratory tract infection	10 (14.7)	4 (5.9)	5 (7.4)	1 (1.5)	0
Clostridium difficile infection	6 (8.8)	0	5 (7.4)	1 (1.5)	0
Rhinovirus infection	6 (8.8)	5 (7.4)	1 (1.5)	0	0
Clostridium difficile colitis	5 (7.4)	1 (1.5)	2 (2.9)	2 (2.9)	0
Pneumonia	5 (7.4)	0	3 (4.4)	1 (1.5)	1 (1.5)
Urinary tract infection	5 (7.4)	0	3 (4.4)	2 (2.9)	0
Gastroenteritis	4 (5.9)	1 (1.5)	2 (2.9)	1 (1.5)	0
Influenza	4 (5.9)	1 (1.5)	3 (4.4)	0	0
Parainfluenzae virus infection	4 (5.9)	2 (2.9)	1 (1.5)	1 (1.5)	0
Device related infection	3 (4.4)	0	1 (1.5)	2 (2.9)	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia urinary tract infection	3 (4.4)	0	1 (1.5)	2 (2.9)	0
Otitis media	3 (4.4)	0	3 (4.4)	0	0
Sinusitis	3 (4.4)	0	3 (4.4)	0	0
Staphylococcal infection	3 (4.4)	1 (1.5)	0	1 (1.5)	1 (1.5)
Viral infection	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Viral upper respiratory tract infection	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Cytomegalovirus infection	2 (2.9)	2 (2.9)	0	0	0
Ear infection	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Fungal skin infection	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Oral herpes	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Respiratory syncytial virus infection	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Sepsis	2 (2.9)	0	0	0	2 (2.9)
Skin infection	2 (2.9)	0	2 (2.9)	0	0
Staphylococcal bacteraemia	2 (2.9)	0	0	2 (2.9)	0
Vulvovaginal candidiasis	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Abscess limb	1 (1.5)	0	0	1 (1.5)	0
Acute sinusitis	1 (1.5)	0	1 (1.5)	0	0
Bacteraemia	1 (1.5)	0	0	1 (1.5)	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	1 (1.5)	0	0	0	1 (1.5)
Body tinea	1 (1.5)	1 (1.5)	0	0	0
Bronchitis	1 (1.5)	0	1 (1.5)	0	0
Bronchopulmonary aspergillosis	1 (1.5)	0	0	1 (1.5)	0
Campylobacter infection	1 (1.5)	0	0	1 (1.5)	0
Candida sepsis	1 (1.5)	0	0	0	1 (1.5)
Catheter site cellulitis	1 (1.5)	1 (1.5)	0	0	0
Catheter site infection	1 (1.5)	0	0	1 (1.5)	0
Cellulitis	1 (1.5)	0	0	1 (1.5)	0
Cellulitis of male external genital organ	1 (1.5)	0	0	1 (1.5)	0
Cholecystitis infective	1 (1.5)	0	0	1 (1.5)	0
Conjunctivitis	1 (1.5)	0	1 (1.5)	0	0
Corona virus infection	1 (1.5)	0	0	1 (1.5)	0
Croup infectious	1 (1.5)	0	0	1 (1.5)	0
Enterococcal infection	1 (1.5)	1 (1.5)	0	0	0
Enterovirus infection	1 (1.5)	0	0	1 (1.5)	0
Escherichia bacteraemia	1 (1.5)	0	0	1 (1.5)	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia sepsis	1 (1.5)	0	0	0	1 (1.5)
Folliculitis	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis norovirus	1 (1.5)	0	1 (1.5)	0	0
Gastroenteritis viral	1 (1.5)	1 (1.5)	0	0	0
Gingivitis	1 (1.5)	1 (1.5)	0	0	0
Herpes simplex	1 (1.5)	1 (1.5)	0	0	0
Herpes zoster	1 (1.5)	0	0	1 (1.5)	0
Human herpesvirus 6 infection	1 (1.5)	0	1 (1.5)	0	0
Human polyomavirus infection	1 (1.5)	0	0	0	1 (1.5)
Hypopyon	1 (1.5)	0	1 (1.5)	0	0
Klebsiella sepsis	1 (1.5)	0	0	0	1 (1.5)
Meningitis aseptic	1 (1.5)	0	1 (1.5)	0	0
Metapneumovirus infection	1 (1.5)	0	1 (1.5)	0	0
Molluscum contagiosum	1 (1.5)	1 (1.5)	0	0	0
Necrotising fasciitis	1 (1.5)	0	0	1 (1.5)	0
Oral candidiasis	1 (1.5)	1 (1.5)	0	0	0
Orchitis	1 (1.5)	1 (1.5)	0	0	0
Otitis externa	1 (1.5)	0	1 (1.5)	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media acute	1 (1.5)	0	1 (1.5)	0	0
Paronychia	1 (1.5)	1 (1.5)	0	0	0
Pharyngitis	1 (1.5)	0	1 (1.5)	0	0
Pneumonia fungal	1 (1.5)	0	1 (1.5)	0	0
Rash pustular	1 (1.5)	0	1 (1.5)	0	0
Respiratory syncytial virus bronchitis	1 (1.5)	0	0	1 (1.5)	0
Respiratory tract infection	1 (1.5)	0	0	0	1 (1.5)
Respiratory tract infection viral	1 (1.5)	0	0	1 (1.5)	0
Rhinitis	1 (1.5)	1 (1.5)	0	0	0
Rotavirus infection	1 (1.5)	0	0	1 (1.5)	0
Septic embolus	1 (1.5)	0	0	0	1 (1.5)
Staphylococcal scalded skin syndrome	1 (1.5)	0	1 (1.5)	0	0
Staphylococcal sepsis	1 (1.5)	0	0	0	1 (1.5)
Streptococcal bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Streptococcal infection	1 (1.5)	0	1 (1.5)	0	0
Tinea capitis	1 (1.5)	1 (1.5)	0	0	0
Urinary tract infection enterococcal	1 (1.5)	0	0	1 (1.5)	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (1.5)	0	0	1 (1.5)	0
Vulvovaginal mycotic infection	1 (1.5)	0	1 (1.5)	0	0
Injury, poisoning and procedural complications					
-Total	22 (32.4)	11 (16.2)	9 (13.2)	1 (1.5)	1 (1.5)
Infusion related reaction	5 (7.4)	2 (2.9)	3 (4.4)	0	0
Procedural pain	4 (5.9)	2 (2.9)	2 (2.9)	0	0
Transfusion reaction	4 (5.9)	2 (2.9)	2 (2.9)	0	0
Contusion	3 (4.4)	3 (4.4)	0	0	0
Skin abrasion	2 (2.9)	2 (2.9)	0	0	0
Foot fracture	1 (1.5)	0	1 (1.5)	0	0
Incision site pain	1 (1.5)	1 (1.5)	0	0	0
Limb injury	1 (1.5)	1 (1.5)	0	0	0
Mouth injury	1 (1.5)	1 (1.5)	0	0	0
Post procedural haemorrhage	1 (1.5)	1 (1.5)	0	0	0
Procedural headache	1 (1.5)	0	1 (1.5)	0	0
Procedural nausea	1 (1.5)	0	1 (1.5)	0	0
Procedural site reaction	1 (1.5)	1 (1.5)	0	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Radiation skin injury	1 (1.5)	0	1 (1.5)	0	0
Radius fracture	1 (1.5)	0	1 (1.5)	0	0
Skin laceration	1 (1.5)	0	1 (1.5)	0	0
Stoma site irritation	1 (1.5)	1 (1.5)	0	0	0
Subdural haematoma	1 (1.5)	0	1 (1.5)	0	0
Subdural haemorrhage	1 (1.5)	1 (1.5)	0	0	0
Sunburn	1 (1.5)	1 (1.5)	0	0	0
Tibia fracture	1 (1.5)	0	1 (1.5)	0	0
Tongue injury	1 (1.5)	1 (1.5)	0	0	0
Tracheal haemorrhage	1 (1.5)	0	0	1 (1.5)	0
Transfusion related complication	1 (1.5)	0	0	0	1 (1.5)
Wound	1 (1.5)	1 (1.5)	0	0	0
Investigations					
-Total	54 (79.4)	1 (1.5)	4 (5.9)	12 (17.6)	37 (54.4)
White blood cell count decreased	39 (57.4)	4 (5.9)	1 (1.5)	7 (10.3)	27 (39.7)
Neutrophil count decreased	30 (44.1)	1 (1.5)	2 (2.9)	3 (4.4)	24 (35.3)
Alanine aminotransferase increased	23 (33.8)	3 (4.4)	4 (5.9)	15 (22.1)	1 (1.5)

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	21 (30.9)	5 (7.4)	4 (5.9)	8 (11.8)	4 (5.9)
Platelet count decreased	19 (27.9)	3 (4.4)	2 (2.9)	2 (2.9)	12 (17.6)
Lymphocyte count decreased	18 (26.5)	1 (1.5)	3 (4.4)	7 (10.3)	7 (10.3)
International normalised ratio increased	11 (16.2)	9 (13.2)	1 (1.5)	1 (1.5)	0
Blood bilirubin increased	9 (13.2)	2 (2.9)	3 (4.4)	3 (4.4)	1 (1.5)
Prothrombin time prolonged	9 (13.2)	5 (7.4)	3 (4.4)	1 (1.5)	0
Blood creatinine increased	8 (11.8)	5 (7.4)	2 (2.9)	1 (1.5)	0
Activated partial thromboplastin time prolonged	5 (7.4)	2 (2.9)	3 (4.4)	0	0
Weight decreased	5 (7.4)	2 (2.9)	3 (4.4)	0	0
Blood immunoglobulin m decreased	4 (5.9)	4 (5.9)	0	0	0
Transaminases increased	4 (5.9)	3 (4.4)	0	1 (1.5)	0
Blood fibrinogen decreased	3 (4.4)	0	1 (1.5)	2 (2.9)	0
Blood immunoglobulin a decreased	3 (4.4)	3 (4.4)	0	0	0
Haemoglobin decreased	3 (4.4)	2 (2.9)	0	1 (1.5)	0
Lipase increased	3 (4.4)	0	0	0	3 (4.4)
Weight increased	3 (4.4)	2 (2.9)	1 (1.5)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood magnesium decreased	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Blood phosphorus increased	2 (2.9)	2 (2.9)	0	0	0
Blood urea increased	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Blood uric acid increased	2 (2.9)	2 (2.9)	0	0	0
C-reactive protein increased	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Electrocardiogram qt prolonged	2 (2.9)	0	0	2 (2.9)	0
Blood bicarbonate decreased	1 (1.5)	0	1 (1.5)	0	0
Blood immunoglobulin g decreased	1 (1.5)	0	1 (1.5)	0	0
Blood lactate dehydrogenase increased	1 (1.5)	0	0	1 (1.5)	0
Blood lactic acid increased	1 (1.5)	0	0	0	1 (1.5)
Blood sodium increased	1 (1.5)	0	1 (1.5)	0	0
Cardiac murmur	1 (1.5)	1 (1.5)	0	0	0
Computerised tomogram thorax abnormal	1 (1.5)	0	0	1 (1.5)	0
Coronavirus test positive	1 (1.5)	1 (1.5)	0	0	0
Culture stool positive	1 (1.5)	1 (1.5)	0	0	0
Fibrin d dimer increased	1 (1.5)	1 (1.5)	0	0	0
Hepatic enzyme increased	1 (1.5)	0	1 (1.5)	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Norovirus test positive	1 (1.5)	1 (1.5)	0	0	0
Oxygen saturation decreased	1 (1.5)	1 (1.5)	0	0	0
Pulmonary function test decreased	1 (1.5)	0	1 (1.5)	0	0
Serum ferritin increased	1 (1.5)	0	1 (1.5)	0	0
Metabolism and nutrition disorders					
-Total	47 (69.1)	6 (8.8)	10 (14.7)	24 (35.3)	7 (10.3)
Decreased appetite	27 (39.7)	7 (10.3)	7 (10.3)	13 (19.1)	0
Hypokalaemia	21 (30.9)	5 (7.4)	5 (7.4)	7 (10.3)	4 (5.9)
Hypophosphataemia	12 (17.6)	3 (4.4)	0	8 (11.8)	1 (1.5)
Hyperphosphataemia	9 (13.2)	8 (11.8)	1 (1.5)	0	0
Hyperglycaemia	6 (8.8)	0	3 (4.4)	3 (4.4)	0
Hypocalcaemia	6 (8.8)	3 (4.4)	1 (1.5)	1 (1.5)	1 (1.5)
Fluid overload	5 (7.4)	1 (1.5)	3 (4.4)	1 (1.5)	0
Hypernatraemia	5 (7.4)	1 (1.5)	1 (1.5)	0	3 (4.4)
Hypoalbuminaemia	5 (7.4)	1 (1.5)	3 (4.4)	1 (1.5)	0
Dehydration	4 (5.9)	1 (1.5)	0	3 (4.4)	0
Hyperuricaemia	4 (5.9)	3 (4.4)	0	0	1 (1.5)
Hypomagnesaemia	3 (4.4)	2 (2.9)	1 (1.5)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tumour lysis syndrome	3 (4.4)	0	0	3 (4.4)	0
Vitamin d deficiency	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Hyperkalaemia	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Hypertriglyceridaemia	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Hypoglycaemia	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Hyponatraemia	2 (2.9)	0	0	2 (2.9)	0
Acidosis	1 (1.5)	1 (1.5)	0	0	0
Hyperammonaemia	1 (1.5)	1 (1.5)	0	0	0
Malnutrition	1 (1.5)	0	0	1 (1.5)	0
Metabolic acidosis	1 (1.5)	0	1 (1.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	33 (48.5)	16 (23.5)	10 (14.7)	7 (10.3)	0
Pain in extremity	14 (20.6)	7 (10.3)	4 (5.9)	3 (4.4)	0
Arthralgia	6 (8.8)	3 (4.4)	1 (1.5)	2 (2.9)	0
Myalgia	6 (8.8)	4 (5.9)	1 (1.5)	1 (1.5)	0
Musculoskeletal pain	4 (5.9)	2 (2.9)	1 (1.5)	1 (1.5)	0
Back pain	3 (4.4)	1 (1.5)	0	2 (2.9)	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in jaw	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Joint range of motion decreased	2 (2.9)	2 (2.9)	0	0	0
Muscle spasms	2 (2.9)	2 (2.9)	0	0	0
Muscular weakness	2 (2.9)	2 (2.9)	0	0	0
Musculoskeletal chest pain	2 (2.9)	2 (2.9)	0	0	0
Neck pain	2 (2.9)	0	2 (2.9)	0	0
Coccydynia	1 (1.5)	1 (1.5)	0	0	0
Flank pain	1 (1.5)	0	1 (1.5)	0	0
Limb discomfort	1 (1.5)	1 (1.5)	0	0	0
Myopathy	1 (1.5)	0	0	1 (1.5)	0
Myositis	1 (1.5)	0	0	1 (1.5)	0
Osteonecrosis	1 (1.5)	0	1 (1.5)	0	0
Osteopenia	1 (1.5)	0	1 (1.5)	0	0
Synovitis	1 (1.5)	0	1 (1.5)	0	0
Toe walking	1 (1.5)	1 (1.5)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (2.9)	0	2 (2.9)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Myelodysplastic syndrome	1 (1.5)	0	1 (1.5)	0	0
Skin papilloma	1 (1.5)	0	1 (1.5)	0	0
Nervous system disorders					
-Total	39 (57.4)	17 (25.0)	15 (22.1)	5 (7.4)	2 (2.9)
Headache	28 (41.2)	15 (22.1)	9 (13.2)	4 (5.9)	0
Dizziness	6 (8.8)	6 (8.8)	0	0	0
Encephalopathy	4 (5.9)	1 (1.5)	1 (1.5)	2 (2.9)	0
Seizure	4 (5.9)	0	2 (2.9)	1 (1.5)	1 (1.5)
Peroneal nerve palsy	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Neuropathy peripheral	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Tremor	2 (2.9)	2 (2.9)	0	0	0
Asterixis	1 (1.5)	1 (1.5)	0	0	0
Ataxia	1 (1.5)	0	1 (1.5)	0	0
Depressed level of consciousness	1 (1.5)	1 (1.5)	0	0	0
Disturbance in attention	1 (1.5)	1 (1.5)	0	0	0
Dysarthria	1 (1.5)	1 (1.5)	0	0	0
Dysgeusia	1 (1.5)	1 (1.5)	0	0	0
Embolic stroke	1 (1.5)	0	0	0	1 (1.5)

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyporesponsive to stimuli	1 (1.5)	0	0	1 (1.5)	0
Idiopathic intracranial hypertension	1 (1.5)	0	1 (1.5)	0	0
Migraine	1 (1.5)	0	1 (1.5)	0	0
Myoclonus	1 (1.5)	1 (1.5)	0	0	0
Neuralgia	1 (1.5)	0	1 (1.5)	0	0
Peripheral sensory neuropathy	1 (1.5)	0	1 (1.5)	0	0
Pleocytosis	1 (1.5)	1 (1.5)	0	0	0
Somnolence	1 (1.5)	0	1 (1.5)	0	0
Visual field defect	1 (1.5)	0	1 (1.5)	0	0
Product issues					
-Total	1 (1.5)	1 (1.5)	0	0	0
Device occlusion	1 (1.5)	1 (1.5)	0	0	0
Psychiatric disorders					
-Total	24 (35.3)	8 (11.8)	13 (19.1)	3 (4.4)	0
Anxiety	9 (13.2)	3 (4.4)	5 (7.4)	1 (1.5)	0
Confusional state	7 (10.3)	3 (4.4)	4 (5.9)	0	0
Delirium	4 (5.9)	2 (2.9)	1 (1.5)	1 (1.5)	0
Depression	4 (5.9)	2 (2.9)	2 (2.9)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Agitation	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Insomnia	3 (4.4)	0	3 (4.4)	0	0
Mental status changes	3 (4.4)	3 (4.4)	0	0	0
Hallucination	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Irritability	2 (2.9)	2 (2.9)	0	0	0
Adjustment disorder	1 (1.5)	0	1 (1.5)	0	0
Listless	1 (1.5)	1 (1.5)	0	0	0
Panic attack	1 (1.5)	0	1 (1.5)	0	0
Sleep disorder	1 (1.5)	0	1 (1.5)	0	0
Suicidal ideation	1 (1.5)	1 (1.5)	0	0	0
Renal and urinary disorders					
-Total	18 (26.5)	3 (4.4)	4 (5.9)	6 (8.8)	5 (7.4)
Acute kidney injury	12 (17.6)	2 (2.9)	1 (1.5)	5 (7.4)	4 (5.9)
Haematuria	5 (7.4)	0	2 (2.9)	2 (2.9)	1 (1.5)
Dysuria	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Oliguria	3 (4.4)	0	0	3 (4.4)	0
Calculus urinary	1 (1.5)	0	1 (1.5)	0	0
Cystitis haemorrhagic	1 (1.5)	0	0	0	1 (1.5)

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nephrolithiasis	1 (1.5)	0	0	1 (1.5)	0
Pollakiuria	1 (1.5)	1 (1.5)	0	0	0
Renal failure	1 (1.5)	0	0	0	1 (1.5)
Urinary incontinence	1 (1.5)	1 (1.5)	0	0	0
Urinary retention	1 (1.5)	0	1 (1.5)	0	0
Reproductive system and breast disorders					
-Total	6 (8.8)	2 (2.9)	2 (2.9)	2 (2.9)	0
Vulvovaginal adhesion	2 (2.9)	2 (2.9)	0	0	0
Oedema genital	1 (1.5)	0	1 (1.5)	0	0
Ovarian failure	1 (1.5)	0	0	1 (1.5)	0
Scrotal pain	1 (1.5)	0	1 (1.5)	0	0
Vaginal haemorrhage	1 (1.5)	0	0	1 (1.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	40 (58.8)	11 (16.2)	9 (13.2)	9 (13.2)	11 (16.2)
Cough	15 (22.1)	12 (17.6)	2 (2.9)	1 (1.5)	0
Hypoxia	14 (20.6)	0	3 (4.4)	8 (11.8)	3 (4.4)
Epistaxis	12 (17.6)	4 (5.9)	3 (4.4)	4 (5.9)	1 (1.5)

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pleural effusion	9 (13.2)	1 (1.5)	6 (8.8)	2 (2.9)	0
Pulmonary oedema	8 (11.8)	1 (1.5)	0	3 (4.4)	4 (5.9)
Oropharyngeal pain	7 (10.3)	4 (5.9)	2 (2.9)	1 (1.5)	0
Tachypnoea	7 (10.3)	3 (4.4)	2 (2.9)	2 (2.9)	0
Nasal congestion	6 (8.8)	6 (8.8)	0	0	0
Dyspnoea	5 (7.4)	1 (1.5)	1 (1.5)	2 (2.9)	1 (1.5)
Rhinitis allergic	5 (7.4)	4 (5.9)	1 (1.5)	0	0
Rhinorrhoea	5 (7.4)	4 (5.9)	1 (1.5)	0	0
Respiratory failure	4 (5.9)	0	0	0	4 (5.9)
Haemoptysis	3 (4.4)	1 (1.5)	0	1 (1.5)	1 (1.5)
Atelectasis	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Acute respiratory failure	1 (1.5)	0	0	0	1 (1.5)
Aspiration	1 (1.5)	0	0	0	1 (1.5)
Dysphonia	1 (1.5)	1 (1.5)	0	0	0
Idiopathic pneumonia syndrome	1 (1.5)	0	0	0	1 (1.5)
Interstitial lung disease	1 (1.5)	0	0	0	1 (1.5)
Nasal discomfort	1 (1.5)	1 (1.5)	0	0	0
Pharyngeal erythema	1 (1.5)	1 (1.5)	0	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngeal lesion	1 (1.5)	0	0	1 (1.5)	0
Pharyngeal ulceration	1 (1.5)	0	1 (1.5)	0	0
Pulmonary alveolar haemorrhage	1 (1.5)	0	0	0	1 (1.5)
Pulmonary hypertension	1 (1.5)	0	0	1 (1.5)	0
Pulmonary mass	1 (1.5)	0	1 (1.5)	0	0
Respiratory depression	1 (1.5)	0	1 (1.5)	0	0
Respiratory distress	1 (1.5)	0	0	0	1 (1.5)
Wheezing	1 (1.5)	0	1 (1.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	35 (51.5)	20 (29.4)	11 (16.2)	4 (5.9)	0
Rash	8 (11.8)	6 (8.8)	2 (2.9)	0	0
Dry skin	5 (7.4)	5 (7.4)	0	0	0
Erythema	5 (7.4)	5 (7.4)	0	0	0
Rash erythematous	5 (7.4)	2 (2.9)	3 (4.4)	0	0
Rash maculo-papular	5 (7.4)	3 (4.4)	1 (1.5)	1 (1.5)	0
Alopecia	4 (5.9)	2 (2.9)	2 (2.9)	0	0
Petechiae	4 (5.9)	3 (4.4)	1 (1.5)	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pruritus	4 (5.9)	4 (5.9)	0	0	0
Hyperhidrosis	3 (4.4)	3 (4.4)	0	0	0
Ingrowing nail	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Dermatitis acneiform	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Macule	2 (2.9)	2 (2.9)	0	0	0
Night sweats	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Rash macular	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Rash papular	2 (2.9)	2 (2.9)	0	0	0
Rash pruritic	2 (2.9)	2 (2.9)	0	0	0
Acne	1 (1.5)	1 (1.5)	0	0	0
Cold sweat	1 (1.5)	1 (1.5)	0	0	0
Dermatitis atopic	1 (1.5)	1 (1.5)	0	0	0
Dermatitis diaper	1 (1.5)	1 (1.5)	0	0	0
Ecchymosis	1 (1.5)	0	0	1 (1.5)	0
Eczema	1 (1.5)	1 (1.5)	0	0	0
Keloid scar	1 (1.5)	0	1 (1.5)	0	0
Livedo reticularis	1 (1.5)	1 (1.5)	0	0	0
Papule	1 (1.5)	1 (1.5)	0	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pruritus generalised	1 (1.5)	1 (1.5)	0	0	0
Rash follicular	1 (1.5)	1 (1.5)	0	0	0
Rash vesicular	1 (1.5)	1 (1.5)	0	0	0
Skin exfoliation	1 (1.5)	1 (1.5)	0	0	0
Skin fissures	1 (1.5)	1 (1.5)	0	0	0
Skin haemorrhage	1 (1.5)	1 (1.5)	0	0	0
Skin irritation	1 (1.5)	1 (1.5)	0	0	0
Skin ulcer	1 (1.5)	1 (1.5)	0	0	0
Vascular disorders					
-Total	33 (48.5)	3 (4.4)	6 (8.8)	14 (20.6)	10 (14.7)
Hypotension	23 (33.8)	1 (1.5)	0	12 (17.6)	10 (14.7)
Hypertension	15 (22.1)	4 (5.9)	9 (13.2)	2 (2.9)	0
Orthostatic hypotension	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Embolism	1 (1.5)	0	0	1 (1.5)	0
Flushing	1 (1.5)	1 (1.5)	0	0	0
Haematoma	1 (1.5)	0	1 (1.5)	0	0
Hot flush	1 (1.5)	1 (1.5)	0	0	0
Phlebitis	1 (1.5)	0	1 (1.5)	0	0

Baseline extramedullary disease presence: No

Primary system organ class Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Secondary hypertension	1 (1.5)	0	1 (1.5)	0	0
Venous thrombosis limb	1 (1.5)	1 (1.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178p
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	1 (25.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders					
-Total	3 (75.0)	0	0	2 (50.0)	1 (25.0)
Anaemia	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Febrile neutropenia	2 (50.0)	0	0	2 (50.0)	0
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
Thrombocytopenia	1 (25.0)	0	0	1 (25.0)	0
Cardiac disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Bradycardia	1 (25.0)	1 (25.0)	0	0	0
Eye disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0

Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ocular hyperaemia	1 (25.0)	1 (25.0)	0	0	0
Gastrointestinal disorders					
-Total	3 (75.0)	1 (25.0)	0	2 (50.0)	0
Vomiting	2 (50.0)	2 (50.0)	0	0	0
Constipation	1 (25.0)	1 (25.0)	0	0	0
Enterocolitis	1 (25.0)	0	0	1 (25.0)	0
Gastrointestinal haemorrhage	1 (25.0)	1 (25.0)	0	0	0
Nausea	1 (25.0)	0	1 (25.0)	0	0
Stomatitis	1 (25.0)	0	0	1 (25.0)	0
General disorders and administration site conditions					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Fatigue	1 (25.0)	1 (25.0)	0	0	0
Influenza like illness	1 (25.0)	1 (25.0)	0	0	0
Pyrexia	1 (25.0)	0	0	1 (25.0)	0
Immune system disorders					
-Total	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Cytokine release syndrome	3 (75.0)	1 (25.0)	2 (50.0)	0	0

Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	1 (25.0)	0	1 (25.0)	0	0
Infections and infestations					
-Total	3 (75.0)	0	2 (50.0)	1 (25.0)	0
Conjunctivitis	1 (25.0)	0	1 (25.0)	0	0
Corona virus infection	1 (25.0)	0	0	1 (25.0)	0
Fungal skin infection	1 (25.0)	1 (25.0)	0	0	0
Metapneumovirus infection	1 (25.0)	0	1 (25.0)	0	0
Rash pustular	1 (25.0)	0	1 (25.0)	0	0
Respiratory syncytial virus infection	1 (25.0)	0	0	1 (25.0)	0
Viral infection	1 (25.0)	0	1 (25.0)	0	0
Viral upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (25.0)	0	1 (25.0)	0	0
Radiation skin injury	1 (25.0)	0	1 (25.0)	0	0
Skin laceration	1 (25.0)	0	1 (25.0)	0	0
Investigations					
-Total	3 (75.0)	0	1 (25.0)	0	2 (50.0)

Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	3 (75.0)	1 (25.0)	1 (25.0)	0	1 (25.0)
Neutrophil count decreased	2 (50.0)	1 (25.0)	0	0	1 (25.0)
White blood cell count decreased	2 (50.0)	1 (25.0)	0	0	1 (25.0)
Blood bilirubin increased	1 (25.0)	1 (25.0)	0	0	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0	0	0
Fibrin d dimer increased	1 (25.0)	1 (25.0)	0	0	0
Platelet count decreased	1 (25.0)	1 (25.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Decreased appetite	1 (25.0)	1 (25.0)	0	0	0
Hyperphosphataemia	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (50.0)	2 (50.0)	0	0	0
Arthralgia	1 (25.0)	1 (25.0)	0	0	0
Pain in extremity	1 (25.0)	1 (25.0)	0	0	0

Down syndrome: Yes

	All patients N=4				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Headache	1 (25.0)	0	1 (25.0)	0	0
Tremor	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (50.0)	0	2 (50.0)	0	0
Cough	1 (25.0)	0	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	1 (25.0)	0	0
Nasal congestion	1 (25.0)	1 (25.0)	0	0	0
Rhinorrhoea	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (75.0)	3 (75.0)	0	0	0
Dermatitis diaper	1 (25.0)	1 (25.0)	0	0	0
Dry skin	1 (25.0)	1 (25.0)	0	0	0
Erythema	1 (25.0)	1 (25.0)	0	0	0
Rash maculo-papular	1 (25.0)	1 (25.0)	0	0	0
Rash papular	1 (25.0)	1 (25.0)	0	0	0

Down syndrome: Yes

Primary system organ class Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Hypertension	1 (25.0)	1 (25.0)	0	0	0
Hypotension	1 (25.0)	0	0	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178p
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	68 (95.8)	0	2 (2.8)	11 (15.5)	55 (77.5)
Blood and lymphatic system disorders					
-Total	58 (81.7)	1 (1.4)	2 (2.8)	33 (46.5)	22 (31.0)
Febrile neutropenia	34 (47.9)	0	0	33 (46.5)	1 (1.4)
Anaemia	33 (46.5)	1 (1.4)	6 (8.5)	25 (35.2)	1 (1.4)
Neutropenia	15 (21.1)	0	0	4 (5.6)	11 (15.5)
Thrombocytopenia	14 (19.7)	0	1 (1.4)	4 (5.6)	9 (12.7)
Disseminated intravascular coagulation	6 (8.5)	0	2 (2.8)	3 (4.2)	1 (1.4)
Lymphopenia	6 (8.5)	0	2 (2.8)	1 (1.4)	3 (4.2)
Pancytopenia	4 (5.6)	0	0	1 (1.4)	3 (4.2)
Coagulopathy	2 (2.8)	1 (1.4)	0	1 (1.4)	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Eosinophilia	1 (1.4)	0	0	1 (1.4)	0
Hypofibrinogenaemia	1 (1.4)	0	0	0	1 (1.4)
Leukocytosis	1 (1.4)	1 (1.4)	0	0	0
Leukopenia	1 (1.4)	0	0	0	1 (1.4)
Lymphadenopathy	1 (1.4)	0	1 (1.4)	0	0
Splenomegaly	1 (1.4)	1 (1.4)	0	0	0
Cardiac disorders					
-Total	27 (38.0)	10 (14.1)	10 (14.1)	5 (7.0)	2 (2.8)
Tachycardia	17 (23.9)	9 (12.7)	6 (8.5)	2 (2.8)	0
Sinus tachycardia	7 (9.9)	3 (4.2)	2 (2.8)	2 (2.8)	0
Left ventricular dysfunction	3 (4.2)	0	0	3 (4.2)	0
Pericardial effusion	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Bradycardia	2 (2.8)	0	1 (1.4)	0	1 (1.4)
Palpitations	2 (2.8)	2 (2.8)	0	0	0
Ventricular tachycardia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Atrioventricular block second degree	1 (1.4)	1 (1.4)	0	0	0
Cardiac dysfunction	1 (1.4)	1 (1.4)	0	0	0
Cardiovascular insufficiency	1 (1.4)	0	0	0	1 (1.4)

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Right ventricular dysfunction	1 (1.4)	0	0	1 (1.4)	0
Sinus bradycardia	1 (1.4)	1 (1.4)	0	0	0
Ear and labyrinth disorders					
-Total	5 (7.0)	2 (2.8)	3 (4.2)	0	0
Ear pain	2 (2.8)	2 (2.8)	0	0	0
Deafness unilateral	1 (1.4)	0	1 (1.4)	0	0
Hypoacusis	1 (1.4)	0	1 (1.4)	0	0
Tympanic membrane perforation	1 (1.4)	0	1 (1.4)	0	0
Endocrine disorders					
-Total	5 (7.0)	2 (2.8)	3 (4.2)	0	0
Adrenal insufficiency	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Cushingoid	1 (1.4)	1 (1.4)	0	0	0
Hyperthyroidism	1 (1.4)	0	1 (1.4)	0	0
Eye disorders					
-Total	19 (26.8)	10 (14.1)	9 (12.7)	0	0
Periorbital oedema	4 (5.6)	3 (4.2)	1 (1.4)	0	0
Vision blurred	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Conjunctival haemorrhage	3 (4.2)	3 (4.2)	0	0	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye pain	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Photophobia	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Dry eye	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Retinal haemorrhage	2 (2.8)	2 (2.8)	0	0	0
Uveitis	2 (2.8)	0	2 (2.8)	0	0
Conjunctivitis allergic	1 (1.4)	1 (1.4)	0	0	0
Eye irritation	1 (1.4)	1 (1.4)	0	0	0
Ocular hypertension	1 (1.4)	0	1 (1.4)	0	0
Papilloedema	1 (1.4)	0	1 (1.4)	0	0
Retinopathy	1 (1.4)	0	1 (1.4)	0	0
Visual impairment	1 (1.4)	0	1 (1.4)	0	0
Gastrointestinal disorders					
-Total	50 (70.4)	11 (15.5)	20 (28.2)	18 (25.4)	1 (1.4)
Nausea	32 (45.1)	9 (12.7)	16 (22.5)	7 (9.9)	0
Vomiting	28 (39.4)	15 (21.1)	9 (12.7)	4 (5.6)	0
Diarrhoea	26 (36.6)	14 (19.7)	10 (14.1)	2 (2.8)	0
Abdominal pain	17 (23.9)	7 (9.9)	7 (9.9)	3 (4.2)	0
Constipation	10 (14.1)	8 (11.3)	2 (2.8)	0	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	4 (5.6)	1 (1.4)	0	3 (4.2)	0
Stomatitis	4 (5.6)	1 (1.4)	1 (1.4)	1 (1.4)	1 (1.4)
Abdominal pain upper	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Oral pain	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Pancreatitis	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Abdominal distension	2 (2.8)	0	2 (2.8)	0	0
Abdominal pain lower	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Ascites	2 (2.8)	0	0	2 (2.8)	0
Dysphagia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Haematemesis	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Haematochezia	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Abdominal discomfort	1 (1.4)	1 (1.4)	0	0	0
Abdominal tenderness	1 (1.4)	1 (1.4)	0	0	0
Anal fissure	1 (1.4)	0	1 (1.4)	0	0
Anal incontinence	1 (1.4)	1 (1.4)	0	0	0
Dry mouth	1 (1.4)	1 (1.4)	0	0	0
Dyspepsia	1 (1.4)	0	1 (1.4)	0	0
Flatulence	1 (1.4)	1 (1.4)	0	0	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Gastrooesophageal reflux disease	1 (1.4)	1 (1.4)	0	0	0
Gingival discomfort	1 (1.4)	1 (1.4)	0	0	0
Glossodynia	1 (1.4)	1 (1.4)	0	0	0
Ileus	1 (1.4)	0	0	1 (1.4)	0
Intestinal obstruction	1 (1.4)	0	0	1 (1.4)	0
Lip pain	1 (1.4)	0	1 (1.4)	0	0
Mouth haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Oral mucosal blistering	1 (1.4)	1 (1.4)	0	0	0
Pancreatic failure	1 (1.4)	0	1 (1.4)	0	0
Perianal erythema	1 (1.4)	0	1 (1.4)	0	0
Pigmentation lip	1 (1.4)	1 (1.4)	0	0	0
Proctalgia	1 (1.4)	0	1 (1.4)	0	0
Tooth socket haemorrhage	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	50 (70.4)	15 (21.1)	18 (25.4)	13 (18.3)	4 (5.6)
Pyrexia	31 (43.7)	9 (12.7)	15 (21.1)	6 (8.5)	1 (1.4)

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	17 (23.9)	12 (16.9)	3 (4.2)	2 (2.8)	0
Chills	11 (15.5)	9 (12.7)	2 (2.8)	0	0
Catheter site pain	7 (9.9)	3 (4.2)	4 (5.6)	0	0
Pain	7 (9.9)	1 (1.4)	3 (4.2)	3 (4.2)	0
Oedema peripheral	5 (7.0)	3 (4.2)	1 (1.4)	1 (1.4)	0
Generalised oedema	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Malaise	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Multiple organ dysfunction syndrome	4 (5.6)	0	0	1 (1.4)	3 (4.2)
Face oedema	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Non-cardiac chest pain	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Physical deconditioning	2 (2.8)	0	0	2 (2.8)	0
Acquired gene mutation	1 (1.4)	1 (1.4)	0	0	0
Asthenia	1 (1.4)	1 (1.4)	0	0	0
Catheter site extravasation	1 (1.4)	0	1 (1.4)	0	0
Catheter site haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Crying	1 (1.4)	1 (1.4)	0	0	0
Cyst	1 (1.4)	0	0	1 (1.4)	0
Device related thrombosis	1 (1.4)	0	1 (1.4)	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Facial pain	1 (1.4)	0	1 (1.4)	0	0
Gait disturbance	1 (1.4)	1 (1.4)	0	0	0
Influenza like illness	1 (1.4)	1 (1.4)	0	0	0
Injection site haematoma	1 (1.4)	1 (1.4)	0	0	0
Localised oedema	1 (1.4)	0	0	1 (1.4)	0
Medical device pain	1 (1.4)	0	1 (1.4)	0	0
Mucosal haemorrhage	1 (1.4)	0	1 (1.4)	0	0
Peripheral swelling	1 (1.4)	0	1 (1.4)	0	0
Hepatobiliary disorders					
-Total	11 (15.5)	3 (4.2)	3 (4.2)	4 (5.6)	1 (1.4)
Hyperbilirubinaemia	5 (7.0)	0	2 (2.8)	3 (4.2)	0
Hepatomegaly	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Cholecystitis	1 (1.4)	0	0	1 (1.4)	0
Gallbladder enlargement	1 (1.4)	1 (1.4)	0	0	0
Hepatic failure	1 (1.4)	0	0	0	1 (1.4)
Hepatic steatosis	1 (1.4)	0	1 (1.4)	0	0
Hepatosplenomegaly	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	56 (78.9)	5 (7.0)	29 (40.8)	11 (15.5)	11 (15.5)
Cytokine release syndrome	47 (66.2)	5 (7.0)	23 (32.4)	8 (11.3)	11 (15.5)
Hypogammaglobulinaemia	32 (45.1)	4 (5.6)	23 (32.4)	5 (7.0)	0
Graft versus host disease	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Immunodeficiency common variable	2 (2.8)	0	2 (2.8)	0	0
Seasonal allergy	2 (2.8)	2 (2.8)	0	0	0
Chronic graft versus host disease	1 (1.4)	0	1 (1.4)	0	0
Drug hypersensitivity	1 (1.4)	0	1 (1.4)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.4)	0	1 (1.4)	0	0
Graft versus host disease in skin	1 (1.4)	1 (1.4)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (1.4)	0	1 (1.4)	0	0
Immunodeficiency	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	49 (69.0)	4 (5.6)	14 (19.7)	20 (28.2)	11 (15.5)
Upper respiratory tract infection	11 (15.5)	5 (7.0)	5 (7.0)	1 (1.4)	0
Pneumonia	7 (9.9)	0	5 (7.0)	1 (1.4)	1 (1.4)
Clostridium difficile infection	6 (8.5)	0	5 (7.0)	1 (1.4)	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	6 (8.5)	5 (7.0)	1 (1.4)	0	0
Clostridium difficile colitis	5 (7.0)	1 (1.4)	2 (2.8)	2 (2.8)	0
Gastroenteritis	5 (7.0)	1 (1.4)	3 (4.2)	1 (1.4)	0
Sinusitis	5 (7.0)	1 (1.4)	4 (5.6)	0	0
Urinary tract infection	5 (7.0)	0	3 (4.2)	2 (2.8)	0
Device related infection	4 (5.6)	0	1 (1.4)	3 (4.2)	0
Influenza	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Otitis media	4 (5.6)	0	3 (4.2)	1 (1.4)	0
Parainfluenzae virus infection	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Escherichia urinary tract infection	3 (4.2)	0	1 (1.4)	2 (2.8)	0
Staphylococcal infection	3 (4.2)	1 (1.4)	0	1 (1.4)	1 (1.4)
Viral upper respiratory tract infection	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Cytomegalovirus infection	2 (2.8)	2 (2.8)	0	0	0
Ear infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Escherichia bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Oral herpes	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Otitis media acute	2 (2.8)	0	2 (2.8)	0	0
Sepsis	2 (2.8)	0	0	0	2 (2.8)

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	2 (2.8)	0	2 (2.8)	0	0
Staphylococcal bacteraemia	2 (2.8)	0	0	2 (2.8)	0
Viral infection	2 (2.8)	2 (2.8)	0	0	0
Vulvovaginal candidiasis	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Abscess limb	1 (1.4)	0	0	1 (1.4)	0
Acute sinusitis	1 (1.4)	0	1 (1.4)	0	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	0	0	1 (1.4)
Body tinea	1 (1.4)	1 (1.4)	0	0	0
Bronchitis	1 (1.4)	0	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	0	0	1 (1.4)	0
Campylobacter infection	1 (1.4)	0	0	1 (1.4)	0
Candida sepsis	1 (1.4)	0	0	0	1 (1.4)
Catheter site cellulitis	1 (1.4)	1 (1.4)	0	0	0
Catheter site infection	1 (1.4)	0	0	1 (1.4)	0
Cellulitis	1 (1.4)	0	0	1 (1.4)	0
Cellulitis of male external genital organ	1 (1.4)	0	0	1 (1.4)	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (1.4)	0	0	1 (1.4)	0
Croup infectious	1 (1.4)	0	0	1 (1.4)	0
Enterococcal infection	1 (1.4)	1 (1.4)	0	0	0
Enterovirus infection	1 (1.4)	0	0	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	0	0	1 (1.4)
Folliculitis	1 (1.4)	0	1 (1.4)	0	0
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis norovirus	1 (1.4)	0	1 (1.4)	0	0
Gastroenteritis viral	1 (1.4)	1 (1.4)	0	0	0
Gingivitis	1 (1.4)	1 (1.4)	0	0	0
Haemophilus infection	1 (1.4)	0	1 (1.4)	0	0
Herpes simplex	1 (1.4)	1 (1.4)	0	0	0
Herpes zoster	1 (1.4)	0	0	1 (1.4)	0
Human herpesvirus 6 infection	1 (1.4)	0	1 (1.4)	0	0
Human polyomavirus infection	1 (1.4)	0	0	0	1 (1.4)
Hypopyon	1 (1.4)	0	1 (1.4)	0	0
Klebsiella sepsis	1 (1.4)	0	0	0	1 (1.4)
Meningitis aseptic	1 (1.4)	0	1 (1.4)	0	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Molluscum contagiosum	1 (1.4)	1 (1.4)	0	0	0
Necrotising fasciitis	1 (1.4)	0	0	1 (1.4)	0
Oral candidiasis	1 (1.4)	1 (1.4)	0	0	0
Orchitis	1 (1.4)	1 (1.4)	0	0	0
Otitis externa	1 (1.4)	0	1 (1.4)	0	0
Paronychia	1 (1.4)	1 (1.4)	0	0	0
Pharyngitis	1 (1.4)	0	1 (1.4)	0	0
Pneumonia fungal	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	0	0	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory tract infection	1 (1.4)	0	0	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	0	0	1 (1.4)	0
Rhinitis	1 (1.4)	1 (1.4)	0	0	0
Rotavirus infection	1 (1.4)	0	0	1 (1.4)	0
Septic embolus	1 (1.4)	0	0	0	1 (1.4)
Staphylococcal scalded skin syndrome	1 (1.4)	0	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	0	0	1 (1.4)

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Streptococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Streptococcal infection	1 (1.4)	0	1 (1.4)	0	0
Subcutaneous abscess	1 (1.4)	0	1 (1.4)	0	0
Tinea capitis	1 (1.4)	1 (1.4)	0	0	0
Urinary tract infection enterococcal	1 (1.4)	0	0	1 (1.4)	0
Vascular device infection	1 (1.4)	0	0	1 (1.4)	0
Vulvovaginal mycotic infection	1 (1.4)	0	1 (1.4)	0	0
Injury, poisoning and procedural complications					
-Total	25 (35.2)	12 (16.9)	9 (12.7)	3 (4.2)	1 (1.4)
Infusion related reaction	5 (7.0)	2 (2.8)	3 (4.2)	0	0
Procedural pain	5 (7.0)	2 (2.8)	2 (2.8)	1 (1.4)	0
Transfusion reaction	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Contusion	3 (4.2)	3 (4.2)	0	0	0
Skin abrasion	2 (2.8)	2 (2.8)	0	0	0
Subdural haematoma	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Arthropod bite	1 (1.4)	1 (1.4)	0	0	0
Extradural haematoma	1 (1.4)	0	0	1 (1.4)	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Foot fracture	1 (1.4)	0	1 (1.4)	0	0
Incision site pain	1 (1.4)	1 (1.4)	0	0	0
Limb injury	1 (1.4)	1 (1.4)	0	0	0
Mouth injury	1 (1.4)	1 (1.4)	0	0	0
Post procedural haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Procedural complication	1 (1.4)	1 (1.4)	0	0	0
Procedural headache	1 (1.4)	0	1 (1.4)	0	0
Procedural nausea	1 (1.4)	0	1 (1.4)	0	0
Procedural site reaction	1 (1.4)	1 (1.4)	0	0	0
Radiation skin injury	1 (1.4)	0	1 (1.4)	0	0
Radius fracture	1 (1.4)	0	1 (1.4)	0	0
Stoma site irritation	1 (1.4)	1 (1.4)	0	0	0
Subdural haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Sunburn	1 (1.4)	1 (1.4)	0	0	0
Tibia fracture	1 (1.4)	0	1 (1.4)	0	0
Tongue injury	1 (1.4)	1 (1.4)	0	0	0
Tracheal haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Transfusion related complication	1 (1.4)	0	0	0	1 (1.4)

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Wound	1 (1.4)	1 (1.4)	0	0	0
Investigations					
-Total	55 (77.5)	1 (1.4)	3 (4.2)	12 (16.9)	39 (54.9)
White blood cell count decreased	40 (56.3)	3 (4.2)	1 (1.4)	8 (11.3)	28 (39.4)
Neutrophil count decreased	30 (42.3)	0	2 (2.8)	3 (4.2)	25 (35.2)
Alanine aminotransferase increased	26 (36.6)	3 (4.2)	4 (5.6)	18 (25.4)	1 (1.4)
Aspartate aminotransferase increased	24 (33.8)	5 (7.0)	5 (7.0)	9 (12.7)	5 (7.0)
Platelet count decreased	20 (28.2)	2 (2.8)	2 (2.8)	3 (4.2)	13 (18.3)
Lymphocyte count decreased	16 (22.5)	0	2 (2.8)	7 (9.9)	7 (9.9)
International normalised ratio increased	11 (15.5)	9 (12.7)	1 (1.4)	1 (1.4)	0
Blood bilirubin increased	9 (12.7)	1 (1.4)	3 (4.2)	4 (5.6)	1 (1.4)
Prothrombin time prolonged	9 (12.7)	5 (7.0)	3 (4.2)	1 (1.4)	0
Blood creatinine increased	8 (11.3)	4 (5.6)	2 (2.8)	2 (2.8)	0
Activated partial thromboplastin time prolonged	6 (8.5)	3 (4.2)	3 (4.2)	0	0
Weight decreased	5 (7.0)	2 (2.8)	3 (4.2)	0	0
Blood fibrinogen decreased	4 (5.6)	0	1 (1.4)	2 (2.8)	1 (1.4)

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	4 (5.6)	1 (1.4)	2 (2.8)	1 (1.4)	0
Transaminases increased	4 (5.6)	3 (4.2)	0	1 (1.4)	0
Blood immunoglobulin m decreased	3 (4.2)	3 (4.2)	0	0	0
Blood urea increased	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Haemoglobin decreased	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Lipase increased	3 (4.2)	0	0	0	3 (4.2)
Weight increased	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Blood immunoglobulin a decreased	2 (2.8)	2 (2.8)	0	0	0
Blood lactate dehydrogenase increased	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Blood lactic acid increased	2 (2.8)	0	1 (1.4)	0	1 (1.4)
Blood magnesium decreased	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Blood phosphorus increased	2 (2.8)	2 (2.8)	0	0	0
Blood uric acid increased	2 (2.8)	2 (2.8)	0	0	0
Electrocardiogram qt prolonged	2 (2.8)	0	0	2 (2.8)	0
Serum ferritin increased	2 (2.8)	0	2 (2.8)	0	0
Blood alkaline phosphatase increased	1 (1.4)	1 (1.4)	0	0	0
Blood bicarbonate decreased	1 (1.4)	0	1 (1.4)	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood immunoglobulin g decreased	1 (1.4)	0	1 (1.4)	0	0
Blood phosphorus decreased	1 (1.4)	1 (1.4)	0	0	0
Blood sodium increased	1 (1.4)	0	1 (1.4)	0	0
Cardiac murmur	1 (1.4)	1 (1.4)	0	0	0
Computerised tomogram thorax abnormal	1 (1.4)	0	0	1 (1.4)	0
Coronavirus test positive	1 (1.4)	1 (1.4)	0	0	0
Culture stool positive	1 (1.4)	1 (1.4)	0	0	0
Hepatic enzyme increased	1 (1.4)	0	1 (1.4)	0	0
Norovirus test positive	1 (1.4)	1 (1.4)	0	0	0
Oxygen saturation decreased	1 (1.4)	1 (1.4)	0	0	0
Protein total decreased	1 (1.4)	0	0	1 (1.4)	0
Pulmonary function test decreased	1 (1.4)	0	1 (1.4)	0	0
Metabolism and nutrition disorders					
-Total	48 (67.6)	5 (7.0)	10 (14.1)	26 (36.6)	7 (9.9)
Decreased appetite	27 (38.0)	6 (8.5)	8 (11.3)	13 (18.3)	0
Hypokalaemia	23 (32.4)	5 (7.0)	5 (7.0)	9 (12.7)	4 (5.6)
Hypophosphataemia	13 (18.3)	4 (5.6)	0	8 (11.3)	1 (1.4)

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	8 (11.3)	7 (9.9)	1 (1.4)	0	0
Hyperglycaemia	7 (9.9)	0	3 (4.2)	4 (5.6)	0
Fluid overload	6 (8.5)	1 (1.4)	4 (5.6)	1 (1.4)	0
Hypernatraemia	6 (8.5)	1 (1.4)	2 (2.8)	0	3 (4.2)
Hypoalbuminaemia	6 (8.5)	1 (1.4)	4 (5.6)	1 (1.4)	0
Hypocalcaemia	6 (8.5)	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)
Dehydration	4 (5.6)	1 (1.4)	0	3 (4.2)	0
Hyperuricaemia	4 (5.6)	3 (4.2)	0	0	1 (1.4)
Hyperkalaemia	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Hypomagnesaemia	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Tumour lysis syndrome	3 (4.2)	0	0	3 (4.2)	0
Vitamin d deficiency	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Acidosis	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Hypertriglyceridaemia	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Hypoglycaemia	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Hyponatraemia	2 (2.8)	0	0	2 (2.8)	0
Malnutrition	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Hyperalbuminaemia	1 (1.4)	1 (1.4)	0	0	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperammonaemia	1 (1.4)	1 (1.4)	0	0	0
Hypercalcaemia	1 (1.4)	1 (1.4)	0	0	0
Hyperchloraemia	1 (1.4)	1 (1.4)	0	0	0
Hypermagnesaemia	1 (1.4)	1 (1.4)	0	0	0
Iron overload	1 (1.4)	0	0	1 (1.4)	0
Metabolic acidosis	1 (1.4)	0	1 (1.4)	0	0
Metabolic alkalosis	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	35 (49.3)	15 (21.1)	12 (16.9)	8 (11.3)	0
Pain in extremity	13 (18.3)	6 (8.5)	4 (5.6)	3 (4.2)	0
Arthralgia	6 (8.5)	3 (4.2)	1 (1.4)	2 (2.8)	0
Myalgia	6 (8.5)	4 (5.6)	1 (1.4)	1 (1.4)	0
Musculoskeletal pain	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Pain in jaw	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Back pain	3 (4.2)	1 (1.4)	0	2 (2.8)	0
Muscle spasms	3 (4.2)	3 (4.2)	0	0	0
Muscular weakness	3 (4.2)	2 (2.8)	1 (1.4)	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal chest pain	3 (4.2)	3 (4.2)	0	0	0
Joint range of motion decreased	2 (2.8)	2 (2.8)	0	0	0
Neck pain	2 (2.8)	0	2 (2.8)	0	0
Bone pain	1 (1.4)	0	0	1 (1.4)	0
Coccydynia	1 (1.4)	1 (1.4)	0	0	0
Flank pain	1 (1.4)	0	1 (1.4)	0	0
Limb discomfort	1 (1.4)	1 (1.4)	0	0	0
Myopathy	1 (1.4)	0	0	1 (1.4)	0
Myositis	1 (1.4)	0	0	1 (1.4)	0
Osteonecrosis	1 (1.4)	0	1 (1.4)	0	0
Osteopenia	1 (1.4)	0	1 (1.4)	0	0
Synovitis	1 (1.4)	0	1 (1.4)	0	0
Toe walking	1 (1.4)	1 (1.4)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	3 (4.2)	0	2 (2.8)	0	1 (1.4)
Glioblastoma multiforme	1 (1.4)	0	0	0	1 (1.4)
Myelodysplastic syndrome	1 (1.4)	0	1 (1.4)	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin papilloma	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	42 (59.2)	17 (23.9)	16 (22.5)	7 (9.9)	2 (2.8)
Headache	28 (39.4)	15 (21.1)	8 (11.3)	5 (7.0)	0
Dizziness	6 (8.5)	6 (8.5)	0	0	0
Seizure	5 (7.0)	0	2 (2.8)	2 (2.8)	1 (1.4)
Encephalopathy	4 (5.6)	1 (1.4)	1 (1.4)	2 (2.8)	0
Peroneal nerve palsy	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Dysarthria	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Neuropathy peripheral	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Somnolence	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Asterixis	1 (1.4)	1 (1.4)	0	0	0
Ataxia	1 (1.4)	0	1 (1.4)	0	0
Depressed level of consciousness	1 (1.4)	1 (1.4)	0	0	0
Disturbance in attention	1 (1.4)	1 (1.4)	0	0	0
Dysgeusia	1 (1.4)	1 (1.4)	0	0	0
Embolic stroke	1 (1.4)	0	0	0	1 (1.4)
Hyporesponsive to stimuli	1 (1.4)	0	0	1 (1.4)	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotonia	1 (1.4)	0	1 (1.4)	0	0
Idiopathic intracranial hypertension	1 (1.4)	0	1 (1.4)	0	0
Migraine	1 (1.4)	0	1 (1.4)	0	0
Myoclonus	1 (1.4)	1 (1.4)	0	0	0
Neuralgia	1 (1.4)	0	1 (1.4)	0	0
Peripheral sensory neuropathy	1 (1.4)	0	1 (1.4)	0	0
Pleocytosis	1 (1.4)	1 (1.4)	0	0	0
Tremor	1 (1.4)	1 (1.4)	0	0	0
Visual field defect	1 (1.4)	0	1 (1.4)	0	0
Product issues					
-Total	2 (2.8)	2 (2.8)	0	0	0
Device occlusion	2 (2.8)	2 (2.8)	0	0	0
Psychiatric disorders					
-Total	26 (36.6)	8 (11.3)	14 (19.7)	4 (5.6)	0
Anxiety	9 (12.7)	3 (4.2)	5 (7.0)	1 (1.4)	0
Confusional state	7 (9.9)	3 (4.2)	4 (5.6)	0	0
Delirium	5 (7.0)	2 (2.8)	2 (2.8)	1 (1.4)	0
Depression	4 (5.6)	2 (2.8)	2 (2.8)	0	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Insomnia	4 (5.6)	0	4 (5.6)	0	0
Mental status changes	4 (5.6)	3 (4.2)	0	1 (1.4)	0
Agitation	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Irritability	3 (4.2)	3 (4.2)	0	0	0
Hallucination	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Adjustment disorder	1 (1.4)	0	1 (1.4)	0	0
Listless	1 (1.4)	1 (1.4)	0	0	0
Panic attack	1 (1.4)	0	1 (1.4)	0	0
Sleep disorder	1 (1.4)	0	1 (1.4)	0	0
Suicidal ideation	1 (1.4)	1 (1.4)	0	0	0
Renal and urinary disorders					
-Total	19 (26.8)	3 (4.2)	4 (5.6)	7 (9.9)	5 (7.0)
Acute kidney injury	12 (16.9)	2 (2.8)	1 (1.4)	5 (7.0)	4 (5.6)
Haematuria	5 (7.0)	0	2 (2.8)	2 (2.8)	1 (1.4)
Dysuria	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Oliguria	3 (4.2)	0	0	3 (4.2)	0
Calculus urinary	1 (1.4)	0	1 (1.4)	0	0
Cystitis haemorrhagic	1 (1.4)	0	0	0	1 (1.4)

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nephrolithiasis	1 (1.4)	0	0	1 (1.4)	0
Pollakiuria	1 (1.4)	1 (1.4)	0	0	0
Renal failure	1 (1.4)	0	0	0	1 (1.4)
Renal impairment	1 (1.4)	0	0	1 (1.4)	0
Urinary incontinence	1 (1.4)	1 (1.4)	0	0	0
Urinary retention	1 (1.4)	0	1 (1.4)	0	0
Reproductive system and breast disorders					
-Total	6 (8.5)	2 (2.8)	2 (2.8)	2 (2.8)	0
Vulvovaginal adhesion	2 (2.8)	2 (2.8)	0	0	0
Oedema genital	1 (1.4)	0	1 (1.4)	0	0
Ovarian failure	1 (1.4)	0	0	1 (1.4)	0
Scrotal pain	1 (1.4)	0	1 (1.4)	0	0
Vaginal haemorrhage	1 (1.4)	0	0	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	42 (59.2)	13 (18.3)	7 (9.9)	10 (14.1)	12 (16.9)
Cough	15 (21.1)	13 (18.3)	1 (1.4)	1 (1.4)	0
Epistaxis	14 (19.7)	4 (5.6)	4 (5.6)	5 (7.0)	1 (1.4)

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	14 (19.7)	0	2 (2.8)	9 (12.7)	3 (4.2)
Pleural effusion	10 (14.1)	1 (1.4)	6 (8.5)	3 (4.2)	0
Pulmonary oedema	9 (12.7)	1 (1.4)	0	4 (5.6)	4 (5.6)
Tachypnoea	8 (11.3)	3 (4.2)	2 (2.8)	3 (4.2)	0
Oropharyngeal pain	7 (9.9)	4 (5.6)	2 (2.8)	1 (1.4)	0
Dyspnoea	5 (7.0)	1 (1.4)	1 (1.4)	2 (2.8)	1 (1.4)
Nasal congestion	5 (7.0)	5 (7.0)	0	0	0
Rhinitis allergic	5 (7.0)	4 (5.6)	1 (1.4)	0	0
Rhinorrhoea	5 (7.0)	5 (7.0)	0	0	0
Respiratory failure	4 (5.6)	0	0	0	4 (5.6)
Haemoptysis	3 (4.2)	1 (1.4)	0	1 (1.4)	1 (1.4)
Atelectasis	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Respiratory distress	2 (2.8)	0	0	0	2 (2.8)
Acute respiratory failure	1 (1.4)	0	0	0	1 (1.4)
Aspiration	1 (1.4)	0	0	0	1 (1.4)
Dysphonia	1 (1.4)	1 (1.4)	0	0	0
Idiopathic pneumonia syndrome	1 (1.4)	0	0	0	1 (1.4)
Interstitial lung disease	1 (1.4)	0	0	0	1 (1.4)

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nasal discomfort	1 (1.4)	1 (1.4)	0	0	0
Oropharyngeal plaque	1 (1.4)	1 (1.4)	0	0	0
Pharyngeal erythema	1 (1.4)	1 (1.4)	0	0	0
Pharyngeal lesion	1 (1.4)	0	0	1 (1.4)	0
Pharyngeal ulceration	1 (1.4)	0	1 (1.4)	0	0
Pulmonary alveolar haemorrhage	1 (1.4)	0	0	0	1 (1.4)
Pulmonary hypertension	1 (1.4)	0	0	1 (1.4)	0
Pulmonary mass	1 (1.4)	0	1 (1.4)	0	0
Respiratory depression	1 (1.4)	0	1 (1.4)	0	0
Wheezing	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	34 (47.9)	18 (25.4)	12 (16.9)	4 (5.6)	0
Rash	9 (12.7)	6 (8.5)	3 (4.2)	0	0
Pruritus	5 (7.0)	5 (7.0)	0	0	0
Rash erythematous	5 (7.0)	2 (2.8)	3 (4.2)	0	0
Alopecia	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Dry skin	4 (5.6)	4 (5.6)	0	0	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Erythema	4 (5.6)	4 (5.6)	0	0	0
Hyperhidrosis	4 (5.6)	4 (5.6)	0	0	0
Petechiae	4 (5.6)	3 (4.2)	1 (1.4)	0	0
Rash maculo-papular	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Ingrowing nail	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Dermatitis acneiform	2 (2.8)	0	1 (1.4)	1 (1.4)	0
Macule	2 (2.8)	2 (2.8)	0	0	0
Night sweats	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Papule	2 (2.8)	2 (2.8)	0	0	0
Rash macular	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Rash papular	2 (2.8)	2 (2.8)	0	0	0
Rash pruritic	2 (2.8)	2 (2.8)	0	0	0
Acne	1 (1.4)	1 (1.4)	0	0	0
Cold sweat	1 (1.4)	1 (1.4)	0	0	0
Dermatitis	1 (1.4)	1 (1.4)	0	0	0
Dermatitis atopic	1 (1.4)	1 (1.4)	0	0	0
Ecchymosis	1 (1.4)	0	0	1 (1.4)	0
Eczema	1 (1.4)	1 (1.4)	0	0	0

Down syndrome: No

	All patients N=71				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Keloid scar	1 (1.4)	0	1 (1.4)	0	0
Livedo reticularis	1 (1.4)	1 (1.4)	0	0	0
Pruritus generalised	1 (1.4)	1 (1.4)	0	0	0
Rash follicular	1 (1.4)	1 (1.4)	0	0	0
Rash vesicular	1 (1.4)	1 (1.4)	0	0	0
Skin exfoliation	1 (1.4)	1 (1.4)	0	0	0
Skin fissures	1 (1.4)	1 (1.4)	0	0	0
Skin haemorrhage	1 (1.4)	1 (1.4)	0	0	0
Skin irritation	1 (1.4)	1 (1.4)	0	0	0
Skin ulcer	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	32 (45.1)	2 (2.8)	6 (8.5)	13 (18.3)	11 (15.5)
Hypotension	23 (32.4)	1 (1.4)	0	11 (15.5)	11 (15.5)
Hypertension	15 (21.1)	3 (4.2)	10 (14.1)	2 (2.8)	0
Flushing	2 (2.8)	2 (2.8)	0	0	0
Orthostatic hypotension	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Capillary leak syndrome	1 (1.4)	0	0	0	1 (1.4)
Embolism	1 (1.4)	0	0	1 (1.4)	0

Down syndrome: No

Primary system organ class Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haematoma	1 (1.4)	0	1 (1.4)	0	0
Hot flush	1 (1.4)	1 (1.4)	0	0	0
Phlebitis	1 (1.4)	0	1 (1.4)	0	0
Secondary hypertension	1 (1.4)	0	1 (1.4)	0	0
Venous thrombosis limb	1 (1.4)	1 (1.4)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178q
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	1 (3.1)	3 (9.4)	28 (87.5)
Blood and lymphatic system disorders					
-Total	29 (90.6)	0	1 (3.1)	19 (59.4)	9 (28.1)
Febrile neutropenia	17 (53.1)	0	0	16 (50.0)	1 (3.1)
Anaemia	15 (46.9)	1 (3.1)	1 (3.1)	13 (40.6)	0
Neutropenia	6 (18.8)	0	0	1 (3.1)	5 (15.6)
Thrombocytopenia	4 (12.5)	0	1 (3.1)	2 (6.3)	1 (3.1)
Pancytopenia	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Disseminated intravascular coagulation	2 (6.3)	0	0	2 (6.3)	0
Coagulopathy	1 (3.1)	0	0	1 (3.1)	0
Hypofibrinogenaemia	1 (3.1)	0	0	0	1 (3.1)

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukocytosis	1 (3.1)	1 (3.1)	0	0	0
Lymphadenopathy	1 (3.1)	0	1 (3.1)	0	0
Lymphopenia	1 (3.1)	0	0	0	1 (3.1)
Splenomegaly	1 (3.1)	1 (3.1)	0	0	0
Cardiac disorders					
-Total	10 (31.3)	7 (21.9)	3 (9.4)	0	0
Tachycardia	6 (18.8)	5 (15.6)	1 (3.1)	0	0
Sinus tachycardia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Atrioventricular block second degree	1 (3.1)	1 (3.1)	0	0	0
Bradycardia	1 (3.1)	1 (3.1)	0	0	0
Cardiac dysfunction	1 (3.1)	1 (3.1)	0	0	0
Pericardial effusion	1 (3.1)	0	1 (3.1)	0	0
Ear and labyrinth disorders					
-Total	1 (3.1)	1 (3.1)	0	0	0
Ear pain	1 (3.1)	1 (3.1)	0	0	0
Endocrine disorders					
-Total	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Adrenal insufficiency	1 (3.1)	1 (3.1)	0	0	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cushingoid	1 (3.1)	1 (3.1)	0	0	0
Hyperthyroidism	1 (3.1)	0	1 (3.1)	0	0
Eye disorders					
-Total	10 (31.3)	7 (21.9)	3 (9.4)	0	0
Vision blurred	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Dry eye	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Eye pain	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Photophobia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Conjunctivitis allergic	1 (3.1)	1 (3.1)	0	0	0
Ocular hyperaemia	1 (3.1)	1 (3.1)	0	0	0
Retinal haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Retinopathy	1 (3.1)	0	1 (3.1)	0	0
Uveitis	1 (3.1)	0	1 (3.1)	0	0
Gastrointestinal disorders					
-Total	27 (84.4)	6 (18.8)	11 (34.4)	10 (31.3)	0
Nausea	18 (56.3)	4 (12.5)	11 (34.4)	3 (9.4)	0
Vomiting	16 (50.0)	9 (28.1)	4 (12.5)	3 (9.4)	0
Diarrhoea	12 (37.5)	6 (18.8)	4 (12.5)	2 (6.3)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	9 (28.1)	4 (12.5)	4 (12.5)	1 (3.1)	0
Constipation	8 (25.0)	7 (21.9)	1 (3.1)	0	0
Oral pain	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Stomatitis	2 (6.3)	0	0	2 (6.3)	0
Abdominal distension	1 (3.1)	0	1 (3.1)	0	0
Abdominal pain upper	1 (3.1)	0	1 (3.1)	0	0
Abdominal tenderness	1 (3.1)	1 (3.1)	0	0	0
Colitis	1 (3.1)	0	0	1 (3.1)	0
Dyspepsia	1 (3.1)	0	1 (3.1)	0	0
Gastrointestinal haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Glossodynia	1 (3.1)	1 (3.1)	0	0	0
Ileus	1 (3.1)	0	0	1 (3.1)	0
Intestinal obstruction	1 (3.1)	0	0	1 (3.1)	0
Oral mucosal blistering	1 (3.1)	1 (3.1)	0	0	0
Pancreatic failure	1 (3.1)	0	1 (3.1)	0	0
Pancreatitis	1 (3.1)	0	1 (3.1)	0	0
General disorders and administration site conditions					

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	21 (65.6)	4 (12.5)	9 (28.1)	8 (25.0)	0
Pyrexia	16 (50.0)	4 (12.5)	7 (21.9)	5 (15.6)	0
Fatigue	6 (18.8)	5 (15.6)	1 (3.1)	0	0
Catheter site pain	5 (15.6)	1 (3.1)	4 (12.5)	0	0
Oedema peripheral	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Malaise	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Generalised oedema	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Catheter site haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Chills	1 (3.1)	0	1 (3.1)	0	0
Crying	1 (3.1)	1 (3.1)	0	0	0
Cyst	1 (3.1)	0	0	1 (3.1)	0
Device related thrombosis	1 (3.1)	0	1 (3.1)	0	0
Gait disturbance	1 (3.1)	1 (3.1)	0	0	0
Influenza like illness	1 (3.1)	1 (3.1)	0	0	0
Injection site haematoma	1 (3.1)	1 (3.1)	0	0	0
Pain	1 (3.1)	0	0	1 (3.1)	0
Physical deconditioning	1 (3.1)	0	0	1 (3.1)	0
Hepatobiliary disorders					

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Hyperbilirubinaemia	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Cholecystitis	1 (3.1)	0	0	1 (3.1)	0
Hepatic steatosis	1 (3.1)	0	1 (3.1)	0	0
Immune system disorders					
-Total	29 (90.6)	1 (3.1)	18 (56.3)	5 (15.6)	5 (15.6)
Cytokine release syndrome	25 (78.1)	3 (9.4)	15 (46.9)	2 (6.3)	5 (15.6)
Hypogammaglobulinaemia	19 (59.4)	1 (3.1)	15 (46.9)	3 (9.4)	0
Seasonal allergy	2 (6.3)	2 (6.3)	0	0	0
Chronic graft versus host disease	1 (3.1)	0	1 (3.1)	0	0
Graft versus host disease	1 (3.1)	0	1 (3.1)	0	0
Graft versus host disease in gastrointestinal tract	1 (3.1)	0	1 (3.1)	0	0
Haemophagocytic lymphohistiocytosis	1 (3.1)	0	1 (3.1)	0	0
Immunodeficiency	1 (3.1)	0	1 (3.1)	0	0
Immunodeficiency common variable	1 (3.1)	0	1 (3.1)	0	0
Infections and infestations					
-Total	24 (75.0)	1 (3.1)	9 (28.1)	10 (31.3)	4 (12.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	6 (18.8)	2 (6.3)	4 (12.5)	0	0
Clostridium difficile infection	5 (15.6)	0	4 (12.5)	1 (3.1)	0
Rhinovirus infection	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Device related infection	3 (9.4)	0	0	3 (9.4)	0
Escherichia urinary tract infection	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Gastroenteritis	3 (9.4)	0	3 (9.4)	0	0
Influenza	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Urinary tract infection	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Viral upper respiratory tract infection	3 (9.4)	2 (6.3)	0	1 (3.1)	0
Cytomegalovirus infection	2 (6.3)	2 (6.3)	0	0	0
Ear infection	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Parainfluenzae virus infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Pneumonia	2 (6.3)	0	2 (6.3)	0	0
Sinusitis	2 (6.3)	0	2 (6.3)	0	0
Skin infection	2 (6.3)	0	2 (6.3)	0	0
Vulvovaginal candidiasis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Abscess limb	1 (3.1)	0	0	1 (3.1)	0
Bacteraemia	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacterial sepsis	1 (3.1)	0	0	0	1 (3.1)
Campylobacter infection	1 (3.1)	0	0	1 (3.1)	0
Catheter site cellulitis	1 (3.1)	1 (3.1)	0	0	0
Catheter site infection	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile colitis	1 (3.1)	0	0	1 (3.1)	0
Conjunctivitis	1 (3.1)	0	1 (3.1)	0	0
Croup infectious	1 (3.1)	0	0	1 (3.1)	0
Enterococcal infection	1 (3.1)	1 (3.1)	0	0	0
Enterovirus infection	1 (3.1)	0	0	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Folliculitis	1 (3.1)	0	1 (3.1)	0	0
Fungal skin infection	1 (3.1)	1 (3.1)	0	0	0
Gastroenteritis norovirus	1 (3.1)	0	1 (3.1)	0	0
Gastroenteritis viral	1 (3.1)	1 (3.1)	0	0	0
Molluscum contagiosum	1 (3.1)	1 (3.1)	0	0	0
Oral candidiasis	1 (3.1)	1 (3.1)	0	0	0
Oral herpes	1 (3.1)	0	1 (3.1)	0	0
Orchitis	1 (3.1)	1 (3.1)	0	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media acute	1 (3.1)	0	1 (3.1)	0	0
Pneumonia fungal	1 (3.1)	0	1 (3.1)	0	0
Respiratory syncytial virus bronchitis	1 (3.1)	0	0	1 (3.1)	0
Respiratory syncytial virus infection	1 (3.1)	0	1 (3.1)	0	0
Respiratory tract infection	1 (3.1)	0	0	0	1 (3.1)
Respiratory tract infection viral	1 (3.1)	0	0	1 (3.1)	0
Rhinitis	1 (3.1)	1 (3.1)	0	0	0
Rotavirus infection	1 (3.1)	0	0	1 (3.1)	0
Sepsis	1 (3.1)	0	0	0	1 (3.1)
Septic embolus	1 (3.1)	0	0	0	1 (3.1)
Staphylococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal infection	1 (3.1)	0	0	1 (3.1)	0
Staphylococcal scalded skin syndrome	1 (3.1)	0	1 (3.1)	0	0
Staphylococcal sepsis	1 (3.1)	0	0	0	1 (3.1)
Streptococcal bacteraemia	1 (3.1)	0	0	1 (3.1)	0
Subcutaneous abscess	1 (3.1)	0	1 (3.1)	0	0
Tinea capitis	1 (3.1)	1 (3.1)	0	0	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Urinary tract infection enterococcal	1 (3.1)	0	0	1 (3.1)	0
Viral infection	1 (3.1)	1 (3.1)	0	0	0
Injury, poisoning and procedural complications					
-Total	13 (40.6)	6 (18.8)	4 (12.5)	2 (6.3)	1 (3.1)
Infusion related reaction	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Procedural pain	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Contusion	2 (6.3)	2 (6.3)	0	0	0
Radiation skin injury	2 (6.3)	0	2 (6.3)	0	0
Transfusion reaction	2 (6.3)	2 (6.3)	0	0	0
Arthropod bite	1 (3.1)	1 (3.1)	0	0	0
Extradural haematoma	1 (3.1)	0	0	1 (3.1)	0
Procedural nausea	1 (3.1)	0	1 (3.1)	0	0
Procedural site reaction	1 (3.1)	1 (3.1)	0	0	0
Skin abrasion	1 (3.1)	1 (3.1)	0	0	0
Skin laceration	1 (3.1)	0	1 (3.1)	0	0
Subdural haematoma	1 (3.1)	0	0	1 (3.1)	0
Subdural haemorrhage	1 (3.1)	1 (3.1)	0	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sunburn	1 (3.1)	1 (3.1)	0	0	0
Transfusion related complication	1 (3.1)	0	0	0	1 (3.1)
Wound	1 (3.1)	1 (3.1)	0	0	0
Investigations					
-Total	30 (93.8)	0	1 (3.1)	5 (15.6)	24 (75.0)
White blood cell count decreased	24 (75.0)	1 (3.1)	0	5 (15.6)	18 (56.3)
Neutrophil count decreased	17 (53.1)	1 (3.1)	0	2 (6.3)	14 (43.8)
Platelet count decreased	12 (37.5)	1 (3.1)	0	2 (6.3)	9 (28.1)
Alanine aminotransferase increased	11 (34.4)	1 (3.1)	1 (3.1)	9 (28.1)	0
Lymphocyte count decreased	11 (34.4)	0	1 (3.1)	5 (15.6)	5 (15.6)
Aspartate aminotransferase increased	10 (31.3)	3 (9.4)	1 (3.1)	5 (15.6)	1 (3.1)
Blood bilirubin increased	5 (15.6)	1 (3.1)	1 (3.1)	3 (9.4)	0
Blood creatinine increased	3 (9.4)	2 (6.3)	1 (3.1)	0	0
C-reactive protein increased	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Prothrombin time prolonged	3 (9.4)	3 (9.4)	0	0	0
Activated partial thromboplastin time prolonged	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Blood immunoglobulin a decreased	2 (6.3)	2 (6.3)	0	0	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood immunoglobulin m decreased	2 (6.3)	2 (6.3)	0	0	0
Lipase increased	2 (6.3)	0	0	0	2 (6.3)
Serum ferritin increased	2 (6.3)	0	2 (6.3)	0	0
Weight decreased	2 (6.3)	2 (6.3)	0	0	0
Weight increased	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Blood alkaline phosphatase increased	1 (3.1)	1 (3.1)	0	0	0
Blood lactate dehydrogenase increased	1 (3.1)	1 (3.1)	0	0	0
Blood lactic acid increased	1 (3.1)	0	0	0	1 (3.1)
Blood magnesium decreased	1 (3.1)	1 (3.1)	0	0	0
Cardiac murmur	1 (3.1)	1 (3.1)	0	0	0
Coronavirus test positive	1 (3.1)	1 (3.1)	0	0	0
Electrocardiogram qt prolonged	1 (3.1)	0	0	1 (3.1)	0
Haemoglobin decreased	1 (3.1)	0	0	1 (3.1)	0
Hepatic enzyme increased	1 (3.1)	0	1 (3.1)	0	0
International normalised ratio increased	1 (3.1)	1 (3.1)	0	0	0
Oxygen saturation decreased	1 (3.1)	1 (3.1)	0	0	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary function test decreased	1 (3.1)	0	1 (3.1)	0	0
Transaminases increased	1 (3.1)	0	0	1 (3.1)	0
Metabolism and nutrition disorders					
-Total	22 (68.8)	3 (9.4)	5 (15.6)	10 (31.3)	4 (12.5)
Decreased appetite	14 (43.8)	3 (9.4)	7 (21.9)	4 (12.5)	0
Hypokalaemia	12 (37.5)	3 (9.4)	1 (3.1)	6 (18.8)	2 (6.3)
Hypophosphataemia	7 (21.9)	3 (9.4)	0	4 (12.5)	0
Hyperglycaemia	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Hypocalcaemia	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Dehydration	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Hyperphosphataemia	3 (9.4)	3 (9.4)	0	0	0
Fluid overload	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Hyperkalaemia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Hyperuricaemia	2 (6.3)	1 (3.1)	0	0	1 (3.1)
Hypomagnesaemia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Vitamin d deficiency	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Hyperammonaemia	1 (3.1)	1 (3.1)	0	0	0
Hypernatraemia	1 (3.1)	0	0	0	1 (3.1)

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertriglyceridaemia	1 (3.1)	0	0	1 (3.1)	0
Hypoglycaemia	1 (3.1)	0	0	1 (3.1)	0
Hyponatraemia	1 (3.1)	0	0	1 (3.1)	0
Iron overload	1 (3.1)	0	0	1 (3.1)	0
Malnutrition	1 (3.1)	0	1 (3.1)	0	0
Tumour lysis syndrome	1 (3.1)	0	0	1 (3.1)	0
Musculoskeletal and connective tissue disorders					
-Total	17 (53.1)	8 (25.0)	6 (18.8)	3 (9.4)	0
Pain in extremity	7 (21.9)	3 (9.4)	4 (12.5)	0	0
Arthralgia	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Muscular weakness	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Pain in jaw	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Musculoskeletal chest pain	2 (6.3)	2 (6.3)	0	0	0
Coccydynia	1 (3.1)	1 (3.1)	0	0	0
Flank pain	1 (3.1)	0	1 (3.1)	0	0
Muscle spasms	1 (3.1)	1 (3.1)	0	0	0
Myalgia	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myopathy	1 (3.1)	0	0	1 (3.1)	0
Myositis	1 (3.1)	0	0	1 (3.1)	0
Synovitis	1 (3.1)	0	1 (3.1)	0	0
Toe walking	1 (3.1)	1 (3.1)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (6.3)	0	2 (6.3)	0	0
Myelodysplastic syndrome	1 (3.1)	0	1 (3.1)	0	0
Skin papilloma	1 (3.1)	0	1 (3.1)	0	0
Nervous system disorders					
-Total	21 (65.6)	7 (21.9)	8 (25.0)	5 (15.6)	1 (3.1)
Headache	17 (53.1)	8 (25.0)	6 (18.8)	3 (9.4)	0
Dizziness	2 (6.3)	2 (6.3)	0	0	0
Peroneal nerve palsy	2 (6.3)	2 (6.3)	0	0	0
Disturbance in attention	1 (3.1)	1 (3.1)	0	0	0
Dysarthria	1 (3.1)	0	1 (3.1)	0	0
Embolic stroke	1 (3.1)	0	0	0	1 (3.1)
Encephalopathy	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Migraine	1 (3.1)	0	1 (3.1)	0	0
Neuralgia	1 (3.1)	0	1 (3.1)	0	0
Neuropathy peripheral	1 (3.1)	1 (3.1)	0	0	0
Seizure	1 (3.1)	0	0	1 (3.1)	0
Somnolence	1 (3.1)	1 (3.1)	0	0	0
Tremor	1 (3.1)	1 (3.1)	0	0	0
Product issues					
-Total	2 (6.3)	2 (6.3)	0	0	0
Device occlusion	2 (6.3)	2 (6.3)	0	0	0
Psychiatric disorders					
-Total	13 (40.6)	5 (15.6)	7 (21.9)	1 (3.1)	0
Anxiety	5 (15.6)	2 (6.3)	3 (9.4)	0	0
Depression	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Mental status changes	3 (9.4)	2 (6.3)	0	1 (3.1)	0
Confusional state	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Delirium	1 (3.1)	1 (3.1)	0	0	0
Hallucination	1 (3.1)	1 (3.1)	0	0	0
Insomnia	1 (3.1)	0	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	1 (3.1)	1 (3.1)	0	0	0
Panic attack	1 (3.1)	0	1 (3.1)	0	0
Sleep disorder	1 (3.1)	0	1 (3.1)	0	0
Renal and urinary disorders					
-Total	7 (21.9)	2 (6.3)	2 (6.3)	3 (9.4)	0
Acute kidney injury	5 (15.6)	2 (6.3)	1 (3.1)	2 (6.3)	0
Calculus urinary	1 (3.1)	0	1 (3.1)	0	0
Dysuria	1 (3.1)	0	1 (3.1)	0	0
Haematuria	1 (3.1)	0	0	1 (3.1)	0
Nephrolithiasis	1 (3.1)	0	0	1 (3.1)	0
Urinary incontinence	1 (3.1)	1 (3.1)	0	0	0
Reproductive system and breast disorders					
-Total	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Ovarian failure	1 (3.1)	0	0	1 (3.1)	0
Vaginal haemorrhage	1 (3.1)	0	0	1 (3.1)	0
Vulvovaginal adhesion	1 (3.1)	1 (3.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	21 (65.6)	8 (25.0)	5 (15.6)	6 (18.8)	2 (6.3)
Cough	8 (25.0)	7 (21.9)	1 (3.1)	0	0
Epistaxis	8 (25.0)	3 (9.4)	1 (3.1)	4 (12.5)	0
Hypoxia	5 (15.6)	0	2 (6.3)	3 (9.4)	0
Nasal congestion	3 (9.4)	3 (9.4)	0	0	0
Oropharyngeal pain	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Rhinorrhoea	3 (9.4)	3 (9.4)	0	0	0
Tachypnoea	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Acute respiratory failure	1 (3.1)	0	0	0	1 (3.1)
Dysphonia	1 (3.1)	1 (3.1)	0	0	0
Dyspnoea	1 (3.1)	1 (3.1)	0	0	0
Idiopathic pneumonia syndrome	1 (3.1)	0	0	0	1 (3.1)
Oropharyngeal plaque	1 (3.1)	1 (3.1)	0	0	0
Pharyngeal erythema	1 (3.1)	1 (3.1)	0	0	0
Pharyngeal lesion	1 (3.1)	0	0	1 (3.1)	0
Pharyngeal ulceration	1 (3.1)	0	1 (3.1)	0	0
Pleural effusion	1 (3.1)	0	1 (3.1)	0	0
Pulmonary mass	1 (3.1)	0	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary oedema	1 (3.1)	1 (3.1)	0	0	0
Respiratory depression	1 (3.1)	0	1 (3.1)	0	0
Rhinitis allergic	1 (3.1)	0	1 (3.1)	0	0
Wheezing	1 (3.1)	0	1 (3.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	17 (53.1)	11 (34.4)	6 (18.8)	0	0
Pruritus	5 (15.6)	5 (15.6)	0	0	0
Rash	5 (15.6)	3 (9.4)	2 (6.3)	0	0
Dry skin	4 (12.5)	4 (12.5)	0	0	0
Erythema	3 (9.4)	3 (9.4)	0	0	0
Alopecia	2 (6.3)	0	2 (6.3)	0	0
Rash erythematous	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Rash papular	2 (6.3)	2 (6.3)	0	0	0
Rash pruritic	2 (6.3)	2 (6.3)	0	0	0
Acne	1 (3.1)	1 (3.1)	0	0	0
Dermatitis	1 (3.1)	1 (3.1)	0	0	0
Hyperhidrosis	1 (3.1)	1 (3.1)	0	0	0

Time since enrollment to CTL019 infusion: > Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ingrowing nail	1 (3.1)	0	1 (3.1)	0	0
Keloid scar	1 (3.1)	0	1 (3.1)	0	0
Livedo reticularis	1 (3.1)	1 (3.1)	0	0	0
Papule	1 (3.1)	1 (3.1)	0	0	0
Petechiae	1 (3.1)	1 (3.1)	0	0	0
Rash follicular	1 (3.1)	1 (3.1)	0	0	0
Rash maculo-papular	1 (3.1)	1 (3.1)	0	0	0
Rash vesicular	1 (3.1)	1 (3.1)	0	0	0
Skin ulcer	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	13 (40.6)	3 (9.4)	4 (12.5)	5 (15.6)	1 (3.1)
Hypertension	9 (28.1)	4 (12.5)	4 (12.5)	1 (3.1)	0
Hypotension	5 (15.6)	1 (3.1)	0	3 (9.4)	1 (3.1)
Embolism	1 (3.1)	0	0	1 (3.1)	0
Flushing	1 (3.1)	1 (3.1)	0	0	0
Hot flush	1 (3.1)	1 (3.1)	0	0	0
Orthostatic hypotension	1 (3.1)	0	1 (3.1)	0	0
Venous thrombosis limb	1 (3.1)	1 (3.1)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178q
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	1 (3.1)	9 (28.1)	22 (68.8)
Blood and lymphatic system disorders					
-Total	29 (90.6)	1 (3.1)	1 (3.1)	15 (46.9)	12 (37.5)
Anaemia	18 (56.3)	1 (3.1)	5 (15.6)	11 (34.4)	1 (3.1)
Febrile neutropenia	17 (53.1)	0	0	17 (53.1)	0
Neutropenia	9 (28.1)	0	0	3 (9.4)	6 (18.8)
Thrombocytopenia	9 (28.1)	0	0	3 (9.4)	6 (18.8)
Lymphopenia	4 (12.5)	0	2 (6.3)	1 (3.1)	1 (3.1)
Disseminated intravascular coagulation	2 (6.3)	0	2 (6.3)	0	0
Coagulopathy	1 (3.1)	1 (3.1)	0	0	0
Eosinophilia	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Leukopenia	1 (3.1)	0	0	0	1 (3.1)
Pancytopenia	1 (3.1)	0	0	0	1 (3.1)
Cardiac disorders					
-Total	16 (50.0)	4 (12.5)	7 (21.9)	5 (15.6)	0
Tachycardia	11 (34.4)	4 (12.5)	5 (15.6)	2 (6.3)	0
Sinus tachycardia	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Left ventricular dysfunction	3 (9.4)	0	0	3 (9.4)	0
Palpitations	2 (6.3)	2 (6.3)	0	0	0
Pericardial effusion	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Bradycardia	1 (3.1)	0	1 (3.1)	0	0
Sinus bradycardia	1 (3.1)	1 (3.1)	0	0	0
Ventricular tachycardia	1 (3.1)	0	1 (3.1)	0	0
Ear and labyrinth disorders					
-Total	4 (12.5)	1 (3.1)	3 (9.4)	0	0
Deafness unilateral	1 (3.1)	0	1 (3.1)	0	0
Ear pain	1 (3.1)	1 (3.1)	0	0	0
Hypoacusis	1 (3.1)	0	1 (3.1)	0	0
Tympanic membrane perforation	1 (3.1)	0	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (3.1)	0	1 (3.1)	0	0
Adrenal insufficiency	1 (3.1)	0	1 (3.1)	0	0
Eye disorders					
-Total	9 (28.1)	4 (12.5)	5 (15.6)	0	0
Periorbital oedema	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Conjunctival haemorrhage	3 (9.4)	3 (9.4)	0	0	0
Eye irritation	1 (3.1)	1 (3.1)	0	0	0
Eye pain	1 (3.1)	0	1 (3.1)	0	0
Ocular hypertension	1 (3.1)	0	1 (3.1)	0	0
Papilloedema	1 (3.1)	0	1 (3.1)	0	0
Retinal haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Uveitis	1 (3.1)	0	1 (3.1)	0	0
Vision blurred	1 (3.1)	0	1 (3.1)	0	0
Visual impairment	1 (3.1)	0	1 (3.1)	0	0
Gastrointestinal disorders					
-Total	23 (71.9)	6 (18.8)	9 (28.1)	7 (21.9)	1 (3.1)
Diarrhoea	14 (43.8)	8 (25.0)	6 (18.8)	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nausea	14 (43.8)	5 (15.6)	6 (18.8)	3 (9.4)	0
Vomiting	13 (40.6)	8 (25.0)	5 (15.6)	0	0
Abdominal pain	7 (21.9)	3 (9.4)	3 (9.4)	1 (3.1)	0
Constipation	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Stomatitis	3 (9.4)	1 (3.1)	1 (3.1)	0	1 (3.1)
Abdominal pain lower	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Abdominal pain upper	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Dysphagia	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Haematemesis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Pancreatitis	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Abdominal discomfort	1 (3.1)	1 (3.1)	0	0	0
Abdominal distension	1 (3.1)	0	1 (3.1)	0	0
Anal fissure	1 (3.1)	0	1 (3.1)	0	0
Anal incontinence	1 (3.1)	1 (3.1)	0	0	0
Ascites	1 (3.1)	0	0	1 (3.1)	0
Colitis	1 (3.1)	1 (3.1)	0	0	0
Dry mouth	1 (3.1)	1 (3.1)	0	0	0
Enterocolitis	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flatulence	1 (3.1)	1 (3.1)	0	0	0
Gastrointestinal haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Gastrooesophageal reflux disease	1 (3.1)	1 (3.1)	0	0	0
Gingival discomfort	1 (3.1)	1 (3.1)	0	0	0
Haematochezia	1 (3.1)	1 (3.1)	0	0	0
Lip pain	1 (3.1)	0	1 (3.1)	0	0
Mouth haemorrhage	1 (3.1)	0	0	1 (3.1)	0
Oral pain	1 (3.1)	0	1 (3.1)	0	0
Perianal erythema	1 (3.1)	0	1 (3.1)	0	0
Pigmentation lip	1 (3.1)	1 (3.1)	0	0	0
Proctalgia	1 (3.1)	0	1 (3.1)	0	0
Tooth socket haemorrhage	1 (3.1)	1 (3.1)	0	0	0
General disorders and administration site conditions					
-Total	25 (78.1)	12 (37.5)	8 (25.0)	4 (12.5)	1 (3.1)
Pyrexia	13 (40.6)	5 (15.6)	6 (18.8)	1 (3.1)	1 (3.1)
Fatigue	12 (37.5)	8 (25.0)	2 (6.3)	2 (6.3)	0
Chills	10 (31.3)	9 (28.1)	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Catheter site pain	2 (6.3)	2 (6.3)	0	0	0
Face oedema	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Generalised oedema	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Acquired gene mutation	1 (3.1)	1 (3.1)	0	0	0
Asthenia	1 (3.1)	1 (3.1)	0	0	0
Catheter site extravasation	1 (3.1)	0	1 (3.1)	0	0
Facial pain	1 (3.1)	0	1 (3.1)	0	0
Influenza like illness	1 (3.1)	1 (3.1)	0	0	0
Localised oedema	1 (3.1)	0	0	1 (3.1)	0
Malaise	1 (3.1)	0	1 (3.1)	0	0
Medical device pain	1 (3.1)	0	1 (3.1)	0	0
Mucosal haemorrhage	1 (3.1)	0	1 (3.1)	0	0
Multiple organ dysfunction syndrome	1 (3.1)	0	0	1 (3.1)	0
Non-cardiac chest pain	1 (3.1)	1 (3.1)	0	0	0
Oedema peripheral	1 (3.1)	0	0	1 (3.1)	0
Peripheral swelling	1 (3.1)	0	1 (3.1)	0	0
Physical deconditioning	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatobiliary disorders					
-Total	6 (18.8)	3 (9.4)	1 (3.1)	2 (6.3)	0
Hepatomegaly	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Hyperbilirubinaemia	2 (6.3)	0	0	2 (6.3)	0
Gallbladder enlargement	1 (3.1)	1 (3.1)	0	0	0
Hepatosplenomegaly	1 (3.1)	1 (3.1)	0	0	0
Immune system disorders					
-Total	30 (93.8)	5 (15.6)	13 (40.6)	6 (18.8)	6 (18.8)
Cytokine release syndrome	25 (78.1)	3 (9.4)	10 (31.3)	6 (18.8)	6 (18.8)
Hypogammaglobulinaemia	14 (43.8)	3 (9.4)	9 (28.1)	2 (6.3)	0
Drug hypersensitivity	1 (3.1)	0	1 (3.1)	0	0
Graft versus host disease	1 (3.1)	1 (3.1)	0	0	0
Graft versus host disease in skin	1 (3.1)	1 (3.1)	0	0	0
Immunodeficiency common variable	1 (3.1)	0	1 (3.1)	0	0
Infections and infestations					
-Total	23 (71.9)	3 (9.4)	7 (21.9)	11 (34.4)	2 (6.3)
Upper respiratory tract infection	5 (15.6)	3 (9.4)	1 (3.1)	1 (3.1)	0
Clostridium difficile colitis	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Pneumonia	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Sinusitis	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Gastroenteritis	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Parainfluenzae virus infection	2 (6.3)	2 (6.3)	0	0	0
Urinary tract infection	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Viral infection	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Acute sinusitis	1 (3.1)	0	1 (3.1)	0	0
Body tinea	1 (3.1)	1 (3.1)	0	0	0
Bronchopulmonary aspergillosis	1 (3.1)	0	0	1 (3.1)	0
Cellulitis	1 (3.1)	0	0	1 (3.1)	0
Cellulitis of male external genital organ	1 (3.1)	0	0	1 (3.1)	0
Cholecystitis infective	1 (3.1)	0	0	1 (3.1)	0
Clostridium difficile infection	1 (3.1)	0	1 (3.1)	0	0
Corona virus infection	1 (3.1)	0	0	1 (3.1)	0
Device related infection	1 (3.1)	0	1 (3.1)	0	0
Escherichia bacteraemia	1 (3.1)	0	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Escherichia sepsis	1 (3.1)	0	0	0	1 (3.1)
Fungal skin infection	1 (3.1)	0	1 (3.1)	0	0
Gingivitis	1 (3.1)	1 (3.1)	0	0	0
Haemophilus infection	1 (3.1)	0	1 (3.1)	0	0
Herpes simplex	1 (3.1)	1 (3.1)	0	0	0
Herpes zoster	1 (3.1)	0	0	1 (3.1)	0
Human herpesvirus 6 infection	1 (3.1)	0	1 (3.1)	0	0
Human polyomavirus infection	1 (3.1)	0	0	0	1 (3.1)
Hypopyon	1 (3.1)	0	1 (3.1)	0	0
Influenza	1 (3.1)	0	1 (3.1)	0	0
Meningitis aseptic	1 (3.1)	0	1 (3.1)	0	0
Metapneumovirus infection	1 (3.1)	0	1 (3.1)	0	0
Necrotising fasciitis	1 (3.1)	0	0	1 (3.1)	0
Oral herpes	1 (3.1)	0	0	1 (3.1)	0
Otitis externa	1 (3.1)	0	1 (3.1)	0	0
Otitis media acute	1 (3.1)	0	1 (3.1)	0	0
Paronychia	1 (3.1)	1 (3.1)	0	0	0
Pharyngitis	1 (3.1)	0	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash pustular	1 (3.1)	0	1 (3.1)	0	0
Respiratory syncytial virus infection	1 (3.1)	0	0	1 (3.1)	0
Rhinovirus infection	1 (3.1)	1 (3.1)	0	0	0
Staphylococcal infection	1 (3.1)	1 (3.1)	0	0	0
Streptococcal infection	1 (3.1)	0	1 (3.1)	0	0
Vascular device infection	1 (3.1)	0	0	1 (3.1)	0
Viral upper respiratory tract infection	1 (3.1)	0	1 (3.1)	0	0
Vulvovaginal mycotic infection	1 (3.1)	0	1 (3.1)	0	0
Injury, poisoning and procedural complications					
-Total	13 (40.6)	6 (18.8)	6 (18.8)	1 (3.1)	0
Infusion related reaction	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Procedural pain	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Transfusion reaction	2 (6.3)	0	2 (6.3)	0	0
Contusion	1 (3.1)	1 (3.1)	0	0	0
Foot fracture	1 (3.1)	0	1 (3.1)	0	0
Incision site pain	1 (3.1)	1 (3.1)	0	0	0
Limb injury	1 (3.1)	1 (3.1)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mouth injury	1 (3.1)	1 (3.1)	0	0	0
Post procedural haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Procedural complication	1 (3.1)	1 (3.1)	0	0	0
Procedural headache	1 (3.1)	0	1 (3.1)	0	0
Radius fracture	1 (3.1)	0	1 (3.1)	0	0
Skin abrasion	1 (3.1)	1 (3.1)	0	0	0
Stoma site irritation	1 (3.1)	1 (3.1)	0	0	0
Subdural haematoma	1 (3.1)	0	1 (3.1)	0	0
Tibia fracture	1 (3.1)	0	1 (3.1)	0	0
Tongue injury	1 (3.1)	1 (3.1)	0	0	0
Tracheal haemorrhage	1 (3.1)	0	0	1 (3.1)	0
Investigations					
-Total	26 (81.3)	1 (3.1)	3 (9.4)	7 (21.9)	15 (46.9)
White blood cell count decreased	17 (53.1)	3 (9.4)	1 (3.1)	3 (9.4)	10 (31.3)
Alanine aminotransferase increased	14 (43.8)	2 (6.3)	3 (9.4)	9 (28.1)	0
Neutrophil count decreased	14 (43.8)	0	2 (6.3)	1 (3.1)	11 (34.4)
Aspartate aminotransferase increased	13 (40.6)	2 (6.3)	4 (12.5)	4 (12.5)	3 (9.4)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	9 (28.1)	8 (25.0)	0	1 (3.1)	0
Platelet count decreased	9 (28.1)	2 (6.3)	2 (6.3)	1 (3.1)	4 (12.5)
Lymphocyte count decreased	8 (25.0)	1 (3.1)	2 (6.3)	2 (6.3)	3 (9.4)
Blood creatinine increased	6 (18.8)	3 (9.4)	1 (3.1)	2 (6.3)	0
Prothrombin time prolonged	6 (18.8)	2 (6.3)	3 (9.4)	1 (3.1)	0
Blood bilirubin increased	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Blood fibrinogen decreased	4 (12.5)	0	1 (3.1)	2 (6.3)	1 (3.1)
Activated partial thromboplastin time prolonged	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Blood urea increased	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Transaminases increased	3 (9.4)	3 (9.4)	0	0	0
Weight decreased	3 (9.4)	0	3 (9.4)	0	0
Blood immunoglobulin m decreased	2 (6.3)	2 (6.3)	0	0	0
Blood phosphorus increased	2 (6.3)	2 (6.3)	0	0	0
Blood uric acid increased	2 (6.3)	2 (6.3)	0	0	0
Haemoglobin decreased	2 (6.3)	2 (6.3)	0	0	0
Blood bicarbonate decreased	1 (3.1)	0	1 (3.1)	0	0
Blood immunoglobulin a decreased	1 (3.1)	1 (3.1)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood immunoglobulin g decreased	1 (3.1)	0	1 (3.1)	0	0
Blood lactic acid increased	1 (3.1)	0	1 (3.1)	0	0
Blood magnesium decreased	1 (3.1)	0	0	1 (3.1)	0
Blood phosphorus decreased	1 (3.1)	1 (3.1)	0	0	0
Blood sodium increased	1 (3.1)	0	1 (3.1)	0	0
C-reactive protein increased	1 (3.1)	0	1 (3.1)	0	0
Culture stool positive	1 (3.1)	1 (3.1)	0	0	0
Fibrin d dimer increased	1 (3.1)	1 (3.1)	0	0	0
Lipase increased	1 (3.1)	0	0	0	1 (3.1)
Norovirus test positive	1 (3.1)	1 (3.1)	0	0	0
Protein total decreased	1 (3.1)	0	0	1 (3.1)	0
Metabolism and nutrition disorders					
-Total	23 (71.9)	3 (9.4)	4 (12.5)	15 (46.9)	1 (3.1)
Decreased appetite	14 (43.8)	4 (12.5)	1 (3.1)	9 (28.1)	0
Hypokalaemia	9 (28.1)	2 (6.3)	4 (12.5)	3 (9.4)	0
Hyperphosphataemia	6 (18.8)	5 (15.6)	1 (3.1)	0	0
Hypoalbuminaemia	5 (15.6)	1 (3.1)	3 (9.4)	1 (3.1)	0
Hypophosphataemia	5 (15.6)	1 (3.1)	0	3 (9.4)	1 (3.1)

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Fluid overload	3 (9.4)	0	3 (9.4)	0	0
Hypernatraemia	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Acidosis	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Hyperglycaemia	2 (6.3)	0	0	2 (6.3)	0
Hyperuricaemia	2 (6.3)	2 (6.3)	0	0	0
Hypocalcaemia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Tumour lysis syndrome	2 (6.3)	0	0	2 (6.3)	0
Dehydration	1 (3.1)	0	0	1 (3.1)	0
Hyperalbuminaemia	1 (3.1)	1 (3.1)	0	0	0
Hypercalcaemia	1 (3.1)	1 (3.1)	0	0	0
Hyperchloraemia	1 (3.1)	1 (3.1)	0	0	0
Hypermagnesaemia	1 (3.1)	1 (3.1)	0	0	0
Hypertriglyceridaemia	1 (3.1)	1 (3.1)	0	0	0
Hypomagnesaemia	1 (3.1)	1 (3.1)	0	0	0
Hyponatraemia	1 (3.1)	0	0	1 (3.1)	0
Malnutrition	1 (3.1)	0	0	1 (3.1)	0
Metabolic acidosis	1 (3.1)	0	1 (3.1)	0	0
Metabolic alkalosis	1 (3.1)	1 (3.1)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vitamin d deficiency	1 (3.1)	1 (3.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	18 (56.3)	9 (28.1)	5 (15.6)	4 (12.5)	0
Pain in extremity	6 (18.8)	4 (12.5)	0	2 (6.3)	0
Myalgia	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Musculoskeletal pain	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Arthralgia	2 (6.3)	2 (6.3)	0	0	0
Back pain	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Joint range of motion decreased	2 (6.3)	2 (6.3)	0	0	0
Muscle spasms	2 (6.3)	2 (6.3)	0	0	0
Neck pain	2 (6.3)	0	2 (6.3)	0	0
Bone pain	1 (3.1)	0	0	1 (3.1)	0
Limb discomfort	1 (3.1)	1 (3.1)	0	0	0
Musculoskeletal chest pain	1 (3.1)	1 (3.1)	0	0	0
Osteonecrosis	1 (3.1)	0	1 (3.1)	0	0
Osteopenia	1 (3.1)	0	1 (3.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.1)	0	0	0	1 (3.1)
Glioblastoma multiforme	1 (3.1)	0	0	0	1 (3.1)
Nervous system disorders					
-Total	20 (62.5)	10 (31.3)	8 (25.0)	2 (6.3)	0
Headache	11 (34.4)	7 (21.9)	3 (9.4)	1 (3.1)	0
Dizziness	4 (12.5)	4 (12.5)	0	0	0
Encephalopathy	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Seizure	3 (9.4)	0	2 (6.3)	1 (3.1)	0
Asterixis	1 (3.1)	1 (3.1)	0	0	0
Ataxia	1 (3.1)	0	1 (3.1)	0	0
Depressed level of consciousness	1 (3.1)	1 (3.1)	0	0	0
Dysarthria	1 (3.1)	1 (3.1)	0	0	0
Dysgeusia	1 (3.1)	1 (3.1)	0	0	0
Hypotonia	1 (3.1)	0	1 (3.1)	0	0
Idiopathic intracranial hypertension	1 (3.1)	0	1 (3.1)	0	0
Myoclonus	1 (3.1)	1 (3.1)	0	0	0
Neuropathy peripheral	1 (3.1)	0	1 (3.1)	0	0
Peripheral sensory neuropathy	1 (3.1)	0	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Peroneal nerve palsy	1 (3.1)	0	1 (3.1)	0	0
Pleocytosis	1 (3.1)	1 (3.1)	0	0	0
Tremor	1 (3.1)	1 (3.1)	0	0	0
Visual field defect	1 (3.1)	0	1 (3.1)	0	0
Psychiatric disorders					
-Total	10 (31.3)	3 (9.4)	6 (18.8)	1 (3.1)	0
Anxiety	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Confusional state	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Delirium	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Insomnia	3 (9.4)	0	3 (9.4)	0	0
Agitation	2 (6.3)	0	2 (6.3)	0	0
Irritability	2 (6.3)	2 (6.3)	0	0	0
Adjustment disorder	1 (3.1)	0	1 (3.1)	0	0
Depression	1 (3.1)	0	1 (3.1)	0	0
Hallucination	1 (3.1)	0	1 (3.1)	0	0
Listless	1 (3.1)	1 (3.1)	0	0	0
Mental status changes	1 (3.1)	1 (3.1)	0	0	0
Suicidal ideation	1 (3.1)	1 (3.1)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	9 (28.1)	1 (3.1)	1 (3.1)	3 (9.4)	4 (12.5)
Acute kidney injury	5 (15.6)	0	0	2 (6.3)	3 (9.4)
Haematuria	4 (12.5)	0	2 (6.3)	1 (3.1)	1 (3.1)
Dysuria	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Oliguria	2 (6.3)	0	0	2 (6.3)	0
Cystitis haemorrhagic	1 (3.1)	0	0	0	1 (3.1)
Pollakiuria	1 (3.1)	1 (3.1)	0	0	0
Renal failure	1 (3.1)	0	0	0	1 (3.1)
Renal impairment	1 (3.1)	0	0	1 (3.1)	0
Reproductive system and breast disorders					
-Total	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Oedema genital	1 (3.1)	0	1 (3.1)	0	0
Scrotal pain	1 (3.1)	0	1 (3.1)	0	0
Vulvovaginal adhesion	1 (3.1)	1 (3.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	19 (59.4)	5 (15.6)	4 (12.5)	3 (9.4)	7 (21.9)

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cough	7 (21.9)	6 (18.8)	1 (3.1)	0	0
Hypoxia	7 (21.9)	0	1 (3.1)	3 (9.4)	3 (9.4)
Pleural effusion	7 (21.9)	1 (3.1)	4 (12.5)	2 (6.3)	0
Pulmonary oedema	6 (18.8)	0	0	4 (12.5)	2 (6.3)
Epistaxis	5 (15.6)	1 (3.1)	2 (6.3)	1 (3.1)	1 (3.1)
Rhinitis allergic	4 (12.5)	4 (12.5)	0	0	0
Tachypnoea	4 (12.5)	2 (6.3)	0	2 (6.3)	0
Dyspnoea	3 (9.4)	0	1 (3.1)	1 (3.1)	1 (3.1)
Nasal congestion	3 (9.4)	3 (9.4)	0	0	0
Oropharyngeal pain	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Respiratory failure	3 (9.4)	0	0	0	3 (9.4)
Rhinorrhoea	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Atelectasis	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Haemoptysis	2 (6.3)	1 (3.1)	0	0	1 (3.1)
Interstitial lung disease	1 (3.1)	0	0	0	1 (3.1)
Nasal discomfort	1 (3.1)	1 (3.1)	0	0	0
Respiratory distress	1 (3.1)	0	0	0	1 (3.1)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	20 (62.5)	10 (31.3)	6 (18.8)	4 (12.5)	0
Rash	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Rash maculo-papular	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Hyperhidrosis	3 (9.4)	3 (9.4)	0	0	0
Petechiae	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Rash erythematous	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Alopecia	2 (6.3)	2 (6.3)	0	0	0
Dermatitis acneiform	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Erythema	2 (6.3)	2 (6.3)	0	0	0
Ingrowing nail	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Macule	2 (6.3)	2 (6.3)	0	0	0
Night sweats	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Rash macular	2 (6.3)	1 (3.1)	0	1 (3.1)	0
Cold sweat	1 (3.1)	1 (3.1)	0	0	0
Dermatitis atopic	1 (3.1)	1 (3.1)	0	0	0
Dermatitis diaper	1 (3.1)	1 (3.1)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dry skin	1 (3.1)	1 (3.1)	0	0	0
Ecchymosis	1 (3.1)	0	0	1 (3.1)	0
Eczema	1 (3.1)	1 (3.1)	0	0	0
Papule	1 (3.1)	1 (3.1)	0	0	0
Pruritus generalised	1 (3.1)	1 (3.1)	0	0	0
Rash papular	1 (3.1)	1 (3.1)	0	0	0
Skin exfoliation	1 (3.1)	1 (3.1)	0	0	0
Skin fissures	1 (3.1)	1 (3.1)	0	0	0
Skin haemorrhage	1 (3.1)	1 (3.1)	0	0	0
Skin irritation	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	16 (50.0)	0	2 (6.3)	7 (21.9)	7 (21.9)
Hypotension	14 (43.8)	0	0	7 (21.9)	7 (21.9)
Hypertension	6 (18.8)	0	5 (15.6)	1 (3.1)	0
Capillary leak syndrome	1 (3.1)	0	0	0	1 (3.1)
Flushing	1 (3.1)	1 (3.1)	0	0	0
Haematoma	1 (3.1)	0	1 (3.1)	0	0
Orthostatic hypotension	1 (3.1)	1 (3.1)	0	0	0

Time since enrollment to CTL019 infusion: <=Median

Primary system organ class Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Phlebitis	1 (3.1)	0	1 (3.1)	0	0
Secondary hypertension	1 (3.1)	0	1 (3.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178q
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	0	1 (9.1)	0	7 (63.6)
Blood and lymphatic system disorders					
-Total	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Anaemia	2 (18.2)	0	0	2 (18.2)	0
Disseminated intravascular coagulation	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Thrombocytopenia	2 (18.2)	0	0	0	2 (18.2)
Lymphopenia	1 (9.1)	0	0	0	1 (9.1)
Neutropenia	1 (9.1)	0	0	0	1 (9.1)
Cardiac disorders					

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (18.2)	0	0	0	2 (18.2)
Bradycardia	1 (9.1)	0	0	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	0	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	0	0	1 (9.1)	0
Sinus tachycardia	1 (9.1)	0	0	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	0	0	1 (9.1)	0
Endocrine disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Adrenal insufficiency	1 (9.1)	0	1 (9.1)	0	0
Eye disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Photophobia	1 (9.1)	0	1 (9.1)	0	0
Gastrointestinal disorders					
-Total	3 (27.3)	0	0	3 (27.3)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
Abdominal pain	1 (9.1)	0	0	1 (9.1)	0
Ascites	1 (9.1)	0	0	1 (9.1)	0
Haematochezia	1 (9.1)	0	0	1 (9.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (9.1)	0	0	1 (9.1)	0
Vomiting	1 (9.1)	0	0	1 (9.1)	0
General disorders and administration site conditions					
-Total	6 (54.5)	0	1 (9.1)	2 (18.2)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	0	0	3 (27.3)
Pyrexia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Non-cardiac chest pain	1 (9.1)	0	0	1 (9.1)	0
Hepatobiliary disorders					
-Total	1 (9.1)	0	0	0	1 (9.1)
Hepatic failure	1 (9.1)	0	0	0	1 (9.1)
Infections and infestations					
-Total	5 (45.5)	0	0	0	5 (45.5)
Bronchitis	1 (9.1)	0	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	0	0	1 (9.1)
Klebsiella sepsis	1 (9.1)	0	0	0	1 (9.1)
Pneumonia	1 (9.1)	0	0	0	1 (9.1)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (9.1)	0	0	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	0	0	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	0	0	1 (9.1)
Investigations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Activated partial thromboplastin time prolonged	1 (9.1)	0	1 (9.1)	0	0
Alanine aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	0	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	0	0	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	0	0	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	0	0	1 (9.1)	0
International normalised ratio increased	1 (9.1)	0	1 (9.1)	0	0
Neutrophil count decreased	1 (9.1)	0	0	0	1 (9.1)
Weight increased	1 (9.1)	1 (9.1)	0	0	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					
-Total	4 (36.4)	0	1 (9.1)	1 (9.1)	2 (18.2)
Hypernatraemia	2 (18.2)	0	0	0	2 (18.2)
Hypokalaemia	2 (18.2)	0	0	0	2 (18.2)
Fluid overload	1 (9.1)	0	0	1 (9.1)	0
Hyperglycaemia	1 (9.1)	0	1 (9.1)	0	0
Hyperkalaemia	1 (9.1)	0	0	1 (9.1)	0
Hypoalbuminaemia	1 (9.1)	0	1 (9.1)	0	0
Hypoglycaemia	1 (9.1)	0	1 (9.1)	0	0
Hypophosphataemia	1 (9.1)	0	0	1 (9.1)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Arthralgia	1 (9.1)	0	0	1 (9.1)	0
Back pain	1 (9.1)	0	0	1 (9.1)	0
Pain in extremity	1 (9.1)	0	0	1 (9.1)	0
Pain in jaw	1 (9.1)	0	1 (9.1)	0	0

Time since enrollment to CTL019 infusion: Missing

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nervous system disorders					
-Total	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Headache	1 (9.1)	0	0	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	0	0	1 (9.1)	0
Seizure	1 (9.1)	0	0	0	1 (9.1)
Somnolence	1 (9.1)	0	1 (9.1)	0	0
Psychiatric disorders					
-Total	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Agitation	1 (9.1)	0	0	1 (9.1)	0
Confusional state	1 (9.1)	0	1 (9.1)	0	0
Delirium	1 (9.1)	0	0	1 (9.1)	0
Renal and urinary disorders					
-Total	3 (27.3)	0	1 (9.1)	1 (9.1)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Oliguria	1 (9.1)	0	0	1 (9.1)	0
Urinary retention	1 (9.1)	0	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders					

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Hypoxia	3 (27.3)	0	0	3 (27.3)	0
Pleural effusion	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Aspiration	1 (9.1)	0	0	0	1 (9.1)
Cough	1 (9.1)	0	0	1 (9.1)	0
Dyspnoea	1 (9.1)	0	0	1 (9.1)	0
Epistaxis	1 (9.1)	0	1 (9.1)	0	0
Haemoptysis	1 (9.1)	0	0	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	0	0	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	0	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	0	0	1 (9.1)	0
Respiratory distress	1 (9.1)	0	0	0	1 (9.1)
Respiratory failure	1 (9.1)	0	0	0	1 (9.1)
Tachypnoea	1 (9.1)	0	0	1 (9.1)	0
Vascular disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Hypotension	5 (45.5)	0	0	2 (18.2)	3 (27.3)

Time since enrollment to CTL019 infusion: Missing

Primary system organ class Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (9.1)	0	1 (9.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178r
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	0	1 (12.5)	7 (87.5)
Blood and lymphatic system disorders					
-Total	6 (75.0)	0	0	4 (50.0)	2 (25.0)
Anaemia	5 (62.5)	1 (12.5)	0	3 (37.5)	1 (12.5)
Febrile neutropenia	4 (50.0)	0	0	4 (50.0)	0
Neutropenia	2 (25.0)	0	0	0	2 (25.0)
Thrombocytopenia	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Cardiac disorders					
-Total	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Left ventricular dysfunction	2 (25.0)	0	0	2 (25.0)	0
Tachycardia	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Palpitations	1 (12.5)	1 (12.5)	0	0	0

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pericardial effusion	1 (12.5)	1 (12.5)	0	0	0
Endocrine disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Adrenal insufficiency	1 (12.5)	1 (12.5)	0	0	0
Eye disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Eye pain	1 (12.5)	1 (12.5)	0	0	0
Gastrointestinal disorders					
-Total	7 (87.5)	2 (25.0)	1 (12.5)	3 (37.5)	1 (12.5)
Nausea	5 (62.5)	1 (12.5)	2 (25.0)	2 (25.0)	0
Vomiting	5 (62.5)	3 (37.5)	2 (25.0)	0	0
Diarrhoea	4 (50.0)	3 (37.5)	1 (12.5)	0	0
Abdominal pain	3 (37.5)	2 (25.0)	1 (12.5)	0	0
Oral pain	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Constipation	1 (12.5)	1 (12.5)	0	0	0
Enterocolitis	1 (12.5)	0	0	1 (12.5)	0
Stomatitis	1 (12.5)	0	0	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	6 (75.0)	1 (12.5)	1 (12.5)	3 (37.5)	1 (12.5)
Pyrexia	5 (62.5)	1 (12.5)	1 (12.5)	2 (25.0)	1 (12.5)
Fatigue	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Pain	2 (25.0)	0	0	2 (25.0)	0
Asthenia	1 (12.5)	1 (12.5)	0	0	0
Catheter site pain	1 (12.5)	0	1 (12.5)	0	0
Chills	1 (12.5)	1 (12.5)	0	0	0
Hepatobiliary disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hepatomegaly	1 (12.5)	0	1 (12.5)	0	0
Immune system disorders					
-Total	7 (87.5)	0	4 (50.0)	0	3 (37.5)
Cytokine release syndrome	5 (62.5)	0	2 (25.0)	0	3 (37.5)
Hypogammaglobulinaemia	4 (50.0)	0	4 (50.0)	0	0
Graft versus host disease	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (75.0)	1 (12.5)	2 (25.0)	1 (12.5)	2 (25.0)
Upper respiratory tract infection	2 (25.0)	0	2 (25.0)	0	0
Viral infection	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Cellulitis	1 (12.5)	0	0	1 (12.5)	0
Clostridium difficile infection	1 (12.5)	0	1 (12.5)	0	0
Corona virus infection	1 (12.5)	0	0	1 (12.5)	0
Ear infection	1 (12.5)	1 (12.5)	0	0	0
Gastroenteritis	1 (12.5)	0	1 (12.5)	0	0
Human polyomavirus infection	1 (12.5)	0	0	0	1 (12.5)
Oral herpes	1 (12.5)	0	0	1 (12.5)	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Respiratory syncytial virus infection	1 (12.5)	0	0	1 (12.5)	0
Rhinovirus infection	1 (12.5)	1 (12.5)	0	0	0
Skin infection	1 (12.5)	0	1 (12.5)	0	0
Tinea capitis	1 (12.5)	1 (12.5)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Contusion	1 (12.5)	1 (12.5)	0	0	0
Infusion related reaction	1 (12.5)	0	1 (12.5)	0	0
Procedural nausea	1 (12.5)	0	1 (12.5)	0	0
Sunburn	1 (12.5)	1 (12.5)	0	0	0
Tracheal haemorrhage	1 (12.5)	0	0	1 (12.5)	0
Wound	1 (12.5)	1 (12.5)	0	0	0
Investigations					
-Total	7 (87.5)	0	1 (12.5)	2 (25.0)	4 (50.0)
Neutrophil count decreased	4 (50.0)	0	1 (12.5)	0	3 (37.5)
White blood cell count decreased	4 (50.0)	1 (12.5)	0	0	3 (37.5)
Blood magnesium decreased	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Lymphocyte count decreased	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Activated partial thromboplastin time prolonged	1 (12.5)	1 (12.5)	0	0	0
Aspartate aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)
Blood bilirubin increased	1 (12.5)	0	0	1 (12.5)	0
Blood creatinine increased	1 (12.5)	0	1 (12.5)	0	0
Blood fibrinogen decreased	1 (12.5)	0	1 (12.5)	0	0

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (12.5)	1 (12.5)	0	0	0
Blood phosphorus increased	1 (12.5)	1 (12.5)	0	0	0
Blood uric acid increased	1 (12.5)	1 (12.5)	0	0	0
Cardiac murmur	1 (12.5)	1 (12.5)	0	0	0
Fibrin d dimer increased	1 (12.5)	1 (12.5)	0	0	0
International normalised ratio increased	1 (12.5)	1 (12.5)	0	0	0
Prothrombin time prolonged	1 (12.5)	0	1 (12.5)	0	0
Weight decreased	1 (12.5)	1 (12.5)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (62.5)	2 (25.0)	2 (25.0)	1 (12.5)	0
Decreased appetite	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Hypokalaemia	3 (37.5)	2 (25.0)	1 (12.5)	0	0
Hypernatraemia	1 (12.5)	0	1 (12.5)	0	0
Hypoalbuminaemia	1 (12.5)	1 (12.5)	0	0	0
Hypophosphataemia	1 (12.5)	0	0	1 (12.5)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (62.5)	2 (25.0)	1 (12.5)	2 (25.0)	0

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain in extremity	3 (37.5)	2 (25.0)	0	1 (12.5)	0
Arthralgia	1 (12.5)	0	0	1 (12.5)	0
Muscular weakness	1 (12.5)	1 (12.5)	0	0	0
Neck pain	1 (12.5)	0	1 (12.5)	0	0
Pain in jaw	1 (12.5)	1 (12.5)	0	0	0
Nervous system disorders					
-Total	5 (62.5)	5 (62.5)	0	0	0
Headache	3 (37.5)	3 (37.5)	0	0	0
Dizziness	1 (12.5)	1 (12.5)	0	0	0
Dysgeusia	1 (12.5)	1 (12.5)	0	0	0
Peroneal nerve palsy	1 (12.5)	1 (12.5)	0	0	0
Psychiatric disorders					
-Total	4 (50.0)	0	4 (50.0)	0	0
Confusional state	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Depression	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Anxiety	1 (12.5)	1 (12.5)	0	0	0
Delirium	1 (12.5)	1 (12.5)	0	0	0
Insomnia	1 (12.5)	0	1 (12.5)	0	0

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sleep disorder	1 (12.5)	0	1 (12.5)	0	0
Renal and urinary disorders					
-Total	2 (25.0)	0	0	0	2 (25.0)
Haematuria	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Acute kidney injury	1 (12.5)	0	0	0	1 (12.5)
Cystitis haemorrhagic	1 (12.5)	0	0	0	1 (12.5)
Oliguria	1 (12.5)	0	0	1 (12.5)	0
Renal failure	1 (12.5)	0	0	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders					
-Total	7 (87.5)	2 (25.0)	1 (12.5)	1 (12.5)	3 (37.5)
Cough	3 (37.5)	3 (37.5)	0	0	0
Epistaxis	3 (37.5)	0	1 (12.5)	1 (12.5)	1 (12.5)
Hypoxia	3 (37.5)	0	0	2 (25.0)	1 (12.5)
Pleural effusion	2 (25.0)	0	2 (25.0)	0	0
Rhinorrhoea	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Aspiration	1 (12.5)	0	0	0	1 (12.5)
Dyspnoea	1 (12.5)	0	0	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoptysis	1 (12.5)	0	0	0	1 (12.5)
Interstitial lung disease	1 (12.5)	0	0	0	1 (12.5)
Nasal congestion	1 (12.5)	1 (12.5)	0	0	0
Oropharyngeal pain	1 (12.5)	0	1 (12.5)	0	0
Pharyngeal erythema	1 (12.5)	1 (12.5)	0	0	0
Pharyngeal lesion	1 (12.5)	0	0	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)
Respiratory failure	1 (12.5)	0	0	0	1 (12.5)
Skin and subcutaneous tissue disorders					
-Total	4 (50.0)	3 (37.5)	1 (12.5)	0	0
Erythema	2 (25.0)	2 (25.0)	0	0	0
Alopecia	1 (12.5)	0	1 (12.5)	0	0
Dermatitis diaper	1 (12.5)	1 (12.5)	0	0	0
Dry skin	1 (12.5)	1 (12.5)	0	0	0
Livedo reticularis	1 (12.5)	1 (12.5)	0	0	0
Rash erythematous	1 (12.5)	0	1 (12.5)	0	0
Rash maculo-papular	1 (12.5)	1 (12.5)	0	0	0

Number of previous relapses: 0

Primary system organ class Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	6 (75.0)	0	1 (12.5)	2 (25.0)	3 (37.5)
Hypotension	5 (62.5)	0	0	2 (25.0)	3 (37.5)
Hypertension	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Haematoma	1 (12.5)	0	1 (12.5)	0	0
Hot flush	1 (12.5)	1 (12.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178r
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (91.3)	0	2 (8.7)	2 (8.7)	17 (73.9)
Blood and lymphatic system disorders					
-Total	19 (82.6)	0	0	11 (47.8)	8 (34.8)
Febrile neutropenia	13 (56.5)	0	0	13 (56.5)	0
Anaemia	10 (43.5)	0	1 (4.3)	9 (39.1)	0
Disseminated intravascular coagulation	4 (17.4)	0	1 (4.3)	3 (13.0)	0
Neutropenia	4 (17.4)	0	0	1 (4.3)	3 (13.0)
Lymphopenia	3 (13.0)	0	0	0	3 (13.0)
Thrombocytopenia	3 (13.0)	0	0	1 (4.3)	2 (8.7)
Pancytopenia	2 (8.7)	0	0	0	2 (8.7)
Coagulopathy	1 (4.3)	0	0	1 (4.3)	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypofibrinogenaemia	1 (4.3)	0	0	0	1 (4.3)
Leukocytosis	1 (4.3)	1 (4.3)	0	0	0
Leukopenia	1 (4.3)	0	0	0	1 (4.3)
Splenomegaly	1 (4.3)	1 (4.3)	0	0	0
Cardiac disorders					
-Total	9 (39.1)	2 (8.7)	6 (26.1)	0	1 (4.3)
Tachycardia	5 (21.7)	3 (13.0)	2 (8.7)	0	0
Sinus tachycardia	3 (13.0)	1 (4.3)	1 (4.3)	1 (4.3)	0
Bradycardia	2 (8.7)	0	1 (4.3)	0	1 (4.3)
Pericardial effusion	2 (8.7)	0	2 (8.7)	0	0
Ventricular tachycardia	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Right ventricular dysfunction	1 (4.3)	0	0	1 (4.3)	0
Ear and labyrinth disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Tympanic membrane perforation	1 (4.3)	0	1 (4.3)	0	0
Endocrine disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Adrenal insufficiency	1 (4.3)	0	1 (4.3)	0	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	8 (34.8)	5 (21.7)	3 (13.0)	0	0
Conjunctival haemorrhage	2 (8.7)	2 (8.7)	0	0	0
Periorbital oedema	2 (8.7)	2 (8.7)	0	0	0
Vision blurred	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Dry eye	1 (4.3)	1 (4.3)	0	0	0
Eye irritation	1 (4.3)	1 (4.3)	0	0	0
Photophobia	1 (4.3)	0	1 (4.3)	0	0
Retinal haemorrhage	1 (4.3)	1 (4.3)	0	0	0
Retinopathy	1 (4.3)	0	1 (4.3)	0	0
Uveitis	1 (4.3)	0	1 (4.3)	0	0
Gastrointestinal disorders					
-Total	16 (69.6)	2 (8.7)	6 (26.1)	8 (34.8)	0
Nausea	11 (47.8)	4 (17.4)	4 (17.4)	3 (13.0)	0
Vomiting	9 (39.1)	4 (17.4)	3 (13.0)	2 (8.7)	0
Diarrhoea	8 (34.8)	4 (17.4)	3 (13.0)	1 (4.3)	0
Constipation	6 (26.1)	6 (26.1)	0	0	0
Abdominal pain	5 (21.7)	2 (8.7)	2 (8.7)	1 (4.3)	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphagia	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Haematochezia	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Abdominal pain lower	1 (4.3)	1 (4.3)	0	0	0
Abdominal pain upper	1 (4.3)	0	1 (4.3)	0	0
Colitis	1 (4.3)	1 (4.3)	0	0	0
Dry mouth	1 (4.3)	1 (4.3)	0	0	0
Flatulence	1 (4.3)	1 (4.3)	0	0	0
Gastrooesophageal reflux disease	1 (4.3)	1 (4.3)	0	0	0
Glossodynia	1 (4.3)	1 (4.3)	0	0	0
Haematemesis	1 (4.3)	0	1 (4.3)	0	0
Ileus	1 (4.3)	0	0	1 (4.3)	0
Oral mucosal blistering	1 (4.3)	1 (4.3)	0	0	0
Pancreatic failure	1 (4.3)	0	1 (4.3)	0	0
Pancreatitis	1 (4.3)	0	1 (4.3)	0	0
Perianal erythema	1 (4.3)	0	1 (4.3)	0	0
Stomatitis	1 (4.3)	0	0	1 (4.3)	0
Tooth socket haemorrhage	1 (4.3)	1 (4.3)	0	0	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	16 (69.6)	4 (17.4)	4 (17.4)	8 (34.8)	0
Pyrexia	9 (39.1)	1 (4.3)	4 (17.4)	4 (17.4)	0
Fatigue	5 (21.7)	5 (21.7)	0	0	0
Oedema peripheral	3 (13.0)	1 (4.3)	1 (4.3)	1 (4.3)	0
Catheter site pain	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Chills	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Generalised oedema	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Physical deconditioning	2 (8.7)	0	0	2 (8.7)	0
Acquired gene mutation	1 (4.3)	1 (4.3)	0	0	0
Catheter site haemorrhage	1 (4.3)	1 (4.3)	0	0	0
Device related thrombosis	1 (4.3)	0	1 (4.3)	0	0
Face oedema	1 (4.3)	0	0	1 (4.3)	0
Injection site haematoma	1 (4.3)	1 (4.3)	0	0	0
Localised oedema	1 (4.3)	0	0	1 (4.3)	0
Mucosal haemorrhage	1 (4.3)	0	1 (4.3)	0	0
Multiple organ dysfunction syndrome	1 (4.3)	0	0	1 (4.3)	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Non-cardiac chest pain	1 (4.3)	0	0	1 (4.3)	0
Pain	1 (4.3)	0	1 (4.3)	0	0
Hepatobiliary disorders					
-Total	4 (17.4)	2 (8.7)	0	2 (8.7)	0
Hyperbilirubinaemia	2 (8.7)	0	0	2 (8.7)	0
Gallbladder enlargement	1 (4.3)	1 (4.3)	0	0	0
Hepatic steatosis	1 (4.3)	0	1 (4.3)	0	0
Hepatosplenomegaly	1 (4.3)	1 (4.3)	0	0	0
Immune system disorders					
-Total	17 (73.9)	2 (8.7)	7 (30.4)	3 (13.0)	5 (21.7)
Cytokine release syndrome	16 (69.6)	2 (8.7)	7 (30.4)	2 (8.7)	5 (21.7)
Hypogammaglobulinaemia	10 (43.5)	1 (4.3)	7 (30.4)	2 (8.7)	0
Immunodeficiency common variable	2 (8.7)	0	2 (8.7)	0	0
Chronic graft versus host disease	1 (4.3)	0	1 (4.3)	0	0
Graft versus host disease in gastrointestinal tract	1 (4.3)	0	1 (4.3)	0	0
Seasonal allergy	1 (4.3)	1 (4.3)	0	0	0
Infections and infestations					

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	17 (73.9)	1 (4.3)	5 (21.7)	10 (43.5)	1 (4.3)
Pneumonia	4 (17.4)	0	3 (13.0)	1 (4.3)	0
Gastroenteritis	3 (13.0)	0	2 (8.7)	1 (4.3)	0
Influenza	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Clostridium difficile infection	2 (8.7)	0	2 (8.7)	0	0
Device related infection	2 (8.7)	0	0	2 (8.7)	0
Escherichia bacteraemia	2 (8.7)	0	0	2 (8.7)	0
Escherichia urinary tract infection	2 (8.7)	0	0	2 (8.7)	0
Otitis media	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Parainfluenzae virus infection	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Rhinovirus infection	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Sinusitis	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Staphylococcal infection	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Upper respiratory tract infection	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Urinary tract infection	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Abscess limb	1 (4.3)	0	0	1 (4.3)	0
Bronchopulmonary aspergillosis	1 (4.3)	0	0	1 (4.3)	0
Catheter site cellulitis	1 (4.3)	1 (4.3)	0	0	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Clostridium difficile colitis	1 (4.3)	0	0	1 (4.3)	0
Cytomegalovirus infection	1 (4.3)	1 (4.3)	0	0	0
Enterococcal infection	1 (4.3)	1 (4.3)	0	0	0
Gastroenteritis norovirus	1 (4.3)	0	1 (4.3)	0	0
Gingivitis	1 (4.3)	1 (4.3)	0	0	0
Haemophilus infection	1 (4.3)	0	1 (4.3)	0	0
Herpes zoster	1 (4.3)	0	0	1 (4.3)	0
Meningitis aseptic	1 (4.3)	0	1 (4.3)	0	0
Metapneumovirus infection	1 (4.3)	0	1 (4.3)	0	0
Oral herpes	1 (4.3)	0	1 (4.3)	0	0
Otitis media acute	1 (4.3)	0	1 (4.3)	0	0
Pharyngitis	1 (4.3)	0	1 (4.3)	0	0
Pneumonia fungal	1 (4.3)	0	1 (4.3)	0	0
Rash pustular	1 (4.3)	0	1 (4.3)	0	0
Respiratory syncytial virus bronchitis	1 (4.3)	0	0	1 (4.3)	0
Respiratory syncytial virus infection	1 (4.3)	0	1 (4.3)	0	0
Rhinitis	1 (4.3)	1 (4.3)	0	0	0
Sepsis	1 (4.3)	0	0	0	1 (4.3)

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (4.3)	0	0	1 (4.3)	0
Staphylococcal scalded skin syndrome	1 (4.3)	0	1 (4.3)	0	0
Staphylococcal sepsis	1 (4.3)	0	0	0	1 (4.3)
Streptococcal infection	1 (4.3)	0	1 (4.3)	0	0
Subcutaneous abscess	1 (4.3)	0	1 (4.3)	0	0
Viral infection	1 (4.3)	1 (4.3)	0	0	0
Viral upper respiratory tract infection	1 (4.3)	0	0	1 (4.3)	0
Vulvovaginal mycotic infection	1 (4.3)	0	1 (4.3)	0	0
Injury, poisoning and procedural complications					
-Total	6 (26.1)	4 (17.4)	1 (4.3)	0	1 (4.3)
Contusion	1 (4.3)	1 (4.3)	0	0	0
Post procedural haemorrhage	1 (4.3)	1 (4.3)	0	0	0
Procedural complication	1 (4.3)	1 (4.3)	0	0	0
Radiation skin injury	1 (4.3)	0	1 (4.3)	0	0
Subdural haemorrhage	1 (4.3)	1 (4.3)	0	0	0
Transfusion reaction	1 (4.3)	1 (4.3)	0	0	0
Transfusion related complication	1 (4.3)	0	0	0	1 (4.3)

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	17 (73.9)	0	0	3 (13.0)	14 (60.9)
White blood cell count decreased	14 (60.9)	2 (8.7)	0	3 (13.0)	9 (39.1)
Neutrophil count decreased	10 (43.5)	0	0	2 (8.7)	8 (34.8)
Platelet count decreased	9 (39.1)	0	2 (8.7)	1 (4.3)	6 (26.1)
Alanine aminotransferase increased	7 (30.4)	1 (4.3)	2 (8.7)	4 (17.4)	0
Aspartate aminotransferase increased	7 (30.4)	1 (4.3)	2 (8.7)	3 (13.0)	1 (4.3)
Lymphocyte count decreased	6 (26.1)	0	0	3 (13.0)	3 (13.0)
Blood creatinine increased	4 (17.4)	2 (8.7)	1 (4.3)	1 (4.3)	0
Activated partial thromboplastin time prolonged	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Blood bilirubin increased	3 (13.0)	0	2 (8.7)	1 (4.3)	0
International normalised ratio increased	3 (13.0)	3 (13.0)	0	0	0
Prothrombin time prolonged	3 (13.0)	3 (13.0)	0	0	0
Lipase increased	2 (8.7)	0	0	0	2 (8.7)
Blood fibrinogen decreased	1 (4.3)	0	0	0	1 (4.3)
Blood immunoglobulin a decreased	1 (4.3)	1 (4.3)	0	0	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (4.3)	1 (4.3)	0	0	0
Blood lactate dehydrogenase increased	1 (4.3)	0	0	1 (4.3)	0
Blood lactic acid increased	1 (4.3)	0	1 (4.3)	0	0
Blood phosphorus decreased	1 (4.3)	1 (4.3)	0	0	0
Blood phosphorus increased	1 (4.3)	1 (4.3)	0	0	0
Blood urea increased	1 (4.3)	0	0	1 (4.3)	0
C-reactive protein increased	1 (4.3)	0	1 (4.3)	0	0
Computerised tomogram thorax abnormal	1 (4.3)	0	0	1 (4.3)	0
Electrocardiogram qt prolonged	1 (4.3)	0	0	1 (4.3)	0
Haemoglobin decreased	1 (4.3)	0	0	1 (4.3)	0
Hepatic enzyme increased	1 (4.3)	0	1 (4.3)	0	0
Protein total decreased	1 (4.3)	0	0	1 (4.3)	0
Serum ferritin increased	1 (4.3)	0	1 (4.3)	0	0
Transaminases increased	1 (4.3)	0	0	1 (4.3)	0
Weight decreased	1 (4.3)	1 (4.3)	0	0	0
Weight increased	1 (4.3)	1 (4.3)	0	0	0
Metabolism and nutrition disorders					

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (65.2)	1 (4.3)	2 (8.7)	8 (34.8)	4 (17.4)
Decreased appetite	10 (43.5)	3 (13.0)	3 (13.0)	4 (17.4)	0
Hypokalaemia	6 (26.1)	1 (4.3)	0	3 (13.0)	2 (8.7)
Hyperglycaemia	4 (17.4)	0	2 (8.7)	2 (8.7)	0
Hyperphosphataemia	4 (17.4)	4 (17.4)	0	0	0
Hypernatraemia	3 (13.0)	1 (4.3)	1 (4.3)	0	1 (4.3)
Hypophosphataemia	3 (13.0)	1 (4.3)	0	2 (8.7)	0
Acidosis	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Dehydration	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Fluid overload	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Hyperkalaemia	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Hyperuricaemia	2 (8.7)	1 (4.3)	0	0	1 (4.3)
Hypocalcaemia	2 (8.7)	2 (8.7)	0	0	0
Vitamin d deficiency	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Hyperalbuminaemia	1 (4.3)	1 (4.3)	0	0	0
Hyperammonaemia	1 (4.3)	1 (4.3)	0	0	0
Hypercalcaemia	1 (4.3)	1 (4.3)	0	0	0
Hyperchloraemia	1 (4.3)	1 (4.3)	0	0	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypermagnesaemia	1 (4.3)	1 (4.3)	0	0	0
Hypertriglyceridaemia	1 (4.3)	0	0	1 (4.3)	0
Hypoalbuminaemia	1 (4.3)	0	1 (4.3)	0	0
Iron overload	1 (4.3)	0	0	1 (4.3)	0
Malnutrition	1 (4.3)	0	1 (4.3)	0	0
Metabolic alkalosis	1 (4.3)	1 (4.3)	0	0	0
Tumour lysis syndrome	1 (4.3)	0	0	1 (4.3)	0
Musculoskeletal and connective tissue disorders					
-Total	11 (47.8)	2 (8.7)	5 (21.7)	4 (17.4)	0
Arthralgia	3 (13.0)	2 (8.7)	0	1 (4.3)	0
Musculoskeletal chest pain	3 (13.0)	3 (13.0)	0	0	0
Pain in extremity	3 (13.0)	1 (4.3)	1 (4.3)	1 (4.3)	0
Back pain	2 (8.7)	0	0	2 (8.7)	0
Muscular weakness	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Bone pain	1 (4.3)	0	0	1 (4.3)	0
Coccydynia	1 (4.3)	1 (4.3)	0	0	0
Flank pain	1 (4.3)	0	1 (4.3)	0	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal pain	1 (4.3)	0	1 (4.3)	0	0
Myopathy	1 (4.3)	0	0	1 (4.3)	0
Myositis	1 (4.3)	0	0	1 (4.3)	0
Osteonecrosis	1 (4.3)	0	1 (4.3)	0	0
Synovitis	1 (4.3)	0	1 (4.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	2 (8.7)	0	1 (4.3)	0	1 (4.3)
Glioblastoma multiforme	1 (4.3)	0	0	0	1 (4.3)
Myelodysplastic syndrome	1 (4.3)	0	1 (4.3)	0	0
Nervous system disorders					
-Total	16 (69.6)	4 (17.4)	8 (34.8)	3 (13.0)	1 (4.3)
Headache	12 (52.2)	5 (21.7)	5 (21.7)	2 (8.7)	0
Seizure	3 (13.0)	0	1 (4.3)	1 (4.3)	1 (4.3)
Dysarthria	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Encephalopathy	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Tremor	2 (8.7)	2 (8.7)	0	0	0
Asterixis	1 (4.3)	1 (4.3)	0	0	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ataxia	1 (4.3)	0	1 (4.3)	0	0
Depressed level of consciousness	1 (4.3)	1 (4.3)	0	0	0
Dizziness	1 (4.3)	1 (4.3)	0	0	0
Hyporesponsive to stimuli	1 (4.3)	0	0	1 (4.3)	0
Hypotonia	1 (4.3)	0	1 (4.3)	0	0
Neuropathy peripheral	1 (4.3)	0	1 (4.3)	0	0
Pleocytosis	1 (4.3)	1 (4.3)	0	0	0
Somnolence	1 (4.3)	1 (4.3)	0	0	0
Product issues					
-Total	1 (4.3)	1 (4.3)	0	0	0
Device occlusion	1 (4.3)	1 (4.3)	0	0	0
Psychiatric disorders					
-Total	9 (39.1)	4 (17.4)	4 (17.4)	1 (4.3)	0
Agitation	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Anxiety	2 (8.7)	0	2 (8.7)	0	0
Delirium	2 (8.7)	0	2 (8.7)	0	0
Depression	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Insomnia	2 (8.7)	0	2 (8.7)	0	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	2 (8.7)	2 (8.7)	0	0	0
Adjustment disorder	1 (4.3)	0	1 (4.3)	0	0
Confusional state	1 (4.3)	1 (4.3)	0	0	0
Hallucination	1 (4.3)	1 (4.3)	0	0	0
Irritability	1 (4.3)	1 (4.3)	0	0	0
Suicidal ideation	1 (4.3)	1 (4.3)	0	0	0
Renal and urinary disorders					
-Total	8 (34.8)	1 (4.3)	2 (8.7)	5 (21.7)	0
Acute kidney injury	6 (26.1)	2 (8.7)	1 (4.3)	3 (13.0)	0
Calculus urinary	1 (4.3)	0	1 (4.3)	0	0
Dysuria	1 (4.3)	0	1 (4.3)	0	0
Haematuria	1 (4.3)	0	0	1 (4.3)	0
Nephrolithiasis	1 (4.3)	0	0	1 (4.3)	0
Oliguria	1 (4.3)	0	0	1 (4.3)	0
Renal impairment	1 (4.3)	0	0	1 (4.3)	0
Reproductive system and breast disorders					
-Total	2 (8.7)	1 (4.3)	0	1 (4.3)	0

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ovarian failure	1 (4.3)	0	0	1 (4.3)	0
Vulvovaginal adhesion	1 (4.3)	1 (4.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	13 (56.5)	4 (17.4)	1 (4.3)	4 (17.4)	4 (17.4)
Epistaxis	5 (21.7)	2 (8.7)	1 (4.3)	2 (8.7)	0
Hypoxia	5 (21.7)	0	1 (4.3)	4 (17.4)	0
Pulmonary oedema	5 (21.7)	1 (4.3)	0	2 (8.7)	2 (8.7)
Tachypnoea	5 (21.7)	2 (8.7)	1 (4.3)	2 (8.7)	0
Cough	4 (17.4)	3 (13.0)	0	1 (4.3)	0
Oropharyngeal pain	3 (13.0)	1 (4.3)	1 (4.3)	1 (4.3)	0
Pleural effusion	3 (13.0)	0	2 (8.7)	1 (4.3)	0
Haemoptysis	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Nasal congestion	2 (8.7)	2 (8.7)	0	0	0
Respiratory distress	2 (8.7)	0	0	0	2 (8.7)
Acute respiratory failure	1 (4.3)	0	0	0	1 (4.3)
Dyspnoea	1 (4.3)	0	0	1 (4.3)	0
Nasal discomfort	1 (4.3)	1 (4.3)	0	0	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal plaque	1 (4.3)	1 (4.3)	0	0	0
Pulmonary alveolar haemorrhage	1 (4.3)	0	0	0	1 (4.3)
Pulmonary hypertension	1 (4.3)	0	0	1 (4.3)	0
Pulmonary mass	1 (4.3)	0	1 (4.3)	0	0
Respiratory failure	1 (4.3)	0	0	0	1 (4.3)
Rhinorrhoea	1 (4.3)	1 (4.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	12 (52.2)	7 (30.4)	4 (17.4)	1 (4.3)	0
Dry skin	4 (17.4)	4 (17.4)	0	0	0
Hyperhidrosis	3 (13.0)	3 (13.0)	0	0	0
Petechiae	3 (13.0)	3 (13.0)	0	0	0
Rash	3 (13.0)	2 (8.7)	1 (4.3)	0	0
Rash erythematous	3 (13.0)	2 (8.7)	1 (4.3)	0	0
Papule	2 (8.7)	2 (8.7)	0	0	0
Pruritus	2 (8.7)	2 (8.7)	0	0	0
Rash pruritic	2 (8.7)	2 (8.7)	0	0	0
Cold sweat	1 (4.3)	1 (4.3)	0	0	0

Number of previous relapses: 1

	All patients N=23				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ecchymosis	1 (4.3)	0	0	1 (4.3)	0
Eczema	1 (4.3)	1 (4.3)	0	0	0
Erythema	1 (4.3)	1 (4.3)	0	0	0
Ingrowing nail	1 (4.3)	0	1 (4.3)	0	0
Keloid scar	1 (4.3)	0	1 (4.3)	0	0
Macule	1 (4.3)	1 (4.3)	0	0	0
Night sweats	1 (4.3)	1 (4.3)	0	0	0
Pruritus generalised	1 (4.3)	1 (4.3)	0	0	0
Rash macular	1 (4.3)	1 (4.3)	0	0	0
Rash papular	1 (4.3)	1 (4.3)	0	0	0
Rash vesicular	1 (4.3)	1 (4.3)	0	0	0
Skin exfoliation	1 (4.3)	1 (4.3)	0	0	0
Skin fissures	1 (4.3)	1 (4.3)	0	0	0
Vascular disorders					
-Total	8 (34.8)	0	2 (8.7)	2 (8.7)	4 (17.4)
Hypotension	6 (26.1)	0	0	2 (8.7)	4 (17.4)
Hypertension	4 (17.4)	1 (4.3)	3 (13.0)	0	0
Capillary leak syndrome	1 (4.3)	0	0	0	1 (4.3)

Number of previous relapses: 1

Primary system organ class Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Flushing	1 (4.3)	1 (4.3)	0	0	0
Orthostatic hypotension	1 (4.3)	0	1 (4.3)	0	0
Secondary hypertension	1 (4.3)	0	1 (4.3)	0	0
Venous thrombosis limb	1 (4.3)	1 (4.3)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178r
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (95.8)	0	1 (4.2)	4 (16.7)	18 (75.0)
Blood and lymphatic system disorders					
-Total	20 (83.3)	1 (4.2)	1 (4.2)	10 (41.7)	8 (33.3)
Febrile neutropenia	11 (45.8)	0	0	10 (41.7)	1 (4.2)
Anaemia	10 (41.7)	0	4 (16.7)	6 (25.0)	0
Neutropenia	6 (25.0)	0	0	2 (8.3)	4 (16.7)
Thrombocytopenia	5 (20.8)	0	1 (4.2)	0	4 (16.7)
Lymphopenia	2 (8.3)	0	1 (4.2)	1 (4.2)	0
Pancytopenia	2 (8.3)	0	0	1 (4.2)	1 (4.2)
Coagulopathy	1 (4.2)	1 (4.2)	0	0	0

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=24 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Disseminated intravascular coagulation	1 (4.2)	0	1 (4.2)	0	0
Lymphadenopathy	1 (4.2)	0	1 (4.2)	0	0
Cardiac disorders					
-Total	7 (29.2)	3 (12.5)	3 (12.5)	1 (4.2)	0
Tachycardia	5 (20.8)	2 (8.3)	3 (12.5)	0	0
Atrioventricular block second degree	1 (4.2)	1 (4.2)	0	0	0
Left ventricular dysfunction	1 (4.2)	0	0	1 (4.2)	0
Palpitations	1 (4.2)	1 (4.2)	0	0	0
Sinus bradycardia	1 (4.2)	1 (4.2)	0	0	0
Sinus tachycardia	1 (4.2)	0	1 (4.2)	0	0
Ear and labyrinth disorders					
-Total	1 (4.2)	0	1 (4.2)	0	0
Hypoacusis	1 (4.2)	0	1 (4.2)	0	0
Endocrine disorders					
-Total	1 (4.2)	0	1 (4.2)	0	0
Adrenal insufficiency	1 (4.2)	0	1 (4.2)	0	0
Eye disorders					

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (25.0)	4 (16.7)	2 (8.3)	0	0
Eye pain	2 (8.3)	0	2 (8.3)	0	0
Photophobia	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Vision blurred	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Conjunctival haemorrhage	1 (4.2)	1 (4.2)	0	0	0
Conjunctivitis allergic	1 (4.2)	1 (4.2)	0	0	0
Periorbital oedema	1 (4.2)	1 (4.2)	0	0	0
Retinal haemorrhage	1 (4.2)	1 (4.2)	0	0	0
Gastrointestinal disorders					
-Total	16 (66.7)	5 (20.8)	7 (29.2)	4 (16.7)	0
Nausea	11 (45.8)	2 (8.3)	7 (29.2)	2 (8.3)	0
Vomiting	9 (37.5)	5 (20.8)	2 (8.3)	2 (8.3)	0
Diarrhoea	8 (33.3)	4 (16.7)	3 (12.5)	1 (4.2)	0
Abdominal pain	3 (12.5)	1 (4.2)	1 (4.2)	1 (4.2)	0
Constipation	3 (12.5)	1 (4.2)	2 (8.3)	0	0
Pancreatitis	2 (8.3)	0	1 (4.2)	1 (4.2)	0
Abdominal discomfort	1 (4.2)	1 (4.2)	0	0	0
Abdominal pain upper	1 (4.2)	0	1 (4.2)	0	0

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anal fissure	1 (4.2)	0	1 (4.2)	0	0
Anal incontinence	1 (4.2)	1 (4.2)	0	0	0
Ascites	1 (4.2)	0	0	1 (4.2)	0
Dyspepsia	1 (4.2)	0	1 (4.2)	0	0
Gastrointestinal haemorrhage	1 (4.2)	1 (4.2)	0	0	0
Gingival discomfort	1 (4.2)	1 (4.2)	0	0	0
Intestinal obstruction	1 (4.2)	0	0	1 (4.2)	0
Oral pain	1 (4.2)	0	1 (4.2)	0	0
Proctalgia	1 (4.2)	0	1 (4.2)	0	0
Stomatitis	1 (4.2)	0	1 (4.2)	0	0
General disorders and administration site conditions					
-Total	13 (54.2)	5 (20.8)	8 (33.3)	0	0
Pyrexia	8 (33.3)	2 (8.3)	6 (25.0)	0	0
Chills	6 (25.0)	5 (20.8)	1 (4.2)	0	0
Fatigue	5 (20.8)	3 (12.5)	2 (8.3)	0	0
Catheter site pain	3 (12.5)	1 (4.2)	2 (8.3)	0	0
Malaise	3 (12.5)	1 (4.2)	2 (8.3)	0	0

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=24 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Influenza like illness	1 (4.2)	1 (4.2)	0	0	0
Non-cardiac chest pain	1 (4.2)	1 (4.2)	0	0	0
Pain	1 (4.2)	0	1 (4.2)	0	0
Hepatobiliary disorders					
-Total	3 (12.5)	1 (4.2)	2 (8.3)	0	0
Hyperbilirubinaemia	2 (8.3)	0	2 (8.3)	0	0
Hepatomegaly	1 (4.2)	1 (4.2)	0	0	0
Immune system disorders					
-Total	20 (83.3)	0	13 (54.2)	6 (25.0)	1 (4.2)
Cytokine release syndrome	18 (75.0)	1 (4.2)	12 (50.0)	4 (16.7)	1 (4.2)
Hypogammaglobulinaemia	12 (50.0)	1 (4.2)	8 (33.3)	3 (12.5)	0
Drug hypersensitivity	1 (4.2)	0	1 (4.2)	0	0
Immunodeficiency	1 (4.2)	0	1 (4.2)	0	0
Seasonal allergy	1 (4.2)	1 (4.2)	0	0	0
Infections and infestations					
-Total	15 (62.5)	1 (4.2)	6 (25.0)	3 (12.5)	5 (20.8)
Clostridium difficile colitis	3 (12.5)	1 (4.2)	1 (4.2)	1 (4.2)	0
Rhinovirus infection	3 (12.5)	3 (12.5)	0	0	0

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (8.3)	0	2 (8.3)	0	0
Sinusitis	2 (8.3)	0	2 (8.3)	0	0
Upper respiratory tract infection	2 (8.3)	0	2 (8.3)	0	0
Viral upper respiratory tract infection	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Acute sinusitis	1 (4.2)	0	1 (4.2)	0	0
Bacterial sepsis	1 (4.2)	0	0	0	1 (4.2)
Candida sepsis	1 (4.2)	0	0	0	1 (4.2)
Catheter site infection	1 (4.2)	0	0	1 (4.2)	0
Cholecystitis infective	1 (4.2)	0	0	1 (4.2)	0
Clostridium difficile infection	1 (4.2)	0	1 (4.2)	0	0
Escherichia sepsis	1 (4.2)	0	0	0	1 (4.2)
Escherichia urinary tract infection	1 (4.2)	0	1 (4.2)	0	0
Folliculitis	1 (4.2)	0	1 (4.2)	0	0
Gastroenteritis	1 (4.2)	1 (4.2)	0	0	0
Gastroenteritis viral	1 (4.2)	1 (4.2)	0	0	0
Influenza	1 (4.2)	0	1 (4.2)	0	0
Molluscum contagiosum	1 (4.2)	1 (4.2)	0	0	0
Orchitis	1 (4.2)	1 (4.2)	0	0	0

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis externa	1 (4.2)	0	1 (4.2)	0	0
Parainfluenzae virus infection	1 (4.2)	0	0	1 (4.2)	0
Paronychia	1 (4.2)	1 (4.2)	0	0	0
Respiratory tract infection	1 (4.2)	0	0	0	1 (4.2)
Septic embolus	1 (4.2)	0	0	0	1 (4.2)
Urinary tract infection	1 (4.2)	0	1 (4.2)	0	0
Urinary tract infection enterococcal	1 (4.2)	0	0	1 (4.2)	0
Injury, poisoning and procedural complications					
-Total	9 (37.5)	5 (20.8)	3 (12.5)	1 (4.2)	0
Procedural pain	3 (12.5)	2 (8.3)	0	1 (4.2)	0
Infusion related reaction	2 (8.3)	2 (8.3)	0	0	0
Transfusion reaction	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Arthropod bite	1 (4.2)	1 (4.2)	0	0	0
Foot fracture	1 (4.2)	0	1 (4.2)	0	0
Incision site pain	1 (4.2)	1 (4.2)	0	0	0
Radius fracture	1 (4.2)	0	1 (4.2)	0	0
Skin abrasion	1 (4.2)	1 (4.2)	0	0	0

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stoma site irritation	1 (4.2)	1 (4.2)	0	0	0
Tibia fracture	1 (4.2)	0	1 (4.2)	0	0
Investigations					
-Total	20 (83.3)	0	0	7 (29.2)	13 (54.2)
White blood cell count decreased	15 (62.5)	0	0	4 (16.7)	11 (45.8)
Alanine aminotransferase increased	11 (45.8)	1 (4.2)	0	10 (41.7)	0
Aspartate aminotransferase increased	8 (33.3)	2 (8.3)	1 (4.2)	5 (20.8)	0
Neutrophil count decreased	8 (33.3)	0	0	1 (4.2)	7 (29.2)
Platelet count decreased	6 (25.0)	2 (8.3)	0	2 (8.3)	2 (8.3)
Lymphocyte count decreased	5 (20.8)	0	0	3 (12.5)	2 (8.3)
Prothrombin time prolonged	4 (16.7)	2 (8.3)	1 (4.2)	1 (4.2)	0
Transaminases increased	3 (12.5)	3 (12.5)	0	0	0
Weight decreased	3 (12.5)	0	3 (12.5)	0	0
Blood bilirubin increased	2 (8.3)	0	1 (4.2)	1 (4.2)	0
Blood fibrinogen decreased	2 (8.3)	0	0	2 (8.3)	0
C-reactive protein increased	2 (8.3)	1 (4.2)	0	1 (4.2)	0
International normalised ratio increased	2 (8.3)	1 (4.2)	0	1 (4.2)	0

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood alkaline phosphatase increased	1 (4.2)	1 (4.2)	0	0	0
Blood creatinine increased	1 (4.2)	1 (4.2)	0	0	0
Blood immunoglobulin g decreased	1 (4.2)	0	1 (4.2)	0	0
Blood immunoglobulin m decreased	1 (4.2)	1 (4.2)	0	0	0
Blood lactate dehydrogenase increased	1 (4.2)	1 (4.2)	0	0	0
Blood sodium increased	1 (4.2)	0	1 (4.2)	0	0
Blood urea increased	1 (4.2)	1 (4.2)	0	0	0
Haemoglobin decreased	1 (4.2)	1 (4.2)	0	0	0
Lipase increased	1 (4.2)	0	0	0	1 (4.2)
Oxygen saturation decreased	1 (4.2)	1 (4.2)	0	0	0
Metabolism and nutrition disorders					
-Total	16 (66.7)	1 (4.2)	3 (12.5)	10 (41.7)	2 (8.3)
Decreased appetite	10 (41.7)	1 (4.2)	3 (12.5)	6 (25.0)	0
Hypokalaemia	7 (29.2)	1 (4.2)	2 (8.3)	3 (12.5)	1 (4.2)
Hypophosphataemia	6 (25.0)	1 (4.2)	0	4 (16.7)	1 (4.2)
Fluid overload	2 (8.3)	0	2 (8.3)	0	0
Hyperphosphataemia	2 (8.3)	2 (8.3)	0	0	0

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=24 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypomagnesaemia	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Hyponatraemia	2 (8.3)	0	0	2 (8.3)	0
Tumour lysis syndrome	2 (8.3)	0	0	2 (8.3)	0
Dehydration	1 (4.2)	0	0	1 (4.2)	0
Hyperglycaemia	1 (4.2)	0	0	1 (4.2)	0
Hypernatraemia	1 (4.2)	0	0	0	1 (4.2)
Hypertriglyceridaemia	1 (4.2)	1 (4.2)	0	0	0
Hypoalbuminaemia	1 (4.2)	0	0	1 (4.2)	0
Hypocalcaemia	1 (4.2)	0	0	0	1 (4.2)
Malnutrition	1 (4.2)	0	0	1 (4.2)	0
Metabolic acidosis	1 (4.2)	0	1 (4.2)	0	0
Musculoskeletal and connective tissue disorders					
-Total	8 (33.3)	5 (20.8)	3 (12.5)	0	0
Pain in extremity	3 (12.5)	2 (8.3)	1 (4.2)	0	0
Arthralgia	1 (4.2)	0	1 (4.2)	0	0
Limb discomfort	1 (4.2)	1 (4.2)	0	0	0
Musculoskeletal pain	1 (4.2)	1 (4.2)	0	0	0

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	1 (4.2)	1 (4.2)	0	0	0
Osteopenia	1 (4.2)	0	1 (4.2)	0	0
Pain in jaw	1 (4.2)	0	1 (4.2)	0	0
Toe walking	1 (4.2)	1 (4.2)	0	0	0
Nervous system disorders					
-Total	12 (50.0)	5 (20.8)	4 (16.7)	2 (8.3)	1 (4.2)
Headache	7 (29.2)	4 (16.7)	1 (4.2)	2 (8.3)	0
Dizziness	2 (8.3)	2 (8.3)	0	0	0
Peroneal nerve palsy	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Disturbance in attention	1 (4.2)	1 (4.2)	0	0	0
Embolic stroke	1 (4.2)	0	0	0	1 (4.2)
Encephalopathy	1 (4.2)	0	0	1 (4.2)	0
Migraine	1 (4.2)	0	1 (4.2)	0	0
Neuropathy peripheral	1 (4.2)	1 (4.2)	0	0	0
Peripheral sensory neuropathy	1 (4.2)	0	1 (4.2)	0	0
Seizure	1 (4.2)	0	1 (4.2)	0	0
Product issues					
-Total	1 (4.2)	1 (4.2)	0	0	0

Number of previous relapses: 2

	All patients N=24				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device occlusion	1 (4.2)	1 (4.2)	0	0	0
Psychiatric disorders					
-Total	6 (25.0)	3 (12.5)	3 (12.5)	0	0
Anxiety	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Confusional state	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Delirium	1 (4.2)	1 (4.2)	0	0	0
Mental status changes	1 (4.2)	1 (4.2)	0	0	0
Panic attack	1 (4.2)	0	1 (4.2)	0	0
Renal and urinary disorders					
-Total	6 (25.0)	1 (4.2)	1 (4.2)	2 (8.3)	2 (8.3)
Acute kidney injury	4 (16.7)	0	0	2 (8.3)	2 (8.3)
Dysuria	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Haematuria	1 (4.2)	0	1 (4.2)	0	0
Pollakiuria	1 (4.2)	1 (4.2)	0	0	0
Reproductive system and breast disorders					
-Total	1 (4.2)	0	0	1 (4.2)	0
Vaginal haemorrhage	1 (4.2)	0	0	1 (4.2)	0

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=24 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	12 (50.0)	3 (12.5)	5 (20.8)	1 (4.2)	3 (12.5)
Cough	5 (20.8)	4 (16.7)	1 (4.2)	0	0
Hypoxia	3 (12.5)	0	1 (4.2)	1 (4.2)	1 (4.2)
Rhinitis allergic	3 (12.5)	2 (8.3)	1 (4.2)	0	0
Epistaxis	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Pleural effusion	2 (8.3)	1 (4.2)	0	1 (4.2)	0
Pulmonary oedema	2 (8.3)	0	0	1 (4.2)	1 (4.2)
Respiratory failure	2 (8.3)	0	0	0	2 (8.3)
Rhinorrhoea	2 (8.3)	2 (8.3)	0	0	0
Atelectasis	1 (4.2)	1 (4.2)	0	0	0
Dysphonia	1 (4.2)	1 (4.2)	0	0	0
Nasal congestion	1 (4.2)	1 (4.2)	0	0	0
Oropharyngeal pain	1 (4.2)	1 (4.2)	0	0	0
Pharyngeal ulceration	1 (4.2)	0	1 (4.2)	0	0
Respiratory depression	1 (4.2)	0	1 (4.2)	0	0
Tachypnoea	1 (4.2)	1 (4.2)	0	0	0

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=24 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	11 (45.8)	6 (25.0)	3 (12.5)	2 (8.3)	0
Alopecia	3 (12.5)	2 (8.3)	1 (4.2)	0	0
Erythema	2 (8.3)	2 (8.3)	0	0	0
Ingrowing nail	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Pruritus	2 (8.3)	2 (8.3)	0	0	0
Rash	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Rash maculo-papular	2 (8.3)	0	1 (4.2)	1 (4.2)	0
Acne	1 (4.2)	1 (4.2)	0	0	0
Dermatitis	1 (4.2)	1 (4.2)	0	0	0
Dermatitis acneiform	1 (4.2)	0	0	1 (4.2)	0
Hyperhidrosis	1 (4.2)	1 (4.2)	0	0	0
Skin ulcer	1 (4.2)	1 (4.2)	0	0	0
Vascular disorders					
-Total	9 (37.5)	1 (4.2)	3 (12.5)	3 (12.5)	2 (8.3)
Hypotension	5 (20.8)	0	0	3 (12.5)	2 (8.3)
Hypertension	4 (16.7)	1 (4.2)	3 (12.5)	0	0

Number of previous relapses: 2

Primary system organ class Preferred term	All patients N=24 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Orthostatic hypotension	1 (4.2)	1 (4.2)	0	0	0
Phlebitis	1 (4.2)	0	1 (4.2)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 178r
Adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (100)	0	0	5 (25.0)	15 (75.0)
Blood and lymphatic system disorders					
-Total	16 (80.0)	0	1 (5.0)	10 (50.0)	5 (25.0)
Anaemia	10 (50.0)	1 (5.0)	1 (5.0)	8 (40.0)	0
Febrile neutropenia	8 (40.0)	0	0	8 (40.0)	0
Thrombocytopenia	5 (25.0)	0	0	3 (15.0)	2 (10.0)
Neutropenia	4 (20.0)	0	0	1 (5.0)	3 (15.0)
Disseminated intravascular coagulation	1 (5.0)	0	0	0	1 (5.0)
Eosinophilia	1 (5.0)	0	0	1 (5.0)	0
Lymphopenia	1 (5.0)	0	1 (5.0)	0	0

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	9 (45.0)	5 (25.0)	1 (5.0)	2 (10.0)	1 (5.0)
Tachycardia	5 (25.0)	3 (15.0)	1 (5.0)	1 (5.0)	0
Sinus tachycardia	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Bradycardia	1 (5.0)	1 (5.0)	0	0	0
Cardiac dysfunction	1 (5.0)	1 (5.0)	0	0	0
Cardiovascular insufficiency	1 (5.0)	0	0	0	1 (5.0)
Ear and labyrinth disorders					
-Total	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Ear pain	2 (10.0)	2 (10.0)	0	0	0
Deafness unilateral	1 (5.0)	0	1 (5.0)	0	0
Endocrine disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Cushingoid	1 (5.0)	1 (5.0)	0	0	0
Hyperthyroidism	1 (5.0)	0	1 (5.0)	0	0
Eye disorders					
-Total	5 (25.0)	1 (5.0)	4 (20.0)	0	0
Dry eye	1 (5.0)	0	1 (5.0)	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Ocular hyperaemia	1 (5.0)	1 (5.0)	0	0	0
Ocular hypertension	1 (5.0)	0	1 (5.0)	0	0
Papilloedema	1 (5.0)	0	1 (5.0)	0	0
Periorbital oedema	1 (5.0)	0	1 (5.0)	0	0
Uveitis	1 (5.0)	0	1 (5.0)	0	0
Visual impairment	1 (5.0)	0	1 (5.0)	0	0
Gastrointestinal disorders					
-Total	14 (70.0)	3 (15.0)	6 (30.0)	5 (25.0)	0
Vomiting	7 (35.0)	5 (25.0)	2 (10.0)	0	0
Abdominal pain	6 (30.0)	2 (10.0)	3 (15.0)	1 (5.0)	0
Diarrhoea	6 (30.0)	3 (15.0)	3 (15.0)	0	0
Nausea	6 (30.0)	2 (10.0)	4 (20.0)	0	0
Colitis	3 (15.0)	0	0	3 (15.0)	0
Abdominal distension	2 (10.0)	0	2 (10.0)	0	0
Stomatitis	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Abdominal pain lower	1 (5.0)	0	1 (5.0)	0	0
Abdominal pain upper	1 (5.0)	1 (5.0)	0	0	0
Abdominal tenderness	1 (5.0)	1 (5.0)	0	0	0

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	1 (5.0)	0	0	1 (5.0)	0
Constipation	1 (5.0)	1 (5.0)	0	0	0
Gastrointestinal haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Haematemesis	1 (5.0)	1 (5.0)	0	0	0
Lip pain	1 (5.0)	0	1 (5.0)	0	0
Mouth haemorrhage	1 (5.0)	0	0	1 (5.0)	0
Pigmentation lip	1 (5.0)	1 (5.0)	0	0	0
General disorders and administration site conditions					
-Total	17 (85.0)	6 (30.0)	5 (25.0)	3 (15.0)	3 (15.0)
Pyrexia	10 (50.0)	5 (25.0)	4 (20.0)	1 (5.0)	0
Fatigue	6 (30.0)	4 (20.0)	1 (5.0)	1 (5.0)	0
Multiple organ dysfunction syndrome	3 (15.0)	0	0	0	3 (15.0)
Pain	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Chills	2 (10.0)	2 (10.0)	0	0	0
Generalised oedema	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Oedema peripheral	2 (10.0)	2 (10.0)	0	0	0
Catheter site extravasation	1 (5.0)	0	1 (5.0)	0	0

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site pain	1 (5.0)	1 (5.0)	0	0	0
Crying	1 (5.0)	1 (5.0)	0	0	0
Cyst	1 (5.0)	0	0	1 (5.0)	0
Face oedema	1 (5.0)	0	1 (5.0)	0	0
Facial pain	1 (5.0)	0	1 (5.0)	0	0
Gait disturbance	1 (5.0)	1 (5.0)	0	0	0
Influenza like illness	1 (5.0)	1 (5.0)	0	0	0
Malaise	1 (5.0)	0	1 (5.0)	0	0
Medical device pain	1 (5.0)	0	1 (5.0)	0	0
Peripheral swelling	1 (5.0)	0	1 (5.0)	0	0
Hepatobiliary disorders					
-Total	3 (15.0)	0	0	2 (10.0)	1 (5.0)
Cholecystitis	1 (5.0)	0	0	1 (5.0)	0
Hepatic failure	1 (5.0)	0	0	0	1 (5.0)
Hepatomegaly	1 (5.0)	0	1 (5.0)	0	0
Hyperbilirubinaemia	1 (5.0)	0	0	1 (5.0)	0
Immune system disorders					
-Total	15 (75.0)	4 (20.0)	7 (35.0)	2 (10.0)	2 (10.0)

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	11 (55.0)	3 (15.0)	4 (20.0)	2 (10.0)	2 (10.0)
Hypogammaglobulinaemia	7 (35.0)	2 (10.0)	5 (25.0)	0	0
Graft versus host disease	1 (5.0)	1 (5.0)	0	0	0
Graft versus host disease in skin	1 (5.0)	1 (5.0)	0	0	0
Haemophagocytic lymphohistiocytosis	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	14 (70.0)	1 (5.0)	3 (15.0)	7 (35.0)	3 (15.0)
Upper respiratory tract infection	5 (25.0)	4 (20.0)	0	1 (5.0)	0
Clostridium difficile infection	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Device related infection	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Fungal skin infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Otitis media	2 (10.0)	0	2 (10.0)	0	0
Urinary tract infection	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Vulvovaginal candidiasis	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Body tinea	1 (5.0)	1 (5.0)	0	0	0
Bronchitis	1 (5.0)	0	1 (5.0)	0	0

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (5.0)	0	0	1 (5.0)	0
Cellulitis of male external genital organ	1 (5.0)	0	0	1 (5.0)	0
Clostridium difficile colitis	1 (5.0)	0	1 (5.0)	0	0
Conjunctivitis	1 (5.0)	0	1 (5.0)	0	0
Croup infectious	1 (5.0)	0	0	1 (5.0)	0
Cytomegalovirus infection	1 (5.0)	1 (5.0)	0	0	0
Ear infection	1 (5.0)	0	1 (5.0)	0	0
Enterovirus infection	1 (5.0)	0	0	1 (5.0)	0
Herpes simplex	1 (5.0)	1 (5.0)	0	0	0
Human herpesvirus 6 infection	1 (5.0)	0	1 (5.0)	0	0
Hypopyon	1 (5.0)	0	1 (5.0)	0	0
Klebsiella sepsis	1 (5.0)	0	0	0	1 (5.0)
Necrotising fasciitis	1 (5.0)	0	0	1 (5.0)	0
Oral candidiasis	1 (5.0)	1 (5.0)	0	0	0
Otitis media acute	1 (5.0)	0	1 (5.0)	0	0
Parainfluenzae virus infection	1 (5.0)	1 (5.0)	0	0	0
Respiratory tract infection viral	1 (5.0)	0	0	1 (5.0)	0

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rotavirus infection	1 (5.0)	0	0	1 (5.0)	0
Sepsis	1 (5.0)	0	0	0	1 (5.0)
Sinusitis	1 (5.0)	0	1 (5.0)	0	0
Skin infection	1 (5.0)	0	1 (5.0)	0	0
Staphylococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Staphylococcal infection	1 (5.0)	0	0	0	1 (5.0)
Streptococcal bacteraemia	1 (5.0)	0	0	1 (5.0)	0
Vascular device infection	1 (5.0)	0	0	1 (5.0)	0
Viral upper respiratory tract infection	1 (5.0)	1 (5.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	8 (40.0)	2 (10.0)	5 (25.0)	1 (5.0)	0
Infusion related reaction	2 (10.0)	0	2 (10.0)	0	0
Procedural pain	2 (10.0)	0	2 (10.0)	0	0
Subdural haematoma	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Contusion	1 (5.0)	1 (5.0)	0	0	0
Extradural haematoma	1 (5.0)	0	0	1 (5.0)	0
Limb injury	1 (5.0)	1 (5.0)	0	0	0

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mouth injury	1 (5.0)	1 (5.0)	0	0	0
Procedural headache	1 (5.0)	0	1 (5.0)	0	0
Procedural site reaction	1 (5.0)	1 (5.0)	0	0	0
Radiation skin injury	1 (5.0)	0	1 (5.0)	0	0
Skin abrasion	1 (5.0)	1 (5.0)	0	0	0
Skin laceration	1 (5.0)	0	1 (5.0)	0	0
Tongue injury	1 (5.0)	1 (5.0)	0	0	0
Transfusion reaction	1 (5.0)	0	1 (5.0)	0	0
Investigations					
-Total	14 (70.0)	1 (5.0)	3 (15.0)	0	10 (50.0)
Neutrophil count decreased	10 (50.0)	1 (5.0)	1 (5.0)	0	8 (40.0)
White blood cell count decreased	9 (45.0)	1 (5.0)	1 (5.0)	1 (5.0)	6 (30.0)
Alanine aminotransferase increased	8 (40.0)	1 (5.0)	2 (10.0)	4 (20.0)	1 (5.0)
Aspartate aminotransferase increased	8 (40.0)	2 (10.0)	2 (10.0)	1 (5.0)	3 (15.0)
Lymphocyte count decreased	6 (30.0)	0	2 (10.0)	1 (5.0)	3 (15.0)
Platelet count decreased	6 (30.0)	1 (5.0)	0	0	5 (25.0)
International normalised ratio increased	5 (25.0)	4 (20.0)	1 (5.0)	0	0

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	4 (20.0)	2 (10.0)	0	1 (5.0)	1 (5.0)
Blood creatinine increased	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Activated partial thromboplastin time prolonged	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Blood immunoglobulin a decreased	2 (10.0)	2 (10.0)	0	0	0
Weight increased	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Blood bicarbonate decreased	1 (5.0)	0	1 (5.0)	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Blood lactic acid increased	1 (5.0)	0	0	0	1 (5.0)
Blood urea increased	1 (5.0)	0	1 (5.0)	0	0
Blood uric acid increased	1 (5.0)	1 (5.0)	0	0	0
C-reactive protein increased	1 (5.0)	0	1 (5.0)	0	0
Coronavirus test positive	1 (5.0)	1 (5.0)	0	0	0
Culture stool positive	1 (5.0)	1 (5.0)	0	0	0
Electrocardiogram qt prolonged	1 (5.0)	0	0	1 (5.0)	0
Haemoglobin decreased	1 (5.0)	1 (5.0)	0	0	0
Norovirus test positive	1 (5.0)	1 (5.0)	0	0	0
Prothrombin time prolonged	1 (5.0)	0	1 (5.0)	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary function test decreased	1 (5.0)	0	1 (5.0)	0	0
Serum ferritin increased	1 (5.0)	0	1 (5.0)	0	0
Metabolism and nutrition disorders					
-Total	13 (65.0)	2 (10.0)	3 (15.0)	7 (35.0)	1 (5.0)
Hypokalaemia	7 (35.0)	1 (5.0)	2 (10.0)	3 (15.0)	1 (5.0)
Decreased appetite	5 (25.0)	2 (10.0)	1 (5.0)	2 (10.0)	0
Hyperphosphataemia	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Hypoalbuminaemia	3 (15.0)	0	3 (15.0)	0	0
Hypocalcaemia	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Hypophosphataemia	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Fluid overload	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Hyperglycaemia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Hyperuricaemia	2 (10.0)	2 (10.0)	0	0	0
Hypoglycaemia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Dehydration	1 (5.0)	0	0	1 (5.0)	0
Hyperkalaemia	1 (5.0)	1 (5.0)	0	0	0
Hypernatraemia	1 (5.0)	0	0	0	1 (5.0)
Hypomagnesaemia	1 (5.0)	1 (5.0)	0	0	0

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vitamin d deficiency	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	13 (65.0)	8 (40.0)	3 (15.0)	2 (10.0)	0
Myalgia	5 (25.0)	3 (15.0)	1 (5.0)	1 (5.0)	0
Pain in extremity	5 (25.0)	2 (10.0)	2 (10.0)	1 (5.0)	0
Muscle spasms	3 (15.0)	3 (15.0)	0	0	0
Arthralgia	2 (10.0)	2 (10.0)	0	0	0
Joint range of motion decreased	2 (10.0)	2 (10.0)	0	0	0
Musculoskeletal pain	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Pain in jaw	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Back pain	1 (5.0)	1 (5.0)	0	0	0
Neck pain	1 (5.0)	0	1 (5.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (5.0)	0	1 (5.0)	0	0
Skin papilloma	1 (5.0)	0	1 (5.0)	0	0
Nervous system disorders					
-Total	10 (50.0)	3 (15.0)	5 (25.0)	2 (10.0)	0

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	7 (35.0)	3 (15.0)	3 (15.0)	1 (5.0)	0
Dizziness	2 (10.0)	2 (10.0)	0	0	0
Encephalopathy	1 (5.0)	1 (5.0)	0	0	0
Idiopathic intracranial hypertension	1 (5.0)	0	1 (5.0)	0	0
Myoclonus	1 (5.0)	1 (5.0)	0	0	0
Neuralgia	1 (5.0)	0	1 (5.0)	0	0
Seizure	1 (5.0)	0	0	1 (5.0)	0
Somnolence	1 (5.0)	0	1 (5.0)	0	0
Visual field defect	1 (5.0)	0	1 (5.0)	0	0
Psychiatric disorders					
-Total	7 (35.0)	1 (5.0)	3 (15.0)	3 (15.0)	0
Anxiety	4 (20.0)	1 (5.0)	2 (10.0)	1 (5.0)	0
Irritability	2 (10.0)	2 (10.0)	0	0	0
Agitation	1 (5.0)	0	1 (5.0)	0	0
Confusional state	1 (5.0)	0	1 (5.0)	0	0
Delirium	1 (5.0)	0	0	1 (5.0)	0
Hallucination	1 (5.0)	0	1 (5.0)	0	0
Insomnia	1 (5.0)	0	1 (5.0)	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Listless	1 (5.0)	1 (5.0)	0	0	0
Mental status changes	1 (5.0)	0	0	1 (5.0)	0
Renal and urinary disorders					
-Total	3 (15.0)	1 (5.0)	1 (5.0)	0	1 (5.0)
Acute kidney injury	1 (5.0)	0	0	0	1 (5.0)
Haematuria	1 (5.0)	0	1 (5.0)	0	0
Oliguria	1 (5.0)	0	0	1 (5.0)	0
Urinary incontinence	1 (5.0)	1 (5.0)	0	0	0
Urinary retention	1 (5.0)	0	1 (5.0)	0	0
Reproductive system and breast disorders					
-Total	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Oedema genital	1 (5.0)	0	1 (5.0)	0	0
Scrotal pain	1 (5.0)	0	1 (5.0)	0	0
Vulvovaginal adhesion	1 (5.0)	1 (5.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	12 (60.0)	4 (20.0)	2 (10.0)	4 (20.0)	2 (10.0)
Cough	4 (20.0)	3 (15.0)	1 (5.0)	0	0

Number of previous relapses: >=3

Primary system organ class Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Epistaxis	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0
Hypoxia	4 (20.0)	0	1 (5.0)	2 (10.0)	1 (5.0)
Dyspnoea	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Pleural effusion	3 (15.0)	0	2 (10.0)	1 (5.0)	0
Nasal congestion	2 (10.0)	2 (10.0)	0	0	0
Oropharyngeal pain	2 (10.0)	2 (10.0)	0	0	0
Rhinitis allergic	2 (10.0)	2 (10.0)	0	0	0
Tachypnoea	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Atelectasis	1 (5.0)	0	1 (5.0)	0	0
Idiopathic pneumonia syndrome	1 (5.0)	0	0	0	1 (5.0)
Pulmonary oedema	1 (5.0)	0	0	1 (5.0)	0
Rhinorrhoea	1 (5.0)	1 (5.0)	0	0	0
Wheezing	1 (5.0)	0	1 (5.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	10 (50.0)	5 (25.0)	4 (20.0)	1 (5.0)	0
Rash	4 (20.0)	3 (15.0)	1 (5.0)	0	0
Rash maculo-papular	2 (10.0)	2 (10.0)	0	0	0

Number of previous relapses: >=3

	All patients N=20				
Primary system organ class Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash papular	2 (10.0)	2 (10.0)	0	0	0
Dermatitis acneiform	1 (5.0)	0	1 (5.0)	0	0
Dermatitis atopic	1 (5.0)	1 (5.0)	0	0	0
Macule	1 (5.0)	1 (5.0)	0	0	0
Night sweats	1 (5.0)	0	1 (5.0)	0	0
Petechiae	1 (5.0)	0	1 (5.0)	0	0
Pruritus	1 (5.0)	1 (5.0)	0	0	0
Rash erythematous	1 (5.0)	0	1 (5.0)	0	0
Rash follicular	1 (5.0)	1 (5.0)	0	0	0
Rash macular	1 (5.0)	0	0	1 (5.0)	0
Skin haemorrhage	1 (5.0)	1 (5.0)	0	0	0
Skin irritation	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	11 (55.0)	2 (10.0)	0	7 (35.0)	2 (10.0)
Hypotension	8 (40.0)	1 (5.0)	0	5 (25.0)	2 (10.0)
Hypertension	5 (25.0)	1 (5.0)	2 (10.0)	2 (10.0)	0
Embolism	1 (5.0)	0	0	1 (5.0)	0
Flushing	1 (5.0)	1 (5.0)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (75.0)	6 (30.0)	5 (25.0)
Blood and lymphatic system disorders			
-Total	6 (30.0)	6 (30.0)	0
Febrile neutropenia	6 (30.0)	6 (30.0)	0
Cardiac disorders			
-Total	1 (5.0)	0	0
Atrioventricular block second degree	1 (5.0)	0	0
Gastrointestinal disorders			
-Total	1 (5.0)	1 (5.0)	0
Pancreatitis	1 (5.0)	1 (5.0)	0
Immune system disorders			
-Total	12 (60.0)	3 (15.0)	2 (10.0)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	12 (60.0)	3 (15.0)	2 (10.0)
Infections and infestations			
-Total	4 (20.0)	2 (10.0)	1 (5.0)
Clostridium difficile infection	2 (10.0)	0	0
Catheter site infection	1 (5.0)	1 (5.0)	0
Pneumonia	1 (5.0)	1 (5.0)	0
Rhinovirus infection	1 (5.0)	0	0
Septic embolus	1 (5.0)	0	1 (5.0)
Nervous system disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Embolic stroke	1 (5.0)	0	1 (5.0)
Seizure	1 (5.0)	1 (5.0)	0
Renal and urinary disorders			
-Total	1 (5.0)	1 (5.0)	0
Acute kidney injury	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Hypoxia	1 (5.0)	1 (5.0)	0

Timing: within 8 weeks post infusion, Age: <10 years

Group term Preferred term	All patients N=20 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pleural effusion	1 (5.0)	1 (5.0)	0
Respiratory failure	1 (5.0)	0	1 (5.0)
Vascular disorders			
-Total	3 (15.0)	2 (10.0)	1 (5.0)
Hypotension	2 (10.0)	1 (5.0)	1 (5.0)
Embolism	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (67.6)	11 (32.4)	9 (26.5)
Blood and lymphatic system disorders			
-Total	15 (44.1)	13 (38.2)	1 (2.9)
Febrile neutropenia	13 (38.2)	13 (38.2)	0
Disseminated intravascular coagulation	2 (5.9)	0	0
Neutropenia	1 (2.9)	0	1 (2.9)
Cardiac disorders			
-Total	1 (2.9)	0	0
Ventricular tachycardia	1 (2.9)	0	0
Eye disorders			
-Total	1 (2.9)	0	0
Vision blurred	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	3 (8.8)	1 (2.9)	0
Diarrhoea	1 (2.9)	0	0
Stomatitis	1 (2.9)	0	0
Vomiting	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			
-Total	3 (8.8)	1 (2.9)	0
Malaise	1 (2.9)	0	0
Physical deconditioning	1 (2.9)	1 (2.9)	0
Pyrexia	1 (2.9)	0	0
Immune system disorders			
-Total	23 (67.6)	5 (14.7)	5 (14.7)
Cytokine release syndrome	23 (67.6)	5 (14.7)	5 (14.7)
Infections and infestations			
-Total	5 (14.7)	2 (5.9)	0
Clostridium difficile colitis	2 (5.9)	0	0
Gastroenteritis	1 (2.9)	1 (2.9)	0
Gastroenteritis norovirus	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (2.9)	1 (2.9)	0
Injury, poisoning and procedural complications			
-Total	1 (2.9)	0	1 (2.9)
Transfusion related complication	1 (2.9)	0	1 (2.9)
Metabolism and nutrition disorders			
-Total	3 (8.8)	3 (8.8)	0
Acidosis	1 (2.9)	0	0
Decreased appetite	1 (2.9)	1 (2.9)	0
Dehydration	1 (2.9)	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	1 (2.9)	0
Nervous system disorders			
-Total	6 (17.6)	2 (5.9)	0
Encephalopathy	4 (11.8)	2 (5.9)	0
Seizure	2 (5.9)	0	0
Headache	1 (2.9)	1 (2.9)	0
Psychiatric disorders			
-Total	1 (2.9)	0	0
Delirium	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	2 (5.9)	1 (2.9)	1 (2.9)
Acute kidney injury	1 (2.9)	1 (2.9)	0
Renal failure	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (11.8)	0	2 (5.9)
Hypoxia	2 (5.9)	0	0
Respiratory failure	2 (5.9)	0	2 (5.9)
Pulmonary oedema	1 (2.9)	0	1 (2.9)
Skin and subcutaneous tissue disorders			
-Total	1 (2.9)	1 (2.9)	0
Ecchymosis	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	5 (14.7)	3 (8.8)	2 (5.9)
Hypotension	5 (14.7)	3 (8.8)	2 (5.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (80.0)	3 (30.0)	3 (30.0)
Blood and lymphatic system disorders			
-Total	2 (20.0)	2 (20.0)	0
Febrile neutropenia	2 (20.0)	2 (20.0)	0
Eye disorders			
-Total	1 (10.0)	0	0
Papilloedema	1 (10.0)	0	0
Gastrointestinal disorders			
-Total	1 (10.0)	1 (10.0)	0
Intestinal obstruction	1 (10.0)	1 (10.0)	0
General disorders and administration site conditions			

Timing: within 8 weeks post infusion, Age: >=18

		All patients N=10	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (10.0)	0	0
Pyrexia	1 (10.0)	0	0
Immune system disorders			
-Total	6 (60.0)	0	3 (30.0)
Cytokine release syndrome	6 (60.0)	0	3 (30.0)
Nervous system disorders			
-Total	1 (10.0)	0	0
Idiopathic intracranial hypertension	1 (10.0)	0	0
Renal and urinary disorders			
-Total	1 (10.0)	0	1 (10.0)
Acute kidney injury	1 (10.0)	0	1 (10.0)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (20.0)	0	1 (10.0)
Hypoxia	1 (10.0)	0	1 (10.0)
Pleural effusion	1 (10.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (38.9)	4 (22.2)	0
Gastrointestinal disorders			
-Total	1 (5.6)	1 (5.6)	0
Enterocolitis	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	3 (16.7)	0	0
Pyrexia	3 (16.7)	0	0
Infections and infestations			
-Total	3 (16.7)	3 (16.7)	0
Corona virus infection	1 (5.6)	1 (5.6)	0
Enterovirus infection	1 (5.6)	1 (5.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (5.6)	1 (5.6)	0
Respiratory syncytial virus infection	1 (5.6)	1 (5.6)	0
Rotavirus infection	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	1 (5.6)	1 (5.6)	0
Tumour lysis syndrome	1 (5.6)	1 (5.6)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (5.6)	0	0
Pain in extremity	1 (5.6)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (35.5)	8 (25.8)	3 (9.7)
Blood and lymphatic system disorders			
-Total	5 (16.1)	3 (9.7)	2 (6.5)
Febrile neutropenia	3 (9.7)	3 (9.7)	0
Neutropenia	2 (6.5)	0	2 (6.5)
Eosinophilia	1 (3.2)	1 (3.2)	0
Gastrointestinal disorders			
-Total	1 (3.2)	1 (3.2)	0
Vomiting	1 (3.2)	1 (3.2)	0
General disorders and administration site conditions			
-Total	2 (6.5)	1 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	2 (6.5)	1 (3.2)	0
Immune system disorders			
-Total	1 (3.2)	0	0
Graft versus host disease in gastrointestinal tract	1 (3.2)	0	0
Infections and infestations			
-Total	6 (19.4)	5 (16.1)	0
Cellulitis of male external genital organ	1 (3.2)	1 (3.2)	0
Gastroenteritis norovirus	1 (3.2)	0	0
Herpes zoster	1 (3.2)	1 (3.2)	0
Upper respiratory tract infection	1 (3.2)	1 (3.2)	0
Vascular device infection	1 (3.2)	1 (3.2)	0
Viral upper respiratory tract infection	1 (3.2)	1 (3.2)	0
Investigations			
-Total	2 (6.5)	1 (3.2)	1 (3.2)
Alanine aminotransferase increased	1 (3.2)	1 (3.2)	0
White blood cell count decreased	1 (3.2)	0	1 (3.2)
Musculoskeletal and connective tissue disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (6.5)	0	0
Flank pain	1 (3.2)	0	0
Osteonecrosis	1 (3.2)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.2)	0	0
Myelodysplastic syndrome	1 (3.2)	0	0
Renal and urinary disorders			
-Total	1 (3.2)	1 (3.2)	0
Acute kidney injury	1 (3.2)	1 (3.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.5)	1 (3.2)	1 (3.2)
Acute respiratory failure	1 (3.2)	0	1 (3.2)
Pulmonary oedema	1 (3.2)	1 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (42.9)	1 (14.3)	2 (28.6)
Infections and infestations			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Bacterial sepsis	1 (14.3)	0	1 (14.3)
Cholecystitis infective	1 (14.3)	1 (14.3)	0
Sepsis	1 (14.3)	0	1 (14.3)
Reproductive system and breast disorders			
-Total	1 (14.3)	1 (14.3)	0
Vaginal haemorrhage	1 (14.3)	1 (14.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (27.3)	1 (9.1)	2 (18.2)
Infections and infestations			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Campylobacter infection	1 (9.1)	1 (9.1)	0
Clostridium difficile infection	1 (9.1)	1 (9.1)	0
Respiratory tract infection	1 (9.1)	0	1 (9.1)
Respiratory tract infection viral	1 (9.1)	1 (9.1)	0
Urinary tract infection	1 (9.1)	0	0
Vulvovaginal candidiasis	1 (9.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (9.1)	0	1 (9.1)

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Glioblastoma multiforme	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	1 (9.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

		All patients N=22	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (13.6)	1 (4.5)	1 (4.5)
Blood and lymphatic system disorders			
-Total	1 (4.5)	0	1 (4.5)
Febrile neutropenia	1 (4.5)	0	1 (4.5)
Gastrointestinal disorders			
-Total	1 (4.5)	0	0
Diarrhoea	1 (4.5)	0	0
Infections and infestations			
-Total	2 (9.1)	1 (4.5)	0
Cellulitis of male external genital organ	1 (4.5)	1 (4.5)	0
Pneumonia	1 (4.5)	0	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (4.5)	1 (4.5)	0
Injury, poisoning and procedural complications			
-Total	1 (4.5)	1 (4.5)	0
Procedural pain	1 (4.5)	1 (4.5)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (80.0)	6 (30.0)	7 (35.0)
Blood and lymphatic system disorders			
-Total	6 (30.0)	6 (30.0)	0
Febrile neutropenia	6 (30.0)	6 (30.0)	0
Cardiac disorders			
-Total	1 (5.0)	0	0
Atrioventricular block second degree	1 (5.0)	0	0
Gastrointestinal disorders			
-Total	2 (10.0)	2 (10.0)	0
Enterocolitis	1 (5.0)	1 (5.0)	0
Pancreatitis	1 (5.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	3 (15.0)	0	0
Pyrexia	3 (15.0)	0	0
Immune system disorders			
-Total	12 (60.0)	3 (15.0)	2 (10.0)
Cytokine release syndrome	12 (60.0)	3 (15.0)	2 (10.0)
Infections and infestations			
-Total	7 (35.0)	4 (20.0)	2 (10.0)
Clostridium difficile infection	3 (15.0)	1 (5.0)	0
Campylobacter infection	1 (5.0)	1 (5.0)	0
Catheter site infection	1 (5.0)	1 (5.0)	0
Corona virus infection	1 (5.0)	1 (5.0)	0
Enterovirus infection	1 (5.0)	1 (5.0)	0
Parainfluenzae virus infection	1 (5.0)	1 (5.0)	0
Pneumonia	1 (5.0)	1 (5.0)	0
Respiratory syncytial virus infection	1 (5.0)	1 (5.0)	0
Respiratory tract infection	1 (5.0)	0	1 (5.0)
Respiratory tract infection viral	1 (5.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (5.0)	0	0
Rotavirus infection	1 (5.0)	1 (5.0)	0
Septic embolus	1 (5.0)	0	1 (5.0)
Urinary tract infection	1 (5.0)	0	0
Vulvovaginal candidiasis	1 (5.0)	0	0
Metabolism and nutrition disorders			
-Total	1 (5.0)	1 (5.0)	0
Tumour lysis syndrome	1 (5.0)	1 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (5.0)	0	0
Pain in extremity	1 (5.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (5.0)	0	1 (5.0)
Glioblastoma multiforme	1 (5.0)	0	1 (5.0)
Nervous system disorders			
-Total	3 (15.0)	2 (10.0)	1 (5.0)
Seizure	2 (10.0)	2 (10.0)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Embolic stroke	1 (5.0)	0	1 (5.0)
Renal and urinary disorders			
-Total	1 (5.0)	1 (5.0)	0
Acute kidney injury	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Hypoxia	1 (5.0)	1 (5.0)	0
Pleural effusion	1 (5.0)	1 (5.0)	0
Respiratory failure	1 (5.0)	0	1 (5.0)
Vascular disorders			
-Total	3 (15.0)	2 (10.0)	1 (5.0)
Hypotension	2 (10.0)	1 (5.0)	1 (5.0)
Embolism	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (79.4)	12 (35.3)	12 (35.3)
Blood and lymphatic system disorders			
-Total	19 (55.9)	14 (41.2)	4 (11.8)
Febrile neutropenia	15 (44.1)	14 (41.2)	1 (2.9)
Neutropenia	3 (8.8)	0	3 (8.8)
Disseminated intravascular coagulation	2 (5.9)	0	0
Eosinophilia	1 (2.9)	1 (2.9)	0
Cardiac disorders			
-Total	1 (2.9)	0	0
Ventricular tachycardia	1 (2.9)	0	0
Eye disorders			

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.9)	0	0
Vision blurred	1 (2.9)	0	0
Gastrointestinal disorders			
-Total	4 (11.8)	1 (2.9)	0
Diarrhoea	2 (5.9)	0	0
Stomatitis	1 (2.9)	0	0
Vomiting	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			
-Total	5 (14.7)	2 (5.9)	0
Pyrexia	3 (8.8)	1 (2.9)	0
Malaise	1 (2.9)	0	0
Physical deconditioning	1 (2.9)	1 (2.9)	0
Immune system disorders			
-Total	23 (67.6)	5 (14.7)	5 (14.7)
Cytokine release syndrome	23 (67.6)	5 (14.7)	5 (14.7)
Graft versus host disease in gastrointestinal tract	1 (2.9)	0	0
Infections and infestations			

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (26.5)	6 (17.6)	0
Clostridium difficile colitis	2 (5.9)	0	0
Cellulitis of male external genital organ	1 (2.9)	1 (2.9)	0
Gastroenteritis	1 (2.9)	1 (2.9)	0
Gastroenteritis norovirus	1 (2.9)	0	0
Herpes zoster	1 (2.9)	1 (2.9)	0
Pneumonia	1 (2.9)	0	0
Staphylococcal infection	1 (2.9)	1 (2.9)	0
Upper respiratory tract infection	1 (2.9)	1 (2.9)	0
Urinary tract infection	1 (2.9)	1 (2.9)	0
Vascular device infection	1 (2.9)	1 (2.9)	0
Viral upper respiratory tract infection	1 (2.9)	1 (2.9)	0
Injury, poisoning and procedural complications			
-Total	2 (5.9)	1 (2.9)	1 (2.9)
Procedural pain	1 (2.9)	1 (2.9)	0
Transfusion related complication	1 (2.9)	0	1 (2.9)
Investigations			

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (5.9)	1 (2.9)	1 (2.9)
Alanine aminotransferase increased	1 (2.9)	1 (2.9)	0
White blood cell count decreased	1 (2.9)	0	1 (2.9)
Metabolism and nutrition disorders			
-Total	3 (8.8)	3 (8.8)	0
Acidosis	1 (2.9)	0	0
Decreased appetite	1 (2.9)	1 (2.9)	0
Dehydration	1 (2.9)	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	1 (2.9)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (5.9)	0	0
Flank pain	1 (2.9)	0	0
Osteonecrosis	1 (2.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.9)	0	0
Myelodysplastic syndrome	1 (2.9)	0	0
Nervous system disorders			

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (17.6)	2 (5.9)	0
Encephalopathy	4 (11.8)	2 (5.9)	0
Seizure	2 (5.9)	0	0
Headache	1 (2.9)	1 (2.9)	0
Psychiatric disorders			
-Total	1 (2.9)	0	0
Delirium	1 (2.9)	0	0
Renal and urinary disorders			
-Total	3 (8.8)	2 (5.9)	1 (2.9)
Acute kidney injury	2 (5.9)	2 (5.9)	0
Renal failure	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (17.6)	1 (2.9)	3 (8.8)
Hypoxia	2 (5.9)	0	0
Pulmonary oedema	2 (5.9)	1 (2.9)	1 (2.9)
Respiratory failure	2 (5.9)	0	2 (5.9)
Acute respiratory failure	1 (2.9)	0	1 (2.9)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders			
-Total	1 (2.9)	1 (2.9)	0
Ecchymosis	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	5 (14.7)	3 (8.8)	2 (5.9)
Hypotension	5 (14.7)	3 (8.8)	2 (5.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179a
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (90.0)	3 (30.0)	5 (50.0)
Blood and lymphatic system disorders			
-Total	2 (20.0)	2 (20.0)	0
Febrile neutropenia	2 (20.0)	2 (20.0)	0
Eye disorders			
-Total	1 (10.0)	0	0
Papilloedema	1 (10.0)	0	0
Gastrointestinal disorders			
-Total	1 (10.0)	1 (10.0)	0
Intestinal obstruction	1 (10.0)	1 (10.0)	0
General disorders and administration site conditions			

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (10.0)	0	0
Pyrexia	1 (10.0)	0	0
Immune system disorders			
-Total	6 (60.0)	0	3 (30.0)
Cytokine release syndrome	6 (60.0)	0	3 (30.0)
Infections and infestations			
-Total	3 (30.0)	1 (10.0)	2 (20.0)
Bacterial sepsis	1 (10.0)	0	1 (10.0)
Cholecystitis infective	1 (10.0)	1 (10.0)	0
Sepsis	1 (10.0)	0	1 (10.0)
Nervous system disorders			
-Total	1 (10.0)	0	0
Idiopathic intracranial hypertension	1 (10.0)	0	0
Renal and urinary disorders			
-Total	1 (10.0)	0	1 (10.0)
Acute kidney injury	1 (10.0)	0	1 (10.0)
Reproductive system and breast disorders			
-Total	1 (10.0)	1 (10.0)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal haemorrhage	1 (10.0)	1 (10.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (20.0)	0	1 (10.0)
Hypoxia	1 (10.0)	0	1 (10.0)
Pleural effusion	1 (10.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179b
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (66.7)	11 (36.7)	5 (16.7)
Blood and lymphatic system disorders			
-Total	9 (30.0)	9 (30.0)	0
Febrile neutropenia	9 (30.0)	9 (30.0)	0
Disseminated intravascular coagulation	1 (3.3)	0	0
Gastrointestinal disorders			
-Total	2 (6.7)	0	0
Diarrhoea	1 (3.3)	0	0
Stomatitis	1 (3.3)	0	0
General disorders and administration site conditions			
-Total	1 (3.3)	0	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	1 (3.3)	0	0
Immune system disorders			
-Total	19 (63.3)	3 (10.0)	5 (16.7)
Cytokine release syndrome	19 (63.3)	3 (10.0)	5 (16.7)
Infections and infestations			
-Total	2 (6.7)	1 (3.3)	0
Clostridium difficile infection	1 (3.3)	0	0
Gastroenteritis	1 (3.3)	1 (3.3)	0
Metabolism and nutrition disorders			
-Total	1 (3.3)	1 (3.3)	0
Dehydration	1 (3.3)	1 (3.3)	0
Nervous system disorders			
-Total	3 (10.0)	1 (3.3)	0
Encephalopathy	2 (6.7)	1 (3.3)	0
Headache	1 (3.3)	1 (3.3)	0
Seizure	1 (3.3)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.7)	0	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	2 (6.7)	0	0
Vascular disorders			
-Total	4 (13.3)	4 (13.3)	0
Hypotension	4 (13.3)	4 (13.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179b
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Female

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (76.5)	9 (26.5)	12 (35.3)
Blood and lymphatic system disorders			
-Total	14 (41.2)	12 (35.3)	1 (2.9)
Febrile neutropenia	12 (35.3)	12 (35.3)	0
Disseminated intravascular coagulation	1 (2.9)	0	0
Neutropenia	1 (2.9)	0	1 (2.9)
Cardiac disorders			
-Total	2 (5.9)	0	0
Atrioventricular block second degree	1 (2.9)	0	0
Ventricular tachycardia	1 (2.9)	0	0
Eye disorders			
-Total	2 (5.9)	0	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Papilloedema	1 (2.9)	0	0
Vision blurred	1 (2.9)	0	0
Gastrointestinal disorders			
-Total	3 (8.8)	3 (8.8)	0
Intestinal obstruction	1 (2.9)	1 (2.9)	0
Pancreatitis	1 (2.9)	1 (2.9)	0
Vomiting	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			
-Total	3 (8.8)	1 (2.9)	0
Pyrexia	2 (5.9)	0	0
Physical deconditioning	1 (2.9)	1 (2.9)	0
Immune system disorders			
-Total	22 (64.7)	5 (14.7)	5 (14.7)
Cytokine release syndrome	22 (64.7)	5 (14.7)	5 (14.7)
Infections and infestations			
-Total	7 (20.6)	3 (8.8)	1 (2.9)
Clostridium difficile colitis	2 (5.9)	0	0
Catheter site infection	1 (2.9)	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (2.9)	0	0
Gastroenteritis norovirus	1 (2.9)	0	0
Pneumonia	1 (2.9)	1 (2.9)	0
Rhinovirus infection	1 (2.9)	0	0
Septic embolus	1 (2.9)	0	1 (2.9)
Staphylococcal infection	1 (2.9)	1 (2.9)	0
Injury, poisoning and procedural complications			
-Total	1 (2.9)	0	1 (2.9)
Transfusion related complication	1 (2.9)	0	1 (2.9)
Metabolism and nutrition disorders			
-Total	2 (5.9)	2 (5.9)	0
Acidosis	1 (2.9)	0	0
Decreased appetite	1 (2.9)	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	1 (2.9)	0
Nervous system disorders			
-Total	6 (17.6)	2 (5.9)	1 (2.9)
Encephalopathy	2 (5.9)	1 (2.9)	0
Seizure	2 (5.9)	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Embolic stroke	1 (2.9)	0	1 (2.9)
Idiopathic intracranial hypertension	1 (2.9)	0	0
Psychiatric disorders			
-Total	1 (2.9)	0	0
Delirium	1 (2.9)	0	0
Renal and urinary disorders			
-Total	4 (11.8)	2 (5.9)	2 (5.9)
Acute kidney injury	3 (8.8)	2 (5.9)	1 (2.9)
Renal failure	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (17.6)	1 (2.9)	4 (11.8)
Respiratory failure	3 (8.8)	0	3 (8.8)
Hypoxia	2 (5.9)	1 (2.9)	1 (2.9)
Pleural effusion	2 (5.9)	1 (2.9)	0
Pulmonary oedema	1 (2.9)	0	1 (2.9)
Skin and subcutaneous tissue disorders			
-Total	1 (2.9)	1 (2.9)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ecchymosis	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	4 (11.8)	1 (2.9)	3 (8.8)
Hypotension	3 (8.8)	0	3 (8.8)
Embolism	1 (2.9)	1 (2.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179b
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (25.9)	5 (18.5)	2 (7.4)
Blood and lymphatic system disorders			
-Total	4 (14.8)	2 (7.4)	2 (7.4)
Febrile neutropenia	2 (7.4)	2 (7.4)	0
Neutropenia	2 (7.4)	0	2 (7.4)
Eosinophilia	1 (3.7)	1 (3.7)	0
Gastrointestinal disorders			
-Total	1 (3.7)	1 (3.7)	0
Enterocolitis	1 (3.7)	1 (3.7)	0
General disorders and administration site conditions			
-Total	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (3.7)	0	0
Infections and infestations			
-Total	5 (18.5)	5 (18.5)	0
Cellulitis of male external genital organ	1 (3.7)	1 (3.7)	0
Cholecystitis infective	1 (3.7)	1 (3.7)	0
Corona virus infection	1 (3.7)	1 (3.7)	0
Herpes zoster	1 (3.7)	1 (3.7)	0
Respiratory syncytial virus infection	1 (3.7)	1 (3.7)	0
Viral upper respiratory tract infection	1 (3.7)	1 (3.7)	0
Investigations			
-Total	1 (3.7)	0	1 (3.7)
White blood cell count decreased	1 (3.7)	0	1 (3.7)
Musculoskeletal and connective tissue disorders			
-Total	1 (3.7)	0	0
Osteonecrosis	1 (3.7)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.7)	1 (3.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	1 (3.7)	1 (3.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179b
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (48.3)	8 (27.6)	3 (10.3)
Blood and lymphatic system disorders			
-Total	1 (3.4)	1 (3.4)	0
Febrile neutropenia	1 (3.4)	1 (3.4)	0
Gastrointestinal disorders			
-Total	1 (3.4)	1 (3.4)	0
Vomiting	1 (3.4)	1 (3.4)	0
General disorders and administration site conditions			
-Total	4 (13.8)	1 (3.4)	0
Pyrexia	4 (13.8)	1 (3.4)	0
Immune system disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.4)	0	0
Graft versus host disease in gastrointestinal tract	1 (3.4)	0	0
Infections and infestations			
-Total	7 (24.1)	4 (13.8)	2 (6.9)
Bacterial sepsis	1 (3.4)	0	1 (3.4)
Enterovirus infection	1 (3.4)	1 (3.4)	0
Gastroenteritis norovirus	1 (3.4)	0	0
Parainfluenzae virus infection	1 (3.4)	1 (3.4)	0
Rotavirus infection	1 (3.4)	1 (3.4)	0
Sepsis	1 (3.4)	0	1 (3.4)
Upper respiratory tract infection	1 (3.4)	1 (3.4)	0
Vascular device infection	1 (3.4)	1 (3.4)	0
Investigations			
-Total	1 (3.4)	1 (3.4)	0
Alanine aminotransferase increased	1 (3.4)	1 (3.4)	0
Metabolism and nutrition disorders			
-Total	1 (3.4)	1 (3.4)	0
Tumour lysis syndrome	1 (3.4)	1 (3.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	2 (6.9)	0	0
Flank pain	1 (3.4)	0	0
Pain in extremity	1 (3.4)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.4)	0	0
Myelodysplastic syndrome	1 (3.4)	0	0
Renal and urinary disorders			
-Total	1 (3.4)	1 (3.4)	0
Acute kidney injury	1 (3.4)	1 (3.4)	0
Reproductive system and breast disorders			
-Total	1 (3.4)	1 (3.4)	0
Vaginal haemorrhage	1 (3.4)	1 (3.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.4)	0	1 (3.4)
Acute respiratory failure	1 (3.4)	0	1 (3.4)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179b
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (10.0)	1 (5.0)	1 (5.0)
Gastrointestinal disorders			
-Total	1 (5.0)	0	0
Diarrhoea	1 (5.0)	0	0
Infections and infestations			
-Total	1 (5.0)	1 (5.0)	0
Cellulitis of male external genital organ	1 (5.0)	1 (5.0)	0
Urinary tract infection	1 (5.0)	1 (5.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (5.0)	0	1 (5.0)

Timing: >1 year post-CTL019 infusion, Gender: Male

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Glioblastoma multiforme	1 (5.0)	0	1 (5.0)
Nervous system disorders			
-Total	1 (5.0)	1 (5.0)	0
Seizure	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179b
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Female

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (28.6)	1 (7.1)	2 (14.3)
Blood and lymphatic system disorders			
-Total	1 (7.1)	0	1 (7.1)
Febrile neutropenia	1 (7.1)	0	1 (7.1)
Infections and infestations			
-Total	3 (21.4)	1 (7.1)	1 (7.1)
Campylobacter infection	1 (7.1)	1 (7.1)	0
Clostridium difficile infection	1 (7.1)	1 (7.1)	0
Pneumonia	1 (7.1)	0	0
Respiratory tract infection	1 (7.1)	0	1 (7.1)
Respiratory tract infection viral	1 (7.1)	1 (7.1)	0
Urinary tract infection	1 (7.1)	0	0

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal candidiasis	1 (7.1)	0	0
Injury, poisoning and procedural complications			
-Total	1 (7.1)	1 (7.1)	0
Procedural pain	1 (7.1)	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179b
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (73.3)	11 (36.7)	8 (26.7)
Blood and lymphatic system disorders			
-Total	11 (36.7)	9 (30.0)	2 (6.7)
Febrile neutropenia	9 (30.0)	9 (30.0)	0
Neutropenia	2 (6.7)	0	2 (6.7)
Disseminated intravascular coagulation	1 (3.3)	0	0
Eosinophilia	1 (3.3)	1 (3.3)	0
Gastrointestinal disorders			
-Total	4 (13.3)	1 (3.3)	0
Diarrhoea	2 (6.7)	0	0
Enterocolitis	1 (3.3)	1 (3.3)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (3.3)	0	0
General disorders and administration site conditions			
-Total	2 (6.7)	0	0
Malaise	1 (3.3)	0	0
Pyrexia	1 (3.3)	0	0
Immune system disorders			
-Total	19 (63.3)	3 (10.0)	5 (16.7)
Cytokine release syndrome	19 (63.3)	3 (10.0)	5 (16.7)
Infections and infestations			
-Total	6 (20.0)	5 (16.7)	0
Cellulitis of male external genital organ	1 (3.3)	1 (3.3)	0
Cholecystitis infective	1 (3.3)	1 (3.3)	0
Clostridium difficile infection	1 (3.3)	0	0
Corona virus infection	1 (3.3)	1 (3.3)	0
Gastroenteritis	1 (3.3)	1 (3.3)	0
Herpes zoster	1 (3.3)	1 (3.3)	0
Respiratory syncytial virus infection	1 (3.3)	1 (3.3)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (3.3)	1 (3.3)	0
Viral upper respiratory tract infection	1 (3.3)	1 (3.3)	0
Investigations			
-Total	1 (3.3)	0	1 (3.3)
White blood cell count decreased	1 (3.3)	0	1 (3.3)
Metabolism and nutrition disorders			
-Total	1 (3.3)	1 (3.3)	0
Dehydration	1 (3.3)	1 (3.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (3.3)	0	0
Osteonecrosis	1 (3.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.3)	0	1 (3.3)
Glioblastoma multiforme	1 (3.3)	0	1 (3.3)
Nervous system disorders			
-Total	4 (13.3)	2 (6.7)	0
Encephalopathy	2 (6.7)	1 (3.3)	0

Timing: Any time post CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=30 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Seizure	2 (6.7)	1 (3.3)	0
Headache	1 (3.3)	1 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (10.0)	1 (3.3)	0
Hypoxia	2 (6.7)	0	0
Pulmonary oedema	1 (3.3)	1 (3.3)	0
Vascular disorders			
-Total	4 (13.3)	4 (13.3)	0
Hypotension	4 (13.3)	4 (13.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179b
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (88.2)	10 (29.4)	16 (47.1)
Blood and lymphatic system disorders			
-Total	16 (47.1)	13 (38.2)	2 (5.9)
Febrile neutropenia	14 (41.2)	13 (38.2)	1 (2.9)
Disseminated intravascular coagulation	1 (2.9)	0	0
Neutropenia	1 (2.9)	0	1 (2.9)
Cardiac disorders			
-Total	2 (5.9)	0	0
Atrioventricular block second degree	1 (2.9)	0	0
Ventricular tachycardia	1 (2.9)	0	0
Eye disorders			

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (5.9)	0	0
Papilloedema	1 (2.9)	0	0
Vision blurred	1 (2.9)	0	0
Gastrointestinal disorders			
-Total	3 (8.8)	3 (8.8)	0
Intestinal obstruction	1 (2.9)	1 (2.9)	0
Pancreatitis	1 (2.9)	1 (2.9)	0
Vomiting	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			
-Total	7 (20.6)	2 (5.9)	0
Pyrexia	6 (17.6)	1 (2.9)	0
Physical deconditioning	1 (2.9)	1 (2.9)	0
Immune system disorders			
-Total	22 (64.7)	5 (14.7)	5 (14.7)
Cytokine release syndrome	22 (64.7)	5 (14.7)	5 (14.7)
Graft versus host disease in gastrointestinal tract	1 (2.9)	0	0
Infections and infestations			

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (38.2)	6 (17.6)	4 (11.8)
Clostridium difficile colitis	2 (5.9)	0	0
Clostridium difficile infection	2 (5.9)	1 (2.9)	0
Pneumonia	2 (5.9)	1 (2.9)	0
Bacterial sepsis	1 (2.9)	0	1 (2.9)
Campylobacter infection	1 (2.9)	1 (2.9)	0
Catheter site infection	1 (2.9)	1 (2.9)	0
Enterovirus infection	1 (2.9)	1 (2.9)	0
Gastroenteritis norovirus	1 (2.9)	0	0
Parainfluenzae virus infection	1 (2.9)	1 (2.9)	0
Respiratory tract infection	1 (2.9)	0	1 (2.9)
Respiratory tract infection viral	1 (2.9)	1 (2.9)	0
Rhinovirus infection	1 (2.9)	0	0
Rotavirus infection	1 (2.9)	1 (2.9)	0
Sepsis	1 (2.9)	0	1 (2.9)
Septic embolus	1 (2.9)	0	1 (2.9)
Staphylococcal infection	1 (2.9)	1 (2.9)	0
Upper respiratory tract infection	1 (2.9)	1 (2.9)	0
Urinary tract infection	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (2.9)	1 (2.9)	0
Vulvovaginal candidiasis	1 (2.9)	0	0
Injury, poisoning and procedural complications			
-Total	2 (5.9)	1 (2.9)	1 (2.9)
Procedural pain	1 (2.9)	1 (2.9)	0
Transfusion related complication	1 (2.9)	0	1 (2.9)
Investigations			
-Total	1 (2.9)	1 (2.9)	0
Alanine aminotransferase increased	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders			
-Total	3 (8.8)	3 (8.8)	0
Tumour lysis syndrome	2 (5.9)	2 (5.9)	0
Acidosis	1 (2.9)	0	0
Decreased appetite	1 (2.9)	1 (2.9)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (5.9)	0	0
Flank pain	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	1 (2.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.9)	0	0
Myelodysplastic syndrome	1 (2.9)	0	0
Nervous system disorders			
-Total	6 (17.6)	2 (5.9)	1 (2.9)
Encephalopathy	2 (5.9)	1 (2.9)	0
Seizure	2 (5.9)	1 (2.9)	0
Embolic stroke	1 (2.9)	0	1 (2.9)
Idiopathic intracranial hypertension	1 (2.9)	0	0
Psychiatric disorders			
-Total	1 (2.9)	0	0
Delirium	1 (2.9)	0	0
Renal and urinary disorders			
-Total	5 (14.7)	3 (8.8)	2 (5.9)
Acute kidney injury	4 (11.8)	3 (8.8)	1 (2.9)
Renal failure	1 (2.9)	0	1 (2.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (2.9)	1 (2.9)	0
Vaginal haemorrhage	1 (2.9)	1 (2.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (20.6)	1 (2.9)	5 (14.7)
Respiratory failure	3 (8.8)	0	3 (8.8)
Hypoxia	2 (5.9)	1 (2.9)	1 (2.9)
Pleural effusion	2 (5.9)	1 (2.9)	0
Acute respiratory failure	1 (2.9)	0	1 (2.9)
Pulmonary oedema	1 (2.9)	0	1 (2.9)
Skin and subcutaneous tissue disorders			
-Total	1 (2.9)	1 (2.9)	0
Ecchymosis	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	4 (11.8)	1 (2.9)	3 (8.8)
Hypotension	3 (8.8)	0	3 (8.8)
Embolism	1 (2.9)	1 (2.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (71.2)	18 (34.6)	14 (26.9)
Blood and lymphatic system disorders			
-Total	19 (36.5)	18 (34.6)	1 (1.9)
Febrile neutropenia	18 (34.6)	18 (34.6)	0
Disseminated intravascular coagulation	1 (1.9)	0	0
Neutropenia	1 (1.9)	0	1 (1.9)
Eye disorders			
-Total	2 (3.8)	0	0
Papilloedema	1 (1.9)	0	0
Vision blurred	1 (1.9)	0	0
Gastrointestinal disorders			
-Total	4 (7.7)	3 (5.8)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Intestinal obstruction	1 (1.9)	1 (1.9)	0
Pancreatitis	1 (1.9)	1 (1.9)	0
Stomatitis	1 (1.9)	0	0
Vomiting	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	2 (3.8)	0	0
Pyrexia	2 (3.8)	0	0
Immune system disorders			
-Total	33 (63.5)	7 (13.5)	9 (17.3)
Cytokine release syndrome	33 (63.5)	7 (13.5)	9 (17.3)
Infections and infestations			
-Total	7 (13.5)	3 (5.8)	1 (1.9)
Clostridium difficile infection	2 (3.8)	0	0
Catheter site infection	1 (1.9)	1 (1.9)	0
Clostridium difficile colitis	1 (1.9)	0	0
Gastroenteritis norovirus	1 (1.9)	0	0
Pneumonia	1 (1.9)	1 (1.9)	0
Rhinovirus infection	1 (1.9)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic embolus	1 (1.9)	0	1 (1.9)
Staphylococcal infection	1 (1.9)	1 (1.9)	0
Metabolism and nutrition disorders			
-Total	1 (1.9)	1 (1.9)	0
Decreased appetite	1 (1.9)	1 (1.9)	0
Nervous system disorders			
-Total	7 (13.5)	3 (5.8)	1 (1.9)
Encephalopathy	3 (5.8)	2 (3.8)	0
Seizure	2 (3.8)	1 (1.9)	0
Embolic stroke	1 (1.9)	0	1 (1.9)
Headache	1 (1.9)	1 (1.9)	0
Idiopathic intracranial hypertension	1 (1.9)	0	0
Renal and urinary disorders			
-Total	3 (5.8)	1 (1.9)	2 (3.8)
Acute kidney injury	2 (3.8)	1 (1.9)	1 (1.9)
Renal failure	1 (1.9)	0	1 (1.9)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (13.5)	1 (1.9)	3 (5.8)

Timing: within 8 weeks post infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	4 (7.7)	1 (1.9)	1 (1.9)
Pleural effusion	2 (3.8)	1 (1.9)	0
Respiratory failure	2 (3.8)	0	2 (3.8)
Vascular disorders			
-Total	6 (11.5)	4 (7.7)	2 (3.8)
Hypotension	6 (11.5)	4 (7.7)	2 (3.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	2 (40.0)	0
Blood and lymphatic system disorders			
-Total	1 (20.0)	1 (20.0)	0
Febrile neutropenia	1 (20.0)	1 (20.0)	0
Cardiac disorders			
-Total	1 (20.0)	0	0
Atrioventricular block second degree	1 (20.0)	0	0
Gastrointestinal disorders			
-Total	1 (20.0)	0	0
Diarrhoea	1 (20.0)	0	0
Immune system disorders			
-Total	3 (60.0)	0	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	3 (60.0)	0	0
Infections and infestations			
-Total	1 (20.0)	1 (20.0)	0
Gastroenteritis	1 (20.0)	1 (20.0)	0
Metabolism and nutrition disorders			
-Total	1 (20.0)	1 (20.0)	0
Dehydration	1 (20.0)	1 (20.0)	0
Vascular disorders			
-Total	1 (20.0)	1 (20.0)	0
Embolism	1 (20.0)	1 (20.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	0	3 (42.9)
Blood and lymphatic system disorders			
-Total	3 (42.9)	2 (28.6)	0
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Disseminated intravascular coagulation	1 (14.3)	0	0
Cardiac disorders			
-Total	1 (14.3)	0	0
Ventricular tachycardia	1 (14.3)	0	0
General disorders and administration site conditions			
-Total	2 (28.6)	1 (14.3)	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	1 (14.3)	0	0
Physical deconditioning	1 (14.3)	1 (14.3)	0
Immune system disorders			
-Total	5 (71.4)	1 (14.3)	1 (14.3)
Cytokine release syndrome	5 (71.4)	1 (14.3)	1 (14.3)
Infections and infestations			
-Total	1 (14.3)	0	0
Clostridium difficile colitis	1 (14.3)	0	0
Injury, poisoning and procedural complications			
-Total	1 (14.3)	0	1 (14.3)
Transfusion related complication	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
-Total	1 (14.3)	1 (14.3)	0
Acidosis	1 (14.3)	0	0
Tumour lysis syndrome	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	2 (28.6)	0	0
Encephalopathy	1 (14.3)	0	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (14.3)	0	0
Psychiatric disorders			
-Total	1 (14.3)	0	0
Delirium	1 (14.3)	0	0
Renal and urinary disorders			
-Total	1 (14.3)	1 (14.3)	0
Acute kidney injury	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (14.3)	0	1 (14.3)
Pulmonary oedema	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)
Skin and subcutaneous tissue disorders			
-Total	1 (14.3)	1 (14.3)	0
Ecchymosis	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	1 (14.3)	0	1 (14.3)
Hypotension	1 (14.3)	0	1 (14.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (34.1)	10 (22.7)	4 (9.1)
Blood and lymphatic system disorders			
-Total	3 (6.8)	1 (2.3)	2 (4.5)
Neutropenia	2 (4.5)	0	2 (4.5)
Eosinophilia	1 (2.3)	1 (2.3)	0
Febrile neutropenia	1 (2.3)	1 (2.3)	0
Gastrointestinal disorders			
-Total	2 (4.5)	2 (4.5)	0
Enterocolitis	1 (2.3)	1 (2.3)	0
Vomiting	1 (2.3)	1 (2.3)	0
General disorders and administration site conditions			

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (6.8)	1 (2.3)	0
Pyrexia	3 (6.8)	1 (2.3)	0
Immune system disorders			
-Total	1 (2.3)	0	0
Graft versus host disease in gastrointestinal tract	1 (2.3)	0	0
Infections and infestations			
-Total	9 (20.5)	7 (15.9)	1 (2.3)
Bacterial sepsis	1 (2.3)	0	1 (2.3)
Cellulitis of male external genital organ	1 (2.3)	1 (2.3)	0
Cholecystitis infective	1 (2.3)	1 (2.3)	0
Corona virus infection	1 (2.3)	1 (2.3)	0
Enterovirus infection	1 (2.3)	1 (2.3)	0
Gastroenteritis norovirus	1 (2.3)	0	0
Parainfluenzae virus infection	1 (2.3)	1 (2.3)	0
Respiratory syncytial virus infection	1 (2.3)	1 (2.3)	0
Rotavirus infection	1 (2.3)	1 (2.3)	0
Upper respiratory tract infection	1 (2.3)	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (2.3)	1 (2.3)	0
Investigations			
-Total	2 (4.5)	1 (2.3)	1 (2.3)
Alanine aminotransferase increased	1 (2.3)	1 (2.3)	0
White blood cell count decreased	1 (2.3)	0	1 (2.3)
Metabolism and nutrition disorders			
-Total	1 (2.3)	1 (2.3)	0
Tumour lysis syndrome	1 (2.3)	1 (2.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (2.3)	0	0
Flank pain	1 (2.3)	0	0
Renal and urinary disorders			
-Total	1 (2.3)	1 (2.3)	0
Acute kidney injury	1 (2.3)	1 (2.3)	0
Reproductive system and breast disorders			
-Total	1 (2.3)	1 (2.3)	0
Vaginal haemorrhage	1 (2.3)	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (2.3)	0	1 (2.3)
Acute respiratory failure	1 (2.3)	0	1 (2.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (60.0)	1 (20.0)	0
Blood and lymphatic system disorders			
-Total	1 (20.0)	1 (20.0)	0
Febrile neutropenia	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
-Total	2 (40.0)	0	0
Pyrexia	2 (40.0)	0	0
Infections and infestations			
-Total	1 (20.0)	1 (20.0)	0
Herpes zoster	1 (20.0)	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	2 (40.0)	0	0
Osteonecrosis	1 (20.0)	0	0
Pain in extremity	1 (20.0)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (20.0)	1 (20.0)	0
Pulmonary oedema	1 (20.0)	1 (20.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (42.9)	2 (28.6)	1 (14.3)
Blood and lymphatic system disorders			
-Total	1 (14.3)	1 (14.3)	0
Febrile neutropenia	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Sepsis	1 (14.3)	0	1 (14.3)
Vascular device infection	1 (14.3)	1 (14.3)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (14.3)	0	0
Myelodysplastic syndrome	1 (14.3)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (14.3)	2 (7.1)	1 (3.6)
Gastrointestinal disorders			
-Total	1 (3.6)	0	0
Diarrhoea	1 (3.6)	0	0
Infections and infestations			
-Total	3 (10.7)	2 (7.1)	0
Urinary tract infection	2 (7.1)	1 (3.6)	0
Campylobacter infection	1 (3.6)	1 (3.6)	0
Cellulitis of male external genital organ	1 (3.6)	1 (3.6)	0
Clostridium difficile infection	1 (3.6)	1 (3.6)	0
Pneumonia	1 (3.6)	0	0

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (3.6)	1 (3.6)	0
Vulvovaginal candidiasis	1 (3.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.6)	0	1 (3.6)
Glioblastoma multiforme	1 (3.6)	0	1 (3.6)
Nervous system disorders			
-Total	1 (3.6)	1 (3.6)	0
Seizure	1 (3.6)	1 (3.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Asian

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)
Respiratory tract infection	1 (50.0)	0	1 (50.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (25.0)	0	1 (25.0)
Blood and lymphatic system disorders			
-Total	1 (25.0)	0	1 (25.0)
Febrile neutropenia	1 (25.0)	0	1 (25.0)
Injury, poisoning and procedural complications			
-Total	1 (25.0)	1 (25.0)	0
Procedural pain	1 (25.0)	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	41 (78.8)	18 (34.6)	18 (34.6)
Blood and lymphatic system disorders			
-Total	21 (40.4)	18 (34.6)	3 (5.8)
Febrile neutropenia	18 (34.6)	18 (34.6)	0
Neutropenia	3 (5.8)	0	3 (5.8)
Disseminated intravascular coagulation	1 (1.9)	0	0
Eosinophilia	1 (1.9)	1 (1.9)	0
Eye disorders			
-Total	2 (3.8)	0	0
Papilloedema	1 (1.9)	0	0
Vision blurred	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	6 (11.5)	4 (7.7)	0
Diarrhoea	1 (1.9)	0	0
Enterocolitis	1 (1.9)	1 (1.9)	0
Intestinal obstruction	1 (1.9)	1 (1.9)	0
Pancreatitis	1 (1.9)	1 (1.9)	0
Stomatitis	1 (1.9)	0	0
Vomiting	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	5 (9.6)	1 (1.9)	0
Pyrexia	5 (9.6)	1 (1.9)	0
Immune system disorders			
-Total	33 (63.5)	7 (13.5)	9 (17.3)
Cytokine release syndrome	33 (63.5)	7 (13.5)	9 (17.3)
Graft versus host disease in gastrointestinal tract	1 (1.9)	0	0
Infections and infestations			
-Total	15 (28.8)	9 (17.3)	2 (3.8)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	3 (5.8)	1 (1.9)	0
Pneumonia	2 (3.8)	1 (1.9)	0
Urinary tract infection	2 (3.8)	1 (1.9)	0
Bacterial sepsis	1 (1.9)	0	1 (1.9)
Campylobacter infection	1 (1.9)	1 (1.9)	0
Catheter site infection	1 (1.9)	1 (1.9)	0
Cellulitis of male external genital organ	1 (1.9)	1 (1.9)	0
Cholecystitis infective	1 (1.9)	1 (1.9)	0
Clostridium difficile colitis	1 (1.9)	0	0
Corona virus infection	1 (1.9)	1 (1.9)	0
Enterovirus infection	1 (1.9)	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	0
Parainfluenzae virus infection	1 (1.9)	1 (1.9)	0
Respiratory syncytial virus infection	1 (1.9)	1 (1.9)	0
Respiratory tract infection viral	1 (1.9)	1 (1.9)	0
Rhinovirus infection	1 (1.9)	0	0
Rotavirus infection	1 (1.9)	1 (1.9)	0
Septic embolus	1 (1.9)	0	1 (1.9)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (1.9)	1 (1.9)	0
Upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Viral upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Vulvovaginal candidiasis	1 (1.9)	0	0
Investigations			
-Total	2 (3.8)	1 (1.9)	1 (1.9)
Alanine aminotransferase increased	1 (1.9)	1 (1.9)	0
White blood cell count decreased	1 (1.9)	0	1 (1.9)
Metabolism and nutrition disorders			
-Total	2 (3.8)	2 (3.8)	0
Decreased appetite	1 (1.9)	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	1 (1.9)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (1.9)	0	0
Flank pain	1 (1.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.9)	0	1 (1.9)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Glioblastoma multiforme	1 (1.9)	0	1 (1.9)
Nervous system disorders			
-Total	8 (15.4)	4 (7.7)	1 (1.9)
Encephalopathy	3 (5.8)	2 (3.8)	0
Seizure	3 (5.8)	2 (3.8)	0
Embolic stroke	1 (1.9)	0	1 (1.9)
Headache	1 (1.9)	1 (1.9)	0
Idiopathic intracranial hypertension	1 (1.9)	0	0
Renal and urinary disorders			
-Total	4 (7.7)	2 (3.8)	2 (3.8)
Acute kidney injury	3 (5.8)	2 (3.8)	1 (1.9)
Renal failure	1 (1.9)	0	1 (1.9)
Reproductive system and breast disorders			
-Total	1 (1.9)	1 (1.9)	0
Vaginal haemorrhage	1 (1.9)	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	8 (15.4)	1 (1.9)	4 (7.7)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	4 (7.7)	1 (1.9)	1 (1.9)
Pleural effusion	2 (3.8)	1 (1.9)	0
Respiratory failure	2 (3.8)	0	2 (3.8)
Acute respiratory failure	1 (1.9)	0	1 (1.9)
Vascular disorders			
-Total	6 (11.5)	4 (7.7)	2 (3.8)
Hypotension	6 (11.5)	4 (7.7)	2 (3.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	2 (40.0)	1 (20.0)
Blood and lymphatic system disorders			
-Total	1 (20.0)	1 (20.0)	0
Febrile neutropenia	1 (20.0)	1 (20.0)	0
Cardiac disorders			
-Total	1 (20.0)	0	0
Atrioventricular block second degree	1 (20.0)	0	0
Gastrointestinal disorders			
-Total	1 (20.0)	0	0
Diarrhoea	1 (20.0)	0	0
General disorders and administration site conditions			

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (40.0)	0	0
Pyrexia	2 (40.0)	0	0
Immune system disorders			
-Total	3 (60.0)	0	0
Cytokine release syndrome	3 (60.0)	0	0
Infections and infestations			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Gastroenteritis	1 (20.0)	1 (20.0)	0
Herpes zoster	1 (20.0)	1 (20.0)	0
Respiratory tract infection	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
-Total	1 (20.0)	1 (20.0)	0
Dehydration	1 (20.0)	1 (20.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (40.0)	0	0
Osteonecrosis	1 (20.0)	0	0
Pain in extremity	1 (20.0)	0	0

Timing: Any time post CTL019 infusion, Race: Asian

Group term Preferred term	All patients N=5 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (20.0)	1 (20.0)	0
Pulmonary oedema	1 (20.0)	1 (20.0)	0
Vascular disorders			
-Total	1 (20.0)	1 (20.0)	0
Embolism	1 (20.0)	1 (20.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179c
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	1 (14.3)	5 (71.4)
Blood and lymphatic system disorders			
-Total	5 (71.4)	3 (42.9)	1 (14.3)
Febrile neutropenia	4 (57.1)	3 (42.9)	1 (14.3)
Disseminated intravascular coagulation	1 (14.3)	0	0
Cardiac disorders			
-Total	1 (14.3)	0	0
Ventricular tachycardia	1 (14.3)	0	0
General disorders and administration site conditions			
-Total	2 (28.6)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	1 (14.3)	0	0
Physical deconditioning	1 (14.3)	1 (14.3)	0
Immune system disorders			
-Total	5 (71.4)	1 (14.3)	1 (14.3)
Cytokine release syndrome	5 (71.4)	1 (14.3)	1 (14.3)
Infections and infestations			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Clostridium difficile colitis	1 (14.3)	0	0
Sepsis	1 (14.3)	0	1 (14.3)
Vascular device infection	1 (14.3)	1 (14.3)	0
Injury, poisoning and procedural complications			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Procedural pain	1 (14.3)	1 (14.3)	0
Transfusion related complication	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
-Total	1 (14.3)	1 (14.3)	0
Acidosis	1 (14.3)	0	0
Tumour lysis syndrome	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (14.3)	0	0
Myelodysplastic syndrome	1 (14.3)	0	0
Nervous system disorders			
-Total	2 (28.6)	0	0
Encephalopathy	1 (14.3)	0	0
Seizure	1 (14.3)	0	0
Psychiatric disorders			
-Total	1 (14.3)	0	0
Delirium	1 (14.3)	0	0
Renal and urinary disorders			
-Total	1 (14.3)	1 (14.3)	0
Acute kidney injury	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (14.3)	0	1 (14.3)
Pulmonary oedema	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)

Timing: Any time post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=7 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Skin and subcutaneous tissue disorders			
-Total	1 (14.3)	1 (14.3)	0
Ecchymosis	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	1 (14.3)	0	1 (14.3)
Hypotension	1 (14.3)	0	1 (14.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179d
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (72.0)	11 (44.0)	5 (20.0)
Blood and lymphatic system disorders			
-Total	14 (56.0)	13 (52.0)	0
Febrile neutropenia	13 (52.0)	13 (52.0)	0
Disseminated intravascular coagulation	1 (4.0)	0	0
Cardiac disorders			
-Total	1 (4.0)	0	0
Ventricular tachycardia	1 (4.0)	0	0
Gastrointestinal disorders			
-Total	2 (8.0)	2 (8.0)	0
Pancreatitis	1 (4.0)	1 (4.0)	0
Vomiting	1 (4.0)	1 (4.0)	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	3 (12.0)	1 (4.0)	0
Malaise	1 (4.0)	0	0
Physical deconditioning	1 (4.0)	1 (4.0)	0
Pyrexia	1 (4.0)	0	0
Immune system disorders			
-Total	16 (64.0)	3 (12.0)	3 (12.0)
Cytokine release syndrome	16 (64.0)	3 (12.0)	3 (12.0)
Infections and infestations			
-Total	2 (8.0)	1 (4.0)	0
Gastroenteritis norovirus	1 (4.0)	0	0
Staphylococcal infection	1 (4.0)	1 (4.0)	0
Metabolism and nutrition disorders			
-Total	1 (4.0)	1 (4.0)	0
Acidosis	1 (4.0)	0	0
Tumour lysis syndrome	1 (4.0)	1 (4.0)	0
Nervous system disorders			
-Total	3 (12.0)	1 (4.0)	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	2 (8.0)	0	0
Encephalopathy	1 (4.0)	1 (4.0)	0
Psychiatric disorders			
-Total	1 (4.0)	0	0
Delirium	1 (4.0)	0	0
Renal and urinary disorders			
-Total	2 (8.0)	2 (8.0)	0
Acute kidney injury	2 (8.0)	2 (8.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (12.0)	0	2 (8.0)
Respiratory failure	2 (8.0)	0	2 (8.0)
Hypoxia	1 (4.0)	0	0
Pleural effusion	1 (4.0)	1 (4.0)	0
Pulmonary oedema	1 (4.0)	0	1 (4.0)
Skin and subcutaneous tissue disorders			
-Total	1 (4.0)	1 (4.0)	0
Ecchymosis	1 (4.0)	1 (4.0)	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	3 (12.0)	2 (8.0)	1 (4.0)
Hypotension	3 (12.0)	2 (8.0)	1 (4.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179d
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (71.8)	9 (23.1)	12 (30.8)
Blood and lymphatic system disorders			
-Total	9 (23.1)	8 (20.5)	1 (2.6)
Febrile neutropenia	8 (20.5)	8 (20.5)	0
Disseminated intravascular coagulation	1 (2.6)	0	0
Neutropenia	1 (2.6)	0	1 (2.6)
Cardiac disorders			
-Total	1 (2.6)	0	0
Atrioventricular block second degree	1 (2.6)	0	0
Eye disorders			
-Total	2 (5.1)	0	0
Papilloedema	1 (2.6)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vision blurred	1 (2.6)	0	0
Gastrointestinal disorders			
-Total	3 (7.7)	1 (2.6)	0
Diarrhoea	1 (2.6)	0	0
Intestinal obstruction	1 (2.6)	1 (2.6)	0
Stomatitis	1 (2.6)	0	0
General disorders and administration site conditions			
-Total	1 (2.6)	0	0
Pyrexia	1 (2.6)	0	0
Immune system disorders			
-Total	25 (64.1)	5 (12.8)	7 (17.9)
Cytokine release syndrome	25 (64.1)	5 (12.8)	7 (17.9)
Infections and infestations			
-Total	7 (17.9)	3 (7.7)	1 (2.6)
Clostridium difficile colitis	2 (5.1)	0	0
Clostridium difficile infection	2 (5.1)	0	0
Catheter site infection	1 (2.6)	1 (2.6)	0
Gastroenteritis	1 (2.6)	1 (2.6)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (2.6)	1 (2.6)	0
Rhinovirus infection	1 (2.6)	0	0
Septic embolus	1 (2.6)	0	1 (2.6)
Injury, poisoning and procedural complications			
-Total	1 (2.6)	0	1 (2.6)
Transfusion related complication	1 (2.6)	0	1 (2.6)
Metabolism and nutrition disorders			
-Total	2 (5.1)	2 (5.1)	0
Decreased appetite	1 (2.6)	1 (2.6)	0
Dehydration	1 (2.6)	1 (2.6)	0
Nervous system disorders			
-Total	6 (15.4)	2 (5.1)	1 (2.6)
Encephalopathy	3 (7.7)	1 (2.6)	0
Embolic stroke	1 (2.6)	0	1 (2.6)
Headache	1 (2.6)	1 (2.6)	0
Idiopathic intracranial hypertension	1 (2.6)	0	0
Seizure	1 (2.6)	1 (2.6)	0
Renal and urinary disorders			

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (5.1)	0	2 (5.1)
Acute kidney injury	1 (2.6)	0	1 (2.6)
Renal failure	1 (2.6)	0	1 (2.6)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (12.8)	1 (2.6)	2 (5.1)
Hypoxia	3 (7.7)	1 (2.6)	1 (2.6)
Pleural effusion	1 (2.6)	0	0
Respiratory failure	1 (2.6)	0	1 (2.6)
Vascular disorders			
-Total	5 (12.8)	3 (7.7)	2 (5.1)
Hypotension	4 (10.3)	2 (5.1)	2 (5.1)
Embolism	1 (2.6)	1 (2.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179d
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=23	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (39.1)	6 (26.1)	2 (8.7)
Blood and lymphatic system disorders			
-Total	3 (13.0)	2 (8.7)	1 (4.3)
Febrile neutropenia	2 (8.7)	2 (8.7)	0
Eosinophilia	1 (4.3)	1 (4.3)	0
Neutropenia	1 (4.3)	0	1 (4.3)
Gastrointestinal disorders			
-Total	2 (8.7)	2 (8.7)	0
Enterocolitis	1 (4.3)	1 (4.3)	0
Vomiting	1 (4.3)	1 (4.3)	0
General disorders and administration site conditions			

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (8.7)	0	0
Pyrexia	2 (8.7)	0	0
Immune system disorders			
-Total	1 (4.3)	0	0
Graft versus host disease in gastrointestinal tract	1 (4.3)	0	0
Infections and infestations			
-Total	4 (17.4)	3 (13.0)	0
Cellulitis of male external genital organ	1 (4.3)	1 (4.3)	0
Corona virus infection	1 (4.3)	1 (4.3)	0
Gastroenteritis norovirus	1 (4.3)	0	0
Respiratory syncytial virus infection	1 (4.3)	1 (4.3)	0
Viral upper respiratory tract infection	1 (4.3)	1 (4.3)	0
Metabolism and nutrition disorders			
-Total	1 (4.3)	1 (4.3)	0
Tumour lysis syndrome	1 (4.3)	1 (4.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (4.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flank pain	1 (4.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (4.3)	0	0
Myelodysplastic syndrome	1 (4.3)	0	0
Renal and urinary disorders			
-Total	1 (4.3)	1 (4.3)	0
Acute kidney injury	1 (4.3)	1 (4.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (4.3)	0	1 (4.3)
Acute respiratory failure	1 (4.3)	0	1 (4.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179d
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (36.4)	7 (21.2)	3 (9.1)
Blood and lymphatic system disorders			
-Total	2 (6.1)	1 (3.0)	1 (3.0)
Febrile neutropenia	1 (3.0)	1 (3.0)	0
Neutropenia	1 (3.0)	0	1 (3.0)
General disorders and administration site conditions			
-Total	3 (9.1)	1 (3.0)	0
Pyrexia	3 (9.1)	1 (3.0)	0
Infections and infestations			
-Total	8 (24.2)	6 (18.2)	2 (6.1)
Bacterial sepsis	1 (3.0)	0	1 (3.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (3.0)	1 (3.0)	0
Enterovirus infection	1 (3.0)	1 (3.0)	0
Herpes zoster	1 (3.0)	1 (3.0)	0
Parainfluenzae virus infection	1 (3.0)	1 (3.0)	0
Rotavirus infection	1 (3.0)	1 (3.0)	0
Sepsis	1 (3.0)	0	1 (3.0)
Upper respiratory tract infection	1 (3.0)	1 (3.0)	0
Vascular device infection	1 (3.0)	1 (3.0)	0
Investigations			
-Total	2 (6.1)	1 (3.0)	1 (3.0)
Alanine aminotransferase increased	1 (3.0)	1 (3.0)	0
White blood cell count decreased	1 (3.0)	0	1 (3.0)
Musculoskeletal and connective tissue disorders			
-Total	2 (6.1)	0	0
Osteonecrosis	1 (3.0)	0	0
Pain in extremity	1 (3.0)	0	0
Reproductive system and breast disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.0)	1 (3.0)	0
Vaginal haemorrhage	1 (3.0)	1 (3.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.0)	1 (3.0)	0
Pulmonary oedema	1 (3.0)	1 (3.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179d
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=17	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (11.8)	1 (5.9)	1 (5.9)
Blood and lymphatic system disorders			
-Total	1 (5.9)	0	1 (5.9)
Febrile neutropenia	1 (5.9)	0	1 (5.9)
Gastrointestinal disorders			
-Total	1 (5.9)	0	0
Diarrhoea	1 (5.9)	0	0
Infections and infestations			
-Total	1 (5.9)	1 (5.9)	0
Cellulitis of male external genital organ	1 (5.9)	1 (5.9)	0
Urinary tract infection	1 (5.9)	1 (5.9)	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (5.9)	1 (5.9)	0
Procedural pain	1 (5.9)	1 (5.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179d
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (23.5)	1 (5.9)	2 (11.8)
Infections and infestations			
-Total	3 (17.6)	1 (5.9)	1 (5.9)
Campylobacter infection	1 (5.9)	1 (5.9)	0
Clostridium difficile infection	1 (5.9)	1 (5.9)	0
Pneumonia	1 (5.9)	0	0
Respiratory tract infection	1 (5.9)	0	1 (5.9)
Respiratory tract infection viral	1 (5.9)	1 (5.9)	0
Urinary tract infection	1 (5.9)	0	0
Vulvovaginal candidiasis	1 (5.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.9)	0	1 (5.9)
Glioblastoma multiforme	1 (5.9)	0	1 (5.9)
Nervous system disorders			
-Total	1 (5.9)	1 (5.9)	0
Seizure	1 (5.9)	1 (5.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179d
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (80.0)	12 (48.0)	7 (28.0)
Blood and lymphatic system disorders			
-Total	17 (68.0)	14 (56.0)	2 (8.0)
Febrile neutropenia	15 (60.0)	14 (56.0)	1 (4.0)
Disseminated intravascular coagulation	1 (4.0)	0	0
Eosinophilia	1 (4.0)	1 (4.0)	0
Neutropenia	1 (4.0)	0	1 (4.0)
Cardiac disorders			
-Total	1 (4.0)	0	0
Ventricular tachycardia	1 (4.0)	0	0
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (16.0)	3 (12.0)	0
Diarrhoea	1 (4.0)	0	0
Enterocolitis	1 (4.0)	1 (4.0)	0
Pancreatitis	1 (4.0)	1 (4.0)	0
Vomiting	1 (4.0)	1 (4.0)	0
General disorders and administration site conditions			
-Total	5 (20.0)	1 (4.0)	0
Pyrexia	3 (12.0)	0	0
Malaise	1 (4.0)	0	0
Physical deconditioning	1 (4.0)	1 (4.0)	0
Immune system disorders			
-Total	16 (64.0)	3 (12.0)	3 (12.0)
Cytokine release syndrome	16 (64.0)	3 (12.0)	3 (12.0)
Graft versus host disease in gastrointestinal tract	1 (4.0)	0	0
Infections and infestations			
-Total	5 (20.0)	4 (16.0)	0
Cellulitis of male external genital organ	1 (4.0)	1 (4.0)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	1 (4.0)	1 (4.0)	0
Gastroenteritis norovirus	1 (4.0)	0	0
Respiratory syncytial virus infection	1 (4.0)	1 (4.0)	0
Staphylococcal infection	1 (4.0)	1 (4.0)	0
Urinary tract infection	1 (4.0)	1 (4.0)	0
Viral upper respiratory tract infection	1 (4.0)	1 (4.0)	0
Injury, poisoning and procedural complications			
-Total	1 (4.0)	1 (4.0)	0
Procedural pain	1 (4.0)	1 (4.0)	0
Metabolism and nutrition disorders			
-Total	2 (8.0)	2 (8.0)	0
Tumour lysis syndrome	2 (8.0)	2 (8.0)	0
Acidosis	1 (4.0)	0	0
Musculoskeletal and connective tissue disorders			
-Total	1 (4.0)	0	0
Flank pain	1 (4.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.0)	0	0
Myelodysplastic syndrome	1 (4.0)	0	0
Nervous system disorders			
-Total	3 (12.0)	1 (4.0)	0
Seizure	2 (8.0)	0	0
Encephalopathy	1 (4.0)	1 (4.0)	0
Psychiatric disorders			
-Total	1 (4.0)	0	0
Delirium	1 (4.0)	0	0
Renal and urinary disorders			
-Total	3 (12.0)	3 (12.0)	0
Acute kidney injury	3 (12.0)	3 (12.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (16.0)	0	3 (12.0)
Respiratory failure	2 (8.0)	0	2 (8.0)
Acute respiratory failure	1 (4.0)	0	1 (4.0)
Hypoxia	1 (4.0)	0	0
Pleural effusion	1 (4.0)	1 (4.0)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	1 (4.0)	0	1 (4.0)
Skin and subcutaneous tissue disorders			
-Total	1 (4.0)	1 (4.0)	0
Ecchymosis	1 (4.0)	1 (4.0)	0
Vascular disorders			
-Total	3 (12.0)	2 (8.0)	1 (4.0)
Hypotension	3 (12.0)	2 (8.0)	1 (4.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179d
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (82.1)	9 (23.1)	17 (43.6)
Blood and lymphatic system disorders			
-Total	10 (25.6)	8 (20.5)	2 (5.1)
Febrile neutropenia	8 (20.5)	8 (20.5)	0
Neutropenia	2 (5.1)	0	2 (5.1)
Disseminated intravascular coagulation	1 (2.6)	0	0
Cardiac disorders			
-Total	1 (2.6)	0	0
Atrioventricular block second degree	1 (2.6)	0	0
Eye disorders			
-Total	2 (5.1)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Papilloedema	1 (2.6)	0	0
Vision blurred	1 (2.6)	0	0
Gastrointestinal disorders			
-Total	3 (7.7)	1 (2.6)	0
Diarrhoea	1 (2.6)	0	0
Intestinal obstruction	1 (2.6)	1 (2.6)	0
Stomatitis	1 (2.6)	0	0
General disorders and administration site conditions			
-Total	4 (10.3)	1 (2.6)	0
Pyrexia	4 (10.3)	1 (2.6)	0
Immune system disorders			
-Total	25 (64.1)	5 (12.8)	7 (17.9)
Cytokine release syndrome	25 (64.1)	5 (12.8)	7 (17.9)
Infections and infestations			
-Total	14 (35.9)	7 (17.9)	4 (10.3)
Clostridium difficile infection	3 (7.7)	1 (2.6)	0
Clostridium difficile colitis	2 (5.1)	0	0
Pneumonia	2 (5.1)	1 (2.6)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	1 (2.6)	0	1 (2.6)
Campylobacter infection	1 (2.6)	1 (2.6)	0
Catheter site infection	1 (2.6)	1 (2.6)	0
Cholecystitis infective	1 (2.6)	1 (2.6)	0
Enterovirus infection	1 (2.6)	1 (2.6)	0
Gastroenteritis	1 (2.6)	1 (2.6)	0
Herpes zoster	1 (2.6)	1 (2.6)	0
Parainfluenzae virus infection	1 (2.6)	1 (2.6)	0
Respiratory tract infection	1 (2.6)	0	1 (2.6)
Respiratory tract infection viral	1 (2.6)	1 (2.6)	0
Rhinovirus infection	1 (2.6)	0	0
Rotavirus infection	1 (2.6)	1 (2.6)	0
Sepsis	1 (2.6)	0	1 (2.6)
Septic embolus	1 (2.6)	0	1 (2.6)
Upper respiratory tract infection	1 (2.6)	1 (2.6)	0
Urinary tract infection	1 (2.6)	0	0
Vascular device infection	1 (2.6)	1 (2.6)	0
Vulvovaginal candidiasis	1 (2.6)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (2.6)	0	1 (2.6)
Transfusion related complication	1 (2.6)	0	1 (2.6)
Investigations			
-Total	2 (5.1)	1 (2.6)	1 (2.6)
Alanine aminotransferase increased	1 (2.6)	1 (2.6)	0
White blood cell count decreased	1 (2.6)	0	1 (2.6)
Metabolism and nutrition disorders			
-Total	2 (5.1)	2 (5.1)	0
Decreased appetite	1 (2.6)	1 (2.6)	0
Dehydration	1 (2.6)	1 (2.6)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (5.1)	0	0
Osteonecrosis	1 (2.6)	0	0
Pain in extremity	1 (2.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.6)	0	1 (2.6)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Glioblastoma multiforme	1 (2.6)	0	1 (2.6)
Nervous system disorders			
-Total	7 (17.9)	3 (7.7)	1 (2.6)
Encephalopathy	3 (7.7)	1 (2.6)	0
Seizure	2 (5.1)	2 (5.1)	0
Embolic stroke	1 (2.6)	0	1 (2.6)
Headache	1 (2.6)	1 (2.6)	0
Idiopathic intracranial hypertension	1 (2.6)	0	0
Renal and urinary disorders			
-Total	2 (5.1)	0	2 (5.1)
Acute kidney injury	1 (2.6)	0	1 (2.6)
Renal failure	1 (2.6)	0	1 (2.6)
Reproductive system and breast disorders			
-Total	1 (2.6)	1 (2.6)	0
Vaginal haemorrhage	1 (2.6)	1 (2.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (15.4)	2 (5.1)	2 (5.1)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	3 (7.7)	1 (2.6)	1 (2.6)
Pleural effusion	1 (2.6)	0	0
Pulmonary oedema	1 (2.6)	1 (2.6)	0
Respiratory failure	1 (2.6)	0	1 (2.6)
Vascular disorders			
-Total	5 (12.8)	3 (7.7)	2 (5.1)
Hypotension	4 (10.3)	2 (5.1)	2 (5.1)
Embolism	1 (2.6)	1 (2.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179e
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	2 (28.6)	3 (42.9)
Blood and lymphatic system disorders			
-Total	2 (28.6)	2 (28.6)	0
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Immune system disorders			
-Total	5 (71.4)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	3 (42.9)
Renal and urinary disorders			
-Total	1 (14.3)	0	1 (14.3)
Renal failure	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (14.3)	0	1 (14.3)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	1 (14.3)	0	1 (14.3)
Vascular disorders			
-Total	2 (28.6)	2 (28.6)	0
Hypotension	2 (28.6)	2 (28.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179e
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

		All patients N=57	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	41 (71.9)	18 (31.6)	14 (24.6)
Blood and lymphatic system disorders			
-Total	21 (36.8)	19 (33.3)	1 (1.8)
Febrile neutropenia	19 (33.3)	19 (33.3)	0
Disseminated intravascular coagulation	2 (3.5)	0	0
Neutropenia	1 (1.8)	0	1 (1.8)
Cardiac disorders			
-Total	2 (3.5)	0	0
Atrioventricular block second degree	1 (1.8)	0	0
Ventricular tachycardia	1 (1.8)	0	0
Eye disorders			
-Total	2 (3.5)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Papilloedema	1 (1.8)	0	0
Vision blurred	1 (1.8)	0	0
Gastrointestinal disorders			
-Total	5 (8.8)	3 (5.3)	0
Diarrhoea	1 (1.8)	0	0
Intestinal obstruction	1 (1.8)	1 (1.8)	0
Pancreatitis	1 (1.8)	1 (1.8)	0
Stomatitis	1 (1.8)	0	0
Vomiting	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions			
-Total	4 (7.0)	1 (1.8)	0
Pyrexia	2 (3.5)	0	0
Malaise	1 (1.8)	0	0
Physical deconditioning	1 (1.8)	1 (1.8)	0
Immune system disorders			
-Total	36 (63.2)	8 (14.0)	7 (12.3)
Cytokine release syndrome	36 (63.2)	8 (14.0)	7 (12.3)
Infections and infestations			

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (15.8)	4 (7.0)	1 (1.8)
Clostridium difficile colitis	2 (3.5)	0	0
Clostridium difficile infection	2 (3.5)	0	0
Catheter site infection	1 (1.8)	1 (1.8)	0
Gastroenteritis	1 (1.8)	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	0	0
Pneumonia	1 (1.8)	1 (1.8)	0
Rhinovirus infection	1 (1.8)	0	0
Septic embolus	1 (1.8)	0	1 (1.8)
Staphylococcal infection	1 (1.8)	1 (1.8)	0
Injury, poisoning and procedural complications			
-Total	1 (1.8)	0	1 (1.8)
Transfusion related complication	1 (1.8)	0	1 (1.8)
Metabolism and nutrition disorders			
-Total	3 (5.3)	3 (5.3)	0
Acidosis	1 (1.8)	0	0
Decreased appetite	1 (1.8)	1 (1.8)	0
Dehydration	1 (1.8)	1 (1.8)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (1.8)	1 (1.8)	0
Nervous system disorders			
-Total	9 (15.8)	3 (5.3)	1 (1.8)
Encephalopathy	4 (7.0)	2 (3.5)	0
Seizure	3 (5.3)	1 (1.8)	0
Embolic stroke	1 (1.8)	0	1 (1.8)
Headache	1 (1.8)	1 (1.8)	0
Idiopathic intracranial hypertension	1 (1.8)	0	0
Psychiatric disorders			
-Total	1 (1.8)	0	0
Delirium	1 (1.8)	0	0
Renal and urinary disorders			
-Total	3 (5.3)	2 (3.5)	1 (1.8)
Acute kidney injury	3 (5.3)	2 (3.5)	1 (1.8)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (12.3)	1 (1.8)	3 (5.3)
Hypoxia	4 (7.0)	1 (1.8)	1 (1.8)
Pleural effusion	2 (3.5)	1 (1.8)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	2 (3.5)	0	2 (3.5)
Pulmonary oedema	1 (1.8)	0	1 (1.8)
Skin and subcutaneous tissue disorders			
-Total	1 (1.8)	1 (1.8)	0
Ecchymosis	1 (1.8)	1 (1.8)	0
Vascular disorders			
-Total	6 (10.5)	3 (5.3)	3 (5.3)
Hypotension	5 (8.8)	2 (3.5)	3 (5.3)
Embolism	1 (1.8)	1 (1.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179e
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (40.0)	1 (20.0)	0
Gastrointestinal disorders			
-Total	1 (20.0)	1 (20.0)	0
Enterocolitis	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
-Total	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	0
Infections and infestations			
-Total	1 (20.0)	1 (20.0)	0
Corona virus infection	1 (20.0)	1 (20.0)	0
Respiratory syncytial virus infection	1 (20.0)	1 (20.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179e
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=51	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (37.3)	12 (23.5)	5 (9.8)
Blood and lymphatic system disorders			
-Total	5 (9.8)	3 (5.9)	2 (3.9)
Febrile neutropenia	3 (5.9)	3 (5.9)	0
Neutropenia	2 (3.9)	0	2 (3.9)
Eosinophilia	1 (2.0)	1 (2.0)	0
Gastrointestinal disorders			
-Total	1 (2.0)	1 (2.0)	0
Vomiting	1 (2.0)	1 (2.0)	0
General disorders and administration site conditions			
-Total	4 (7.8)	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	4 (7.8)	1 (2.0)	0
Immune system disorders			
-Total	1 (2.0)	0	0
Graft versus host disease in gastrointestinal tract	1 (2.0)	0	0
Infections and infestations			
-Total	11 (21.6)	8 (15.7)	2 (3.9)
Bacterial sepsis	1 (2.0)	0	1 (2.0)
Cellulitis of male external genital organ	1 (2.0)	1 (2.0)	0
Cholecystitis infective	1 (2.0)	1 (2.0)	0
Enterovirus infection	1 (2.0)	1 (2.0)	0
Gastroenteritis norovirus	1 (2.0)	0	0
Herpes zoster	1 (2.0)	1 (2.0)	0
Parainfluenzae virus infection	1 (2.0)	1 (2.0)	0
Rotavirus infection	1 (2.0)	1 (2.0)	0
Sepsis	1 (2.0)	0	1 (2.0)
Upper respiratory tract infection	1 (2.0)	1 (2.0)	0
Vascular device infection	1 (2.0)	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (2.0)	1 (2.0)	0
Investigations			
-Total	2 (3.9)	1 (2.0)	1 (2.0)
Alanine aminotransferase increased	1 (2.0)	1 (2.0)	0
White blood cell count decreased	1 (2.0)	0	1 (2.0)
Metabolism and nutrition disorders			
-Total	1 (2.0)	1 (2.0)	0
Tumour lysis syndrome	1 (2.0)	1 (2.0)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (5.9)	0	0
Flank pain	1 (2.0)	0	0
Osteonecrosis	1 (2.0)	0	0
Pain in extremity	1 (2.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.0)	0	0
Myelodysplastic syndrome	1 (2.0)	0	0
Renal and urinary disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.0)	1 (2.0)	0
Acute kidney injury	1 (2.0)	1 (2.0)	0
Reproductive system and breast disorders			
-Total	1 (2.0)	1 (2.0)	0
Vaginal haemorrhage	1 (2.0)	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.9)	1 (2.0)	1 (2.0)
Acute respiratory failure	1 (2.0)	0	1 (2.0)
Pulmonary oedema	1 (2.0)	1 (2.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179e
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=29	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (20.7)	2 (6.9)	3 (10.3)
Blood and lymphatic system disorders			
-Total	1 (3.4)	0	1 (3.4)
Febrile neutropenia	1 (3.4)	0	1 (3.4)
Gastrointestinal disorders			
-Total	1 (3.4)	0	0
Diarrhoea	1 (3.4)	0	0
Infections and infestations			
-Total	4 (13.8)	2 (6.9)	1 (3.4)
Urinary tract infection	2 (6.9)	1 (3.4)	0
Campylobacter infection	1 (3.4)	1 (3.4)	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (3.4)	1 (3.4)	0
Clostridium difficile infection	1 (3.4)	1 (3.4)	0
Pneumonia	1 (3.4)	0	0
Respiratory tract infection	1 (3.4)	0	1 (3.4)
Respiratory tract infection viral	1 (3.4)	1 (3.4)	0
Vulvovaginal candidiasis	1 (3.4)	0	0
Injury, poisoning and procedural complications			
-Total	1 (3.4)	1 (3.4)	0
Procedural pain	1 (3.4)	1 (3.4)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.4)	0	1 (3.4)
Glioblastoma multiforme	1 (3.4)	0	1 (3.4)
Nervous system disorders			
-Total	1 (3.4)	1 (3.4)	0
Seizure	1 (3.4)	1 (3.4)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179e
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	2 (28.6)	3 (42.9)
Blood and lymphatic system disorders			
-Total	2 (28.6)	2 (28.6)	0
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Gastrointestinal disorders			
-Total	1 (14.3)	1 (14.3)	0
Enterocolitis	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	1 (14.3)	0	0
Pyrexia	1 (14.3)	0	0
Immune system disorders			

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (71.4)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	3 (42.9)
Infections and infestations			
-Total	1 (14.3)	1 (14.3)	0
Corona virus infection	1 (14.3)	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	1 (14.3)	0	1 (14.3)
Renal failure	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)
Vascular disorders			
-Total	2 (28.6)	2 (28.6)	0
Hypotension	2 (28.6)	2 (28.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179e
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=57	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	47 (82.5)	19 (33.3)	21 (36.8)
Blood and lymphatic system disorders			
-Total	25 (43.9)	20 (35.1)	4 (7.0)
Febrile neutropenia	21 (36.8)	20 (35.1)	1 (1.8)
Neutropenia	3 (5.3)	0	3 (5.3)
Disseminated intravascular coagulation	2 (3.5)	0	0
Eosinophilia	1 (1.8)	1 (1.8)	0
Cardiac disorders			
-Total	2 (3.5)	0	0
Atrioventricular block second degree	1 (1.8)	0	0
Ventricular tachycardia	1 (1.8)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders			
-Total	2 (3.5)	0	0
Papilloedema	1 (1.8)	0	0
Vision blurred	1 (1.8)	0	0
Gastrointestinal disorders			
-Total	6 (10.5)	3 (5.3)	0
Diarrhoea	2 (3.5)	0	0
Intestinal obstruction	1 (1.8)	1 (1.8)	0
Pancreatitis	1 (1.8)	1 (1.8)	0
Stomatitis	1 (1.8)	0	0
Vomiting	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions			
-Total	8 (14.0)	2 (3.5)	0
Pyrexia	6 (10.5)	1 (1.8)	0
Malaise	1 (1.8)	0	0
Physical deconditioning	1 (1.8)	1 (1.8)	0
Immune system disorders			
-Total	36 (63.2)	8 (14.0)	7 (12.3)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	36 (63.2)	8 (14.0)	7 (12.3)
Graft versus host disease in gastrointestinal tract	1 (1.8)	0	0
Infections and infestations			
-Total	18 (31.6)	10 (17.5)	4 (7.0)
Clostridium difficile infection	3 (5.3)	1 (1.8)	0
Clostridium difficile colitis	2 (3.5)	0	0
Pneumonia	2 (3.5)	1 (1.8)	0
Urinary tract infection	2 (3.5)	1 (1.8)	0
Bacterial sepsis	1 (1.8)	0	1 (1.8)
Campylobacter infection	1 (1.8)	1 (1.8)	0
Catheter site infection	1 (1.8)	1 (1.8)	0
Cellulitis of male external genital organ	1 (1.8)	1 (1.8)	0
Cholecystitis infective	1 (1.8)	1 (1.8)	0
Enterovirus infection	1 (1.8)	1 (1.8)	0
Gastroenteritis	1 (1.8)	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	0	0
Herpes zoster	1 (1.8)	1 (1.8)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (1.8)	1 (1.8)	0
Respiratory tract infection	1 (1.8)	0	1 (1.8)
Respiratory tract infection viral	1 (1.8)	1 (1.8)	0
Rhinovirus infection	1 (1.8)	0	0
Rotavirus infection	1 (1.8)	1 (1.8)	0
Sepsis	1 (1.8)	0	1 (1.8)
Septic embolus	1 (1.8)	0	1 (1.8)
Staphylococcal infection	1 (1.8)	1 (1.8)	0
Upper respiratory tract infection	1 (1.8)	1 (1.8)	0
Vascular device infection	1 (1.8)	1 (1.8)	0
Viral upper respiratory tract infection	1 (1.8)	1 (1.8)	0
Vulvovaginal candidiasis	1 (1.8)	0	0
Injury, poisoning and procedural complications			
-Total	2 (3.5)	1 (1.8)	1 (1.8)
Procedural pain	1 (1.8)	1 (1.8)	0
Transfusion related complication	1 (1.8)	0	1 (1.8)
Investigations			
-Total	2 (3.5)	1 (1.8)	1 (1.8)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (1.8)	1 (1.8)	0
White blood cell count decreased	1 (1.8)	0	1 (1.8)
Metabolism and nutrition disorders			
-Total	4 (7.0)	4 (7.0)	0
Tumour lysis syndrome	2 (3.5)	2 (3.5)	0
Acidosis	1 (1.8)	0	0
Decreased appetite	1 (1.8)	1 (1.8)	0
Dehydration	1 (1.8)	1 (1.8)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (5.3)	0	0
Flank pain	1 (1.8)	0	0
Osteonecrosis	1 (1.8)	0	0
Pain in extremity	1 (1.8)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (3.5)	0	1 (1.8)
Glioblastoma multiforme	1 (1.8)	0	1 (1.8)
Myelodysplastic syndrome	1 (1.8)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	10 (17.5)	4 (7.0)	1 (1.8)
Encephalopathy	4 (7.0)	2 (3.5)	0
Seizure	4 (7.0)	2 (3.5)	0
Embolic stroke	1 (1.8)	0	1 (1.8)
Headache	1 (1.8)	1 (1.8)	0
Idiopathic intracranial hypertension	1 (1.8)	0	0
Psychiatric disorders			
-Total	1 (1.8)	0	0
Delirium	1 (1.8)	0	0
Renal and urinary disorders			
-Total	4 (7.0)	3 (5.3)	1 (1.8)
Acute kidney injury	4 (7.0)	3 (5.3)	1 (1.8)
Reproductive system and breast disorders			
-Total	1 (1.8)	1 (1.8)	0
Vaginal haemorrhage	1 (1.8)	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders			

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (15.8)	2 (3.5)	4 (7.0)
Hypoxia	4 (7.0)	1 (1.8)	1 (1.8)
Pleural effusion	2 (3.5)	1 (1.8)	0
Pulmonary oedema	2 (3.5)	1 (1.8)	1 (1.8)
Respiratory failure	2 (3.5)	0	2 (3.5)
Acute respiratory failure	1 (1.8)	0	1 (1.8)
Skin and subcutaneous tissue disorders			
-Total	1 (1.8)	1 (1.8)	0
Ecchymosis	1 (1.8)	1 (1.8)	0
Vascular disorders			
-Total	6 (10.5)	3 (5.3)	3 (5.3)
Hypotension	5 (8.8)	2 (3.5)	3 (5.3)
Embolism	1 (1.8)	1 (1.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179f
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (74.2)	20 (32.3)	17 (27.4)
Blood and lymphatic system disorders			
-Total	23 (37.1)	21 (33.9)	1 (1.6)
Febrile neutropenia	21 (33.9)	21 (33.9)	0
Disseminated intravascular coagulation	2 (3.2)	0	0
Neutropenia	1 (1.6)	0	1 (1.6)
Cardiac disorders			
-Total	2 (3.2)	0	0
Atrioventricular block second degree	1 (1.6)	0	0
Ventricular tachycardia	1 (1.6)	0	0
Eye disorders			
-Total	2 (3.2)	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Papilloedema	1 (1.6)	0	0
Vision blurred	1 (1.6)	0	0
Gastrointestinal disorders			
-Total	5 (8.1)	3 (4.8)	0
Diarrhoea	1 (1.6)	0	0
Intestinal obstruction	1 (1.6)	1 (1.6)	0
Pancreatitis	1 (1.6)	1 (1.6)	0
Stomatitis	1 (1.6)	0	0
Vomiting	1 (1.6)	1 (1.6)	0
General disorders and administration site conditions			
-Total	4 (6.5)	1 (1.6)	0
Pyrexia	2 (3.2)	0	0
Malaise	1 (1.6)	0	0
Physical deconditioning	1 (1.6)	1 (1.6)	0
Immune system disorders			
-Total	41 (66.1)	8 (12.9)	10 (16.1)
Cytokine release syndrome	41 (66.1)	8 (12.9)	10 (16.1)
Infections and infestations			

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (14.5)	4 (6.5)	1 (1.6)
Clostridium difficile colitis	2 (3.2)	0	0
Clostridium difficile infection	2 (3.2)	0	0
Catheter site infection	1 (1.6)	1 (1.6)	0
Gastroenteritis	1 (1.6)	1 (1.6)	0
Gastroenteritis norovirus	1 (1.6)	0	0
Pneumonia	1 (1.6)	1 (1.6)	0
Rhinovirus infection	1 (1.6)	0	0
Septic embolus	1 (1.6)	0	1 (1.6)
Staphylococcal infection	1 (1.6)	1 (1.6)	0
Injury, poisoning and procedural complications			
-Total	1 (1.6)	0	1 (1.6)
Transfusion related complication	1 (1.6)	0	1 (1.6)
Metabolism and nutrition disorders			
-Total	3 (4.8)	3 (4.8)	0
Acidosis	1 (1.6)	0	0
Decreased appetite	1 (1.6)	1 (1.6)	0
Dehydration	1 (1.6)	1 (1.6)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (1.6)	1 (1.6)	0
Nervous system disorders			
-Total	9 (14.5)	3 (4.8)	1 (1.6)
Encephalopathy	4 (6.5)	2 (3.2)	0
Seizure	3 (4.8)	1 (1.6)	0
Embolic stroke	1 (1.6)	0	1 (1.6)
Headache	1 (1.6)	1 (1.6)	0
Idiopathic intracranial hypertension	1 (1.6)	0	0
Psychiatric disorders			
-Total	1 (1.6)	0	0
Delirium	1 (1.6)	0	0
Renal and urinary disorders			
-Total	4 (6.5)	2 (3.2)	2 (3.2)
Acute kidney injury	3 (4.8)	2 (3.2)	1 (1.6)
Renal failure	1 (1.6)	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (12.9)	1 (1.6)	4 (6.5)
Hypoxia	4 (6.5)	1 (1.6)	1 (1.6)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	3 (4.8)	0	3 (4.8)
Pleural effusion	2 (3.2)	1 (1.6)	0
Pulmonary oedema	1 (1.6)	0	1 (1.6)
Skin and subcutaneous tissue disorders			
-Total	1 (1.6)	1 (1.6)	0
Ecchymosis	1 (1.6)	1 (1.6)	0
Vascular disorders			
-Total	8 (12.9)	5 (8.1)	3 (4.8)
Hypotension	7 (11.3)	4 (6.5)	3 (4.8)
Embolism	1 (1.6)	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179f
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
Blood and lymphatic system disorders			
-Total	1 (50.0)	0	1 (50.0)
Eosinophilia	1 (50.0)	1 (50.0)	0
Neutropenia	1 (50.0)	0	1 (50.0)
General disorders and administration site conditions			
-Total	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	1 (50.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179f
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=54	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (37.0)	13 (24.1)	4 (7.4)
Blood and lymphatic system disorders			
-Total	4 (7.4)	3 (5.6)	1 (1.9)
Febrile neutropenia	3 (5.6)	3 (5.6)	0
Neutropenia	1 (1.9)	0	1 (1.9)
Gastrointestinal disorders			
-Total	2 (3.7)	2 (3.7)	0
Enterocolitis	1 (1.9)	1 (1.9)	0
Vomiting	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	4 (7.4)	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	4 (7.4)	1 (1.9)	0
Immune system disorders			
-Total	1 (1.9)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.9)	0	0
Infections and infestations			
-Total	11 (20.4)	8 (14.8)	2 (3.7)
Bacterial sepsis	1 (1.9)	0	1 (1.9)
Cholecystitis infective	1 (1.9)	1 (1.9)	0
Corona virus infection	1 (1.9)	1 (1.9)	0
Enterovirus infection	1 (1.9)	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	0
Herpes zoster	1 (1.9)	1 (1.9)	0
Parainfluenzae virus infection	1 (1.9)	1 (1.9)	0
Respiratory syncytial virus infection	1 (1.9)	1 (1.9)	0
Rotavirus infection	1 (1.9)	1 (1.9)	0
Sepsis	1 (1.9)	0	1 (1.9)
Upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Vascular device infection	1 (1.9)	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Investigations			
-Total	2 (3.7)	1 (1.9)	1 (1.9)
Alanine aminotransferase increased	1 (1.9)	1 (1.9)	0
White blood cell count decreased	1 (1.9)	0	1 (1.9)
Metabolism and nutrition disorders			
-Total	1 (1.9)	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	1 (1.9)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (5.6)	0	0
Flank pain	1 (1.9)	0	0
Osteonecrosis	1 (1.9)	0	0
Pain in extremity	1 (1.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.9)	0	0
Myelodysplastic syndrome	1 (1.9)	0	0
Renal and urinary disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.9)	1 (1.9)	0
Acute kidney injury	1 (1.9)	1 (1.9)	0
Reproductive system and breast disorders			
-Total	1 (1.9)	1 (1.9)	0
Vaginal haemorrhage	1 (1.9)	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.7)	1 (1.9)	1 (1.9)
Acute respiratory failure	1 (1.9)	0	1 (1.9)
Pulmonary oedema	1 (1.9)	1 (1.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179f
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Gastrointestinal disorders			
-Total	1 (100)	0	0
Diarrhoea	1 (100)	0	0
Infections and infestations			
-Total	1 (100)	1 (100)	0
Cellulitis of male external genital organ	1 (100)	1 (100)	0
Urinary tract infection	1 (100)	1 (100)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients

column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179f
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (15.2)	1 (3.0)	3 (9.1)
Blood and lymphatic system disorders			
-Total	1 (3.0)	0	1 (3.0)
Febrile neutropenia	1 (3.0)	0	1 (3.0)
Infections and infestations			
-Total	3 (9.1)	1 (3.0)	1 (3.0)
Campylobacter infection	1 (3.0)	1 (3.0)	0
Clostridium difficile infection	1 (3.0)	1 (3.0)	0
Pneumonia	1 (3.0)	0	0
Respiratory tract infection	1 (3.0)	0	1 (3.0)
Respiratory tract infection viral	1 (3.0)	1 (3.0)	0
Urinary tract infection	1 (3.0)	0	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal candidiasis	1 (3.0)	0	0
Injury, poisoning and procedural complications			
-Total	1 (3.0)	1 (3.0)	0
Procedural pain	1 (3.0)	1 (3.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.0)	0	1 (3.0)
Glioblastoma multiforme	1 (3.0)	0	1 (3.0)
Nervous system disorders			
-Total	1 (3.0)	1 (3.0)	0
Seizure	1 (3.0)	1 (3.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179f
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
Blood and lymphatic system disorders			
-Total	1 (50.0)	0	1 (50.0)
Eosinophilia	1 (50.0)	1 (50.0)	0
Neutropenia	1 (50.0)	0	1 (50.0)
Gastrointestinal disorders			
-Total	1 (50.0)	0	0
Diarrhoea	1 (50.0)	0	0
General disorders and administration site conditions			
-Total	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	1 (50.0)	0
Urinary tract infection	1 (50.0)	1 (50.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179f
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (82.3)	21 (33.9)	23 (37.1)
Blood and lymphatic system disorders			
-Total	26 (41.9)	22 (35.5)	3 (4.8)
Febrile neutropenia	23 (37.1)	22 (35.5)	1 (1.6)
Disseminated intravascular coagulation	2 (3.2)	0	0
Neutropenia	2 (3.2)	0	2 (3.2)
Cardiac disorders			
-Total	2 (3.2)	0	0
Atrioventricular block second degree	1 (1.6)	0	0
Ventricular tachycardia	1 (1.6)	0	0
Eye disorders			

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (3.2)	0	0
Papilloedema	1 (1.6)	0	0
Vision blurred	1 (1.6)	0	0
Gastrointestinal disorders			
-Total	6 (9.7)	4 (6.5)	0
Diarrhoea	1 (1.6)	0	0
Enterocolitis	1 (1.6)	1 (1.6)	0
Intestinal obstruction	1 (1.6)	1 (1.6)	0
Pancreatitis	1 (1.6)	1 (1.6)	0
Stomatitis	1 (1.6)	0	0
Vomiting	1 (1.6)	1 (1.6)	0
General disorders and administration site conditions			
-Total	8 (12.9)	2 (3.2)	0
Pyrexia	6 (9.7)	1 (1.6)	0
Malaise	1 (1.6)	0	0
Physical deconditioning	1 (1.6)	1 (1.6)	0
Immune system disorders			
-Total	41 (66.1)	8 (12.9)	10 (16.1)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	41 (66.1)	8 (12.9)	10 (16.1)
Graft versus host disease in gastrointestinal tract	1 (1.6)	0	0
Infections and infestations			
-Total	18 (29.0)	10 (16.1)	4 (6.5)
Clostridium difficile infection	3 (4.8)	1 (1.6)	0
Clostridium difficile colitis	2 (3.2)	0	0
Pneumonia	2 (3.2)	1 (1.6)	0
Bacterial sepsis	1 (1.6)	0	1 (1.6)
Campylobacter infection	1 (1.6)	1 (1.6)	0
Catheter site infection	1 (1.6)	1 (1.6)	0
Cholecystitis infective	1 (1.6)	1 (1.6)	0
Corona virus infection	1 (1.6)	1 (1.6)	0
Enterovirus infection	1 (1.6)	1 (1.6)	0
Gastroenteritis	1 (1.6)	1 (1.6)	0
Gastroenteritis norovirus	1 (1.6)	0	0
Herpes zoster	1 (1.6)	1 (1.6)	0
Parainfluenzae virus infection	1 (1.6)	1 (1.6)	0
Respiratory syncytial virus infection	1 (1.6)	1 (1.6)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	1 (1.6)	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	1 (1.6)	0
Rhinovirus infection	1 (1.6)	0	0
Rotavirus infection	1 (1.6)	1 (1.6)	0
Sepsis	1 (1.6)	0	1 (1.6)
Septic embolus	1 (1.6)	0	1 (1.6)
Staphylococcal infection	1 (1.6)	1 (1.6)	0
Upper respiratory tract infection	1 (1.6)	1 (1.6)	0
Urinary tract infection	1 (1.6)	0	0
Vascular device infection	1 (1.6)	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	1 (1.6)	0
Vulvovaginal candidiasis	1 (1.6)	0	0
Injury, poisoning and procedural complications			
-Total	2 (3.2)	1 (1.6)	1 (1.6)
Procedural pain	1 (1.6)	1 (1.6)	0
Transfusion related complication	1 (1.6)	0	1 (1.6)
Investigations			
-Total	2 (3.2)	1 (1.6)	1 (1.6)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (1.6)	1 (1.6)	0
White blood cell count decreased	1 (1.6)	0	1 (1.6)
Metabolism and nutrition disorders			
-Total	4 (6.5)	4 (6.5)	0
Tumour lysis syndrome	2 (3.2)	2 (3.2)	0
Acidosis	1 (1.6)	0	0
Decreased appetite	1 (1.6)	1 (1.6)	0
Dehydration	1 (1.6)	1 (1.6)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (4.8)	0	0
Flank pain	1 (1.6)	0	0
Osteonecrosis	1 (1.6)	0	0
Pain in extremity	1 (1.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (3.2)	0	1 (1.6)
Glioblastoma multiforme	1 (1.6)	0	1 (1.6)
Myelodysplastic syndrome	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	10 (16.1)	4 (6.5)	1 (1.6)
Encephalopathy	4 (6.5)	2 (3.2)	0
Seizure	4 (6.5)	2 (3.2)	0
Embolic stroke	1 (1.6)	0	1 (1.6)
Headache	1 (1.6)	1 (1.6)	0
Idiopathic intracranial hypertension	1 (1.6)	0	0
Psychiatric disorders			
-Total	1 (1.6)	0	0
Delirium	1 (1.6)	0	0
Renal and urinary disorders			
-Total	5 (8.1)	3 (4.8)	2 (3.2)
Acute kidney injury	4 (6.5)	3 (4.8)	1 (1.6)
Renal failure	1 (1.6)	0	1 (1.6)
Reproductive system and breast disorders			
-Total	1 (1.6)	1 (1.6)	0
Vaginal haemorrhage	1 (1.6)	1 (1.6)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	10 (16.1)	2 (3.2)	5 (8.1)
Hypoxia	4 (6.5)	1 (1.6)	1 (1.6)
Respiratory failure	3 (4.8)	0	3 (4.8)
Pleural effusion	2 (3.2)	1 (1.6)	0
Pulmonary oedema	2 (3.2)	1 (1.6)	1 (1.6)
Acute respiratory failure	1 (1.6)	0	1 (1.6)
Skin and subcutaneous tissue disorders			
-Total	1 (1.6)	1 (1.6)	0
Ecchymosis	1 (1.6)	1 (1.6)	0
Vascular disorders			
-Total	8 (12.9)	5 (8.1)	3 (4.8)
Hypotension	7 (11.3)	4 (6.5)	3 (4.8)
Embolism	1 (1.6)	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients

column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179g
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	2 (66.7)
Immune system disorders			
-Total	2 (66.7)	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	2 (66.7)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179g
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	44 (72.1)	20 (32.8)	15 (24.6)
Blood and lymphatic system disorders			
-Total	23 (37.7)	21 (34.4)	1 (1.6)
Febrile neutropenia	21 (34.4)	21 (34.4)	0
Disseminated intravascular coagulation	2 (3.3)	0	0
Neutropenia	1 (1.6)	0	1 (1.6)
Cardiac disorders			
-Total	2 (3.3)	0	0
Atrioventricular block second degree	1 (1.6)	0	0
Ventricular tachycardia	1 (1.6)	0	0
Eye disorders			
-Total	2 (3.3)	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Papilloedema	1 (1.6)	0	0
Vision blurred	1 (1.6)	0	0
Gastrointestinal disorders			
-Total	5 (8.2)	3 (4.9)	0
Diarrhoea	1 (1.6)	0	0
Intestinal obstruction	1 (1.6)	1 (1.6)	0
Pancreatitis	1 (1.6)	1 (1.6)	0
Stomatitis	1 (1.6)	0	0
Vomiting	1 (1.6)	1 (1.6)	0
General disorders and administration site conditions			
-Total	4 (6.6)	1 (1.6)	0
Pyrexia	2 (3.3)	0	0
Malaise	1 (1.6)	0	0
Physical deconditioning	1 (1.6)	1 (1.6)	0
Immune system disorders			
-Total	39 (63.9)	8 (13.1)	8 (13.1)
Cytokine release syndrome	39 (63.9)	8 (13.1)	8 (13.1)
Infections and infestations			

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (14.8)	4 (6.6)	1 (1.6)
Clostridium difficile colitis	2 (3.3)	0	0
Clostridium difficile infection	2 (3.3)	0	0
Catheter site infection	1 (1.6)	1 (1.6)	0
Gastroenteritis	1 (1.6)	1 (1.6)	0
Gastroenteritis norovirus	1 (1.6)	0	0
Pneumonia	1 (1.6)	1 (1.6)	0
Rhinovirus infection	1 (1.6)	0	0
Septic embolus	1 (1.6)	0	1 (1.6)
Staphylococcal infection	1 (1.6)	1 (1.6)	0
Injury, poisoning and procedural complications			
-Total	1 (1.6)	0	1 (1.6)
Transfusion related complication	1 (1.6)	0	1 (1.6)
Metabolism and nutrition disorders			
-Total	3 (4.9)	3 (4.9)	0
Acidosis	1 (1.6)	0	0
Decreased appetite	1 (1.6)	1 (1.6)	0
Dehydration	1 (1.6)	1 (1.6)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (1.6)	1 (1.6)	0
Nervous system disorders			
-Total	9 (14.8)	3 (4.9)	1 (1.6)
Encephalopathy	4 (6.6)	2 (3.3)	0
Seizure	3 (4.9)	1 (1.6)	0
Embolic stroke	1 (1.6)	0	1 (1.6)
Headache	1 (1.6)	1 (1.6)	0
Idiopathic intracranial hypertension	1 (1.6)	0	0
Psychiatric disorders			
-Total	1 (1.6)	0	0
Delirium	1 (1.6)	0	0
Renal and urinary disorders			
-Total	4 (6.6)	2 (3.3)	2 (3.3)
Acute kidney injury	3 (4.9)	2 (3.3)	1 (1.6)
Renal failure	1 (1.6)	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (13.1)	1 (1.6)	4 (6.6)
Hypoxia	4 (6.6)	1 (1.6)	1 (1.6)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	3 (4.9)	0	3 (4.9)
Pleural effusion	2 (3.3)	1 (1.6)	0
Pulmonary oedema	1 (1.6)	0	1 (1.6)
Skin and subcutaneous tissue disorders			
-Total	1 (1.6)	1 (1.6)	0
Ecchymosis	1 (1.6)	1 (1.6)	0
Vascular disorders			
-Total	8 (13.1)	5 (8.2)	3 (4.9)
Hypotension	7 (11.5)	4 (6.6)	3 (4.9)
Embolism	1 (1.6)	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179g
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=54	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (38.9)	13 (24.1)	5 (9.3)
Blood and lymphatic system disorders			
-Total	5 (9.3)	3 (5.6)	2 (3.7)
Febrile neutropenia	3 (5.6)	3 (5.6)	0
Neutropenia	2 (3.7)	0	2 (3.7)
Eosinophilia	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders			
-Total	2 (3.7)	2 (3.7)	0
Enterocolitis	1 (1.9)	1 (1.9)	0
Vomiting	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (9.3)	1 (1.9)	0
Pyrexia	5 (9.3)	1 (1.9)	0
Immune system disorders			
-Total	1 (1.9)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.9)	0	0
Infections and infestations			
-Total	12 (22.2)	9 (16.7)	2 (3.7)
Bacterial sepsis	1 (1.9)	0	1 (1.9)
Cellulitis of male external genital organ	1 (1.9)	1 (1.9)	0
Cholecystitis infective	1 (1.9)	1 (1.9)	0
Corona virus infection	1 (1.9)	1 (1.9)	0
Enterovirus infection	1 (1.9)	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	0
Herpes zoster	1 (1.9)	1 (1.9)	0
Parainfluenzae virus infection	1 (1.9)	1 (1.9)	0
Respiratory syncytial virus infection	1 (1.9)	1 (1.9)	0
Rotavirus infection	1 (1.9)	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (1.9)	0	1 (1.9)
Upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Vascular device infection	1 (1.9)	1 (1.9)	0
Viral upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Investigations			
-Total	2 (3.7)	1 (1.9)	1 (1.9)
Alanine aminotransferase increased	1 (1.9)	1 (1.9)	0
White blood cell count decreased	1 (1.9)	0	1 (1.9)
Metabolism and nutrition disorders			
-Total	1 (1.9)	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	1 (1.9)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (5.6)	0	0
Flank pain	1 (1.9)	0	0
Osteonecrosis	1 (1.9)	0	0
Pain in extremity	1 (1.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.9)	0	0
Myelodysplastic syndrome	1 (1.9)	0	0
Renal and urinary disorders			
-Total	1 (1.9)	1 (1.9)	0
Acute kidney injury	1 (1.9)	1 (1.9)	0
Reproductive system and breast disorders			
-Total	1 (1.9)	1 (1.9)	0
Vaginal haemorrhage	1 (1.9)	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.7)	1 (1.9)	1 (1.9)
Acute respiratory failure	1 (1.9)	0	1 (1.9)
Pulmonary oedema	1 (1.9)	1 (1.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179g
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (18.2)	2 (6.1)	3 (9.1)
Blood and lymphatic system disorders			
-Total	1 (3.0)	0	1 (3.0)
Febrile neutropenia	1 (3.0)	0	1 (3.0)
Gastrointestinal disorders			
-Total	1 (3.0)	0	0
Diarrhoea	1 (3.0)	0	0
Infections and infestations			
-Total	4 (12.1)	2 (6.1)	1 (3.0)
Urinary tract infection	2 (6.1)	1 (3.0)	0
Campylobacter infection	1 (3.0)	1 (3.0)	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (3.0)	1 (3.0)	0
Clostridium difficile infection	1 (3.0)	1 (3.0)	0
Pneumonia	1 (3.0)	0	0
Respiratory tract infection	1 (3.0)	0	1 (3.0)
Respiratory tract infection viral	1 (3.0)	1 (3.0)	0
Vulvovaginal candidiasis	1 (3.0)	0	0
Injury, poisoning and procedural complications			
-Total	1 (3.0)	1 (3.0)	0
Procedural pain	1 (3.0)	1 (3.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.0)	0	1 (3.0)
Glioblastoma multiforme	1 (3.0)	0	1 (3.0)
Nervous system disorders			
-Total	1 (3.0)	1 (3.0)	0
Seizure	1 (3.0)	1 (3.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179g
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	2 (66.7)
Immune system disorders			
-Total	2 (66.7)	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	2 (66.7)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179g
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (82.0)	21 (34.4)	22 (36.1)
Blood and lymphatic system disorders			
-Total	27 (44.3)	22 (36.1)	4 (6.6)
Febrile neutropenia	23 (37.7)	22 (36.1)	1 (1.6)
Neutropenia	3 (4.9)	0	3 (4.9)
Disseminated intravascular coagulation	2 (3.3)	0	0
Eosinophilia	1 (1.6)	1 (1.6)	0
Cardiac disorders			
-Total	2 (3.3)	0	0
Atrioventricular block second degree	1 (1.6)	0	0
Ventricular tachycardia	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders			
-Total	2 (3.3)	0	0
Papilloedema	1 (1.6)	0	0
Vision blurred	1 (1.6)	0	0
Gastrointestinal disorders			
-Total	7 (11.5)	4 (6.6)	0
Diarrhoea	2 (3.3)	0	0
Enterocolitis	1 (1.6)	1 (1.6)	0
Intestinal obstruction	1 (1.6)	1 (1.6)	0
Pancreatitis	1 (1.6)	1 (1.6)	0
Stomatitis	1 (1.6)	0	0
Vomiting	1 (1.6)	1 (1.6)	0
General disorders and administration site conditions			
-Total	9 (14.8)	2 (3.3)	0
Pyrexia	7 (11.5)	1 (1.6)	0
Malaise	1 (1.6)	0	0
Physical deconditioning	1 (1.6)	1 (1.6)	0
Immune system disorders			

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	39 (63.9)	8 (13.1)	8 (13.1)
Cytokine release syndrome	39 (63.9)	8 (13.1)	8 (13.1)
Graft versus host disease in gastrointestinal tract	1 (1.6)	0	0
Infections and infestations			
-Total	19 (31.1)	11 (18.0)	4 (6.6)
Clostridium difficile infection	3 (4.9)	1 (1.6)	0
Clostridium difficile colitis	2 (3.3)	0	0
Pneumonia	2 (3.3)	1 (1.6)	0
Urinary tract infection	2 (3.3)	1 (1.6)	0
Bacterial sepsis	1 (1.6)	0	1 (1.6)
Campylobacter infection	1 (1.6)	1 (1.6)	0
Catheter site infection	1 (1.6)	1 (1.6)	0
Cellulitis of male external genital organ	1 (1.6)	1 (1.6)	0
Cholecystitis infective	1 (1.6)	1 (1.6)	0
Corona virus infection	1 (1.6)	1 (1.6)	0
Enterovirus infection	1 (1.6)	1 (1.6)	0
Gastroenteritis	1 (1.6)	1 (1.6)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (1.6)	0	0
Herpes zoster	1 (1.6)	1 (1.6)	0
Parainfluenzae virus infection	1 (1.6)	1 (1.6)	0
Respiratory syncytial virus infection	1 (1.6)	1 (1.6)	0
Respiratory tract infection	1 (1.6)	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	1 (1.6)	0
Rhinovirus infection	1 (1.6)	0	0
Rotavirus infection	1 (1.6)	1 (1.6)	0
Sepsis	1 (1.6)	0	1 (1.6)
Septic embolus	1 (1.6)	0	1 (1.6)
Staphylococcal infection	1 (1.6)	1 (1.6)	0
Upper respiratory tract infection	1 (1.6)	1 (1.6)	0
Vascular device infection	1 (1.6)	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	1 (1.6)	0
Vulvovaginal candidiasis	1 (1.6)	0	0
Injury, poisoning and procedural complications			
-Total	2 (3.3)	1 (1.6)	1 (1.6)
Procedural pain	1 (1.6)	1 (1.6)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion related complication	1 (1.6)	0	1 (1.6)
Investigations			
-Total	2 (3.3)	1 (1.6)	1 (1.6)
Alanine aminotransferase increased	1 (1.6)	1 (1.6)	0
White blood cell count decreased	1 (1.6)	0	1 (1.6)
Metabolism and nutrition disorders			
-Total	4 (6.6)	4 (6.6)	0
Tumour lysis syndrome	2 (3.3)	2 (3.3)	0
Acidosis	1 (1.6)	0	0
Decreased appetite	1 (1.6)	1 (1.6)	0
Dehydration	1 (1.6)	1 (1.6)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (4.9)	0	0
Flank pain	1 (1.6)	0	0
Osteonecrosis	1 (1.6)	0	0
Pain in extremity	1 (1.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (3.3)	0	1 (1.6)
Glioblastoma multiforme	1 (1.6)	0	1 (1.6)
Myelodysplastic syndrome	1 (1.6)	0	0
Nervous system disorders			
-Total	10 (16.4)	4 (6.6)	1 (1.6)
Encephalopathy	4 (6.6)	2 (3.3)	0
Seizure	4 (6.6)	2 (3.3)	0
Embolic stroke	1 (1.6)	0	1 (1.6)
Headache	1 (1.6)	1 (1.6)	0
Idiopathic intracranial hypertension	1 (1.6)	0	0
Psychiatric disorders			
-Total	1 (1.6)	0	0
Delirium	1 (1.6)	0	0
Renal and urinary disorders			
-Total	5 (8.2)	3 (4.9)	2 (3.3)
Acute kidney injury	4 (6.6)	3 (4.9)	1 (1.6)
Renal failure	1 (1.6)	0	1 (1.6)
Reproductive system and breast disorders			

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.6)	1 (1.6)	0
Vaginal haemorrhage	1 (1.6)	1 (1.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	10 (16.4)	2 (3.3)	5 (8.2)
Hypoxia	4 (6.6)	1 (1.6)	1 (1.6)
Respiratory failure	3 (4.9)	0	3 (4.9)
Pleural effusion	2 (3.3)	1 (1.6)	0
Pulmonary oedema	2 (3.3)	1 (1.6)	1 (1.6)
Acute respiratory failure	1 (1.6)	0	1 (1.6)
Skin and subcutaneous tissue disorders			
-Total	1 (1.6)	1 (1.6)	0
Ecchymosis	1 (1.6)	1 (1.6)	0
Vascular disorders			
-Total	8 (13.1)	5 (8.2)	3 (4.9)
Hypotension	7 (11.5)	4 (6.6)	3 (4.9)
Embolism	1 (1.6)	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179h
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Blood and lymphatic system disorders			
-Total	1 (100)	1 (100)	0
Febrile neutropenia	1 (100)	1 (100)	0
Immune system disorders			
-Total	1 (100)	0	0
Cytokine release syndrome	1 (100)	0	0
Nervous system disorders			
-Total	1 (100)	0	0
Encephalopathy	1 (100)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179h
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (71.4)	19 (30.2)	17 (27.0)
Blood and lymphatic system disorders			
-Total	22 (34.9)	20 (31.7)	1 (1.6)
Febrile neutropenia	20 (31.7)	20 (31.7)	0
Disseminated intravascular coagulation	2 (3.2)	0	0
Neutropenia	1 (1.6)	0	1 (1.6)
Cardiac disorders			
-Total	2 (3.2)	0	0
Atrioventricular block second degree	1 (1.6)	0	0
Ventricular tachycardia	1 (1.6)	0	0
Eye disorders			
-Total	2 (3.2)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Papilloedema	1 (1.6)	0	0
Vision blurred	1 (1.6)	0	0
Gastrointestinal disorders			
-Total	5 (7.9)	3 (4.8)	0
Diarrhoea	1 (1.6)	0	0
Intestinal obstruction	1 (1.6)	1 (1.6)	0
Pancreatitis	1 (1.6)	1 (1.6)	0
Stomatitis	1 (1.6)	0	0
Vomiting	1 (1.6)	1 (1.6)	0
General disorders and administration site conditions			
-Total	4 (6.3)	1 (1.6)	0
Pyrexia	2 (3.2)	0	0
Malaise	1 (1.6)	0	0
Physical deconditioning	1 (1.6)	1 (1.6)	0
Immune system disorders			
-Total	40 (63.5)	8 (12.7)	10 (15.9)
Cytokine release syndrome	40 (63.5)	8 (12.7)	10 (15.9)
Infections and infestations			

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (14.3)	4 (6.3)	1 (1.6)
Clostridium difficile colitis	2 (3.2)	0	0
Clostridium difficile infection	2 (3.2)	0	0
Catheter site infection	1 (1.6)	1 (1.6)	0
Gastroenteritis	1 (1.6)	1 (1.6)	0
Gastroenteritis norovirus	1 (1.6)	0	0
Pneumonia	1 (1.6)	1 (1.6)	0
Rhinovirus infection	1 (1.6)	0	0
Septic embolus	1 (1.6)	0	1 (1.6)
Staphylococcal infection	1 (1.6)	1 (1.6)	0
Injury, poisoning and procedural complications			
-Total	1 (1.6)	0	1 (1.6)
Transfusion related complication	1 (1.6)	0	1 (1.6)
Metabolism and nutrition disorders			
-Total	3 (4.8)	3 (4.8)	0
Acidosis	1 (1.6)	0	0
Decreased appetite	1 (1.6)	1 (1.6)	0
Dehydration	1 (1.6)	1 (1.6)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (1.6)	1 (1.6)	0
Nervous system disorders			
-Total	8 (12.7)	3 (4.8)	1 (1.6)
Encephalopathy	3 (4.8)	2 (3.2)	0
Seizure	3 (4.8)	1 (1.6)	0
Embolic stroke	1 (1.6)	0	1 (1.6)
Headache	1 (1.6)	1 (1.6)	0
Idiopathic intracranial hypertension	1 (1.6)	0	0
Psychiatric disorders			
-Total	1 (1.6)	0	0
Delirium	1 (1.6)	0	0
Renal and urinary disorders			
-Total	4 (6.3)	2 (3.2)	2 (3.2)
Acute kidney injury	3 (4.8)	2 (3.2)	1 (1.6)
Renal failure	1 (1.6)	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (12.7)	1 (1.6)	4 (6.3)
Hypoxia	4 (6.3)	1 (1.6)	1 (1.6)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	3 (4.8)	0	3 (4.8)
Pleural effusion	2 (3.2)	1 (1.6)	0
Pulmonary oedema	1 (1.6)	0	1 (1.6)
Skin and subcutaneous tissue disorders			
-Total	1 (1.6)	1 (1.6)	0
Ecchymosis	1 (1.6)	1 (1.6)	0
Vascular disorders			
-Total	8 (12.7)	5 (7.9)	3 (4.8)
Hypotension	7 (11.1)	4 (6.3)	3 (4.8)
Embolism	1 (1.6)	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179h
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (38.2)	13 (23.6)	5 (9.1)
Blood and lymphatic system disorders			
-Total	5 (9.1)	3 (5.5)	2 (3.6)
Febrile neutropenia	3 (5.5)	3 (5.5)	0
Neutropenia	2 (3.6)	0	2 (3.6)
Eosinophilia	1 (1.8)	1 (1.8)	0
Gastrointestinal disorders			
-Total	2 (3.6)	2 (3.6)	0
Enterocolitis	1 (1.8)	1 (1.8)	0
Vomiting	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions			

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (9.1)	1 (1.8)	0
Pyrexia	5 (9.1)	1 (1.8)	0
Immune system disorders			
-Total	1 (1.8)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.8)	0	0
Infections and infestations			
-Total	12 (21.8)	9 (16.4)	2 (3.6)
Bacterial sepsis	1 (1.8)	0	1 (1.8)
Cellulitis of male external genital organ	1 (1.8)	1 (1.8)	0
Cholecystitis infective	1 (1.8)	1 (1.8)	0
Corona virus infection	1 (1.8)	1 (1.8)	0
Enterovirus infection	1 (1.8)	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	0	0
Herpes zoster	1 (1.8)	1 (1.8)	0
Parainfluenzae virus infection	1 (1.8)	1 (1.8)	0
Respiratory syncytial virus infection	1 (1.8)	1 (1.8)	0
Rotavirus infection	1 (1.8)	1 (1.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (1.8)	0	1 (1.8)
Upper respiratory tract infection	1 (1.8)	1 (1.8)	0
Vascular device infection	1 (1.8)	1 (1.8)	0
Viral upper respiratory tract infection	1 (1.8)	1 (1.8)	0
Investigations			
-Total	2 (3.6)	1 (1.8)	1 (1.8)
Alanine aminotransferase increased	1 (1.8)	1 (1.8)	0
White blood cell count decreased	1 (1.8)	0	1 (1.8)
Metabolism and nutrition disorders			
-Total	1 (1.8)	1 (1.8)	0
Tumour lysis syndrome	1 (1.8)	1 (1.8)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (5.5)	0	0
Flank pain	1 (1.8)	0	0
Osteonecrosis	1 (1.8)	0	0
Pain in extremity	1 (1.8)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.8)	0	0
Myelodysplastic syndrome	1 (1.8)	0	0
Renal and urinary disorders			
-Total	1 (1.8)	1 (1.8)	0
Acute kidney injury	1 (1.8)	1 (1.8)	0
Reproductive system and breast disorders			
-Total	1 (1.8)	1 (1.8)	0
Vaginal haemorrhage	1 (1.8)	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.6)	1 (1.8)	1 (1.8)
Acute respiratory failure	1 (1.8)	0	1 (1.8)
Pulmonary oedema	1 (1.8)	1 (1.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179h
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (18.2)	2 (6.1)	3 (9.1)
Blood and lymphatic system disorders			
-Total	1 (3.0)	0	1 (3.0)
Febrile neutropenia	1 (3.0)	0	1 (3.0)
Gastrointestinal disorders			
-Total	1 (3.0)	0	0
Diarrhoea	1 (3.0)	0	0
Infections and infestations			
-Total	4 (12.1)	2 (6.1)	1 (3.0)
Urinary tract infection	2 (6.1)	1 (3.0)	0
Campylobacter infection	1 (3.0)	1 (3.0)	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (3.0)	1 (3.0)	0
Clostridium difficile infection	1 (3.0)	1 (3.0)	0
Pneumonia	1 (3.0)	0	0
Respiratory tract infection	1 (3.0)	0	1 (3.0)
Respiratory tract infection viral	1 (3.0)	1 (3.0)	0
Vulvovaginal candidiasis	1 (3.0)	0	0
Injury, poisoning and procedural complications			
-Total	1 (3.0)	1 (3.0)	0
Procedural pain	1 (3.0)	1 (3.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.0)	0	1 (3.0)
Glioblastoma multiforme	1 (3.0)	0	1 (3.0)
Nervous system disorders			
-Total	1 (3.0)	1 (3.0)	0
Seizure	1 (3.0)	1 (3.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179h
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Blood and lymphatic system disorders			
-Total	1 (100)	1 (100)	0
Febrile neutropenia	1 (100)	1 (100)	0
Immune system disorders			
-Total	1 (100)	0	0
Cytokine release syndrome	1 (100)	0	0
Nervous system disorders			
-Total	1 (100)	0	0
Encephalopathy	1 (100)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179h
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (81.0)	20 (31.7)	24 (38.1)
Blood and lymphatic system disorders			
-Total	26 (41.3)	21 (33.3)	4 (6.3)
Febrile neutropenia	22 (34.9)	21 (33.3)	1 (1.6)
Neutropenia	3 (4.8)	0	3 (4.8)
Disseminated intravascular coagulation	2 (3.2)	0	0
Eosinophilia	1 (1.6)	1 (1.6)	0
Cardiac disorders			
-Total	2 (3.2)	0	0
Atrioventricular block second degree	1 (1.6)	0	0
Ventricular tachycardia	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders			
-Total	2 (3.2)	0	0
Papilloedema	1 (1.6)	0	0
Vision blurred	1 (1.6)	0	0
Gastrointestinal disorders			
-Total	7 (11.1)	4 (6.3)	0
Diarrhoea	2 (3.2)	0	0
Enterocolitis	1 (1.6)	1 (1.6)	0
Intestinal obstruction	1 (1.6)	1 (1.6)	0
Pancreatitis	1 (1.6)	1 (1.6)	0
Stomatitis	1 (1.6)	0	0
Vomiting	1 (1.6)	1 (1.6)	0
General disorders and administration site conditions			
-Total	9 (14.3)	2 (3.2)	0
Pyrexia	7 (11.1)	1 (1.6)	0
Malaise	1 (1.6)	0	0
Physical deconditioning	1 (1.6)	1 (1.6)	0
Immune system disorders			

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	40 (63.5)	8 (12.7)	10 (15.9)
Cytokine release syndrome	40 (63.5)	8 (12.7)	10 (15.9)
Graft versus host disease in gastrointestinal tract	1 (1.6)	0	0
Infections and infestations			
-Total	19 (30.2)	11 (17.5)	4 (6.3)
Clostridium difficile infection	3 (4.8)	1 (1.6)	0
Clostridium difficile colitis	2 (3.2)	0	0
Pneumonia	2 (3.2)	1 (1.6)	0
Urinary tract infection	2 (3.2)	1 (1.6)	0
Bacterial sepsis	1 (1.6)	0	1 (1.6)
Campylobacter infection	1 (1.6)	1 (1.6)	0
Catheter site infection	1 (1.6)	1 (1.6)	0
Cellulitis of male external genital organ	1 (1.6)	1 (1.6)	0
Cholecystitis infective	1 (1.6)	1 (1.6)	0
Corona virus infection	1 (1.6)	1 (1.6)	0
Enterovirus infection	1 (1.6)	1 (1.6)	0
Gastroenteritis	1 (1.6)	1 (1.6)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (1.6)	0	0
Herpes zoster	1 (1.6)	1 (1.6)	0
Parainfluenzae virus infection	1 (1.6)	1 (1.6)	0
Respiratory syncytial virus infection	1 (1.6)	1 (1.6)	0
Respiratory tract infection	1 (1.6)	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	1 (1.6)	0
Rhinovirus infection	1 (1.6)	0	0
Rotavirus infection	1 (1.6)	1 (1.6)	0
Sepsis	1 (1.6)	0	1 (1.6)
Septic embolus	1 (1.6)	0	1 (1.6)
Staphylococcal infection	1 (1.6)	1 (1.6)	0
Upper respiratory tract infection	1 (1.6)	1 (1.6)	0
Vascular device infection	1 (1.6)	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	1 (1.6)	0
Vulvovaginal candidiasis	1 (1.6)	0	0
Injury, poisoning and procedural complications			
-Total	2 (3.2)	1 (1.6)	1 (1.6)
Procedural pain	1 (1.6)	1 (1.6)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion related complication	1 (1.6)	0	1 (1.6)
Investigations			
-Total	2 (3.2)	1 (1.6)	1 (1.6)
Alanine aminotransferase increased	1 (1.6)	1 (1.6)	0
White blood cell count decreased	1 (1.6)	0	1 (1.6)
Metabolism and nutrition disorders			
-Total	4 (6.3)	4 (6.3)	0
Tumour lysis syndrome	2 (3.2)	2 (3.2)	0
Acidosis	1 (1.6)	0	0
Decreased appetite	1 (1.6)	1 (1.6)	0
Dehydration	1 (1.6)	1 (1.6)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (4.8)	0	0
Flank pain	1 (1.6)	0	0
Osteonecrosis	1 (1.6)	0	0
Pain in extremity	1 (1.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (3.2)	0	1 (1.6)
Glioblastoma multiforme	1 (1.6)	0	1 (1.6)
Myelodysplastic syndrome	1 (1.6)	0	0
Nervous system disorders			
-Total	9 (14.3)	4 (6.3)	1 (1.6)
Seizure	4 (6.3)	2 (3.2)	0
Encephalopathy	3 (4.8)	2 (3.2)	0
Embolic stroke	1 (1.6)	0	1 (1.6)
Headache	1 (1.6)	1 (1.6)	0
Idiopathic intracranial hypertension	1 (1.6)	0	0
Psychiatric disorders			
-Total	1 (1.6)	0	0
Delirium	1 (1.6)	0	0
Renal and urinary disorders			
-Total	5 (7.9)	3 (4.8)	2 (3.2)
Acute kidney injury	4 (6.3)	3 (4.8)	1 (1.6)
Renal failure	1 (1.6)	0	1 (1.6)
Reproductive system and breast disorders			

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.6)	1 (1.6)	0
Vaginal haemorrhage	1 (1.6)	1 (1.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	10 (15.9)	2 (3.2)	5 (7.9)
Hypoxia	4 (6.3)	1 (1.6)	1 (1.6)
Respiratory failure	3 (4.8)	0	3 (4.8)
Pleural effusion	2 (3.2)	1 (1.6)	0
Pulmonary oedema	2 (3.2)	1 (1.6)	1 (1.6)
Acute respiratory failure	1 (1.6)	0	1 (1.6)
Skin and subcutaneous tissue disorders			
-Total	1 (1.6)	1 (1.6)	0
Ecchymosis	1 (1.6)	1 (1.6)	0
Vascular disorders			
-Total	8 (12.7)	5 (7.9)	3 (4.8)
Hypotension	7 (11.1)	4 (6.3)	3 (4.8)
Embolism	1 (1.6)	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179i
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	1 (25.0)	1 (25.0)
Blood and lymphatic system disorders			
-Total	2 (50.0)	2 (50.0)	0
Febrile neutropenia	2 (50.0)	2 (50.0)	0
Gastrointestinal disorders			
-Total	1 (25.0)	0	0
Diarrhoea	1 (25.0)	0	0
Immune system disorders			
-Total	2 (50.0)	1 (25.0)	0
Cytokine release syndrome	2 (50.0)	1 (25.0)	0
Infections and infestations			
-Total	1 (25.0)	1 (25.0)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (25.0)	1 (25.0)	0
Metabolism and nutrition disorders			
-Total	1 (25.0)	1 (25.0)	0
Dehydration	1 (25.0)	1 (25.0)	0
Vascular disorders			
-Total	1 (25.0)	0	1 (25.0)
Hypotension	1 (25.0)	0	1 (25.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179i
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	44 (73.3)	19 (31.7)	16 (26.7)
Blood and lymphatic system disorders			
-Total	21 (35.0)	19 (31.7)	1 (1.7)
Febrile neutropenia	19 (31.7)	19 (31.7)	0
Disseminated intravascular coagulation	2 (3.3)	0	0
Neutropenia	1 (1.7)	0	1 (1.7)
Cardiac disorders			
-Total	2 (3.3)	0	0
Atrioventricular block second degree	1 (1.7)	0	0
Ventricular tachycardia	1 (1.7)	0	0
Eye disorders			
-Total	2 (3.3)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Papilloedema	1 (1.7)	0	0
Vision blurred	1 (1.7)	0	0
Gastrointestinal disorders			
-Total	4 (6.7)	3 (5.0)	0
Intestinal obstruction	1 (1.7)	1 (1.7)	0
Pancreatitis	1 (1.7)	1 (1.7)	0
Stomatitis	1 (1.7)	0	0
Vomiting	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	4 (6.7)	1 (1.7)	0
Pyrexia	2 (3.3)	0	0
Malaise	1 (1.7)	0	0
Physical deconditioning	1 (1.7)	1 (1.7)	0
Immune system disorders			
-Total	39 (65.0)	7 (11.7)	10 (16.7)
Cytokine release syndrome	39 (65.0)	7 (11.7)	10 (16.7)
Infections and infestations			
-Total	8 (13.3)	3 (5.0)	1 (1.7)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	2 (3.3)	0	0
Clostridium difficile infection	2 (3.3)	0	0
Catheter site infection	1 (1.7)	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	0	0
Pneumonia	1 (1.7)	1 (1.7)	0
Rhinovirus infection	1 (1.7)	0	0
Septic embolus	1 (1.7)	0	1 (1.7)
Staphylococcal infection	1 (1.7)	1 (1.7)	0
Injury, poisoning and procedural complications			
-Total	1 (1.7)	0	1 (1.7)
Transfusion related complication	1 (1.7)	0	1 (1.7)
Metabolism and nutrition disorders			
-Total	2 (3.3)	2 (3.3)	0
Acidosis	1 (1.7)	0	0
Decreased appetite	1 (1.7)	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	1 (1.7)	0
Nervous system disorders			
-Total	9 (15.0)	3 (5.0)	1 (1.7)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	4 (6.7)	2 (3.3)	0
Seizure	3 (5.0)	1 (1.7)	0
Embolic stroke	1 (1.7)	0	1 (1.7)
Headache	1 (1.7)	1 (1.7)	0
Idiopathic intracranial hypertension	1 (1.7)	0	0
Psychiatric disorders			
-Total	1 (1.7)	0	0
Delirium	1 (1.7)	0	0
Renal and urinary disorders			
-Total	4 (6.7)	2 (3.3)	2 (3.3)
Acute kidney injury	3 (5.0)	2 (3.3)	1 (1.7)
Renal failure	1 (1.7)	0	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (13.3)	1 (1.7)	4 (6.7)
Hypoxia	4 (6.7)	1 (1.7)	1 (1.7)
Respiratory failure	3 (5.0)	0	3 (5.0)
Pleural effusion	2 (3.3)	1 (1.7)	0
Pulmonary oedema	1 (1.7)	0	1 (1.7)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders			
-Total	1 (1.7)	1 (1.7)	0
Ecchymosis	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	7 (11.7)	5 (8.3)	2 (3.3)
Hypotension	6 (10.0)	4 (6.7)	2 (3.3)
Embolism	1 (1.7)	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179i
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

		All patients N=4	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (25.0)	1 (25.0)	0
Blood and lymphatic system disorders			
-Total	1 (25.0)	1 (25.0)	0
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	1 (25.0)	1 (25.0)	0
Herpes zoster	1 (25.0)	1 (25.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (25.0)	0	0
Osteonecrosis	1 (25.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Pulmonary oedema	1 (25.0)	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179i
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (38.5)	12 (23.1)	5 (9.6)
Blood and lymphatic system disorders			
-Total	4 (7.7)	2 (3.8)	2 (3.8)
Febrile neutropenia	2 (3.8)	2 (3.8)	0
Neutropenia	2 (3.8)	0	2 (3.8)
Eosinophilia	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders			
-Total	2 (3.8)	2 (3.8)	0
Enterocolitis	1 (1.9)	1 (1.9)	0
Vomiting	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (9.6)	1 (1.9)	0
Pyrexia	5 (9.6)	1 (1.9)	0
Immune system disorders			
-Total	1 (1.9)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.9)	0	0
Infections and infestations			
-Total	11 (21.2)	8 (15.4)	2 (3.8)
Bacterial sepsis	1 (1.9)	0	1 (1.9)
Cellulitis of male external genital organ	1 (1.9)	1 (1.9)	0
Cholecystitis infective	1 (1.9)	1 (1.9)	0
Corona virus infection	1 (1.9)	1 (1.9)	0
Enterovirus infection	1 (1.9)	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	0
Parainfluenzae virus infection	1 (1.9)	1 (1.9)	0
Respiratory syncytial virus infection	1 (1.9)	1 (1.9)	0
Rotavirus infection	1 (1.9)	1 (1.9)	0
Sepsis	1 (1.9)	0	1 (1.9)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Vascular device infection	1 (1.9)	1 (1.9)	0
Viral upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Investigations			
-Total	2 (3.8)	1 (1.9)	1 (1.9)
Alanine aminotransferase increased	1 (1.9)	1 (1.9)	0
White blood cell count decreased	1 (1.9)	0	1 (1.9)
Metabolism and nutrition disorders			
-Total	1 (1.9)	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	1 (1.9)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (3.8)	0	0
Flank pain	1 (1.9)	0	0
Pain in extremity	1 (1.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.9)	0	0
Myelodysplastic syndrome	1 (1.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	1 (1.9)	1 (1.9)	0
Acute kidney injury	1 (1.9)	1 (1.9)	0
Reproductive system and breast disorders			
-Total	1 (1.9)	1 (1.9)	0
Vaginal haemorrhage	1 (1.9)	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.9)	0	1 (1.9)
Acute respiratory failure	1 (1.9)	0	1 (1.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179i
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (19.4)	2 (6.5)	3 (9.7)
Blood and lymphatic system disorders			
-Total	1 (3.2)	0	1 (3.2)
Febrile neutropenia	1 (3.2)	0	1 (3.2)
Gastrointestinal disorders			
-Total	1 (3.2)	0	0
Diarrhoea	1 (3.2)	0	0
Infections and infestations			
-Total	4 (12.9)	2 (6.5)	1 (3.2)
Urinary tract infection	2 (6.5)	1 (3.2)	0
Campylobacter infection	1 (3.2)	1 (3.2)	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (3.2)	1 (3.2)	0
Clostridium difficile infection	1 (3.2)	1 (3.2)	0
Pneumonia	1 (3.2)	0	0
Respiratory tract infection	1 (3.2)	0	1 (3.2)
Respiratory tract infection viral	1 (3.2)	1 (3.2)	0
Vulvovaginal candidiasis	1 (3.2)	0	0
Injury, poisoning and procedural complications			
-Total	1 (3.2)	1 (3.2)	0
Procedural pain	1 (3.2)	1 (3.2)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.2)	0	1 (3.2)
Glioblastoma multiforme	1 (3.2)	0	1 (3.2)
Nervous system disorders			
-Total	1 (3.2)	1 (3.2)	0
Seizure	1 (3.2)	1 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179i
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	1 (25.0)	1 (25.0)
Blood and lymphatic system disorders			
-Total	2 (50.0)	2 (50.0)	0
Febrile neutropenia	2 (50.0)	2 (50.0)	0
Gastrointestinal disorders			
-Total	1 (25.0)	0	0
Diarrhoea	1 (25.0)	0	0
Immune system disorders			
-Total	2 (50.0)	1 (25.0)	0
Cytokine release syndrome	2 (50.0)	1 (25.0)	0
Infections and infestations			
-Total	1 (25.0)	1 (25.0)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (25.0)	1 (25.0)	0
Herpes zoster	1 (25.0)	1 (25.0)	0
Metabolism and nutrition disorders			
-Total	1 (25.0)	1 (25.0)	0
Dehydration	1 (25.0)	1 (25.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (25.0)	0	0
Osteonecrosis	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Pulmonary oedema	1 (25.0)	1 (25.0)	0
Vascular disorders			
-Total	1 (25.0)	0	1 (25.0)
Hypotension	1 (25.0)	0	1 (25.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients

column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179i
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (83.3)	20 (33.3)	23 (38.3)
Blood and lymphatic system disorders			
-Total	25 (41.7)	20 (33.3)	4 (6.7)
Febrile neutropenia	21 (35.0)	20 (33.3)	1 (1.7)
Neutropenia	3 (5.0)	0	3 (5.0)
Disseminated intravascular coagulation	2 (3.3)	0	0
Eosinophilia	1 (1.7)	1 (1.7)	0
Cardiac disorders			
-Total	2 (3.3)	0	0
Atrioventricular block second degree	1 (1.7)	0	0
Ventricular tachycardia	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders			
-Total	2 (3.3)	0	0
Papilloedema	1 (1.7)	0	0
Vision blurred	1 (1.7)	0	0
Gastrointestinal disorders			
-Total	6 (10.0)	4 (6.7)	0
Diarrhoea	1 (1.7)	0	0
Enterocolitis	1 (1.7)	1 (1.7)	0
Intestinal obstruction	1 (1.7)	1 (1.7)	0
Pancreatitis	1 (1.7)	1 (1.7)	0
Stomatitis	1 (1.7)	0	0
Vomiting	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	9 (15.0)	2 (3.3)	0
Pyrexia	7 (11.7)	1 (1.7)	0
Malaise	1 (1.7)	0	0
Physical deconditioning	1 (1.7)	1 (1.7)	0
Immune system disorders			

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	39 (65.0)	7 (11.7)	10 (16.7)
Cytokine release syndrome	39 (65.0)	7 (11.7)	10 (16.7)
Graft versus host disease in gastrointestinal tract	1 (1.7)	0	0
Infections and infestations			
-Total	18 (30.0)	10 (16.7)	4 (6.7)
Clostridium difficile infection	3 (5.0)	1 (1.7)	0
Clostridium difficile colitis	2 (3.3)	0	0
Pneumonia	2 (3.3)	1 (1.7)	0
Urinary tract infection	2 (3.3)	1 (1.7)	0
Bacterial sepsis	1 (1.7)	0	1 (1.7)
Campylobacter infection	1 (1.7)	1 (1.7)	0
Catheter site infection	1 (1.7)	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	1 (1.7)	0
Cholecystitis infective	1 (1.7)	1 (1.7)	0
Corona virus infection	1 (1.7)	1 (1.7)	0
Enterovirus infection	1 (1.7)	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (1.7)	1 (1.7)	0
Respiratory syncytial virus infection	1 (1.7)	1 (1.7)	0
Respiratory tract infection	1 (1.7)	0	1 (1.7)
Respiratory tract infection viral	1 (1.7)	1 (1.7)	0
Rhinovirus infection	1 (1.7)	0	0
Rotavirus infection	1 (1.7)	1 (1.7)	0
Sepsis	1 (1.7)	0	1 (1.7)
Septic embolus	1 (1.7)	0	1 (1.7)
Staphylococcal infection	1 (1.7)	1 (1.7)	0
Upper respiratory tract infection	1 (1.7)	1 (1.7)	0
Vascular device infection	1 (1.7)	1 (1.7)	0
Viral upper respiratory tract infection	1 (1.7)	1 (1.7)	0
Vulvovaginal candidiasis	1 (1.7)	0	0
Injury, poisoning and procedural complications			
-Total	2 (3.3)	1 (1.7)	1 (1.7)
Procedural pain	1 (1.7)	1 (1.7)	0
Transfusion related complication	1 (1.7)	0	1 (1.7)
Investigations			

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (3.3)	1 (1.7)	1 (1.7)
Alanine aminotransferase increased	1 (1.7)	1 (1.7)	0
White blood cell count decreased	1 (1.7)	0	1 (1.7)
Metabolism and nutrition disorders			
-Total	3 (5.0)	3 (5.0)	0
Tumour lysis syndrome	2 (3.3)	2 (3.3)	0
Acidosis	1 (1.7)	0	0
Decreased appetite	1 (1.7)	1 (1.7)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (3.3)	0	0
Flank pain	1 (1.7)	0	0
Pain in extremity	1 (1.7)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (3.3)	0	1 (1.7)
Glioblastoma multiforme	1 (1.7)	0	1 (1.7)
Myelodysplastic syndrome	1 (1.7)	0	0
Nervous system disorders			

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (16.7)	4 (6.7)	1 (1.7)
Encephalopathy	4 (6.7)	2 (3.3)	0
Seizure	4 (6.7)	2 (3.3)	0
Embolic stroke	1 (1.7)	0	1 (1.7)
Headache	1 (1.7)	1 (1.7)	0
Idiopathic intracranial hypertension	1 (1.7)	0	0
Psychiatric disorders			
-Total	1 (1.7)	0	0
Delirium	1 (1.7)	0	0
Renal and urinary disorders			
-Total	5 (8.3)	3 (5.0)	2 (3.3)
Acute kidney injury	4 (6.7)	3 (5.0)	1 (1.7)
Renal failure	1 (1.7)	0	1 (1.7)
Reproductive system and breast disorders			
-Total	1 (1.7)	1 (1.7)	0
Vaginal haemorrhage	1 (1.7)	1 (1.7)	0
Respiratory, thoracic and mediastinal disorders			

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (15.0)	1 (1.7)	5 (8.3)
Hypoxia	4 (6.7)	1 (1.7)	1 (1.7)
Respiratory failure	3 (5.0)	0	3 (5.0)
Pleural effusion	2 (3.3)	1 (1.7)	0
Acute respiratory failure	1 (1.7)	0	1 (1.7)
Pulmonary oedema	1 (1.7)	0	1 (1.7)
Skin and subcutaneous tissue disorders			
-Total	1 (1.7)	1 (1.7)	0
Ecchymosis	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	7 (11.7)	5 (8.3)	2 (3.3)
Hypotension	6 (10.0)	4 (6.7)	2 (3.3)
Embolism	1 (1.7)	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179j
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (94.7)	6 (31.6)	9 (47.4)
Blood and lymphatic system disorders			
-Total	8 (42.1)	8 (42.1)	0
Febrile neutropenia	8 (42.1)	8 (42.1)	0
Cardiac disorders			
-Total	1 (5.3)	0	0
Atrioventricular block second degree	1 (5.3)	0	0
Eye disorders			
-Total	1 (5.3)	0	0
Vision blurred	1 (5.3)	0	0
Gastrointestinal disorders			
-Total	2 (10.5)	1 (5.3)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (5.3)	0	0
Intestinal obstruction	1 (5.3)	1 (5.3)	0
Immune system disorders			
-Total	16 (84.2)	3 (15.8)	5 (26.3)
Cytokine release syndrome	16 (84.2)	3 (15.8)	5 (26.3)
Infections and infestations			
-Total	4 (21.1)	2 (10.5)	1 (5.3)
Clostridium difficile colitis	1 (5.3)	0	0
Clostridium difficile infection	1 (5.3)	0	0
Gastroenteritis	1 (5.3)	1 (5.3)	0
Rhinovirus infection	1 (5.3)	0	0
Septic embolus	1 (5.3)	0	1 (5.3)
Staphylococcal infection	1 (5.3)	1 (5.3)	0
Injury, poisoning and procedural complications			
-Total	1 (5.3)	0	1 (5.3)
Transfusion related complication	1 (5.3)	0	1 (5.3)
Metabolism and nutrition disorders			
-Total	1 (5.3)	1 (5.3)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (5.3)	1 (5.3)	0
Nervous system disorders			
-Total	4 (21.1)	2 (10.5)	1 (5.3)
Encephalopathy	2 (10.5)	1 (5.3)	0
Embolic stroke	1 (5.3)	0	1 (5.3)
Seizure	1 (5.3)	1 (5.3)	0
Renal and urinary disorders			
-Total	1 (5.3)	0	1 (5.3)
Acute kidney injury	1 (5.3)	0	1 (5.3)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (10.5)	0	1 (5.3)
Hypoxia	2 (10.5)	0	1 (5.3)
Vascular disorders			
-Total	2 (10.5)	0	2 (10.5)
Hypotension	2 (10.5)	0	2 (10.5)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179j
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (62.2)	14 (31.1)	8 (17.8)
Blood and lymphatic system disorders			
-Total	15 (33.3)	13 (28.9)	1 (2.2)
Febrile neutropenia	13 (28.9)	13 (28.9)	0
Disseminated intravascular coagulation	2 (4.4)	0	0
Neutropenia	1 (2.2)	0	1 (2.2)
Cardiac disorders			
-Total	1 (2.2)	0	0
Ventricular tachycardia	1 (2.2)	0	0
Eye disorders			
-Total	1 (2.2)	0	0
Papilloedema	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	3 (6.7)	2 (4.4)	0
Pancreatitis	1 (2.2)	1 (2.2)	0
Stomatitis	1 (2.2)	0	0
Vomiting	1 (2.2)	1 (2.2)	0
General disorders and administration site conditions			
-Total	4 (8.9)	1 (2.2)	0
Pyrexia	2 (4.4)	0	0
Malaise	1 (2.2)	0	0
Physical deconditioning	1 (2.2)	1 (2.2)	0
Immune system disorders			
-Total	25 (55.6)	5 (11.1)	5 (11.1)
Cytokine release syndrome	25 (55.6)	5 (11.1)	5 (11.1)
Infections and infestations			
-Total	5 (11.1)	2 (4.4)	0
Catheter site infection	1 (2.2)	1 (2.2)	0
Clostridium difficile colitis	1 (2.2)	0	0
Clostridium difficile infection	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (2.2)	0	0
Pneumonia	1 (2.2)	1 (2.2)	0
Metabolism and nutrition disorders			
-Total	2 (4.4)	2 (4.4)	0
Acidosis	1 (2.2)	0	0
Decreased appetite	1 (2.2)	1 (2.2)	0
Tumour lysis syndrome	1 (2.2)	1 (2.2)	0
Nervous system disorders			
-Total	5 (11.1)	1 (2.2)	0
Encephalopathy	2 (4.4)	1 (2.2)	0
Seizure	2 (4.4)	0	0
Headache	1 (2.2)	1 (2.2)	0
Idiopathic intracranial hypertension	1 (2.2)	0	0
Psychiatric disorders			
-Total	1 (2.2)	0	0
Delirium	1 (2.2)	0	0
Renal and urinary disorders			
-Total	3 (6.7)	2 (4.4)	1 (2.2)
Acute kidney injury	2 (4.4)	2 (4.4)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	1 (2.2)	0	1 (2.2)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (13.3)	1 (2.2)	3 (6.7)
Respiratory failure	3 (6.7)	0	3 (6.7)
Hypoxia	2 (4.4)	1 (2.2)	0
Pleural effusion	2 (4.4)	1 (2.2)	0
Pulmonary oedema	1 (2.2)	0	1 (2.2)
Skin and subcutaneous tissue disorders			
-Total	1 (2.2)	1 (2.2)	0
Ecchymosis	1 (2.2)	1 (2.2)	0
Vascular disorders			
-Total	6 (13.3)	5 (11.1)	1 (2.2)
Hypotension	5 (11.1)	4 (8.9)	1 (2.2)
Embolism	1 (2.2)	1 (2.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients

column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179j
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (50.0)	3 (16.7)	4 (22.2)
Blood and lymphatic system disorders			
-Total	3 (16.7)	1 (5.6)	2 (11.1)
Neutropenia	2 (11.1)	0	2 (11.1)
Eosinophilia	1 (5.6)	1 (5.6)	0
Febrile neutropenia	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	3 (16.7)	0	0
Pyrexia	3 (16.7)	0	0
Infections and infestations			
-Total	5 (27.8)	4 (22.2)	1 (5.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Cellulitis of male external genital organ	1 (5.6)	1 (5.6)	0
Enterovirus infection	1 (5.6)	1 (5.6)	0
Herpes zoster	1 (5.6)	1 (5.6)	0
Rotavirus infection	1 (5.6)	1 (5.6)	0
Vascular device infection	1 (5.6)	1 (5.6)	0
Investigations			
-Total	1 (5.6)	0	1 (5.6)
White blood cell count decreased	1 (5.6)	0	1 (5.6)
Musculoskeletal and connective tissue disorders			
-Total	2 (11.1)	0	0
Osteonecrosis	1 (5.6)	0	0
Pain in extremity	1 (5.6)	0	0
Renal and urinary disorders			
-Total	1 (5.6)	1 (5.6)	0
Acute kidney injury	1 (5.6)	1 (5.6)	0
Reproductive system and breast disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.6)	1 (5.6)	0
Vaginal haemorrhage	1 (5.6)	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Acute respiratory failure	1 (5.6)	0	1 (5.6)
Pulmonary oedema	1 (5.6)	1 (5.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179j
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=38	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (31.6)	10 (26.3)	1 (2.6)
Blood and lymphatic system disorders			
-Total	2 (5.3)	2 (5.3)	0
Febrile neutropenia	2 (5.3)	2 (5.3)	0
Gastrointestinal disorders			
-Total	2 (5.3)	2 (5.3)	0
Enterocolitis	1 (2.6)	1 (2.6)	0
Vomiting	1 (2.6)	1 (2.6)	0
General disorders and administration site conditions			
-Total	2 (5.3)	1 (2.6)	0
Pyrexia	2 (5.3)	1 (2.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	1 (2.6)	0	0
Graft versus host disease in gastrointestinal tract	1 (2.6)	0	0
Infections and infestations			
-Total	7 (18.4)	5 (13.2)	1 (2.6)
Cholecystitis infective	1 (2.6)	1 (2.6)	0
Corona virus infection	1 (2.6)	1 (2.6)	0
Gastroenteritis norovirus	1 (2.6)	0	0
Parainfluenzae virus infection	1 (2.6)	1 (2.6)	0
Respiratory syncytial virus infection	1 (2.6)	1 (2.6)	0
Sepsis	1 (2.6)	0	1 (2.6)
Upper respiratory tract infection	1 (2.6)	1 (2.6)	0
Viral upper respiratory tract infection	1 (2.6)	1 (2.6)	0
Investigations			
-Total	1 (2.6)	1 (2.6)	0
Alanine aminotransferase increased	1 (2.6)	1 (2.6)	0
Metabolism and nutrition disorders			
-Total	1 (2.6)	1 (2.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (2.6)	1 (2.6)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (2.6)	0	0
Flank pain	1 (2.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.6)	0	0
Myelodysplastic syndrome	1 (2.6)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179j
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (27.3)	2 (18.2)	1 (9.1)
Gastrointestinal disorders			
-Total	1 (9.1)	0	0
Diarrhoea	1 (9.1)	0	0
Infections and infestations			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Urinary tract infection	2 (18.2)	1 (9.1)	0
Campylobacter infection	1 (9.1)	1 (9.1)	0
Cellulitis of male external genital organ	1 (9.1)	1 (9.1)	0
Clostridium difficile infection	1 (9.1)	1 (9.1)	0
Respiratory tract infection	1 (9.1)	0	1 (9.1)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (9.1)	1 (9.1)	0
Vulvovaginal candidiasis	1 (9.1)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179j
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=23	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (13.0)	0	2 (8.7)
Blood and lymphatic system disorders			
-Total	1 (4.3)	0	1 (4.3)
Febrile neutropenia	1 (4.3)	0	1 (4.3)
Infections and infestations			
-Total	1 (4.3)	0	0
Pneumonia	1 (4.3)	0	0
Injury, poisoning and procedural complications			
-Total	1 (4.3)	1 (4.3)	0
Procedural pain	1 (4.3)	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (4.3)	0	1 (4.3)
Glioblastoma multiforme	1 (4.3)	0	1 (4.3)
Nervous system disorders			
-Total	1 (4.3)	1 (4.3)	0
Seizure	1 (4.3)	1 (4.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179j
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (100)	4 (21.1)	13 (68.4)
Blood and lymphatic system disorders			
-Total	10 (52.6)	8 (42.1)	2 (10.5)
Febrile neutropenia	8 (42.1)	8 (42.1)	0
Neutropenia	2 (10.5)	0	2 (10.5)
Eosinophilia	1 (5.3)	1 (5.3)	0
Cardiac disorders			
-Total	1 (5.3)	0	0
Atrioventricular block second degree	1 (5.3)	0	0
Eye disorders			
-Total	1 (5.3)	0	0
Vision blurred	1 (5.3)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	3 (15.8)	1 (5.3)	0
Diarrhoea	2 (10.5)	0	0
Intestinal obstruction	1 (5.3)	1 (5.3)	0
General disorders and administration site conditions			
-Total	3 (15.8)	0	0
Pyrexia	3 (15.8)	0	0
Immune system disorders			
-Total	16 (84.2)	3 (15.8)	5 (26.3)
Cytokine release syndrome	16 (84.2)	3 (15.8)	5 (26.3)
Infections and infestations			
-Total	8 (42.1)	5 (26.3)	3 (15.8)
Clostridium difficile infection	2 (10.5)	1 (5.3)	0
Urinary tract infection	2 (10.5)	1 (5.3)	0
Bacterial sepsis	1 (5.3)	0	1 (5.3)
Campylobacter infection	1 (5.3)	1 (5.3)	0
Cellulitis of male external genital organ	1 (5.3)	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	1 (5.3)	0	0
Enterovirus infection	1 (5.3)	1 (5.3)	0
Gastroenteritis	1 (5.3)	1 (5.3)	0
Herpes zoster	1 (5.3)	1 (5.3)	0
Respiratory tract infection	1 (5.3)	0	1 (5.3)
Respiratory tract infection viral	1 (5.3)	1 (5.3)	0
Rhinovirus infection	1 (5.3)	0	0
Rotavirus infection	1 (5.3)	1 (5.3)	0
Septic embolus	1 (5.3)	0	1 (5.3)
Staphylococcal infection	1 (5.3)	1 (5.3)	0
Vascular device infection	1 (5.3)	1 (5.3)	0
Vulvovaginal candidiasis	1 (5.3)	0	0
Injury, poisoning and procedural complications			
-Total	1 (5.3)	0	1 (5.3)
Transfusion related complication	1 (5.3)	0	1 (5.3)
Investigations			
-Total	1 (5.3)	0	1 (5.3)
White blood cell count decreased	1 (5.3)	0	1 (5.3)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	1 (5.3)	1 (5.3)	0
Dehydration	1 (5.3)	1 (5.3)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (10.5)	0	0
Osteonecrosis	1 (5.3)	0	0
Pain in extremity	1 (5.3)	0	0
Nervous system disorders			
-Total	4 (21.1)	2 (10.5)	1 (5.3)
Encephalopathy	2 (10.5)	1 (5.3)	0
Embolic stroke	1 (5.3)	0	1 (5.3)
Seizure	1 (5.3)	1 (5.3)	0
Renal and urinary disorders			
-Total	2 (10.5)	1 (5.3)	1 (5.3)
Acute kidney injury	2 (10.5)	1 (5.3)	1 (5.3)
Reproductive system and breast disorders			
-Total	1 (5.3)	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal haemorrhage	1 (5.3)	1 (5.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (21.1)	1 (5.3)	2 (10.5)
Hypoxia	2 (10.5)	0	1 (5.3)
Acute respiratory failure	1 (5.3)	0	1 (5.3)
Pulmonary oedema	1 (5.3)	1 (5.3)	0
Vascular disorders			
-Total	2 (10.5)	0	2 (10.5)
Hypotension	2 (10.5)	0	2 (10.5)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179j
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=45	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (73.3)	17 (37.8)	11 (24.4)
Blood and lymphatic system disorders			
-Total	17 (37.8)	14 (31.1)	2 (4.4)
Febrile neutropenia	15 (33.3)	14 (31.1)	1 (2.2)
Disseminated intravascular coagulation	2 (4.4)	0	0
Neutropenia	1 (2.2)	0	1 (2.2)
Cardiac disorders			
-Total	1 (2.2)	0	0
Ventricular tachycardia	1 (2.2)	0	0
Eye disorders			
-Total	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Papilloedema	1 (2.2)	0	0
Gastrointestinal disorders			
-Total	4 (8.9)	3 (6.7)	0
Enterocolitis	1 (2.2)	1 (2.2)	0
Pancreatitis	1 (2.2)	1 (2.2)	0
Stomatitis	1 (2.2)	0	0
Vomiting	1 (2.2)	1 (2.2)	0
General disorders and administration site conditions			
-Total	6 (13.3)	2 (4.4)	0
Pyrexia	4 (8.9)	1 (2.2)	0
Malaise	1 (2.2)	0	0
Physical deconditioning	1 (2.2)	1 (2.2)	0
Immune system disorders			
-Total	25 (55.6)	5 (11.1)	5 (11.1)
Cytokine release syndrome	25 (55.6)	5 (11.1)	5 (11.1)
Graft versus host disease in gastrointestinal tract	1 (2.2)	0	0
Infections and infestations			

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (24.4)	6 (13.3)	1 (2.2)
Pneumonia	2 (4.4)	1 (2.2)	0
Catheter site infection	1 (2.2)	1 (2.2)	0
Cholecystitis infective	1 (2.2)	1 (2.2)	0
Clostridium difficile colitis	1 (2.2)	0	0
Clostridium difficile infection	1 (2.2)	0	0
Corona virus infection	1 (2.2)	1 (2.2)	0
Gastroenteritis norovirus	1 (2.2)	0	0
Parainfluenzae virus infection	1 (2.2)	1 (2.2)	0
Respiratory syncytial virus infection	1 (2.2)	1 (2.2)	0
Sepsis	1 (2.2)	0	1 (2.2)
Upper respiratory tract infection	1 (2.2)	1 (2.2)	0
Viral upper respiratory tract infection	1 (2.2)	1 (2.2)	0
Injury, poisoning and procedural complications			
-Total	1 (2.2)	1 (2.2)	0
Procedural pain	1 (2.2)	1 (2.2)	0
Investigations			
-Total	1 (2.2)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (2.2)	1 (2.2)	0
Metabolism and nutrition disorders			
-Total	3 (6.7)	3 (6.7)	0
Tumour lysis syndrome	2 (4.4)	2 (4.4)	0
Acidosis	1 (2.2)	0	0
Decreased appetite	1 (2.2)	1 (2.2)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (2.2)	0	0
Flank pain	1 (2.2)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (4.4)	0	1 (2.2)
Glioblastoma multiforme	1 (2.2)	0	1 (2.2)
Myelodysplastic syndrome	1 (2.2)	0	0
Nervous system disorders			
-Total	6 (13.3)	2 (4.4)	0
Seizure	3 (6.7)	1 (2.2)	0
Encephalopathy	2 (4.4)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (2.2)	1 (2.2)	0
Idiopathic intracranial hypertension	1 (2.2)	0	0
Psychiatric disorders			
-Total	1 (2.2)	0	0
Delirium	1 (2.2)	0	0
Renal and urinary disorders			
-Total	3 (6.7)	2 (4.4)	1 (2.2)
Acute kidney injury	2 (4.4)	2 (4.4)	0
Renal failure	1 (2.2)	0	1 (2.2)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (13.3)	1 (2.2)	3 (6.7)
Respiratory failure	3 (6.7)	0	3 (6.7)
Hypoxia	2 (4.4)	1 (2.2)	0
Pleural effusion	2 (4.4)	1 (2.2)	0
Pulmonary oedema	1 (2.2)	0	1 (2.2)
Skin and subcutaneous tissue disorders			
-Total	1 (2.2)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ecchymosis	1 (2.2)	1 (2.2)	0
Vascular disorders			
-Total	6 (13.3)	5 (11.1)	1 (2.2)
Hypotension	5 (11.1)	4 (8.9)	1 (2.2)
Embolism	1 (2.2)	1 (2.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179k
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (71.9)	20 (31.3)	17 (26.6)
Blood and lymphatic system disorders			
-Total	23 (35.9)	21 (32.8)	1 (1.6)
Febrile neutropenia	21 (32.8)	21 (32.8)	0
Disseminated intravascular coagulation	2 (3.1)	0	0
Neutropenia	1 (1.6)	0	1 (1.6)
Cardiac disorders			
-Total	2 (3.1)	0	0
Atrioventricular block second degree	1 (1.6)	0	0
Ventricular tachycardia	1 (1.6)	0	0
Eye disorders			
-Total	2 (3.1)	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Papilloedema	1 (1.6)	0	0
Vision blurred	1 (1.6)	0	0
Gastrointestinal disorders			
-Total	5 (7.8)	3 (4.7)	0
Diarrhoea	1 (1.6)	0	0
Intestinal obstruction	1 (1.6)	1 (1.6)	0
Pancreatitis	1 (1.6)	1 (1.6)	0
Stomatitis	1 (1.6)	0	0
Vomiting	1 (1.6)	1 (1.6)	0
General disorders and administration site conditions			
-Total	4 (6.3)	1 (1.6)	0
Pyrexia	2 (3.1)	0	0
Malaise	1 (1.6)	0	0
Physical deconditioning	1 (1.6)	1 (1.6)	0
Immune system disorders			
-Total	41 (64.1)	8 (12.5)	10 (15.6)
Cytokine release syndrome	41 (64.1)	8 (12.5)	10 (15.6)
Infections and infestations			

Timing: within 8 weeks post infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (14.1)	4 (6.3)	1 (1.6)
Clostridium difficile colitis	2 (3.1)	0	0
Clostridium difficile infection	2 (3.1)	0	0
Catheter site infection	1 (1.6)	1 (1.6)	0
Gastroenteritis	1 (1.6)	1 (1.6)	0
Gastroenteritis norovirus	1 (1.6)	0	0
Pneumonia	1 (1.6)	1 (1.6)	0
Rhinovirus infection	1 (1.6)	0	0
Septic embolus	1 (1.6)	0	1 (1.6)
Staphylococcal infection	1 (1.6)	1 (1.6)	0
Injury, poisoning and procedural complications			
-Total	1 (1.6)	0	1 (1.6)
Transfusion related complication	1 (1.6)	0	1 (1.6)
Metabolism and nutrition disorders			
-Total	3 (4.7)	3 (4.7)	0
Acidosis	1 (1.6)	0	0
Decreased appetite	1 (1.6)	1 (1.6)	0
Dehydration	1 (1.6)	1 (1.6)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (1.6)	1 (1.6)	0
Nervous system disorders			
-Total	9 (14.1)	3 (4.7)	1 (1.6)
Encephalopathy	4 (6.3)	2 (3.1)	0
Seizure	3 (4.7)	1 (1.6)	0
Embolic stroke	1 (1.6)	0	1 (1.6)
Headache	1 (1.6)	1 (1.6)	0
Idiopathic intracranial hypertension	1 (1.6)	0	0
Psychiatric disorders			
-Total	1 (1.6)	0	0
Delirium	1 (1.6)	0	0
Renal and urinary disorders			
-Total	4 (6.3)	2 (3.1)	2 (3.1)
Acute kidney injury	3 (4.7)	2 (3.1)	1 (1.6)
Renal failure	1 (1.6)	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (12.5)	1 (1.6)	4 (6.3)
Hypoxia	4 (6.3)	1 (1.6)	1 (1.6)

Timing: within 8 weeks post infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	3 (4.7)	0	3 (4.7)
Pleural effusion	2 (3.1)	1 (1.6)	0
Pulmonary oedema	1 (1.6)	0	1 (1.6)
Skin and subcutaneous tissue disorders			
-Total	1 (1.6)	1 (1.6)	0
Ecchymosis	1 (1.6)	1 (1.6)	0
Vascular disorders			
-Total	8 (12.5)	5 (7.8)	3 (4.7)
Hypotension	7 (10.9)	4 (6.3)	3 (4.7)
Embolism	1 (1.6)	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179k
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

		All patients N=56	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (37.5)	13 (23.2)	5 (8.9)
Blood and lymphatic system disorders			
-Total	5 (8.9)	3 (5.4)	2 (3.6)
Febrile neutropenia	3 (5.4)	3 (5.4)	0
Neutropenia	2 (3.6)	0	2 (3.6)
Eosinophilia	1 (1.8)	1 (1.8)	0
Gastrointestinal disorders			
-Total	2 (3.6)	2 (3.6)	0
Enterocolitis	1 (1.8)	1 (1.8)	0
Vomiting	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions			
-Total	5 (8.9)	1 (1.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	5 (8.9)	1 (1.8)	0
Immune system disorders			
-Total	1 (1.8)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.8)	0	0
Infections and infestations			
-Total	12 (21.4)	9 (16.1)	2 (3.6)
Bacterial sepsis	1 (1.8)	0	1 (1.8)
Cellulitis of male external genital organ	1 (1.8)	1 (1.8)	0
Cholecystitis infective	1 (1.8)	1 (1.8)	0
Corona virus infection	1 (1.8)	1 (1.8)	0
Enterovirus infection	1 (1.8)	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	0	0
Herpes zoster	1 (1.8)	1 (1.8)	0
Parainfluenzae virus infection	1 (1.8)	1 (1.8)	0
Respiratory syncytial virus infection	1 (1.8)	1 (1.8)	0
Rotavirus infection	1 (1.8)	1 (1.8)	0
Sepsis	1 (1.8)	0	1 (1.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (1.8)	1 (1.8)	0
Vascular device infection	1 (1.8)	1 (1.8)	0
Viral upper respiratory tract infection	1 (1.8)	1 (1.8)	0
Investigations			
-Total	2 (3.6)	1 (1.8)	1 (1.8)
Alanine aminotransferase increased	1 (1.8)	1 (1.8)	0
White blood cell count decreased	1 (1.8)	0	1 (1.8)
Metabolism and nutrition disorders			
-Total	1 (1.8)	1 (1.8)	0
Tumour lysis syndrome	1 (1.8)	1 (1.8)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (5.4)	0	0
Flank pain	1 (1.8)	0	0
Osteonecrosis	1 (1.8)	0	0
Pain in extremity	1 (1.8)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myelodysplastic syndrome	1 (1.8)	0	0
Renal and urinary disorders			
-Total	1 (1.8)	1 (1.8)	0
Acute kidney injury	1 (1.8)	1 (1.8)	0
Reproductive system and breast disorders			
-Total	1 (1.8)	1 (1.8)	0
Vaginal haemorrhage	1 (1.8)	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.6)	1 (1.8)	1 (1.8)
Acute respiratory failure	1 (1.8)	0	1 (1.8)
Pulmonary oedema	1 (1.8)	1 (1.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179k
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (17.6)	2 (5.9)	3 (8.8)
Blood and lymphatic system disorders			
-Total	1 (2.9)	0	1 (2.9)
Febrile neutropenia	1 (2.9)	0	1 (2.9)
Gastrointestinal disorders			
-Total	1 (2.9)	0	0
Diarrhoea	1 (2.9)	0	0
Infections and infestations			
-Total	4 (11.8)	2 (5.9)	1 (2.9)
Urinary tract infection	2 (5.9)	1 (2.9)	0
Campylobacter infection	1 (2.9)	1 (2.9)	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (2.9)	1 (2.9)	0
Clostridium difficile infection	1 (2.9)	1 (2.9)	0
Pneumonia	1 (2.9)	0	0
Respiratory tract infection	1 (2.9)	0	1 (2.9)
Respiratory tract infection viral	1 (2.9)	1 (2.9)	0
Vulvovaginal candidiasis	1 (2.9)	0	0
Injury, poisoning and procedural complications			
-Total	1 (2.9)	1 (2.9)	0
Procedural pain	1 (2.9)	1 (2.9)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.9)	0	1 (2.9)
Glioblastoma multiforme	1 (2.9)	0	1 (2.9)
Nervous system disorders			
-Total	1 (2.9)	1 (2.9)	0
Seizure	1 (2.9)	1 (2.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179k
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (81.3)	21 (32.8)	24 (37.5)
Blood and lymphatic system disorders			
-Total	27 (42.2)	22 (34.4)	4 (6.3)
Febrile neutropenia	23 (35.9)	22 (34.4)	1 (1.6)
Neutropenia	3 (4.7)	0	3 (4.7)
Disseminated intravascular coagulation	2 (3.1)	0	0
Eosinophilia	1 (1.6)	1 (1.6)	0
Cardiac disorders			
-Total	2 (3.1)	0	0
Atrioventricular block second degree	1 (1.6)	0	0
Ventricular tachycardia	1 (1.6)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders			
-Total	2 (3.1)	0	0
Papilloedema	1 (1.6)	0	0
Vision blurred	1 (1.6)	0	0
Gastrointestinal disorders			
-Total	7 (10.9)	4 (6.3)	0
Diarrhoea	2 (3.1)	0	0
Enterocolitis	1 (1.6)	1 (1.6)	0
Intestinal obstruction	1 (1.6)	1 (1.6)	0
Pancreatitis	1 (1.6)	1 (1.6)	0
Stomatitis	1 (1.6)	0	0
Vomiting	1 (1.6)	1 (1.6)	0
General disorders and administration site conditions			
-Total	9 (14.1)	2 (3.1)	0
Pyrexia	7 (10.9)	1 (1.6)	0
Malaise	1 (1.6)	0	0
Physical deconditioning	1 (1.6)	1 (1.6)	0
Immune system disorders			

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	41 (64.1)	8 (12.5)	10 (15.6)
Cytokine release syndrome	41 (64.1)	8 (12.5)	10 (15.6)
Graft versus host disease in gastrointestinal tract	1 (1.6)	0	0
Infections and infestations			
-Total	19 (29.7)	11 (17.2)	4 (6.3)
Clostridium difficile infection	3 (4.7)	1 (1.6)	0
Clostridium difficile colitis	2 (3.1)	0	0
Pneumonia	2 (3.1)	1 (1.6)	0
Urinary tract infection	2 (3.1)	1 (1.6)	0
Bacterial sepsis	1 (1.6)	0	1 (1.6)
Campylobacter infection	1 (1.6)	1 (1.6)	0
Catheter site infection	1 (1.6)	1 (1.6)	0
Cellulitis of male external genital organ	1 (1.6)	1 (1.6)	0
Cholecystitis infective	1 (1.6)	1 (1.6)	0
Corona virus infection	1 (1.6)	1 (1.6)	0
Enterovirus infection	1 (1.6)	1 (1.6)	0
Gastroenteritis	1 (1.6)	1 (1.6)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis norovirus	1 (1.6)	0	0
Herpes zoster	1 (1.6)	1 (1.6)	0
Parainfluenzae virus infection	1 (1.6)	1 (1.6)	0
Respiratory syncytial virus infection	1 (1.6)	1 (1.6)	0
Respiratory tract infection	1 (1.6)	0	1 (1.6)
Respiratory tract infection viral	1 (1.6)	1 (1.6)	0
Rhinovirus infection	1 (1.6)	0	0
Rotavirus infection	1 (1.6)	1 (1.6)	0
Sepsis	1 (1.6)	0	1 (1.6)
Septic embolus	1 (1.6)	0	1 (1.6)
Staphylococcal infection	1 (1.6)	1 (1.6)	0
Upper respiratory tract infection	1 (1.6)	1 (1.6)	0
Vascular device infection	1 (1.6)	1 (1.6)	0
Viral upper respiratory tract infection	1 (1.6)	1 (1.6)	0
Vulvovaginal candidiasis	1 (1.6)	0	0
Injury, poisoning and procedural complications			
-Total	2 (3.1)	1 (1.6)	1 (1.6)
Procedural pain	1 (1.6)	1 (1.6)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion related complication	1 (1.6)	0	1 (1.6)
Investigations			
-Total	2 (3.1)	1 (1.6)	1 (1.6)
Alanine aminotransferase increased	1 (1.6)	1 (1.6)	0
White blood cell count decreased	1 (1.6)	0	1 (1.6)
Metabolism and nutrition disorders			
-Total	4 (6.3)	4 (6.3)	0
Tumour lysis syndrome	2 (3.1)	2 (3.1)	0
Acidosis	1 (1.6)	0	0
Decreased appetite	1 (1.6)	1 (1.6)	0
Dehydration	1 (1.6)	1 (1.6)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (4.7)	0	0
Flank pain	1 (1.6)	0	0
Osteonecrosis	1 (1.6)	0	0
Pain in extremity	1 (1.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (3.1)	0	1 (1.6)
Glioblastoma multiforme	1 (1.6)	0	1 (1.6)
Myelodysplastic syndrome	1 (1.6)	0	0
Nervous system disorders			
-Total	10 (15.6)	4 (6.3)	1 (1.6)
Encephalopathy	4 (6.3)	2 (3.1)	0
Seizure	4 (6.3)	2 (3.1)	0
Embolic stroke	1 (1.6)	0	1 (1.6)
Headache	1 (1.6)	1 (1.6)	0
Idiopathic intracranial hypertension	1 (1.6)	0	0
Psychiatric disorders			
-Total	1 (1.6)	0	0
Delirium	1 (1.6)	0	0
Renal and urinary disorders			
-Total	5 (7.8)	3 (4.7)	2 (3.1)
Acute kidney injury	4 (6.3)	3 (4.7)	1 (1.6)
Renal failure	1 (1.6)	0	1 (1.6)
Reproductive system and breast disorders			

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.6)	1 (1.6)	0
Vaginal haemorrhage	1 (1.6)	1 (1.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	10 (15.6)	2 (3.1)	5 (7.8)
Hypoxia	4 (6.3)	1 (1.6)	1 (1.6)
Respiratory failure	3 (4.7)	0	3 (4.7)
Pleural effusion	2 (3.1)	1 (1.6)	0
Pulmonary oedema	2 (3.1)	1 (1.6)	1 (1.6)
Acute respiratory failure	1 (1.6)	0	1 (1.6)
Skin and subcutaneous tissue disorders			
-Total	1 (1.6)	1 (1.6)	0
Ecchymosis	1 (1.6)	1 (1.6)	0
Vascular disorders			
-Total	8 (12.5)	5 (7.8)	3 (4.7)
Hypotension	7 (10.9)	4 (6.3)	3 (4.7)
Embolism	1 (1.6)	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179l
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (64.3)	7 (25.0)	6 (21.4)
Blood and lymphatic system disorders			
-Total	9 (32.1)	9 (32.1)	0
Febrile neutropenia	9 (32.1)	9 (32.1)	0
Disseminated intravascular coagulation	1 (3.6)	0	0
Eye disorders			
-Total	2 (7.1)	0	0
Papilloedema	1 (3.6)	0	0
Vision blurred	1 (3.6)	0	0
Gastrointestinal disorders			
-Total	2 (7.1)	1 (3.6)	0
Stomatitis	1 (3.6)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (3.6)	1 (3.6)	0
General disorders and administration site conditions			
-Total	2 (7.1)	0	0
Malaise	1 (3.6)	0	0
Pyrexia	1 (3.6)	0	0
Immune system disorders			
-Total	17 (60.7)	4 (14.3)	2 (7.1)
Cytokine release syndrome	17 (60.7)	4 (14.3)	2 (7.1)
Infections and infestations			
-Total	3 (10.7)	0	1 (3.6)
Clostridium difficile colitis	1 (3.6)	0	0
Clostridium difficile infection	1 (3.6)	0	0
Gastroenteritis norovirus	1 (3.6)	0	0
Rhinovirus infection	1 (3.6)	0	0
Septic embolus	1 (3.6)	0	1 (3.6)
Injury, poisoning and procedural complications			
-Total	1 (3.6)	0	1 (3.6)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transfusion related complication	1 (3.6)	0	1 (3.6)
Nervous system disorders			
-Total	5 (17.9)	2 (7.1)	1 (3.6)
Encephalopathy	2 (7.1)	1 (3.6)	0
Embolic stroke	1 (3.6)	0	1 (3.6)
Headache	1 (3.6)	1 (3.6)	0
Idiopathic intracranial hypertension	1 (3.6)	0	0
Seizure	1 (3.6)	1 (3.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (10.7)	0	0
Hypoxia	2 (7.1)	0	0
Pleural effusion	1 (3.6)	0	0
Vascular disorders			
-Total	5 (17.9)	3 (10.7)	2 (7.1)
Hypotension	4 (14.3)	2 (7.1)	2 (7.1)
Embolism	1 (3.6)	1 (3.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179l
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (77.8)	13 (36.1)	11 (30.6)
Blood and lymphatic system disorders			
-Total	14 (38.9)	12 (33.3)	1 (2.8)
Febrile neutropenia	12 (33.3)	12 (33.3)	0
Disseminated intravascular coagulation	1 (2.8)	0	0
Neutropenia	1 (2.8)	0	1 (2.8)
Cardiac disorders			
-Total	2 (5.6)	0	0
Atrioventricular block second degree	1 (2.8)	0	0
Ventricular tachycardia	1 (2.8)	0	0
Gastrointestinal disorders			
-Total	3 (8.3)	2 (5.6)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (2.8)	0	0
Intestinal obstruction	1 (2.8)	1 (2.8)	0
Pancreatitis	1 (2.8)	1 (2.8)	0
General disorders and administration site conditions			
-Total	2 (5.6)	1 (2.8)	0
Physical deconditioning	1 (2.8)	1 (2.8)	0
Pyrexia	1 (2.8)	0	0
Immune system disorders			
-Total	24 (66.7)	4 (11.1)	8 (22.2)
Cytokine release syndrome	24 (66.7)	4 (11.1)	8 (22.2)
Infections and infestations			
-Total	6 (16.7)	4 (11.1)	0
Catheter site infection	1 (2.8)	1 (2.8)	0
Clostridium difficile colitis	1 (2.8)	0	0
Clostridium difficile infection	1 (2.8)	0	0
Gastroenteritis	1 (2.8)	1 (2.8)	0
Pneumonia	1 (2.8)	1 (2.8)	0
Staphylococcal infection	1 (2.8)	1 (2.8)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	3 (8.3)	3 (8.3)	0
Acidosis	1 (2.8)	0	0
Decreased appetite	1 (2.8)	1 (2.8)	0
Dehydration	1 (2.8)	1 (2.8)	0
Tumour lysis syndrome	1 (2.8)	1 (2.8)	0
Nervous system disorders			
-Total	4 (11.1)	1 (2.8)	0
Encephalopathy	2 (5.6)	1 (2.8)	0
Seizure	2 (5.6)	0	0
Psychiatric disorders			
-Total	1 (2.8)	0	0
Delirium	1 (2.8)	0	0
Renal and urinary disorders			
-Total	4 (11.1)	2 (5.6)	2 (5.6)
Acute kidney injury	3 (8.3)	2 (5.6)	1 (2.8)
Renal failure	1 (2.8)	0	1 (2.8)
Respiratory, thoracic and mediastinal disorders			

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (13.9)	1 (2.8)	4 (11.1)
Respiratory failure	3 (8.3)	0	3 (8.3)
Hypoxia	2 (5.6)	1 (2.8)	1 (2.8)
Pleural effusion	1 (2.8)	1 (2.8)	0
Pulmonary oedema	1 (2.8)	0	1 (2.8)
Skin and subcutaneous tissue disorders			
-Total	1 (2.8)	1 (2.8)	0
Ecchymosis	1 (2.8)	1 (2.8)	0
Vascular disorders			
-Total	3 (8.3)	2 (5.6)	1 (2.8)
Hypotension	3 (8.3)	2 (5.6)	1 (2.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179l
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

		All patients N=25	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (36.0)	6 (24.0)	2 (8.0)
Blood and lymphatic system disorders			
-Total	2 (8.0)	1 (4.0)	1 (4.0)
Eosinophilia	1 (4.0)	1 (4.0)	0
Febrile neutropenia	1 (4.0)	1 (4.0)	0
Neutropenia	1 (4.0)	0	1 (4.0)
Gastrointestinal disorders			
-Total	1 (4.0)	1 (4.0)	0
Vomiting	1 (4.0)	1 (4.0)	0
General disorders and administration site conditions			
-Total	2 (8.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	2 (8.0)	0	0
Immune system disorders			
-Total	1 (4.0)	0	0
Graft versus host disease in gastrointestinal tract	1 (4.0)	0	0
Infections and infestations			
-Total	7 (28.0)	5 (20.0)	1 (4.0)
Cellulitis of male external genital organ	1 (4.0)	1 (4.0)	0
Cholecystitis infective	1 (4.0)	1 (4.0)	0
Enterovirus infection	1 (4.0)	1 (4.0)	0
Gastroenteritis norovirus	1 (4.0)	0	0
Rotavirus infection	1 (4.0)	1 (4.0)	0
Sepsis	1 (4.0)	0	1 (4.0)
Upper respiratory tract infection	1 (4.0)	1 (4.0)	0
Vascular device infection	1 (4.0)	1 (4.0)	0
Investigations			
-Total	1 (4.0)	1 (4.0)	0
Alanine aminotransferase increased	1 (4.0)	1 (4.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	1 (4.0)	0	0
Flank pain	1 (4.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (4.0)	0	0
Myelodysplastic syndrome	1 (4.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179l
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (38.7)	7 (22.6)	3 (9.7)
Blood and lymphatic system disorders			
-Total	3 (9.7)	2 (6.5)	1 (3.2)
Febrile neutropenia	2 (6.5)	2 (6.5)	0
Neutropenia	1 (3.2)	0	1 (3.2)
Gastrointestinal disorders			
-Total	1 (3.2)	1 (3.2)	0
Enterocolitis	1 (3.2)	1 (3.2)	0
General disorders and administration site conditions			
-Total	3 (9.7)	1 (3.2)	0
Pyrexia	3 (9.7)	1 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	5 (16.1)	4 (12.9)	1 (3.2)
Bacterial sepsis	1 (3.2)	0	1 (3.2)
Corona virus infection	1 (3.2)	1 (3.2)	0
Herpes zoster	1 (3.2)	1 (3.2)	0
Parainfluenzae virus infection	1 (3.2)	1 (3.2)	0
Respiratory syncytial virus infection	1 (3.2)	1 (3.2)	0
Viral upper respiratory tract infection	1 (3.2)	1 (3.2)	0
Investigations			
-Total	1 (3.2)	0	1 (3.2)
White blood cell count decreased	1 (3.2)	0	1 (3.2)
Metabolism and nutrition disorders			
-Total	1 (3.2)	1 (3.2)	0
Tumour lysis syndrome	1 (3.2)	1 (3.2)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (6.5)	0	0
Osteonecrosis	1 (3.2)	0	0
Pain in extremity	1 (3.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	1 (3.2)	1 (3.2)	0
Acute kidney injury	1 (3.2)	1 (3.2)	0
Reproductive system and breast disorders			
-Total	1 (3.2)	1 (3.2)	0
Vaginal haemorrhage	1 (3.2)	1 (3.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.5)	1 (3.2)	1 (3.2)
Acute respiratory failure	1 (3.2)	0	1 (3.2)
Pulmonary oedema	1 (3.2)	1 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179l
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (21.4)	2 (14.3)	1 (7.1)
Gastrointestinal disorders			
-Total	1 (7.1)	0	0
Diarrhoea	1 (7.1)	0	0
Infections and infestations			
-Total	2 (14.3)	2 (14.3)	0
Urinary tract infection	2 (14.3)	1 (7.1)	0
Campylobacter infection	1 (7.1)	1 (7.1)	0
Cellulitis of male external genital organ	1 (7.1)	1 (7.1)	0
Clostridium difficile infection	1 (7.1)	1 (7.1)	0
Respiratory tract infection viral	1 (7.1)	1 (7.1)	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal candidiasis	1 (7.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (7.1)	0	1 (7.1)
Glioblastoma multiforme	1 (7.1)	0	1 (7.1)
Nervous system disorders			
-Total	1 (7.1)	1 (7.1)	0
Seizure	1 (7.1)	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179l
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (15.0)	0	2 (10.0)
Blood and lymphatic system disorders			
-Total	1 (5.0)	0	1 (5.0)
Febrile neutropenia	1 (5.0)	0	1 (5.0)
Infections and infestations			
-Total	2 (10.0)	0	1 (5.0)
Pneumonia	1 (5.0)	0	0
Respiratory tract infection	1 (5.0)	0	1 (5.0)
Injury, poisoning and procedural complications			
-Total	1 (5.0)	1 (5.0)	0
Procedural pain	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179l
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (75.0)	9 (32.1)	9 (32.1)
Blood and lymphatic system disorders			
-Total	11 (39.3)	10 (35.7)	1 (3.6)
Febrile neutropenia	10 (35.7)	10 (35.7)	0
Disseminated intravascular coagulation	1 (3.6)	0	0
Eosinophilia	1 (3.6)	1 (3.6)	0
Neutropenia	1 (3.6)	0	1 (3.6)
Eye disorders			
-Total	2 (7.1)	0	0
Papilloedema	1 (3.6)	0	0
Vision blurred	1 (3.6)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	3 (10.7)	1 (3.6)	0
Diarrhoea	1 (3.6)	0	0
Stomatitis	1 (3.6)	0	0
Vomiting	1 (3.6)	1 (3.6)	0
General disorders and administration site conditions			
-Total	4 (14.3)	0	0
Pyrexia	3 (10.7)	0	0
Malaise	1 (3.6)	0	0
Immune system disorders			
-Total	17 (60.7)	4 (14.3)	2 (7.1)
Cytokine release syndrome	17 (60.7)	4 (14.3)	2 (7.1)
Graft versus host disease in gastrointestinal tract	1 (3.6)	0	0
Infections and infestations			
-Total	8 (28.6)	5 (17.9)	2 (7.1)
Clostridium difficile infection	2 (7.1)	1 (3.6)	0
Urinary tract infection	2 (7.1)	1 (3.6)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (3.6)	1 (3.6)	0
Cellulitis of male external genital organ	1 (3.6)	1 (3.6)	0
Cholecystitis infective	1 (3.6)	1 (3.6)	0
Clostridium difficile colitis	1 (3.6)	0	0
Enterovirus infection	1 (3.6)	1 (3.6)	0
Gastroenteritis norovirus	1 (3.6)	0	0
Respiratory tract infection viral	1 (3.6)	1 (3.6)	0
Rhinovirus infection	1 (3.6)	0	0
Rotavirus infection	1 (3.6)	1 (3.6)	0
Sepsis	1 (3.6)	0	1 (3.6)
Septic embolus	1 (3.6)	0	1 (3.6)
Upper respiratory tract infection	1 (3.6)	1 (3.6)	0
Vascular device infection	1 (3.6)	1 (3.6)	0
Vulvovaginal candidiasis	1 (3.6)	0	0
Injury, poisoning and procedural complications			
-Total	1 (3.6)	0	1 (3.6)
Transfusion related complication	1 (3.6)	0	1 (3.6)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	1 (3.6)	1 (3.6)	0
Alanine aminotransferase increased	1 (3.6)	1 (3.6)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (3.6)	0	0
Flank pain	1 (3.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (7.1)	0	1 (3.6)
Glioblastoma multiforme	1 (3.6)	0	1 (3.6)
Myelodysplastic syndrome	1 (3.6)	0	0
Nervous system disorders			
-Total	6 (21.4)	3 (10.7)	1 (3.6)
Encephalopathy	2 (7.1)	1 (3.6)	0
Seizure	2 (7.1)	2 (7.1)	0
Embolic stroke	1 (3.6)	0	1 (3.6)
Headache	1 (3.6)	1 (3.6)	0
Idiopathic intracranial hypertension	1 (3.6)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	3 (10.7)	0	0
Hypoxia	2 (7.1)	0	0
Pleural effusion	1 (3.6)	0	0
Vascular disorders			
-Total	5 (17.9)	3 (10.7)	2 (7.1)
Hypotension	4 (14.3)	2 (7.1)	2 (7.1)
Embolism	1 (3.6)	1 (3.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179l
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (86.1)	12 (33.3)	15 (41.7)
Blood and lymphatic system disorders			
-Total	16 (44.4)	12 (33.3)	3 (8.3)
Febrile neutropenia	13 (36.1)	12 (33.3)	1 (2.8)
Neutropenia	2 (5.6)	0	2 (5.6)
Disseminated intravascular coagulation	1 (2.8)	0	0
Cardiac disorders			
-Total	2 (5.6)	0	0
Atrioventricular block second degree	1 (2.8)	0	0
Ventricular tachycardia	1 (2.8)	0	0
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (11.1)	3 (8.3)	0
Diarrhoea	1 (2.8)	0	0
Enterocolitis	1 (2.8)	1 (2.8)	0
Intestinal obstruction	1 (2.8)	1 (2.8)	0
Pancreatitis	1 (2.8)	1 (2.8)	0
General disorders and administration site conditions			
-Total	5 (13.9)	2 (5.6)	0
Pyrexia	4 (11.1)	1 (2.8)	0
Physical deconditioning	1 (2.8)	1 (2.8)	0
Immune system disorders			
-Total	24 (66.7)	4 (11.1)	8 (22.2)
Cytokine release syndrome	24 (66.7)	4 (11.1)	8 (22.2)
Infections and infestations			
-Total	11 (30.6)	6 (16.7)	2 (5.6)
Pneumonia	2 (5.6)	1 (2.8)	0
Bacterial sepsis	1 (2.8)	0	1 (2.8)
Catheter site infection	1 (2.8)	1 (2.8)	0
Clostridium difficile colitis	1 (2.8)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (2.8)	0	0
Corona virus infection	1 (2.8)	1 (2.8)	0
Gastroenteritis	1 (2.8)	1 (2.8)	0
Herpes zoster	1 (2.8)	1 (2.8)	0
Parainfluenzae virus infection	1 (2.8)	1 (2.8)	0
Respiratory syncytial virus infection	1 (2.8)	1 (2.8)	0
Respiratory tract infection	1 (2.8)	0	1 (2.8)
Staphylococcal infection	1 (2.8)	1 (2.8)	0
Viral upper respiratory tract infection	1 (2.8)	1 (2.8)	0
Injury, poisoning and procedural complications			
-Total	1 (2.8)	1 (2.8)	0
Procedural pain	1 (2.8)	1 (2.8)	0
Investigations			
-Total	1 (2.8)	0	1 (2.8)
White blood cell count decreased	1 (2.8)	0	1 (2.8)
Metabolism and nutrition disorders			
-Total	4 (11.1)	4 (11.1)	0
Tumour lysis syndrome	2 (5.6)	2 (5.6)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acidosis	1 (2.8)	0	0
Decreased appetite	1 (2.8)	1 (2.8)	0
Dehydration	1 (2.8)	1 (2.8)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (5.6)	0	0
Osteonecrosis	1 (2.8)	0	0
Pain in extremity	1 (2.8)	0	0
Nervous system disorders			
-Total	4 (11.1)	1 (2.8)	0
Encephalopathy	2 (5.6)	1 (2.8)	0
Seizure	2 (5.6)	0	0
Psychiatric disorders			
-Total	1 (2.8)	0	0
Delirium	1 (2.8)	0	0
Renal and urinary disorders			
-Total	5 (13.9)	3 (8.3)	2 (5.6)
Acute kidney injury	4 (11.1)	3 (8.3)	1 (2.8)
Renal failure	1 (2.8)	0	1 (2.8)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (2.8)	1 (2.8)	0
Vaginal haemorrhage	1 (2.8)	1 (2.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (19.4)	2 (5.6)	5 (13.9)
Respiratory failure	3 (8.3)	0	3 (8.3)
Hypoxia	2 (5.6)	1 (2.8)	1 (2.8)
Pulmonary oedema	2 (5.6)	1 (2.8)	1 (2.8)
Acute respiratory failure	1 (2.8)	0	1 (2.8)
Pleural effusion	1 (2.8)	1 (2.8)	0
Skin and subcutaneous tissue disorders			
-Total	1 (2.8)	1 (2.8)	0
Ecchymosis	1 (2.8)	1 (2.8)	0
Vascular disorders			
-Total	3 (8.3)	2 (5.6)	1 (2.8)
Hypotension	3 (8.3)	2 (5.6)	1 (2.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179m
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (92.9)	9 (64.3)	2 (14.3)
Blood and lymphatic system disorders			
-Total	8 (57.1)	8 (57.1)	0
Febrile neutropenia	8 (57.1)	8 (57.1)	0
Cardiac disorders			
-Total	1 (7.1)	0	0
Atrioventricular block second degree	1 (7.1)	0	0
Gastrointestinal disorders			
-Total	2 (14.3)	2 (14.3)	0
Intestinal obstruction	1 (7.1)	1 (7.1)	0
Pancreatitis	1 (7.1)	1 (7.1)	0
Immune system disorders			

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (64.3)	2 (14.3)	1 (7.1)
Cytokine release syndrome	9 (64.3)	2 (14.3)	1 (7.1)
Infections and infestations			
-Total	2 (14.3)	2 (14.3)	0
Catheter site infection	1 (7.1)	1 (7.1)	0
Pneumonia	1 (7.1)	1 (7.1)	0
Renal and urinary disorders			
-Total	1 (7.1)	1 (7.1)	0
Acute kidney injury	1 (7.1)	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (21.4)	1 (7.1)	1 (7.1)
Hypoxia	2 (14.3)	1 (7.1)	0
Pleural effusion	1 (7.1)	1 (7.1)	0
Respiratory failure	1 (7.1)	0	1 (7.1)
Vascular disorders			
-Total	1 (7.1)	1 (7.1)	0
Hypotension	1 (7.1)	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179m
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (66.0)	11 (22.0)	15 (30.0)
Blood and lymphatic system disorders			
-Total	15 (30.0)	13 (26.0)	1 (2.0)
Febrile neutropenia	13 (26.0)	13 (26.0)	0
Disseminated intravascular coagulation	2 (4.0)	0	0
Neutropenia	1 (2.0)	0	1 (2.0)
Cardiac disorders			
-Total	1 (2.0)	0	0
Ventricular tachycardia	1 (2.0)	0	0
Eye disorders			
-Total	2 (4.0)	0	0
Papilloedema	1 (2.0)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vision blurred	1 (2.0)	0	0
Gastrointestinal disorders			
-Total	3 (6.0)	1 (2.0)	0
Diarrhoea	1 (2.0)	0	0
Stomatitis	1 (2.0)	0	0
Vomiting	1 (2.0)	1 (2.0)	0
General disorders and administration site conditions			
-Total	4 (8.0)	1 (2.0)	0
Pyrexia	2 (4.0)	0	0
Malaise	1 (2.0)	0	0
Physical deconditioning	1 (2.0)	1 (2.0)	0
Immune system disorders			
-Total	32 (64.0)	6 (12.0)	9 (18.0)
Cytokine release syndrome	32 (64.0)	6 (12.0)	9 (18.0)
Infections and infestations			
-Total	7 (14.0)	2 (4.0)	1 (2.0)
Clostridium difficile colitis	2 (4.0)	0	0
Clostridium difficile infection	2 (4.0)	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (2.0)	1 (2.0)	0
Gastroenteritis norovirus	1 (2.0)	0	0
Rhinovirus infection	1 (2.0)	0	0
Septic embolus	1 (2.0)	0	1 (2.0)
Staphylococcal infection	1 (2.0)	1 (2.0)	0
Injury, poisoning and procedural complications			
-Total	1 (2.0)	0	1 (2.0)
Transfusion related complication	1 (2.0)	0	1 (2.0)
Metabolism and nutrition disorders			
-Total	3 (6.0)	3 (6.0)	0
Acidosis	1 (2.0)	0	0
Decreased appetite	1 (2.0)	1 (2.0)	0
Dehydration	1 (2.0)	1 (2.0)	0
Tumour lysis syndrome	1 (2.0)	1 (2.0)	0
Nervous system disorders			
-Total	9 (18.0)	3 (6.0)	1 (2.0)
Encephalopathy	4 (8.0)	2 (4.0)	0
Seizure	3 (6.0)	1 (2.0)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Embolic stroke	1 (2.0)	0	1 (2.0)
Headache	1 (2.0)	1 (2.0)	0
Idiopathic intracranial hypertension	1 (2.0)	0	0
Psychiatric disorders			
-Total	1 (2.0)	0	0
Delirium	1 (2.0)	0	0
Renal and urinary disorders			
-Total	3 (6.0)	1 (2.0)	2 (4.0)
Acute kidney injury	2 (4.0)	1 (2.0)	1 (2.0)
Renal failure	1 (2.0)	0	1 (2.0)
Respiratory, thoracic and mediastinal disorders			
-Total	5 (10.0)	0	3 (6.0)
Hypoxia	2 (4.0)	0	1 (2.0)
Respiratory failure	2 (4.0)	0	2 (4.0)
Pleural effusion	1 (2.0)	0	0
Pulmonary oedema	1 (2.0)	0	1 (2.0)
Skin and subcutaneous tissue disorders			

Timing: within 8 weeks post infusion, Eligibility for SCT: No

Group term Preferred term	All patients N=50 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	1 (2.0)	1 (2.0)	0
Ecchymosis	1 (2.0)	1 (2.0)	0
Vascular disorders			
-Total	7 (14.0)	4 (8.0)	3 (6.0)
Hypotension	6 (12.0)	3 (6.0)	3 (6.0)
Embolism	1 (2.0)	1 (2.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179m
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

		All patients N=12	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (58.3)	5 (41.7)	1 (8.3)
Blood and lymphatic system disorders			
-Total	1 (8.3)	1 (8.3)	0
Febrile neutropenia	1 (8.3)	1 (8.3)	0
Gastrointestinal disorders			
-Total	1 (8.3)	1 (8.3)	0
Enterocolitis	1 (8.3)	1 (8.3)	0
General disorders and administration site conditions			
-Total	1 (8.3)	0	0
Pyrexia	1 (8.3)	0	0
Infections and infestations			

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=12		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (33.3)	3 (25.0)	1 (8.3)
Bacterial sepsis	1 (8.3)	0	1 (8.3)
Corona virus infection	1 (8.3)	1 (8.3)	0
Parainfluenzae virus infection	1 (8.3)	1 (8.3)	0
Respiratory syncytial virus infection	1 (8.3)	1 (8.3)	0
Viral upper respiratory tract infection	1 (8.3)	1 (8.3)	0
Metabolism and nutrition disorders			
-Total	1 (8.3)	1 (8.3)	0
Tumour lysis syndrome	1 (8.3)	1 (8.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (8.3)	0	0
Pain in extremity	1 (8.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (8.3)	0	0
Myelodysplastic syndrome	1 (8.3)	0	0
Reproductive system and breast disorders			
-Total	1 (8.3)	1 (8.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=12		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal haemorrhage	1 (8.3)	1 (8.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179m
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

		All patients N=44	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (31.8)	8 (18.2)	4 (9.1)
Blood and lymphatic system disorders			
-Total	4 (9.1)	2 (4.5)	2 (4.5)
Febrile neutropenia	2 (4.5)	2 (4.5)	0
Neutropenia	2 (4.5)	0	2 (4.5)
Eosinophilia	1 (2.3)	1 (2.3)	0
Gastrointestinal disorders			
-Total	1 (2.3)	1 (2.3)	0
Vomiting	1 (2.3)	1 (2.3)	0
General disorders and administration site conditions			
-Total	4 (9.1)	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	4 (9.1)	1 (2.3)	0
Immune system disorders			
-Total	1 (2.3)	0	0
Graft versus host disease in gastrointestinal tract	1 (2.3)	0	0
Infections and infestations			
-Total	8 (18.2)	6 (13.6)	1 (2.3)
Cellulitis of male external genital organ	1 (2.3)	1 (2.3)	0
Cholecystitis infective	1 (2.3)	1 (2.3)	0
Enterovirus infection	1 (2.3)	1 (2.3)	0
Gastroenteritis norovirus	1 (2.3)	0	0
Herpes zoster	1 (2.3)	1 (2.3)	0
Rotavirus infection	1 (2.3)	1 (2.3)	0
Sepsis	1 (2.3)	0	1 (2.3)
Upper respiratory tract infection	1 (2.3)	1 (2.3)	0
Vascular device infection	1 (2.3)	1 (2.3)	0
Investigations			
-Total	2 (4.5)	1 (2.3)	1 (2.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (2.3)	1 (2.3)	0
White blood cell count decreased	1 (2.3)	0	1 (2.3)
Musculoskeletal and connective tissue disorders			
-Total	2 (4.5)	0	0
Flank pain	1 (2.3)	0	0
Osteonecrosis	1 (2.3)	0	0
Renal and urinary disorders			
-Total	1 (2.3)	1 (2.3)	0
Acute kidney injury	1 (2.3)	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (4.5)	1 (2.3)	1 (2.3)
Acute respiratory failure	1 (2.3)	0	1 (2.3)
Pulmonary oedema	1 (2.3)	1 (2.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179m
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (11.1)	0	1 (11.1)
Infections and infestations			
-Total	1 (11.1)	0	1 (11.1)
Respiratory tract infection	1 (11.1)	0	1 (11.1)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179m
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (20.0)	2 (8.0)	2 (8.0)
Blood and lymphatic system disorders			
-Total	1 (4.0)	0	1 (4.0)
Febrile neutropenia	1 (4.0)	0	1 (4.0)
Gastrointestinal disorders			
-Total	1 (4.0)	0	0
Diarrhoea	1 (4.0)	0	0
Infections and infestations			
-Total	3 (12.0)	2 (8.0)	0
Urinary tract infection	2 (8.0)	1 (4.0)	0
Campylobacter infection	1 (4.0)	1 (4.0)	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (4.0)	1 (4.0)	0
Clostridium difficile infection	1 (4.0)	1 (4.0)	0
Pneumonia	1 (4.0)	0	0
Respiratory tract infection viral	1 (4.0)	1 (4.0)	0
Vulvovaginal candidiasis	1 (4.0)	0	0
Injury, poisoning and procedural complications			
-Total	1 (4.0)	1 (4.0)	0
Procedural pain	1 (4.0)	1 (4.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (4.0)	0	1 (4.0)
Glioblastoma multiforme	1 (4.0)	0	1 (4.0)
Nervous system disorders			
-Total	1 (4.0)	1 (4.0)	0
Seizure	1 (4.0)	1 (4.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179m
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (92.9)	9 (64.3)	4 (28.6)
Blood and lymphatic system disorders			
-Total	9 (64.3)	9 (64.3)	0
Febrile neutropenia	9 (64.3)	9 (64.3)	0
Cardiac disorders			
-Total	1 (7.1)	0	0
Atrioventricular block second degree	1 (7.1)	0	0
Gastrointestinal disorders			
-Total	3 (21.4)	3 (21.4)	0
Enterocolitis	1 (7.1)	1 (7.1)	0
Intestinal obstruction	1 (7.1)	1 (7.1)	0
Pancreatitis	1 (7.1)	1 (7.1)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (7.1)	0	0
Pyrexia	1 (7.1)	0	0
Immune system disorders			
-Total	9 (64.3)	2 (14.3)	1 (7.1)
Cytokine release syndrome	9 (64.3)	2 (14.3)	1 (7.1)
Infections and infestations			
-Total	6 (42.9)	4 (28.6)	2 (14.3)
Bacterial sepsis	1 (7.1)	0	1 (7.1)
Catheter site infection	1 (7.1)	1 (7.1)	0
Corona virus infection	1 (7.1)	1 (7.1)	0
Parainfluenzae virus infection	1 (7.1)	1 (7.1)	0
Pneumonia	1 (7.1)	1 (7.1)	0
Respiratory syncytial virus infection	1 (7.1)	1 (7.1)	0
Respiratory tract infection	1 (7.1)	0	1 (7.1)
Viral upper respiratory tract infection	1 (7.1)	1 (7.1)	0
Metabolism and nutrition disorders			
-Total	1 (7.1)	1 (7.1)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (7.1)	1 (7.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (7.1)	0	0
Pain in extremity	1 (7.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (7.1)	0	0
Myelodysplastic syndrome	1 (7.1)	0	0
Renal and urinary disorders			
-Total	1 (7.1)	1 (7.1)	0
Acute kidney injury	1 (7.1)	1 (7.1)	0
Reproductive system and breast disorders			
-Total	1 (7.1)	1 (7.1)	0
Vaginal haemorrhage	1 (7.1)	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (21.4)	1 (7.1)	1 (7.1)
Hypoxia	2 (14.3)	1 (7.1)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	1 (7.1)	1 (7.1)	0
Respiratory failure	1 (7.1)	0	1 (7.1)
Vascular disorders			
-Total	1 (7.1)	1 (7.1)	0
Hypotension	1 (7.1)	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179m
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (78.0)	12 (24.0)	20 (40.0)
Blood and lymphatic system disorders			
-Total	18 (36.0)	13 (26.0)	4 (8.0)
Febrile neutropenia	14 (28.0)	13 (26.0)	1 (2.0)
Neutropenia	3 (6.0)	0	3 (6.0)
Disseminated intravascular coagulation	2 (4.0)	0	0
Eosinophilia	1 (2.0)	1 (2.0)	0
Cardiac disorders			
-Total	1 (2.0)	0	0
Ventricular tachycardia	1 (2.0)	0	0
Eye disorders			

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (4.0)	0	0
Papilloedema	1 (2.0)	0	0
Vision blurred	1 (2.0)	0	0
Gastrointestinal disorders			
-Total	4 (8.0)	1 (2.0)	0
Diarrhoea	2 (4.0)	0	0
Stomatitis	1 (2.0)	0	0
Vomiting	1 (2.0)	1 (2.0)	0
General disorders and administration site conditions			
-Total	8 (16.0)	2 (4.0)	0
Pyrexia	6 (12.0)	1 (2.0)	0
Malaise	1 (2.0)	0	0
Physical deconditioning	1 (2.0)	1 (2.0)	0
Immune system disorders			
-Total	32 (64.0)	6 (12.0)	9 (18.0)
Cytokine release syndrome	32 (64.0)	6 (12.0)	9 (18.0)
Graft versus host disease in gastrointestinal tract	1 (2.0)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	13 (26.0)	7 (14.0)	2 (4.0)
Clostridium difficile infection	3 (6.0)	1 (2.0)	0
Clostridium difficile colitis	2 (4.0)	0	0
Urinary tract infection	2 (4.0)	1 (2.0)	0
Campylobacter infection	1 (2.0)	1 (2.0)	0
Cellulitis of male external genital organ	1 (2.0)	1 (2.0)	0
Cholecystitis infective	1 (2.0)	1 (2.0)	0
Enterovirus infection	1 (2.0)	1 (2.0)	0
Gastroenteritis	1 (2.0)	1 (2.0)	0
Gastroenteritis norovirus	1 (2.0)	0	0
Herpes zoster	1 (2.0)	1 (2.0)	0
Pneumonia	1 (2.0)	0	0
Respiratory tract infection viral	1 (2.0)	1 (2.0)	0
Rhinovirus infection	1 (2.0)	0	0
Rotavirus infection	1 (2.0)	1 (2.0)	0
Sepsis	1 (2.0)	0	1 (2.0)
Septic embolus	1 (2.0)	0	1 (2.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (2.0)	1 (2.0)	0
Upper respiratory tract infection	1 (2.0)	1 (2.0)	0
Vascular device infection	1 (2.0)	1 (2.0)	0
Vulvovaginal candidiasis	1 (2.0)	0	0
Injury, poisoning and procedural complications			
-Total	2 (4.0)	1 (2.0)	1 (2.0)
Procedural pain	1 (2.0)	1 (2.0)	0
Transfusion related complication	1 (2.0)	0	1 (2.0)
Investigations			
-Total	2 (4.0)	1 (2.0)	1 (2.0)
Alanine aminotransferase increased	1 (2.0)	1 (2.0)	0
White blood cell count decreased	1 (2.0)	0	1 (2.0)
Metabolism and nutrition disorders			
-Total	3 (6.0)	3 (6.0)	0
Acidosis	1 (2.0)	0	0
Decreased appetite	1 (2.0)	1 (2.0)	0
Dehydration	1 (2.0)	1 (2.0)	0
Tumour lysis syndrome	1 (2.0)	1 (2.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	2 (4.0)	0	0
Flank pain	1 (2.0)	0	0
Osteonecrosis	1 (2.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.0)	0	1 (2.0)
Glioblastoma multiforme	1 (2.0)	0	1 (2.0)
Nervous system disorders			
-Total	10 (20.0)	4 (8.0)	1 (2.0)
Encephalopathy	4 (8.0)	2 (4.0)	0
Seizure	4 (8.0)	2 (4.0)	0
Embolic stroke	1 (2.0)	0	1 (2.0)
Headache	1 (2.0)	1 (2.0)	0
Idiopathic intracranial hypertension	1 (2.0)	0	0
Psychiatric disorders			
-Total	1 (2.0)	0	0
Delirium	1 (2.0)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	4 (8.0)	2 (4.0)	2 (4.0)
Acute kidney injury	3 (6.0)	2 (4.0)	1 (2.0)
Renal failure	1 (2.0)	0	1 (2.0)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (14.0)	1 (2.0)	4 (8.0)
Hypoxia	2 (4.0)	0	1 (2.0)
Pulmonary oedema	2 (4.0)	1 (2.0)	1 (2.0)
Respiratory failure	2 (4.0)	0	2 (4.0)
Acute respiratory failure	1 (2.0)	0	1 (2.0)
Pleural effusion	1 (2.0)	0	0
Skin and subcutaneous tissue disorders			
-Total	1 (2.0)	1 (2.0)	0
Ecchymosis	1 (2.0)	1 (2.0)	0
Vascular disorders			
-Total	7 (14.0)	4 (8.0)	3 (6.0)
Hypotension	6 (12.0)	3 (6.0)	3 (6.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Embolism	1 (2.0)	1 (2.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179n
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (70.0)	10 (50.0)	3 (15.0)
Blood and lymphatic system disorders			
-Total	8 (40.0)	8 (40.0)	0
Febrile neutropenia	8 (40.0)	8 (40.0)	0
Disseminated intravascular coagulation	1 (5.0)	0	0
Gastrointestinal disorders			
-Total	3 (15.0)	1 (5.0)	0
Diarrhoea	1 (5.0)	0	0
Intestinal obstruction	1 (5.0)	1 (5.0)	0
Stomatitis	1 (5.0)	0	0
Immune system disorders			
-Total	14 (70.0)	3 (15.0)	2 (10.0)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	14 (70.0)	3 (15.0)	2 (10.0)
Infections and infestations			
-Total	2 (10.0)	1 (5.0)	0
Clostridium difficile colitis	1 (5.0)	0	0
Gastroenteritis	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	1 (5.0)	1 (5.0)	0
Dehydration	1 (5.0)	1 (5.0)	0
Nervous system disorders			
-Total	4 (20.0)	1 (5.0)	0
Encephalopathy	3 (15.0)	1 (5.0)	0
Headache	1 (5.0)	1 (5.0)	0
Seizure	1 (5.0)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (10.0)	0	0
Hypoxia	2 (10.0)	0	0
Vascular disorders			
-Total	5 (25.0)	4 (20.0)	1 (5.0)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	4 (20.0)	3 (15.0)	1 (5.0)
Embolism	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179n
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (72.7)	10 (22.7)	14 (31.8)
Blood and lymphatic system disorders			
-Total	15 (34.1)	13 (29.5)	1 (2.3)
Febrile neutropenia	13 (29.5)	13 (29.5)	0
Disseminated intravascular coagulation	1 (2.3)	0	0
Neutropenia	1 (2.3)	0	1 (2.3)
Cardiac disorders			
-Total	2 (4.5)	0	0
Atrioventricular block second degree	1 (2.3)	0	0
Ventricular tachycardia	1 (2.3)	0	0
Eye disorders			
-Total	2 (4.5)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Papilloedema	1 (2.3)	0	0
Vision blurred	1 (2.3)	0	0
Gastrointestinal disorders			
-Total	2 (4.5)	2 (4.5)	0
Pancreatitis	1 (2.3)	1 (2.3)	0
Vomiting	1 (2.3)	1 (2.3)	0
General disorders and administration site conditions			
-Total	4 (9.1)	1 (2.3)	0
Pyrexia	2 (4.5)	0	0
Malaise	1 (2.3)	0	0
Physical deconditioning	1 (2.3)	1 (2.3)	0
Immune system disorders			
-Total	27 (61.4)	5 (11.4)	8 (18.2)
Cytokine release syndrome	27 (61.4)	5 (11.4)	8 (18.2)
Infections and infestations			
-Total	7 (15.9)	3 (6.8)	1 (2.3)
Clostridium difficile infection	2 (4.5)	0	0
Catheter site infection	1 (2.3)	1 (2.3)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	1 (2.3)	0	0
Gastroenteritis norovirus	1 (2.3)	0	0
Pneumonia	1 (2.3)	1 (2.3)	0
Rhinovirus infection	1 (2.3)	0	0
Septic embolus	1 (2.3)	0	1 (2.3)
Staphylococcal infection	1 (2.3)	1 (2.3)	0
Injury, poisoning and procedural complications			
-Total	1 (2.3)	0	1 (2.3)
Transfusion related complication	1 (2.3)	0	1 (2.3)
Metabolism and nutrition disorders			
-Total	2 (4.5)	2 (4.5)	0
Acidosis	1 (2.3)	0	0
Decreased appetite	1 (2.3)	1 (2.3)	0
Tumour lysis syndrome	1 (2.3)	1 (2.3)	0
Nervous system disorders			
-Total	5 (11.4)	2 (4.5)	1 (2.3)
Seizure	2 (4.5)	1 (2.3)	0
Embolic stroke	1 (2.3)	0	1 (2.3)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (2.3)	1 (2.3)	0
Idiopathic intracranial hypertension	1 (2.3)	0	0
Psychiatric disorders			
-Total	1 (2.3)	0	0
Delirium	1 (2.3)	0	0
Renal and urinary disorders			
-Total	4 (9.1)	2 (4.5)	2 (4.5)
Acute kidney injury	3 (6.8)	2 (4.5)	1 (2.3)
Renal failure	1 (2.3)	0	1 (2.3)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (13.6)	1 (2.3)	4 (9.1)
Respiratory failure	3 (6.8)	0	3 (6.8)
Hypoxia	2 (4.5)	1 (2.3)	1 (2.3)
Pleural effusion	2 (4.5)	1 (2.3)	0
Pulmonary oedema	1 (2.3)	0	1 (2.3)
Skin and subcutaneous tissue disorders			
-Total	1 (2.3)	1 (2.3)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ecchymosis	1 (2.3)	1 (2.3)	0
Vascular disorders			
-Total	3 (6.8)	1 (2.3)	2 (4.5)
Hypotension	3 (6.8)	1 (2.3)	2 (4.5)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179n
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (50.0)	6 (30.0)	2 (10.0)
Blood and lymphatic system disorders			
-Total	3 (15.0)	2 (10.0)	1 (5.0)
Febrile neutropenia	2 (10.0)	2 (10.0)	0
Neutropenia	1 (5.0)	0	1 (5.0)
Gastrointestinal disorders			
-Total	1 (5.0)	1 (5.0)	0
Enterocolitis	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	3 (15.0)	1 (5.0)	0
Pyrexia	3 (15.0)	1 (5.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	5 (25.0)	4 (20.0)	1 (5.0)
Bacterial sepsis	1 (5.0)	0	1 (5.0)
Cholecystitis infective	1 (5.0)	1 (5.0)	0
Corona virus infection	1 (5.0)	1 (5.0)	0
Herpes zoster	1 (5.0)	1 (5.0)	0
Respiratory syncytial virus infection	1 (5.0)	1 (5.0)	0
Vascular device infection	1 (5.0)	1 (5.0)	0
Investigations			
-Total	1 (5.0)	0	1 (5.0)
White blood cell count decreased	1 (5.0)	0	1 (5.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (5.0)	0	0
Osteonecrosis	1 (5.0)	0	0
Reproductive system and breast disorders			
-Total	1 (5.0)	1 (5.0)	0
Vaginal haemorrhage	1 (5.0)	1 (5.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.0)	1 (5.0)	0
Pulmonary oedema	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179n
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=36	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (30.6)	7 (19.4)	3 (8.3)
Blood and lymphatic system disorders			
-Total	2 (5.6)	1 (2.8)	1 (2.8)
Eosinophilia	1 (2.8)	1 (2.8)	0
Febrile neutropenia	1 (2.8)	1 (2.8)	0
Neutropenia	1 (2.8)	0	1 (2.8)
Gastrointestinal disorders			
-Total	1 (2.8)	1 (2.8)	0
Vomiting	1 (2.8)	1 (2.8)	0
General disorders and administration site conditions			
-Total	2 (5.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	2 (5.6)	0	0
Immune system disorders			
-Total	1 (2.8)	0	0
Graft versus host disease in gastrointestinal tract	1 (2.8)	0	0
Infections and infestations			
-Total	7 (19.4)	5 (13.9)	1 (2.8)
Cellulitis of male external genital organ	1 (2.8)	1 (2.8)	0
Enterovirus infection	1 (2.8)	1 (2.8)	0
Gastroenteritis norovirus	1 (2.8)	0	0
Parainfluenzae virus infection	1 (2.8)	1 (2.8)	0
Rotavirus infection	1 (2.8)	1 (2.8)	0
Sepsis	1 (2.8)	0	1 (2.8)
Upper respiratory tract infection	1 (2.8)	1 (2.8)	0
Viral upper respiratory tract infection	1 (2.8)	1 (2.8)	0
Investigations			
-Total	1 (2.8)	1 (2.8)	0
Alanine aminotransferase increased	1 (2.8)	1 (2.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=36	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	1 (2.8)	1 (2.8)	0
Tumour lysis syndrome	1 (2.8)	1 (2.8)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (5.6)	0	0
Flank pain	1 (2.8)	0	0
Pain in extremity	1 (2.8)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.8)	0	0
Myelodysplastic syndrome	1 (2.8)	0	0
Renal and urinary disorders			
-Total	1 (2.8)	1 (2.8)	0
Acute kidney injury	1 (2.8)	1 (2.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (2.8)	0	1 (2.8)
Acute respiratory failure	1 (2.8)	0	1 (2.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179n
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (7.1)	0	1 (7.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (7.1)	0	1 (7.1)
Glioblastoma multiforme	1 (7.1)	0	1 (7.1)
Nervous system disorders			
-Total	1 (7.1)	1 (7.1)	0
Seizure	1 (7.1)	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179n
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (25.0)	2 (10.0)	2 (10.0)
Blood and lymphatic system disorders			
-Total	1 (5.0)	0	1 (5.0)
Febrile neutropenia	1 (5.0)	0	1 (5.0)
Gastrointestinal disorders			
-Total	1 (5.0)	0	0
Diarrhoea	1 (5.0)	0	0
Infections and infestations			
-Total	4 (20.0)	2 (10.0)	1 (5.0)
Urinary tract infection	2 (10.0)	1 (5.0)	0
Campylobacter infection	1 (5.0)	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (5.0)	1 (5.0)	0
Clostridium difficile infection	1 (5.0)	1 (5.0)	0
Pneumonia	1 (5.0)	0	0
Respiratory tract infection	1 (5.0)	0	1 (5.0)
Respiratory tract infection viral	1 (5.0)	1 (5.0)	0
Vulvovaginal candidiasis	1 (5.0)	0	0
Injury, poisoning and procedural complications			
-Total	1 (5.0)	1 (5.0)	0
Procedural pain	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179n
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (80.0)	10 (50.0)	6 (30.0)
Blood and lymphatic system disorders			
-Total	9 (45.0)	8 (40.0)	1 (5.0)
Febrile neutropenia	8 (40.0)	8 (40.0)	0
Disseminated intravascular coagulation	1 (5.0)	0	0
Neutropenia	1 (5.0)	0	1 (5.0)
Gastrointestinal disorders			
-Total	4 (20.0)	2 (10.0)	0
Diarrhoea	1 (5.0)	0	0
Enterocolitis	1 (5.0)	1 (5.0)	0
Intestinal obstruction	1 (5.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (5.0)	0	0
General disorders and administration site conditions			
-Total	3 (15.0)	1 (5.0)	0
Pyrexia	3 (15.0)	1 (5.0)	0
Immune system disorders			
-Total	14 (70.0)	3 (15.0)	2 (10.0)
Cytokine release syndrome	14 (70.0)	3 (15.0)	2 (10.0)
Infections and infestations			
-Total	5 (25.0)	4 (20.0)	1 (5.0)
Bacterial sepsis	1 (5.0)	0	1 (5.0)
Cholecystitis infective	1 (5.0)	1 (5.0)	0
Clostridium difficile colitis	1 (5.0)	0	0
Corona virus infection	1 (5.0)	1 (5.0)	0
Gastroenteritis	1 (5.0)	1 (5.0)	0
Herpes zoster	1 (5.0)	1 (5.0)	0
Respiratory syncytial virus infection	1 (5.0)	1 (5.0)	0
Vascular device infection	1 (5.0)	1 (5.0)	0
Investigations			

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.0)	0	1 (5.0)
White blood cell count decreased	1 (5.0)	0	1 (5.0)
Metabolism and nutrition disorders			
-Total	1 (5.0)	1 (5.0)	0
Dehydration	1 (5.0)	1 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (5.0)	0	0
Osteonecrosis	1 (5.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (5.0)	0	1 (5.0)
Glioblastoma multiforme	1 (5.0)	0	1 (5.0)
Nervous system disorders			
-Total	5 (25.0)	2 (10.0)	0
Encephalopathy	3 (15.0)	1 (5.0)	0
Seizure	2 (10.0)	1 (5.0)	0
Headache	1 (5.0)	1 (5.0)	0
Reproductive system and breast disorders			

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.0)	1 (5.0)	0
Vaginal haemorrhage	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (15.0)	1 (5.0)	0
Hypoxia	2 (10.0)	0	0
Pulmonary oedema	1 (5.0)	1 (5.0)	0
Vascular disorders			
-Total	5 (25.0)	4 (20.0)	1 (5.0)
Hypotension	4 (20.0)	3 (15.0)	1 (5.0)
Embolism	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179n
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

		All patients N=44	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (81.8)	11 (25.0)	18 (40.9)
Blood and lymphatic system disorders			
-Total	18 (40.9)	14 (31.8)	3 (6.8)
Febrile neutropenia	15 (34.1)	14 (31.8)	1 (2.3)
Neutropenia	2 (4.5)	0	2 (4.5)
Disseminated intravascular coagulation	1 (2.3)	0	0
Eosinophilia	1 (2.3)	1 (2.3)	0
Cardiac disorders			
-Total	2 (4.5)	0	0
Atrioventricular block second degree	1 (2.3)	0	0
Ventricular tachycardia	1 (2.3)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders			
-Total	2 (4.5)	0	0
Papilloedema	1 (2.3)	0	0
Vision blurred	1 (2.3)	0	0
Gastrointestinal disorders			
-Total	3 (6.8)	2 (4.5)	0
Diarrhoea	1 (2.3)	0	0
Pancreatitis	1 (2.3)	1 (2.3)	0
Vomiting	1 (2.3)	1 (2.3)	0
General disorders and administration site conditions			
-Total	6 (13.6)	1 (2.3)	0
Pyrexia	4 (9.1)	0	0
Malaise	1 (2.3)	0	0
Physical deconditioning	1 (2.3)	1 (2.3)	0
Immune system disorders			
-Total	27 (61.4)	5 (11.4)	8 (18.2)
Cytokine release syndrome	27 (61.4)	5 (11.4)	8 (18.2)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease in gastrointestinal tract	1 (2.3)	0	0
Infections and infestations			
-Total	14 (31.8)	7 (15.9)	3 (6.8)
Clostridium difficile infection	3 (6.8)	1 (2.3)	0
Pneumonia	2 (4.5)	1 (2.3)	0
Urinary tract infection	2 (4.5)	1 (2.3)	0
Campylobacter infection	1 (2.3)	1 (2.3)	0
Catheter site infection	1 (2.3)	1 (2.3)	0
Cellulitis of male external genital organ	1 (2.3)	1 (2.3)	0
Clostridium difficile colitis	1 (2.3)	0	0
Enterovirus infection	1 (2.3)	1 (2.3)	0
Gastroenteritis norovirus	1 (2.3)	0	0
Parainfluenzae virus infection	1 (2.3)	1 (2.3)	0
Respiratory tract infection	1 (2.3)	0	1 (2.3)
Respiratory tract infection viral	1 (2.3)	1 (2.3)	0
Rhinovirus infection	1 (2.3)	0	0
Rotavirus infection	1 (2.3)	1 (2.3)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (2.3)	0	1 (2.3)
Septic embolus	1 (2.3)	0	1 (2.3)
Staphylococcal infection	1 (2.3)	1 (2.3)	0
Upper respiratory tract infection	1 (2.3)	1 (2.3)	0
Viral upper respiratory tract infection	1 (2.3)	1 (2.3)	0
Vulvovaginal candidiasis	1 (2.3)	0	0
Injury, poisoning and procedural complications			
-Total	2 (4.5)	1 (2.3)	1 (2.3)
Procedural pain	1 (2.3)	1 (2.3)	0
Transfusion related complication	1 (2.3)	0	1 (2.3)
Investigations			
-Total	1 (2.3)	1 (2.3)	0
Alanine aminotransferase increased	1 (2.3)	1 (2.3)	0
Metabolism and nutrition disorders			
-Total	3 (6.8)	3 (6.8)	0
Tumour lysis syndrome	2 (4.5)	2 (4.5)	0
Acidosis	1 (2.3)	0	0
Decreased appetite	1 (2.3)	1 (2.3)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	2 (4.5)	0	0
Flank pain	1 (2.3)	0	0
Pain in extremity	1 (2.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.3)	0	0
Myelodysplastic syndrome	1 (2.3)	0	0
Nervous system disorders			
-Total	5 (11.4)	2 (4.5)	1 (2.3)
Seizure	2 (4.5)	1 (2.3)	0
Embolic stroke	1 (2.3)	0	1 (2.3)
Encephalopathy	1 (2.3)	1 (2.3)	0
Idiopathic intracranial hypertension	1 (2.3)	0	0
Psychiatric disorders			
-Total	1 (2.3)	0	0
Delirium	1 (2.3)	0	0
Renal and urinary disorders			

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (11.4)	3 (6.8)	2 (4.5)
Acute kidney injury	4 (9.1)	3 (6.8)	1 (2.3)
Renal failure	1 (2.3)	0	1 (2.3)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (15.9)	1 (2.3)	5 (11.4)
Respiratory failure	3 (6.8)	0	3 (6.8)
Hypoxia	2 (4.5)	1 (2.3)	1 (2.3)
Pleural effusion	2 (4.5)	1 (2.3)	0
Acute respiratory failure	1 (2.3)	0	1 (2.3)
Pulmonary oedema	1 (2.3)	0	1 (2.3)
Skin and subcutaneous tissue disorders			
-Total	1 (2.3)	1 (2.3)	0
Ecchymosis	1 (2.3)	1 (2.3)	0
Vascular disorders			
-Total	3 (6.8)	1 (2.3)	2 (4.5)
Hypotension	3 (6.8)	1 (2.3)	2 (4.5)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179o
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (60.0)	1 (20.0)	1 (20.0)
Blood and lymphatic system disorders			
-Total	1 (20.0)	1 (20.0)	0
Febrile neutropenia	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
-Total	1 (20.0)	0	0
Malaise	1 (20.0)	0	0
Immune system disorders			
-Total	3 (60.0)	0	1 (20.0)
Cytokine release syndrome	3 (60.0)	0	1 (20.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179o
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=59	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	43 (72.9)	19 (32.2)	16 (27.1)
Blood and lymphatic system disorders			
-Total	22 (37.3)	20 (33.9)	1 (1.7)
Febrile neutropenia	20 (33.9)	20 (33.9)	0
Disseminated intravascular coagulation	2 (3.4)	0	0
Neutropenia	1 (1.7)	0	1 (1.7)
Cardiac disorders			
-Total	2 (3.4)	0	0
Atrioventricular block second degree	1 (1.7)	0	0
Ventricular tachycardia	1 (1.7)	0	0
Eye disorders			
-Total	2 (3.4)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=59	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Papilloedema	1 (1.7)	0	0
Vision blurred	1 (1.7)	0	0
Gastrointestinal disorders			
-Total	5 (8.5)	3 (5.1)	0
Diarrhoea	1 (1.7)	0	0
Intestinal obstruction	1 (1.7)	1 (1.7)	0
Pancreatitis	1 (1.7)	1 (1.7)	0
Stomatitis	1 (1.7)	0	0
Vomiting	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	3 (5.1)	1 (1.7)	0
Pyrexia	2 (3.4)	0	0
Physical deconditioning	1 (1.7)	1 (1.7)	0
Immune system disorders			
-Total	38 (64.4)	8 (13.6)	9 (15.3)
Cytokine release syndrome	38 (64.4)	8 (13.6)	9 (15.3)
Infections and infestations			
-Total	9 (15.3)	4 (6.8)	1 (1.7)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	2 (3.4)	0	0
Clostridium difficile infection	2 (3.4)	0	0
Catheter site infection	1 (1.7)	1 (1.7)	0
Gastroenteritis	1 (1.7)	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	0	0
Pneumonia	1 (1.7)	1 (1.7)	0
Rhinovirus infection	1 (1.7)	0	0
Septic embolus	1 (1.7)	0	1 (1.7)
Staphylococcal infection	1 (1.7)	1 (1.7)	0
Injury, poisoning and procedural complications			
-Total	1 (1.7)	0	1 (1.7)
Transfusion related complication	1 (1.7)	0	1 (1.7)
Metabolism and nutrition disorders			
-Total	3 (5.1)	3 (5.1)	0
Acidosis	1 (1.7)	0	0
Decreased appetite	1 (1.7)	1 (1.7)	0
Dehydration	1 (1.7)	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	1 (1.7)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

		All patients N=59	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	9 (15.3)	3 (5.1)	1 (1.7)
Encephalopathy	4 (6.8)	2 (3.4)	0
Seizure	3 (5.1)	1 (1.7)	0
Embolic stroke	1 (1.7)	0	1 (1.7)
Headache	1 (1.7)	1 (1.7)	0
Idiopathic intracranial hypertension	1 (1.7)	0	0
Psychiatric disorders			
-Total	1 (1.7)	0	0
Delirium	1 (1.7)	0	0
Renal and urinary disorders			
-Total	4 (6.8)	2 (3.4)	2 (3.4)
Acute kidney injury	3 (5.1)	2 (3.4)	1 (1.7)
Renal failure	1 (1.7)	0	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (13.6)	1 (1.7)	4 (6.8)
Hypoxia	4 (6.8)	1 (1.7)	1 (1.7)
Respiratory failure	3 (5.1)	0	3 (5.1)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	2 (3.4)	1 (1.7)	0
Pulmonary oedema	1 (1.7)	0	1 (1.7)
Skin and subcutaneous tissue disorders			
-Total	1 (1.7)	1 (1.7)	0
Ecchymosis	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	8 (13.6)	5 (8.5)	3 (5.1)
Hypotension	7 (11.9)	4 (6.8)	3 (5.1)
Embolism	1 (1.7)	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179o
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (20.0)	1 (20.0)	0
Infections and infestations			
-Total	1 (20.0)	1 (20.0)	0
Viral upper respiratory tract infection	1 (20.0)	1 (20.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179o
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=51	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (39.2)	12 (23.5)	5 (9.8)
Blood and lymphatic system disorders			
-Total	5 (9.8)	3 (5.9)	2 (3.9)
Febrile neutropenia	3 (5.9)	3 (5.9)	0
Neutropenia	2 (3.9)	0	2 (3.9)
Eosinophilia	1 (2.0)	1 (2.0)	0
Gastrointestinal disorders			
-Total	2 (3.9)	2 (3.9)	0
Enterocolitis	1 (2.0)	1 (2.0)	0
Vomiting	1 (2.0)	1 (2.0)	0
General disorders and administration site conditions			

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (9.8)	1 (2.0)	0
Pyrexia	5 (9.8)	1 (2.0)	0
Immune system disorders			
-Total	1 (2.0)	0	0
Graft versus host disease in gastrointestinal tract	1 (2.0)	0	0
Infections and infestations			
-Total	11 (21.6)	8 (15.7)	2 (3.9)
Bacterial sepsis	1 (2.0)	0	1 (2.0)
Cellulitis of male external genital organ	1 (2.0)	1 (2.0)	0
Cholecystitis infective	1 (2.0)	1 (2.0)	0
Corona virus infection	1 (2.0)	1 (2.0)	0
Enterovirus infection	1 (2.0)	1 (2.0)	0
Gastroenteritis norovirus	1 (2.0)	0	0
Herpes zoster	1 (2.0)	1 (2.0)	0
Parainfluenzae virus infection	1 (2.0)	1 (2.0)	0
Respiratory syncytial virus infection	1 (2.0)	1 (2.0)	0
Rotavirus infection	1 (2.0)	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (2.0)	0	1 (2.0)
Upper respiratory tract infection	1 (2.0)	1 (2.0)	0
Vascular device infection	1 (2.0)	1 (2.0)	0
Investigations			
-Total	2 (3.9)	1 (2.0)	1 (2.0)
Alanine aminotransferase increased	1 (2.0)	1 (2.0)	0
White blood cell count decreased	1 (2.0)	0	1 (2.0)
Metabolism and nutrition disorders			
-Total	1 (2.0)	1 (2.0)	0
Tumour lysis syndrome	1 (2.0)	1 (2.0)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (5.9)	0	0
Flank pain	1 (2.0)	0	0
Osteonecrosis	1 (2.0)	0	0
Pain in extremity	1 (2.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myelodysplastic syndrome	1 (2.0)	0	0
Renal and urinary disorders			
-Total	1 (2.0)	1 (2.0)	0
Acute kidney injury	1 (2.0)	1 (2.0)	0
Reproductive system and breast disorders			
-Total	1 (2.0)	1 (2.0)	0
Vaginal haemorrhage	1 (2.0)	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.9)	1 (2.0)	1 (2.0)
Acute respiratory failure	1 (2.0)	0	1 (2.0)
Pulmonary oedema	1 (2.0)	1 (2.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179o
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	2 (66.7)
Blood and lymphatic system disorders			
-Total	1 (33.3)	0	1 (33.3)
Febrile neutropenia	1 (33.3)	0	1 (33.3)
Injury, poisoning and procedural complications			
-Total	1 (33.3)	1 (33.3)	0
Procedural pain	1 (33.3)	1 (33.3)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (33.3)	0	1 (33.3)
Glioblastoma multiforme	1 (33.3)	0	1 (33.3)

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	1 (33.3)	1 (33.3)	0
Seizure	1 (33.3)	1 (33.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179o
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (12.9)	2 (6.5)	1 (3.2)
Gastrointestinal disorders			
-Total	1 (3.2)	0	0
Diarrhoea	1 (3.2)	0	0
Infections and infestations			
-Total	4 (12.9)	2 (6.5)	1 (3.2)
Urinary tract infection	2 (6.5)	1 (3.2)	0
Campylobacter infection	1 (3.2)	1 (3.2)	0
Cellulitis of male external genital organ	1 (3.2)	1 (3.2)	0
Clostridium difficile infection	1 (3.2)	1 (3.2)	0
Pneumonia	1 (3.2)	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	1 (3.2)	0	1 (3.2)
Respiratory tract infection viral	1 (3.2)	1 (3.2)	0
Vulvovaginal candidiasis	1 (3.2)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179o
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	1 (20.0)	3 (60.0)
Blood and lymphatic system disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Febrile neutropenia	2 (40.0)	1 (20.0)	1 (20.0)
General disorders and administration site conditions			
-Total	1 (20.0)	0	0
Malaise	1 (20.0)	0	0
Immune system disorders			
-Total	3 (60.0)	0	1 (20.0)
Cytokine release syndrome	3 (60.0)	0	1 (20.0)
Infections and infestations			

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (20.0)	1 (20.0)	0
Viral upper respiratory tract infection	1 (20.0)	1 (20.0)	0
Injury, poisoning and procedural complications			
-Total	1 (20.0)	1 (20.0)	0
Procedural pain	1 (20.0)	1 (20.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (20.0)	0	1 (20.0)
Glioblastoma multiforme	1 (20.0)	0	1 (20.0)
Nervous system disorders			
-Total	1 (20.0)	1 (20.0)	0
Seizure	1 (20.0)	1 (20.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179o
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=59	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	47 (79.7)	20 (33.9)	21 (35.6)
Blood and lymphatic system disorders			
-Total	25 (42.4)	21 (35.6)	3 (5.1)
Febrile neutropenia	21 (35.6)	21 (35.6)	0
Neutropenia	3 (5.1)	0	3 (5.1)
Disseminated intravascular coagulation	2 (3.4)	0	0
Eosinophilia	1 (1.7)	1 (1.7)	0
Cardiac disorders			
-Total	2 (3.4)	0	0
Atrioventricular block second degree	1 (1.7)	0	0
Ventricular tachycardia	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders			
-Total	2 (3.4)	0	0
Papilloedema	1 (1.7)	0	0
Vision blurred	1 (1.7)	0	0
Gastrointestinal disorders			
-Total	7 (11.9)	4 (6.8)	0
Diarrhoea	2 (3.4)	0	0
Enterocolitis	1 (1.7)	1 (1.7)	0
Intestinal obstruction	1 (1.7)	1 (1.7)	0
Pancreatitis	1 (1.7)	1 (1.7)	0
Stomatitis	1 (1.7)	0	0
Vomiting	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	8 (13.6)	2 (3.4)	0
Pyrexia	7 (11.9)	1 (1.7)	0
Physical deconditioning	1 (1.7)	1 (1.7)	0
Immune system disorders			
-Total	38 (64.4)	8 (13.6)	9 (15.3)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	38 (64.4)	8 (13.6)	9 (15.3)
Graft versus host disease in gastrointestinal tract	1 (1.7)	0	0
Infections and infestations			
-Total	18 (30.5)	10 (16.9)	4 (6.8)
Clostridium difficile infection	3 (5.1)	1 (1.7)	0
Clostridium difficile colitis	2 (3.4)	0	0
Pneumonia	2 (3.4)	1 (1.7)	0
Urinary tract infection	2 (3.4)	1 (1.7)	0
Bacterial sepsis	1 (1.7)	0	1 (1.7)
Campylobacter infection	1 (1.7)	1 (1.7)	0
Catheter site infection	1 (1.7)	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	1 (1.7)	0
Cholecystitis infective	1 (1.7)	1 (1.7)	0
Corona virus infection	1 (1.7)	1 (1.7)	0
Enterovirus infection	1 (1.7)	1 (1.7)	0
Gastroenteritis	1 (1.7)	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	1 (1.7)	1 (1.7)	0
Parainfluenzae virus infection	1 (1.7)	1 (1.7)	0
Respiratory syncytial virus infection	1 (1.7)	1 (1.7)	0
Respiratory tract infection	1 (1.7)	0	1 (1.7)
Respiratory tract infection viral	1 (1.7)	1 (1.7)	0
Rhinovirus infection	1 (1.7)	0	0
Rotavirus infection	1 (1.7)	1 (1.7)	0
Sepsis	1 (1.7)	0	1 (1.7)
Septic embolus	1 (1.7)	0	1 (1.7)
Staphylococcal infection	1 (1.7)	1 (1.7)	0
Upper respiratory tract infection	1 (1.7)	1 (1.7)	0
Vascular device infection	1 (1.7)	1 (1.7)	0
Vulvovaginal candidiasis	1 (1.7)	0	0
Injury, poisoning and procedural complications			
-Total	1 (1.7)	0	1 (1.7)
Transfusion related complication	1 (1.7)	0	1 (1.7)
Investigations			
-Total	2 (3.4)	1 (1.7)	1 (1.7)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (1.7)	1 (1.7)	0
White blood cell count decreased	1 (1.7)	0	1 (1.7)
Metabolism and nutrition disorders			
-Total	4 (6.8)	4 (6.8)	0
Tumour lysis syndrome	2 (3.4)	2 (3.4)	0
Acidosis	1 (1.7)	0	0
Decreased appetite	1 (1.7)	1 (1.7)	0
Dehydration	1 (1.7)	1 (1.7)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (5.1)	0	0
Flank pain	1 (1.7)	0	0
Osteonecrosis	1 (1.7)	0	0
Pain in extremity	1 (1.7)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.7)	0	0
Myelodysplastic syndrome	1 (1.7)	0	0
Nervous system disorders			

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (15.3)	3 (5.1)	1 (1.7)
Encephalopathy	4 (6.8)	2 (3.4)	0
Seizure	3 (5.1)	1 (1.7)	0
Embolic stroke	1 (1.7)	0	1 (1.7)
Headache	1 (1.7)	1 (1.7)	0
Idiopathic intracranial hypertension	1 (1.7)	0	0
Psychiatric disorders			
-Total	1 (1.7)	0	0
Delirium	1 (1.7)	0	0
Renal and urinary disorders			
-Total	5 (8.5)	3 (5.1)	2 (3.4)
Acute kidney injury	4 (6.8)	3 (5.1)	1 (1.7)
Renal failure	1 (1.7)	0	1 (1.7)
Reproductive system and breast disorders			
-Total	1 (1.7)	1 (1.7)	0
Vaginal haemorrhage	1 (1.7)	1 (1.7)	0
Respiratory, thoracic and mediastinal disorders			

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (16.9)	2 (3.4)	5 (8.5)
Hypoxia	4 (6.8)	1 (1.7)	1 (1.7)
Respiratory failure	3 (5.1)	0	3 (5.1)
Pleural effusion	2 (3.4)	1 (1.7)	0
Pulmonary oedema	2 (3.4)	1 (1.7)	1 (1.7)
Acute respiratory failure	1 (1.7)	0	1 (1.7)
Skin and subcutaneous tissue disorders			
-Total	1 (1.7)	1 (1.7)	0
Ecchymosis	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	8 (13.6)	5 (8.5)	3 (5.1)
Hypotension	7 (11.9)	4 (6.8)	3 (5.1)
Embolism	1 (1.7)	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179p
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	2 (50.0)	0
Blood and lymphatic system disorders			
-Total	2 (50.0)	2 (50.0)	0
Febrile neutropenia	2 (50.0)	2 (50.0)	0
Immune system disorders			
-Total	2 (50.0)	0	0
Cytokine release syndrome	2 (50.0)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	0
Vascular disorders			
-Total	1 (25.0)	1 (25.0)	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	1 (25.0)	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179p
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	44 (73.3)	18 (30.0)	17 (28.3)
Blood and lymphatic system disorders			
-Total	21 (35.0)	19 (31.7)	1 (1.7)
Febrile neutropenia	19 (31.7)	19 (31.7)	0
Disseminated intravascular coagulation	2 (3.3)	0	0
Neutropenia	1 (1.7)	0	1 (1.7)
Cardiac disorders			
-Total	2 (3.3)	0	0
Atrioventricular block second degree	1 (1.7)	0	0
Ventricular tachycardia	1 (1.7)	0	0
Eye disorders			
-Total	2 (3.3)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Papilloedema	1 (1.7)	0	0
Vision blurred	1 (1.7)	0	0
Gastrointestinal disorders			
-Total	5 (8.3)	3 (5.0)	0
Diarrhoea	1 (1.7)	0	0
Intestinal obstruction	1 (1.7)	1 (1.7)	0
Pancreatitis	1 (1.7)	1 (1.7)	0
Stomatitis	1 (1.7)	0	0
Vomiting	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	4 (6.7)	1 (1.7)	0
Pyrexia	2 (3.3)	0	0
Malaise	1 (1.7)	0	0
Physical deconditioning	1 (1.7)	1 (1.7)	0
Immune system disorders			
-Total	39 (65.0)	8 (13.3)	10 (16.7)
Cytokine release syndrome	39 (65.0)	8 (13.3)	10 (16.7)
Infections and infestations			

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (15.0)	4 (6.7)	1 (1.7)
Clostridium difficile colitis	2 (3.3)	0	0
Clostridium difficile infection	2 (3.3)	0	0
Catheter site infection	1 (1.7)	1 (1.7)	0
Gastroenteritis	1 (1.7)	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	0	0
Pneumonia	1 (1.7)	1 (1.7)	0
Rhinovirus infection	1 (1.7)	0	0
Septic embolus	1 (1.7)	0	1 (1.7)
Staphylococcal infection	1 (1.7)	1 (1.7)	0
Injury, poisoning and procedural complications			
-Total	1 (1.7)	0	1 (1.7)
Transfusion related complication	1 (1.7)	0	1 (1.7)
Metabolism and nutrition disorders			
-Total	3 (5.0)	3 (5.0)	0
Acidosis	1 (1.7)	0	0
Decreased appetite	1 (1.7)	1 (1.7)	0
Dehydration	1 (1.7)	1 (1.7)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (1.7)	1 (1.7)	0
Nervous system disorders			
-Total	9 (15.0)	3 (5.0)	1 (1.7)
Encephalopathy	4 (6.7)	2 (3.3)	0
Seizure	3 (5.0)	1 (1.7)	0
Embolic stroke	1 (1.7)	0	1 (1.7)
Headache	1 (1.7)	1 (1.7)	0
Idiopathic intracranial hypertension	1 (1.7)	0	0
Psychiatric disorders			
-Total	1 (1.7)	0	0
Delirium	1 (1.7)	0	0
Renal and urinary disorders			
-Total	4 (6.7)	2 (3.3)	2 (3.3)
Acute kidney injury	3 (5.0)	2 (3.3)	1 (1.7)
Renal failure	1 (1.7)	0	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (11.7)	1 (1.7)	4 (6.7)
Hypoxia	3 (5.0)	1 (1.7)	1 (1.7)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	3 (5.0)	0	3 (5.0)
Pleural effusion	2 (3.3)	1 (1.7)	0
Pulmonary oedema	1 (1.7)	0	1 (1.7)
Skin and subcutaneous tissue disorders			
-Total	1 (1.7)	1 (1.7)	0
Ecchymosis	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	7 (11.7)	4 (6.7)	3 (5.0)
Hypotension	6 (10.0)	3 (5.0)	3 (5.0)
Embolism	1 (1.7)	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179p
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

		All patients N=4	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	2 (50.0)	0
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Enterocolitis	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
-Total	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	1 (25.0)	1 (25.0)	0
Corona virus infection	1 (25.0)	1 (25.0)	0
Respiratory syncytial virus infection	1 (25.0)	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179p
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (36.5)	11 (21.2)	5 (9.6)
Blood and lymphatic system disorders			
-Total	5 (9.6)	3 (5.8)	2 (3.8)
Febrile neutropenia	3 (5.8)	3 (5.8)	0
Neutropenia	2 (3.8)	0	2 (3.8)
Eosinophilia	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders			
-Total	1 (1.9)	1 (1.9)	0
Vomiting	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	4 (7.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	4 (7.7)	0	0
Immune system disorders			
-Total	1 (1.9)	0	0
Graft versus host disease in gastrointestinal tract	1 (1.9)	0	0
Infections and infestations			
-Total	11 (21.2)	8 (15.4)	2 (3.8)
Bacterial sepsis	1 (1.9)	0	1 (1.9)
Cellulitis of male external genital organ	1 (1.9)	1 (1.9)	0
Cholecystitis infective	1 (1.9)	1 (1.9)	0
Enterovirus infection	1 (1.9)	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	0
Herpes zoster	1 (1.9)	1 (1.9)	0
Parainfluenzae virus infection	1 (1.9)	1 (1.9)	0
Rotavirus infection	1 (1.9)	1 (1.9)	0
Sepsis	1 (1.9)	0	1 (1.9)
Upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Vascular device infection	1 (1.9)	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Investigations			
-Total	2 (3.8)	1 (1.9)	1 (1.9)
Alanine aminotransferase increased	1 (1.9)	1 (1.9)	0
White blood cell count decreased	1 (1.9)	0	1 (1.9)
Metabolism and nutrition disorders			
-Total	1 (1.9)	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	1 (1.9)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (5.8)	0	0
Flank pain	1 (1.9)	0	0
Osteonecrosis	1 (1.9)	0	0
Pain in extremity	1 (1.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.9)	0	0
Myelodysplastic syndrome	1 (1.9)	0	0
Renal and urinary disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.9)	1 (1.9)	0
Acute kidney injury	1 (1.9)	1 (1.9)	0
Reproductive system and breast disorders			
-Total	1 (1.9)	1 (1.9)	0
Vaginal haemorrhage	1 (1.9)	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.8)	1 (1.9)	1 (1.9)
Acute respiratory failure	1 (1.9)	0	1 (1.9)
Pulmonary oedema	1 (1.9)	1 (1.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179p
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (19.4)	2 (6.5)	3 (9.7)
Blood and lymphatic system disorders			
-Total	1 (3.2)	0	1 (3.2)
Febrile neutropenia	1 (3.2)	0	1 (3.2)
Gastrointestinal disorders			
-Total	1 (3.2)	0	0
Diarrhoea	1 (3.2)	0	0
Infections and infestations			
-Total	4 (12.9)	2 (6.5)	1 (3.2)
Urinary tract infection	2 (6.5)	1 (3.2)	0
Campylobacter infection	1 (3.2)	1 (3.2)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (3.2)	1 (3.2)	0
Clostridium difficile infection	1 (3.2)	1 (3.2)	0
Pneumonia	1 (3.2)	0	0
Respiratory tract infection	1 (3.2)	0	1 (3.2)
Respiratory tract infection viral	1 (3.2)	1 (3.2)	0
Vulvovaginal candidiasis	1 (3.2)	0	0
Injury, poisoning and procedural complications			
-Total	1 (3.2)	1 (3.2)	0
Procedural pain	1 (3.2)	1 (3.2)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.2)	0	1 (3.2)
Glioblastoma multiforme	1 (3.2)	0	1 (3.2)
Nervous system disorders			
-Total	1 (3.2)	1 (3.2)	0
Seizure	1 (3.2)	1 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179p
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	3 (75.0)	0
Blood and lymphatic system disorders			
-Total	2 (50.0)	2 (50.0)	0
Febrile neutropenia	2 (50.0)	2 (50.0)	0
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Enterocolitis	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
-Total	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0
Immune system disorders			

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (50.0)	0	0
Cytokine release syndrome	2 (50.0)	0	0
Infections and infestations			
-Total	1 (25.0)	1 (25.0)	0
Corona virus infection	1 (25.0)	1 (25.0)	0
Respiratory syncytial virus infection	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	0
Vascular disorders			
-Total	1 (25.0)	1 (25.0)	0
Hypotension	1 (25.0)	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179p
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	49 (81.7)	18 (30.0)	24 (40.0)
Blood and lymphatic system disorders			
-Total	25 (41.7)	20 (33.3)	4 (6.7)
Febrile neutropenia	21 (35.0)	20 (33.3)	1 (1.7)
Neutropenia	3 (5.0)	0	3 (5.0)
Disseminated intravascular coagulation	2 (3.3)	0	0
Eosinophilia	1 (1.7)	1 (1.7)	0
Cardiac disorders			
-Total	2 (3.3)	0	0
Atrioventricular block second degree	1 (1.7)	0	0
Ventricular tachycardia	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders			
-Total	2 (3.3)	0	0
Papilloedema	1 (1.7)	0	0
Vision blurred	1 (1.7)	0	0
Gastrointestinal disorders			
-Total	6 (10.0)	3 (5.0)	0
Diarrhoea	2 (3.3)	0	0
Intestinal obstruction	1 (1.7)	1 (1.7)	0
Pancreatitis	1 (1.7)	1 (1.7)	0
Stomatitis	1 (1.7)	0	0
Vomiting	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	8 (13.3)	1 (1.7)	0
Pyrexia	6 (10.0)	0	0
Malaise	1 (1.7)	0	0
Physical deconditioning	1 (1.7)	1 (1.7)	0
Immune system disorders			
-Total	39 (65.0)	8 (13.3)	10 (16.7)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	39 (65.0)	8 (13.3)	10 (16.7)
Graft versus host disease in gastrointestinal tract	1 (1.7)	0	0
Infections and infestations			
-Total	18 (30.0)	10 (16.7)	4 (6.7)
Clostridium difficile infection	3 (5.0)	1 (1.7)	0
Clostridium difficile colitis	2 (3.3)	0	0
Pneumonia	2 (3.3)	1 (1.7)	0
Urinary tract infection	2 (3.3)	1 (1.7)	0
Bacterial sepsis	1 (1.7)	0	1 (1.7)
Campylobacter infection	1 (1.7)	1 (1.7)	0
Catheter site infection	1 (1.7)	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	1 (1.7)	0
Cholecystitis infective	1 (1.7)	1 (1.7)	0
Enterovirus infection	1 (1.7)	1 (1.7)	0
Gastroenteritis	1 (1.7)	1 (1.7)	0
Gastroenteritis norovirus	1 (1.7)	0	0
Herpes zoster	1 (1.7)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (1.7)	1 (1.7)	0
Respiratory tract infection	1 (1.7)	0	1 (1.7)
Respiratory tract infection viral	1 (1.7)	1 (1.7)	0
Rhinovirus infection	1 (1.7)	0	0
Rotavirus infection	1 (1.7)	1 (1.7)	0
Sepsis	1 (1.7)	0	1 (1.7)
Septic embolus	1 (1.7)	0	1 (1.7)
Staphylococcal infection	1 (1.7)	1 (1.7)	0
Upper respiratory tract infection	1 (1.7)	1 (1.7)	0
Vascular device infection	1 (1.7)	1 (1.7)	0
Viral upper respiratory tract infection	1 (1.7)	1 (1.7)	0
Vulvovaginal candidiasis	1 (1.7)	0	0
Injury, poisoning and procedural complications			
-Total	2 (3.3)	1 (1.7)	1 (1.7)
Procedural pain	1 (1.7)	1 (1.7)	0
Transfusion related complication	1 (1.7)	0	1 (1.7)
Investigations			
-Total	2 (3.3)	1 (1.7)	1 (1.7)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (1.7)	1 (1.7)	0
White blood cell count decreased	1 (1.7)	0	1 (1.7)
Metabolism and nutrition disorders			
-Total	4 (6.7)	4 (6.7)	0
Tumour lysis syndrome	2 (3.3)	2 (3.3)	0
Acidosis	1 (1.7)	0	0
Decreased appetite	1 (1.7)	1 (1.7)	0
Dehydration	1 (1.7)	1 (1.7)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (5.0)	0	0
Flank pain	1 (1.7)	0	0
Osteonecrosis	1 (1.7)	0	0
Pain in extremity	1 (1.7)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (3.3)	0	1 (1.7)
Glioblastoma multiforme	1 (1.7)	0	1 (1.7)
Myelodysplastic syndrome	1 (1.7)	0	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	10 (16.7)	4 (6.7)	1 (1.7)
Encephalopathy	4 (6.7)	2 (3.3)	0
Seizure	4 (6.7)	2 (3.3)	0
Embolic stroke	1 (1.7)	0	1 (1.7)
Headache	1 (1.7)	1 (1.7)	0
Idiopathic intracranial hypertension	1 (1.7)	0	0
Psychiatric disorders			
-Total	1 (1.7)	0	0
Delirium	1 (1.7)	0	0
Renal and urinary disorders			
-Total	5 (8.3)	3 (5.0)	2 (3.3)
Acute kidney injury	4 (6.7)	3 (5.0)	1 (1.7)
Renal failure	1 (1.7)	0	1 (1.7)
Reproductive system and breast disorders			
-Total	1 (1.7)	1 (1.7)	0
Vaginal haemorrhage	1 (1.7)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	9 (15.0)	2 (3.3)	5 (8.3)
Hypoxia	3 (5.0)	1 (1.7)	1 (1.7)
Respiratory failure	3 (5.0)	0	3 (5.0)
Pleural effusion	2 (3.3)	1 (1.7)	0
Pulmonary oedema	2 (3.3)	1 (1.7)	1 (1.7)
Acute respiratory failure	1 (1.7)	0	1 (1.7)
Skin and subcutaneous tissue disorders			
-Total	1 (1.7)	1 (1.7)	0
Ecchymosis	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	7 (11.7)	4 (6.7)	3 (5.0)
Hypotension	6 (10.0)	3 (5.0)	3 (5.0)
Embolism	1 (1.7)	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients

column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179q
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (71.9)	11 (34.4)	6 (18.8)
Blood and lymphatic system disorders			
-Total	9 (28.1)	9 (28.1)	0
Febrile neutropenia	9 (28.1)	9 (28.1)	0
Cardiac disorders			
-Total	1 (3.1)	0	0
Atrioventricular block second degree	1 (3.1)	0	0
Eye disorders			
-Total	1 (3.1)	0	0
Vision blurred	1 (3.1)	0	0
Gastrointestinal disorders			
-Total	2 (6.3)	2 (6.3)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Intestinal obstruction	1 (3.1)	1 (3.1)	0
Vomiting	1 (3.1)	1 (3.1)	0
General disorders and administration site conditions			
-Total	1 (3.1)	0	0
Malaise	1 (3.1)	0	0
Immune system disorders			
-Total	19 (59.4)	2 (6.3)	4 (12.5)
Cytokine release syndrome	19 (59.4)	2 (6.3)	4 (12.5)
Infections and infestations			
-Total	5 (15.6)	2 (6.3)	1 (3.1)
Clostridium difficile infection	2 (6.3)	0	0
Catheter site infection	1 (3.1)	1 (3.1)	0
Gastroenteritis norovirus	1 (3.1)	0	0
Rhinovirus infection	1 (3.1)	0	0
Septic embolus	1 (3.1)	0	1 (3.1)
Staphylococcal infection	1 (3.1)	1 (3.1)	0
Injury, poisoning and procedural complications			

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.1)	0	1 (3.1)
Transfusion related complication	1 (3.1)	0	1 (3.1)
Nervous system disorders			
-Total	3 (9.4)	2 (6.3)	1 (3.1)
Embolic stroke	1 (3.1)	0	1 (3.1)
Encephalopathy	1 (3.1)	1 (3.1)	0
Seizure	1 (3.1)	1 (3.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.1)	0	0
Hypoxia	1 (3.1)	0	0
Vascular disorders			
-Total	3 (9.4)	3 (9.4)	0
Hypotension	2 (6.3)	2 (6.3)	0
Embolism	1 (3.1)	1 (3.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179q
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (71.9)	9 (28.1)	11 (34.4)
Blood and lymphatic system disorders			
-Total	14 (43.8)	12 (37.5)	1 (3.1)
Febrile neutropenia	12 (37.5)	12 (37.5)	0
Disseminated intravascular coagulation	2 (6.3)	0	0
Neutropenia	1 (3.1)	0	1 (3.1)
Cardiac disorders			
-Total	1 (3.1)	0	0
Ventricular tachycardia	1 (3.1)	0	0
Eye disorders			
-Total	1 (3.1)	0	0
Papilloedema	1 (3.1)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	3 (9.4)	1 (3.1)	0
Diarrhoea	1 (3.1)	0	0
Pancreatitis	1 (3.1)	1 (3.1)	0
Stomatitis	1 (3.1)	0	0
General disorders and administration site conditions			
-Total	3 (9.4)	1 (3.1)	0
Pyrexia	2 (6.3)	0	0
Physical deconditioning	1 (3.1)	1 (3.1)	0
Immune system disorders			
-Total	22 (68.8)	6 (18.8)	6 (18.8)
Cytokine release syndrome	22 (68.8)	6 (18.8)	6 (18.8)
Infections and infestations			
-Total	4 (12.5)	2 (6.3)	0
Clostridium difficile colitis	2 (6.3)	0	0
Gastroenteritis	1 (3.1)	1 (3.1)	0
Pneumonia	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (9.4)	3 (9.4)	0
Acidosis	1 (3.1)	0	0
Decreased appetite	1 (3.1)	1 (3.1)	0
Dehydration	1 (3.1)	1 (3.1)	0
Tumour lysis syndrome	1 (3.1)	1 (3.1)	0
Nervous system disorders			
-Total	6 (18.8)	1 (3.1)	0
Encephalopathy	3 (9.4)	1 (3.1)	0
Seizure	2 (6.3)	0	0
Headache	1 (3.1)	1 (3.1)	0
Idiopathic intracranial hypertension	1 (3.1)	0	0
Psychiatric disorders			
-Total	1 (3.1)	0	0
Delirium	1 (3.1)	0	0
Renal and urinary disorders			
-Total	4 (12.5)	2 (6.3)	2 (6.3)
Acute kidney injury	3 (9.4)	2 (6.3)	1 (3.1)
Renal failure	1 (3.1)	0	1 (3.1)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	7 (21.9)	1 (3.1)	4 (12.5)
Hypoxia	3 (9.4)	1 (3.1)	1 (3.1)
Respiratory failure	3 (9.4)	0	3 (9.4)
Pleural effusion	2 (6.3)	1 (3.1)	0
Pulmonary oedema	1 (3.1)	0	1 (3.1)
Skin and subcutaneous tissue disorders			
-Total	1 (3.1)	1 (3.1)	0
Ecchymosis	1 (3.1)	1 (3.1)	0
Vascular disorders			
-Total	5 (15.6)	2 (6.3)	3 (9.4)
Hypotension	5 (15.6)	2 (6.3)	3 (9.4)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179q
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=29	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (44.8)	6 (20.7)	4 (13.8)
Blood and lymphatic system disorders			
-Total	2 (6.9)	1 (3.4)	1 (3.4)
Febrile neutropenia	1 (3.4)	1 (3.4)	0
Neutropenia	1 (3.4)	0	1 (3.4)
Gastrointestinal disorders			
-Total	1 (3.4)	1 (3.4)	0
Vomiting	1 (3.4)	1 (3.4)	0
General disorders and administration site conditions			
-Total	4 (13.8)	1 (3.4)	0
Pyrexia	4 (13.8)	1 (3.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	1 (3.4)	0	0
Graft versus host disease in gastrointestinal tract	1 (3.4)	0	0
Infections and infestations			
-Total	6 (20.7)	3 (10.3)	2 (6.9)
Bacterial sepsis	1 (3.4)	0	1 (3.4)
Enterovirus infection	1 (3.4)	1 (3.4)	0
Gastroenteritis norovirus	1 (3.4)	0	0
Parainfluenzae virus infection	1 (3.4)	1 (3.4)	0
Rotavirus infection	1 (3.4)	1 (3.4)	0
Sepsis	1 (3.4)	0	1 (3.4)
Viral upper respiratory tract infection	1 (3.4)	1 (3.4)	0
Investigations			
-Total	1 (3.4)	0	1 (3.4)
White blood cell count decreased	1 (3.4)	0	1 (3.4)
Musculoskeletal and connective tissue disorders			
-Total	2 (6.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flank pain	1 (3.4)	0	0
Pain in extremity	1 (3.4)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.4)	0	0
Myelodysplastic syndrome	1 (3.4)	0	0
Renal and urinary disorders			
-Total	1 (3.4)	1 (3.4)	0
Acute kidney injury	1 (3.4)	1 (3.4)	0
Reproductive system and breast disorders			
-Total	1 (3.4)	1 (3.4)	0
Vaginal haemorrhage	1 (3.4)	1 (3.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.4)	0	1 (3.4)
Acute respiratory failure	1 (3.4)	0	1 (3.4)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179q
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=27	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (29.6)	7 (25.9)	1 (3.7)
Blood and lymphatic system disorders			
-Total	3 (11.1)	2 (7.4)	1 (3.7)
Febrile neutropenia	2 (7.4)	2 (7.4)	0
Eosinophilia	1 (3.7)	1 (3.7)	0
Neutropenia	1 (3.7)	0	1 (3.7)
Gastrointestinal disorders			
-Total	1 (3.7)	1 (3.7)	0
Enterocolitis	1 (3.7)	1 (3.7)	0
General disorders and administration site conditions			
-Total	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (3.7)	0	0
Infections and infestations			
-Total	6 (22.2)	6 (22.2)	0
Cellulitis of male external genital organ	1 (3.7)	1 (3.7)	0
Cholecystitis infective	1 (3.7)	1 (3.7)	0
Corona virus infection	1 (3.7)	1 (3.7)	0
Herpes zoster	1 (3.7)	1 (3.7)	0
Respiratory syncytial virus infection	1 (3.7)	1 (3.7)	0
Upper respiratory tract infection	1 (3.7)	1 (3.7)	0
Vascular device infection	1 (3.7)	1 (3.7)	0
Investigations			
-Total	1 (3.7)	1 (3.7)	0
Alanine aminotransferase increased	1 (3.7)	1 (3.7)	0
Metabolism and nutrition disorders			
-Total	1 (3.7)	1 (3.7)	0
Tumour lysis syndrome	1 (3.7)	1 (3.7)	0
Musculoskeletal and connective tissue disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.7)	0	0
Osteonecrosis	1 (3.7)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.7)	1 (3.7)	0
Pulmonary oedema	1 (3.7)	1 (3.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179q
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (22.2)	1 (5.6)	2 (11.1)
Blood and lymphatic system disorders			
-Total	1 (5.6)	0	1 (5.6)
Febrile neutropenia	1 (5.6)	0	1 (5.6)
Infections and infestations			
-Total	3 (16.7)	1 (5.6)	1 (5.6)
Campylobacter infection	1 (5.6)	1 (5.6)	0
Clostridium difficile infection	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	0
Respiratory tract infection	1 (5.6)	0	1 (5.6)
Respiratory tract infection viral	1 (5.6)	1 (5.6)	0
Urinary tract infection	1 (5.6)	0	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal candidiasis	1 (5.6)	0	0
Injury, poisoning and procedural complications			
-Total	1 (5.6)	1 (5.6)	0
Procedural pain	1 (5.6)	1 (5.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179q
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=16	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (12.5)	1 (6.3)	1 (6.3)
Gastrointestinal disorders			
-Total	1 (6.3)	0	0
Diarrhoea	1 (6.3)	0	0
Infections and infestations			
-Total	1 (6.3)	1 (6.3)	0
Cellulitis of male external genital organ	1 (6.3)	1 (6.3)	0
Urinary tract infection	1 (6.3)	1 (6.3)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (6.3)	0	1 (6.3)

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Glioblastoma multiforme	1 (6.3)	0	1 (6.3)
Nervous system disorders			
-Total	1 (6.3)	1 (6.3)	0
Seizure	1 (6.3)	1 (6.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179q
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (84.4)	11 (34.4)	11 (34.4)
Blood and lymphatic system disorders			
-Total	12 (37.5)	10 (31.3)	2 (6.3)
Febrile neutropenia	11 (34.4)	10 (31.3)	1 (3.1)
Neutropenia	1 (3.1)	0	1 (3.1)
Cardiac disorders			
-Total	1 (3.1)	0	0
Atrioventricular block second degree	1 (3.1)	0	0
Eye disorders			
-Total	1 (3.1)	0	0
Vision blurred	1 (3.1)	0	0
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (6.3)	2 (6.3)	0
Intestinal obstruction	1 (3.1)	1 (3.1)	0
Vomiting	1 (3.1)	1 (3.1)	0
General disorders and administration site conditions			
-Total	5 (15.6)	1 (3.1)	0
Pyrexia	4 (12.5)	1 (3.1)	0
Malaise	1 (3.1)	0	0
Immune system disorders			
-Total	19 (59.4)	2 (6.3)	4 (12.5)
Cytokine release syndrome	19 (59.4)	2 (6.3)	4 (12.5)
Graft versus host disease in gastrointestinal tract	1 (3.1)	0	0
Infections and infestations			
-Total	11 (34.4)	4 (12.5)	4 (12.5)
Clostridium difficile infection	3 (9.4)	1 (3.1)	0
Bacterial sepsis	1 (3.1)	0	1 (3.1)
Campylobacter infection	1 (3.1)	1 (3.1)	0
Catheter site infection	1 (3.1)	1 (3.1)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterovirus infection	1 (3.1)	1 (3.1)	0
Gastroenteritis norovirus	1 (3.1)	0	0
Parainfluenzae virus infection	1 (3.1)	1 (3.1)	0
Pneumonia	1 (3.1)	0	0
Respiratory tract infection	1 (3.1)	0	1 (3.1)
Respiratory tract infection viral	1 (3.1)	1 (3.1)	0
Rhinovirus infection	1 (3.1)	0	0
Rotavirus infection	1 (3.1)	1 (3.1)	0
Sepsis	1 (3.1)	0	1 (3.1)
Septic embolus	1 (3.1)	0	1 (3.1)
Staphylococcal infection	1 (3.1)	1 (3.1)	0
Urinary tract infection	1 (3.1)	0	0
Viral upper respiratory tract infection	1 (3.1)	1 (3.1)	0
Vulvovaginal candidiasis	1 (3.1)	0	0
Injury, poisoning and procedural complications			
-Total	2 (6.3)	1 (3.1)	1 (3.1)
Procedural pain	1 (3.1)	1 (3.1)	0
Transfusion related complication	1 (3.1)	0	1 (3.1)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	1 (3.1)	0	1 (3.1)
White blood cell count decreased	1 (3.1)	0	1 (3.1)
Musculoskeletal and connective tissue disorders			
-Total	2 (6.3)	0	0
Flank pain	1 (3.1)	0	0
Pain in extremity	1 (3.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.1)	0	0
Myelodysplastic syndrome	1 (3.1)	0	0
Nervous system disorders			
-Total	3 (9.4)	2 (6.3)	1 (3.1)
Embolic stroke	1 (3.1)	0	1 (3.1)
Encephalopathy	1 (3.1)	1 (3.1)	0
Seizure	1 (3.1)	1 (3.1)	0
Renal and urinary disorders			
-Total	1 (3.1)	1 (3.1)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (3.1)	1 (3.1)	0
Reproductive system and breast disorders			
-Total	1 (3.1)	1 (3.1)	0
Vaginal haemorrhage	1 (3.1)	1 (3.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.3)	0	1 (3.1)
Acute respiratory failure	1 (3.1)	0	1 (3.1)
Hypoxia	1 (3.1)	0	0
Vascular disorders			
-Total	3 (9.4)	3 (9.4)	0
Hypotension	2 (6.3)	2 (6.3)	0
Embolism	1 (3.1)	1 (3.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179q
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (78.1)	10 (31.3)	13 (40.6)
Blood and lymphatic system disorders			
-Total	15 (46.9)	12 (37.5)	2 (6.3)
Febrile neutropenia	12 (37.5)	12 (37.5)	0
Disseminated intravascular coagulation	2 (6.3)	0	0
Neutropenia	2 (6.3)	0	2 (6.3)
Eosinophilia	1 (3.1)	1 (3.1)	0
Cardiac disorders			
-Total	1 (3.1)	0	0
Ventricular tachycardia	1 (3.1)	0	0
Eye disorders			

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.1)	0	0
Papilloedema	1 (3.1)	0	0
Gastrointestinal disorders			
-Total	5 (15.6)	2 (6.3)	0
Diarrhoea	2 (6.3)	0	0
Enterocolitis	1 (3.1)	1 (3.1)	0
Pancreatitis	1 (3.1)	1 (3.1)	0
Stomatitis	1 (3.1)	0	0
General disorders and administration site conditions			
-Total	4 (12.5)	1 (3.1)	0
Pyrexia	3 (9.4)	0	0
Physical deconditioning	1 (3.1)	1 (3.1)	0
Immune system disorders			
-Total	22 (68.8)	6 (18.8)	6 (18.8)
Cytokine release syndrome	22 (68.8)	6 (18.8)	6 (18.8)
Infections and infestations			
-Total	8 (25.0)	7 (21.9)	0
Clostridium difficile colitis	2 (6.3)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (3.1)	1 (3.1)	0
Cholecystitis infective	1 (3.1)	1 (3.1)	0
Corona virus infection	1 (3.1)	1 (3.1)	0
Gastroenteritis	1 (3.1)	1 (3.1)	0
Herpes zoster	1 (3.1)	1 (3.1)	0
Pneumonia	1 (3.1)	1 (3.1)	0
Respiratory syncytial virus infection	1 (3.1)	1 (3.1)	0
Upper respiratory tract infection	1 (3.1)	1 (3.1)	0
Urinary tract infection	1 (3.1)	1 (3.1)	0
Vascular device infection	1 (3.1)	1 (3.1)	0
Investigations			
-Total	1 (3.1)	1 (3.1)	0
Alanine aminotransferase increased	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			
-Total	4 (12.5)	4 (12.5)	0
Tumour lysis syndrome	2 (6.3)	2 (6.3)	0
Acidosis	1 (3.1)	0	0
Decreased appetite	1 (3.1)	1 (3.1)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (3.1)	1 (3.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (3.1)	0	0
Osteonecrosis	1 (3.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.1)	0	1 (3.1)
Glioblastoma multiforme	1 (3.1)	0	1 (3.1)
Nervous system disorders			
-Total	7 (21.9)	2 (6.3)	0
Encephalopathy	3 (9.4)	1 (3.1)	0
Seizure	3 (9.4)	1 (3.1)	0
Headache	1 (3.1)	1 (3.1)	0
Idiopathic intracranial hypertension	1 (3.1)	0	0
Psychiatric disorders			
-Total	1 (3.1)	0	0
Delirium	1 (3.1)	0	0
Renal and urinary disorders			

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (12.5)	2 (6.3)	2 (6.3)
Acute kidney injury	3 (9.4)	2 (6.3)	1 (3.1)
Renal failure	1 (3.1)	0	1 (3.1)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (25.0)	2 (6.3)	4 (12.5)
Hypoxia	3 (9.4)	1 (3.1)	1 (3.1)
Respiratory failure	3 (9.4)	0	3 (9.4)
Pleural effusion	2 (6.3)	1 (3.1)	0
Pulmonary oedema	2 (6.3)	1 (3.1)	1 (3.1)
Skin and subcutaneous tissue disorders			
-Total	1 (3.1)	1 (3.1)	0
Ecchymosis	1 (3.1)	1 (3.1)	0
Vascular disorders			
-Total	5 (15.6)	2 (6.3)	3 (9.4)
Hypotension	5 (15.6)	2 (6.3)	3 (9.4)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	2 (28.6)	3 (42.9)
Blood and lymphatic system disorders			
-Total	2 (28.6)	2 (28.6)	0
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Immune system disorders			
-Total	5 (71.4)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	3 (42.9)
Renal and urinary disorders			
-Total	1 (14.3)	0	1 (14.3)
Renal failure	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (14.3)	0	1 (14.3)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	1 (14.3)	0	1 (14.3)
Vascular disorders			
-Total	2 (28.6)	2 (28.6)	0
Hypotension	2 (28.6)	2 (28.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 1

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (70.0)	5 (25.0)	6 (30.0)
Blood and lymphatic system disorders			
-Total	9 (45.0)	8 (40.0)	0
Febrile neutropenia	8 (40.0)	8 (40.0)	0
Disseminated intravascular coagulation	1 (5.0)	0	0
Cardiac disorders			
-Total	1 (5.0)	0	0
Ventricular tachycardia	1 (5.0)	0	0
Gastrointestinal disorders			
-Total	2 (10.0)	1 (5.0)	0
Diarrhoea	1 (5.0)	0	0
Vomiting	1 (5.0)	1 (5.0)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (5.0)	1 (5.0)	0
Physical deconditioning	1 (5.0)	1 (5.0)	0
Immune system disorders			
-Total	14 (70.0)	2 (10.0)	4 (20.0)
Cytokine release syndrome	14 (70.0)	2 (10.0)	4 (20.0)
Infections and infestations			
-Total	5 (25.0)	3 (15.0)	0
Clostridium difficile infection	1 (5.0)	0	0
Gastroenteritis	1 (5.0)	1 (5.0)	0
Gastroenteritis norovirus	1 (5.0)	0	0
Pneumonia	1 (5.0)	1 (5.0)	0
Staphylococcal infection	1 (5.0)	1 (5.0)	0
Injury, poisoning and procedural complications			
-Total	1 (5.0)	0	1 (5.0)
Transfusion related complication	1 (5.0)	0	1 (5.0)
Metabolism and nutrition disorders			

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (10.0)	2 (10.0)	0
Acidosis	1 (5.0)	0	0
Dehydration	1 (5.0)	1 (5.0)	0
Tumour lysis syndrome	1 (5.0)	1 (5.0)	0
Nervous system disorders			
-Total	3 (15.0)	1 (5.0)	0
Encephalopathy	2 (10.0)	1 (5.0)	0
Seizure	1 (5.0)	0	0
Psychiatric disorders			
-Total	1 (5.0)	0	0
Delirium	1 (5.0)	0	0
Renal and urinary disorders			
-Total	1 (5.0)	1 (5.0)	0
Acute kidney injury	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Hypoxia	1 (5.0)	1 (5.0)	0
Pulmonary oedema	1 (5.0)	0	1 (5.0)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	1 (5.0)	0	1 (5.0)
Skin and subcutaneous tissue disorders			
-Total	1 (5.0)	1 (5.0)	0
Ecchymosis	1 (5.0)	1 (5.0)	0
Vascular disorders			
-Total	1 (5.0)	0	1 (5.0)
Hypotension	1 (5.0)	0	1 (5.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (85.7)	9 (42.9)	5 (23.8)
Blood and lymphatic system disorders			
-Total	9 (42.9)	8 (38.1)	1 (4.8)
Febrile neutropenia	8 (38.1)	8 (38.1)	0
Disseminated intravascular coagulation	1 (4.8)	0	0
Neutropenia	1 (4.8)	0	1 (4.8)
Cardiac disorders			
-Total	1 (4.8)	0	0
Atrioventricular block second degree	1 (4.8)	0	0
Eye disorders			
-Total	1 (4.8)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vision blurred	1 (4.8)	0	0
Gastrointestinal disorders			
-Total	3 (14.3)	2 (9.5)	0
Intestinal obstruction	1 (4.8)	1 (4.8)	0
Pancreatitis	1 (4.8)	1 (4.8)	0
Stomatitis	1 (4.8)	0	0
General disorders and administration site conditions			
-Total	2 (9.5)	0	0
Pyrexia	2 (9.5)	0	0
Immune system disorders			
-Total	14 (66.7)	4 (19.0)	1 (4.8)
Cytokine release syndrome	14 (66.7)	4 (19.0)	1 (4.8)
Infections and infestations			
-Total	3 (14.3)	1 (4.8)	1 (4.8)
Catheter site infection	1 (4.8)	1 (4.8)	0
Clostridium difficile colitis	1 (4.8)	0	0
Clostridium difficile infection	1 (4.8)	0	0
Rhinovirus infection	1 (4.8)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic embolus	1 (4.8)	0	1 (4.8)
Metabolism and nutrition disorders			
-Total	1 (4.8)	1 (4.8)	0
Decreased appetite	1 (4.8)	1 (4.8)	0
Nervous system disorders			
-Total	3 (14.3)	1 (4.8)	1 (4.8)
Embolic stroke	1 (4.8)	0	1 (4.8)
Encephalopathy	1 (4.8)	1 (4.8)	0
Headache	1 (4.8)	1 (4.8)	0
Seizure	1 (4.8)	0	0
Renal and urinary disorders			
-Total	2 (9.5)	1 (4.8)	1 (4.8)
Acute kidney injury	2 (9.5)	1 (4.8)	1 (4.8)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (14.3)	0	2 (9.5)
Hypoxia	2 (9.5)	0	1 (4.8)
Pleural effusion	1 (4.8)	1 (4.8)	0
Respiratory failure	1 (4.8)	0	1 (4.8)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	2 (9.5)	1 (4.8)	1 (4.8)
Hypotension	2 (9.5)	1 (4.8)	1 (4.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

		All patients N=16	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (56.3)	4 (25.0)	3 (18.8)
Blood and lymphatic system disorders			
-Total	3 (18.8)	3 (18.8)	0
Febrile neutropenia	3 (18.8)	3 (18.8)	0
Eye disorders			
-Total	1 (6.3)	0	0
Papilloedema	1 (6.3)	0	0
General disorders and administration site conditions			
-Total	1 (6.3)	0	0
Malaise	1 (6.3)	0	0
Immune system disorders			

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (50.0)	2 (12.5)	2 (12.5)
Cytokine release syndrome	8 (50.0)	2 (12.5)	2 (12.5)
Infections and infestations			
-Total	1 (6.3)	0	0
Clostridium difficile colitis	1 (6.3)	0	0
Nervous system disorders			
-Total	3 (18.8)	1 (6.3)	0
Encephalopathy	1 (6.3)	0	0
Idiopathic intracranial hypertension	1 (6.3)	0	0
Seizure	1 (6.3)	1 (6.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (12.5)	0	0
Hypoxia	1 (6.3)	0	0
Pleural effusion	1 (6.3)	0	0
Vascular disorders			
-Total	3 (18.8)	2 (12.5)	1 (6.3)
Hypotension	2 (12.5)	1 (6.3)	1 (6.3)
Embolism	1 (6.3)	1 (6.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (40.0)	1 (20.0)	0
Gastrointestinal disorders			
-Total	1 (20.0)	1 (20.0)	0
Enterocolitis	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
-Total	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	0
Infections and infestations			
-Total	1 (20.0)	1 (20.0)	0
Corona virus infection	1 (20.0)	1 (20.0)	0
Respiratory syncytial virus infection	1 (20.0)	1 (20.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (36.8)	5 (26.3)	2 (10.5)
Blood and lymphatic system disorders			
-Total	2 (10.5)	2 (10.5)	0
Febrile neutropenia	2 (10.5)	2 (10.5)	0
Gastrointestinal disorders			
-Total	1 (5.3)	1 (5.3)	0
Vomiting	1 (5.3)	1 (5.3)	0
General disorders and administration site conditions			
-Total	1 (5.3)	1 (5.3)	0
Pyrexia	1 (5.3)	1 (5.3)	0
Immune system disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.3)	0	0
Graft versus host disease in gastrointestinal tract	1 (5.3)	0	0
Infections and infestations			
-Total	4 (21.1)	2 (10.5)	1 (5.3)
Gastroenteritis norovirus	1 (5.3)	0	0
Herpes zoster	1 (5.3)	1 (5.3)	0
Sepsis	1 (5.3)	0	1 (5.3)
Viral upper respiratory tract infection	1 (5.3)	1 (5.3)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (10.5)	0	0
Flank pain	1 (5.3)	0	0
Osteonecrosis	1 (5.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (5.3)	0	0
Myelodysplastic syndrome	1 (5.3)	0	0
Renal and urinary disorders			
-Total	1 (5.3)	1 (5.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (5.3)	1 (5.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (10.5)	1 (5.3)	1 (5.3)
Acute respiratory failure	1 (5.3)	0	1 (5.3)
Pulmonary oedema	1 (5.3)	1 (5.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (38.9)	4 (22.2)	2 (11.1)
Blood and lymphatic system disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Febrile neutropenia	1 (5.6)	1 (5.6)	0
Neutropenia	1 (5.6)	0	1 (5.6)
General disorders and administration site conditions			
-Total	1 (5.6)	0	0
Pyrexia	1 (5.6)	0	0
Infections and infestations			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Bacterial sepsis	1 (5.6)	0	1 (5.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (5.6)	1 (5.6)	0
Parainfluenzae virus infection	1 (5.6)	1 (5.6)	0
Investigations			
-Total	1 (5.6)	0	1 (5.6)
White blood cell count decreased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
-Total	1 (5.6)	1 (5.6)	0
Tumour lysis syndrome	1 (5.6)	1 (5.6)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (5.6)	0	0
Pain in extremity	1 (5.6)	0	0
Reproductive system and breast disorders			
-Total	1 (5.6)	1 (5.6)	0
Vaginal haemorrhage	1 (5.6)	1 (5.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients

column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (35.7)	3 (21.4)	1 (7.1)
Blood and lymphatic system disorders			
-Total	1 (7.1)	0	1 (7.1)
Eosinophilia	1 (7.1)	1 (7.1)	0
Neutropenia	1 (7.1)	0	1 (7.1)
General disorders and administration site conditions			
-Total	2 (14.3)	0	0
Pyrexia	2 (14.3)	0	0
Infections and infestations			
-Total	4 (28.6)	4 (28.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (7.1)	1 (7.1)	0
Enterovirus infection	1 (7.1)	1 (7.1)	0
Rotavirus infection	1 (7.1)	1 (7.1)	0
Upper respiratory tract infection	1 (7.1)	1 (7.1)	0
Vascular device infection	1 (7.1)	1 (7.1)	0
Investigations			
-Total	1 (7.1)	1 (7.1)	0
Alanine aminotransferase increased	1 (7.1)	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (9.1)	0	1 (9.1)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (9.1)	0	1 (9.1)
Glioblastoma multiforme	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	1 (9.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

		All patients N=10	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (30.0)	0	2 (20.0)
Blood and lymphatic system disorders			
-Total	1 (10.0)	0	1 (10.0)
Febrile neutropenia	1 (10.0)	0	1 (10.0)
Infections and infestations			
-Total	2 (20.0)	0	1 (10.0)
Pneumonia	1 (10.0)	0	0
Respiratory tract infection	1 (10.0)	0	1 (10.0)
Injury, poisoning and procedural complications			
-Total	1 (10.0)	1 (10.0)	0
Procedural pain	1 (10.0)	1 (10.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

		All patients N=8	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (25.0)	2 (25.0)	0
Gastrointestinal disorders			
-Total	1 (12.5)	0	0
Diarrhoea	1 (12.5)	0	0
Infections and infestations			
-Total	2 (25.0)	2 (25.0)	0
Urinary tract infection	2 (25.0)	1 (12.5)	0
Campylobacter infection	1 (12.5)	1 (12.5)	0
Cellulitis of male external genital organ	1 (12.5)	1 (12.5)	0
Clostridium difficile infection	1 (12.5)	1 (12.5)	0
Respiratory tract infection viral	1 (12.5)	1 (12.5)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal candidiasis	1 (12.5)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	2 (28.6)	3 (42.9)
Blood and lymphatic system disorders			
-Total	2 (28.6)	2 (28.6)	0
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Gastrointestinal disorders			
-Total	1 (14.3)	1 (14.3)	0
Enterocolitis	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	1 (14.3)	0	0
Pyrexia	1 (14.3)	0	0
Immune system disorders			

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (71.4)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	3 (42.9)
Infections and infestations			
-Total	1 (14.3)	1 (14.3)	0
Corona virus infection	1 (14.3)	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	1 (14.3)	0	1 (14.3)
Renal failure	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)
Vascular disorders			
-Total	2 (28.6)	2 (28.6)	0
Hypotension	2 (28.6)	2 (28.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (85.0)	7 (35.0)	8 (40.0)
Blood and lymphatic system disorders			
-Total	10 (50.0)	9 (45.0)	0
Febrile neutropenia	9 (45.0)	9 (45.0)	0
Disseminated intravascular coagulation	1 (5.0)	0	0
Cardiac disorders			
-Total	1 (5.0)	0	0
Ventricular tachycardia	1 (5.0)	0	0
Gastrointestinal disorders			
-Total	2 (10.0)	1 (5.0)	0
Diarrhoea	1 (5.0)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	2 (10.0)	2 (10.0)	0
Physical deconditioning	1 (5.0)	1 (5.0)	0
Pyrexia	1 (5.0)	1 (5.0)	0
Immune system disorders			
-Total	14 (70.0)	2 (10.0)	4 (20.0)
Cytokine release syndrome	14 (70.0)	2 (10.0)	4 (20.0)
Graft versus host disease in gastrointestinal tract	1 (5.0)	0	0
Infections and infestations			
-Total	7 (35.0)	4 (20.0)	1 (5.0)
Clostridium difficile infection	1 (5.0)	0	0
Gastroenteritis	1 (5.0)	1 (5.0)	0
Gastroenteritis norovirus	1 (5.0)	0	0
Herpes zoster	1 (5.0)	1 (5.0)	0
Pneumonia	1 (5.0)	1 (5.0)	0
Sepsis	1 (5.0)	0	1 (5.0)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (5.0)	1 (5.0)	0
Viral upper respiratory tract infection	1 (5.0)	1 (5.0)	0
Injury, poisoning and procedural complications			
-Total	1 (5.0)	0	1 (5.0)
Transfusion related complication	1 (5.0)	0	1 (5.0)
Metabolism and nutrition disorders			
-Total	2 (10.0)	2 (10.0)	0
Acidosis	1 (5.0)	0	0
Dehydration	1 (5.0)	1 (5.0)	0
Tumour lysis syndrome	1 (5.0)	1 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (10.0)	0	0
Flank pain	1 (5.0)	0	0
Osteonecrosis	1 (5.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (10.0)	0	1 (5.0)
Glioblastoma multiforme	1 (5.0)	0	1 (5.0)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myelodysplastic syndrome	1 (5.0)	0	0
Nervous system disorders			
-Total	4 (20.0)	2 (10.0)	0
Encephalopathy	2 (10.0)	1 (5.0)	0
Seizure	2 (10.0)	1 (5.0)	0
Psychiatric disorders			
-Total	1 (5.0)	0	0
Delirium	1 (5.0)	0	0
Renal and urinary disorders			
-Total	2 (10.0)	2 (10.0)	0
Acute kidney injury	2 (10.0)	2 (10.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (20.0)	2 (10.0)	2 (10.0)
Pulmonary oedema	2 (10.0)	1 (5.0)	1 (5.0)
Acute respiratory failure	1 (5.0)	0	1 (5.0)
Hypoxia	1 (5.0)	1 (5.0)	0
Respiratory failure	1 (5.0)	0	1 (5.0)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders			
-Total	1 (5.0)	1 (5.0)	0
Ecchymosis	1 (5.0)	1 (5.0)	0
Vascular disorders			
-Total	1 (5.0)	0	1 (5.0)
Hypotension	1 (5.0)	0	1 (5.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (95.2)	8 (38.1)	9 (42.9)
Blood and lymphatic system disorders			
-Total	11 (52.4)	8 (38.1)	3 (14.3)
Febrile neutropenia	9 (42.9)	8 (38.1)	1 (4.8)
Neutropenia	2 (9.5)	0	2 (9.5)
Disseminated intravascular coagulation	1 (4.8)	0	0
Cardiac disorders			
-Total	1 (4.8)	0	0
Atrioventricular block second degree	1 (4.8)	0	0
Eye disorders			
-Total	1 (4.8)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vision blurred	1 (4.8)	0	0
Gastrointestinal disorders			
-Total	3 (14.3)	2 (9.5)	0
Intestinal obstruction	1 (4.8)	1 (4.8)	0
Pancreatitis	1 (4.8)	1 (4.8)	0
Stomatitis	1 (4.8)	0	0
General disorders and administration site conditions			
-Total	3 (14.3)	0	0
Pyrexia	3 (14.3)	0	0
Immune system disorders			
-Total	14 (66.7)	4 (19.0)	1 (4.8)
Cytokine release syndrome	14 (66.7)	4 (19.0)	1 (4.8)
Infections and infestations			
-Total	7 (33.3)	2 (9.5)	3 (14.3)
Bacterial sepsis	1 (4.8)	0	1 (4.8)
Catheter site infection	1 (4.8)	1 (4.8)	0
Cholecystitis infective	1 (4.8)	1 (4.8)	0
Clostridium difficile colitis	1 (4.8)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (4.8)	0	0
Parainfluenzae virus infection	1 (4.8)	1 (4.8)	0
Pneumonia	1 (4.8)	0	0
Respiratory tract infection	1 (4.8)	0	1 (4.8)
Rhinovirus infection	1 (4.8)	0	0
Septic embolus	1 (4.8)	0	1 (4.8)
Injury, poisoning and procedural complications			
-Total	1 (4.8)	1 (4.8)	0
Procedural pain	1 (4.8)	1 (4.8)	0
Investigations			
-Total	1 (4.8)	0	1 (4.8)
White blood cell count decreased	1 (4.8)	0	1 (4.8)
Metabolism and nutrition disorders			
-Total	2 (9.5)	2 (9.5)	0
Decreased appetite	1 (4.8)	1 (4.8)	0
Tumour lysis syndrome	1 (4.8)	1 (4.8)	0
Musculoskeletal and connective tissue disorders			

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.8)	0	0
Pain in extremity	1 (4.8)	0	0
Nervous system disorders			
-Total	3 (14.3)	1 (4.8)	1 (4.8)
Embolic stroke	1 (4.8)	0	1 (4.8)
Encephalopathy	1 (4.8)	1 (4.8)	0
Headache	1 (4.8)	1 (4.8)	0
Seizure	1 (4.8)	0	0
Renal and urinary disorders			
-Total	2 (9.5)	1 (4.8)	1 (4.8)
Acute kidney injury	2 (9.5)	1 (4.8)	1 (4.8)
Reproductive system and breast disorders			
-Total	1 (4.8)	1 (4.8)	0
Vaginal haemorrhage	1 (4.8)	1 (4.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (14.3)	0	2 (9.5)
Hypoxia	2 (9.5)	0	1 (4.8)

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	1 (4.8)	1 (4.8)	0
Respiratory failure	1 (4.8)	0	1 (4.8)
Vascular disorders			
-Total	2 (9.5)	1 (4.8)	1 (4.8)
Hypotension	2 (9.5)	1 (4.8)	1 (4.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 179r
Serious adverse events post CTL019 infusion, regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (62.5)	4 (25.0)	4 (25.0)
Blood and lymphatic system disorders			
-Total	4 (25.0)	3 (18.8)	1 (6.3)
Febrile neutropenia	3 (18.8)	3 (18.8)	0
Eosinophilia	1 (6.3)	1 (6.3)	0
Neutropenia	1 (6.3)	0	1 (6.3)
Eye disorders			
-Total	1 (6.3)	0	0
Papilloedema	1 (6.3)	0	0
Gastrointestinal disorders			
-Total	1 (6.3)	0	0
Diarrhoea	1 (6.3)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	3 (18.8)	0	0
Pyrexia	2 (12.5)	0	0
Malaise	1 (6.3)	0	0
Immune system disorders			
-Total	8 (50.0)	2 (12.5)	2 (12.5)
Cytokine release syndrome	8 (50.0)	2 (12.5)	2 (12.5)
Infections and infestations			
-Total	4 (25.0)	4 (25.0)	0
Urinary tract infection	2 (12.5)	1 (6.3)	0
Campylobacter infection	1 (6.3)	1 (6.3)	0
Cellulitis of male external genital organ	1 (6.3)	1 (6.3)	0
Clostridium difficile colitis	1 (6.3)	0	0
Clostridium difficile infection	1 (6.3)	1 (6.3)	0
Enterovirus infection	1 (6.3)	1 (6.3)	0
Respiratory tract infection viral	1 (6.3)	1 (6.3)	0
Rotavirus infection	1 (6.3)	1 (6.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (6.3)	1 (6.3)	0
Vascular device infection	1 (6.3)	1 (6.3)	0
Vulvovaginal candidiasis	1 (6.3)	0	0
Investigations			
-Total	1 (6.3)	1 (6.3)	0
Alanine aminotransferase increased	1 (6.3)	1 (6.3)	0
Nervous system disorders			
-Total	3 (18.8)	1 (6.3)	0
Encephalopathy	1 (6.3)	0	0
Idiopathic intracranial hypertension	1 (6.3)	0	0
Seizure	1 (6.3)	1 (6.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (12.5)	0	0
Hypoxia	1 (6.3)	0	0
Pleural effusion	1 (6.3)	0	0
Vascular disorders			
-Total	3 (18.8)	2 (12.5)	1 (6.3)
Hypotension	2 (12.5)	1 (6.3)	1 (6.3)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Embolism	1 (6.3)	1 (6.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180a
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (36.4)	6 (27.3)	1 (4.5)
Blood and lymphatic system disorders			
-Total	4 (18.2)	4 (18.2)	0
Febrile neutropenia	4 (18.2)	4 (18.2)	0
Gastrointestinal disorders			
-Total	1 (4.5)	1 (4.5)	0
Colitis	1 (4.5)	1 (4.5)	0
General disorders and administration site conditions			
-Total	1 (4.5)	0	0
Pyrexia	1 (4.5)	0	0
Hepatobiliary disorders			

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (4.5)	1 (4.5)	0
Cholecystitis	1 (4.5)	1 (4.5)	0
Infections and infestations			
-Total	5 (22.7)	4 (18.2)	0
Alpha haemolytic streptococcal infection	1 (4.5)	1 (4.5)	0
Bronchopulmonary aspergillosis	1 (4.5)	1 (4.5)	0
Device related infection	1 (4.5)	1 (4.5)	0
Enterococcal bacteraemia	1 (4.5)	1 (4.5)	0
Respiratory syncytial virus infection	1 (4.5)	0	0
Staphylococcal infection	1 (4.5)	1 (4.5)	0
Streptococcal bacteraemia	1 (4.5)	1 (4.5)	0
Investigations			
-Total	1 (4.5)	1 (4.5)	0
Blast cell count increased	1 (4.5)	1 (4.5)	0
Metabolism and nutrition disorders			
-Total	1 (4.5)	1 (4.5)	0
Hypocalcaemia	1 (4.5)	0	0

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypophosphataemia	1 (4.5)	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (9.1)	0	1 (4.5)
Hypoxia	1 (4.5)	0	0
Idiopathic pneumonia syndrome	1 (4.5)	0	1 (4.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180a
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (46.2)	14 (35.9)	4 (10.3)
Blood and lymphatic system disorders			
-Total	7 (17.9)	5 (12.8)	2 (5.1)
Febrile neutropenia	7 (17.9)	7 (17.9)	0
Neutropenia	1 (2.6)	0	1 (2.6)
Pancytopenia	1 (2.6)	0	1 (2.6)
Thrombocytopenia	1 (2.6)	0	1 (2.6)
Gastrointestinal disorders			
-Total	7 (17.9)	6 (15.4)	0
Abdominal pain	3 (7.7)	2 (5.1)	0
Stomatitis	3 (7.7)	3 (7.7)	0
Colitis	2 (5.1)	2 (5.1)	0

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (2.6)	1 (2.6)	0
General disorders and administration site conditions			
-Total	3 (7.7)	0	1 (2.6)
Pyrexia	2 (5.1)	0	0
Chills	1 (2.6)	0	0
Multiple organ dysfunction syndrome	1 (2.6)	0	1 (2.6)
Infections and infestations			
-Total	12 (30.8)	8 (20.5)	3 (7.7)
Device related infection	2 (5.1)	2 (5.1)	0
Staphylococcal bacteraemia	2 (5.1)	2 (5.1)	0
Bacteraemia	1 (2.6)	1 (2.6)	0
Candida sepsis	1 (2.6)	0	1 (2.6)
Cellulitis	1 (2.6)	1 (2.6)	0
Escherichia bacteraemia	1 (2.6)	1 (2.6)	0
Escherichia urinary tract infection	1 (2.6)	1 (2.6)	0
Gastroenteritis	1 (2.6)	1 (2.6)	0
Klebsiella sepsis	1 (2.6)	0	1 (2.6)

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	1 (2.6)	0	0
Pneumonia	1 (2.6)	0	0
Pneumonia fungal	1 (2.6)	1 (2.6)	0
Respiratory syncytial virus bronchitis	1 (2.6)	1 (2.6)	0
Sepsis	1 (2.6)	0	1 (2.6)
Injury, poisoning and procedural complications			
-Total	1 (2.6)	1 (2.6)	0
Extradural haematoma	1 (2.6)	1 (2.6)	0
Subdural haematoma	1 (2.6)	1 (2.6)	0
Investigations			
-Total	1 (2.6)	1 (2.6)	0
Electrocardiogram qt prolonged	1 (2.6)	1 (2.6)	0
Metabolism and nutrition disorders			
-Total	3 (7.7)	1 (2.6)	1 (2.6)
Dehydration	1 (2.6)	1 (2.6)	0
Hypernatraemia	1 (2.6)	0	1 (2.6)
Malnutrition	1 (2.6)	0	0

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	1 (2.6)	1 (2.6)	0
Back pain	1 (2.6)	1 (2.6)	0
Nervous system disorders			
-Total	1 (2.6)	1 (2.6)	0
Headache	1 (2.6)	1 (2.6)	0
Psychiatric disorders			
-Total	1 (2.6)	1 (2.6)	0
Mental status changes	1 (2.6)	1 (2.6)	0
Renal and urinary disorders			
-Total	1 (2.6)	0	1 (2.6)
Acute kidney injury	1 (2.6)	0	1 (2.6)
Reproductive system and breast disorders			
-Total	1 (2.6)	0	0
Scrotal pain	1 (2.6)	0	0
Respiratory, thoracic and mediastinal disorders			

Age: >=10 years to <18 years

Group term Preferred term	All patients N=39 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (7.7)	0	1 (2.6)
Hypoxia	2 (5.1)	0	0
Pulmonary mass	1 (2.6)	0	0
Pulmonary oedema	1 (2.6)	0	1 (2.6)
Respiratory failure	1 (2.6)	0	1 (2.6)
Vascular disorders			
-Total	3 (7.7)	2 (5.1)	1 (2.6)
Hypotension	3 (7.7)	2 (5.1)	1 (2.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180a
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (57.1)	2 (14.3)	5 (35.7)
Blood and lymphatic system disorders			
-Total	1 (7.1)	0	1 (7.1)
Pancytopenia	1 (7.1)	0	1 (7.1)
Cardiac disorders			
-Total	1 (7.1)	0	1 (7.1)
Cardiovascular insufficiency	1 (7.1)	0	1 (7.1)
General disorders and administration site conditions			
-Total	5 (35.7)	3 (21.4)	1 (7.1)
Pyrexia	3 (21.4)	2 (14.3)	0

Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	1 (7.1)	0	1 (7.1)
Physical deconditioning	1 (7.1)	1 (7.1)	0
Hepatobiliary disorders			
-Total	1 (7.1)	1 (7.1)	0
Hyperbilirubinaemia	1 (7.1)	1 (7.1)	0
Infections and infestations			
-Total	5 (35.7)	1 (7.1)	4 (28.6)
Abscess limb	1 (7.1)	1 (7.1)	0
Escherichia sepsis	1 (7.1)	0	1 (7.1)
Klebsiella sepsis	1 (7.1)	0	1 (7.1)
Pneumonia	1 (7.1)	0	1 (7.1)
Pneumonia fungal	1 (7.1)	0	0
Serratia infection	1 (7.1)	1 (7.1)	0
Staphylococcal scalded skin syndrome	1 (7.1)	0	0
Staphylococcal sepsis	1 (7.1)	0	1 (7.1)
Injury, poisoning and procedural complications			
-Total	1 (7.1)	0	0

Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Subdural haematoma	1 (7.1)	0	0
Investigations			
-Total	1 (7.1)	1 (7.1)	0
Transaminases increased	1 (7.1)	1 (7.1)	0
Metabolism and nutrition disorders			
-Total	1 (7.1)	0	0
Hypocalcaemia	1 (7.1)	0	0
Musculoskeletal and connective tissue disorders			
-Total	1 (7.1)	1 (7.1)	0
Myopathy	1 (7.1)	1 (7.1)	0
Myositis	1 (7.1)	1 (7.1)	0
Nervous system disorders			
-Total	1 (7.1)	1 (7.1)	0
Headache	1 (7.1)	1 (7.1)	0
Renal and urinary disorders			
-Total	1 (7.1)	0	0
Acute kidney injury	1 (7.1)	0	0

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (14.3)	0	2 (14.3)
Hypoxia	2 (14.3)	2 (14.3)	0
Aspiration	1 (7.1)	0	1 (7.1)
Respiratory distress	1 (7.1)	0	1 (7.1)
Vascular disorders			
-Total	1 (7.1)	0	1 (7.1)
Hypotension	1 (7.1)	0	1 (7.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180b
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (45.0)	12 (30.0)	6 (15.0)
Blood and lymphatic system disorders			
-Total	6 (15.0)	5 (12.5)	1 (2.5)
Febrile neutropenia	6 (15.0)	6 (15.0)	0
Neutropenia	1 (2.5)	0	1 (2.5)
Thrombocytopenia	1 (2.5)	0	1 (2.5)
Cardiac disorders			
-Total	1 (2.5)	0	1 (2.5)
Cardiovascular insufficiency	1 (2.5)	0	1 (2.5)
Gastrointestinal disorders			
-Total	5 (12.5)	4 (10.0)	0
Abdominal pain	2 (5.0)	1 (2.5)	0

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Colitis	2 (5.0)	2 (5.0)	0
Stomatitis	2 (5.0)	2 (5.0)	0
Gastrointestinal haemorrhage	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	7 (17.5)	2 (5.0)	2 (5.0)
Pyrexia	5 (12.5)	2 (5.0)	0
Multiple organ dysfunction syndrome	2 (5.0)	0	2 (5.0)
Chills	1 (2.5)	0	0
Infections and infestations			
-Total	11 (27.5)	5 (12.5)	5 (12.5)
Klebsiella sepsis	2 (5.0)	0	2 (5.0)
Bacteraemia	1 (2.5)	1 (2.5)	0
Candida sepsis	1 (2.5)	0	1 (2.5)
Device related infection	1 (2.5)	1 (2.5)	0
Gastroenteritis	1 (2.5)	1 (2.5)	0
Pneumonia	1 (2.5)	0	1 (2.5)
Pneumonia fungal	1 (2.5)	1 (2.5)	0

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	1 (2.5)	0	0
Sepsis	1 (2.5)	0	1 (2.5)
Serratia infection	1 (2.5)	1 (2.5)	0
Staphylococcal bacteraemia	1 (2.5)	1 (2.5)	0
Injury, poisoning and procedural complications			
-Total	1 (2.5)	1 (2.5)	0
Extradural haematoma	1 (2.5)	1 (2.5)	0
Subdural haematoma	1 (2.5)	1 (2.5)	0
Investigations			
-Total	1 (2.5)	1 (2.5)	0
Electrocardiogram qt prolonged	1 (2.5)	1 (2.5)	0
Metabolism and nutrition disorders			
-Total	3 (7.5)	1 (2.5)	1 (2.5)
Dehydration	1 (2.5)	1 (2.5)	0
Hypernatraemia	1 (2.5)	0	1 (2.5)
Malnutrition	1 (2.5)	0	0
Nervous system disorders			

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (5.0)	2 (5.0)	0
Headache	2 (5.0)	2 (5.0)	0
Psychiatric disorders			
-Total	1 (2.5)	1 (2.5)	0
Mental status changes	1 (2.5)	1 (2.5)	0
Renal and urinary disorders			
-Total	1 (2.5)	0	1 (2.5)
Acute kidney injury	1 (2.5)	0	1 (2.5)
Reproductive system and breast disorders			
-Total	1 (2.5)	0	0
Scrotal pain	1 (2.5)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (10.0)	0	3 (7.5)
Hypoxia	3 (7.5)	2 (5.0)	0
Aspiration	1 (2.5)	0	1 (2.5)
Pulmonary oedema	1 (2.5)	0	1 (2.5)
Respiratory distress	1 (2.5)	0	1 (2.5)

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	1 (2.5)	0	1 (2.5)
Vascular disorders			
-Total	4 (10.0)	2 (5.0)	2 (5.0)
Hypotension	4 (10.0)	2 (5.0)	2 (5.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180b
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (45.7)	10 (28.6)	4 (11.4)
Blood and lymphatic system disorders			
-Total	6 (17.1)	4 (11.4)	2 (5.7)
Febrile neutropenia	5 (14.3)	5 (14.3)	0
Pancytopenia	2 (5.7)	0	2 (5.7)
Gastrointestinal disorders			
-Total	3 (8.6)	3 (8.6)	0
Abdominal pain	1 (2.9)	1 (2.9)	0
Colitis	1 (2.9)	1 (2.9)	0
Stomatitis	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (5.7)	1 (2.9)	0
Physical deconditioning	1 (2.9)	1 (2.9)	0
Pyrexia	1 (2.9)	0	0
Hepatobiliary disorders			
-Total	2 (5.7)	2 (5.7)	0
Cholecystitis	1 (2.9)	1 (2.9)	0
Hyperbilirubinaemia	1 (2.9)	1 (2.9)	0
Infections and infestations			
-Total	11 (31.4)	8 (22.9)	2 (5.7)
Device related infection	2 (5.7)	2 (5.7)	0
Abscess limb	1 (2.9)	1 (2.9)	0
Alpha haemolytic streptococcal infection	1 (2.9)	1 (2.9)	0
Bronchopulmonary aspergillosis	1 (2.9)	1 (2.9)	0
Cellulitis	1 (2.9)	1 (2.9)	0
Enterococcal bacteraemia	1 (2.9)	1 (2.9)	0
Escherichia bacteraemia	1 (2.9)	1 (2.9)	0
Escherichia sepsis	1 (2.9)	0	1 (2.9)

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia urinary tract infection	1 (2.9)	1 (2.9)	0
Parainfluenzae virus infection	1 (2.9)	0	0
Pneumonia	1 (2.9)	0	0
Pneumonia fungal	1 (2.9)	0	0
Respiratory syncytial virus bronchitis	1 (2.9)	1 (2.9)	0
Staphylococcal bacteraemia	1 (2.9)	1 (2.9)	0
Staphylococcal infection	1 (2.9)	1 (2.9)	0
Staphylococcal scalded skin syndrome	1 (2.9)	0	0
Staphylococcal sepsis	1 (2.9)	0	1 (2.9)
Streptococcal bacteraemia	1 (2.9)	1 (2.9)	0
Injury, poisoning and procedural complications			
-Total	1 (2.9)	0	0
Subdural haematoma	1 (2.9)	0	0
Investigations			
-Total	2 (5.7)	2 (5.7)	0
Blast cell count increased	1 (2.9)	1 (2.9)	0
Transaminases increased	1 (2.9)	1 (2.9)	0

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	2 (5.7)	1 (2.9)	0
Hypocalcaemia	2 (5.7)	0	0
Hypophosphataemia	1 (2.9)	1 (2.9)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (5.7)	2 (5.7)	0
Back pain	1 (2.9)	1 (2.9)	0
Myopathy	1 (2.9)	1 (2.9)	0
Myositis	1 (2.9)	1 (2.9)	0
Renal and urinary disorders			
-Total	1 (2.9)	0	0
Acute kidney injury	1 (2.9)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (8.6)	0	1 (2.9)
Hypoxia	2 (5.7)	0	0
Idiopathic pneumonia syndrome	1 (2.9)	0	1 (2.9)
Pulmonary mass	1 (2.9)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180c
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (38.3)	16 (26.7)	6 (10.0)
Blood and lymphatic system disorders			
-Total	9 (15.0)	8 (13.3)	1 (1.7)
Febrile neutropenia	9 (15.0)	9 (15.0)	0
Neutropenia	1 (1.7)	0	1 (1.7)
Thrombocytopenia	1 (1.7)	0	1 (1.7)
Gastrointestinal disorders			
-Total	6 (10.0)	5 (8.3)	0
Colitis	3 (5.0)	3 (5.0)	0
Abdominal pain	2 (3.3)	1 (1.7)	0
Stomatitis	2 (3.3)	2 (3.3)	0
Gastrointestinal haemorrhage	1 (1.7)	1 (1.7)	0

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	6 (10.0)	2 (3.3)	1 (1.7)
Pyrexia	5 (8.3)	2 (3.3)	0
Chills	1 (1.7)	0	0
Multiple organ dysfunction syndrome	1 (1.7)	0	1 (1.7)
Hepatobiliary disorders			
-Total	1 (1.7)	1 (1.7)	0
Cholecystitis	1 (1.7)	1 (1.7)	0
Infections and infestations			
-Total	15 (25.0)	8 (13.3)	5 (8.3)
Pneumonia	2 (3.3)	0	1 (1.7)
Staphylococcal bacteraemia	2 (3.3)	2 (3.3)	0
Bacteraemia	1 (1.7)	1 (1.7)	0
Bronchopulmonary aspergillosis	1 (1.7)	1 (1.7)	0
Candida sepsis	1 (1.7)	0	1 (1.7)
Cellulitis	1 (1.7)	1 (1.7)	0
Device related infection	1 (1.7)	1 (1.7)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Enterococcal bacteraemia	1 (1.7)	1 (1.7)	0
Escherichia bacteraemia	1 (1.7)	1 (1.7)	0
Escherichia sepsis	1 (1.7)	0	1 (1.7)
Klebsiella sepsis	1 (1.7)	0	1 (1.7)
Parainfluenzae virus infection	1 (1.7)	0	0
Pneumonia fungal	1 (1.7)	1 (1.7)	0
Respiratory syncytial virus bronchitis	1 (1.7)	1 (1.7)	0
Respiratory syncytial virus infection	1 (1.7)	0	0
Sepsis	1 (1.7)	0	1 (1.7)
Serratia infection	1 (1.7)	1 (1.7)	0
Streptococcal bacteraemia	1 (1.7)	1 (1.7)	0
Injury, poisoning and procedural complications			
-Total	1 (1.7)	0	0
Subdural haematoma	1 (1.7)	0	0
Investigations			
-Total	2 (3.3)	2 (3.3)	0
Blast cell count increased	1 (1.7)	1 (1.7)	0

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Electrocardiogram qt prolonged	1 (1.7)	1 (1.7)	0
Metabolism and nutrition disorders			
-Total	3 (5.0)	1 (1.7)	1 (1.7)
Hypernatraemia	1 (1.7)	0	1 (1.7)
Hypocalcaemia	1 (1.7)	0	0
Hypophosphataemia	1 (1.7)	1 (1.7)	0
Malnutrition	1 (1.7)	0	0
Renal and urinary disorders			
-Total	1 (1.7)	0	1 (1.7)
Acute kidney injury	1 (1.7)	0	1 (1.7)
Reproductive system and breast disorders			
-Total	1 (1.7)	0	0
Scrotal pain	1 (1.7)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (10.0)	0	3 (5.0)
Hypoxia	4 (6.7)	1 (1.7)	0
Aspiration	1 (1.7)	0	1 (1.7)

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Idiopathic pneumonia syndrome	1 (1.7)	0	1 (1.7)
Pulmonary mass	1 (1.7)	0	0
Pulmonary oedema	1 (1.7)	0	1 (1.7)
Respiratory failure	1 (1.7)	0	1 (1.7)
Vascular disorders			
-Total	4 (6.7)	2 (3.3)	2 (3.3)
Hypotension	4 (6.7)	2 (3.3)	2 (3.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180c
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (66.7)	3 (50.0)	0
General disorders and administration site conditions			
-Total	1 (16.7)	0	0
Pyrexia	1 (16.7)	0	0
Infections and infestations			
-Total	3 (50.0)	3 (50.0)	0
Alpha haemolytic streptococcal infection	1 (16.7)	1 (16.7)	0
Device related infection	1 (16.7)	1 (16.7)	0
Gastroenteritis	1 (16.7)	1 (16.7)	0
Staphylococcal infection	1 (16.7)	1 (16.7)	0

Race: Asian

Group term Preferred term	All patients N=6 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders			
-Total	1 (16.7)	1 (16.7)	0
Dehydration	1 (16.7)	1 (16.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180c
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (77.8)	3 (33.3)	4 (44.4)
Blood and lymphatic system disorders			
-Total	3 (33.3)	1 (11.1)	2 (22.2)
Febrile neutropenia	2 (22.2)	2 (22.2)	0
Pancytopenia	2 (22.2)	0	2 (22.2)
Cardiac disorders			
-Total	1 (11.1)	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	1 (11.1)
Gastrointestinal disorders			
-Total	2 (22.2)	2 (22.2)	0
Abdominal pain	1 (11.1)	1 (11.1)	0

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Multiple organ dysfunction syndrome	1 (11.1)	0	1 (11.1)
Physical deconditioning	1 (11.1)	1 (11.1)	0
Hepatobiliary disorders			
-Total	1 (11.1)	1 (11.1)	0
Hyperbilirubinaemia	1 (11.1)	1 (11.1)	0
Infections and infestations			
-Total	4 (44.4)	2 (22.2)	2 (22.2)
Abscess limb	1 (11.1)	1 (11.1)	0
Device related infection	1 (11.1)	1 (11.1)	0
Escherichia urinary tract infection	1 (11.1)	1 (11.1)	0
Klebsiella sepsis	1 (11.1)	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	0
Staphylococcal scalded skin syndrome	1 (11.1)	0	0
Staphylococcal sepsis	1 (11.1)	0	1 (11.1)

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Injury, poisoning and procedural complications			
-Total	1 (11.1)	1 (11.1)	0
Extradural haematoma	1 (11.1)	1 (11.1)	0
Subdural haematoma	1 (11.1)	1 (11.1)	0
Investigations			
-Total	1 (11.1)	1 (11.1)	0
Transaminases increased	1 (11.1)	1 (11.1)	0
Metabolism and nutrition disorders			
-Total	1 (11.1)	0	0
Hypocalcaemia	1 (11.1)	0	0
Musculoskeletal and connective tissue disorders			
-Total	2 (22.2)	2 (22.2)	0
Back pain	1 (11.1)	1 (11.1)	0
Myopathy	1 (11.1)	1 (11.1)	0
Myositis	1 (11.1)	1 (11.1)	0
Nervous system disorders			
-Total	2 (22.2)	2 (22.2)	0

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Headache	2 (22.2)	2 (22.2)	0
Psychiatric disorders			
-Total	1 (11.1)	1 (11.1)	0
Mental status changes	1 (11.1)	1 (11.1)	0
Renal and urinary disorders			
-Total	1 (11.1)	0	0
Acute kidney injury	1 (11.1)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (11.1)	0	1 (11.1)
Hypoxia	1 (11.1)	1 (11.1)	0
Respiratory distress	1 (11.1)	0	1 (11.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of

all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180d
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (56.7)	11 (36.7)	6 (20.0)
Blood and lymphatic system disorders			
-Total	6 (20.0)	4 (13.3)	2 (6.7)
Febrile neutropenia	6 (20.0)	6 (20.0)	0
Neutropenia	1 (3.3)	0	1 (3.3)
Pancytopenia	1 (3.3)	0	1 (3.3)
Thrombocytopenia	1 (3.3)	0	1 (3.3)
Cardiac disorders			
-Total	1 (3.3)	0	1 (3.3)
Cardiovascular insufficiency	1 (3.3)	0	1 (3.3)
Gastrointestinal disorders			
-Total	4 (13.3)	4 (13.3)	0

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (3.3)	1 (3.3)	0
Colitis	1 (3.3)	1 (3.3)	0
Gastrointestinal haemorrhage	1 (3.3)	1 (3.3)	0
Stomatitis	1 (3.3)	1 (3.3)	0
General disorders and administration site conditions			
-Total	5 (16.7)	1 (3.3)	1 (3.3)
Pyrexia	4 (13.3)	1 (3.3)	0
Chills	1 (3.3)	0	0
Multiple organ dysfunction syndrome	1 (3.3)	0	1 (3.3)
Hepatobiliary disorders			
-Total	1 (3.3)	1 (3.3)	0
Cholecystitis	1 (3.3)	1 (3.3)	0
Infections and infestations			
-Total	11 (36.7)	6 (20.0)	4 (13.3)
Bacteraemia	1 (3.3)	1 (3.3)	0
Candida sepsis	1 (3.3)	0	1 (3.3)
Device related infection	1 (3.3)	1 (3.3)	0

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterococcal bacteraemia	1 (3.3)	1 (3.3)	0
Escherichia bacteraemia	1 (3.3)	1 (3.3)	0
Escherichia sepsis	1 (3.3)	0	1 (3.3)
Escherichia urinary tract infection	1 (3.3)	1 (3.3)	0
Klebsiella sepsis	1 (3.3)	0	1 (3.3)
Parainfluenzae virus infection	1 (3.3)	0	0
Pneumonia	1 (3.3)	0	0
Pneumonia fungal	1 (3.3)	1 (3.3)	0
Respiratory syncytial virus bronchitis	1 (3.3)	1 (3.3)	0
Sepsis	1 (3.3)	0	1 (3.3)
Serratia infection	1 (3.3)	1 (3.3)	0
Staphylococcal bacteraemia	1 (3.3)	1 (3.3)	0
Streptococcal bacteraemia	1 (3.3)	1 (3.3)	0
Injury, poisoning and procedural complications			
-Total	1 (3.3)	1 (3.3)	0
Extradural haematoma	1 (3.3)	1 (3.3)	0
Subdural haematoma	1 (3.3)	1 (3.3)	0

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	2 (6.7)	2 (6.7)	0
Blast cell count increased	1 (3.3)	1 (3.3)	0
Electrocardiogram qt prolonged	1 (3.3)	1 (3.3)	0
Metabolism and nutrition disorders			
-Total	3 (10.0)	1 (3.3)	1 (3.3)
Hypernatraemia	1 (3.3)	0	1 (3.3)
Hypocalcaemia	1 (3.3)	0	0
Hypophosphataemia	1 (3.3)	1 (3.3)	0
Malnutrition	1 (3.3)	0	0
Musculoskeletal and connective tissue disorders			
-Total	1 (3.3)	1 (3.3)	0
Back pain	1 (3.3)	1 (3.3)	0
Nervous system disorders			
-Total	1 (3.3)	1 (3.3)	0
Headache	1 (3.3)	1 (3.3)	0
Psychiatric disorders			

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.3)	1 (3.3)	0
Mental status changes	1 (3.3)	1 (3.3)	0
Renal and urinary disorders			
-Total	1 (3.3)	0	1 (3.3)
Acute kidney injury	1 (3.3)	0	1 (3.3)
Reproductive system and breast disorders			
-Total	1 (3.3)	0	0
Scrotal pain	1 (3.3)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (13.3)	0	2 (6.7)
Hypoxia	2 (6.7)	0	0
Idiopathic pneumonia syndrome	1 (3.3)	0	1 (3.3)
Pulmonary mass	1 (3.3)	0	0
Pulmonary oedema	1 (3.3)	0	1 (3.3)
Respiratory failure	1 (3.3)	0	1 (3.3)
Vascular disorders			
-Total	2 (6.7)	1 (3.3)	1 (3.3)

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=30 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	2 (6.7)	1 (3.3)	1 (3.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180d
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (37.8)	11 (24.4)	4 (8.9)
Blood and lymphatic system disorders			
-Total	6 (13.3)	5 (11.1)	1 (2.2)
Febrile neutropenia	5 (11.1)	5 (11.1)	0
Pancytopenia	1 (2.2)	0	1 (2.2)
Gastrointestinal disorders			
-Total	4 (8.9)	3 (6.7)	0
Abdominal pain	2 (4.4)	1 (2.2)	0
Colitis	2 (4.4)	2 (4.4)	0
Stomatitis	2 (4.4)	2 (4.4)	0
General disorders and administration site conditions			

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (8.9)	2 (4.4)	1 (2.2)
Pyrexia	2 (4.4)	1 (2.2)	0
Multiple organ dysfunction syndrome	1 (2.2)	0	1 (2.2)
Physical deconditioning	1 (2.2)	1 (2.2)	0
Hepatobiliary disorders			
-Total	1 (2.2)	1 (2.2)	0
Hyperbilirubinaemia	1 (2.2)	1 (2.2)	0
Infections and infestations			
-Total	11 (24.4)	7 (15.6)	3 (6.7)
Device related infection	2 (4.4)	2 (4.4)	0
Abscess limb	1 (2.2)	1 (2.2)	0
Alpha haemolytic streptococcal infection	1 (2.2)	1 (2.2)	0
Bronchopulmonary aspergillosis	1 (2.2)	1 (2.2)	0
Cellulitis	1 (2.2)	1 (2.2)	0
Gastroenteritis	1 (2.2)	1 (2.2)	0
Klebsiella sepsis	1 (2.2)	0	1 (2.2)
Pneumonia	1 (2.2)	0	1 (2.2)

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (2.2)	0	0
Respiratory syncytial virus infection	1 (2.2)	0	0
Staphylococcal bacteraemia	1 (2.2)	1 (2.2)	0
Staphylococcal infection	1 (2.2)	1 (2.2)	0
Staphylococcal scalded skin syndrome	1 (2.2)	0	0
Staphylococcal sepsis	1 (2.2)	0	1 (2.2)
Injury, poisoning and procedural complications			
-Total	1 (2.2)	0	0
Subdural haematoma	1 (2.2)	0	0
Investigations			
-Total	1 (2.2)	1 (2.2)	0
Transaminases increased	1 (2.2)	1 (2.2)	0
Metabolism and nutrition disorders			
-Total	2 (4.4)	1 (2.2)	0
Dehydration	1 (2.2)	1 (2.2)	0
Hypocalcaemia	1 (2.2)	0	0

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal and connective tissue disorders			
-Total	1 (2.2)	1 (2.2)	0
Myopathy	1 (2.2)	1 (2.2)	0
Myositis	1 (2.2)	1 (2.2)	0
Nervous system disorders			
-Total	1 (2.2)	1 (2.2)	0
Headache	1 (2.2)	1 (2.2)	0
Renal and urinary disorders			
-Total	1 (2.2)	0	0
Acute kidney injury	1 (2.2)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.7)	0	2 (4.4)
Hypoxia	3 (6.7)	2 (4.4)	0
Aspiration	1 (2.2)	0	1 (2.2)
Respiratory distress	1 (2.2)	0	1 (2.2)
Vascular disorders			
-Total	2 (4.4)	1 (2.2)	1 (2.2)

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	2 (4.4)	1 (2.2)	1 (2.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180e
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (37.5)	2 (25.0)	1 (12.5)
Blood and lymphatic system disorders			
-Total	1 (12.5)	1 (12.5)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Infections and infestations			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Cellulitis	1 (12.5)	1 (12.5)	0
Pneumonia	1 (12.5)	0	1 (12.5)

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=8 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Aspiration	1 (12.5)	0	1 (12.5)
Hypoxia	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypotension	1 (12.5)	0	1 (12.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180e
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (46.3)	20 (29.9)	9 (13.4)
Blood and lymphatic system disorders			
-Total	11 (16.4)	8 (11.9)	3 (4.5)
Febrile neutropenia	10 (14.9)	10 (14.9)	0
Pancytopenia	2 (3.0)	0	2 (3.0)
Neutropenia	1 (1.5)	0	1 (1.5)
Thrombocytopenia	1 (1.5)	0	1 (1.5)
Cardiac disorders			
-Total	1 (1.5)	0	1 (1.5)
Cardiovascular insufficiency	1 (1.5)	0	1 (1.5)
Gastrointestinal disorders			
-Total	8 (11.9)	7 (10.4)	0

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	3 (4.5)	2 (3.0)	0
Colitis	3 (4.5)	3 (4.5)	0
Stomatitis	3 (4.5)	3 (4.5)	0
Gastrointestinal haemorrhage	1 (1.5)	1 (1.5)	0
General disorders and administration site conditions			
-Total	8 (11.9)	2 (3.0)	2 (3.0)
Pyrexia	5 (7.5)	1 (1.5)	0
Multiple organ dysfunction syndrome	2 (3.0)	0	2 (3.0)
Chills	1 (1.5)	0	0
Physical deconditioning	1 (1.5)	1 (1.5)	0
Hepatobiliary disorders			
-Total	2 (3.0)	2 (3.0)	0
Cholecystitis	1 (1.5)	1 (1.5)	0
Hyperbilirubinaemia	1 (1.5)	1 (1.5)	0
Infections and infestations			
-Total	20 (29.9)	12 (17.9)	6 (9.0)
Device related infection	3 (4.5)	3 (4.5)	0
Klebsiella sepsis	2 (3.0)	0	2 (3.0)

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	2 (3.0)	1 (1.5)	0
Staphylococcal bacteraemia	2 (3.0)	2 (3.0)	0
Abscess limb	1 (1.5)	1 (1.5)	0
Alpha haemolytic streptococcal infection	1 (1.5)	1 (1.5)	0
Bacteraemia	1 (1.5)	1 (1.5)	0
Bronchopulmonary aspergillosis	1 (1.5)	1 (1.5)	0
Candida sepsis	1 (1.5)	0	1 (1.5)
Enterococcal bacteraemia	1 (1.5)	1 (1.5)	0
Escherichia bacteraemia	1 (1.5)	1 (1.5)	0
Escherichia sepsis	1 (1.5)	0	1 (1.5)
Escherichia urinary tract infection	1 (1.5)	1 (1.5)	0
Gastroenteritis	1 (1.5)	1 (1.5)	0
Parainfluenzae virus infection	1 (1.5)	0	0
Pneumonia	1 (1.5)	0	0
Respiratory syncytial virus bronchitis	1 (1.5)	1 (1.5)	0
Respiratory syncytial virus infection	1 (1.5)	0	0
Sepsis	1 (1.5)	0	1 (1.5)
Serratia infection	1 (1.5)	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (1.5)	1 (1.5)	0
Staphylococcal scalded skin syndrome	1 (1.5)	0	0
Staphylococcal sepsis	1 (1.5)	0	1 (1.5)
Streptococcal bacteraemia	1 (1.5)	1 (1.5)	0
Injury, poisoning and procedural complications			
-Total	2 (3.0)	1 (1.5)	0
Subdural haematoma	2 (3.0)	1 (1.5)	0
Extradural haematoma	1 (1.5)	1 (1.5)	0
Investigations			
-Total	3 (4.5)	3 (4.5)	0
Blast cell count increased	1 (1.5)	1 (1.5)	0
Electrocardiogram qt prolonged	1 (1.5)	1 (1.5)	0
Transaminases increased	1 (1.5)	1 (1.5)	0
Metabolism and nutrition disorders			
-Total	5 (7.5)	2 (3.0)	1 (1.5)
Hypocalcaemia	2 (3.0)	0	0
Dehydration	1 (1.5)	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	1 (1.5)	0	1 (1.5)
Hypophosphataemia	1 (1.5)	1 (1.5)	0
Malnutrition	1 (1.5)	0	0
Musculoskeletal and connective tissue disorders			
-Total	2 (3.0)	2 (3.0)	0
Back pain	1 (1.5)	1 (1.5)	0
Myopathy	1 (1.5)	1 (1.5)	0
Myositis	1 (1.5)	1 (1.5)	0
Nervous system disorders			
-Total	2 (3.0)	2 (3.0)	0
Headache	2 (3.0)	2 (3.0)	0
Psychiatric disorders			
-Total	1 (1.5)	1 (1.5)	0
Mental status changes	1 (1.5)	1 (1.5)	0
Renal and urinary disorders			
-Total	2 (3.0)	0	1 (1.5)
Acute kidney injury	2 (3.0)	0	1 (1.5)

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (1.5)	0	0
Scrotal pain	1 (1.5)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (9.0)	0	3 (4.5)
Hypoxia	4 (6.0)	1 (1.5)	0
Idiopathic pneumonia syndrome	1 (1.5)	0	1 (1.5)
Pulmonary mass	1 (1.5)	0	0
Pulmonary oedema	1 (1.5)	0	1 (1.5)
Respiratory distress	1 (1.5)	0	1 (1.5)
Respiratory failure	1 (1.5)	0	1 (1.5)
Vascular disorders			
-Total	3 (4.5)	2 (3.0)	1 (1.5)
Hypotension	3 (4.5)	2 (3.0)	1 (1.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180f
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Bacteraemia	1 (50.0)	1 (50.0)	0
Reproductive system and breast disorders			
-Total	1 (50.0)	0	0
Scrotal pain	1 (50.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180f
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (45.2)	21 (28.8)	10 (13.7)
Blood and lymphatic system disorders			
-Total	12 (16.4)	9 (12.3)	3 (4.1)
Febrile neutropenia	11 (15.1)	11 (15.1)	0
Pancytopenia	2 (2.7)	0	2 (2.7)
Neutropenia	1 (1.4)	0	1 (1.4)
Thrombocytopenia	1 (1.4)	0	1 (1.4)
Cardiac disorders			
-Total	1 (1.4)	0	1 (1.4)
Cardiovascular insufficiency	1 (1.4)	0	1 (1.4)
Gastrointestinal disorders			
-Total	8 (11.0)	7 (9.6)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	3 (4.1)	2 (2.7)	0
Colitis	3 (4.1)	3 (4.1)	0
Stomatitis	3 (4.1)	3 (4.1)	0
Gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	8 (11.0)	3 (4.1)	2 (2.7)
Pyrexia	5 (6.8)	2 (2.7)	0
Multiple organ dysfunction syndrome	2 (2.7)	0	2 (2.7)
Chills	1 (1.4)	0	0
Physical deconditioning	1 (1.4)	1 (1.4)	0
Hepatobiliary disorders			
-Total	2 (2.7)	2 (2.7)	0
Cholecystitis	1 (1.4)	1 (1.4)	0
Hyperbilirubinaemia	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	21 (28.8)	12 (16.4)	7 (9.6)
Device related infection	3 (4.1)	3 (4.1)	0
Klebsiella sepsis	2 (2.7)	0	2 (2.7)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (2.7)	0	1 (1.4)
Pneumonia fungal	2 (2.7)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.7)	2 (2.7)	0
Abscess limb	1 (1.4)	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	1 (1.4)	0
Candida sepsis	1 (1.4)	0	1 (1.4)
Cellulitis	1 (1.4)	1 (1.4)	0
Enterococcal bacteraemia	1 (1.4)	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	1 (1.4)	0
Gastroenteritis	1 (1.4)	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	0
Sepsis	1 (1.4)	0	1 (1.4)
Serratia infection	1 (1.4)	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (1.4)	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	1 (1.4)	0
Injury, poisoning and procedural complications			
-Total	2 (2.7)	1 (1.4)	0
Subdural haematoma	2 (2.7)	1 (1.4)	0
Extradural haematoma	1 (1.4)	1 (1.4)	0
Investigations			
-Total	3 (4.1)	3 (4.1)	0
Blast cell count increased	1 (1.4)	1 (1.4)	0
Electrocardiogram qt prolonged	1 (1.4)	1 (1.4)	0
Transaminases increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	5 (6.8)	2 (2.7)	1 (1.4)
Hypocalcaemia	2 (2.7)	0	0
Dehydration	1 (1.4)	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	1 (1.4)	0	1 (1.4)
Hypophosphataemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders			
-Total	2 (2.7)	2 (2.7)	0
Back pain	1 (1.4)	1 (1.4)	0
Myopathy	1 (1.4)	1 (1.4)	0
Myositis	1 (1.4)	1 (1.4)	0
Nervous system disorders			
-Total	2 (2.7)	2 (2.7)	0
Headache	2 (2.7)	2 (2.7)	0
Psychiatric disorders			
-Total	1 (1.4)	1 (1.4)	0
Mental status changes	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	2 (2.7)	0	1 (1.4)
Acute kidney injury	2 (2.7)	0	1 (1.4)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	7 (9.6)	0	4 (5.5)
Hypoxia	5 (6.8)	2 (2.7)	0
Aspiration	1 (1.4)	0	1 (1.4)
Idiopathic pneumonia syndrome	1 (1.4)	0	1 (1.4)
Pulmonary mass	1 (1.4)	0	0
Pulmonary oedema	1 (1.4)	0	1 (1.4)
Respiratory distress	1 (1.4)	0	1 (1.4)
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	4 (5.5)	2 (2.7)	2 (2.7)
Hypotension	4 (5.5)	2 (2.7)	2 (2.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of

all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180g
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (47.2)	22 (30.6)	10 (13.9)
Blood and lymphatic system disorders			
-Total	12 (16.7)	9 (12.5)	3 (4.2)
Febrile neutropenia	11 (15.3)	11 (15.3)	0
Pancytopenia	2 (2.8)	0	2 (2.8)
Neutropenia	1 (1.4)	0	1 (1.4)
Thrombocytopenia	1 (1.4)	0	1 (1.4)
Cardiac disorders			
-Total	1 (1.4)	0	1 (1.4)
Cardiovascular insufficiency	1 (1.4)	0	1 (1.4)
Gastrointestinal disorders			
-Total	8 (11.1)	7 (9.7)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	3 (4.2)	2 (2.8)	0
Colitis	3 (4.2)	3 (4.2)	0
Stomatitis	3 (4.2)	3 (4.2)	0
Gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	9 (12.5)	3 (4.2)	2 (2.8)
Pyrexia	6 (8.3)	2 (2.8)	0
Multiple organ dysfunction syndrome	2 (2.8)	0	2 (2.8)
Chills	1 (1.4)	0	0
Physical deconditioning	1 (1.4)	1 (1.4)	0
Hepatobiliary disorders			
-Total	2 (2.8)	2 (2.8)	0
Cholecystitis	1 (1.4)	1 (1.4)	0
Hyperbilirubinaemia	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	22 (30.6)	13 (18.1)	7 (9.7)
Device related infection	3 (4.2)	3 (4.2)	0
Klebsiella sepsis	2 (2.8)	0	2 (2.8)

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (2.8)	0	1 (1.4)
Pneumonia fungal	2 (2.8)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.8)	2 (2.8)	0
Abscess limb	1 (1.4)	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	1 (1.4)	0
Bacteraemia	1 (1.4)	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	1 (1.4)	0
Candida sepsis	1 (1.4)	0	1 (1.4)
Cellulitis	1 (1.4)	1 (1.4)	0
Enterococcal bacteraemia	1 (1.4)	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	1 (1.4)	0
Gastroenteritis	1 (1.4)	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	0
Sepsis	1 (1.4)	0	1 (1.4)

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serratia infection	1 (1.4)	1 (1.4)	0
Staphylococcal infection	1 (1.4)	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	1 (1.4)	0
Injury, poisoning and procedural complications			
-Total	2 (2.8)	1 (1.4)	0
Subdural haematoma	2 (2.8)	1 (1.4)	0
Extradural haematoma	1 (1.4)	1 (1.4)	0
Investigations			
-Total	3 (4.2)	3 (4.2)	0
Blast cell count increased	1 (1.4)	1 (1.4)	0
Electrocardiogram qt prolonged	1 (1.4)	1 (1.4)	0
Transaminases increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	5 (6.9)	2 (2.8)	1 (1.4)
Hypocalcaemia	2 (2.8)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (1.4)	1 (1.4)	0
Hypernatraemia	1 (1.4)	0	1 (1.4)
Hypophosphataemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders			
-Total	2 (2.8)	2 (2.8)	0
Back pain	1 (1.4)	1 (1.4)	0
Myopathy	1 (1.4)	1 (1.4)	0
Myositis	1 (1.4)	1 (1.4)	0
Nervous system disorders			
-Total	2 (2.8)	2 (2.8)	0
Headache	2 (2.8)	2 (2.8)	0
Psychiatric disorders			
-Total	1 (1.4)	1 (1.4)	0
Mental status changes	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	2 (2.8)	0	1 (1.4)
Acute kidney injury	2 (2.8)	0	1 (1.4)

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (1.4)	0	0
Scrotal pain	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (9.7)	0	4 (5.6)
Hypoxia	5 (6.9)	2 (2.8)	0
Aspiration	1 (1.4)	0	1 (1.4)
Idiopathic pneumonia syndrome	1 (1.4)	0	1 (1.4)
Pulmonary mass	1 (1.4)	0	0
Pulmonary oedema	1 (1.4)	0	1 (1.4)
Respiratory distress	1 (1.4)	0	1 (1.4)
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	4 (5.6)	2 (2.8)	2 (2.8)
Hypotension	4 (5.6)	2 (2.8)	2 (2.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility

- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180h
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (45.9)	22 (29.7)	10 (13.5)
Blood and lymphatic system disorders			
-Total	12 (16.2)	9 (12.2)	3 (4.1)
Febrile neutropenia	11 (14.9)	11 (14.9)	0
Pancytopenia	2 (2.7)	0	2 (2.7)
Neutropenia	1 (1.4)	0	1 (1.4)
Thrombocytopenia	1 (1.4)	0	1 (1.4)
Cardiac disorders			
-Total	1 (1.4)	0	1 (1.4)
Cardiovascular insufficiency	1 (1.4)	0	1 (1.4)
Gastrointestinal disorders			
-Total	8 (10.8)	7 (9.5)	0

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	3 (4.1)	2 (2.7)	0
Colitis	3 (4.1)	3 (4.1)	0
Stomatitis	3 (4.1)	3 (4.1)	0
Gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	9 (12.2)	3 (4.1)	2 (2.7)
Pyrexia	6 (8.1)	2 (2.7)	0
Multiple organ dysfunction syndrome	2 (2.7)	0	2 (2.7)
Chills	1 (1.4)	0	0
Physical deconditioning	1 (1.4)	1 (1.4)	0
Hepatobiliary disorders			
-Total	2 (2.7)	2 (2.7)	0
Cholecystitis	1 (1.4)	1 (1.4)	0
Hyperbilirubinaemia	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	22 (29.7)	13 (17.6)	7 (9.5)
Device related infection	3 (4.1)	3 (4.1)	0

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella sepsis	2 (2.7)	0	2 (2.7)
Pneumonia	2 (2.7)	0	1 (1.4)
Pneumonia fungal	2 (2.7)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.7)	2 (2.7)	0
Abscess limb	1 (1.4)	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	1 (1.4)	0
Bacteraemia	1 (1.4)	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	1 (1.4)	0
Candida sepsis	1 (1.4)	0	1 (1.4)
Cellulitis	1 (1.4)	1 (1.4)	0
Enterococcal bacteraemia	1 (1.4)	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	1 (1.4)	0
Gastroenteritis	1 (1.4)	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	1 (1.4)	0

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (1.4)	0	0
Sepsis	1 (1.4)	0	1 (1.4)
Serratia infection	1 (1.4)	1 (1.4)	0
Staphylococcal infection	1 (1.4)	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	1 (1.4)	0
Injury, poisoning and procedural complications			
-Total	2 (2.7)	1 (1.4)	0
Subdural haematoma	2 (2.7)	1 (1.4)	0
Extradural haematoma	1 (1.4)	1 (1.4)	0
Investigations			
-Total	3 (4.1)	3 (4.1)	0
Blast cell count increased	1 (1.4)	1 (1.4)	0
Electrocardiogram qt prolonged	1 (1.4)	1 (1.4)	0
Transaminases increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (6.8)	2 (2.7)	1 (1.4)
Hypocalcaemia	2 (2.7)	0	0
Dehydration	1 (1.4)	1 (1.4)	0
Hypernatraemia	1 (1.4)	0	1 (1.4)
Hypophosphataemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders			
-Total	2 (2.7)	2 (2.7)	0
Back pain	1 (1.4)	1 (1.4)	0
Myopathy	1 (1.4)	1 (1.4)	0
Myositis	1 (1.4)	1 (1.4)	0
Nervous system disorders			
-Total	2 (2.7)	2 (2.7)	0
Headache	2 (2.7)	2 (2.7)	0
Psychiatric disorders			
-Total	1 (1.4)	1 (1.4)	0
Mental status changes	1 (1.4)	1 (1.4)	0

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	2 (2.7)	0	1 (1.4)
Acute kidney injury	2 (2.7)	0	1 (1.4)
Reproductive system and breast disorders			
-Total	1 (1.4)	0	0
Scrotal pain	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (9.5)	0	4 (5.4)
Hypoxia	5 (6.8)	2 (2.7)	0
Aspiration	1 (1.4)	0	1 (1.4)
Idiopathic pneumonia syndrome	1 (1.4)	0	1 (1.4)
Pulmonary mass	1 (1.4)	0	0
Pulmonary oedema	1 (1.4)	0	1 (1.4)
Respiratory distress	1 (1.4)	0	1 (1.4)
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	4 (5.4)	2 (2.7)	2 (2.7)

Hypodiploidy: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (5.4)	2 (2.7)	2 (2.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180i
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	1 (25.0)	1 (25.0)
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Colitis	1 (25.0)	1 (25.0)	0
Hepatobiliary disorders			
-Total	1 (25.0)	1 (25.0)	0
Cholecystitis	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	2 (50.0)	2 (50.0)	0
Enterococcal bacteraemia	1 (25.0)	1 (25.0)	0
Gastroenteritis	1 (25.0)	1 (25.0)	0
Streptococcal bacteraemia	1 (25.0)	1 (25.0)	0

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders			
-Total	1 (25.0)	1 (25.0)	0
Dehydration	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	0	1 (25.0)
Idiopathic pneumonia syndrome	1 (25.0)	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180i
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (45.1)	21 (29.6)	9 (12.7)
Blood and lymphatic system disorders			
-Total	12 (16.9)	9 (12.7)	3 (4.2)
Febrile neutropenia	11 (15.5)	11 (15.5)	0
Pancytopenia	2 (2.8)	0	2 (2.8)
Neutropenia	1 (1.4)	0	1 (1.4)
Thrombocytopenia	1 (1.4)	0	1 (1.4)
Cardiac disorders			
-Total	1 (1.4)	0	1 (1.4)
Cardiovascular insufficiency	1 (1.4)	0	1 (1.4)
Gastrointestinal disorders			
-Total	7 (9.9)	6 (8.5)	0

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	3 (4.2)	2 (2.8)	0
Stomatitis	3 (4.2)	3 (4.2)	0
Colitis	2 (2.8)	2 (2.8)	0
Gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	9 (12.7)	3 (4.2)	2 (2.8)
Pyrexia	6 (8.5)	2 (2.8)	0
Multiple organ dysfunction syndrome	2 (2.8)	0	2 (2.8)
Chills	1 (1.4)	0	0
Physical deconditioning	1 (1.4)	1 (1.4)	0
Hepatobiliary disorders			
-Total	1 (1.4)	1 (1.4)	0
Hyperbilirubinaemia	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	20 (28.2)	11 (15.5)	7 (9.9)
Device related infection	3 (4.2)	3 (4.2)	0
Klebsiella sepsis	2 (2.8)	0	2 (2.8)

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (2.8)	0	1 (1.4)
Pneumonia fungal	2 (2.8)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.8)	2 (2.8)	0
Abscess limb	1 (1.4)	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	1 (1.4)	0
Bacteraemia	1 (1.4)	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	1 (1.4)	0
Candida sepsis	1 (1.4)	0	1 (1.4)
Cellulitis	1 (1.4)	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	0
Sepsis	1 (1.4)	0	1 (1.4)
Serratia infection	1 (1.4)	1 (1.4)	0

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (1.4)	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Injury, poisoning and procedural complications			
-Total	2 (2.8)	1 (1.4)	0
Subdural haematoma	2 (2.8)	1 (1.4)	0
Extradural haematoma	1 (1.4)	1 (1.4)	0
Investigations			
-Total	3 (4.2)	3 (4.2)	0
Blast cell count increased	1 (1.4)	1 (1.4)	0
Electrocardiogram qt prolonged	1 (1.4)	1 (1.4)	0
Transaminases increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	4 (5.6)	1 (1.4)	1 (1.4)
Hypocalcaemia	2 (2.8)	0	0
Hypernatraemia	1 (1.4)	0	1 (1.4)
Hypophosphataemia	1 (1.4)	1 (1.4)	0

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malnutrition	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders			
-Total	2 (2.8)	2 (2.8)	0
Back pain	1 (1.4)	1 (1.4)	0
Myopathy	1 (1.4)	1 (1.4)	0
Myositis	1 (1.4)	1 (1.4)	0
Nervous system disorders			
-Total	2 (2.8)	2 (2.8)	0
Headache	2 (2.8)	2 (2.8)	0
Psychiatric disorders			
-Total	1 (1.4)	1 (1.4)	0
Mental status changes	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	2 (2.8)	0	1 (1.4)
Acute kidney injury	2 (2.8)	0	1 (1.4)
Reproductive system and breast disorders			
-Total	1 (1.4)	0	0

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Scrotal pain	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (8.5)	0	3 (4.2)
Hypoxia	5 (7.0)	2 (2.8)	0
Aspiration	1 (1.4)	0	1 (1.4)
Pulmonary mass	1 (1.4)	0	0
Pulmonary oedema	1 (1.4)	0	1 (1.4)
Respiratory distress	1 (1.4)	0	1 (1.4)
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	4 (5.6)	2 (2.8)	2 (2.8)
Hypotension	4 (5.6)	2 (2.8)	2 (2.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180j
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (40.9)	7 (31.8)	2 (9.1)
Blood and lymphatic system disorders			
-Total	4 (18.2)	3 (13.6)	1 (4.5)
Febrile neutropenia	4 (18.2)	4 (18.2)	0
Neutropenia	1 (4.5)	0	1 (4.5)
Thrombocytopenia	1 (4.5)	0	1 (4.5)
Gastrointestinal disorders			
-Total	3 (13.6)	3 (13.6)	0
Stomatitis	2 (9.1)	2 (9.1)	0
Gastrointestinal haemorrhage	1 (4.5)	1 (4.5)	0
General disorders and administration site conditions			
-Total	2 (9.1)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	2 (9.1)	0	0
Chills	1 (4.5)	0	0
Infections and infestations			
-Total	7 (31.8)	4 (18.2)	2 (9.1)
Device related infection	2 (9.1)	2 (9.1)	0
Alpha haemolytic streptococcal infection	1 (4.5)	1 (4.5)	0
Bacteraemia	1 (4.5)	1 (4.5)	0
Candida sepsis	1 (4.5)	0	1 (4.5)
Gastroenteritis	1 (4.5)	1 (4.5)	0
Parainfluenzae virus infection	1 (4.5)	0	0
Pneumonia fungal	1 (4.5)	1 (4.5)	0
Sepsis	1 (4.5)	0	1 (4.5)
Metabolism and nutrition disorders			
-Total	2 (9.1)	1 (4.5)	1 (4.5)
Dehydration	1 (4.5)	1 (4.5)	0
Hypernatraemia	1 (4.5)	0	1 (4.5)
Renal and urinary disorders			
-Total	1 (4.5)	0	1 (4.5)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (4.5)	0	1 (4.5)
Reproductive system and breast disorders			
-Total	1 (4.5)	0	0
Scrotal pain	1 (4.5)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (9.1)	0	1 (4.5)
Hypoxia	1 (4.5)	0	0
Pulmonary oedema	1 (4.5)	0	1 (4.5)
Respiratory failure	1 (4.5)	0	1 (4.5)
Vascular disorders			
-Total	2 (9.1)	1 (4.5)	1 (4.5)
Hypotension	2 (9.1)	1 (4.5)	1 (4.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180j
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (47.2)	15 (28.3)	8 (15.1)
Blood and lymphatic system disorders			
-Total	8 (15.1)	6 (11.3)	2 (3.8)
Febrile neutropenia	7 (13.2)	7 (13.2)	0
Pancytopenia	2 (3.8)	0	2 (3.8)
Cardiac disorders			
-Total	1 (1.9)	0	1 (1.9)
Cardiovascular insufficiency	1 (1.9)	0	1 (1.9)
Gastrointestinal disorders			
-Total	5 (9.4)	4 (7.5)	0
Abdominal pain	3 (5.7)	2 (3.8)	0
Colitis	3 (5.7)	3 (5.7)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	7 (13.2)	3 (5.7)	2 (3.8)
Pyrexia	4 (7.5)	2 (3.8)	0
Multiple organ dysfunction syndrome	2 (3.8)	0	2 (3.8)
Physical deconditioning	1 (1.9)	1 (1.9)	0
Hepatobiliary disorders			
-Total	2 (3.8)	2 (3.8)	0
Cholecystitis	1 (1.9)	1 (1.9)	0
Hyperbilirubinaemia	1 (1.9)	1 (1.9)	0
Infections and infestations			
-Total	15 (28.3)	9 (17.0)	5 (9.4)
Klebsiella sepsis	2 (3.8)	0	2 (3.8)
Pneumonia	2 (3.8)	0	1 (1.9)
Staphylococcal bacteraemia	2 (3.8)	2 (3.8)	0
Abscess limb	1 (1.9)	1 (1.9)	0
Bronchopulmonary aspergillosis	1 (1.9)	1 (1.9)	0
Cellulitis	1 (1.9)	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (1.9)	1 (1.9)	0
Enterococcal bacteraemia	1 (1.9)	1 (1.9)	0
Escherichia bacteraemia	1 (1.9)	1 (1.9)	0
Escherichia sepsis	1 (1.9)	0	1 (1.9)
Escherichia urinary tract infection	1 (1.9)	1 (1.9)	0
Pneumonia fungal	1 (1.9)	0	0
Respiratory syncytial virus bronchitis	1 (1.9)	1 (1.9)	0
Respiratory syncytial virus infection	1 (1.9)	0	0
Serratia infection	1 (1.9)	1 (1.9)	0
Staphylococcal infection	1 (1.9)	1 (1.9)	0
Staphylococcal scalded skin syndrome	1 (1.9)	0	0
Staphylococcal sepsis	1 (1.9)	0	1 (1.9)
Streptococcal bacteraemia	1 (1.9)	1 (1.9)	0
Injury, poisoning and procedural complications			
-Total	2 (3.8)	1 (1.9)	0
Subdural haematoma	2 (3.8)	1 (1.9)	0
Extradural haematoma	1 (1.9)	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	3 (5.7)	3 (5.7)	0
Blast cell count increased	1 (1.9)	1 (1.9)	0
Electrocardiogram qt prolonged	1 (1.9)	1 (1.9)	0
Transaminases increased	1 (1.9)	1 (1.9)	0
Metabolism and nutrition disorders			
-Total	3 (5.7)	1 (1.9)	0
Hypocalcaemia	2 (3.8)	0	0
Hypophosphataemia	1 (1.9)	1 (1.9)	0
Malnutrition	1 (1.9)	0	0
Musculoskeletal and connective tissue disorders			
-Total	2 (3.8)	2 (3.8)	0
Back pain	1 (1.9)	1 (1.9)	0
Myopathy	1 (1.9)	1 (1.9)	0
Myositis	1 (1.9)	1 (1.9)	0
Nervous system disorders			
-Total	2 (3.8)	2 (3.8)	0
Headache	2 (3.8)	2 (3.8)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	1 (1.9)	1 (1.9)	0
Mental status changes	1 (1.9)	1 (1.9)	0
Renal and urinary disorders			
-Total	1 (1.9)	0	0
Acute kidney injury	1 (1.9)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (9.4)	0	3 (5.7)
Hypoxia	4 (7.5)	2 (3.8)	0
Aspiration	1 (1.9)	0	1 (1.9)
Idiopathic pneumonia syndrome	1 (1.9)	0	1 (1.9)
Pulmonary mass	1 (1.9)	0	0
Respiratory distress	1 (1.9)	0	1 (1.9)
Vascular disorders			
-Total	2 (3.8)	1 (1.9)	1 (1.9)
Hypotension	2 (3.8)	1 (1.9)	1 (1.9)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180k
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=75		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (45.3)	22 (29.3)	10 (13.3)
Blood and lymphatic system disorders			
-Total	12 (16.0)	9 (12.0)	3 (4.0)
Febrile neutropenia	11 (14.7)	11 (14.7)	0
Pancytopenia	2 (2.7)	0	2 (2.7)
Neutropenia	1 (1.3)	0	1 (1.3)
Thrombocytopenia	1 (1.3)	0	1 (1.3)
Cardiac disorders			
-Total	1 (1.3)	0	1 (1.3)
Cardiovascular insufficiency	1 (1.3)	0	1 (1.3)
Gastrointestinal disorders			
-Total	8 (10.7)	7 (9.3)	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Abdominal pain	3 (4.0)	2 (2.7)	0
Colitis	3 (4.0)	3 (4.0)	0
Stomatitis	3 (4.0)	3 (4.0)	0
Gastrointestinal haemorrhage	1 (1.3)	1 (1.3)	0
General disorders and administration site conditions			
-Total	9 (12.0)	3 (4.0)	2 (2.7)
Pyrexia	6 (8.0)	2 (2.7)	0
Multiple organ dysfunction syndrome	2 (2.7)	0	2 (2.7)
Chills	1 (1.3)	0	0
Physical deconditioning	1 (1.3)	1 (1.3)	0
Hepatobiliary disorders			
-Total	2 (2.7)	2 (2.7)	0
Cholecystitis	1 (1.3)	1 (1.3)	0
Hyperbilirubinaemia	1 (1.3)	1 (1.3)	0
Infections and infestations			
-Total	22 (29.3)	13 (17.3)	7 (9.3)
Device related infection	3 (4.0)	3 (4.0)	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella sepsis	2 (2.7)	0	2 (2.7)
Pneumonia	2 (2.7)	0	1 (1.3)
Pneumonia fungal	2 (2.7)	1 (1.3)	0
Staphylococcal bacteraemia	2 (2.7)	2 (2.7)	0
Abscess limb	1 (1.3)	1 (1.3)	0
Alpha haemolytic streptococcal infection	1 (1.3)	1 (1.3)	0
Bacteraemia	1 (1.3)	1 (1.3)	0
Bronchopulmonary aspergillosis	1 (1.3)	1 (1.3)	0
Candida sepsis	1 (1.3)	0	1 (1.3)
Cellulitis	1 (1.3)	1 (1.3)	0
Enterococcal bacteraemia	1 (1.3)	1 (1.3)	0
Escherichia bacteraemia	1 (1.3)	1 (1.3)	0
Escherichia sepsis	1 (1.3)	0	1 (1.3)
Escherichia urinary tract infection	1 (1.3)	1 (1.3)	0
Gastroenteritis	1 (1.3)	1 (1.3)	0
Parainfluenzae virus infection	1 (1.3)	0	0
Respiratory syncytial virus bronchitis	1 (1.3)	1 (1.3)	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus infection	1 (1.3)	0	0
Sepsis	1 (1.3)	0	1 (1.3)
Serratia infection	1 (1.3)	1 (1.3)	0
Staphylococcal infection	1 (1.3)	1 (1.3)	0
Staphylococcal scalded skin syndrome	1 (1.3)	0	0
Staphylococcal sepsis	1 (1.3)	0	1 (1.3)
Streptococcal bacteraemia	1 (1.3)	1 (1.3)	0
Injury, poisoning and procedural complications			
-Total	2 (2.7)	1 (1.3)	0
Subdural haematoma	2 (2.7)	1 (1.3)	0
Extradural haematoma	1 (1.3)	1 (1.3)	0
Investigations			
-Total	3 (4.0)	3 (4.0)	0
Blast cell count increased	1 (1.3)	1 (1.3)	0
Electrocardiogram qt prolonged	1 (1.3)	1 (1.3)	0
Transaminases increased	1 (1.3)	1 (1.3)	0
Metabolism and nutrition disorders			

Region: US

	All patients N=75		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (6.7)	2 (2.7)	1 (1.3)
Hypocalcaemia	2 (2.7)	0	0
Dehydration	1 (1.3)	1 (1.3)	0
Hypernatraemia	1 (1.3)	0	1 (1.3)
Hypophosphataemia	1 (1.3)	1 (1.3)	0
Malnutrition	1 (1.3)	0	0
Musculoskeletal and connective tissue disorders			
-Total	2 (2.7)	2 (2.7)	0
Back pain	1 (1.3)	1 (1.3)	0
Myopathy	1 (1.3)	1 (1.3)	0
Myositis	1 (1.3)	1 (1.3)	0
Nervous system disorders			
-Total	2 (2.7)	2 (2.7)	0
Headache	2 (2.7)	2 (2.7)	0
Psychiatric disorders			
-Total	1 (1.3)	1 (1.3)	0
Mental status changes	1 (1.3)	1 (1.3)	0

Region: US

	All patients N=75		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	2 (2.7)	0	1 (1.3)
Acute kidney injury	2 (2.7)	0	1 (1.3)
Reproductive system and breast disorders			
-Total	1 (1.3)	0	0
Scrotal pain	1 (1.3)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (9.3)	0	4 (5.3)
Hypoxia	5 (6.7)	2 (2.7)	0
Aspiration	1 (1.3)	0	1 (1.3)
Idiopathic pneumonia syndrome	1 (1.3)	0	1 (1.3)
Pulmonary mass	1 (1.3)	0	0
Pulmonary oedema	1 (1.3)	0	1 (1.3)
Respiratory distress	1 (1.3)	0	1 (1.3)
Respiratory failure	1 (1.3)	0	1 (1.3)
Vascular disorders			
-Total	4 (5.3)	2 (2.7)	2 (2.7)

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (5.3)	2 (2.7)	2 (2.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180l
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (56.3)	10 (31.3)	6 (18.8)
Blood and lymphatic system disorders			
-Total	5 (15.6)	4 (12.5)	1 (3.1)
Febrile neutropenia	4 (12.5)	4 (12.5)	0
Pancytopenia	1 (3.1)	0	1 (3.1)
Cardiac disorders			
-Total	1 (3.1)	0	1 (3.1)
Cardiovascular insufficiency	1 (3.1)	0	1 (3.1)
Gastrointestinal disorders			
-Total	6 (18.8)	5 (15.6)	0
Colitis	3 (9.4)	3 (9.4)	0
Stomatitis	3 (9.4)	3 (9.4)	0

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	2 (6.3)	1 (3.1)	0
General disorders and administration site conditions			
-Total	6 (18.8)	1 (3.1)	2 (6.3)
Pyrexia	3 (9.4)	0	0
Multiple organ dysfunction syndrome	2 (6.3)	0	2 (6.3)
Chills	1 (3.1)	0	0
Physical deconditioning	1 (3.1)	1 (3.1)	0
Hepatobiliary disorders			
-Total	2 (6.3)	2 (6.3)	0
Cholecystitis	1 (3.1)	1 (3.1)	0
Hyperbilirubinaemia	1 (3.1)	1 (3.1)	0
Infections and infestations			
-Total	11 (34.4)	6 (18.8)	5 (15.6)
Klebsiella sepsis	2 (6.3)	0	2 (6.3)
Staphylococcal bacteraemia	2 (6.3)	2 (6.3)	0
Abscess limb	1 (3.1)	1 (3.1)	0
Bacteraemia	1 (3.1)	1 (3.1)	0

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (3.1)	1 (3.1)	0
Enterococcal bacteraemia	1 (3.1)	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	1 (3.1)	0
Escherichia sepsis	1 (3.1)	0	1 (3.1)
Escherichia urinary tract infection	1 (3.1)	1 (3.1)	0
Pneumonia	1 (3.1)	0	0
Pneumonia fungal	1 (3.1)	0	0
Respiratory syncytial virus bronchitis	1 (3.1)	1 (3.1)	0
Sepsis	1 (3.1)	0	1 (3.1)
Staphylococcal scalded skin syndrome	1 (3.1)	0	0
Staphylococcal sepsis	1 (3.1)	0	1 (3.1)
Streptococcal bacteraemia	1 (3.1)	1 (3.1)	0
Injury, poisoning and procedural complications			
-Total	2 (6.3)	1 (3.1)	0
Subdural haematoma	2 (6.3)	1 (3.1)	0
Extradural haematoma	1 (3.1)	1 (3.1)	0
Investigations			

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (6.3)	2 (6.3)	0
Electrocardiogram qt prolonged	1 (3.1)	1 (3.1)	0
Transaminases increased	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			
-Total	1 (3.1)	0	0
Hypocalcaemia	1 (3.1)	0	0
Musculoskeletal and connective tissue disorders			
-Total	1 (3.1)	1 (3.1)	0
Myopathy	1 (3.1)	1 (3.1)	0
Myositis	1 (3.1)	1 (3.1)	0
Nervous system disorders			
-Total	1 (3.1)	1 (3.1)	0
Headache	1 (3.1)	1 (3.1)	0
Psychiatric disorders			
-Total	1 (3.1)	1 (3.1)	0
Mental status changes	1 (3.1)	1 (3.1)	0
Renal and urinary disorders			

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.1)	0	0
Acute kidney injury	1 (3.1)	0	0
Reproductive system and breast disorders			
-Total	1 (3.1)	0	0
Scrotal pain	1 (3.1)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (9.4)	0	1 (3.1)
Hypoxia	2 (6.3)	0	0
Idiopathic pneumonia syndrome	1 (3.1)	0	1 (3.1)
Pulmonary mass	1 (3.1)	0	0
Vascular disorders			
-Total	2 (6.3)	2 (6.3)	0
Hypotension	2 (6.3)	2 (6.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180l
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (37.2)	12 (27.9)	4 (9.3)
Blood and lymphatic system disorders			
-Total	7 (16.3)	5 (11.6)	2 (4.7)
Febrile neutropenia	7 (16.3)	7 (16.3)	0
Neutropenia	1 (2.3)	0	1 (2.3)
Pancytopenia	1 (2.3)	0	1 (2.3)
Thrombocytopenia	1 (2.3)	0	1 (2.3)
Gastrointestinal disorders			
-Total	2 (4.7)	2 (4.7)	0
Abdominal pain	1 (2.3)	1 (2.3)	0
Gastrointestinal haemorrhage	1 (2.3)	1 (2.3)	0

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	3 (7.0)	2 (4.7)	0
Pyrexia	3 (7.0)	2 (4.7)	0
Infections and infestations			
-Total	11 (25.6)	7 (16.3)	2 (4.7)
Device related infection	2 (4.7)	2 (4.7)	0
Alpha haemolytic streptococcal infection	1 (2.3)	1 (2.3)	0
Bronchopulmonary aspergillosis	1 (2.3)	1 (2.3)	0
Candida sepsis	1 (2.3)	0	1 (2.3)
Cellulitis	1 (2.3)	1 (2.3)	0
Gastroenteritis	1 (2.3)	1 (2.3)	0
Parainfluenzae virus infection	1 (2.3)	0	0
Pneumonia	1 (2.3)	0	1 (2.3)
Pneumonia fungal	1 (2.3)	1 (2.3)	0
Respiratory syncytial virus infection	1 (2.3)	0	0
Serratia infection	1 (2.3)	1 (2.3)	0
Staphylococcal infection	1 (2.3)	1 (2.3)	0

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	1 (2.3)	1 (2.3)	0
Blast cell count increased	1 (2.3)	1 (2.3)	0
Metabolism and nutrition disorders			
-Total	4 (9.3)	2 (4.7)	1 (2.3)
Dehydration	1 (2.3)	1 (2.3)	0
Hypernatraemia	1 (2.3)	0	1 (2.3)
Hypocalcaemia	1 (2.3)	0	0
Hypophosphataemia	1 (2.3)	1 (2.3)	0
Malnutrition	1 (2.3)	0	0
Musculoskeletal and connective tissue disorders			
-Total	1 (2.3)	1 (2.3)	0
Back pain	1 (2.3)	1 (2.3)	0
Nervous system disorders			
-Total	1 (2.3)	1 (2.3)	0
Headache	1 (2.3)	1 (2.3)	0
Renal and urinary disorders			

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.3)	0	1 (2.3)
Acute kidney injury	1 (2.3)	0	1 (2.3)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (9.3)	0	3 (7.0)
Hypoxia	3 (7.0)	2 (4.7)	0
Aspiration	1 (2.3)	0	1 (2.3)
Pulmonary oedema	1 (2.3)	0	1 (2.3)
Respiratory distress	1 (2.3)	0	1 (2.3)
Respiratory failure	1 (2.3)	0	1 (2.3)
Vascular disorders			
-Total	2 (4.7)	0	2 (4.7)
Hypotension	2 (4.7)	0	2 (4.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180m
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (44.4)	7 (38.9)	1 (5.6)
Blood and lymphatic system disorders			
-Total	3 (16.7)	3 (16.7)	0
Febrile neutropenia	3 (16.7)	3 (16.7)	0
Gastrointestinal disorders			
-Total	1 (5.6)	1 (5.6)	0
Stomatitis	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	2 (11.1)	2 (11.1)	0
Pyrexia	2 (11.1)	2 (11.1)	0
Infections and infestations			

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (27.8)	4 (22.2)	1 (5.6)
Device related infection	2 (11.1)	2 (11.1)	0
Alpha haemolytic streptococcal infection	1 (5.6)	1 (5.6)	0
Bronchopulmonary aspergillosis	1 (5.6)	1 (5.6)	0
Escherichia urinary tract infection	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Investigations			
-Total	1 (5.6)	1 (5.6)	0
Blast cell count increased	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	2 (11.1)	1 (5.6)	0
Hypocalcaemia	1 (5.6)	0	0
Hypophosphataemia	1 (5.6)	1 (5.6)	0
Malnutrition	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (16.7)	0	1 (5.6)
Hypoxia	3 (16.7)	1 (5.6)	0

Eligibility for SCT: Yes

Group term Preferred term	All patients N=18 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspiration	1 (5.6)	0	1 (5.6)
Vascular disorders			
-Total	1 (5.6)	0	1 (5.6)
Hypotension	1 (5.6)	0	1 (5.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180m
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (45.6)	15 (26.3)	9 (15.8)
Blood and lymphatic system disorders			
-Total	9 (15.8)	6 (10.5)	3 (5.3)
Febrile neutropenia	8 (14.0)	8 (14.0)	0
Pancytopenia	2 (3.5)	0	2 (3.5)
Neutropenia	1 (1.8)	0	1 (1.8)
Thrombocytopenia	1 (1.8)	0	1 (1.8)
Cardiac disorders			
-Total	1 (1.8)	0	1 (1.8)
Cardiovascular insufficiency	1 (1.8)	0	1 (1.8)
Gastrointestinal disorders			
-Total	7 (12.3)	6 (10.5)	0

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	3 (5.3)	2 (3.5)	0
Colitis	3 (5.3)	3 (5.3)	0
Stomatitis	2 (3.5)	2 (3.5)	0
Gastrointestinal haemorrhage	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions			
-Total	7 (12.3)	1 (1.8)	2 (3.5)
Pyrexia	4 (7.0)	0	0
Multiple organ dysfunction syndrome	2 (3.5)	0	2 (3.5)
Chills	1 (1.8)	0	0
Physical deconditioning	1 (1.8)	1 (1.8)	0
Hepatobiliary disorders			
-Total	2 (3.5)	2 (3.5)	0
Cholecystitis	1 (1.8)	1 (1.8)	0
Hyperbilirubinaemia	1 (1.8)	1 (1.8)	0
Infections and infestations			
-Total	17 (29.8)	9 (15.8)	6 (10.5)
Klebsiella sepsis	2 (3.5)	0	2 (3.5)

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	2 (3.5)	1 (1.8)	0
Staphylococcal bacteraemia	2 (3.5)	2 (3.5)	0
Abscess limb	1 (1.8)	1 (1.8)	0
Bacteraemia	1 (1.8)	1 (1.8)	0
Candida sepsis	1 (1.8)	0	1 (1.8)
Cellulitis	1 (1.8)	1 (1.8)	0
Device related infection	1 (1.8)	1 (1.8)	0
Enterococcal bacteraemia	1 (1.8)	1 (1.8)	0
Escherichia bacteraemia	1 (1.8)	1 (1.8)	0
Escherichia sepsis	1 (1.8)	0	1 (1.8)
Gastroenteritis	1 (1.8)	1 (1.8)	0
Parainfluenzae virus infection	1 (1.8)	0	0
Pneumonia	1 (1.8)	0	0
Respiratory syncytial virus bronchitis	1 (1.8)	1 (1.8)	0
Respiratory syncytial virus infection	1 (1.8)	0	0
Sepsis	1 (1.8)	0	1 (1.8)
Serratia infection	1 (1.8)	1 (1.8)	0
Staphylococcal infection	1 (1.8)	1 (1.8)	0

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal scalded skin syndrome	1 (1.8)	0	0
Staphylococcal sepsis	1 (1.8)	0	1 (1.8)
Streptococcal bacteraemia	1 (1.8)	1 (1.8)	0
Injury, poisoning and procedural complications			
-Total	2 (3.5)	1 (1.8)	0
Subdural haematoma	2 (3.5)	1 (1.8)	0
Extradural haematoma	1 (1.8)	1 (1.8)	0
Investigations			
-Total	2 (3.5)	2 (3.5)	0
Electrocardiogram qt prolonged	1 (1.8)	1 (1.8)	0
Transaminases increased	1 (1.8)	1 (1.8)	0
Metabolism and nutrition disorders			
-Total	3 (5.3)	1 (1.8)	1 (1.8)
Dehydration	1 (1.8)	1 (1.8)	0
Hypernatraemia	1 (1.8)	0	1 (1.8)
Hypocalcaemia	1 (1.8)	0	0

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	2 (3.5)	2 (3.5)	0
Back pain	1 (1.8)	1 (1.8)	0
Myopathy	1 (1.8)	1 (1.8)	0
Myositis	1 (1.8)	1 (1.8)	0
Nervous system disorders			
-Total	2 (3.5)	2 (3.5)	0
Headache	2 (3.5)	2 (3.5)	0
Psychiatric disorders			
-Total	1 (1.8)	1 (1.8)	0
Mental status changes	1 (1.8)	1 (1.8)	0
Renal and urinary disorders			
-Total	2 (3.5)	0	1 (1.8)
Acute kidney injury	2 (3.5)	0	1 (1.8)
Reproductive system and breast disorders			
-Total	1 (1.8)	0	0
Scrotal pain	1 (1.8)	0	0

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	4 (7.0)	0	3 (5.3)
Hypoxia	2 (3.5)	1 (1.8)	0
Idiopathic pneumonia syndrome	1 (1.8)	0	1 (1.8)
Pulmonary mass	1 (1.8)	0	0
Pulmonary oedema	1 (1.8)	0	1 (1.8)
Respiratory distress	1 (1.8)	0	1 (1.8)
Respiratory failure	1 (1.8)	0	1 (1.8)
Vascular disorders			
-Total	3 (5.3)	2 (3.5)	1 (1.8)
Hypotension	3 (5.3)	2 (3.5)	1 (1.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of

all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180n
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (27.3)	4 (18.2)	1 (4.5)
Blood and lymphatic system disorders			
-Total	2 (9.1)	2 (9.1)	0
Febrile neutropenia	2 (9.1)	2 (9.1)	0
Gastrointestinal disorders			
-Total	3 (13.6)	2 (9.1)	0
Abdominal pain	2 (9.1)	1 (4.5)	0
Stomatitis	2 (9.1)	2 (9.1)	0
Colitis	1 (4.5)	1 (4.5)	0
General disorders and administration site conditions			
-Total	1 (4.5)	0	0
Pyrexia	1 (4.5)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	2 (9.1)	2 (9.1)	0
Gastroenteritis	1 (4.5)	1 (4.5)	0
Staphylococcal bacteraemia	1 (4.5)	1 (4.5)	0
Metabolism and nutrition disorders			
-Total	1 (4.5)	1 (4.5)	0
Dehydration	1 (4.5)	1 (4.5)	0
Nervous system disorders			
-Total	1 (4.5)	1 (4.5)	0
Headache	1 (4.5)	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (9.1)	0	1 (4.5)
Hypoxia	2 (9.1)	1 (4.5)	0
Respiratory distress	1 (4.5)	0	1 (4.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180n
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (52.8)	18 (34.0)	9 (17.0)
Blood and lymphatic system disorders			
-Total	10 (18.9)	7 (13.2)	3 (5.7)
Febrile neutropenia	9 (17.0)	9 (17.0)	0
Pancytopenia	2 (3.8)	0	2 (3.8)
Neutropenia	1 (1.9)	0	1 (1.9)
Thrombocytopenia	1 (1.9)	0	1 (1.9)
Cardiac disorders			
-Total	1 (1.9)	0	1 (1.9)
Cardiovascular insufficiency	1 (1.9)	0	1 (1.9)
Gastrointestinal disorders			
-Total	5 (9.4)	5 (9.4)	0

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	2 (3.8)	2 (3.8)	0
Abdominal pain	1 (1.9)	1 (1.9)	0
Gastrointestinal haemorrhage	1 (1.9)	1 (1.9)	0
Stomatitis	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	8 (15.1)	3 (5.7)	2 (3.8)
Pyrexia	5 (9.4)	2 (3.8)	0
Multiple organ dysfunction syndrome	2 (3.8)	0	2 (3.8)
Chills	1 (1.9)	0	0
Physical deconditioning	1 (1.9)	1 (1.9)	0
Hepatobiliary disorders			
-Total	2 (3.8)	2 (3.8)	0
Cholecystitis	1 (1.9)	1 (1.9)	0
Hyperbilirubinaemia	1 (1.9)	1 (1.9)	0
Infections and infestations			
-Total	20 (37.7)	11 (20.8)	7 (13.2)
Device related infection	3 (5.7)	3 (5.7)	0
Klebsiella sepsis	2 (3.8)	0	2 (3.8)

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (3.8)	0	1 (1.9)
Pneumonia fungal	2 (3.8)	1 (1.9)	0
Abscess limb	1 (1.9)	1 (1.9)	0
Alpha haemolytic streptococcal infection	1 (1.9)	1 (1.9)	0
Bacteraemia	1 (1.9)	1 (1.9)	0
Bronchopulmonary aspergillosis	1 (1.9)	1 (1.9)	0
Candida sepsis	1 (1.9)	0	1 (1.9)
Cellulitis	1 (1.9)	1 (1.9)	0
Enterococcal bacteraemia	1 (1.9)	1 (1.9)	0
Escherichia bacteraemia	1 (1.9)	1 (1.9)	0
Escherichia sepsis	1 (1.9)	0	1 (1.9)
Escherichia urinary tract infection	1 (1.9)	1 (1.9)	0
Parainfluenzae virus infection	1 (1.9)	0	0
Respiratory syncytial virus bronchitis	1 (1.9)	1 (1.9)	0
Respiratory syncytial virus infection	1 (1.9)	0	0
Sepsis	1 (1.9)	0	1 (1.9)
Serratia infection	1 (1.9)	1 (1.9)	0
Staphylococcal bacteraemia	1 (1.9)	1 (1.9)	0

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (1.9)	1 (1.9)	0
Staphylococcal scalded skin syndrome	1 (1.9)	0	0
Staphylococcal sepsis	1 (1.9)	0	1 (1.9)
Streptococcal bacteraemia	1 (1.9)	1 (1.9)	0
Injury, poisoning and procedural complications			
-Total	2 (3.8)	1 (1.9)	0
Subdural haematoma	2 (3.8)	1 (1.9)	0
Extradural haematoma	1 (1.9)	1 (1.9)	0
Investigations			
-Total	3 (5.7)	3 (5.7)	0
Blast cell count increased	1 (1.9)	1 (1.9)	0
Electrocardiogram qt prolonged	1 (1.9)	1 (1.9)	0
Transaminases increased	1 (1.9)	1 (1.9)	0
Metabolism and nutrition disorders			
-Total	4 (7.5)	1 (1.9)	1 (1.9)
Hypocalcaemia	2 (3.8)	0	0
Hypernatraemia	1 (1.9)	0	1 (1.9)

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	1 (1.9)	1 (1.9)	0
Malnutrition	1 (1.9)	0	0
Musculoskeletal and connective tissue disorders			
-Total	2 (3.8)	2 (3.8)	0
Back pain	1 (1.9)	1 (1.9)	0
Myopathy	1 (1.9)	1 (1.9)	0
Myositis	1 (1.9)	1 (1.9)	0
Nervous system disorders			
-Total	1 (1.9)	1 (1.9)	0
Headache	1 (1.9)	1 (1.9)	0
Psychiatric disorders			
-Total	1 (1.9)	1 (1.9)	0
Mental status changes	1 (1.9)	1 (1.9)	0
Renal and urinary disorders			
-Total	2 (3.8)	0	1 (1.9)
Acute kidney injury	2 (3.8)	0	1 (1.9)
Reproductive system and breast disorders			

Baseline bone marrow tumor burden: High

Group term Preferred term	All patients N=53 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	1 (1.9)	0	0
Scrotal pain	1 (1.9)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (9.4)	0	3 (5.7)
Hypoxia	3 (5.7)	1 (1.9)	0
Aspiration	1 (1.9)	0	1 (1.9)
Idiopathic pneumonia syndrome	1 (1.9)	0	1 (1.9)
Pulmonary mass	1 (1.9)	0	0
Pulmonary oedema	1 (1.9)	0	1 (1.9)
Respiratory failure	1 (1.9)	0	1 (1.9)
Vascular disorders			
-Total	4 (7.5)	2 (3.8)	2 (3.8)
Hypotension	4 (7.5)	2 (3.8)	2 (3.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180o
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (28.6)	2 (28.6)	0
Blood and lymphatic system disorders			
-Total	1 (14.3)	1 (14.3)	0
Febrile neutropenia	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	1 (14.3)	1 (14.3)	0
Device related infection	1 (14.3)	1 (14.3)	0
Injury, poisoning and procedural complications			
-Total	1 (14.3)	1 (14.3)	0
Extradural haematoma	1 (14.3)	1 (14.3)	0
Subdural haematoma	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=7 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	1 (14.3)	0	0
Malnutrition	1 (14.3)	0	0
Nervous system disorders			
-Total	1 (14.3)	1 (14.3)	0
Headache	1 (14.3)	1 (14.3)	0
Psychiatric disorders			
-Total	1 (14.3)	1 (14.3)	0
Mental status changes	1 (14.3)	1 (14.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180o
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (47.1)	20 (29.4)	10 (14.7)
Blood and lymphatic system disorders			
-Total	11 (16.2)	8 (11.8)	3 (4.4)
Febrile neutropenia	10 (14.7)	10 (14.7)	0
Pancytopenia	2 (2.9)	0	2 (2.9)
Neutropenia	1 (1.5)	0	1 (1.5)
Thrombocytopenia	1 (1.5)	0	1 (1.5)
Cardiac disorders			
-Total	1 (1.5)	0	1 (1.5)
Cardiovascular insufficiency	1 (1.5)	0	1 (1.5)
Gastrointestinal disorders			
-Total	8 (11.8)	7 (10.3)	0

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	3 (4.4)	2 (2.9)	0
Colitis	3 (4.4)	3 (4.4)	0
Stomatitis	3 (4.4)	3 (4.4)	0
Gastrointestinal haemorrhage	1 (1.5)	1 (1.5)	0
General disorders and administration site conditions			
-Total	9 (13.2)	3 (4.4)	2 (2.9)
Pyrexia	6 (8.8)	2 (2.9)	0
Multiple organ dysfunction syndrome	2 (2.9)	0	2 (2.9)
Chills	1 (1.5)	0	0
Physical deconditioning	1 (1.5)	1 (1.5)	0
Hepatobiliary disorders			
-Total	2 (2.9)	2 (2.9)	0
Cholecystitis	1 (1.5)	1 (1.5)	0
Hyperbilirubinaemia	1 (1.5)	1 (1.5)	0
Infections and infestations			
-Total	21 (30.9)	12 (17.6)	7 (10.3)
Device related infection	2 (2.9)	2 (2.9)	0
Klebsiella sepsis	2 (2.9)	0	2 (2.9)

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	2 (2.9)	0	1 (1.5)
Pneumonia fungal	2 (2.9)	1 (1.5)	0
Staphylococcal bacteraemia	2 (2.9)	2 (2.9)	0
Abscess limb	1 (1.5)	1 (1.5)	0
Alpha haemolytic streptococcal infection	1 (1.5)	1 (1.5)	0
Bacteraemia	1 (1.5)	1 (1.5)	0
Bronchopulmonary aspergillosis	1 (1.5)	1 (1.5)	0
Candida sepsis	1 (1.5)	0	1 (1.5)
Cellulitis	1 (1.5)	1 (1.5)	0
Enterococcal bacteraemia	1 (1.5)	1 (1.5)	0
Escherichia bacteraemia	1 (1.5)	1 (1.5)	0
Escherichia sepsis	1 (1.5)	0	1 (1.5)
Escherichia urinary tract infection	1 (1.5)	1 (1.5)	0
Gastroenteritis	1 (1.5)	1 (1.5)	0
Parainfluenzae virus infection	1 (1.5)	0	0
Respiratory syncytial virus bronchitis	1 (1.5)	1 (1.5)	0
Respiratory syncytial virus infection	1 (1.5)	0	0
Sepsis	1 (1.5)	0	1 (1.5)

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serratia infection	1 (1.5)	1 (1.5)	0
Staphylococcal infection	1 (1.5)	1 (1.5)	0
Staphylococcal scalded skin syndrome	1 (1.5)	0	0
Staphylococcal sepsis	1 (1.5)	0	1 (1.5)
Streptococcal bacteraemia	1 (1.5)	1 (1.5)	0
Injury, poisoning and procedural complications			
-Total	1 (1.5)	0	0
Subdural haematoma	1 (1.5)	0	0
Investigations			
-Total	3 (4.4)	3 (4.4)	0
Blast cell count increased	1 (1.5)	1 (1.5)	0
Electrocardiogram qt prolonged	1 (1.5)	1 (1.5)	0
Transaminases increased	1 (1.5)	1 (1.5)	0
Metabolism and nutrition disorders			
-Total	4 (5.9)	2 (2.9)	1 (1.5)
Hypocalcaemia	2 (2.9)	0	0
Dehydration	1 (1.5)	1 (1.5)	0

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	1 (1.5)	0	1 (1.5)
Hypophosphataemia	1 (1.5)	1 (1.5)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (2.9)	2 (2.9)	0
Back pain	1 (1.5)	1 (1.5)	0
Myopathy	1 (1.5)	1 (1.5)	0
Myositis	1 (1.5)	1 (1.5)	0
Nervous system disorders			
-Total	1 (1.5)	1 (1.5)	0
Headache	1 (1.5)	1 (1.5)	0
Renal and urinary disorders			
-Total	2 (2.9)	0	1 (1.5)
Acute kidney injury	2 (2.9)	0	1 (1.5)
Reproductive system and breast disorders			
-Total	1 (1.5)	0	0
Scrotal pain	1 (1.5)	0	0
Respiratory, thoracic and mediastinal disorders			

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=68 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	7 (10.3)	0	4 (5.9)
Hypoxia	5 (7.4)	2 (2.9)	0
Aspiration	1 (1.5)	0	1 (1.5)
Idiopathic pneumonia syndrome	1 (1.5)	0	1 (1.5)
Pulmonary mass	1 (1.5)	0	0
Pulmonary oedema	1 (1.5)	0	1 (1.5)
Respiratory distress	1 (1.5)	0	1 (1.5)
Respiratory failure	1 (1.5)	0	1 (1.5)
Vascular disorders			
-Total	4 (5.9)	2 (2.9)	2 (2.9)
Hypotension	4 (5.9)	2 (2.9)	2 (2.9)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180p
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (25.0)	1 (25.0)	0
Blood and lymphatic system disorders			
-Total	1 (25.0)	1 (25.0)	0
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Stomatitis	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180p
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (46.5)	21 (29.6)	10 (14.1)
Blood and lymphatic system disorders			
-Total	11 (15.5)	8 (11.3)	3 (4.2)
Febrile neutropenia	10 (14.1)	10 (14.1)	0
Pancytopenia	2 (2.8)	0	2 (2.8)
Neutropenia	1 (1.4)	0	1 (1.4)
Thrombocytopenia	1 (1.4)	0	1 (1.4)
Cardiac disorders			
-Total	1 (1.4)	0	1 (1.4)
Cardiovascular insufficiency	1 (1.4)	0	1 (1.4)
Gastrointestinal disorders			
-Total	7 (9.9)	6 (8.5)	0

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	3 (4.2)	2 (2.8)	0
Colitis	3 (4.2)	3 (4.2)	0
Stomatitis	2 (2.8)	2 (2.8)	0
Gastrointestinal haemorrhage	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	9 (12.7)	3 (4.2)	2 (2.8)
Pyrexia	6 (8.5)	2 (2.8)	0
Multiple organ dysfunction syndrome	2 (2.8)	0	2 (2.8)
Chills	1 (1.4)	0	0
Physical deconditioning	1 (1.4)	1 (1.4)	0
Hepatobiliary disorders			
-Total	2 (2.8)	2 (2.8)	0
Cholecystitis	1 (1.4)	1 (1.4)	0
Hyperbilirubinaemia	1 (1.4)	1 (1.4)	0
Infections and infestations			
-Total	22 (31.0)	13 (18.3)	7 (9.9)
Device related infection	3 (4.2)	3 (4.2)	0

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella sepsis	2 (2.8)	0	2 (2.8)
Pneumonia	2 (2.8)	0	1 (1.4)
Pneumonia fungal	2 (2.8)	1 (1.4)	0
Staphylococcal bacteraemia	2 (2.8)	2 (2.8)	0
Abscess limb	1 (1.4)	1 (1.4)	0
Alpha haemolytic streptococcal infection	1 (1.4)	1 (1.4)	0
Bacteraemia	1 (1.4)	1 (1.4)	0
Bronchopulmonary aspergillosis	1 (1.4)	1 (1.4)	0
Candida sepsis	1 (1.4)	0	1 (1.4)
Cellulitis	1 (1.4)	1 (1.4)	0
Enterococcal bacteraemia	1 (1.4)	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	1 (1.4)	0
Gastroenteritis	1 (1.4)	1 (1.4)	0
Parainfluenzae virus infection	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	1 (1.4)	0

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (1.4)	0	0
Sepsis	1 (1.4)	0	1 (1.4)
Serratia infection	1 (1.4)	1 (1.4)	0
Staphylococcal infection	1 (1.4)	1 (1.4)	0
Staphylococcal scalded skin syndrome	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	1 (1.4)	0
Injury, poisoning and procedural complications			
-Total	2 (2.8)	1 (1.4)	0
Subdural haematoma	2 (2.8)	1 (1.4)	0
Extradural haematoma	1 (1.4)	1 (1.4)	0
Investigations			
-Total	3 (4.2)	3 (4.2)	0
Blast cell count increased	1 (1.4)	1 (1.4)	0
Electrocardiogram qt prolonged	1 (1.4)	1 (1.4)	0
Transaminases increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (7.0)	2 (2.8)	1 (1.4)
Hypocalcaemia	2 (2.8)	0	0
Dehydration	1 (1.4)	1 (1.4)	0
Hypernatraemia	1 (1.4)	0	1 (1.4)
Hypophosphataemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders			
-Total	2 (2.8)	2 (2.8)	0
Back pain	1 (1.4)	1 (1.4)	0
Myopathy	1 (1.4)	1 (1.4)	0
Myositis	1 (1.4)	1 (1.4)	0
Nervous system disorders			
-Total	2 (2.8)	2 (2.8)	0
Headache	2 (2.8)	2 (2.8)	0
Psychiatric disorders			
-Total	1 (1.4)	1 (1.4)	0
Mental status changes	1 (1.4)	1 (1.4)	0

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	2 (2.8)	0	1 (1.4)
Acute kidney injury	2 (2.8)	0	1 (1.4)
Reproductive system and breast disorders			
-Total	1 (1.4)	0	0
Scrotal pain	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (8.5)	0	4 (5.6)
Hypoxia	4 (5.6)	2 (2.8)	0
Aspiration	1 (1.4)	0	1 (1.4)
Idiopathic pneumonia syndrome	1 (1.4)	0	1 (1.4)
Pulmonary mass	1 (1.4)	0	0
Pulmonary oedema	1 (1.4)	0	1 (1.4)
Respiratory distress	1 (1.4)	0	1 (1.4)
Respiratory failure	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	4 (5.6)	2 (2.8)	2 (2.8)

Down syndrome: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	4 (5.6)	2 (2.8)	2 (2.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180q
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (46.9)	12 (37.5)	2 (6.3)
Blood and lymphatic system disorders			
-Total	6 (18.8)	5 (15.6)	1 (3.1)
Febrile neutropenia	5 (15.6)	5 (15.6)	0
Pancytopenia	1 (3.1)	0	1 (3.1)
Gastrointestinal disorders			
-Total	3 (9.4)	3 (9.4)	0
Stomatitis	2 (6.3)	2 (6.3)	0
Colitis	1 (3.1)	1 (3.1)	0
General disorders and administration site conditions			
-Total	3 (9.4)	2 (6.3)	0
Pyrexia	2 (6.3)	1 (3.1)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Physical deconditioning	1 (3.1)	1 (3.1)	0
Hepatobiliary disorders			
-Total	2 (6.3)	2 (6.3)	0
Cholecystitis	1 (3.1)	1 (3.1)	0
Hyperbilirubinaemia	1 (3.1)	1 (3.1)	0
Infections and infestations			
-Total	9 (28.1)	6 (18.8)	1 (3.1)
Device related infection	3 (9.4)	3 (9.4)	0
Abscess limb	1 (3.1)	1 (3.1)	0
Alpha haemolytic streptococcal infection	1 (3.1)	1 (3.1)	0
Enterococcal bacteraemia	1 (3.1)	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	1 (3.1)	0
Escherichia urinary tract infection	1 (3.1)	1 (3.1)	0
Parainfluenzae virus infection	1 (3.1)	0	0
Pneumonia	1 (3.1)	0	0
Pneumonia fungal	1 (3.1)	0	0
Respiratory syncytial virus bronchitis	1 (3.1)	1 (3.1)	0
Respiratory syncytial virus infection	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (3.1)	1 (3.1)	0
Staphylococcal scalded skin syndrome	1 (3.1)	0	0
Staphylococcal sepsis	1 (3.1)	0	1 (3.1)
Streptococcal bacteraemia	1 (3.1)	1 (3.1)	0
Injury, poisoning and procedural complications			
-Total	1 (3.1)	1 (3.1)	0
Extradural haematoma	1 (3.1)	1 (3.1)	0
Subdural haematoma	1 (3.1)	1 (3.1)	0
Investigations			
-Total	2 (6.3)	2 (6.3)	0
Electrocardiogram qt prolonged	1 (3.1)	1 (3.1)	0
Transaminases increased	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			
-Total	2 (6.3)	0	0
Hypocalcaemia	1 (3.1)	0	0
Malnutrition	1 (3.1)	0	0
Musculoskeletal and connective tissue disorders			

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.1)	1 (3.1)	0
Myopathy	1 (3.1)	1 (3.1)	0
Myositis	1 (3.1)	1 (3.1)	0
Nervous system disorders			
-Total	1 (3.1)	1 (3.1)	0
Headache	1 (3.1)	1 (3.1)	0
Psychiatric disorders			
-Total	1 (3.1)	1 (3.1)	0
Mental status changes	1 (3.1)	1 (3.1)	0
Renal and urinary disorders			
-Total	1 (3.1)	0	0
Acute kidney injury	1 (3.1)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (9.4)	0	1 (3.1)
Hypoxia	2 (6.3)	0	0
Idiopathic pneumonia syndrome	1 (3.1)	0	1 (3.1)
Pulmonary mass	1 (3.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180q
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (37.5)	9 (28.1)	2 (6.3)
Blood and lymphatic system disorders			
-Total	5 (15.6)	4 (12.5)	1 (3.1)
Febrile neutropenia	5 (15.6)	5 (15.6)	0
Pancytopenia	1 (3.1)	0	1 (3.1)
Gastrointestinal disorders			
-Total	2 (6.3)	1 (3.1)	0
Abdominal pain	2 (6.3)	1 (3.1)	0
General disorders and administration site conditions			
-Total	2 (6.3)	0	0
Pyrexia	2 (6.3)	0	0
Infections and infestations			

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (21.9)	6 (18.8)	1 (3.1)
Bacteraemia	1 (3.1)	1 (3.1)	0
Bronchopulmonary aspergillosis	1 (3.1)	1 (3.1)	0
Cellulitis	1 (3.1)	1 (3.1)	0
Escherichia sepsis	1 (3.1)	0	1 (3.1)
Gastroenteritis	1 (3.1)	1 (3.1)	0
Serratia infection	1 (3.1)	1 (3.1)	0
Staphylococcal infection	1 (3.1)	1 (3.1)	0
Injury, poisoning and procedural complications			
-Total	1 (3.1)	0	0
Subdural haematoma	1 (3.1)	0	0
Investigations			
-Total	1 (3.1)	1 (3.1)	0
Blast cell count increased	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			
-Total	2 (6.3)	2 (6.3)	0
Dehydration	1 (3.1)	1 (3.1)	0
Hypocalcaemia	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	1 (3.1)	1 (3.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (3.1)	1 (3.1)	0
Back pain	1 (3.1)	1 (3.1)	0
Reproductive system and breast disorders			
-Total	1 (3.1)	0	0
Scrotal pain	1 (3.1)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.1)	0	0
Hypoxia	1 (3.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180q
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (63.6)	1 (9.1)	6 (54.5)
Blood and lymphatic system disorders			
-Total	1 (9.1)	0	1 (9.1)
Febrile neutropenia	1 (9.1)	1 (9.1)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
-Total	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	3 (27.3)	3 (27.3)	0
Colitis	2 (18.2)	2 (18.2)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	4 (36.4)	1 (9.1)	2 (18.2)
Multiple organ dysfunction syndrome	2 (18.2)	0	2 (18.2)
Pyrexia	2 (18.2)	1 (9.1)	0
Chills	1 (9.1)	0	0
Infections and infestations			
-Total	6 (54.5)	1 (9.1)	5 (45.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Candida sepsis	1 (9.1)	0	1 (9.1)
Pneumonia	1 (9.1)	0	1 (9.1)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Metabolism and nutrition disorders			
-Total	1 (9.1)	0	1 (9.1)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (27.3)	0	3 (27.3)
Hypoxia	2 (18.2)	2 (18.2)	0
Aspiration	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
-Total	4 (36.4)	2 (18.2)	2 (18.2)
Hypotension	4 (36.4)	2 (18.2)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180r
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (37.5)	2 (25.0)	1 (12.5)
Blood and lymphatic system disorders			
-Total	1 (12.5)	1 (12.5)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Infections and infestations			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Cellulitis	1 (12.5)	1 (12.5)	0
Pneumonia	1 (12.5)	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Aspiration	1 (12.5)	0	1 (12.5)
Hypoxia	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypotension	1 (12.5)	0	1 (12.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180r
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (52.2)	9 (39.1)	3 (13.0)
Blood and lymphatic system disorders			
-Total	5 (21.7)	3 (13.0)	2 (8.7)
Febrile neutropenia	4 (17.4)	4 (17.4)	0
Pancytopenia	2 (8.7)	0	2 (8.7)
Gastrointestinal disorders			
-Total	2 (8.7)	2 (8.7)	0
Abdominal pain	1 (4.3)	1 (4.3)	0
Stomatitis	1 (4.3)	1 (4.3)	0
General disorders and administration site conditions			
-Total	2 (8.7)	1 (4.3)	0

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Physical deconditioning	1 (4.3)	1 (4.3)	0
Pyrexia	1 (4.3)	0	0
Hepatobiliary disorders			
-Total	1 (4.3)	1 (4.3)	0
Hyperbilirubinaemia	1 (4.3)	1 (4.3)	0
Infections and infestations			
-Total	10 (43.5)	7 (30.4)	1 (4.3)
Device related infection	2 (8.7)	2 (8.7)	0
Abscess limb	1 (4.3)	1 (4.3)	0
Bronchopulmonary aspergillosis	1 (4.3)	1 (4.3)	0
Escherichia bacteraemia	1 (4.3)	1 (4.3)	0
Escherichia urinary tract infection	1 (4.3)	1 (4.3)	0
Gastroenteritis	1 (4.3)	1 (4.3)	0
Parainfluenzae virus infection	1 (4.3)	0	0
Pneumonia	1 (4.3)	0	0
Pneumonia fungal	1 (4.3)	0	0
Respiratory syncytial virus bronchitis	1 (4.3)	1 (4.3)	0
Respiratory syncytial virus infection	1 (4.3)	0	0

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serratia infection	1 (4.3)	1 (4.3)	0
Staphylococcal bacteraemia	1 (4.3)	1 (4.3)	0
Staphylococcal scalded skin syndrome	1 (4.3)	0	0
Staphylococcal sepsis	1 (4.3)	0	1 (4.3)
Investigations			
-Total	1 (4.3)	1 (4.3)	0
Transaminases increased	1 (4.3)	1 (4.3)	0
Metabolism and nutrition disorders			
-Total	3 (13.0)	1 (4.3)	0
Dehydration	1 (4.3)	1 (4.3)	0
Hypocalcaemia	1 (4.3)	0	0
Malnutrition	1 (4.3)	0	0
Musculoskeletal and connective tissue disorders			
-Total	2 (8.7)	2 (8.7)	0
Back pain	1 (4.3)	1 (4.3)	0
Myopathy	1 (4.3)	1 (4.3)	0
Myositis	1 (4.3)	1 (4.3)	0

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	1 (4.3)	1 (4.3)	0
Headache	1 (4.3)	1 (4.3)	0
Renal and urinary disorders			
-Total	1 (4.3)	0	0
Acute kidney injury	1 (4.3)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (13.0)	0	1 (4.3)
Hypoxia	3 (13.0)	1 (4.3)	0
Pulmonary mass	1 (4.3)	0	0
Respiratory distress	1 (4.3)	0	1 (4.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of

all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180r
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (33.3)	6 (25.0)	2 (8.3)
Blood and lymphatic system disorders			
-Total	4 (16.7)	3 (12.5)	1 (4.2)
Febrile neutropenia	4 (16.7)	4 (16.7)	0
Neutropenia	1 (4.2)	0	1 (4.2)
Thrombocytopenia	1 (4.2)	0	1 (4.2)
Gastrointestinal disorders			
-Total	2 (8.3)	1 (4.2)	0
Abdominal pain	1 (4.2)	0	0
Gastrointestinal haemorrhage	1 (4.2)	1 (4.2)	0

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (4.2)	1 (4.2)	0
Pyrexia	1 (4.2)	1 (4.2)	0
Infections and infestations			
-Total	4 (16.7)	2 (8.3)	2 (8.3)
Alpha haemolytic streptococcal infection	1 (4.2)	1 (4.2)	0
Candida sepsis	1 (4.2)	0	1 (4.2)
Device related infection	1 (4.2)	1 (4.2)	0
Escherichia sepsis	1 (4.2)	0	1 (4.2)
Pneumonia fungal	1 (4.2)	1 (4.2)	0
Staphylococcal infection	1 (4.2)	1 (4.2)	0
Investigations			
-Total	1 (4.2)	1 (4.2)	0
Blast cell count increased	1 (4.2)	1 (4.2)	0
Metabolism and nutrition disorders			
-Total	2 (8.3)	1 (4.2)	1 (4.2)
Hypernatraemia	1 (4.2)	0	1 (4.2)

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	1 (4.2)	0	0
Hypophosphataemia	1 (4.2)	1 (4.2)	0
Renal and urinary disorders			
-Total	1 (4.2)	0	1 (4.2)
Acute kidney injury	1 (4.2)	0	1 (4.2)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (4.2)	0	1 (4.2)
Pulmonary oedema	1 (4.2)	0	1 (4.2)
Respiratory failure	1 (4.2)	0	1 (4.2)
Vascular disorders			
-Total	1 (4.2)	0	1 (4.2)
Hypotension	1 (4.2)	0	1 (4.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 180r
Serious adverse events before study treatment, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (55.0)	5 (25.0)	4 (20.0)
Blood and lymphatic system disorders			
-Total	2 (10.0)	2 (10.0)	0
Febrile neutropenia	2 (10.0)	2 (10.0)	0
Cardiac disorders			
-Total	1 (5.0)	0	1 (5.0)
Cardiovascular insufficiency	1 (5.0)	0	1 (5.0)
Gastrointestinal disorders			
-Total	4 (20.0)	4 (20.0)	0
Colitis	3 (15.0)	3 (15.0)	0
Stomatitis	2 (10.0)	2 (10.0)	0

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	5 (25.0)	0	2 (10.0)
Pyrexia	3 (15.0)	0	0
Multiple organ dysfunction syndrome	2 (10.0)	0	2 (10.0)
Chills	1 (5.0)	0	0
Hepatobiliary disorders			
-Total	1 (5.0)	1 (5.0)	0
Cholecystitis	1 (5.0)	1 (5.0)	0
Infections and infestations			
-Total	6 (30.0)	3 (15.0)	3 (15.0)
Klebsiella sepsis	2 (10.0)	0	2 (10.0)
Bacteraemia	1 (5.0)	1 (5.0)	0
Enterococcal bacteraemia	1 (5.0)	1 (5.0)	0
Sepsis	1 (5.0)	0	1 (5.0)
Staphylococcal bacteraemia	1 (5.0)	1 (5.0)	0
Streptococcal bacteraemia	1 (5.0)	1 (5.0)	0

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications			
-Total	2 (10.0)	1 (5.0)	0
Subdural haematoma	2 (10.0)	1 (5.0)	0
Extradural haematoma	1 (5.0)	1 (5.0)	0
Investigations			
-Total	1 (5.0)	1 (5.0)	0
Electrocardiogram qt prolonged	1 (5.0)	1 (5.0)	0
Nervous system disorders			
-Total	1 (5.0)	1 (5.0)	0
Headache	1 (5.0)	1 (5.0)	0
Psychiatric disorders			
-Total	1 (5.0)	1 (5.0)	0
Mental status changes	1 (5.0)	1 (5.0)	0
Reproductive system and breast disorders			
-Total	1 (5.0)	0	0
Scrotal pain	1 (5.0)	0	0

Number of previous relapses: >=3

Group term Preferred term	All patients N=20 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (10.0)	0	1 (5.0)
Hypoxia	1 (5.0)	0	0
Idiopathic pneumonia syndrome	1 (5.0)	0	1 (5.0)
Vascular disorders			
-Total	2 (10.0)	2 (10.0)	0
Hypotension	2 (10.0)	2 (10.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181a
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (15.0)	3 (15.0)	0
Blood and lymphatic system disorders			
-Total	2 (10.0)	2 (10.0)	0
Febrile neutropenia	2 (10.0)	2 (10.0)	0
Infections and infestations			
-Total	2 (10.0)	2 (10.0)	0
Bacteraemia	1 (5.0)	1 (5.0)	0
Device related infection	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.0)	1 (5.0)	0

Age: <10 years

Group term Preferred term	All patients N=20 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Epistaxis	1 (5.0)	1 (5.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181a
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (15.2)	4 (12.1)	1 (3.0)
Blood and lymphatic system disorders			
-Total	5 (15.2)	5 (15.2)	0
Febrile neutropenia	4 (12.1)	4 (12.1)	0
Pancytopenia	1 (3.0)	1 (3.0)	0
Gastrointestinal disorders			
-Total	1 (3.0)	1 (3.0)	0
Ascites	1 (3.0)	1 (3.0)	0
General disorders and administration site conditions			
-Total	1 (3.0)	0	1 (3.0)

Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	1 (3.0)	0	1 (3.0)
Hepatobiliary disorders			
-Total	1 (3.0)	0	1 (3.0)
Hepatic failure	1 (3.0)	0	1 (3.0)
Infections and infestations			
-Total	1 (3.0)	0	1 (3.0)
Bronchitis	1 (3.0)	0	0
Staphylococcal infection	1 (3.0)	0	1 (3.0)
Vascular disorders			
-Total	1 (3.0)	1 (3.0)	0
Hypotension	1 (3.0)	1 (3.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181a
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=18

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (12.5)	1 (12.5)	0
Infections and infestations			
-Total	1 (12.5)	1 (12.5)	0
Necrotising fasciitis	1 (12.5)	1 (12.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of

all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181b
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Male

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (17.2)	4 (13.8)	1 (3.4)
Blood and lymphatic system disorders			
-Total	4 (13.8)	4 (13.8)	0
Febrile neutropenia	3 (10.3)	3 (10.3)	0
Pancytopenia	1 (3.4)	1 (3.4)	0
Gastrointestinal disorders			
-Total	1 (3.4)	1 (3.4)	0
Ascites	1 (3.4)	1 (3.4)	0
General disorders and administration site conditions			
-Total	1 (3.4)	0	1 (3.4)

Gender: Male

Group term Preferred term	All patients N=29 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Multiple organ dysfunction syndrome	1 (3.4)	0	1 (3.4)
Hepatobiliary disorders			
-Total	1 (3.4)	0	1 (3.4)
Hepatic failure	1 (3.4)	0	1 (3.4)
Infections and infestations			
-Total	1 (3.4)	0	1 (3.4)
Bronchitis	1 (3.4)	0	0
Staphylococcal infection	1 (3.4)	0	1 (3.4)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.4)	1 (3.4)	0
Epistaxis	1 (3.4)	1 (3.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of

all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181b
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Female

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (12.5)	4 (12.5)	0
Blood and lymphatic system disorders			
-Total	3 (9.4)	3 (9.4)	0
Febrile neutropenia	3 (9.4)	3 (9.4)	0
Infections and infestations			
-Total	3 (9.4)	3 (9.4)	0
Bacteraemia	1 (3.1)	1 (3.1)	0
Device related infection	1 (3.1)	1 (3.1)	0
Necrotising fasciitis	1 (3.1)	1 (3.1)	0
Vascular disorders			
-Total	1 (3.1)	1 (3.1)	0

Gender: Female

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (3.1)	1 (3.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181c
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: White

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (16.0)	7 (14.0)	1 (2.0)
Blood and lymphatic system disorders			
-Total	6 (12.0)	6 (12.0)	0
Febrile neutropenia	5 (10.0)	5 (10.0)	0
Pancytopenia	1 (2.0)	1 (2.0)	0
Gastrointestinal disorders			
-Total	1 (2.0)	1 (2.0)	0
Ascites	1 (2.0)	1 (2.0)	0
General disorders and administration site conditions			
-Total	1 (2.0)	0	1 (2.0)

Race: White

Group term Preferred term	All patients N=50 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Multiple organ dysfunction syndrome	1 (2.0)	0	1 (2.0)
Hepatobiliary disorders			
-Total	1 (2.0)	0	1 (2.0)
Hepatic failure	1 (2.0)	0	1 (2.0)
Infections and infestations			
-Total	4 (8.0)	3 (6.0)	1 (2.0)
Bacteraemia	1 (2.0)	1 (2.0)	0
Bronchitis	1 (2.0)	0	0
Device related infection	1 (2.0)	1 (2.0)	0
Necrotising fasciitis	1 (2.0)	1 (2.0)	0
Staphylococcal infection	1 (2.0)	0	1 (2.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (2.0)	1 (2.0)	0
Epistaxis	1 (2.0)	1 (2.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion

(for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181c
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Other

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (16.7)	1 (16.7)	0
Blood and lymphatic system disorders			
-Total	1 (16.7)	1 (16.7)	0
Febrile neutropenia	1 (16.7)	1 (16.7)	0
Vascular disorders			
-Total	1 (16.7)	1 (16.7)	0
Hypotension	1 (16.7)	1 (16.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181d
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Hispanic or Latino

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (17.4)	4 (17.4)	0
Blood and lymphatic system disorders			
-Total	4 (17.4)	4 (17.4)	0
Febrile neutropenia	4 (17.4)	4 (17.4)	0
Infections and infestations			
-Total	1 (4.3)	1 (4.3)	0
Bacteraemia	1 (4.3)	1 (4.3)	0
Vascular disorders			
-Total	1 (4.3)	1 (4.3)	0
Hypotension	1 (4.3)	1 (4.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion
(for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181d
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Other

	All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (13.2)	4 (10.5)	1 (2.6)
Blood and lymphatic system disorders			
-Total	3 (7.9)	3 (7.9)	0
Febrile neutropenia	2 (5.3)	2 (5.3)	0
Pancytopenia	1 (2.6)	1 (2.6)	0
Gastrointestinal disorders			
-Total	1 (2.6)	1 (2.6)	0
Ascites	1 (2.6)	1 (2.6)	0
General disorders and administration site conditions			
-Total	1 (2.6)	0	1 (2.6)

Ethnicity: Other

Group term Preferred term	All patients N=38 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Multiple organ dysfunction syndrome	1 (2.6)	0	1 (2.6)
Hepatobiliary disorders			
-Total	1 (2.6)	0	1 (2.6)
Hepatic failure	1 (2.6)	0	1 (2.6)
Infections and infestations			
-Total	3 (7.9)	2 (5.3)	1 (2.6)
Bronchitis	1 (2.6)	0	0
Device related infection	1 (2.6)	1 (2.6)	0
Necrotising fasciitis	1 (2.6)	1 (2.6)	0
Staphylococcal infection	1 (2.6)	0	1 (2.6)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (2.6)	1 (2.6)	0
Epistaxis	1 (2.6)	1 (2.6)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181e
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Relapsed disease

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (16.7)	8 (14.8)	1 (1.9)
Blood and lymphatic system disorders			
-Total	7 (13.0)	7 (13.0)	0
Febrile neutropenia	6 (11.1)	6 (11.1)	0
Pancytopenia	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders			
-Total	1 (1.9)	1 (1.9)	0
Ascites	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	1 (1.9)	0	1 (1.9)
Multiple organ dysfunction syndrome	1 (1.9)	0	1 (1.9)

Response status at study entry: Relapsed disease

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders			
-Total	1 (1.9)	0	1 (1.9)
Hepatic failure	1 (1.9)	0	1 (1.9)
Infections and infestations			
-Total	4 (7.4)	3 (5.6)	1 (1.9)
Bacteraemia	1 (1.9)	1 (1.9)	0
Bronchitis	1 (1.9)	0	0
Device related infection	1 (1.9)	1 (1.9)	0
Necrotising fasciitis	1 (1.9)	1 (1.9)	0
Staphylococcal infection	1 (1.9)	0	1 (1.9)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.9)	1 (1.9)	0
Epistaxis	1 (1.9)	1 (1.9)	0
Vascular disorders			
-Total	1 (1.9)	1 (1.9)	0
Hypotension	1 (1.9)	1 (1.9)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion
(for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181f
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (15.3)	8 (13.6)	1 (1.7)
Blood and lymphatic system disorders			
-Total	7 (11.9)	7 (11.9)	0
Febrile neutropenia	6 (10.2)	6 (10.2)	0
Pancytopenia	1 (1.7)	1 (1.7)	0
Gastrointestinal disorders			
-Total	1 (1.7)	1 (1.7)	0
Ascites	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	1 (1.7)	0	1 (1.7)
Multiple organ dysfunction syndrome	1 (1.7)	0	1 (1.7)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders			
-Total	1 (1.7)	0	1 (1.7)
Hepatic failure	1 (1.7)	0	1 (1.7)
Infections and infestations			
-Total	4 (6.8)	3 (5.1)	1 (1.7)
Bacteraemia	1 (1.7)	1 (1.7)	0
Bronchitis	1 (1.7)	0	0
Device related infection	1 (1.7)	1 (1.7)	0
Necrotising fasciitis	1 (1.7)	1 (1.7)	0
Staphylococcal infection	1 (1.7)	0	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.7)	1 (1.7)	0
Epistaxis	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	1 (1.7)	1 (1.7)	0
Hypotension	1 (1.7)	1 (1.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion
(for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181g
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: No

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (15.5)	8 (13.8)	1 (1.7)
Blood and lymphatic system disorders			
-Total	7 (12.1)	7 (12.1)	0
Febrile neutropenia	6 (10.3)	6 (10.3)	0
Pancytopenia	1 (1.7)	1 (1.7)	0
Gastrointestinal disorders			
-Total	1 (1.7)	1 (1.7)	0
Ascites	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	1 (1.7)	0	1 (1.7)
Multiple organ dysfunction syndrome	1 (1.7)	0	1 (1.7)

Mixed-lineage leukemia rearrangement: No			
		All patients N=58	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders			
-Total	1 (1.7)	0	1 (1.7)
Hepatic failure	1 (1.7)	0	1 (1.7)
Infections and infestations			
-Total	4 (6.9)	3 (5.2)	1 (1.7)
Bacteraemia	1 (1.7)	1 (1.7)	0
Bronchitis	1 (1.7)	0	0
Device related infection	1 (1.7)	1 (1.7)	0
Necrotising fasciitis	1 (1.7)	1 (1.7)	0
Staphylococcal infection	1 (1.7)	0	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.7)	1 (1.7)	0
Epistaxis	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	1 (1.7)	1 (1.7)	0
Hypotension	1 (1.7)	1 (1.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion
(for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181h
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (15.0)	8 (13.3)	1 (1.7)
Blood and lymphatic system disorders			
-Total	7 (11.7)	7 (11.7)	0
Febrile neutropenia	6 (10.0)	6 (10.0)	0
Pancytopenia	1 (1.7)	1 (1.7)	0
Gastrointestinal disorders			
-Total	1 (1.7)	1 (1.7)	0
Ascites	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	1 (1.7)	0	1 (1.7)

Hypodiploidy: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	1 (1.7)	0	1 (1.7)
Hepatobiliary disorders			
-Total	1 (1.7)	0	1 (1.7)
Hepatic failure	1 (1.7)	0	1 (1.7)
Infections and infestations			
-Total	4 (6.7)	3 (5.0)	1 (1.7)
Bacteraemia	1 (1.7)	1 (1.7)	0
Bronchitis	1 (1.7)	0	0
Device related infection	1 (1.7)	1 (1.7)	0
Necrotising fasciitis	1 (1.7)	1 (1.7)	0
Staphylococcal infection	1 (1.7)	0	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.7)	1 (1.7)	0
Epistaxis	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	1 (1.7)	1 (1.7)	0
Hypotension	1 (1.7)	1 (1.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion
(for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181i
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (25.0)	1 (25.0)	0
Blood and lymphatic system disorders			
-Total	1 (25.0)	1 (25.0)	0
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	1 (25.0)	1 (25.0)	0
Bacteraemia	1 (25.0)	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181i
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (14.0)	7 (12.3)	1 (1.8)
Blood and lymphatic system disorders			
-Total	6 (10.5)	6 (10.5)	0
Febrile neutropenia	5 (8.8)	5 (8.8)	0
Pancytopenia	1 (1.8)	1 (1.8)	0
Gastrointestinal disorders			
-Total	1 (1.8)	1 (1.8)	0
Ascites	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions			
-Total	1 (1.8)	0	1 (1.8)

BCR-ABL1-like: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	1 (1.8)	0	1 (1.8)
Hepatobiliary disorders			
-Total	1 (1.8)	0	1 (1.8)
Hepatic failure	1 (1.8)	0	1 (1.8)
Infections and infestations			
-Total	3 (5.3)	2 (3.5)	1 (1.8)
Bronchitis	1 (1.8)	0	0
Device related infection	1 (1.8)	1 (1.8)	0
Necrotising fasciitis	1 (1.8)	1 (1.8)	0
Staphylococcal infection	1 (1.8)	0	1 (1.8)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.8)	1 (1.8)	0
Epistaxis	1 (1.8)	1 (1.8)	0
Vascular disorders			
-Total	1 (1.8)	1 (1.8)	0
Hypotension	1 (1.8)	1 (1.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion
(for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181j
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (5.6)	1 (5.6)	0
Blood and lymphatic system disorders			
-Total	1 (5.6)	1 (5.6)	0
Pancytopenia	1 (5.6)	1 (5.6)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181j
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (18.6)	7 (16.3)	1 (2.3)
Blood and lymphatic system disorders			
-Total	6 (14.0)	6 (14.0)	0
Febrile neutropenia	6 (14.0)	6 (14.0)	0
Gastrointestinal disorders			
-Total	1 (2.3)	1 (2.3)	0
Ascites	1 (2.3)	1 (2.3)	0
General disorders and administration site conditions			
-Total	1 (2.3)	0	1 (2.3)
Multiple organ dysfunction syndrome	1 (2.3)	0	1 (2.3)
Hepatobiliary disorders			

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.3)	0	1 (2.3)
Hepatic failure	1 (2.3)	0	1 (2.3)
Infections and infestations			
-Total	4 (9.3)	3 (7.0)	1 (2.3)
Bacteraemia	1 (2.3)	1 (2.3)	0
Bronchitis	1 (2.3)	0	0
Device related infection	1 (2.3)	1 (2.3)	0
Necrotising fasciitis	1 (2.3)	1 (2.3)	0
Staphylococcal infection	1 (2.3)	0	1 (2.3)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (2.3)	1 (2.3)	0
Epistaxis	1 (2.3)	1 (2.3)	0
Vascular disorders			
-Total	1 (2.3)	1 (2.3)	0
Hypotension	1 (2.3)	1 (2.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181k
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: US

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (14.8)	8 (13.1)	1 (1.6)
Blood and lymphatic system disorders			
-Total	7 (11.5)	7 (11.5)	0
Febrile neutropenia	6 (9.8)	6 (9.8)	0
Pancytopenia	1 (1.6)	1 (1.6)	0
Gastrointestinal disorders			
-Total	1 (1.6)	1 (1.6)	0
Ascites	1 (1.6)	1 (1.6)	0
General disorders and administration site conditions			
-Total	1 (1.6)	0	1 (1.6)

Region: US

Group term Preferred term	All patients N=61 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Multiple organ dysfunction syndrome	1 (1.6)	0	1 (1.6)
Hepatobiliary disorders			
-Total	1 (1.6)	0	1 (1.6)
Hepatic failure	1 (1.6)	0	1 (1.6)
Infections and infestations			
-Total	4 (6.6)	3 (4.9)	1 (1.6)
Bacteraemia	1 (1.6)	1 (1.6)	0
Bronchitis	1 (1.6)	0	0
Device related infection	1 (1.6)	1 (1.6)	0
Necrotising fasciitis	1 (1.6)	1 (1.6)	0
Staphylococcal infection	1 (1.6)	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.6)	1 (1.6)	0
Epistaxis	1 (1.6)	1 (1.6)	0
Vascular disorders			
-Total	1 (1.6)	1 (1.6)	0
Hypotension	1 (1.6)	1 (1.6)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion
(for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181l
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (17.9)	4 (14.3)	1 (3.6)
Blood and lymphatic system disorders			
-Total	4 (14.3)	4 (14.3)	0
Febrile neutropenia	4 (14.3)	4 (14.3)	0
Gastrointestinal disorders			
-Total	1 (3.6)	1 (3.6)	0
Ascites	1 (3.6)	1 (3.6)	0
General disorders and administration site conditions			
-Total	1 (3.6)	0	1 (3.6)
Multiple organ dysfunction syndrome	1 (3.6)	0	1 (3.6)

Prior SCT therapy: Yes

Group term Preferred term	All patients N=28 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatobiliary disorders			
-Total	1 (3.6)	0	1 (3.6)
Hepatic failure	1 (3.6)	0	1 (3.6)
Infections and infestations			
-Total	4 (14.3)	3 (10.7)	1 (3.6)
Bacteraemia	1 (3.6)	1 (3.6)	0
Bronchitis	1 (3.6)	0	0
Device related infection	1 (3.6)	1 (3.6)	0
Necrotising fasciitis	1 (3.6)	1 (3.6)	0
Staphylococcal infection	1 (3.6)	0	1 (3.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181l
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (12.1)	4 (12.1)	0
Blood and lymphatic system disorders			
-Total	3 (9.1)	3 (9.1)	0
Febrile neutropenia	2 (6.1)	2 (6.1)	0
Pancytopenia	1 (3.0)	1 (3.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.0)	1 (3.0)	0
Epistaxis	1 (3.0)	1 (3.0)	0
Vascular disorders			
-Total	1 (3.0)	1 (3.0)	0

Prior SCT therapy: No

Group term Preferred term	All patients N=33 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	1 (3.0)	1 (3.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181m
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (7.1)	1 (7.1)	0
Blood and lymphatic system disorders			
-Total	1 (7.1)	1 (7.1)	0
Febrile neutropenia	1 (7.1)	1 (7.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181m
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: No

	All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (17.0)	7 (14.9)	1 (2.1)
Blood and lymphatic system disorders			
-Total	6 (12.8)	6 (12.8)	0
Febrile neutropenia	5 (10.6)	5 (10.6)	0
Pancytopenia	1 (2.1)	1 (2.1)	0
Gastrointestinal disorders			
-Total	1 (2.1)	1 (2.1)	0
Ascites	1 (2.1)	1 (2.1)	0
General disorders and administration site conditions			
-Total	1 (2.1)	0	1 (2.1)

Eligibility for SCT: No

	All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	1 (2.1)	0	1 (2.1)
Hepatobiliary disorders			
-Total	1 (2.1)	0	1 (2.1)
Hepatic failure	1 (2.1)	0	1 (2.1)
Infections and infestations			
-Total	4 (8.5)	3 (6.4)	1 (2.1)
Bacteraemia	1 (2.1)	1 (2.1)	0
Bronchitis	1 (2.1)	0	0
Device related infection	1 (2.1)	1 (2.1)	0
Necrotising fasciitis	1 (2.1)	1 (2.1)	0
Staphylococcal infection	1 (2.1)	0	1 (2.1)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (2.1)	1 (2.1)	0
Epistaxis	1 (2.1)	1 (2.1)	0
Vascular disorders			
-Total	1 (2.1)	1 (2.1)	0
Hypotension	1 (2.1)	1 (2.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion
(for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181n
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: Low

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (14.3)	2 (9.5)	1 (4.8)
Blood and lymphatic system disorders			
-Total	3 (14.3)	3 (14.3)	0
Febrile neutropenia	2 (9.5)	2 (9.5)	0
Pancytopenia	1 (4.8)	1 (4.8)	0
Gastrointestinal disorders			
-Total	1 (4.8)	1 (4.8)	0
Ascites	1 (4.8)	1 (4.8)	0
General disorders and administration site conditions			
-Total	1 (4.8)	0	1 (4.8)
Multiple organ dysfunction syndrome	1 (4.8)	0	1 (4.8)

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=21 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hepatobiliary disorders			
-Total	1 (4.8)	0	1 (4.8)
Hepatic failure	1 (4.8)	0	1 (4.8)
Infections and infestations			
-Total	2 (9.5)	1 (4.8)	1 (4.8)
Bronchitis	1 (4.8)	0	0
Device related infection	1 (4.8)	1 (4.8)	0
Staphylococcal infection	1 (4.8)	0	1 (4.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181n
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: High

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (15.0)	6 (15.0)	0
Blood and lymphatic system disorders			
-Total	4 (10.0)	4 (10.0)	0
Febrile neutropenia	4 (10.0)	4 (10.0)	0
Infections and infestations			
-Total	2 (5.0)	2 (5.0)	0
Bacteraemia	1 (2.5)	1 (2.5)	0
Necrotising fasciitis	1 (2.5)	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (2.5)	1 (2.5)	0
Epistaxis	1 (2.5)	1 (2.5)	0

Baseline bone marrow tumor burden: High

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	1 (2.5)	1 (2.5)	0
Hypotension	1 (2.5)	1 (2.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181o
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (15.8)	8 (14.0)	1 (1.8)
Blood and lymphatic system disorders			
-Total	7 (12.3)	7 (12.3)	0
Febrile neutropenia	6 (10.5)	6 (10.5)	0
Pancytopenia	1 (1.8)	1 (1.8)	0
Gastrointestinal disorders			
-Total	1 (1.8)	1 (1.8)	0
Ascites	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions			
-Total	1 (1.8)	0	1 (1.8)
Multiple organ dysfunction syndrome	1 (1.8)	0	1 (1.8)

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=57 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hepatobiliary disorders			
-Total	1 (1.8)	0	1 (1.8)
Hepatic failure	1 (1.8)	0	1 (1.8)
Infections and infestations			
-Total	4 (7.0)	3 (5.3)	1 (1.8)
Bacteraemia	1 (1.8)	1 (1.8)	0
Bronchitis	1 (1.8)	0	0
Device related infection	1 (1.8)	1 (1.8)	0
Necrotising fasciitis	1 (1.8)	1 (1.8)	0
Staphylococcal infection	1 (1.8)	0	1 (1.8)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.8)	1 (1.8)	0
Epistaxis	1 (1.8)	1 (1.8)	0
Vascular disorders			
-Total	1 (1.8)	1 (1.8)	0
Hypotension	1 (1.8)	1 (1.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion
(for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181p
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (15.8)	8 (14.0)	1 (1.8)
Blood and lymphatic system disorders			
-Total	7 (12.3)	7 (12.3)	0
Febrile neutropenia	6 (10.5)	6 (10.5)	0
Pancytopenia	1 (1.8)	1 (1.8)	0
Gastrointestinal disorders			
-Total	1 (1.8)	1 (1.8)	0
Ascites	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions			
-Total	1 (1.8)	0	1 (1.8)

Down syndrome: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	1 (1.8)	0	1 (1.8)
Hepatobiliary disorders			
-Total	1 (1.8)	0	1 (1.8)
Hepatic failure	1 (1.8)	0	1 (1.8)
Infections and infestations			
-Total	4 (7.0)	3 (5.3)	1 (1.8)
Bacteraemia	1 (1.8)	1 (1.8)	0
Bronchitis	1 (1.8)	0	0
Device related infection	1 (1.8)	1 (1.8)	0
Necrotising fasciitis	1 (1.8)	1 (1.8)	0
Staphylococcal infection	1 (1.8)	0	1 (1.8)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.8)	1 (1.8)	0
Epistaxis	1 (1.8)	1 (1.8)	0
Vascular disorders			
-Total	1 (1.8)	1 (1.8)	0
Hypotension	1 (1.8)	1 (1.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion
(for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181q
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: > Median

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (12.9)	4 (12.9)	0
Blood and lymphatic system disorders			
-Total	3 (9.7)	3 (9.7)	0
Febrile neutropenia	2 (6.5)	2 (6.5)	0
Pancytopenia	1 (3.2)	1 (3.2)	0
Infections and infestations			
-Total	2 (6.5)	2 (6.5)	0
Bacteraemia	1 (3.2)	1 (3.2)	0
Device related infection	1 (3.2)	1 (3.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.2)	1 (3.2)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	1 (3.2)	1 (3.2)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181q
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: <=Median

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (13.8)	4 (13.8)	0
Blood and lymphatic system disorders			
-Total	3 (10.3)	3 (10.3)	0
Febrile neutropenia	3 (10.3)	3 (10.3)	0
Infections and infestations			
-Total	1 (3.4)	1 (3.4)	0
Necrotising fasciitis	1 (3.4)	1 (3.4)	0
Vascular disorders			
-Total	1 (3.4)	1 (3.4)	0
Hypotension	1 (3.4)	1 (3.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion
(for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181q
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: Missing

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Blood and lymphatic system disorders			
-Total	1 (100)	1 (100)	0
Febrile neutropenia	1 (100)	1 (100)	0
Gastrointestinal disorders			
-Total	1 (100)	1 (100)	0
Ascites	1 (100)	1 (100)	0
General disorders and administration site conditions			
-Total	1 (100)	0	1 (100)
Multiple organ dysfunction syndrome	1 (100)	0	1 (100)

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=1 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hepatobiliary disorders			
-Total	1 (100)	0	1 (100)
Hepatic failure	1 (100)	0	1 (100)
Infections and infestations			
-Total	1 (100)	0	1 (100)
Bronchitis	1 (100)	0	0
Staphylococcal infection	1 (100)	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181r
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 1

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (10.5)	2 (10.5)	0
Blood and lymphatic system disorders			
-Total	1 (5.3)	1 (5.3)	0
Febrile neutropenia	1 (5.3)	1 (5.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.3)	1 (5.3)	0
Epistaxis	1 (5.3)	1 (5.3)	0
Vascular disorders			
-Total	1 (5.3)	1 (5.3)	0
Hypotension	1 (5.3)	1 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion
(for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181r
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 2

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (10.5)	2 (10.5)	0
Blood and lymphatic system disorders			
-Total	2 (10.5)	2 (10.5)	0
Febrile neutropenia	1 (5.3)	1 (5.3)	0
Pancytopenia	1 (5.3)	1 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of

all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 181r
Serious adverse events during the lymphodepleting period, regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (31.3)	4 (25.0)	1 (6.3)
Blood and lymphatic system disorders			
-Total	4 (25.0)	4 (25.0)	0
Febrile neutropenia	4 (25.0)	4 (25.0)	0
Gastrointestinal disorders			
-Total	1 (6.3)	1 (6.3)	0
Ascites	1 (6.3)	1 (6.3)	0
General disorders and administration site conditions			
-Total	1 (6.3)	0	1 (6.3)
Multiple organ dysfunction syndrome	1 (6.3)	0	1 (6.3)

Number of previous relapses: >=3

Group term Preferred term	All patients N=16 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hepatobiliary disorders			
-Total	1 (6.3)	0	1 (6.3)
Hepatic failure	1 (6.3)	0	1 (6.3)
Infections and infestations			
-Total	4 (25.0)	3 (18.8)	1 (6.3)
Bacteraemia	1 (6.3)	1 (6.3)	0
Bronchitis	1 (6.3)	0	0
Device related infection	1 (6.3)	1 (6.3)	0
Necrotising fasciitis	1 (6.3)	1 (6.3)	0
Staphylococcal infection	1 (6.3)	0	1 (6.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
Only AEs started after the first day of Lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182a
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=10 years to <18 years

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	4 (80.0)
Blood and lymphatic system disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Febrile neutropenia	2 (40.0)	2 (40.0)	0
Neutropenia	1 (20.0)	0	1 (20.0)
Thrombocytopenia	1 (20.0)	0	1 (20.0)
Gastrointestinal disorders			
-Total	3 (60.0)	3 (60.0)	0
Colitis	2 (40.0)	2 (40.0)	0
Abdominal pain	1 (20.0)	1 (20.0)	0
Ascites	1 (20.0)	1 (20.0)	0
Gastrointestinal haemorrhage	1 (20.0)	1 (20.0)	0

Age: >=10 years to <18 years

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
-Total	3 (60.0)	0	2 (40.0)
Multiple organ dysfunction syndrome	2 (40.0)	0	2 (40.0)
Chills	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	0
Hepatobiliary disorders			
-Total	1 (20.0)	0	1 (20.0)
Hepatic failure	1 (20.0)	0	1 (20.0)
Infections and infestations			
-Total	4 (80.0)	0	4 (80.0)
Bronchitis	1 (20.0)	0	0
Candida sepsis	1 (20.0)	0	1 (20.0)
Klebsiella sepsis	1 (20.0)	0	1 (20.0)
Pneumonia fungal	1 (20.0)	1 (20.0)	0
Sepsis	1 (20.0)	0	1 (20.0)
Staphylococcal bacteraemia	1 (20.0)	1 (20.0)	0

Age: >=10 years to <18 years

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
-Total	1 (20.0)	0	1 (20.0)
Hypernatraemia	1 (20.0)	0	1 (20.0)
Renal and urinary disorders			
-Total	1 (20.0)	0	1 (20.0)
Acute kidney injury	1 (20.0)	0	1 (20.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (20.0)	0	1 (20.0)
Pulmonary oedema	1 (20.0)	0	1 (20.0)
Respiratory failure	1 (20.0)	0	1 (20.0)
Vascular disorders			
-Total	3 (60.0)	2 (40.0)	1 (20.0)
Hypotension	3 (60.0)	2 (40.0)	1 (20.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182a
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=18

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	0	3 (75.0)
Cardiac disorders			
-Total	1 (25.0)	0	1 (25.0)
Cardiovascular insufficiency	1 (25.0)	0	1 (25.0)
General disorders and administration site conditions			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Multiple organ dysfunction syndrome	1 (25.0)	0	1 (25.0)
Pyrexia	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	2 (50.0)	0	2 (50.0)
Klebsiella sepsis	1 (25.0)	0	1 (25.0)

Age: >=18

Group term Preferred term	All patients N=4 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	1 (25.0)	0	1 (25.0)
Nervous system disorders			
-Total	1 (25.0)	1 (25.0)	0
Headache	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (50.0)	0	2 (50.0)
Hypoxia	2 (50.0)	2 (50.0)	0
Aspiration	1 (25.0)	0	1 (25.0)
Respiratory distress	1 (25.0)	0	1 (25.0)
Vascular disorders			
-Total	1 (25.0)	0	1 (25.0)
Hypotension	1 (25.0)	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182b
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Male

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (70.0)	0	7 (70.0)
Blood and lymphatic system disorders			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Febrile neutropenia	2 (20.0)	2 (20.0)	0
Neutropenia	1 (10.0)	0	1 (10.0)
Thrombocytopenia	1 (10.0)	0	1 (10.0)
Cardiac disorders			
-Total	1 (10.0)	0	1 (10.0)
Cardiovascular insufficiency	1 (10.0)	0	1 (10.0)
Gastrointestinal disorders			
-Total	3 (30.0)	3 (30.0)	0
Colitis	2 (20.0)	2 (20.0)	0

Gender: Male

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (10.0)	1 (10.0)	0
Ascites	1 (10.0)	1 (10.0)	0
Gastrointestinal haemorrhage	1 (10.0)	1 (10.0)	0
Stomatitis	1 (10.0)	1 (10.0)	0
General disorders and administration site conditions			
-Total	5 (50.0)	1 (10.0)	3 (30.0)
Multiple organ dysfunction syndrome	3 (30.0)	0	3 (30.0)
Pyrexia	2 (20.0)	1 (10.0)	0
Chills	1 (10.0)	0	0
Hepatobiliary disorders			
-Total	1 (10.0)	0	1 (10.0)
Hepatic failure	1 (10.0)	0	1 (10.0)
Infections and infestations			
-Total	6 (60.0)	0	6 (60.0)
Klebsiella sepsis	2 (20.0)	0	2 (20.0)
Bronchitis	1 (10.0)	0	0
Candida sepsis	1 (10.0)	0	1 (10.0)

Gender: Male

Group term Preferred term	All patients N=10 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	1 (10.0)	0	1 (10.0)
Pneumonia fungal	1 (10.0)	1 (10.0)	0
Sepsis	1 (10.0)	0	1 (10.0)
Staphylococcal bacteraemia	1 (10.0)	1 (10.0)	0
Staphylococcal infection	1 (10.0)	0	1 (10.0)
Metabolism and nutrition disorders			
-Total	1 (10.0)	0	1 (10.0)
Hypernatraemia	1 (10.0)	0	1 (10.0)
Nervous system disorders			
-Total	1 (10.0)	1 (10.0)	0
Headache	1 (10.0)	1 (10.0)	0
Renal and urinary disorders			
-Total	1 (10.0)	0	1 (10.0)
Acute kidney injury	1 (10.0)	0	1 (10.0)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (30.0)	0	3 (30.0)
Hypoxia	2 (20.0)	2 (20.0)	0

Gender: Male

Group term Preferred term	All patients N=10 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspiration	1 (10.0)	0	1 (10.0)
Pulmonary oedema	1 (10.0)	0	1 (10.0)
Respiratory distress	1 (10.0)	0	1 (10.0)
Respiratory failure	1 (10.0)	0	1 (10.0)
Vascular disorders			
-Total	4 (40.0)	2 (20.0)	2 (20.0)
Hypotension	4 (40.0)	2 (20.0)	2 (20.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182c
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: White

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (62.5)	0	5 (62.5)
Blood and lymphatic system disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Febrile neutropenia	2 (25.0)	2 (25.0)	0
Neutropenia	1 (12.5)	0	1 (12.5)
Thrombocytopenia	1 (12.5)	0	1 (12.5)
Gastrointestinal disorders			
-Total	3 (37.5)	3 (37.5)	0
Colitis	2 (25.0)	2 (25.0)	0
Abdominal pain	1 (12.5)	1 (12.5)	0
Ascites	1 (12.5)	1 (12.5)	0
Gastrointestinal haemorrhage	1 (12.5)	1 (12.5)	0

Race: White

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Stomatitis	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	4 (50.0)	1 (12.5)	2 (25.0)
Multiple organ dysfunction syndrome	2 (25.0)	0	2 (25.0)
Pyrexia	2 (25.0)	1 (12.5)	0
Chills	1 (12.5)	0	0
Hepatobiliary disorders			
-Total	1 (12.5)	0	1 (12.5)
Hepatic failure	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	5 (62.5)	0	5 (62.5)
Bronchitis	1 (12.5)	0	0
Candida sepsis	1 (12.5)	0	1 (12.5)
Klebsiella sepsis	1 (12.5)	0	1 (12.5)
Pneumonia	1 (12.5)	0	1 (12.5)
Pneumonia fungal	1 (12.5)	1 (12.5)	0
Sepsis	1 (12.5)	0	1 (12.5)

Race: White

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	1 (12.5)	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Metabolism and nutrition disorders			
-Total	1 (12.5)	0	1 (12.5)
Hypernatraemia	1 (12.5)	0	1 (12.5)
Renal and urinary disorders			
-Total	1 (12.5)	0	1 (12.5)
Acute kidney injury	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (25.0)	0	2 (25.0)
Aspiration	1 (12.5)	0	1 (12.5)
Hypoxia	1 (12.5)	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	1 (12.5)
Respiratory failure	1 (12.5)	0	1 (12.5)
Vascular disorders			
-Total	4 (50.0)	2 (25.0)	2 (25.0)
Hypotension	4 (50.0)	2 (25.0)	2 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182c
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Other

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Cardiac disorders			
-Total	1 (50.0)	0	1 (50.0)
Cardiovascular insufficiency	1 (50.0)	0	1 (50.0)
General disorders and administration site conditions			
-Total	1 (50.0)	0	1 (50.0)
Multiple organ dysfunction syndrome	1 (50.0)	0	1 (50.0)
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)
Klebsiella sepsis	1 (50.0)	0	1 (50.0)
Nervous system disorders			

Race: Other

Group term Preferred term	All patients N=2 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (50.0)	1 (50.0)	0
Headache	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Hypoxia	1 (50.0)	1 (50.0)	0
Respiratory distress	1 (50.0)	0	1 (50.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182d
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Hispanic or Latino

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (60.0)	0	3 (60.0)
Blood and lymphatic system disorders			
-Total	1 (20.0)	0	1 (20.0)
Febrile neutropenia	1 (20.0)	1 (20.0)	0
Neutropenia	1 (20.0)	0	1 (20.0)
Thrombocytopenia	1 (20.0)	0	1 (20.0)
Cardiac disorders			
-Total	1 (20.0)	0	1 (20.0)
Cardiovascular insufficiency	1 (20.0)	0	1 (20.0)
Gastrointestinal disorders			
-Total	1 (20.0)	1 (20.0)	0
Gastrointestinal haemorrhage	1 (20.0)	1 (20.0)	0

Ethnicity: Hispanic or Latino

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	2 (40.0)	0	1 (20.0)
Chills	1 (20.0)	0	0
Multiple organ dysfunction syndrome	1 (20.0)	0	1 (20.0)
Pyrexia	1 (20.0)	0	0
Infections and infestations			
-Total	3 (60.0)	0	3 (60.0)
Candida sepsis	1 (20.0)	0	1 (20.0)
Klebsiella sepsis	1 (20.0)	0	1 (20.0)
Pneumonia fungal	1 (20.0)	1 (20.0)	0
Sepsis	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
-Total	1 (20.0)	0	1 (20.0)
Hypernatraemia	1 (20.0)	0	1 (20.0)
Renal and urinary disorders			
-Total	1 (20.0)	0	1 (20.0)
Acute kidney injury	1 (20.0)	0	1 (20.0)

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=5 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (20.0)	0	1 (20.0)
Pulmonary oedema	1 (20.0)	0	1 (20.0)
Respiratory failure	1 (20.0)	0	1 (20.0)
Vascular disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Hypotension	2 (40.0)	1 (20.0)	1 (20.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182d
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Other

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (66.7)	0	4 (66.7)
Blood and lymphatic system disorders			
-Total	1 (16.7)	1 (16.7)	0
Febrile neutropenia	1 (16.7)	1 (16.7)	0
Gastrointestinal disorders			
-Total	2 (33.3)	2 (33.3)	0
Colitis	2 (33.3)	2 (33.3)	0
Abdominal pain	1 (16.7)	1 (16.7)	0
Ascites	1 (16.7)	1 (16.7)	0
Stomatitis	1 (16.7)	1 (16.7)	0
General disorders and administration site conditions			

Ethnicity: Other

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Multiple organ dysfunction syndrome	2 (33.3)	0	2 (33.3)
Pyrexia	1 (16.7)	1 (16.7)	0
Hepatobiliary disorders			
-Total	1 (16.7)	0	1 (16.7)
Hepatic failure	1 (16.7)	0	1 (16.7)
Infections and infestations			
-Total	3 (50.0)	0	3 (50.0)
Bronchitis	1 (16.7)	0	0
Klebsiella sepsis	1 (16.7)	0	1 (16.7)
Pneumonia	1 (16.7)	0	1 (16.7)
Staphylococcal bacteraemia	1 (16.7)	1 (16.7)	0
Staphylococcal infection	1 (16.7)	0	1 (16.7)
Nervous system disorders			
-Total	1 (16.7)	1 (16.7)	0
Headache	1 (16.7)	1 (16.7)	0
Respiratory, thoracic and mediastinal disorders			

Ethnicity: Other

Group term Preferred term	All patients N=6 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (33.3)	0	2 (33.3)
Hypoxia	2 (33.3)	2 (33.3)	0
Aspiration	1 (16.7)	0	1 (16.7)
Respiratory distress	1 (16.7)	0	1 (16.7)
Vascular disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Hypotension	2 (33.3)	1 (16.7)	1 (16.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182e
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Primary refractory

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
General disorders and administration site conditions			
-Total	1 (100)	1 (100)	0
Pyrexia	1 (100)	1 (100)	0
Infections and infestations			
-Total	1 (100)	0	1 (100)
Pneumonia	1 (100)	0	1 (100)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (100)	0	1 (100)
Aspiration	1 (100)	0	1 (100)
Hypoxia	1 (100)	1 (100)	0

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=1 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Vascular disorders			
-Total	1 (100)	0	1 (100)
Hypotension	1 (100)	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182e
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Relapsed disease

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (60.0)	0	6 (60.0)
Blood and lymphatic system disorders			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Febrile neutropenia	2 (20.0)	2 (20.0)	0
Neutropenia	1 (10.0)	0	1 (10.0)
Thrombocytopenia	1 (10.0)	0	1 (10.0)
Cardiac disorders			
-Total	1 (10.0)	0	1 (10.0)
Cardiovascular insufficiency	1 (10.0)	0	1 (10.0)
Gastrointestinal disorders			
-Total	3 (30.0)	3 (30.0)	0
Colitis	2 (20.0)	2 (20.0)	0

Response status at study entry: Relapsed disease

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (10.0)	1 (10.0)	0
Ascites	1 (10.0)	1 (10.0)	0
Gastrointestinal haemorrhage	1 (10.0)	1 (10.0)	0
Stomatitis	1 (10.0)	1 (10.0)	0
General disorders and administration site conditions			
-Total	4 (40.0)	0	3 (30.0)
Multiple organ dysfunction syndrome	3 (30.0)	0	3 (30.0)
Chills	1 (10.0)	0	0
Pyrexia	1 (10.0)	0	0
Hepatobiliary disorders			
-Total	1 (10.0)	0	1 (10.0)
Hepatic failure	1 (10.0)	0	1 (10.0)
Infections and infestations			
-Total	5 (50.0)	0	5 (50.0)
Klebsiella sepsis	2 (20.0)	0	2 (20.0)
Bronchitis	1 (10.0)	0	0
Candida sepsis	1 (10.0)	0	1 (10.0)
Pneumonia fungal	1 (10.0)	1 (10.0)	0

Response status at study entry: Relapsed disease

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (10.0)	0	1 (10.0)
Staphylococcal bacteraemia	1 (10.0)	1 (10.0)	0
Staphylococcal infection	1 (10.0)	0	1 (10.0)
Metabolism and nutrition disorders			
-Total	1 (10.0)	0	1 (10.0)
Hypernatraemia	1 (10.0)	0	1 (10.0)
Nervous system disorders			
-Total	1 (10.0)	1 (10.0)	0
Headache	1 (10.0)	1 (10.0)	0
Renal and urinary disorders			
-Total	1 (10.0)	0	1 (10.0)
Acute kidney injury	1 (10.0)	0	1 (10.0)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (20.0)	0	2 (20.0)
Hypoxia	1 (10.0)	1 (10.0)	0
Pulmonary oedema	1 (10.0)	0	1 (10.0)
Respiratory distress	1 (10.0)	0	1 (10.0)
Respiratory failure	1 (10.0)	0	1 (10.0)

Response status at study entry: Relapsed disease

Group term Preferred term	All patients N=10 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Vascular disorders			
-Total	3 (30.0)	2 (20.0)	1 (10.0)
Hypotension	3 (30.0)	2 (20.0)	1 (10.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182f
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set – non – infused patients

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (63.6)	0	7 (63.6)
Blood and lymphatic system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
-Total	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	3 (27.3)	3 (27.3)	0
Colitis	2 (18.2)	2 (18.2)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (9.1)	1 (9.1)	0
Ascites	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	5 (45.5)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Pyrexia	2 (18.2)	1 (9.1)	0
Chills	1 (9.1)	0	0
Hepatobiliary disorders			
-Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	6 (54.5)	0	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Bronchitis	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	1 (9.1)
Pneumonia	1 (9.1)	0	1 (9.1)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	1 (9.1)	0	1 (9.1)
Hypernatraemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (27.3)	0	3 (27.3)
Hypoxia	2 (18.2)	2 (18.2)	0
Aspiration	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)

Philadelphia chromosome/BCR-ABL: Negative

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
-Total	4 (36.4)	2 (18.2)	2 (18.2)
Hypotension	4 (36.4)	2 (18.2)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182g
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set – non – infused patients

Mixed-lineage leukemia rearrangement: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (63.6)	0	7 (63.6)
Blood and lymphatic system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
-Total	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	3 (27.3)	3 (27.3)	0
Colitis	2 (18.2)	2 (18.2)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (9.1)	1 (9.1)	0
Ascites	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	5 (45.5)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Pyrexia	2 (18.2)	1 (9.1)	0
Chills	1 (9.1)	0	0
Hepatobiliary disorders			
-Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	6 (54.5)	0	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Bronchitis	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	1 (9.1)
Pneumonia	1 (9.1)	0	1 (9.1)

Mixed-lineage leukemia rearrangement: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	1 (9.1)	0	1 (9.1)
Hypernatraemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (27.3)	0	3 (27.3)
Hypoxia	2 (18.2)	2 (18.2)	0
Aspiration	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)

Mixed-lineage leukemia rearrangement: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
-Total	4 (36.4)	2 (18.2)	2 (18.2)
Hypotension	4 (36.4)	2 (18.2)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182h
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (63.6)	0	7 (63.6)
Blood and lymphatic system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
-Total	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	3 (27.3)	3 (27.3)	0
Colitis	2 (18.2)	2 (18.2)	0

Hypodiploidy: No

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Abdominal pain	1 (9.1)	1 (9.1)	0
Ascites	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	5 (45.5)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Pyrexia	2 (18.2)	1 (9.1)	0
Chills	1 (9.1)	0	0
Hepatobiliary disorders			
-Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	6 (54.5)	0	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Bronchitis	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	1 (9.1)

Hypodiploidy: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (9.1)	0	1 (9.1)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	1 (9.1)	0	1 (9.1)
Hypernatraemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (27.3)	0	3 (27.3)
Hypoxia	2 (18.2)	2 (18.2)	0

Hypodiploidy: No

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspiration	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
-Total	4 (36.4)	2 (18.2)	2 (18.2)
Hypotension	4 (36.4)	2 (18.2)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182i
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (63.6)	0	7 (63.6)
Blood and lymphatic system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
-Total	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	3 (27.3)	3 (27.3)	0
Colitis	2 (18.2)	2 (18.2)	0

BCR-ABL1-like: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (9.1)	1 (9.1)	0
Ascites	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	5 (45.5)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Pyrexia	2 (18.2)	1 (9.1)	0
Chills	1 (9.1)	0	0
Hepatobiliary disorders			
-Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	6 (54.5)	0	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Bronchitis	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	1 (9.1)

BCR-ABL1-like: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (9.1)	0	1 (9.1)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	1 (9.1)	0	1 (9.1)
Hypernatraemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (27.3)	0	3 (27.3)
Hypoxia	2 (18.2)	2 (18.2)	0

BCR-ABL1-like: No

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspiration	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
-Total	4 (36.4)	2 (18.2)	2 (18.2)
Hypotension	4 (36.4)	2 (18.2)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182j
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	2 (66.7)
Blood and lymphatic system disorders			
-Total	1 (33.3)	0	1 (33.3)
Febrile neutropenia	1 (33.3)	1 (33.3)	0
Neutropenia	1 (33.3)	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	1 (33.3)
Gastrointestinal disorders			
-Total	1 (33.3)	1 (33.3)	0
Gastrointestinal haemorrhage	1 (33.3)	1 (33.3)	0
General disorders and administration site conditions			
-Total	1 (33.3)	0	0
Chills	1 (33.3)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (33.3)	0	0
Infections and infestations			
-Total	2 (66.7)	0	2 (66.7)
Candida sepsis	1 (33.3)	0	1 (33.3)
Pneumonia fungal	1 (33.3)	1 (33.3)	0
Sepsis	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	1 (33.3)	0	1 (33.3)
Hypernatraemia	1 (33.3)	0	1 (33.3)
Renal and urinary disorders			
-Total	1 (33.3)	0	1 (33.3)
Acute kidney injury	1 (33.3)	0	1 (33.3)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	1 (33.3)
Respiratory failure	1 (33.3)	0	1 (33.3)
Vascular disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	2 (66.7)	1 (33.3)	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182j
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (62.5)	0	5 (62.5)
Blood and lymphatic system disorders			
-Total	1 (12.5)	1 (12.5)	0
Febrile neutropenia	1 (12.5)	1 (12.5)	0
Cardiac disorders			
-Total	1 (12.5)	0	1 (12.5)
Cardiovascular insufficiency	1 (12.5)	0	1 (12.5)
Gastrointestinal disorders			
-Total	2 (25.0)	2 (25.0)	0
Colitis	2 (25.0)	2 (25.0)	0
Abdominal pain	1 (12.5)	1 (12.5)	0
Ascites	1 (12.5)	1 (12.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Multiple organ dysfunction syndrome	3 (37.5)	0	3 (37.5)
Pyrexia	1 (12.5)	1 (12.5)	0
Hepatobiliary disorders			
-Total	1 (12.5)	0	1 (12.5)
Hepatic failure	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	4 (50.0)	0	4 (50.0)
Klebsiella sepsis	2 (25.0)	0	2 (25.0)
Bronchitis	1 (12.5)	0	0
Pneumonia	1 (12.5)	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Nervous system disorders			
-Total	1 (12.5)	1 (12.5)	0
Headache	1 (12.5)	1 (12.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (25.0)	0	2 (25.0)
Hypoxia	2 (25.0)	2 (25.0)	0
Aspiration	1 (12.5)	0	1 (12.5)
Respiratory distress	1 (12.5)	0	1 (12.5)
Vascular disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Hypotension	2 (25.0)	1 (12.5)	1 (12.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182k
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: US

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (63.6)	0	7 (63.6)
Blood and lymphatic system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
-Total	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	3 (27.3)	3 (27.3)	0
Colitis	2 (18.2)	2 (18.2)	0

Region: US

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Abdominal pain	1 (9.1)	1 (9.1)	0
Ascites	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	5 (45.5)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Pyrexia	2 (18.2)	1 (9.1)	0
Chills	1 (9.1)	0	0
Hepatobiliary disorders			
-Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	6 (54.5)	0	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Bronchitis	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	1 (9.1)

Region: US

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia	1 (9.1)	0	1 (9.1)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	1 (9.1)	0	1 (9.1)
Hypernatraemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (27.3)	0	3 (27.3)
Hypoxia	2 (18.2)	2 (18.2)	0

Region: US

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspiration	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
-Total	4 (36.4)	2 (18.2)	2 (18.2)
Hypotension	4 (36.4)	2 (18.2)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182l
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	4 (100)
Blood and lymphatic system disorders			
-Total	1 (25.0)	1 (25.0)	0
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Cardiac disorders			
-Total	1 (25.0)	0	1 (25.0)
Cardiovascular insufficiency	1 (25.0)	0	1 (25.0)
Gastrointestinal disorders			
-Total	2 (50.0)	2 (50.0)	0
Colitis	2 (50.0)	2 (50.0)	0
Abdominal pain	1 (25.0)	1 (25.0)	0
Ascites	1 (25.0)	1 (25.0)	0

Prior SCT therapy: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
-Total	4 (100)	0	3 (75.0)
Multiple organ dysfunction syndrome	3 (75.0)	0	3 (75.0)
Chills	1 (25.0)	0	0
Pyrexia	1 (25.0)	0	0
Hepatobiliary disorders			
-Total	1 (25.0)	0	1 (25.0)
Hepatic failure	1 (25.0)	0	1 (25.0)
Infections and infestations			
-Total	4 (100)	0	4 (100)
Klebsiella sepsis	2 (50.0)	0	2 (50.0)
Bronchitis	1 (25.0)	0	0
Sepsis	1 (25.0)	0	1 (25.0)
Staphylococcal bacteraemia	1 (25.0)	1 (25.0)	0
Staphylococcal infection	1 (25.0)	0	1 (25.0)
Vascular disorders			

Prior SCT therapy: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (50.0)	2 (50.0)	0
Hypotension	2 (50.0)	2 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182l
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (42.9)	0	3 (42.9)
Blood and lymphatic system disorders			
-Total	1 (14.3)	0	1 (14.3)
Febrile neutropenia	1 (14.3)	1 (14.3)	0
Neutropenia	1 (14.3)	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	1 (14.3)
Gastrointestinal disorders			
-Total	1 (14.3)	1 (14.3)	0
Gastrointestinal haemorrhage	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	1 (14.3)	1 (14.3)	0

Prior SCT therapy: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	2 (28.6)	0	2 (28.6)
Candida sepsis	1 (14.3)	0	1 (14.3)
Pneumonia	1 (14.3)	0	1 (14.3)
Pneumonia fungal	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	1 (14.3)	0	1 (14.3)
Hypernatraemia	1 (14.3)	0	1 (14.3)
Nervous system disorders			
-Total	1 (14.3)	1 (14.3)	0
Headache	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	1 (14.3)	0	1 (14.3)
Acute kidney injury	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (42.9)	0	3 (42.9)

Prior SCT therapy: No

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (28.6)	2 (28.6)	0
Aspiration	1 (14.3)	0	1 (14.3)
Pulmonary oedema	1 (14.3)	0	1 (14.3)
Respiratory distress	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)
Vascular disorders			
-Total	2 (28.6)	0	2 (28.6)
Hypotension	2 (28.6)	0	2 (28.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182m
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (25.0)	0	1 (25.0)
General disorders and administration site conditions			
-Total	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	1 (25.0)	0	1 (25.0)
Pneumonia	1 (25.0)	0	1 (25.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	0	1 (25.0)
Aspiration	1 (25.0)	0	1 (25.0)

Eligibility for SCT: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	1 (25.0)	1 (25.0)	0
Vascular disorders			
-Total	1 (25.0)	0	1 (25.0)
Hypotension	1 (25.0)	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182m
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	6 (85.7)
Blood and lymphatic system disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Neutropenia	1 (14.3)	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	1 (14.3)
Cardiac disorders			
-Total	1 (14.3)	0	1 (14.3)
Cardiovascular insufficiency	1 (14.3)	0	1 (14.3)
Gastrointestinal disorders			
-Total	3 (42.9)	3 (42.9)	0
Colitis	2 (28.6)	2 (28.6)	0

Eligibility for SCT: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (14.3)	1 (14.3)	0
Ascites	1 (14.3)	1 (14.3)	0
Gastrointestinal haemorrhage	1 (14.3)	1 (14.3)	0
Stomatitis	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	4 (57.1)	0	3 (42.9)
Multiple organ dysfunction syndrome	3 (42.9)	0	3 (42.9)
Chills	1 (14.3)	0	0
Pyrexia	1 (14.3)	0	0
Hepatobiliary disorders			
-Total	1 (14.3)	0	1 (14.3)
Hepatic failure	1 (14.3)	0	1 (14.3)
Infections and infestations			
-Total	5 (71.4)	0	5 (71.4)
Klebsiella sepsis	2 (28.6)	0	2 (28.6)
Bronchitis	1 (14.3)	0	0
Candida sepsis	1 (14.3)	0	1 (14.3)

Eligibility for SCT: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (14.3)	1 (14.3)	0
Sepsis	1 (14.3)	0	1 (14.3)
Staphylococcal bacteraemia	1 (14.3)	1 (14.3)	0
Staphylococcal infection	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
-Total	1 (14.3)	0	1 (14.3)
Hypernatraemia	1 (14.3)	0	1 (14.3)
Nervous system disorders			
-Total	1 (14.3)	1 (14.3)	0
Headache	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	1 (14.3)	0	1 (14.3)
Acute kidney injury	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (28.6)	0	2 (28.6)
Hypoxia	1 (14.3)	1 (14.3)	0
Pulmonary oedema	1 (14.3)	0	1 (14.3)

Eligibility for SCT: No

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory distress	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)
Vascular disorders			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Hypotension	3 (42.9)	2 (28.6)	1 (14.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182n
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: Low

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Blood and lymphatic system disorders			
-Total	1 (50.0)	1 (50.0)	0
Febrile neutropenia	1 (50.0)	1 (50.0)	0
Gastrointestinal disorders			
-Total	1 (50.0)	1 (50.0)	0
Abdominal pain	1 (50.0)	1 (50.0)	0
Ascites	1 (50.0)	1 (50.0)	0
Colitis	1 (50.0)	1 (50.0)	0
Stomatitis	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	1 (50.0)	0	1 (50.0)

Baseline bone marrow tumor burden: Low

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	1 (50.0)	0	1 (50.0)
Hepatobiliary disorders			
-Total	1 (50.0)	0	1 (50.0)
Hepatic failure	1 (50.0)	0	1 (50.0)
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)
Bronchitis	1 (50.0)	0	0
Staphylococcal bacteraemia	1 (50.0)	1 (50.0)	0
Staphylococcal infection	1 (50.0)	0	1 (50.0)
Nervous system disorders			
-Total	1 (50.0)	1 (50.0)	0
Headache	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Hypoxia	1 (50.0)	1 (50.0)	0
Respiratory distress	1 (50.0)	0	1 (50.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182n
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: High

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (55.6)	0	5 (55.6)
Blood and lymphatic system disorders			
-Total	1 (11.1)	0	1 (11.1)
Febrile neutropenia	1 (11.1)	1 (11.1)	0
Neutropenia	1 (11.1)	0	1 (11.1)
Thrombocytopenia	1 (11.1)	0	1 (11.1)
Cardiac disorders			
-Total	1 (11.1)	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	1 (11.1)
Gastrointestinal disorders			
-Total	2 (22.2)	2 (22.2)	0
Colitis	1 (11.1)	1 (11.1)	0

Baseline bone marrow tumor burden: High

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			
-Total	4 (44.4)	1 (11.1)	2 (22.2)
Multiple organ dysfunction syndrome	2 (22.2)	0	2 (22.2)
Pyrexia	2 (22.2)	1 (11.1)	0
Chills	1 (11.1)	0	0
Infections and infestations			
-Total	5 (55.6)	0	5 (55.6)
Klebsiella sepsis	2 (22.2)	0	2 (22.2)
Candida sepsis	1 (11.1)	0	1 (11.1)
Pneumonia	1 (11.1)	0	1 (11.1)
Pneumonia fungal	1 (11.1)	1 (11.1)	0
Sepsis	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			
-Total	1 (11.1)	0	1 (11.1)
Hypernatraemia	1 (11.1)	0	1 (11.1)
Renal and urinary disorders			
-Total	1 (11.1)	0	1 (11.1)

Baseline bone marrow tumor burden: High

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (11.1)	0	1 (11.1)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (22.2)	0	2 (22.2)
Aspiration	1 (11.1)	0	1 (11.1)
Hypoxia	1 (11.1)	1 (11.1)	0
Pulmonary oedema	1 (11.1)	0	1 (11.1)
Respiratory failure	1 (11.1)	0	1 (11.1)
Vascular disorders			
-Total	4 (44.4)	2 (22.2)	2 (22.2)
Hypotension	4 (44.4)	2 (22.2)	2 (22.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182o
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set – non – infused patients

Baseline extramedullary disease presence: No

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (77.8)	0	7 (77.8)
Blood and lymphatic system disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Febrile neutropenia	2 (22.2)	2 (22.2)	0
Neutropenia	1 (11.1)	0	1 (11.1)
Thrombocytopenia	1 (11.1)	0	1 (11.1)
Cardiac disorders			
-Total	1 (11.1)	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	1 (11.1)
Gastrointestinal disorders			
-Total	3 (33.3)	3 (33.3)	0
Colitis	2 (22.2)	2 (22.2)	0

Baseline extramedullary disease presence: No

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (11.1)	1 (11.1)	0
Ascites	1 (11.1)	1 (11.1)	0
Gastrointestinal haemorrhage	1 (11.1)	1 (11.1)	0
Stomatitis	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			
-Total	5 (55.6)	1 (11.1)	3 (33.3)
Multiple organ dysfunction syndrome	3 (33.3)	0	3 (33.3)
Pyrexia	2 (22.2)	1 (11.1)	0
Chills	1 (11.1)	0	0
Hepatobiliary disorders			
-Total	1 (11.1)	0	1 (11.1)
Hepatic failure	1 (11.1)	0	1 (11.1)
Infections and infestations			
-Total	6 (66.7)	0	6 (66.7)
Klebsiella sepsis	2 (22.2)	0	2 (22.2)
Bronchitis	1 (11.1)	0	0
Candida sepsis	1 (11.1)	0	1 (11.1)
Pneumonia	1 (11.1)	0	1 (11.1)

Baseline extramedullary disease presence: No

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (11.1)	1 (11.1)	0
Sepsis	1 (11.1)	0	1 (11.1)
Staphylococcal bacteraemia	1 (11.1)	1 (11.1)	0
Staphylococcal infection	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			
-Total	1 (11.1)	0	1 (11.1)
Hypernatraemia	1 (11.1)	0	1 (11.1)
Nervous system disorders			
-Total	1 (11.1)	1 (11.1)	0
Headache	1 (11.1)	1 (11.1)	0
Renal and urinary disorders			
-Total	1 (11.1)	0	1 (11.1)
Acute kidney injury	1 (11.1)	0	1 (11.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (33.3)	0	3 (33.3)
Hypoxia	2 (22.2)	2 (22.2)	0
Aspiration	1 (11.1)	0	1 (11.1)
Pulmonary oedema	1 (11.1)	0	1 (11.1)

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory distress	1 (11.1)	0	1 (11.1)
Respiratory failure	1 (11.1)	0	1 (11.1)
Vascular disorders			
-Total	4 (44.4)	2 (22.2)	2 (22.2)
Hypotension	4 (44.4)	2 (22.2)	2 (22.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182p
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (63.6)	0	7 (63.6)
Blood and lymphatic system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
-Total	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	3 (27.3)	3 (27.3)	0
Colitis	2 (18.2)	2 (18.2)	0

Down syndrome: No

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Abdominal pain	1 (9.1)	1 (9.1)	0
Ascites	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	5 (45.5)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Pyrexia	2 (18.2)	1 (9.1)	0
Chills	1 (9.1)	0	0
Hepatobiliary disorders			
-Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	6 (54.5)	0	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Bronchitis	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	1 (9.1)

Down syndrome: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (9.1)	0	1 (9.1)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	1 (9.1)	0	1 (9.1)
Hypernatraemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (27.3)	0	3 (27.3)
Hypoxia	2 (18.2)	2 (18.2)	0

Down syndrome: No

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspiration	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
-Total	4 (36.4)	2 (18.2)	2 (18.2)
Hypotension	4 (36.4)	2 (18.2)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182q
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set – non – infused patients

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (63.6)	0	7 (63.6)
Blood and lymphatic system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	1 (9.1)	0	1 (9.1)
Thrombocytopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
-Total	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	3 (27.3)	3 (27.3)	0
Colitis	2 (18.2)	2 (18.2)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (9.1)	1 (9.1)	0
Ascites	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	5 (45.5)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Pyrexia	2 (18.2)	1 (9.1)	0
Chills	1 (9.1)	0	0
Hepatobiliary disorders			
-Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	6 (54.5)	0	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Bronchitis	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	1 (9.1)
Pneumonia	1 (9.1)	0	1 (9.1)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	1 (9.1)	0	1 (9.1)
Hypernatraemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (27.3)	0	3 (27.3)
Hypoxia	2 (18.2)	2 (18.2)	0
Aspiration	1 (9.1)	0	1 (9.1)
Pulmonary oedema	1 (9.1)	0	1 (9.1)

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
-Total	4 (36.4)	2 (18.2)	2 (18.2)
Hypotension	4 (36.4)	2 (18.2)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182r
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 0

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
General disorders and administration site conditions			
-Total	1 (100)	1 (100)	0
Pyrexia	1 (100)	1 (100)	0
Infections and infestations			
-Total	1 (100)	0	1 (100)
Pneumonia	1 (100)	0	1 (100)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (100)	0	1 (100)
Aspiration	1 (100)	0	1 (100)

Number of previous relapses: 0

Group term Preferred term	All patients N=1 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	1 (100)	1 (100)	0
Vascular disorders			
-Total	1 (100)	0	1 (100)
Hypotension	1 (100)	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182r
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 1

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (33.3)	0	1 (33.3)
Nervous system disorders			
-Total	1 (33.3)	1 (33.3)	0
Headache	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Hypoxia	1 (33.3)	1 (33.3)	0
Respiratory distress	1 (33.3)	0	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182r
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 2

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (33.3)	0	1 (33.3)
Blood and lymphatic system disorders			
-Total	1 (33.3)	0	1 (33.3)
Febrile neutropenia	1 (33.3)	1 (33.3)	0
Neutropenia	1 (33.3)	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	1 (33.3)
Gastrointestinal disorders			
-Total	1 (33.3)	1 (33.3)	0
Gastrointestinal haemorrhage	1 (33.3)	1 (33.3)	0
Infections and infestations			
-Total	1 (33.3)	0	1 (33.3)

Number of previous relapses: 2

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida sepsis	1 (33.3)	0	1 (33.3)
Pneumonia fungal	1 (33.3)	1 (33.3)	0
Metabolism and nutrition disorders			
-Total	1 (33.3)	0	1 (33.3)
Hypernatraemia	1 (33.3)	0	1 (33.3)
Renal and urinary disorders			
-Total	1 (33.3)	0	1 (33.3)
Acute kidney injury	1 (33.3)	0	1 (33.3)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	1 (33.3)
Respiratory failure	1 (33.3)	0	1 (33.3)
Vascular disorders			
-Total	1 (33.3)	0	1 (33.3)
Hypotension	1 (33.3)	0	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 182r
Serious adverse events by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: >=3

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	4 (100)
Blood and lymphatic system disorders			
-Total	1 (25.0)	1 (25.0)	0
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Cardiac disorders			
-Total	1 (25.0)	0	1 (25.0)
Cardiovascular insufficiency	1 (25.0)	0	1 (25.0)
Gastrointestinal disorders			
-Total	2 (50.0)	2 (50.0)	0
Colitis	2 (50.0)	2 (50.0)	0
Abdominal pain	1 (25.0)	1 (25.0)	0

Number of previous relapses: >=3

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	1 (25.0)	1 (25.0)	0
Stomatitis	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
-Total	4 (100)	0	3 (75.0)
Multiple organ dysfunction syndrome	3 (75.0)	0	3 (75.0)
Chills	1 (25.0)	0	0
Pyrexia	1 (25.0)	0	0
Hepatobiliary disorders			
-Total	1 (25.0)	0	1 (25.0)
Hepatic failure	1 (25.0)	0	1 (25.0)
Infections and infestations			
-Total	4 (100)	0	4 (100)
Klebsiella sepsis	2 (50.0)	0	2 (50.0)
Bronchitis	1 (25.0)	0	0
Sepsis	1 (25.0)	0	1 (25.0)
Staphylococcal bacteraemia	1 (25.0)	1 (25.0)	0
Staphylococcal infection	1 (25.0)	0	1 (25.0)

Number of previous relapses: >=3

Group term Preferred term	All patients N=4 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Vascular disorders			
-Total	2 (50.0)	2 (50.0)	0
Hypotension	2 (50.0)	2 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183a
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (86.4)	9 (40.9)	8 (36.4)
Blood and lymphatic system disorders			
-Total	10 (45.5)	10 (45.5)	0
Febrile neutropenia	10 (45.5)	10 (45.5)	0
Cardiac disorders			
-Total	1 (4.5)	0	0
Atrioventricular block second degree	1 (4.5)	0	0
Gastrointestinal disorders			
-Total	3 (13.6)	3 (13.6)	0
Colitis	1 (4.5)	1 (4.5)	0
Enterocolitis	1 (4.5)	1 (4.5)	0
Pancreatitis	1 (4.5)	1 (4.5)	0

Age: <10 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	3 (13.6)	0	0
Pyrexia	3 (13.6)	0	0
Hepatobiliary disorders			
-Total	1 (4.5)	1 (4.5)	0
Cholecystitis	1 (4.5)	1 (4.5)	0
Immune system disorders			
-Total	12 (54.5)	3 (13.6)	2 (9.1)
Cytokine release syndrome	12 (54.5)	3 (13.6)	2 (9.1)
Infections and infestations			
-Total	9 (40.9)	6 (27.3)	2 (9.1)
Clostridium difficile infection	3 (13.6)	1 (4.5)	0
Respiratory syncytial virus infection	2 (9.1)	1 (4.5)	0
Bacteraemia	1 (4.5)	1 (4.5)	0
Bronchopulmonary aspergillosis	1 (4.5)	1 (4.5)	0
Campylobacter infection	1 (4.5)	1 (4.5)	0
Catheter site infection	1 (4.5)	1 (4.5)	0

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Corona virus infection	1 (4.5)	1 (4.5)	0
Device related infection	1 (4.5)	1 (4.5)	0
Enterovirus infection	1 (4.5)	1 (4.5)	0
Parainfluenzae virus infection	1 (4.5)	1 (4.5)	0
Pneumonia	1 (4.5)	1 (4.5)	0
Respiratory tract infection	1 (4.5)	0	1 (4.5)
Respiratory tract infection viral	1 (4.5)	1 (4.5)	0
Rhinovirus infection	1 (4.5)	0	0
Rotavirus infection	1 (4.5)	1 (4.5)	0
Septic embolus	1 (4.5)	0	1 (4.5)
Streptococcal bacteraemia	1 (4.5)	1 (4.5)	0
Urinary tract infection	1 (4.5)	0	0
Vulvovaginal candidiasis	1 (4.5)	0	0
Metabolism and nutrition disorders			
-Total	1 (4.5)	1 (4.5)	0
Hypocalcaemia	1 (4.5)	0	0
Hypophosphataemia	1 (4.5)	1 (4.5)	0
Tumour lysis syndrome	1 (4.5)	1 (4.5)	0

Age: <10 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	1 (4.5)	0	0
Pain in extremity	1 (4.5)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (4.5)	0	1 (4.5)
Glioblastoma multiforme	1 (4.5)	0	1 (4.5)
Nervous system disorders			
-Total	3 (13.6)	2 (9.1)	1 (4.5)
Seizure	2 (9.1)	2 (9.1)	0
Embolic stroke	1 (4.5)	0	1 (4.5)
Renal and urinary disorders			
-Total	1 (4.5)	1 (4.5)	0
Acute kidney injury	1 (4.5)	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (18.2)	2 (9.1)	2 (9.1)
Epistaxis	1 (4.5)	1 (4.5)	0

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	1 (4.5)	1 (4.5)	0
Idiopathic pneumonia syndrome	1 (4.5)	0	1 (4.5)
Pleural effusion	1 (4.5)	1 (4.5)	0
Respiratory failure	1 (4.5)	0	1 (4.5)
Vascular disorders			
-Total	3 (13.6)	2 (9.1)	1 (4.5)
Hypotension	2 (9.1)	1 (4.5)	1 (4.5)
Embolism	1 (4.5)	1 (4.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183a
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (82.1)	15 (38.5)	16 (41.0)
Blood and lymphatic system disorders			
-Total	24 (61.5)	19 (48.7)	5 (12.8)
Febrile neutropenia	21 (53.8)	20 (51.3)	1 (2.6)
Neutropenia	3 (7.7)	0	3 (7.7)
Disseminated intravascular coagulation	2 (5.1)	0	0
Pancytopenia	2 (5.1)	1 (2.6)	1 (2.6)
Eosinophilia	1 (2.6)	1 (2.6)	0
Cardiac disorders			
-Total	1 (2.6)	0	0
Ventricular tachycardia	1 (2.6)	0	0

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders			
-Total	1 (2.6)	0	0
Vision blurred	1 (2.6)	0	0
Gastrointestinal disorders			
-Total	9 (23.1)	6 (15.4)	0
Abdominal pain	3 (7.7)	2 (5.1)	0
Stomatitis	3 (7.7)	2 (5.1)	0
Colitis	2 (5.1)	2 (5.1)	0
Diarrhoea	2 (5.1)	0	0
Ascites	1 (2.6)	1 (2.6)	0
Vomiting	1 (2.6)	1 (2.6)	0
General disorders and administration site conditions			
-Total	8 (20.5)	2 (5.1)	2 (5.1)
Pyrexia	4 (10.3)	1 (2.6)	0
Multiple organ dysfunction syndrome	2 (5.1)	0	2 (5.1)
Malaise	1 (2.6)	0	0
Physical deconditioning	1 (2.6)	1 (2.6)	0

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders			
-Total	1 (2.6)	0	1 (2.6)
Hepatic failure	1 (2.6)	0	1 (2.6)
Immune system disorders			
-Total	23 (59.0)	5 (12.8)	5 (12.8)
Cytokine release syndrome	23 (59.0)	5 (12.8)	5 (12.8)
Graft versus host disease in gastrointestinal tract	1 (2.6)	0	0
Infections and infestations			
-Total	15 (38.5)	10 (25.6)	3 (7.7)
Clostridium difficile colitis	2 (5.1)	0	0
Device related infection	2 (5.1)	2 (5.1)	0
Pneumonia	2 (5.1)	0	0
Staphylococcal bacteraemia	2 (5.1)	2 (5.1)	0
Staphylococcal infection	2 (5.1)	1 (2.6)	1 (2.6)
Bronchitis	1 (2.6)	0	0
Candida sepsis	1 (2.6)	0	1 (2.6)
Cellulitis	1 (2.6)	1 (2.6)	0

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (2.6)	1 (2.6)	0
Escherichia bacteraemia	1 (2.6)	1 (2.6)	0
Escherichia urinary tract infection	1 (2.6)	1 (2.6)	0
Gastroenteritis	1 (2.6)	1 (2.6)	0
Gastroenteritis norovirus	1 (2.6)	0	0
Herpes zoster	1 (2.6)	1 (2.6)	0
Parainfluenzae virus infection	1 (2.6)	0	0
Respiratory syncytial virus bronchitis	1 (2.6)	1 (2.6)	0
Sepsis	1 (2.6)	0	1 (2.6)
Upper respiratory tract infection	1 (2.6)	1 (2.6)	0
Urinary tract infection	1 (2.6)	1 (2.6)	0
Vascular device infection	1 (2.6)	1 (2.6)	0
Viral upper respiratory tract infection	1 (2.6)	1 (2.6)	0
Injury, poisoning and procedural complications			
-Total	3 (7.7)	2 (5.1)	1 (2.6)
Extradural haematoma	1 (2.6)	1 (2.6)	0
Procedural pain	1 (2.6)	1 (2.6)	0

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Subdural haematoma	1 (2.6)	1 (2.6)	0
Transfusion related complication	1 (2.6)	0	1 (2.6)
Investigations			
-Total	3 (7.7)	2 (5.1)	1 (2.6)
Alanine aminotransferase increased	1 (2.6)	1 (2.6)	0
Electrocardiogram qt prolonged	1 (2.6)	1 (2.6)	0
White blood cell count decreased	1 (2.6)	0	1 (2.6)
Metabolism and nutrition disorders			
-Total	5 (12.8)	3 (7.7)	1 (2.6)
Acidosis	1 (2.6)	0	0
Decreased appetite	1 (2.6)	1 (2.6)	0
Dehydration	1 (2.6)	1 (2.6)	0
Hypernatraemia	1 (2.6)	0	1 (2.6)
Malnutrition	1 (2.6)	0	0
Tumour lysis syndrome	1 (2.6)	1 (2.6)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (7.7)	1 (2.6)	0

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	1 (2.6)	1 (2.6)	0
Flank pain	1 (2.6)	0	0
Osteonecrosis	1 (2.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.6)	0	0
Myelodysplastic syndrome	1 (2.6)	0	0
Nervous system disorders			
-Total	7 (17.9)	3 (7.7)	0
Encephalopathy	4 (10.3)	2 (5.1)	0
Headache	2 (5.1)	2 (5.1)	0
Seizure	2 (5.1)	0	0
Psychiatric disorders			
-Total	2 (5.1)	1 (2.6)	0
Delirium	1 (2.6)	0	0
Mental status changes	1 (2.6)	1 (2.6)	0
Renal and urinary disorders			
-Total	4 (10.3)	2 (5.1)	2 (5.1)

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	3 (7.7)	2 (5.1)	1 (2.6)
Renal failure	1 (2.6)	0	1 (2.6)
Reproductive system and breast disorders			
-Total	1 (2.6)	0	0
Scrotal pain	1 (2.6)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	8 (20.5)	1 (2.6)	4 (10.3)
Hypoxia	3 (7.7)	0	0
Pulmonary oedema	3 (7.7)	1 (2.6)	2 (5.1)
Respiratory failure	3 (7.7)	0	3 (7.7)
Acute respiratory failure	1 (2.6)	0	1 (2.6)
Pulmonary mass	1 (2.6)	0	0
Skin and subcutaneous tissue disorders			
-Total	1 (2.6)	1 (2.6)	0
Ecchymosis	1 (2.6)	1 (2.6)	0
Vascular disorders			

Age: >=10 years to <18 years

Group term Preferred term	All patients N=39 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	8 (20.5)	5 (12.8)	3 (7.7)
Hypotension	8 (20.5)	5 (12.8)	3 (7.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183a
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (92.9)	3 (21.4)	9 (64.3)
Blood and lymphatic system disorders			
-Total	3 (21.4)	2 (14.3)	1 (7.1)
Febrile neutropenia	2 (14.3)	2 (14.3)	0
Pancytopenia	1 (7.1)	0	1 (7.1)
Cardiac disorders			
-Total	1 (7.1)	0	1 (7.1)
Cardiovascular insufficiency	1 (7.1)	0	1 (7.1)
Eye disorders			
-Total	1 (7.1)	0	0
Papilloedema	1 (7.1)	0	0

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastrointestinal disorders			
-Total	1 (7.1)	1 (7.1)	0
Intestinal obstruction	1 (7.1)	1 (7.1)	0
General disorders and administration site conditions			
-Total	5 (35.7)	2 (14.3)	1 (7.1)
Pyrexia	3 (21.4)	1 (7.1)	0
Multiple organ dysfunction syndrome	1 (7.1)	0	1 (7.1)
Physical deconditioning	1 (7.1)	1 (7.1)	0
Hepatobiliary disorders			
-Total	1 (7.1)	1 (7.1)	0
Hyperbilirubinaemia	1 (7.1)	1 (7.1)	0
Immune system disorders			
-Total	6 (42.9)	0	3 (21.4)
Cytokine release syndrome	6 (42.9)	0	3 (21.4)
Infections and infestations			
-Total	7 (50.0)	2 (14.3)	5 (35.7)
Abscess limb	1 (7.1)	1 (7.1)	0

Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	1 (7.1)	0	1 (7.1)
Cholecystitis infective	1 (7.1)	1 (7.1)	0
Escherichia sepsis	1 (7.1)	0	1 (7.1)
Klebsiella sepsis	1 (7.1)	0	1 (7.1)
Necrotising fasciitis	1 (7.1)	1 (7.1)	0
Pneumonia	1 (7.1)	0	1 (7.1)
Pneumonia fungal	1 (7.1)	0	0
Sepsis	1 (7.1)	0	1 (7.1)
Staphylococcal scalded skin syndrome	1 (7.1)	0	0
Staphylococcal sepsis	1 (7.1)	0	1 (7.1)
Injury, poisoning and procedural complications			
-Total	1 (7.1)	0	0
Subdural haematoma	1 (7.1)	0	0
Investigations			
-Total	1 (7.1)	1 (7.1)	0
Transaminases increased	1 (7.1)	1 (7.1)	0
Metabolism and nutrition disorders			

Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (7.1)	0	0
Hypocalcaemia	1 (7.1)	0	0
Musculoskeletal and connective tissue disorders			
-Total	1 (7.1)	1 (7.1)	0
Myopathy	1 (7.1)	1 (7.1)	0
Myositis	1 (7.1)	1 (7.1)	0
Nervous system disorders			
-Total	2 (14.3)	1 (7.1)	0
Headache	1 (7.1)	1 (7.1)	0
Idiopathic intracranial hypertension	1 (7.1)	0	0
Renal and urinary disorders			
-Total	2 (14.3)	0	1 (7.1)
Acute kidney injury	2 (14.3)	0	1 (7.1)
Reproductive system and breast disorders			
-Total	1 (7.1)	1 (7.1)	0
Vaginal haemorrhage	1 (7.1)	1 (7.1)	0

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (28.6)	0	3 (21.4)
Hypoxia	2 (14.3)	1 (7.1)	1 (7.1)
Aspiration	1 (7.1)	0	1 (7.1)
Pleural effusion	1 (7.1)	0	0
Respiratory distress	1 (7.1)	0	1 (7.1)
Vascular disorders			
-Total	1 (7.1)	0	1 (7.1)
Hypotension	1 (7.1)	0	1 (7.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183b
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (80.0)	15 (37.5)	15 (37.5)
Blood and lymphatic system disorders			
-Total	17 (42.5)	15 (37.5)	2 (5.0)
Febrile neutropenia	15 (37.5)	15 (37.5)	0
Neutropenia	2 (5.0)	0	2 (5.0)
Disseminated intravascular coagulation	1 (2.5)	0	0
Eosinophilia	1 (2.5)	1 (2.5)	0
Pancytopenia	1 (2.5)	1 (2.5)	0
Cardiac disorders			
-Total	1 (2.5)	0	1 (2.5)
Cardiovascular insufficiency	1 (2.5)	0	1 (2.5)

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	7 (17.5)	4 (10.0)	0
Abdominal pain	2 (5.0)	1 (2.5)	0
Colitis	2 (5.0)	2 (5.0)	0
Diarrhoea	2 (5.0)	0	0
Stomatitis	2 (5.0)	1 (2.5)	0
Ascites	1 (2.5)	1 (2.5)	0
Enterocolitis	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	8 (20.0)	1 (2.5)	3 (7.5)
Pyrexia	4 (10.0)	1 (2.5)	0
Multiple organ dysfunction syndrome	3 (7.5)	0	3 (7.5)
Malaise	1 (2.5)	0	0
Hepatobiliary disorders			
-Total	1 (2.5)	0	1 (2.5)
Hepatic failure	1 (2.5)	0	1 (2.5)
Immune system disorders			

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	19 (47.5)	3 (7.5)	5 (12.5)
Cytokine release syndrome	19 (47.5)	3 (7.5)	5 (12.5)
Infections and infestations			
-Total	11 (27.5)	5 (12.5)	5 (12.5)
Respiratory syncytial virus infection	2 (5.0)	1 (2.5)	0
Bronchitis	1 (2.5)	0	0
Candida sepsis	1 (2.5)	0	1 (2.5)
Cellulitis of male external genital organ	1 (2.5)	1 (2.5)	0
Cholecystitis infective	1 (2.5)	1 (2.5)	0
Clostridium difficile infection	1 (2.5)	0	0
Corona virus infection	1 (2.5)	1 (2.5)	0
Device related infection	1 (2.5)	1 (2.5)	0
Gastroenteritis	1 (2.5)	1 (2.5)	0
Herpes zoster	1 (2.5)	1 (2.5)	0
Klebsiella sepsis	1 (2.5)	0	1 (2.5)
Pneumonia	1 (2.5)	0	1 (2.5)
Sepsis	1 (2.5)	0	1 (2.5)

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Staphylococcal bacteraemia	1 (2.5)	1 (2.5)	0
Staphylococcal infection	1 (2.5)	0	1 (2.5)
Urinary tract infection	1 (2.5)	1 (2.5)	0
Viral upper respiratory tract infection	1 (2.5)	1 (2.5)	0
Injury, poisoning and procedural complications			
-Total	1 (2.5)	1 (2.5)	0
Extradural haematoma	1 (2.5)	1 (2.5)	0
Subdural haematoma	1 (2.5)	1 (2.5)	0
Investigations			
-Total	2 (5.0)	1 (2.5)	1 (2.5)
Electrocardiogram qt prolonged	1 (2.5)	1 (2.5)	0
White blood cell count decreased	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			
-Total	3 (7.5)	1 (2.5)	1 (2.5)
Dehydration	1 (2.5)	1 (2.5)	0
Hypernatraemia	1 (2.5)	0	1 (2.5)
Malnutrition	1 (2.5)	0	0

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal and connective tissue disorders			
-Total	1 (2.5)	0	0
Osteonecrosis	1 (2.5)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.5)	0	1 (2.5)
Glioblastoma multiforme	1 (2.5)	0	1 (2.5)
Nervous system disorders			
-Total	6 (15.0)	4 (10.0)	0
Headache	3 (7.5)	3 (7.5)	0
Encephalopathy	2 (5.0)	1 (2.5)	0
Seizure	2 (5.0)	1 (2.5)	0
Psychiatric disorders			
-Total	1 (2.5)	1 (2.5)	0
Mental status changes	1 (2.5)	1 (2.5)	0
Renal and urinary disorders			
-Total	1 (2.5)	0	1 (2.5)
Acute kidney injury	1 (2.5)	0	1 (2.5)

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders			
-Total	1 (2.5)	0	0
Scrotal pain	1 (2.5)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (17.5)	2 (5.0)	3 (7.5)
Hypoxia	3 (7.5)	1 (2.5)	0
Pulmonary oedema	2 (5.0)	1 (2.5)	1 (2.5)
Aspiration	1 (2.5)	0	1 (2.5)
Epistaxis	1 (2.5)	1 (2.5)	0
Respiratory distress	1 (2.5)	0	1 (2.5)
Respiratory failure	1 (2.5)	0	1 (2.5)
Vascular disorders			
-Total	7 (17.5)	5 (12.5)	2 (5.0)
Hypotension	7 (17.5)	5 (12.5)	2 (5.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183b
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (91.4)	12 (34.3)	18 (51.4)
Blood and lymphatic system disorders			
-Total	20 (57.1)	16 (45.7)	4 (11.4)
Febrile neutropenia	18 (51.4)	17 (48.6)	1 (2.9)
Pancytopenia	2 (5.7)	0	2 (5.7)
Disseminated intravascular coagulation	1 (2.9)	0	0
Neutropenia	1 (2.9)	0	1 (2.9)
Cardiac disorders			
-Total	2 (5.7)	0	0
Atrioventricular block second degree	1 (2.9)	0	0
Ventricular tachycardia	1 (2.9)	0	0

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Eye disorders			
-Total	2 (5.7)	0	0
Papilloedema	1 (2.9)	0	0
Vision blurred	1 (2.9)	0	0
Gastrointestinal disorders			
-Total	6 (17.1)	6 (17.1)	0
Abdominal pain	1 (2.9)	1 (2.9)	0
Colitis	1 (2.9)	1 (2.9)	0
Intestinal obstruction	1 (2.9)	1 (2.9)	0
Pancreatitis	1 (2.9)	1 (2.9)	0
Stomatitis	1 (2.9)	1 (2.9)	0
Vomiting	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			
-Total	8 (22.9)	3 (8.6)	0
Pyrexia	6 (17.1)	1 (2.9)	0
Physical deconditioning	2 (5.7)	2 (5.7)	0
Hepatobiliary disorders			

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (5.7)	2 (5.7)	0
Cholecystitis	1 (2.9)	1 (2.9)	0
Hyperbilirubinaemia	1 (2.9)	1 (2.9)	0
Immune system disorders			
-Total	22 (62.9)	5 (14.3)	5 (14.3)
Cytokine release syndrome	22 (62.9)	5 (14.3)	5 (14.3)
Graft versus host disease in gastrointestinal tract	1 (2.9)	0	0
Infections and infestations			
-Total	20 (57.1)	13 (37.1)	5 (14.3)
Pneumonia	3 (8.6)	1 (2.9)	0
Clostridium difficile colitis	2 (5.7)	0	0
Clostridium difficile infection	2 (5.7)	1 (2.9)	0
Device related infection	2 (5.7)	2 (5.7)	0
Parainfluenzae virus infection	2 (5.7)	1 (2.9)	0
Abscess limb	1 (2.9)	1 (2.9)	0
Bacteraemia	1 (2.9)	1 (2.9)	0
Bacterial sepsis	1 (2.9)	0	1 (2.9)

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Bronchopulmonary aspergillosis	1 (2.9)	1 (2.9)	0
Campylobacter infection	1 (2.9)	1 (2.9)	0
Catheter site infection	1 (2.9)	1 (2.9)	0
Cellulitis	1 (2.9)	1 (2.9)	0
Enterovirus infection	1 (2.9)	1 (2.9)	0
Escherichia bacteraemia	1 (2.9)	1 (2.9)	0
Escherichia sepsis	1 (2.9)	0	1 (2.9)
Escherichia urinary tract infection	1 (2.9)	1 (2.9)	0
Gastroenteritis norovirus	1 (2.9)	0	0
Necrotising fasciitis	1 (2.9)	1 (2.9)	0
Pneumonia fungal	1 (2.9)	0	0
Respiratory syncytial virus bronchitis	1 (2.9)	1 (2.9)	0
Respiratory tract infection	1 (2.9)	0	1 (2.9)
Respiratory tract infection viral	1 (2.9)	1 (2.9)	0
Rhinovirus infection	1 (2.9)	0	0
Rotavirus infection	1 (2.9)	1 (2.9)	0
Sepsis	1 (2.9)	0	1 (2.9)
Septic embolus	1 (2.9)	0	1 (2.9)

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal bacteraemia	1 (2.9)	1 (2.9)	0
Staphylococcal infection	1 (2.9)	1 (2.9)	0
Staphylococcal scalded skin syndrome	1 (2.9)	0	0
Staphylococcal sepsis	1 (2.9)	0	1 (2.9)
Streptococcal bacteraemia	1 (2.9)	1 (2.9)	0
Upper respiratory tract infection	1 (2.9)	1 (2.9)	0
Urinary tract infection	1 (2.9)	0	0
Vascular device infection	1 (2.9)	1 (2.9)	0
Vulvovaginal candidiasis	1 (2.9)	0	0
Injury, poisoning and procedural complications			
-Total	3 (8.6)	1 (2.9)	1 (2.9)
Procedural pain	1 (2.9)	1 (2.9)	0
Subdural haematoma	1 (2.9)	0	0
Transfusion related complication	1 (2.9)	0	1 (2.9)
Investigations			
-Total	2 (5.7)	2 (5.7)	0
Alanine aminotransferase increased	1 (2.9)	1 (2.9)	0

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transaminases increased	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders			
-Total	4 (11.4)	3 (8.6)	0
Hypocalcaemia	2 (5.7)	0	0
Tumour lysis syndrome	2 (5.7)	2 (5.7)	0
Acidosis	1 (2.9)	0	0
Decreased appetite	1 (2.9)	1 (2.9)	0
Hypophosphataemia	1 (2.9)	1 (2.9)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (11.4)	2 (5.7)	0
Back pain	1 (2.9)	1 (2.9)	0
Flank pain	1 (2.9)	0	0
Myopathy	1 (2.9)	1 (2.9)	0
Myositis	1 (2.9)	1 (2.9)	0
Pain in extremity	1 (2.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.9)	0	0

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Myelodysplastic syndrome	1 (2.9)	0	0
Nervous system disorders			
-Total	6 (17.1)	2 (5.7)	1 (2.9)
Encephalopathy	2 (5.7)	1 (2.9)	0
Seizure	2 (5.7)	1 (2.9)	0
Embolic stroke	1 (2.9)	0	1 (2.9)
Idiopathic intracranial hypertension	1 (2.9)	0	0
Psychiatric disorders			
-Total	1 (2.9)	0	0
Delirium	1 (2.9)	0	0
Renal and urinary disorders			
-Total	6 (17.1)	3 (8.6)	2 (5.7)
Acute kidney injury	5 (14.3)	3 (8.6)	1 (2.9)
Renal failure	1 (2.9)	0	1 (2.9)
Reproductive system and breast disorders			
-Total	1 (2.9)	1 (2.9)	0
Vaginal haemorrhage	1 (2.9)	1 (2.9)	0

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (25.7)	1 (2.9)	6 (17.1)
Hypoxia	3 (8.6)	1 (2.9)	1 (2.9)
Respiratory failure	3 (8.6)	0	3 (8.6)
Pleural effusion	2 (5.7)	1 (2.9)	0
Acute respiratory failure	1 (2.9)	0	1 (2.9)
Idiopathic pneumonia syndrome	1 (2.9)	0	1 (2.9)
Pulmonary mass	1 (2.9)	0	0
Pulmonary oedema	1 (2.9)	0	1 (2.9)
Skin and subcutaneous tissue disorders			
-Total	1 (2.9)	1 (2.9)	0
Ecchymosis	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	5 (14.3)	2 (5.7)	3 (8.6)
Hypotension	4 (11.4)	1 (2.9)	3 (8.6)
Embolism	1 (2.9)	1 (2.9)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183c
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (85.0)	23 (38.3)	25 (41.7)
Blood and lymphatic system disorders			
-Total	29 (48.3)	26 (43.3)	3 (5.0)
Febrile neutropenia	26 (43.3)	26 (43.3)	0
Neutropenia	3 (5.0)	0	3 (5.0)
Disseminated intravascular coagulation	1 (1.7)	0	0
Eosinophilia	1 (1.7)	1 (1.7)	0
Pancytopenia	1 (1.7)	1 (1.7)	0
Eye disorders			
-Total	2 (3.3)	0	0
Papilloedema	1 (1.7)	0	0

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vision blurred	1 (1.7)	0	0
Gastrointestinal disorders			
-Total	10 (16.7)	8 (13.3)	0
Colitis	3 (5.0)	3 (5.0)	0
Abdominal pain	2 (3.3)	1 (1.7)	0
Stomatitis	2 (3.3)	1 (1.7)	0
Ascites	1 (1.7)	1 (1.7)	0
Diarrhoea	1 (1.7)	0	0
Enterocolitis	1 (1.7)	1 (1.7)	0
Intestinal obstruction	1 (1.7)	1 (1.7)	0
Pancreatitis	1 (1.7)	1 (1.7)	0
Vomiting	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	10 (16.7)	2 (3.3)	2 (3.3)
Pyrexia	8 (13.3)	2 (3.3)	0
Multiple organ dysfunction syndrome	2 (3.3)	0	2 (3.3)
Hepatobiliary disorders			

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (3.3)	1 (1.7)	1 (1.7)
Cholecystitis	1 (1.7)	1 (1.7)	0
Hepatic failure	1 (1.7)	0	1 (1.7)
Immune system disorders			
-Total	33 (55.0)	7 (11.7)	9 (15.0)
Cytokine release syndrome	33 (55.0)	7 (11.7)	9 (15.0)
Graft versus host disease in gastrointestinal tract	1 (1.7)	0	0
Infections and infestations			
-Total	24 (40.0)	14 (23.3)	7 (11.7)
Pneumonia	4 (6.7)	1 (1.7)	1 (1.7)
Clostridium difficile infection	3 (5.0)	1 (1.7)	0
Device related infection	2 (3.3)	2 (3.3)	0
Parainfluenzae virus infection	2 (3.3)	1 (1.7)	0
Respiratory syncytial virus infection	2 (3.3)	1 (1.7)	0
Staphylococcal bacteraemia	2 (3.3)	2 (3.3)	0
Staphylococcal infection	2 (3.3)	1 (1.7)	1 (1.7)
Urinary tract infection	2 (3.3)	1 (1.7)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	1 (1.7)	1 (1.7)	0
Bacterial sepsis	1 (1.7)	0	1 (1.7)
Bronchitis	1 (1.7)	0	0
Bronchopulmonary aspergillosis	1 (1.7)	1 (1.7)	0
Campylobacter infection	1 (1.7)	1 (1.7)	0
Candida sepsis	1 (1.7)	0	1 (1.7)
Catheter site infection	1 (1.7)	1 (1.7)	0
Cellulitis	1 (1.7)	1 (1.7)	0
Cellulitis of male external genital organ	1 (1.7)	1 (1.7)	0
Cholecystitis infective	1 (1.7)	1 (1.7)	0
Clostridium difficile colitis	1 (1.7)	0	0
Corona virus infection	1 (1.7)	1 (1.7)	0
Enterovirus infection	1 (1.7)	1 (1.7)	0
Escherichia bacteraemia	1 (1.7)	1 (1.7)	0
Escherichia sepsis	1 (1.7)	0	1 (1.7)
Gastroenteritis norovirus	1 (1.7)	0	0
Necrotising fasciitis	1 (1.7)	1 (1.7)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory syncytial virus bronchitis	1 (1.7)	1 (1.7)	0
Respiratory tract infection viral	1 (1.7)	1 (1.7)	0
Rhinovirus infection	1 (1.7)	0	0
Rotavirus infection	1 (1.7)	1 (1.7)	0
Sepsis	1 (1.7)	0	1 (1.7)
Septic embolus	1 (1.7)	0	1 (1.7)
Streptococcal bacteraemia	1 (1.7)	1 (1.7)	0
Upper respiratory tract infection	1 (1.7)	1 (1.7)	0
Viral upper respiratory tract infection	1 (1.7)	1 (1.7)	0
Vulvovaginal candidiasis	1 (1.7)	0	0
Injury, poisoning and procedural complications			
-Total	1 (1.7)	0	0
Subdural haematoma	1 (1.7)	0	0
Investigations			
-Total	3 (5.0)	2 (3.3)	1 (1.7)
Alanine aminotransferase increased	1 (1.7)	1 (1.7)	0
Electrocardiogram qt prolonged	1 (1.7)	1 (1.7)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	1 (1.7)	0	1 (1.7)
Metabolism and nutrition disorders			
-Total	4 (6.7)	2 (3.3)	1 (1.7)
Decreased appetite	1 (1.7)	1 (1.7)	0
Hypernatraemia	1 (1.7)	0	1 (1.7)
Hypocalcaemia	1 (1.7)	0	0
Hypophosphataemia	1 (1.7)	1 (1.7)	0
Malnutrition	1 (1.7)	0	0
Tumour lysis syndrome	1 (1.7)	1 (1.7)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (1.7)	0	0
Flank pain	1 (1.7)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.7)	0	1 (1.7)
Glioblastoma multiforme	1 (1.7)	0	1 (1.7)
Nervous system disorders			
-Total	8 (13.3)	4 (6.7)	1 (1.7)

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	3 (5.0)	2 (3.3)	0
Seizure	3 (5.0)	2 (3.3)	0
Embolic stroke	1 (1.7)	0	1 (1.7)
Headache	1 (1.7)	1 (1.7)	0
Idiopathic intracranial hypertension	1 (1.7)	0	0
Renal and urinary disorders			
-Total	5 (8.3)	2 (3.3)	3 (5.0)
Acute kidney injury	4 (6.7)	2 (3.3)	2 (3.3)
Renal failure	1 (1.7)	0	1 (1.7)
Reproductive system and breast disorders			
-Total	2 (3.3)	1 (1.7)	0
Scrotal pain	1 (1.7)	0	0
Vaginal haemorrhage	1 (1.7)	1 (1.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	13 (21.7)	2 (3.3)	7 (11.7)
Hypoxia	6 (10.0)	2 (3.3)	1 (1.7)
Respiratory failure	3 (5.0)	0	3 (5.0)

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pleural effusion	2 (3.3)	1 (1.7)	0
Acute respiratory failure	1 (1.7)	0	1 (1.7)
Aspiration	1 (1.7)	0	1 (1.7)
Epistaxis	1 (1.7)	1 (1.7)	0
Idiopathic pneumonia syndrome	1 (1.7)	0	1 (1.7)
Pulmonary mass	1 (1.7)	0	0
Pulmonary oedema	1 (1.7)	0	1 (1.7)
Vascular disorders			
-Total	9 (15.0)	5 (8.3)	4 (6.7)
Hypotension	9 (15.0)	5 (8.3)	4 (6.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183c
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (66.7)	2 (33.3)	1 (16.7)
Blood and lymphatic system disorders			
-Total	1 (16.7)	1 (16.7)	0
Febrile neutropenia	1 (16.7)	1 (16.7)	0
Cardiac disorders			
-Total	1 (16.7)	0	0
Atrioventricular block second degree	1 (16.7)	0	0
Gastrointestinal disorders			
-Total	1 (16.7)	0	0
Diarrhoea	1 (16.7)	0	0
General disorders and administration site conditions			

Race: Asian

Group term Preferred term	All patients N=6 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (33.3)	0	0
Pyrexia	2 (33.3)	0	0
Immune system disorders			
-Total	3 (50.0)	0	0
Cytokine release syndrome	3 (50.0)	0	0
Infections and infestations			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Gastroenteritis	1 (16.7)	1 (16.7)	0
Herpes zoster	1 (16.7)	1 (16.7)	0
Respiratory tract infection	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	1 (16.7)	1 (16.7)	0
Dehydration	1 (16.7)	1 (16.7)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (33.3)	0	0
Osteonecrosis	1 (16.7)	0	0
Pain in extremity	1 (16.7)	0	0

Race: Asian

Group term Preferred term	All patients N=6 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (16.7)	1 (16.7)	0
Pulmonary oedema	1 (16.7)	1 (16.7)	0
Vascular disorders			
-Total	1 (16.7)	1 (16.7)	0
Embolism	1 (16.7)	1 (16.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183c
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (100)	2 (22.2)	7 (77.8)
Blood and lymphatic system disorders			
-Total	7 (77.8)	4 (44.4)	3 (33.3)
Febrile neutropenia	6 (66.7)	5 (55.6)	1 (11.1)
Pancytopenia	2 (22.2)	0	2 (22.2)
Disseminated intravascular coagulation	1 (11.1)	0	0
Cardiac disorders			
-Total	2 (22.2)	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	1 (11.1)
Ventricular tachycardia	1 (11.1)	0	0

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastrointestinal disorders			
-Total	2 (22.2)	2 (22.2)	0
Abdominal pain	1 (11.1)	1 (11.1)	0
Stomatitis	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			
-Total	4 (44.4)	2 (22.2)	1 (11.1)
Physical deconditioning	2 (22.2)	2 (22.2)	0
Malaise	1 (11.1)	0	0
Multiple organ dysfunction syndrome	1 (11.1)	0	1 (11.1)
Hepatobiliary disorders			
-Total	1 (11.1)	1 (11.1)	0
Hyperbilirubinaemia	1 (11.1)	1 (11.1)	0
Immune system disorders			
-Total	5 (55.6)	1 (11.1)	1 (11.1)
Cytokine release syndrome	5 (55.6)	1 (11.1)	1 (11.1)
Infections and infestations			
-Total	5 (55.6)	3 (33.3)	2 (22.2)

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	1 (11.1)	1 (11.1)	0
Clostridium difficile colitis	1 (11.1)	0	0
Device related infection	1 (11.1)	1 (11.1)	0
Escherichia urinary tract infection	1 (11.1)	1 (11.1)	0
Klebsiella sepsis	1 (11.1)	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	0
Sepsis	1 (11.1)	0	1 (11.1)
Staphylococcal scalded skin syndrome	1 (11.1)	0	0
Staphylococcal sepsis	1 (11.1)	0	1 (11.1)
Vascular device infection	1 (11.1)	1 (11.1)	0
Injury, poisoning and procedural complications			
-Total	3 (33.3)	2 (22.2)	1 (11.1)
Extradural haematoma	1 (11.1)	1 (11.1)	0
Procedural pain	1 (11.1)	1 (11.1)	0
Subdural haematoma	1 (11.1)	1 (11.1)	0
Transfusion related complication	1 (11.1)	0	1 (11.1)
Investigations			

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (11.1)	1 (11.1)	0
Transaminases increased	1 (11.1)	1 (11.1)	0
Metabolism and nutrition disorders			
-Total	2 (22.2)	1 (11.1)	0
Acidosis	1 (11.1)	0	0
Hypocalcaemia	1 (11.1)	0	0
Tumour lysis syndrome	1 (11.1)	1 (11.1)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (22.2)	2 (22.2)	0
Back pain	1 (11.1)	1 (11.1)	0
Myopathy	1 (11.1)	1 (11.1)	0
Myositis	1 (11.1)	1 (11.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (11.1)	0	0
Myelodysplastic syndrome	1 (11.1)	0	0
Nervous system disorders			
-Total	4 (44.4)	2 (22.2)	0

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Headache	2 (22.2)	2 (22.2)	0
Encephalopathy	1 (11.1)	0	0
Seizure	1 (11.1)	0	0
Psychiatric disorders			
-Total	2 (22.2)	1 (11.1)	0
Delirium	1 (11.1)	0	0
Mental status changes	1 (11.1)	1 (11.1)	0
Renal and urinary disorders			
-Total	2 (22.2)	1 (11.1)	0
Acute kidney injury	2 (22.2)	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (22.2)	0	2 (22.2)
Pulmonary oedema	1 (11.1)	0	1 (11.1)
Respiratory distress	1 (11.1)	0	1 (11.1)
Respiratory failure	1 (11.1)	0	1 (11.1)
Skin and subcutaneous tissue disorders			
-Total	1 (11.1)	1 (11.1)	0

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Ecchymosis	1 (11.1)	1 (11.1)	0
Vascular disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Hypotension	2 (22.2)	1 (11.1)	1 (11.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183d
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (86.7)	13 (43.3)	12 (40.0)
Blood and lymphatic system disorders			
-Total	21 (70.0)	18 (60.0)	3 (10.0)
Febrile neutropenia	20 (66.7)	19 (63.3)	1 (3.3)
Disseminated intravascular coagulation	1 (3.3)	0	0
Eosinophilia	1 (3.3)	1 (3.3)	0
Neutropenia	1 (3.3)	0	1 (3.3)
Pancytopenia	1 (3.3)	0	1 (3.3)
Cardiac disorders			
-Total	2 (6.7)	0	1 (3.3)
Cardiovascular insufficiency	1 (3.3)	0	1 (3.3)

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ventricular tachycardia	1 (3.3)	0	0
Gastrointestinal disorders			
-Total	7 (23.3)	6 (20.0)	0
Abdominal pain	1 (3.3)	1 (3.3)	0
Colitis	1 (3.3)	1 (3.3)	0
Diarrhoea	1 (3.3)	0	0
Enterocolitis	1 (3.3)	1 (3.3)	0
Pancreatitis	1 (3.3)	1 (3.3)	0
Stomatitis	1 (3.3)	1 (3.3)	0
Vomiting	1 (3.3)	1 (3.3)	0
General disorders and administration site conditions			
-Total	8 (26.7)	1 (3.3)	1 (3.3)
Pyrexia	5 (16.7)	0	0
Malaise	1 (3.3)	0	0
Multiple organ dysfunction syndrome	1 (3.3)	0	1 (3.3)
Physical deconditioning	1 (3.3)	1 (3.3)	0
Hepatobiliary disorders			

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.3)	1 (3.3)	0
Cholecystitis	1 (3.3)	1 (3.3)	0
Immune system disorders			
-Total	16 (53.3)	3 (10.0)	3 (10.0)
Cytokine release syndrome	16 (53.3)	3 (10.0)	3 (10.0)
Graft versus host disease in gastrointestinal tract	1 (3.3)	0	0
Infections and infestations			
-Total	11 (36.7)	7 (23.3)	4 (13.3)
Bacteraemia	1 (3.3)	1 (3.3)	0
Candida sepsis	1 (3.3)	0	1 (3.3)
Cellulitis of male external genital organ	1 (3.3)	1 (3.3)	0
Corona virus infection	1 (3.3)	1 (3.3)	0
Device related infection	1 (3.3)	1 (3.3)	0
Escherichia bacteraemia	1 (3.3)	1 (3.3)	0
Escherichia sepsis	1 (3.3)	0	1 (3.3)
Escherichia urinary tract infection	1 (3.3)	1 (3.3)	0
Gastroenteritis norovirus	1 (3.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella sepsis	1 (3.3)	0	1 (3.3)
Parainfluenzae virus infection	1 (3.3)	0	0
Pneumonia	1 (3.3)	0	0
Respiratory syncytial virus bronchitis	1 (3.3)	1 (3.3)	0
Respiratory syncytial virus infection	1 (3.3)	1 (3.3)	0
Sepsis	1 (3.3)	0	1 (3.3)
Staphylococcal bacteraemia	1 (3.3)	1 (3.3)	0
Staphylococcal infection	1 (3.3)	1 (3.3)	0
Streptococcal bacteraemia	1 (3.3)	1 (3.3)	0
Urinary tract infection	1 (3.3)	1 (3.3)	0
Viral upper respiratory tract infection	1 (3.3)	1 (3.3)	0
Injury, poisoning and procedural complications			
-Total	2 (6.7)	2 (6.7)	0
Extradural haematoma	1 (3.3)	1 (3.3)	0
Procedural pain	1 (3.3)	1 (3.3)	0
Subdural haematoma	1 (3.3)	1 (3.3)	0
Investigations			

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.3)	1 (3.3)	0
Electrocardiogram qt prolonged	1 (3.3)	1 (3.3)	0
Metabolism and nutrition disorders			
-Total	4 (13.3)	2 (6.7)	1 (3.3)
Tumour lysis syndrome	2 (6.7)	2 (6.7)	0
Acidosis	1 (3.3)	0	0
Hypernatraemia	1 (3.3)	0	1 (3.3)
Hypocalcaemia	1 (3.3)	0	0
Hypophosphataemia	1 (3.3)	1 (3.3)	0
Malnutrition	1 (3.3)	0	0
Musculoskeletal and connective tissue disorders			
-Total	2 (6.7)	1 (3.3)	0
Back pain	1 (3.3)	1 (3.3)	0
Flank pain	1 (3.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.3)	0	0
Myelodysplastic syndrome	1 (3.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	4 (13.3)	2 (6.7)	0
Seizure	2 (6.7)	0	0
Encephalopathy	1 (3.3)	1 (3.3)	0
Headache	1 (3.3)	1 (3.3)	0
Psychiatric disorders			
-Total	2 (6.7)	1 (3.3)	0
Delirium	1 (3.3)	0	0
Mental status changes	1 (3.3)	1 (3.3)	0
Renal and urinary disorders			
-Total	4 (13.3)	3 (10.0)	1 (3.3)
Acute kidney injury	4 (13.3)	3 (10.0)	1 (3.3)
Reproductive system and breast disorders			
-Total	1 (3.3)	0	0
Scrotal pain	1 (3.3)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (23.3)	0	5 (16.7)

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	3 (10.0)	0	3 (10.0)
Hypoxia	2 (6.7)	0	0
Pulmonary oedema	2 (6.7)	0	2 (6.7)
Acute respiratory failure	1 (3.3)	0	1 (3.3)
Idiopathic pneumonia syndrome	1 (3.3)	0	1 (3.3)
Pleural effusion	1 (3.3)	1 (3.3)	0
Pulmonary mass	1 (3.3)	0	0
Skin and subcutaneous tissue disorders			
-Total	1 (3.3)	1 (3.3)	0
Ecchymosis	1 (3.3)	1 (3.3)	0
Vascular disorders			
-Total	6 (20.0)	4 (13.3)	2 (6.7)
Hypotension	6 (20.0)	4 (13.3)	2 (6.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183d
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (84.4)	14 (31.1)	21 (46.7)
Blood and lymphatic system disorders			
-Total	16 (35.6)	13 (28.9)	3 (6.7)
Febrile neutropenia	13 (28.9)	13 (28.9)	0
Neutropenia	2 (4.4)	0	2 (4.4)
Pancytopenia	2 (4.4)	1 (2.2)	1 (2.2)
Disseminated intravascular coagulation	1 (2.2)	0	0
Cardiac disorders			
-Total	1 (2.2)	0	0
Atrioventricular block second degree	1 (2.2)	0	0
Eye disorders			

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (4.4)	0	0
Papilloedema	1 (2.2)	0	0
Vision blurred	1 (2.2)	0	0
Gastrointestinal disorders			
-Total	6 (13.3)	4 (8.9)	0
Abdominal pain	2 (4.4)	1 (2.2)	0
Colitis	2 (4.4)	2 (4.4)	0
Stomatitis	2 (4.4)	1 (2.2)	0
Ascites	1 (2.2)	1 (2.2)	0
Diarrhoea	1 (2.2)	0	0
Intestinal obstruction	1 (2.2)	1 (2.2)	0
General disorders and administration site conditions			
-Total	8 (17.8)	3 (6.7)	2 (4.4)
Pyrexia	5 (11.1)	2 (4.4)	0
Multiple organ dysfunction syndrome	2 (4.4)	0	2 (4.4)
Physical deconditioning	1 (2.2)	1 (2.2)	0
Hepatobiliary disorders			

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (4.4)	1 (2.2)	1 (2.2)
Hepatic failure	1 (2.2)	0	1 (2.2)
Hyperbilirubinaemia	1 (2.2)	1 (2.2)	0
Immune system disorders			
-Total	25 (55.6)	5 (11.1)	7 (15.6)
Cytokine release syndrome	25 (55.6)	5 (11.1)	7 (15.6)
Infections and infestations			
-Total	20 (44.4)	11 (24.4)	6 (13.3)
Clostridium difficile infection	3 (6.7)	1 (2.2)	0
Pneumonia	3 (6.7)	1 (2.2)	1 (2.2)
Clostridium difficile colitis	2 (4.4)	0	0
Device related infection	2 (4.4)	2 (4.4)	0
Abscess limb	1 (2.2)	1 (2.2)	0
Bacterial sepsis	1 (2.2)	0	1 (2.2)
Bronchitis	1 (2.2)	0	0
Bronchopulmonary aspergillosis	1 (2.2)	1 (2.2)	0
Campylobacter infection	1 (2.2)	1 (2.2)	0
Catheter site infection	1 (2.2)	1 (2.2)	0

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Cellulitis	1 (2.2)	1 (2.2)	0
Cholecystitis infective	1 (2.2)	1 (2.2)	0
Enterovirus infection	1 (2.2)	1 (2.2)	0
Gastroenteritis	1 (2.2)	1 (2.2)	0
Herpes zoster	1 (2.2)	1 (2.2)	0
Necrotising fasciitis	1 (2.2)	1 (2.2)	0
Parainfluenzae virus infection	1 (2.2)	1 (2.2)	0
Pneumonia fungal	1 (2.2)	0	0
Respiratory syncytial virus infection	1 (2.2)	0	0
Respiratory tract infection	1 (2.2)	0	1 (2.2)
Respiratory tract infection viral	1 (2.2)	1 (2.2)	0
Rhinovirus infection	1 (2.2)	0	0
Rotavirus infection	1 (2.2)	1 (2.2)	0
Sepsis	1 (2.2)	0	1 (2.2)
Septic embolus	1 (2.2)	0	1 (2.2)
Staphylococcal bacteraemia	1 (2.2)	1 (2.2)	0
Staphylococcal infection	1 (2.2)	0	1 (2.2)

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal scalded skin syndrome	1 (2.2)	0	0
Staphylococcal sepsis	1 (2.2)	0	1 (2.2)
Upper respiratory tract infection	1 (2.2)	1 (2.2)	0
Urinary tract infection	1 (2.2)	0	0
Vascular device infection	1 (2.2)	1 (2.2)	0
Vulvovaginal candidiasis	1 (2.2)	0	0
Injury, poisoning and procedural complications			
-Total	2 (4.4)	0	1 (2.2)
Subdural haematoma	1 (2.2)	0	0
Transfusion related complication	1 (2.2)	0	1 (2.2)
Investigations			
-Total	3 (6.7)	2 (4.4)	1 (2.2)
Alanine aminotransferase increased	1 (2.2)	1 (2.2)	0
Transaminases increased	1 (2.2)	1 (2.2)	0
White blood cell count decreased	1 (2.2)	0	1 (2.2)
Metabolism and nutrition disorders			
-Total	3 (6.7)	2 (4.4)	0

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	1 (2.2)	1 (2.2)	0
Dehydration	1 (2.2)	1 (2.2)	0
Hypocalcaemia	1 (2.2)	0	0
Musculoskeletal and connective tissue disorders			
-Total	3 (6.7)	1 (2.2)	0
Myopathy	1 (2.2)	1 (2.2)	0
Myositis	1 (2.2)	1 (2.2)	0
Osteonecrosis	1 (2.2)	0	0
Pain in extremity	1 (2.2)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (2.2)	0	1 (2.2)
Glioblastoma multiforme	1 (2.2)	0	1 (2.2)
Nervous system disorders			
-Total	8 (17.8)	4 (8.9)	1 (2.2)
Encephalopathy	3 (6.7)	1 (2.2)	0
Headache	2 (4.4)	2 (4.4)	0
Seizure	2 (4.4)	2 (4.4)	0

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Embolic stroke	1 (2.2)	0	1 (2.2)
Idiopathic intracranial hypertension	1 (2.2)	0	0
Renal and urinary disorders			
-Total	3 (6.7)	0	2 (4.4)
Acute kidney injury	2 (4.4)	0	1 (2.2)
Renal failure	1 (2.2)	0	1 (2.2)
Reproductive system and breast disorders			
-Total	1 (2.2)	1 (2.2)	0
Vaginal haemorrhage	1 (2.2)	1 (2.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	9 (20.0)	3 (6.7)	4 (8.9)
Hypoxia	4 (8.9)	2 (4.4)	1 (2.2)
Aspiration	1 (2.2)	0	1 (2.2)
Epistaxis	1 (2.2)	1 (2.2)	0
Pleural effusion	1 (2.2)	0	0
Pulmonary oedema	1 (2.2)	1 (2.2)	0
Respiratory distress	1 (2.2)	0	1 (2.2)

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	1 (2.2)	0	1 (2.2)
Vascular disorders			
-Total	6 (13.3)	3 (6.7)	3 (6.7)
Hypotension	5 (11.1)	2 (4.4)	3 (6.7)
Embolism	1 (2.2)	1 (2.2)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183e
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (87.5)	3 (37.5)	4 (50.0)
Blood and lymphatic system disorders			
-Total	3 (37.5)	3 (37.5)	0
Febrile neutropenia	3 (37.5)	3 (37.5)	0
Gastrointestinal disorders			
-Total	1 (12.5)	1 (12.5)	0
Enterocolitis	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	2 (25.0)	1 (12.5)	0
Pyrexia	2 (25.0)	1 (12.5)	0
Immune system disorders			
-Total	5 (62.5)	0	3 (37.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	5 (62.5)	0	3 (37.5)
Infections and infestations			
-Total	3 (37.5)	2 (25.0)	1 (12.5)
Cellulitis	1 (12.5)	1 (12.5)	0
Corona virus infection	1 (12.5)	1 (12.5)	0
Pneumonia	1 (12.5)	0	1 (12.5)
Respiratory syncytial virus infection	1 (12.5)	1 (12.5)	0
Renal and urinary disorders			
-Total	1 (12.5)	0	1 (12.5)
Renal failure	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (25.0)	0	2 (25.0)
Aspiration	1 (12.5)	0	1 (12.5)
Hypoxia	1 (12.5)	1 (12.5)	0
Respiratory failure	1 (12.5)	0	1 (12.5)
Vascular disorders			
-Total	3 (37.5)	2 (25.0)	1 (12.5)
Hypotension	3 (37.5)	2 (25.0)	1 (12.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183e
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	57 (85.1)	24 (35.8)	29 (43.3)
Blood and lymphatic system disorders			
-Total	34 (50.7)	28 (41.8)	6 (9.0)
Febrile neutropenia	30 (44.8)	29 (43.3)	1 (1.5)
Neutropenia	3 (4.5)	0	3 (4.5)
Pancytopenia	3 (4.5)	1 (1.5)	2 (3.0)
Disseminated intravascular coagulation	2 (3.0)	0	0
Eosinophilia	1 (1.5)	1 (1.5)	0
Cardiac disorders			
-Total	3 (4.5)	0	1 (1.5)
Atrioventricular block second degree	1 (1.5)	0	0
Cardiovascular insufficiency	1 (1.5)	0	1 (1.5)

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ventricular tachycardia	1 (1.5)	0	0
Eye disorders			
-Total	2 (3.0)	0	0
Papilloedema	1 (1.5)	0	0
Vision blurred	1 (1.5)	0	0
Gastrointestinal disorders			
-Total	12 (17.9)	9 (13.4)	0
Abdominal pain	3 (4.5)	2 (3.0)	0
Colitis	3 (4.5)	3 (4.5)	0
Stomatitis	3 (4.5)	2 (3.0)	0
Diarrhoea	2 (3.0)	0	0
Ascites	1 (1.5)	1 (1.5)	0
Intestinal obstruction	1 (1.5)	1 (1.5)	0
Pancreatitis	1 (1.5)	1 (1.5)	0
Vomiting	1 (1.5)	1 (1.5)	0
General disorders and administration site conditions			
-Total	14 (20.9)	3 (4.5)	3 (4.5)
Pyrexia	8 (11.9)	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	3 (4.5)	0	3 (4.5)
Physical deconditioning	2 (3.0)	2 (3.0)	0
Malaise	1 (1.5)	0	0
Hepatobiliary disorders			
-Total	3 (4.5)	2 (3.0)	1 (1.5)
Cholecystitis	1 (1.5)	1 (1.5)	0
Hepatic failure	1 (1.5)	0	1 (1.5)
Hyperbilirubinaemia	1 (1.5)	1 (1.5)	0
Immune system disorders			
-Total	36 (53.7)	8 (11.9)	7 (10.4)
Cytokine release syndrome	36 (53.7)	8 (11.9)	7 (10.4)
Graft versus host disease in gastrointestinal tract	1 (1.5)	0	0
Infections and infestations			
-Total	28 (41.8)	16 (23.9)	9 (13.4)
Clostridium difficile infection	3 (4.5)	1 (1.5)	0
Device related infection	3 (4.5)	3 (4.5)	0
Pneumonia	3 (4.5)	1 (1.5)	0
Clostridium difficile colitis	2 (3.0)	0	0

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	2 (3.0)	1 (1.5)	0
Sepsis	2 (3.0)	0	2 (3.0)
Staphylococcal bacteraemia	2 (3.0)	2 (3.0)	0
Staphylococcal infection	2 (3.0)	1 (1.5)	1 (1.5)
Urinary tract infection	2 (3.0)	1 (1.5)	0
Abscess limb	1 (1.5)	1 (1.5)	0
Bacteraemia	1 (1.5)	1 (1.5)	0
Bacterial sepsis	1 (1.5)	0	1 (1.5)
Bronchitis	1 (1.5)	0	0
Bronchopulmonary aspergillosis	1 (1.5)	1 (1.5)	0
Campylobacter infection	1 (1.5)	1 (1.5)	0
Candida sepsis	1 (1.5)	0	1 (1.5)
Catheter site infection	1 (1.5)	1 (1.5)	0
Cellulitis of male external genital organ	1 (1.5)	1 (1.5)	0
Cholecystitis infective	1 (1.5)	1 (1.5)	0
Enterovirus infection	1 (1.5)	1 (1.5)	0
Escherichia bacteraemia	1 (1.5)	1 (1.5)	0
Escherichia sepsis	1 (1.5)	0	1 (1.5)

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia urinary tract infection	1 (1.5)	1 (1.5)	0
Gastroenteritis	1 (1.5)	1 (1.5)	0
Gastroenteritis norovirus	1 (1.5)	0	0
Herpes zoster	1 (1.5)	1 (1.5)	0
Klebsiella sepsis	1 (1.5)	0	1 (1.5)
Necrotising fasciitis	1 (1.5)	1 (1.5)	0
Pneumonia fungal	1 (1.5)	0	0
Respiratory syncytial virus bronchitis	1 (1.5)	1 (1.5)	0
Respiratory syncytial virus infection	1 (1.5)	0	0
Respiratory tract infection	1 (1.5)	0	1 (1.5)
Respiratory tract infection viral	1 (1.5)	1 (1.5)	0
Rhinovirus infection	1 (1.5)	0	0
Rotavirus infection	1 (1.5)	1 (1.5)	0
Septic embolus	1 (1.5)	0	1 (1.5)
Staphylococcal scalded skin syndrome	1 (1.5)	0	0
Staphylococcal sepsis	1 (1.5)	0	1 (1.5)
Streptococcal bacteraemia	1 (1.5)	1 (1.5)	0
Upper respiratory tract infection	1 (1.5)	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (1.5)	1 (1.5)	0
Viral upper respiratory tract infection	1 (1.5)	1 (1.5)	0
Vulvovaginal candidiasis	1 (1.5)	0	0
Injury, poisoning and procedural complications			
-Total	4 (6.0)	2 (3.0)	1 (1.5)
Subdural haematoma	2 (3.0)	1 (1.5)	0
Extradural haematoma	1 (1.5)	1 (1.5)	0
Procedural pain	1 (1.5)	1 (1.5)	0
Transfusion related complication	1 (1.5)	0	1 (1.5)
Investigations			
-Total	4 (6.0)	3 (4.5)	1 (1.5)
Alanine aminotransferase increased	1 (1.5)	1 (1.5)	0
Electrocardiogram qt prolonged	1 (1.5)	1 (1.5)	0
Transaminases increased	1 (1.5)	1 (1.5)	0
White blood cell count decreased	1 (1.5)	0	1 (1.5)
Metabolism and nutrition disorders			
-Total	7 (10.4)	4 (6.0)	1 (1.5)
Hypocalcaemia	2 (3.0)	0	0

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	2 (3.0)	2 (3.0)	0
Acidosis	1 (1.5)	0	0
Decreased appetite	1 (1.5)	1 (1.5)	0
Dehydration	1 (1.5)	1 (1.5)	0
Hypernatraemia	1 (1.5)	0	1 (1.5)
Hypophosphataemia	1 (1.5)	1 (1.5)	0
Malnutrition	1 (1.5)	0	0
Musculoskeletal and connective tissue disorders			
-Total	5 (7.5)	2 (3.0)	0
Back pain	1 (1.5)	1 (1.5)	0
Flank pain	1 (1.5)	0	0
Myopathy	1 (1.5)	1 (1.5)	0
Myositis	1 (1.5)	1 (1.5)	0
Osteonecrosis	1 (1.5)	0	0
Pain in extremity	1 (1.5)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (3.0)	0	1 (1.5)

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Glioblastoma multiforme	1 (1.5)	0	1 (1.5)
Myelodysplastic syndrome	1 (1.5)	0	0
Nervous system disorders			
-Total	12 (17.9)	6 (9.0)	1 (1.5)
Encephalopathy	4 (6.0)	2 (3.0)	0
Seizure	4 (6.0)	2 (3.0)	0
Headache	3 (4.5)	3 (4.5)	0
Embolic stroke	1 (1.5)	0	1 (1.5)
Idiopathic intracranial hypertension	1 (1.5)	0	0
Psychiatric disorders			
-Total	2 (3.0)	1 (1.5)	0
Delirium	1 (1.5)	0	0
Mental status changes	1 (1.5)	1 (1.5)	0
Renal and urinary disorders			
-Total	6 (9.0)	3 (4.5)	2 (3.0)
Acute kidney injury	6 (9.0)	3 (4.5)	2 (3.0)
Reproductive system and breast disorders			
-Total	2 (3.0)	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Scrotal pain	1 (1.5)	0	0
Vaginal haemorrhage	1 (1.5)	1 (1.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	14 (20.9)	3 (4.5)	7 (10.4)
Hypoxia	5 (7.5)	1 (1.5)	1 (1.5)
Pulmonary oedema	3 (4.5)	1 (1.5)	2 (3.0)
Respiratory failure	3 (4.5)	0	3 (4.5)
Pleural effusion	2 (3.0)	1 (1.5)	0
Acute respiratory failure	1 (1.5)	0	1 (1.5)
Epistaxis	1 (1.5)	1 (1.5)	0
Idiopathic pneumonia syndrome	1 (1.5)	0	1 (1.5)
Pulmonary mass	1 (1.5)	0	0
Respiratory distress	1 (1.5)	0	1 (1.5)
Skin and subcutaneous tissue disorders			
-Total	1 (1.5)	1 (1.5)	0
Ecchymosis	1 (1.5)	1 (1.5)	0
Vascular disorders			

Response status at study entry: Relapsed disease

Group term Preferred term	All patients N=67 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	9 (13.4)	5 (7.5)	4 (6.0)
Hypotension	8 (11.9)	4 (6.0)	4 (6.0)
Embolism	1 (1.5)	1 (1.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183f
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
Blood and lymphatic system disorders			
-Total	1 (50.0)	0	1 (50.0)
Eosinophilia	1 (50.0)	1 (50.0)	0
Neutropenia	1 (50.0)	0	1 (50.0)
Gastrointestinal disorders			
-Total	1 (50.0)	0	0
Diarrhoea	1 (50.0)	0	0
General disorders and administration site conditions			
-Total	1 (50.0)	0	0
Pyrexia	1 (50.0)	0	0
Infections and infestations			

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	1 (50.0)	0
Urinary tract infection	1 (50.0)	1 (50.0)	0
Reproductive system and breast disorders			
-Total	1 (50.0)	0	0
Scrotal pain	1 (50.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183f
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	63 (86.3)	27 (37.0)	32 (43.8)
Blood and lymphatic system disorders			
-Total	36 (49.3)	31 (42.5)	5 (6.8)
Febrile neutropenia	33 (45.2)	32 (43.8)	1 (1.4)
Pancytopenia	3 (4.1)	1 (1.4)	2 (2.7)
Disseminated intravascular coagulation	2 (2.7)	0	0
Neutropenia	2 (2.7)	0	2 (2.7)
Cardiac disorders			
-Total	3 (4.1)	0	1 (1.4)
Atrioventricular block second degree	1 (1.4)	0	0
Cardiovascular insufficiency	1 (1.4)	0	1 (1.4)
Ventricular tachycardia	1 (1.4)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders			
-Total	2 (2.7)	0	0
Papilloedema	1 (1.4)	0	0
Vision blurred	1 (1.4)	0	0
Gastrointestinal disorders			
-Total	12 (16.4)	10 (13.7)	0
Abdominal pain	3 (4.1)	2 (2.7)	0
Colitis	3 (4.1)	3 (4.1)	0
Stomatitis	3 (4.1)	2 (2.7)	0
Ascites	1 (1.4)	1 (1.4)	0
Diarrhoea	1 (1.4)	0	0
Enterocolitis	1 (1.4)	1 (1.4)	0
Intestinal obstruction	1 (1.4)	1 (1.4)	0
Pancreatitis	1 (1.4)	1 (1.4)	0
Vomiting	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	15 (20.5)	4 (5.5)	3 (4.1)
Pyrexia	9 (12.3)	2 (2.7)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	3 (4.1)	0	3 (4.1)
Physical deconditioning	2 (2.7)	2 (2.7)	0
Malaise	1 (1.4)	0	0
Hepatobiliary disorders			
-Total	3 (4.1)	2 (2.7)	1 (1.4)
Cholecystitis	1 (1.4)	1 (1.4)	0
Hepatic failure	1 (1.4)	0	1 (1.4)
Hyperbilirubinaemia	1 (1.4)	1 (1.4)	0
Immune system disorders			
-Total	41 (56.2)	8 (11.0)	10 (13.7)
Cytokine release syndrome	41 (56.2)	8 (11.0)	10 (13.7)
Graft versus host disease in gastrointestinal tract	1 (1.4)	0	0
Infections and infestations			
-Total	30 (41.1)	17 (23.3)	10 (13.7)
Pneumonia	4 (5.5)	1 (1.4)	1 (1.4)
Clostridium difficile infection	3 (4.1)	1 (1.4)	0
Device related infection	3 (4.1)	3 (4.1)	0
Clostridium difficile colitis	2 (2.7)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	2 (2.7)	1 (1.4)	0
Respiratory syncytial virus infection	2 (2.7)	1 (1.4)	0
Sepsis	2 (2.7)	0	2 (2.7)
Staphylococcal bacteraemia	2 (2.7)	2 (2.7)	0
Staphylococcal infection	2 (2.7)	1 (1.4)	1 (1.4)
Abscess limb	1 (1.4)	1 (1.4)	0
Bacteraemia	1 (1.4)	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	1 (1.4)
Bronchitis	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	1 (1.4)	0
Campylobacter infection	1 (1.4)	1 (1.4)	0
Candida sepsis	1 (1.4)	0	1 (1.4)
Catheter site infection	1 (1.4)	1 (1.4)	0
Cellulitis	1 (1.4)	1 (1.4)	0
Cholecystitis infective	1 (1.4)	1 (1.4)	0
Corona virus infection	1 (1.4)	1 (1.4)	0
Enterovirus infection	1 (1.4)	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	1 (1.4)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Escherichia urinary tract infection	1 (1.4)	1 (1.4)	0
Gastroenteritis	1 (1.4)	1 (1.4)	0
Gastroenteritis norovirus	1 (1.4)	0	0
Herpes zoster	1 (1.4)	1 (1.4)	0
Klebsiella sepsis	1 (1.4)	0	1 (1.4)
Necrotising fasciitis	1 (1.4)	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	1 (1.4)	0
Rhinovirus infection	1 (1.4)	0	0
Rotavirus infection	1 (1.4)	1 (1.4)	0
Septic embolus	1 (1.4)	0	1 (1.4)
Staphylococcal scalded skin syndrome	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	1 (1.4)	0
Upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Urinary tract infection	1 (1.4)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (1.4)	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Vulvovaginal candidiasis	1 (1.4)	0	0
Injury, poisoning and procedural complications			
-Total	4 (5.5)	2 (2.7)	1 (1.4)
Subdural haematoma	2 (2.7)	1 (1.4)	0
Extradural haematoma	1 (1.4)	1 (1.4)	0
Procedural pain	1 (1.4)	1 (1.4)	0
Transfusion related complication	1 (1.4)	0	1 (1.4)
Investigations			
-Total	4 (5.5)	3 (4.1)	1 (1.4)
Alanine aminotransferase increased	1 (1.4)	1 (1.4)	0
Electrocardiogram qt prolonged	1 (1.4)	1 (1.4)	0
Transaminases increased	1 (1.4)	1 (1.4)	0
White blood cell count decreased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	7 (9.6)	4 (5.5)	1 (1.4)
Hypocalcaemia	2 (2.7)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	2 (2.7)	2 (2.7)	0
Acidosis	1 (1.4)	0	0
Decreased appetite	1 (1.4)	1 (1.4)	0
Dehydration	1 (1.4)	1 (1.4)	0
Hypernatraemia	1 (1.4)	0	1 (1.4)
Hypophosphataemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders			
-Total	5 (6.8)	2 (2.7)	0
Back pain	1 (1.4)	1 (1.4)	0
Flank pain	1 (1.4)	0	0
Myopathy	1 (1.4)	1 (1.4)	0
Myositis	1 (1.4)	1 (1.4)	0
Osteonecrosis	1 (1.4)	0	0
Pain in extremity	1 (1.4)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.7)	0	1 (1.4)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Glioblastoma multiforme	1 (1.4)	0	1 (1.4)
Myelodysplastic syndrome	1 (1.4)	0	0
Nervous system disorders			
-Total	12 (16.4)	6 (8.2)	1 (1.4)
Encephalopathy	4 (5.5)	2 (2.7)	0
Seizure	4 (5.5)	2 (2.7)	0
Headache	3 (4.1)	3 (4.1)	0
Embolic stroke	1 (1.4)	0	1 (1.4)
Idiopathic intracranial hypertension	1 (1.4)	0	0
Psychiatric disorders			
-Total	2 (2.7)	1 (1.4)	0
Delirium	1 (1.4)	0	0
Mental status changes	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	7 (9.6)	3 (4.1)	3 (4.1)
Acute kidney injury	6 (8.2)	3 (4.1)	2 (2.7)
Renal failure	1 (1.4)	0	1 (1.4)
Reproductive system and breast disorders			

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.4)	1 (1.4)	0
Vaginal haemorrhage	1 (1.4)	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	16 (21.9)	3 (4.1)	9 (12.3)
Hypoxia	6 (8.2)	2 (2.7)	1 (1.4)
Respiratory failure	4 (5.5)	0	4 (5.5)
Pulmonary oedema	3 (4.1)	1 (1.4)	2 (2.7)
Pleural effusion	2 (2.7)	1 (1.4)	0
Acute respiratory failure	1 (1.4)	0	1 (1.4)
Aspiration	1 (1.4)	0	1 (1.4)
Epistaxis	1 (1.4)	1 (1.4)	0
Idiopathic pneumonia syndrome	1 (1.4)	0	1 (1.4)
Pulmonary mass	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	1 (1.4)
Skin and subcutaneous tissue disorders			
-Total	1 (1.4)	1 (1.4)	0
Ecchymosis	1 (1.4)	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	12 (16.4)	7 (9.6)	5 (6.8)
Hypotension	11 (15.1)	6 (8.2)	5 (6.8)
Embolism	1 (1.4)	1 (1.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183g
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	2 (66.7)
Immune system disorders			
-Total	2 (66.7)	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	2 (66.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183g
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	62 (86.1)	27 (37.5)	31 (43.1)
Blood and lymphatic system disorders			
-Total	37 (51.4)	31 (43.1)	6 (8.3)
Febrile neutropenia	33 (45.8)	32 (44.4)	1 (1.4)
Neutropenia	3 (4.2)	0	3 (4.2)
Pancytopenia	3 (4.2)	1 (1.4)	2 (2.8)
Disseminated intravascular coagulation	2 (2.8)	0	0
Eosinophilia	1 (1.4)	1 (1.4)	0
Cardiac disorders			
-Total	3 (4.2)	0	1 (1.4)
Atrioventricular block second degree	1 (1.4)	0	0
Cardiovascular insufficiency	1 (1.4)	0	1 (1.4)

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ventricular tachycardia	1 (1.4)	0	0
Eye disorders			
-Total	2 (2.8)	0	0
Papilloedema	1 (1.4)	0	0
Vision blurred	1 (1.4)	0	0
Gastrointestinal disorders			
-Total	13 (18.1)	10 (13.9)	0
Abdominal pain	3 (4.2)	2 (2.8)	0
Colitis	3 (4.2)	3 (4.2)	0
Stomatitis	3 (4.2)	2 (2.8)	0
Diarrhoea	2 (2.8)	0	0
Ascites	1 (1.4)	1 (1.4)	0
Enterocolitis	1 (1.4)	1 (1.4)	0
Intestinal obstruction	1 (1.4)	1 (1.4)	0
Pancreatitis	1 (1.4)	1 (1.4)	0
Vomiting	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			
-Total	16 (22.2)	4 (5.6)	3 (4.2)

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	10 (13.9)	2 (2.8)	0
Multiple organ dysfunction syndrome	3 (4.2)	0	3 (4.2)
Physical deconditioning	2 (2.8)	2 (2.8)	0
Malaise	1 (1.4)	0	0
Hepatobiliary disorders			
-Total	3 (4.2)	2 (2.8)	1 (1.4)
Cholecystitis	1 (1.4)	1 (1.4)	0
Hepatic failure	1 (1.4)	0	1 (1.4)
Hyperbilirubinaemia	1 (1.4)	1 (1.4)	0
Immune system disorders			
-Total	39 (54.2)	8 (11.1)	8 (11.1)
Cytokine release syndrome	39 (54.2)	8 (11.1)	8 (11.1)
Graft versus host disease in gastrointestinal tract	1 (1.4)	0	0
Infections and infestations			
-Total	31 (43.1)	18 (25.0)	10 (13.9)
Pneumonia	4 (5.6)	1 (1.4)	1 (1.4)
Clostridium difficile infection	3 (4.2)	1 (1.4)	0
Device related infection	3 (4.2)	3 (4.2)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	2 (2.8)	0	0
Parainfluenzae virus infection	2 (2.8)	1 (1.4)	0
Respiratory syncytial virus infection	2 (2.8)	1 (1.4)	0
Sepsis	2 (2.8)	0	2 (2.8)
Staphylococcal bacteraemia	2 (2.8)	2 (2.8)	0
Staphylococcal infection	2 (2.8)	1 (1.4)	1 (1.4)
Urinary tract infection	2 (2.8)	1 (1.4)	0
Abscess limb	1 (1.4)	1 (1.4)	0
Bacteraemia	1 (1.4)	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	1 (1.4)
Bronchitis	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	1 (1.4)	0
Campylobacter infection	1 (1.4)	1 (1.4)	0
Candida sepsis	1 (1.4)	0	1 (1.4)
Catheter site infection	1 (1.4)	1 (1.4)	0
Cellulitis	1 (1.4)	1 (1.4)	0
Cellulitis of male external genital organ	1 (1.4)	1 (1.4)	0
Cholecystitis infective	1 (1.4)	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	1 (1.4)	1 (1.4)	0
Enterovirus infection	1 (1.4)	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	1 (1.4)	0
Gastroenteritis	1 (1.4)	1 (1.4)	0
Gastroenteritis norovirus	1 (1.4)	0	0
Herpes zoster	1 (1.4)	1 (1.4)	0
Klebsiella sepsis	1 (1.4)	0	1 (1.4)
Necrotising fasciitis	1 (1.4)	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	1 (1.4)	0
Rhinovirus infection	1 (1.4)	0	0
Rotavirus infection	1 (1.4)	1 (1.4)	0
Septic embolus	1 (1.4)	0	1 (1.4)
Staphylococcal scalded skin syndrome	1 (1.4)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	1 (1.4)	0
Upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Vascular device infection	1 (1.4)	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Vulvovaginal candidiasis	1 (1.4)	0	0
Injury, poisoning and procedural complications			
-Total	4 (5.6)	2 (2.8)	1 (1.4)
Subdural haematoma	2 (2.8)	1 (1.4)	0
Extradural haematoma	1 (1.4)	1 (1.4)	0
Procedural pain	1 (1.4)	1 (1.4)	0
Transfusion related complication	1 (1.4)	0	1 (1.4)
Investigations			
-Total	4 (5.6)	3 (4.2)	1 (1.4)
Alanine aminotransferase increased	1 (1.4)	1 (1.4)	0
Electrocardiogram qt prolonged	1 (1.4)	1 (1.4)	0
Transaminases increased	1 (1.4)	1 (1.4)	0
White blood cell count decreased	1 (1.4)	0	1 (1.4)

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	7 (9.7)	4 (5.6)	1 (1.4)
Hypocalcaemia	2 (2.8)	0	0
Tumour lysis syndrome	2 (2.8)	2 (2.8)	0
Acidosis	1 (1.4)	0	0
Decreased appetite	1 (1.4)	1 (1.4)	0
Dehydration	1 (1.4)	1 (1.4)	0
Hypernatraemia	1 (1.4)	0	1 (1.4)
Hypophosphataemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders			
-Total	5 (6.9)	2 (2.8)	0
Back pain	1 (1.4)	1 (1.4)	0
Flank pain	1 (1.4)	0	0
Myopathy	1 (1.4)	1 (1.4)	0
Myositis	1 (1.4)	1 (1.4)	0
Osteonecrosis	1 (1.4)	0	0
Pain in extremity	1 (1.4)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.8)	0	1 (1.4)
Glioblastoma multiforme	1 (1.4)	0	1 (1.4)
Myelodysplastic syndrome	1 (1.4)	0	0
Nervous system disorders			
-Total	12 (16.7)	6 (8.3)	1 (1.4)
Encephalopathy	4 (5.6)	2 (2.8)	0
Seizure	4 (5.6)	2 (2.8)	0
Headache	3 (4.2)	3 (4.2)	0
Embolic stroke	1 (1.4)	0	1 (1.4)
Idiopathic intracranial hypertension	1 (1.4)	0	0
Psychiatric disorders			
-Total	2 (2.8)	1 (1.4)	0
Delirium	1 (1.4)	0	0
Mental status changes	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	7 (9.7)	3 (4.2)	3 (4.2)
Acute kidney injury	6 (8.3)	3 (4.2)	2 (2.8)

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	1 (1.4)	0	1 (1.4)
Reproductive system and breast disorders			
-Total	2 (2.8)	1 (1.4)	0
Scrotal pain	1 (1.4)	0	0
Vaginal haemorrhage	1 (1.4)	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	16 (22.2)	3 (4.2)	9 (12.5)
Hypoxia	6 (8.3)	2 (2.8)	1 (1.4)
Respiratory failure	4 (5.6)	0	4 (5.6)
Pulmonary oedema	3 (4.2)	1 (1.4)	2 (2.8)
Pleural effusion	2 (2.8)	1 (1.4)	0
Acute respiratory failure	1 (1.4)	0	1 (1.4)
Aspiration	1 (1.4)	0	1 (1.4)
Epistaxis	1 (1.4)	1 (1.4)	0
Idiopathic pneumonia syndrome	1 (1.4)	0	1 (1.4)
Pulmonary mass	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	1 (1.4)

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders			
-Total	1 (1.4)	1 (1.4)	0
Ecchymosis	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	12 (16.7)	7 (9.7)	5 (6.9)
Hypotension	11 (15.3)	6 (8.3)	5 (6.9)
Embolism	1 (1.4)	1 (1.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183h
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Blood and lymphatic system disorders			
-Total	1 (100)	1 (100)	0
Febrile neutropenia	1 (100)	1 (100)	0
Immune system disorders			
-Total	1 (100)	0	0
Cytokine release syndrome	1 (100)	0	0
Nervous system disorders			
-Total	1 (100)	0	0
Encephalopathy	1 (100)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183h
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	63 (85.1)	26 (35.1)	33 (44.6)
Blood and lymphatic system disorders			
-Total	36 (48.6)	30 (40.5)	6 (8.1)
Febrile neutropenia	32 (43.2)	31 (41.9)	1 (1.4)
Neutropenia	3 (4.1)	0	3 (4.1)
Pancytopenia	3 (4.1)	1 (1.4)	2 (2.7)
Disseminated intravascular coagulation	2 (2.7)	0	0
Eosinophilia	1 (1.4)	1 (1.4)	0
Cardiac disorders			
-Total	3 (4.1)	0	1 (1.4)
Atrioventricular block second degree	1 (1.4)	0	0

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiovascular insufficiency	1 (1.4)	0	1 (1.4)
Ventricular tachycardia	1 (1.4)	0	0
Eye disorders			
-Total	2 (2.7)	0	0
Papilloedema	1 (1.4)	0	0
Vision blurred	1 (1.4)	0	0
Gastrointestinal disorders			
-Total	13 (17.6)	10 (13.5)	0
Abdominal pain	3 (4.1)	2 (2.7)	0
Colitis	3 (4.1)	3 (4.1)	0
Stomatitis	3 (4.1)	2 (2.7)	0
Diarrhoea	2 (2.7)	0	0
Ascites	1 (1.4)	1 (1.4)	0
Enterocolitis	1 (1.4)	1 (1.4)	0
Intestinal obstruction	1 (1.4)	1 (1.4)	0
Pancreatitis	1 (1.4)	1 (1.4)	0
Vomiting	1 (1.4)	1 (1.4)	0

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	16 (21.6)	4 (5.4)	3 (4.1)
Pyrexia	10 (13.5)	2 (2.7)	0
Multiple organ dysfunction syndrome	3 (4.1)	0	3 (4.1)
Physical deconditioning	2 (2.7)	2 (2.7)	0
Malaise	1 (1.4)	0	0
Hepatobiliary disorders			
-Total	3 (4.1)	2 (2.7)	1 (1.4)
Cholecystitis	1 (1.4)	1 (1.4)	0
Hepatic failure	1 (1.4)	0	1 (1.4)
Hyperbilirubinaemia	1 (1.4)	1 (1.4)	0
Immune system disorders			
-Total	40 (54.1)	8 (10.8)	10 (13.5)
Cytokine release syndrome	40 (54.1)	8 (10.8)	10 (13.5)
Graft versus host disease in gastrointestinal tract	1 (1.4)	0	0
Infections and infestations			
-Total	31 (41.9)	18 (24.3)	10 (13.5)

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	4 (5.4)	1 (1.4)	1 (1.4)
Clostridium difficile infection	3 (4.1)	1 (1.4)	0
Device related infection	3 (4.1)	3 (4.1)	0
Clostridium difficile colitis	2 (2.7)	0	0
Parainfluenzae virus infection	2 (2.7)	1 (1.4)	0
Respiratory syncytial virus infection	2 (2.7)	1 (1.4)	0
Sepsis	2 (2.7)	0	2 (2.7)
Staphylococcal bacteraemia	2 (2.7)	2 (2.7)	0
Staphylococcal infection	2 (2.7)	1 (1.4)	1 (1.4)
Urinary tract infection	2 (2.7)	1 (1.4)	0
Abscess limb	1 (1.4)	1 (1.4)	0
Bacteraemia	1 (1.4)	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	1 (1.4)
Bronchitis	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	1 (1.4)	0
Campylobacter infection	1 (1.4)	1 (1.4)	0
Candida sepsis	1 (1.4)	0	1 (1.4)
Catheter site infection	1 (1.4)	1 (1.4)	0

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (1.4)	1 (1.4)	0
Cellulitis of male external genital organ	1 (1.4)	1 (1.4)	0
Cholecystitis infective	1 (1.4)	1 (1.4)	0
Corona virus infection	1 (1.4)	1 (1.4)	0
Enterovirus infection	1 (1.4)	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	1 (1.4)	0
Gastroenteritis	1 (1.4)	1 (1.4)	0
Gastroenteritis norovirus	1 (1.4)	0	0
Herpes zoster	1 (1.4)	1 (1.4)	0
Klebsiella sepsis	1 (1.4)	0	1 (1.4)
Necrotising fasciitis	1 (1.4)	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	1 (1.4)	0

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (1.4)	0	0
Rotavirus infection	1 (1.4)	1 (1.4)	0
Septic embolus	1 (1.4)	0	1 (1.4)
Staphylococcal scalded skin syndrome	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	1 (1.4)	0
Upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Vascular device infection	1 (1.4)	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Vulvovaginal candidiasis	1 (1.4)	0	0
Injury, poisoning and procedural complications			
-Total	4 (5.4)	2 (2.7)	1 (1.4)
Subdural haematoma	2 (2.7)	1 (1.4)	0
Extradural haematoma	1 (1.4)	1 (1.4)	0
Procedural pain	1 (1.4)	1 (1.4)	0
Transfusion related complication	1 (1.4)	0	1 (1.4)
Investigations			

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (5.4)	3 (4.1)	1 (1.4)
Alanine aminotransferase increased	1 (1.4)	1 (1.4)	0
Electrocardiogram qt prolonged	1 (1.4)	1 (1.4)	0
Transaminases increased	1 (1.4)	1 (1.4)	0
White blood cell count decreased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	7 (9.5)	4 (5.4)	1 (1.4)
Hypocalcaemia	2 (2.7)	0	0
Tumour lysis syndrome	2 (2.7)	2 (2.7)	0
Acidosis	1 (1.4)	0	0
Decreased appetite	1 (1.4)	1 (1.4)	0
Dehydration	1 (1.4)	1 (1.4)	0
Hypernatraemia	1 (1.4)	0	1 (1.4)
Hypophosphataemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders			
-Total	5 (6.8)	2 (2.7)	0

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	1 (1.4)	1 (1.4)	0
Flank pain	1 (1.4)	0	0
Myopathy	1 (1.4)	1 (1.4)	0
Myositis	1 (1.4)	1 (1.4)	0
Osteonecrosis	1 (1.4)	0	0
Pain in extremity	1 (1.4)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.7)	0	1 (1.4)
Glioblastoma multiforme	1 (1.4)	0	1 (1.4)
Myelodysplastic syndrome	1 (1.4)	0	0
Nervous system disorders			
-Total	11 (14.9)	6 (8.1)	1 (1.4)
Seizure	4 (5.4)	2 (2.7)	0
Encephalopathy	3 (4.1)	2 (2.7)	0
Headache	3 (4.1)	3 (4.1)	0
Embolic stroke	1 (1.4)	0	1 (1.4)
Idiopathic intracranial hypertension	1 (1.4)	0	0

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	2 (2.7)	1 (1.4)	0
Delirium	1 (1.4)	0	0
Mental status changes	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	7 (9.5)	3 (4.1)	3 (4.1)
Acute kidney injury	6 (8.1)	3 (4.1)	2 (2.7)
Renal failure	1 (1.4)	0	1 (1.4)
Reproductive system and breast disorders			
-Total	2 (2.7)	1 (1.4)	0
Scrotal pain	1 (1.4)	0	0
Vaginal haemorrhage	1 (1.4)	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	16 (21.6)	3 (4.1)	9 (12.2)
Hypoxia	6 (8.1)	2 (2.7)	1 (1.4)
Respiratory failure	4 (5.4)	0	4 (5.4)
Pulmonary oedema	3 (4.1)	1 (1.4)	2 (2.7)

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	2 (2.7)	1 (1.4)	0
Acute respiratory failure	1 (1.4)	0	1 (1.4)
Aspiration	1 (1.4)	0	1 (1.4)
Epistaxis	1 (1.4)	1 (1.4)	0
Idiopathic pneumonia syndrome	1 (1.4)	0	1 (1.4)
Pulmonary mass	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	1 (1.4)
Skin and subcutaneous tissue disorders			
-Total	1 (1.4)	1 (1.4)	0
Ecchymosis	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	12 (16.2)	7 (9.5)	5 (6.8)
Hypotension	11 (14.9)	6 (8.1)	5 (6.8)
Embolism	1 (1.4)	1 (1.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183i
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders			
-Total	3 (75.0)	3 (75.0)	0
Febrile neutropenia	3 (75.0)	3 (75.0)	0
Gastrointestinal disorders			
-Total	2 (50.0)	1 (25.0)	0
Colitis	1 (25.0)	1 (25.0)	0
Diarrhoea	1 (25.0)	0	0
Hepatobiliary disorders			
-Total	1 (25.0)	1 (25.0)	0
Cholecystitis	1 (25.0)	1 (25.0)	0
Immune system disorders			

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (50.0)	1 (25.0)	0
Cytokine release syndrome	2 (50.0)	1 (25.0)	0
Infections and infestations			
-Total	2 (50.0)	2 (50.0)	0
Bacteraemia	1 (25.0)	1 (25.0)	0
Gastroenteritis	1 (25.0)	1 (25.0)	0
Herpes zoster	1 (25.0)	1 (25.0)	0
Streptococcal bacteraemia	1 (25.0)	1 (25.0)	0
Metabolism and nutrition disorders			
-Total	1 (25.0)	1 (25.0)	0
Dehydration	1 (25.0)	1 (25.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (25.0)	0	0
Osteonecrosis	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Idiopathic pneumonia syndrome	1 (25.0)	0	1 (25.0)

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary oedema	1 (25.0)	1 (25.0)	0
Vascular disorders			
-Total	1 (25.0)	0	1 (25.0)
Hypotension	1 (25.0)	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183i
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	61 (85.9)	26 (36.6)	31 (43.7)
Blood and lymphatic system disorders			
-Total	34 (47.9)	28 (39.4)	6 (8.5)
Febrile neutropenia	30 (42.3)	29 (40.8)	1 (1.4)
Neutropenia	3 (4.2)	0	3 (4.2)
Pancytopenia	3 (4.2)	1 (1.4)	2 (2.8)
Disseminated intravascular coagulation	2 (2.8)	0	0
Eosinophilia	1 (1.4)	1 (1.4)	0
Cardiac disorders			
-Total	3 (4.2)	0	1 (1.4)
Atrioventricular block second degree	1 (1.4)	0	0

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiovascular insufficiency	1 (1.4)	0	1 (1.4)
Ventricular tachycardia	1 (1.4)	0	0
Eye disorders			
-Total	2 (2.8)	0	0
Papilloedema	1 (1.4)	0	0
Vision blurred	1 (1.4)	0	0
Gastrointestinal disorders			
-Total	11 (15.5)	9 (12.7)	0
Abdominal pain	3 (4.2)	2 (2.8)	0
Stomatitis	3 (4.2)	2 (2.8)	0
Colitis	2 (2.8)	2 (2.8)	0
Ascites	1 (1.4)	1 (1.4)	0
Diarrhoea	1 (1.4)	0	0
Enterocolitis	1 (1.4)	1 (1.4)	0
Intestinal obstruction	1 (1.4)	1 (1.4)	0
Pancreatitis	1 (1.4)	1 (1.4)	0
Vomiting	1 (1.4)	1 (1.4)	0

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	16 (22.5)	4 (5.6)	3 (4.2)
Pyrexia	10 (14.1)	2 (2.8)	0
Multiple organ dysfunction syndrome	3 (4.2)	0	3 (4.2)
Physical deconditioning	2 (2.8)	2 (2.8)	0
Malaise	1 (1.4)	0	0
Hepatobiliary disorders			
-Total	2 (2.8)	1 (1.4)	1 (1.4)
Hepatic failure	1 (1.4)	0	1 (1.4)
Hyperbilirubinaemia	1 (1.4)	1 (1.4)	0
Immune system disorders			
-Total	39 (54.9)	7 (9.9)	10 (14.1)
Cytokine release syndrome	39 (54.9)	7 (9.9)	10 (14.1)
Graft versus host disease in gastrointestinal tract	1 (1.4)	0	0
Infections and infestations			
-Total	29 (40.8)	16 (22.5)	10 (14.1)
Pneumonia	4 (5.6)	1 (1.4)	1 (1.4)

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	3 (4.2)	1 (1.4)	0
Device related infection	3 (4.2)	3 (4.2)	0
Clostridium difficile colitis	2 (2.8)	0	0
Parainfluenzae virus infection	2 (2.8)	1 (1.4)	0
Respiratory syncytial virus infection	2 (2.8)	1 (1.4)	0
Sepsis	2 (2.8)	0	2 (2.8)
Staphylococcal bacteraemia	2 (2.8)	2 (2.8)	0
Staphylococcal infection	2 (2.8)	1 (1.4)	1 (1.4)
Urinary tract infection	2 (2.8)	1 (1.4)	0
Abscess limb	1 (1.4)	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	1 (1.4)
Bronchitis	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	1 (1.4)	0
Campylobacter infection	1 (1.4)	1 (1.4)	0
Candida sepsis	1 (1.4)	0	1 (1.4)
Catheter site infection	1 (1.4)	1 (1.4)	0
Cellulitis	1 (1.4)	1 (1.4)	0

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (1.4)	1 (1.4)	0
Cholecystitis infective	1 (1.4)	1 (1.4)	0
Corona virus infection	1 (1.4)	1 (1.4)	0
Enterovirus infection	1 (1.4)	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	1 (1.4)	0
Gastroenteritis norovirus	1 (1.4)	0	0
Klebsiella sepsis	1 (1.4)	0	1 (1.4)
Necrotising fasciitis	1 (1.4)	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	1 (1.4)	0
Respiratory tract infection	1 (1.4)	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	1 (1.4)	0
Rhinovirus infection	1 (1.4)	0	0
Rotavirus infection	1 (1.4)	1 (1.4)	0
Septic embolus	1 (1.4)	0	1 (1.4)

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal scalded skin syndrome	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Vascular device infection	1 (1.4)	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Vulvovaginal candidiasis	1 (1.4)	0	0
Injury, poisoning and procedural complications			
-Total	4 (5.6)	2 (2.8)	1 (1.4)
Subdural haematoma	2 (2.8)	1 (1.4)	0
Extradural haematoma	1 (1.4)	1 (1.4)	0
Procedural pain	1 (1.4)	1 (1.4)	0
Transfusion related complication	1 (1.4)	0	1 (1.4)
Investigations			
-Total	4 (5.6)	3 (4.2)	1 (1.4)
Alanine aminotransferase increased	1 (1.4)	1 (1.4)	0
Electrocardiogram qt prolonged	1 (1.4)	1 (1.4)	0
Transaminases increased	1 (1.4)	1 (1.4)	0

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	6 (8.5)	3 (4.2)	1 (1.4)
Hypocalcaemia	2 (2.8)	0	0
Tumour lysis syndrome	2 (2.8)	2 (2.8)	0
Acidosis	1 (1.4)	0	0
Decreased appetite	1 (1.4)	1 (1.4)	0
Hypernatraemia	1 (1.4)	0	1 (1.4)
Hypophosphataemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders			
-Total	4 (5.6)	2 (2.8)	0
Back pain	1 (1.4)	1 (1.4)	0
Flank pain	1 (1.4)	0	0
Myopathy	1 (1.4)	1 (1.4)	0
Myositis	1 (1.4)	1 (1.4)	0
Pain in extremity	1 (1.4)	0	0

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.8)	0	1 (1.4)
Glioblastoma multiforme	1 (1.4)	0	1 (1.4)
Myelodysplastic syndrome	1 (1.4)	0	0
Nervous system disorders			
-Total	12 (16.9)	6 (8.5)	1 (1.4)
Encephalopathy	4 (5.6)	2 (2.8)	0
Seizure	4 (5.6)	2 (2.8)	0
Headache	3 (4.2)	3 (4.2)	0
Embolic stroke	1 (1.4)	0	1 (1.4)
Idiopathic intracranial hypertension	1 (1.4)	0	0
Psychiatric disorders			
-Total	2 (2.8)	1 (1.4)	0
Delirium	1 (1.4)	0	0
Mental status changes	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	7 (9.9)	3 (4.2)	3 (4.2)

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	6 (8.5)	3 (4.2)	2 (2.8)
Renal failure	1 (1.4)	0	1 (1.4)
Reproductive system and breast disorders			
-Total	2 (2.8)	1 (1.4)	0
Scrotal pain	1 (1.4)	0	0
Vaginal haemorrhage	1 (1.4)	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	14 (19.7)	2 (2.8)	8 (11.3)
Hypoxia	6 (8.5)	2 (2.8)	1 (1.4)
Respiratory failure	4 (5.6)	0	4 (5.6)
Pleural effusion	2 (2.8)	1 (1.4)	0
Pulmonary oedema	2 (2.8)	0	2 (2.8)
Acute respiratory failure	1 (1.4)	0	1 (1.4)
Aspiration	1 (1.4)	0	1 (1.4)
Epistaxis	1 (1.4)	1 (1.4)	0
Pulmonary mass	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	1 (1.4)

BCR-ABL1-like: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders			
-Total	1 (1.4)	1 (1.4)	0
Ecchymosis	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	11 (15.5)	7 (9.9)	4 (5.6)
Hypotension	10 (14.1)	6 (8.5)	4 (5.6)
Embolism	1 (1.4)	1 (1.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183j
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (95.5)	5 (22.7)	15 (68.2)
Blood and lymphatic system disorders			
-Total	12 (54.5)	10 (45.5)	2 (9.1)
Febrile neutropenia	10 (45.5)	10 (45.5)	0
Neutropenia	2 (9.1)	0	2 (9.1)
Eosinophilia	1 (4.5)	1 (4.5)	0
Pancytopenia	1 (4.5)	1 (4.5)	0
Cardiac disorders			
-Total	1 (4.5)	0	0
Atrioventricular block second degree	1 (4.5)	0	0
Eye disorders			
-Total	1 (4.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vision blurred	1 (4.5)	0	0
Gastrointestinal disorders			
-Total	5 (22.7)	3 (13.6)	0
Diarrhoea	2 (9.1)	0	0
Stomatitis	2 (9.1)	2 (9.1)	0
Intestinal obstruction	1 (4.5)	1 (4.5)	0
General disorders and administration site conditions			
-Total	4 (18.2)	0	0
Pyrexia	4 (18.2)	0	0
Immune system disorders			
-Total	16 (72.7)	3 (13.6)	5 (22.7)
Cytokine release syndrome	16 (72.7)	3 (13.6)	5 (22.7)
Infections and infestations			
-Total	11 (50.0)	6 (27.3)	5 (22.7)
Clostridium difficile infection	2 (9.1)	1 (4.5)	0
Urinary tract infection	2 (9.1)	1 (4.5)	0
Bacterial sepsis	1 (4.5)	0	1 (4.5)
Campylobacter infection	1 (4.5)	1 (4.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Candida sepsis	1 (4.5)	0	1 (4.5)
Cellulitis of male external genital organ	1 (4.5)	1 (4.5)	0
Clostridium difficile colitis	1 (4.5)	0	0
Device related infection	1 (4.5)	1 (4.5)	0
Enterovirus infection	1 (4.5)	1 (4.5)	0
Gastroenteritis	1 (4.5)	1 (4.5)	0
Herpes zoster	1 (4.5)	1 (4.5)	0
Parainfluenzae virus infection	1 (4.5)	0	0
Respiratory tract infection	1 (4.5)	0	1 (4.5)
Respiratory tract infection viral	1 (4.5)	1 (4.5)	0
Rhinovirus infection	1 (4.5)	0	0
Rotavirus infection	1 (4.5)	1 (4.5)	0
Sepsis	1 (4.5)	0	1 (4.5)
Septic embolus	1 (4.5)	0	1 (4.5)
Staphylococcal infection	1 (4.5)	1 (4.5)	0
Vascular device infection	1 (4.5)	1 (4.5)	0
Vulvovaginal candidiasis	1 (4.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (4.5)	0	1 (4.5)
Transfusion related complication	1 (4.5)	0	1 (4.5)
Investigations			
-Total	1 (4.5)	0	1 (4.5)
White blood cell count decreased	1 (4.5)	0	1 (4.5)
Metabolism and nutrition disorders			
-Total	2 (9.1)	1 (4.5)	1 (4.5)
Dehydration	1 (4.5)	1 (4.5)	0
Hypernatraemia	1 (4.5)	0	1 (4.5)
Musculoskeletal and connective tissue disorders			
-Total	2 (9.1)	0	0
Osteonecrosis	1 (4.5)	0	0
Pain in extremity	1 (4.5)	0	0
Nervous system disorders			
-Total	4 (18.2)	2 (9.1)	1 (4.5)
Encephalopathy	2 (9.1)	1 (4.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Embolic stroke	1 (4.5)	0	1 (4.5)
Seizure	1 (4.5)	1 (4.5)	0
Renal and urinary disorders			
-Total	3 (13.6)	1 (4.5)	2 (9.1)
Acute kidney injury	3 (13.6)	1 (4.5)	2 (9.1)
Reproductive system and breast disorders			
-Total	2 (9.1)	1 (4.5)	0
Scrotal pain	1 (4.5)	0	0
Vaginal haemorrhage	1 (4.5)	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (22.7)	1 (4.5)	3 (13.6)
Hypoxia	2 (9.1)	0	1 (4.5)
Pulmonary oedema	2 (9.1)	1 (4.5)	1 (4.5)
Acute respiratory failure	1 (4.5)	0	1 (4.5)
Respiratory failure	1 (4.5)	0	1 (4.5)
Vascular disorders			
-Total	4 (18.2)	1 (4.5)	3 (13.6)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	4 (18.2)	1 (4.5)	3 (13.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183j
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	43 (81.1)	22 (41.5)	18 (34.0)
Blood and lymphatic system disorders			
-Total	25 (47.2)	21 (39.6)	4 (7.5)
Febrile neutropenia	23 (43.4)	22 (41.5)	1 (1.9)
Disseminated intravascular coagulation	2 (3.8)	0	0
Pancytopenia	2 (3.8)	0	2 (3.8)
Neutropenia	1 (1.9)	0	1 (1.9)
Cardiac disorders			
-Total	2 (3.8)	0	1 (1.9)
Cardiovascular insufficiency	1 (1.9)	0	1 (1.9)
Ventricular tachycardia	1 (1.9)	0	0
Eye disorders			

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.9)	0	0
Papilloedema	1 (1.9)	0	0
Gastrointestinal disorders			
-Total	8 (15.1)	7 (13.2)	0
Abdominal pain	3 (5.7)	2 (3.8)	0
Colitis	3 (5.7)	3 (5.7)	0
Ascites	1 (1.9)	1 (1.9)	0
Enterocolitis	1 (1.9)	1 (1.9)	0
Pancreatitis	1 (1.9)	1 (1.9)	0
Stomatitis	1 (1.9)	0	0
Vomiting	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	12 (22.6)	4 (7.5)	3 (5.7)
Pyrexia	6 (11.3)	2 (3.8)	0
Multiple organ dysfunction syndrome	3 (5.7)	0	3 (5.7)
Physical deconditioning	2 (3.8)	2 (3.8)	0
Malaise	1 (1.9)	0	0
Hepatobiliary disorders			

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (5.7)	2 (3.8)	1 (1.9)
Cholecystitis	1 (1.9)	1 (1.9)	0
Hepatic failure	1 (1.9)	0	1 (1.9)
Hyperbilirubinaemia	1 (1.9)	1 (1.9)	0
Immune system disorders			
-Total	25 (47.2)	5 (9.4)	5 (9.4)
Cytokine release syndrome	25 (47.2)	5 (9.4)	5 (9.4)
Graft versus host disease in gastrointestinal tract	1 (1.9)	0	0
Infections and infestations			
-Total	20 (37.7)	12 (22.6)	5 (9.4)
Pneumonia	4 (7.5)	1 (1.9)	1 (1.9)
Device related infection	2 (3.8)	2 (3.8)	0
Respiratory syncytial virus infection	2 (3.8)	1 (1.9)	0
Staphylococcal bacteraemia	2 (3.8)	2 (3.8)	0
Abscess limb	1 (1.9)	1 (1.9)	0
Bacteraemia	1 (1.9)	1 (1.9)	0
Bronchitis	1 (1.9)	0	0
Bronchopulmonary aspergillosis	1 (1.9)	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (1.9)	1 (1.9)	0
Cellulitis	1 (1.9)	1 (1.9)	0
Cholecystitis infective	1 (1.9)	1 (1.9)	0
Clostridium difficile colitis	1 (1.9)	0	0
Clostridium difficile infection	1 (1.9)	0	0
Corona virus infection	1 (1.9)	1 (1.9)	0
Escherichia bacteraemia	1 (1.9)	1 (1.9)	0
Escherichia sepsis	1 (1.9)	0	1 (1.9)
Escherichia urinary tract infection	1 (1.9)	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	0
Klebsiella sepsis	1 (1.9)	0	1 (1.9)
Necrotising fasciitis	1 (1.9)	1 (1.9)	0
Parainfluenzae virus infection	1 (1.9)	1 (1.9)	0
Pneumonia fungal	1 (1.9)	0	0
Respiratory syncytial virus bronchitis	1 (1.9)	1 (1.9)	0
Sepsis	1 (1.9)	0	1 (1.9)
Staphylococcal infection	1 (1.9)	0	1 (1.9)
Staphylococcal scalded skin syndrome	1 (1.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (1.9)	0	1 (1.9)
Streptococcal bacteraemia	1 (1.9)	1 (1.9)	0
Upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Viral upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Injury, poisoning and procedural complications			
-Total	3 (5.7)	2 (3.8)	0
Subdural haematoma	2 (3.8)	1 (1.9)	0
Extradural haematoma	1 (1.9)	1 (1.9)	0
Procedural pain	1 (1.9)	1 (1.9)	0
Investigations			
-Total	3 (5.7)	3 (5.7)	0
Alanine aminotransferase increased	1 (1.9)	1 (1.9)	0
Electrocardiogram qt prolonged	1 (1.9)	1 (1.9)	0
Transaminases increased	1 (1.9)	1 (1.9)	0
Metabolism and nutrition disorders			
-Total	5 (9.4)	3 (5.7)	0
Hypocalcaemia	2 (3.8)	0	0
Tumour lysis syndrome	2 (3.8)	2 (3.8)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acidosis	1 (1.9)	0	0
Decreased appetite	1 (1.9)	1 (1.9)	0
Hypophosphataemia	1 (1.9)	1 (1.9)	0
Malnutrition	1 (1.9)	0	0
Musculoskeletal and connective tissue disorders			
-Total	3 (5.7)	2 (3.8)	0
Back pain	1 (1.9)	1 (1.9)	0
Flank pain	1 (1.9)	0	0
Myopathy	1 (1.9)	1 (1.9)	0
Myositis	1 (1.9)	1 (1.9)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (3.8)	0	1 (1.9)
Glioblastoma multiforme	1 (1.9)	0	1 (1.9)
Myelodysplastic syndrome	1 (1.9)	0	0
Nervous system disorders			
-Total	8 (15.1)	4 (7.5)	0
Headache	3 (5.7)	3 (5.7)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	3 (5.7)	1 (1.9)	0
Encephalopathy	2 (3.8)	1 (1.9)	0
Idiopathic intracranial hypertension	1 (1.9)	0	0
Psychiatric disorders			
-Total	2 (3.8)	1 (1.9)	0
Delirium	1 (1.9)	0	0
Mental status changes	1 (1.9)	1 (1.9)	0
Renal and urinary disorders			
-Total	4 (7.5)	2 (3.8)	1 (1.9)
Acute kidney injury	3 (5.7)	2 (3.8)	0
Renal failure	1 (1.9)	0	1 (1.9)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (20.8)	2 (3.8)	6 (11.3)
Hypoxia	4 (7.5)	2 (3.8)	0
Respiratory failure	3 (5.7)	0	3 (5.7)
Pleural effusion	2 (3.8)	1 (1.9)	0
Aspiration	1 (1.9)	0	1 (1.9)
Epistaxis	1 (1.9)	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Idiopathic pneumonia syndrome	1 (1.9)	0	1 (1.9)
Pulmonary mass	1 (1.9)	0	0
Pulmonary oedema	1 (1.9)	0	1 (1.9)
Respiratory distress	1 (1.9)	0	1 (1.9)
Skin and subcutaneous tissue disorders			
-Total	1 (1.9)	1 (1.9)	0
Ecchymosis	1 (1.9)	1 (1.9)	0
Vascular disorders			
-Total	8 (15.1)	6 (11.3)	2 (3.8)
Hypotension	7 (13.2)	5 (9.4)	2 (3.8)
Embolism	1 (1.9)	1 (1.9)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183k
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=75		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	64 (85.3)	27 (36.0)	33 (44.0)
Blood and lymphatic system disorders			
-Total	37 (49.3)	31 (41.3)	6 (8.0)
Febrile neutropenia	33 (44.0)	32 (42.7)	1 (1.3)
Neutropenia	3 (4.0)	0	3 (4.0)
Pancytopenia	3 (4.0)	1 (1.3)	2 (2.7)
Disseminated intravascular coagulation	2 (2.7)	0	0
Eosinophilia	1 (1.3)	1 (1.3)	0
Cardiac disorders			
-Total	3 (4.0)	0	1 (1.3)
Atrioventricular block second degree	1 (1.3)	0	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiovascular insufficiency	1 (1.3)	0	1 (1.3)
Ventricular tachycardia	1 (1.3)	0	0
Eye disorders			
-Total	2 (2.7)	0	0
Papilloedema	1 (1.3)	0	0
Vision blurred	1 (1.3)	0	0
Gastrointestinal disorders			
-Total	13 (17.3)	10 (13.3)	0
Abdominal pain	3 (4.0)	2 (2.7)	0
Colitis	3 (4.0)	3 (4.0)	0
Stomatitis	3 (4.0)	2 (2.7)	0
Diarrhoea	2 (2.7)	0	0
Ascites	1 (1.3)	1 (1.3)	0
Enterocolitis	1 (1.3)	1 (1.3)	0
Intestinal obstruction	1 (1.3)	1 (1.3)	0
Pancreatitis	1 (1.3)	1 (1.3)	0
Vomiting	1 (1.3)	1 (1.3)	0

Region: US

	All patients N=75		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	16 (21.3)	4 (5.3)	3 (4.0)
Pyrexia	10 (13.3)	2 (2.7)	0
Multiple organ dysfunction syndrome	3 (4.0)	0	3 (4.0)
Physical deconditioning	2 (2.7)	2 (2.7)	0
Malaise	1 (1.3)	0	0
Hepatobiliary disorders			
-Total	3 (4.0)	2 (2.7)	1 (1.3)
Cholecystitis	1 (1.3)	1 (1.3)	0
Hepatic failure	1 (1.3)	0	1 (1.3)
Hyperbilirubinaemia	1 (1.3)	1 (1.3)	0
Immune system disorders			
-Total	41 (54.7)	8 (10.7)	10 (13.3)
Cytokine release syndrome	41 (54.7)	8 (10.7)	10 (13.3)
Graft versus host disease in gastrointestinal tract	1 (1.3)	0	0
Infections and infestations			
-Total	31 (41.3)	18 (24.0)	10 (13.3)

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	4 (5.3)	1 (1.3)	1 (1.3)
Clostridium difficile infection	3 (4.0)	1 (1.3)	0
Device related infection	3 (4.0)	3 (4.0)	0
Clostridium difficile colitis	2 (2.7)	0	0
Parainfluenzae virus infection	2 (2.7)	1 (1.3)	0
Respiratory syncytial virus infection	2 (2.7)	1 (1.3)	0
Sepsis	2 (2.7)	0	2 (2.7)
Staphylococcal bacteraemia	2 (2.7)	2 (2.7)	0
Staphylococcal infection	2 (2.7)	1 (1.3)	1 (1.3)
Urinary tract infection	2 (2.7)	1 (1.3)	0
Abscess limb	1 (1.3)	1 (1.3)	0
Bacteraemia	1 (1.3)	1 (1.3)	0
Bacterial sepsis	1 (1.3)	0	1 (1.3)
Bronchitis	1 (1.3)	0	0
Bronchopulmonary aspergillosis	1 (1.3)	1 (1.3)	0
Campylobacter infection	1 (1.3)	1 (1.3)	0
Candida sepsis	1 (1.3)	0	1 (1.3)
Catheter site infection	1 (1.3)	1 (1.3)	0

Region: US

	All patients N=75		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (1.3)	1 (1.3)	0
Cellulitis of male external genital organ	1 (1.3)	1 (1.3)	0
Cholecystitis infective	1 (1.3)	1 (1.3)	0
Corona virus infection	1 (1.3)	1 (1.3)	0
Enterovirus infection	1 (1.3)	1 (1.3)	0
Escherichia bacteraemia	1 (1.3)	1 (1.3)	0
Escherichia sepsis	1 (1.3)	0	1 (1.3)
Escherichia urinary tract infection	1 (1.3)	1 (1.3)	0
Gastroenteritis	1 (1.3)	1 (1.3)	0
Gastroenteritis norovirus	1 (1.3)	0	0
Herpes zoster	1 (1.3)	1 (1.3)	0
Klebsiella sepsis	1 (1.3)	0	1 (1.3)
Necrotising fasciitis	1 (1.3)	1 (1.3)	0
Pneumonia fungal	1 (1.3)	0	0
Respiratory syncytial virus bronchitis	1 (1.3)	1 (1.3)	0
Respiratory tract infection	1 (1.3)	0	1 (1.3)
Respiratory tract infection viral	1 (1.3)	1 (1.3)	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinovirus infection	1 (1.3)	0	0
Rotavirus infection	1 (1.3)	1 (1.3)	0
Septic embolus	1 (1.3)	0	1 (1.3)
Staphylococcal scalded skin syndrome	1 (1.3)	0	0
Staphylococcal sepsis	1 (1.3)	0	1 (1.3)
Streptococcal bacteraemia	1 (1.3)	1 (1.3)	0
Upper respiratory tract infection	1 (1.3)	1 (1.3)	0
Vascular device infection	1 (1.3)	1 (1.3)	0
Viral upper respiratory tract infection	1 (1.3)	1 (1.3)	0
Vulvovaginal candidiasis	1 (1.3)	0	0
Injury, poisoning and procedural complications			
-Total	4 (5.3)	2 (2.7)	1 (1.3)
Subdural haematoma	2 (2.7)	1 (1.3)	0
Extradural haematoma	1 (1.3)	1 (1.3)	0
Procedural pain	1 (1.3)	1 (1.3)	0
Transfusion related complication	1 (1.3)	0	1 (1.3)
Investigations			

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	4 (5.3)	3 (4.0)	1 (1.3)
Alanine aminotransferase increased	1 (1.3)	1 (1.3)	0
Electrocardiogram qt prolonged	1 (1.3)	1 (1.3)	0
Transaminases increased	1 (1.3)	1 (1.3)	0
White blood cell count decreased	1 (1.3)	0	1 (1.3)
Metabolism and nutrition disorders			
-Total	7 (9.3)	4 (5.3)	1 (1.3)
Hypocalcaemia	2 (2.7)	0	0
Tumour lysis syndrome	2 (2.7)	2 (2.7)	0
Acidosis	1 (1.3)	0	0
Decreased appetite	1 (1.3)	1 (1.3)	0
Dehydration	1 (1.3)	1 (1.3)	0
Hypernatraemia	1 (1.3)	0	1 (1.3)
Hypophosphataemia	1 (1.3)	1 (1.3)	0
Malnutrition	1 (1.3)	0	0
Musculoskeletal and connective tissue disorders			
-Total	5 (6.7)	2 (2.7)	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Back pain	1 (1.3)	1 (1.3)	0
Flank pain	1 (1.3)	0	0
Myopathy	1 (1.3)	1 (1.3)	0
Myositis	1 (1.3)	1 (1.3)	0
Osteonecrosis	1 (1.3)	0	0
Pain in extremity	1 (1.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.7)	0	1 (1.3)
Glioblastoma multiforme	1 (1.3)	0	1 (1.3)
Myelodysplastic syndrome	1 (1.3)	0	0
Nervous system disorders			
-Total	12 (16.0)	6 (8.0)	1 (1.3)
Encephalopathy	4 (5.3)	2 (2.7)	0
Seizure	4 (5.3)	2 (2.7)	0
Headache	3 (4.0)	3 (4.0)	0
Embolic stroke	1 (1.3)	0	1 (1.3)
Idiopathic intracranial hypertension	1 (1.3)	0	0

Region: US

	All patients N=75		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	2 (2.7)	1 (1.3)	0
Delirium	1 (1.3)	0	0
Mental status changes	1 (1.3)	1 (1.3)	0
Renal and urinary disorders			
-Total	7 (9.3)	3 (4.0)	3 (4.0)
Acute kidney injury	6 (8.0)	3 (4.0)	2 (2.7)
Renal failure	1 (1.3)	0	1 (1.3)
Reproductive system and breast disorders			
-Total	2 (2.7)	1 (1.3)	0
Scrotal pain	1 (1.3)	0	0
Vaginal haemorrhage	1 (1.3)	1 (1.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	16 (21.3)	3 (4.0)	9 (12.0)
Hypoxia	6 (8.0)	2 (2.7)	1 (1.3)
Respiratory failure	4 (5.3)	0	4 (5.3)
Pulmonary oedema	3 (4.0)	1 (1.3)	2 (2.7)

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pleural effusion	2 (2.7)	1 (1.3)	0
Acute respiratory failure	1 (1.3)	0	1 (1.3)
Aspiration	1 (1.3)	0	1 (1.3)
Epistaxis	1 (1.3)	1 (1.3)	0
Idiopathic pneumonia syndrome	1 (1.3)	0	1 (1.3)
Pulmonary mass	1 (1.3)	0	0
Respiratory distress	1 (1.3)	0	1 (1.3)
Skin and subcutaneous tissue disorders			
-Total	1 (1.3)	1 (1.3)	0
Ecchymosis	1 (1.3)	1 (1.3)	0
Vascular disorders			
-Total	12 (16.0)	7 (9.3)	5 (6.7)
Hypotension	11 (14.7)	6 (8.0)	5 (6.7)
Embolism	1 (1.3)	1 (1.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183l
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (87.5)	13 (40.6)	15 (46.9)
Blood and lymphatic system disorders			
-Total	18 (56.3)	16 (50.0)	2 (6.3)
Febrile neutropenia	16 (50.0)	16 (50.0)	0
Disseminated intravascular coagulation	1 (3.1)	0	0
Eosinophilia	1 (3.1)	1 (3.1)	0
Neutropenia	1 (3.1)	0	1 (3.1)
Pancytopenia	1 (3.1)	0	1 (3.1)
Cardiac disorders			
-Total	1 (3.1)	0	1 (3.1)
Cardiovascular insufficiency	1 (3.1)	0	1 (3.1)

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders			
-Total	2 (6.3)	0	0
Papilloedema	1 (3.1)	0	0
Vision blurred	1 (3.1)	0	0
Gastrointestinal disorders			
-Total	8 (25.0)	6 (18.8)	0
Colitis	3 (9.4)	3 (9.4)	0
Stomatitis	3 (9.4)	2 (6.3)	0
Abdominal pain	2 (6.3)	1 (3.1)	0
Ascites	1 (3.1)	1 (3.1)	0
Diarrhoea	1 (3.1)	0	0
Vomiting	1 (3.1)	1 (3.1)	0
General disorders and administration site conditions			
-Total	9 (28.1)	1 (3.1)	3 (9.4)
Pyrexia	4 (12.5)	0	0
Multiple organ dysfunction syndrome	3 (9.4)	0	3 (9.4)
Malaise	1 (3.1)	0	0

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Physical deconditioning	1 (3.1)	1 (3.1)	0
Hepatobiliary disorders			
-Total	3 (9.4)	2 (6.3)	1 (3.1)
Cholecystitis	1 (3.1)	1 (3.1)	0
Hepatic failure	1 (3.1)	0	1 (3.1)
Hyperbilirubinaemia	1 (3.1)	1 (3.1)	0
Immune system disorders			
-Total	17 (53.1)	4 (12.5)	2 (6.3)
Cytokine release syndrome	17 (53.1)	4 (12.5)	2 (6.3)
Graft versus host disease in gastrointestinal tract	1 (3.1)	0	0
Infections and infestations			
-Total	17 (53.1)	11 (34.4)	6 (18.8)
Clostridium difficile infection	2 (6.3)	1 (3.1)	0
Device related infection	2 (6.3)	2 (6.3)	0
Sepsis	2 (6.3)	0	2 (6.3)
Staphylococcal bacteraemia	2 (6.3)	2 (6.3)	0
Urinary tract infection	2 (6.3)	1 (3.1)	0

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abscess limb	1 (3.1)	1 (3.1)	0
Bacteraemia	1 (3.1)	1 (3.1)	0
Bronchitis	1 (3.1)	0	0
Campylobacter infection	1 (3.1)	1 (3.1)	0
Cellulitis of male external genital organ	1 (3.1)	1 (3.1)	0
Cholecystitis infective	1 (3.1)	1 (3.1)	0
Clostridium difficile colitis	1 (3.1)	0	0
Enterovirus infection	1 (3.1)	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	1 (3.1)	0
Escherichia sepsis	1 (3.1)	0	1 (3.1)
Escherichia urinary tract infection	1 (3.1)	1 (3.1)	0
Gastroenteritis norovirus	1 (3.1)	0	0
Klebsiella sepsis	1 (3.1)	0	1 (3.1)
Necrotising fasciitis	1 (3.1)	1 (3.1)	0
Pneumonia	1 (3.1)	0	0
Pneumonia fungal	1 (3.1)	0	0
Respiratory syncytial virus bronchitis	1 (3.1)	1 (3.1)	0

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (3.1)	1 (3.1)	0
Rhinovirus infection	1 (3.1)	0	0
Rotavirus infection	1 (3.1)	1 (3.1)	0
Septic embolus	1 (3.1)	0	1 (3.1)
Staphylococcal infection	1 (3.1)	0	1 (3.1)
Staphylococcal scalded skin syndrome	1 (3.1)	0	0
Staphylococcal sepsis	1 (3.1)	0	1 (3.1)
Streptococcal bacteraemia	1 (3.1)	1 (3.1)	0
Upper respiratory tract infection	1 (3.1)	1 (3.1)	0
Vascular device infection	1 (3.1)	1 (3.1)	0
Vulvovaginal candidiasis	1 (3.1)	0	0
Injury, poisoning and procedural complications			
-Total	3 (9.4)	1 (3.1)	1 (3.1)
Subdural haematoma	2 (6.3)	1 (3.1)	0
Extradural haematoma	1 (3.1)	1 (3.1)	0
Transfusion related complication	1 (3.1)	0	1 (3.1)
Investigations			

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (9.4)	3 (9.4)	0
Alanine aminotransferase increased	1 (3.1)	1 (3.1)	0
Electrocardiogram qt prolonged	1 (3.1)	1 (3.1)	0
Transaminases increased	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			
-Total	1 (3.1)	0	0
Hypocalcaemia	1 (3.1)	0	0
Musculoskeletal and connective tissue disorders			
-Total	2 (6.3)	1 (3.1)	0
Flank pain	1 (3.1)	0	0
Myopathy	1 (3.1)	1 (3.1)	0
Myositis	1 (3.1)	1 (3.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (6.3)	0	1 (3.1)
Glioblastoma multiforme	1 (3.1)	0	1 (3.1)
Myelodysplastic syndrome	1 (3.1)	0	0
Nervous system disorders			

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (21.9)	4 (12.5)	1 (3.1)
Encephalopathy	2 (6.3)	1 (3.1)	0
Headache	2 (6.3)	2 (6.3)	0
Seizure	2 (6.3)	2 (6.3)	0
Embolic stroke	1 (3.1)	0	1 (3.1)
Idiopathic intracranial hypertension	1 (3.1)	0	0
Psychiatric disorders			
-Total	1 (3.1)	1 (3.1)	0
Mental status changes	1 (3.1)	1 (3.1)	0
Renal and urinary disorders			
-Total	1 (3.1)	0	0
Acute kidney injury	1 (3.1)	0	0
Reproductive system and breast disorders			
-Total	1 (3.1)	0	0
Scrotal pain	1 (3.1)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (15.6)	0	1 (3.1)

Prior SCT therapy: Yes

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	3 (9.4)	0	0
Idiopathic pneumonia syndrome	1 (3.1)	0	1 (3.1)
Pleural effusion	1 (3.1)	0	0
Pulmonary mass	1 (3.1)	0	0
Vascular disorders			
-Total	6 (18.8)	4 (12.5)	2 (6.3)
Hypotension	5 (15.6)	3 (9.4)	2 (6.3)
Embolism	1 (3.1)	1 (3.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183l
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (83.7)	14 (32.6)	18 (41.9)
Blood and lymphatic system disorders			
-Total	19 (44.2)	15 (34.9)	4 (9.3)
Febrile neutropenia	17 (39.5)	16 (37.2)	1 (2.3)
Neutropenia	2 (4.7)	0	2 (4.7)
Pancytopenia	2 (4.7)	1 (2.3)	1 (2.3)
Disseminated intravascular coagulation	1 (2.3)	0	0
Cardiac disorders			
-Total	2 (4.7)	0	0
Atrioventricular block second degree	1 (2.3)	0	0
Ventricular tachycardia	1 (2.3)	0	0

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	5 (11.6)	4 (9.3)	0
Abdominal pain	1 (2.3)	1 (2.3)	0
Diarrhoea	1 (2.3)	0	0
Enterocolitis	1 (2.3)	1 (2.3)	0
Intestinal obstruction	1 (2.3)	1 (2.3)	0
Pancreatitis	1 (2.3)	1 (2.3)	0
General disorders and administration site conditions			
-Total	7 (16.3)	3 (7.0)	0
Pyrexia	6 (14.0)	2 (4.7)	0
Physical deconditioning	1 (2.3)	1 (2.3)	0
Immune system disorders			
-Total	24 (55.8)	4 (9.3)	8 (18.6)
Cytokine release syndrome	24 (55.8)	4 (9.3)	8 (18.6)
Infections and infestations			
-Total	14 (32.6)	7 (16.3)	4 (9.3)
Pneumonia	3 (7.0)	1 (2.3)	1 (2.3)

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	2 (4.7)	1 (2.3)	0
Respiratory syncytial virus infection	2 (4.7)	1 (2.3)	0
Bacterial sepsis	1 (2.3)	0	1 (2.3)
Bronchopulmonary aspergillosis	1 (2.3)	1 (2.3)	0
Candida sepsis	1 (2.3)	0	1 (2.3)
Catheter site infection	1 (2.3)	1 (2.3)	0
Cellulitis	1 (2.3)	1 (2.3)	0
Clostridium difficile colitis	1 (2.3)	0	0
Clostridium difficile infection	1 (2.3)	0	0
Corona virus infection	1 (2.3)	1 (2.3)	0
Device related infection	1 (2.3)	1 (2.3)	0
Gastroenteritis	1 (2.3)	1 (2.3)	0
Herpes zoster	1 (2.3)	1 (2.3)	0
Respiratory tract infection	1 (2.3)	0	1 (2.3)
Staphylococcal infection	1 (2.3)	1 (2.3)	0
Viral upper respiratory tract infection	1 (2.3)	1 (2.3)	0
Injury, poisoning and procedural complications			

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.3)	1 (2.3)	0
Procedural pain	1 (2.3)	1 (2.3)	0
Investigations			
-Total	1 (2.3)	0	1 (2.3)
White blood cell count decreased	1 (2.3)	0	1 (2.3)
Metabolism and nutrition disorders			
-Total	6 (14.0)	4 (9.3)	1 (2.3)
Tumour lysis syndrome	2 (4.7)	2 (4.7)	0
Acidosis	1 (2.3)	0	0
Decreased appetite	1 (2.3)	1 (2.3)	0
Dehydration	1 (2.3)	1 (2.3)	0
Hypernatraemia	1 (2.3)	0	1 (2.3)
Hypocalcaemia	1 (2.3)	0	0
Hypophosphataemia	1 (2.3)	1 (2.3)	0
Malnutrition	1 (2.3)	0	0
Musculoskeletal and connective tissue disorders			
-Total	3 (7.0)	1 (2.3)	0

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	1 (2.3)	1 (2.3)	0
Osteonecrosis	1 (2.3)	0	0
Pain in extremity	1 (2.3)	0	0
Nervous system disorders			
-Total	5 (11.6)	2 (4.7)	0
Encephalopathy	2 (4.7)	1 (2.3)	0
Seizure	2 (4.7)	0	0
Headache	1 (2.3)	1 (2.3)	0
Psychiatric disorders			
-Total	1 (2.3)	0	0
Delirium	1 (2.3)	0	0
Renal and urinary disorders			
-Total	6 (14.0)	3 (7.0)	3 (7.0)
Acute kidney injury	5 (11.6)	3 (7.0)	2 (4.7)
Renal failure	1 (2.3)	0	1 (2.3)
Reproductive system and breast disorders			
-Total	1 (2.3)	1 (2.3)	0

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vaginal haemorrhage	1 (2.3)	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	11 (25.6)	3 (7.0)	8 (18.6)
Respiratory failure	4 (9.3)	0	4 (9.3)
Hypoxia	3 (7.0)	2 (4.7)	1 (2.3)
Pulmonary oedema	3 (7.0)	1 (2.3)	2 (4.7)
Acute respiratory failure	1 (2.3)	0	1 (2.3)
Aspiration	1 (2.3)	0	1 (2.3)
Epistaxis	1 (2.3)	1 (2.3)	0
Pleural effusion	1 (2.3)	1 (2.3)	0
Respiratory distress	1 (2.3)	0	1 (2.3)
Skin and subcutaneous tissue disorders			
-Total	1 (2.3)	1 (2.3)	0
Ecchymosis	1 (2.3)	1 (2.3)	0
Vascular disorders			
-Total	6 (14.0)	3 (7.0)	3 (7.0)
Hypotension	6 (14.0)	3 (7.0)	3 (7.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183m
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (77.8)	9 (50.0)	5 (27.8)
Blood and lymphatic system disorders			
-Total	9 (50.0)	9 (50.0)	0
Febrile neutropenia	9 (50.0)	9 (50.0)	0
Cardiac disorders			
-Total	1 (5.6)	0	0
Atrioventricular block second degree	1 (5.6)	0	0
Gastrointestinal disorders			
-Total	4 (22.2)	4 (22.2)	0
Enterocolitis	1 (5.6)	1 (5.6)	0
Intestinal obstruction	1 (5.6)	1 (5.6)	0
Pancreatitis	1 (5.6)	1 (5.6)	0

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	2 (11.1)	1 (5.6)	0
Pyrexia	2 (11.1)	1 (5.6)	0
Immune system disorders			
-Total	9 (50.0)	2 (11.1)	1 (5.6)
Cytokine release syndrome	9 (50.0)	2 (11.1)	1 (5.6)
Infections and infestations			
-Total	8 (44.4)	5 (27.8)	3 (16.7)
Pneumonia	2 (11.1)	1 (5.6)	1 (5.6)
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Bronchopulmonary aspergillosis	1 (5.6)	1 (5.6)	0
Catheter site infection	1 (5.6)	1 (5.6)	0
Corona virus infection	1 (5.6)	1 (5.6)	0
Device related infection	1 (5.6)	1 (5.6)	0
Escherichia urinary tract infection	1 (5.6)	1 (5.6)	0
Parainfluenzae virus infection	1 (5.6)	1 (5.6)	0

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (5.6)	1 (5.6)	0
Respiratory tract infection	1 (5.6)	0	1 (5.6)
Viral upper respiratory tract infection	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	2 (11.1)	1 (5.6)	0
Hypocalcaemia	1 (5.6)	0	0
Hypophosphataemia	1 (5.6)	1 (5.6)	0
Malnutrition	1 (5.6)	0	0
Tumour lysis syndrome	1 (5.6)	1 (5.6)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (5.6)	0	0
Pain in extremity	1 (5.6)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (5.6)	0	0
Myelodysplastic syndrome	1 (5.6)	0	0
Renal and urinary disorders			
-Total	1 (5.6)	1 (5.6)	0

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (5.6)	1 (5.6)	0
Reproductive system and breast disorders			
-Total	1 (5.6)	1 (5.6)	0
Vaginal haemorrhage	1 (5.6)	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (22.2)	1 (5.6)	2 (11.1)
Hypoxia	3 (16.7)	2 (11.1)	0
Aspiration	1 (5.6)	0	1 (5.6)
Pleural effusion	1 (5.6)	1 (5.6)	0
Respiratory failure	1 (5.6)	0	1 (5.6)
Vascular disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Hypotension	2 (11.1)	1 (5.6)	1 (5.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183m
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (87.7)	18 (31.6)	28 (49.1)
Blood and lymphatic system disorders			
-Total	28 (49.1)	22 (38.6)	6 (10.5)
Febrile neutropenia	24 (42.1)	23 (40.4)	1 (1.8)
Neutropenia	3 (5.3)	0	3 (5.3)
Pancytopenia	3 (5.3)	1 (1.8)	2 (3.5)
Disseminated intravascular coagulation	2 (3.5)	0	0
Eosinophilia	1 (1.8)	1 (1.8)	0
Cardiac disorders			
-Total	2 (3.5)	0	1 (1.8)
Cardiovascular insufficiency	1 (1.8)	0	1 (1.8)

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ventricular tachycardia	1 (1.8)	0	0
Eye disorders			
-Total	2 (3.5)	0	0
Papilloedema	1 (1.8)	0	0
Vision blurred	1 (1.8)	0	0
Gastrointestinal disorders			
-Total	9 (15.8)	6 (10.5)	0
Abdominal pain	3 (5.3)	2 (3.5)	0
Colitis	3 (5.3)	3 (5.3)	0
Diarrhoea	2 (3.5)	0	0
Stomatitis	2 (3.5)	1 (1.8)	0
Ascites	1 (1.8)	1 (1.8)	0
Vomiting	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions			
-Total	14 (24.6)	3 (5.3)	3 (5.3)
Pyrexia	8 (14.0)	1 (1.8)	0
Multiple organ dysfunction syndrome	3 (5.3)	0	3 (5.3)

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Physical deconditioning	2 (3.5)	2 (3.5)	0
Malaise	1 (1.8)	0	0
Hepatobiliary disorders			
-Total	3 (5.3)	2 (3.5)	1 (1.8)
Cholecystitis	1 (1.8)	1 (1.8)	0
Hepatic failure	1 (1.8)	0	1 (1.8)
Hyperbilirubinaemia	1 (1.8)	1 (1.8)	0
Immune system disorders			
-Total	32 (56.1)	6 (10.5)	9 (15.8)
Cytokine release syndrome	32 (56.1)	6 (10.5)	9 (15.8)
Graft versus host disease in gastrointestinal tract	1 (1.8)	0	0
Infections and infestations			
-Total	23 (40.4)	13 (22.8)	7 (12.3)
Clostridium difficile infection	3 (5.3)	1 (1.8)	0
Clostridium difficile colitis	2 (3.5)	0	0
Device related infection	2 (3.5)	2 (3.5)	0
Pneumonia	2 (3.5)	0	0

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	2 (3.5)	0	2 (3.5)
Staphylococcal bacteraemia	2 (3.5)	2 (3.5)	0
Staphylococcal infection	2 (3.5)	1 (1.8)	1 (1.8)
Urinary tract infection	2 (3.5)	1 (1.8)	0
Abscess limb	1 (1.8)	1 (1.8)	0
Bacteraemia	1 (1.8)	1 (1.8)	0
Bronchitis	1 (1.8)	0	0
Campylobacter infection	1 (1.8)	1 (1.8)	0
Candida sepsis	1 (1.8)	0	1 (1.8)
Cellulitis	1 (1.8)	1 (1.8)	0
Cellulitis of male external genital organ	1 (1.8)	1 (1.8)	0
Cholecystitis infective	1 (1.8)	1 (1.8)	0
Enterovirus infection	1 (1.8)	1 (1.8)	0
Escherichia bacteraemia	1 (1.8)	1 (1.8)	0
Escherichia sepsis	1 (1.8)	0	1 (1.8)
Gastroenteritis	1 (1.8)	1 (1.8)	0
Gastroenteritis norovirus	1 (1.8)	0	0

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	1 (1.8)	1 (1.8)	0
Klebsiella sepsis	1 (1.8)	0	1 (1.8)
Necrotising fasciitis	1 (1.8)	1 (1.8)	0
Parainfluenzae virus infection	1 (1.8)	0	0
Pneumonia fungal	1 (1.8)	0	0
Respiratory syncytial virus bronchitis	1 (1.8)	1 (1.8)	0
Respiratory syncytial virus infection	1 (1.8)	0	0
Respiratory tract infection viral	1 (1.8)	1 (1.8)	0
Rhinovirus infection	1 (1.8)	0	0
Rotavirus infection	1 (1.8)	1 (1.8)	0
Septic embolus	1 (1.8)	0	1 (1.8)
Staphylococcal scalded skin syndrome	1 (1.8)	0	0
Staphylococcal sepsis	1 (1.8)	0	1 (1.8)
Streptococcal bacteraemia	1 (1.8)	1 (1.8)	0
Upper respiratory tract infection	1 (1.8)	1 (1.8)	0
Vascular device infection	1 (1.8)	1 (1.8)	0
Vulvovaginal candidiasis	1 (1.8)	0	0

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications			
-Total	4 (7.0)	2 (3.5)	1 (1.8)
Subdural haematoma	2 (3.5)	1 (1.8)	0
Extradural haematoma	1 (1.8)	1 (1.8)	0
Procedural pain	1 (1.8)	1 (1.8)	0
Transfusion related complication	1 (1.8)	0	1 (1.8)
Investigations			
-Total	4 (7.0)	3 (5.3)	1 (1.8)
Alanine aminotransferase increased	1 (1.8)	1 (1.8)	0
Electrocardiogram qt prolonged	1 (1.8)	1 (1.8)	0
Transaminases increased	1 (1.8)	1 (1.8)	0
White blood cell count decreased	1 (1.8)	0	1 (1.8)
Metabolism and nutrition disorders			
-Total	5 (8.8)	3 (5.3)	1 (1.8)
Acidosis	1 (1.8)	0	0
Decreased appetite	1 (1.8)	1 (1.8)	0
Dehydration	1 (1.8)	1 (1.8)	0

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	1 (1.8)	0	1 (1.8)
Hypocalcaemia	1 (1.8)	0	0
Tumour lysis syndrome	1 (1.8)	1 (1.8)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (7.0)	2 (3.5)	0
Back pain	1 (1.8)	1 (1.8)	0
Flank pain	1 (1.8)	0	0
Myopathy	1 (1.8)	1 (1.8)	0
Myositis	1 (1.8)	1 (1.8)	0
Osteonecrosis	1 (1.8)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.8)	0	1 (1.8)
Glioblastoma multiforme	1 (1.8)	0	1 (1.8)
Nervous system disorders			
-Total	12 (21.1)	6 (10.5)	1 (1.8)
Encephalopathy	4 (7.0)	2 (3.5)	0
Seizure	4 (7.0)	2 (3.5)	0

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	3 (5.3)	3 (5.3)	0
Embolic stroke	1 (1.8)	0	1 (1.8)
Idiopathic intracranial hypertension	1 (1.8)	0	0
Psychiatric disorders			
-Total	2 (3.5)	1 (1.8)	0
Delirium	1 (1.8)	0	0
Mental status changes	1 (1.8)	1 (1.8)	0
Renal and urinary disorders			
-Total	6 (10.5)	2 (3.5)	3 (5.3)
Acute kidney injury	5 (8.8)	2 (3.5)	2 (3.5)
Renal failure	1 (1.8)	0	1 (1.8)
Reproductive system and breast disorders			
-Total	1 (1.8)	0	0
Scrotal pain	1 (1.8)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	12 (21.1)	2 (3.5)	7 (12.3)
Hypoxia	3 (5.3)	0	1 (1.8)

Eligibility for SCT: No

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary oedema	3 (5.3)	1 (1.8)	2 (3.5)
Respiratory failure	3 (5.3)	0	3 (5.3)
Acute respiratory failure	1 (1.8)	0	1 (1.8)
Epistaxis	1 (1.8)	1 (1.8)	0
Idiopathic pneumonia syndrome	1 (1.8)	0	1 (1.8)
Pleural effusion	1 (1.8)	0	0
Pulmonary mass	1 (1.8)	0	0
Respiratory distress	1 (1.8)	0	1 (1.8)
Skin and subcutaneous tissue disorders			
-Total	1 (1.8)	1 (1.8)	0
Ecchymosis	1 (1.8)	1 (1.8)	0
Vascular disorders			
-Total	10 (17.5)	6 (10.5)	4 (7.0)
Hypotension	9 (15.8)	5 (8.8)	4 (7.0)
Embolism	1 (1.8)	1 (1.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183n
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (86.4)	11 (50.0)	8 (36.4)
Blood and lymphatic system disorders			
-Total	11 (50.0)	10 (45.5)	1 (4.5)
Febrile neutropenia	10 (45.5)	10 (45.5)	0
Disseminated intravascular coagulation	1 (4.5)	0	0
Neutropenia	1 (4.5)	0	1 (4.5)
Pancytopenia	1 (4.5)	1 (4.5)	0
Gastrointestinal disorders			
-Total	6 (27.3)	4 (18.2)	0
Abdominal pain	2 (9.1)	1 (4.5)	0
Stomatitis	2 (9.1)	1 (4.5)	0
Ascites	1 (4.5)	1 (4.5)	0

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	1 (4.5)	1 (4.5)	0
Diarrhoea	1 (4.5)	0	0
Enterocolitis	1 (4.5)	1 (4.5)	0
Intestinal obstruction	1 (4.5)	1 (4.5)	0
General disorders and administration site conditions			
-Total	4 (18.2)	1 (4.5)	1 (4.5)
Pyrexia	3 (13.6)	1 (4.5)	0
Multiple organ dysfunction syndrome	1 (4.5)	0	1 (4.5)
Hepatobiliary disorders			
-Total	1 (4.5)	0	1 (4.5)
Hepatic failure	1 (4.5)	0	1 (4.5)
Immune system disorders			
-Total	14 (63.6)	3 (13.6)	2 (9.1)
Cytokine release syndrome	14 (63.6)	3 (13.6)	2 (9.1)
Infections and infestations			
-Total	7 (31.8)	5 (22.7)	2 (9.1)
Bacterial sepsis	1 (4.5)	0	1 (4.5)
Bronchitis	1 (4.5)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (4.5)	1 (4.5)	0
Clostridium difficile colitis	1 (4.5)	0	0
Corona virus infection	1 (4.5)	1 (4.5)	0
Device related infection	1 (4.5)	1 (4.5)	0
Gastroenteritis	1 (4.5)	1 (4.5)	0
Herpes zoster	1 (4.5)	1 (4.5)	0
Respiratory syncytial virus infection	1 (4.5)	1 (4.5)	0
Staphylococcal bacteraemia	1 (4.5)	1 (4.5)	0
Staphylococcal infection	1 (4.5)	0	1 (4.5)
Vascular device infection	1 (4.5)	1 (4.5)	0
Investigations			
-Total	1 (4.5)	0	1 (4.5)
White blood cell count decreased	1 (4.5)	0	1 (4.5)
Metabolism and nutrition disorders			
-Total	1 (4.5)	1 (4.5)	0
Dehydration	1 (4.5)	1 (4.5)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (4.5)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Osteonecrosis	1 (4.5)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (4.5)	0	1 (4.5)
Glioblastoma multiforme	1 (4.5)	0	1 (4.5)
Nervous system disorders			
-Total	6 (27.3)	3 (13.6)	0
Encephalopathy	3 (13.6)	1 (4.5)	0
Headache	2 (9.1)	2 (9.1)	0
Seizure	2 (9.1)	1 (4.5)	0
Reproductive system and breast disorders			
-Total	1 (4.5)	1 (4.5)	0
Vaginal haemorrhage	1 (4.5)	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (18.2)	1 (4.5)	1 (4.5)
Hypoxia	2 (9.1)	0	0
Pulmonary oedema	1 (4.5)	1 (4.5)	0
Respiratory distress	1 (4.5)	0	1 (4.5)

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	5 (22.7)	4 (18.2)	1 (4.5)
Hypotension	4 (18.2)	3 (13.6)	1 (4.5)
Embolism	1 (4.5)	1 (4.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183n
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (84.9)	16 (30.2)	25 (47.2)
Blood and lymphatic system disorders			
-Total	26 (49.1)	21 (39.6)	5 (9.4)
Febrile neutropenia	23 (43.4)	22 (41.5)	1 (1.9)
Neutropenia	2 (3.8)	0	2 (3.8)
Pancytopenia	2 (3.8)	0	2 (3.8)
Disseminated intravascular coagulation	1 (1.9)	0	0
Eosinophilia	1 (1.9)	1 (1.9)	0
Cardiac disorders			
-Total	3 (5.7)	0	1 (1.9)
Atrioventricular block second degree	1 (1.9)	0	0
Cardiovascular insufficiency	1 (1.9)	0	1 (1.9)

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ventricular tachycardia	1 (1.9)	0	0
Eye disorders			
-Total	2 (3.8)	0	0
Papilloedema	1 (1.9)	0	0
Vision blurred	1 (1.9)	0	0
Gastrointestinal disorders			
-Total	7 (13.2)	6 (11.3)	0
Colitis	2 (3.8)	2 (3.8)	0
Abdominal pain	1 (1.9)	1 (1.9)	0
Diarrhoea	1 (1.9)	0	0
Pancreatitis	1 (1.9)	1 (1.9)	0
Stomatitis	1 (1.9)	1 (1.9)	0
Vomiting	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	12 (22.6)	3 (5.7)	2 (3.8)
Pyrexia	7 (13.2)	1 (1.9)	0
Multiple organ dysfunction syndrome	2 (3.8)	0	2 (3.8)
Physical deconditioning	2 (3.8)	2 (3.8)	0

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	1 (1.9)	0	0
Hepatobiliary disorders			
-Total	2 (3.8)	2 (3.8)	0
Cholecystitis	1 (1.9)	1 (1.9)	0
Hyperbilirubinaemia	1 (1.9)	1 (1.9)	0
Immune system disorders			
-Total	27 (50.9)	5 (9.4)	8 (15.1)
Cytokine release syndrome	27 (50.9)	5 (9.4)	8 (15.1)
Graft versus host disease in gastrointestinal tract	1 (1.9)	0	0
Infections and infestations			
-Total	24 (45.3)	13 (24.5)	8 (15.1)
Pneumonia	4 (7.5)	1 (1.9)	1 (1.9)
Clostridium difficile infection	3 (5.7)	1 (1.9)	0
Device related infection	2 (3.8)	2 (3.8)	0
Parainfluenzae virus infection	2 (3.8)	1 (1.9)	0
Sepsis	2 (3.8)	0	2 (3.8)
Urinary tract infection	2 (3.8)	1 (1.9)	0
Abscess limb	1 (1.9)	1 (1.9)	0

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (1.9)	1 (1.9)	0
Bronchopulmonary aspergillosis	1 (1.9)	1 (1.9)	0
Campylobacter infection	1 (1.9)	1 (1.9)	0
Candida sepsis	1 (1.9)	0	1 (1.9)
Catheter site infection	1 (1.9)	1 (1.9)	0
Cellulitis	1 (1.9)	1 (1.9)	0
Cellulitis of male external genital organ	1 (1.9)	1 (1.9)	0
Clostridium difficile colitis	1 (1.9)	0	0
Enterovirus infection	1 (1.9)	1 (1.9)	0
Escherichia bacteraemia	1 (1.9)	1 (1.9)	0
Escherichia sepsis	1 (1.9)	0	1 (1.9)
Escherichia urinary tract infection	1 (1.9)	1 (1.9)	0
Gastroenteritis norovirus	1 (1.9)	0	0
Klebsiella sepsis	1 (1.9)	0	1 (1.9)
Necrotising fasciitis	1 (1.9)	1 (1.9)	0
Pneumonia fungal	1 (1.9)	0	0
Respiratory syncytial virus bronchitis	1 (1.9)	1 (1.9)	0
Respiratory syncytial virus infection	1 (1.9)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	1 (1.9)	0	1 (1.9)
Respiratory tract infection viral	1 (1.9)	1 (1.9)	0
Rhinovirus infection	1 (1.9)	0	0
Rotavirus infection	1 (1.9)	1 (1.9)	0
Septic embolus	1 (1.9)	0	1 (1.9)
Staphylococcal bacteraemia	1 (1.9)	1 (1.9)	0
Staphylococcal infection	1 (1.9)	1 (1.9)	0
Staphylococcal scalded skin syndrome	1 (1.9)	0	0
Staphylococcal sepsis	1 (1.9)	0	1 (1.9)
Streptococcal bacteraemia	1 (1.9)	1 (1.9)	0
Upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Viral upper respiratory tract infection	1 (1.9)	1 (1.9)	0
Vulvovaginal candidiasis	1 (1.9)	0	0
Injury, poisoning and procedural complications			
-Total	4 (7.5)	2 (3.8)	1 (1.9)
Subdural haematoma	2 (3.8)	1 (1.9)	0
Extradural haematoma	1 (1.9)	1 (1.9)	0

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural pain	1 (1.9)	1 (1.9)	0
Transfusion related complication	1 (1.9)	0	1 (1.9)
Investigations			
-Total	3 (5.7)	3 (5.7)	0
Alanine aminotransferase increased	1 (1.9)	1 (1.9)	0
Electrocardiogram qt prolonged	1 (1.9)	1 (1.9)	0
Transaminases increased	1 (1.9)	1 (1.9)	0
Metabolism and nutrition disorders			
-Total	6 (11.3)	3 (5.7)	1 (1.9)
Hypocalcaemia	2 (3.8)	0	0
Tumour lysis syndrome	2 (3.8)	2 (3.8)	0
Acidosis	1 (1.9)	0	0
Decreased appetite	1 (1.9)	1 (1.9)	0
Hypernatraemia	1 (1.9)	0	1 (1.9)
Hypophosphataemia	1 (1.9)	1 (1.9)	0
Malnutrition	1 (1.9)	0	0
Musculoskeletal and connective tissue disorders			
-Total	4 (7.5)	2 (3.8)	0

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	1 (1.9)	1 (1.9)	0
Flank pain	1 (1.9)	0	0
Myopathy	1 (1.9)	1 (1.9)	0
Myositis	1 (1.9)	1 (1.9)	0
Pain in extremity	1 (1.9)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.9)	0	0
Myelodysplastic syndrome	1 (1.9)	0	0
Nervous system disorders			
-Total	6 (11.3)	3 (5.7)	1 (1.9)
Seizure	2 (3.8)	1 (1.9)	0
Embolic stroke	1 (1.9)	0	1 (1.9)
Encephalopathy	1 (1.9)	1 (1.9)	0
Headache	1 (1.9)	1 (1.9)	0
Idiopathic intracranial hypertension	1 (1.9)	0	0
Psychiatric disorders			
-Total	2 (3.8)	1 (1.9)	0
Delirium	1 (1.9)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (1.9)	1 (1.9)	0
Renal and urinary disorders			
-Total	7 (13.2)	3 (5.7)	3 (5.7)
Acute kidney injury	6 (11.3)	3 (5.7)	2 (3.8)
Renal failure	1 (1.9)	0	1 (1.9)
Reproductive system and breast disorders			
-Total	1 (1.9)	0	0
Scrotal pain	1 (1.9)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	12 (22.6)	2 (3.8)	8 (15.1)
Hypoxia	4 (7.5)	2 (3.8)	1 (1.9)
Respiratory failure	4 (7.5)	0	4 (7.5)
Pleural effusion	2 (3.8)	1 (1.9)	0
Pulmonary oedema	2 (3.8)	0	2 (3.8)
Acute respiratory failure	1 (1.9)	0	1 (1.9)
Aspiration	1 (1.9)	0	1 (1.9)
Epistaxis	1 (1.9)	1 (1.9)	0

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Idiopathic pneumonia syndrome	1 (1.9)	0	1 (1.9)
Pulmonary mass	1 (1.9)	0	0
Skin and subcutaneous tissue disorders			
-Total	1 (1.9)	1 (1.9)	0
Ecchymosis	1 (1.9)	1 (1.9)	0
Vascular disorders			
-Total	7 (13.2)	3 (5.7)	4 (7.5)
Hypotension	7 (13.2)	3 (5.7)	4 (7.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183o
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	2 (28.6)	3 (42.9)
Blood and lymphatic system disorders			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Febrile neutropenia	3 (42.9)	2 (28.6)	1 (14.3)
General disorders and administration site conditions			
-Total	1 (14.3)	0	0
Malaise	1 (14.3)	0	0
Immune system disorders			
-Total	3 (42.9)	0	1 (14.3)
Cytokine release syndrome	3 (42.9)	0	1 (14.3)
Infections and infestations			
-Total	1 (14.3)	1 (14.3)	0

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	1 (14.3)	1 (14.3)	0
Viral upper respiratory tract infection	1 (14.3)	1 (14.3)	0
Injury, poisoning and procedural complications			
-Total	2 (28.6)	2 (28.6)	0
Extradural haematoma	1 (14.3)	1 (14.3)	0
Procedural pain	1 (14.3)	1 (14.3)	0
Subdural haematoma	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	1 (14.3)	0	0
Malnutrition	1 (14.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (14.3)	0	1 (14.3)
Glioblastoma multiforme	1 (14.3)	0	1 (14.3)
Nervous system disorders			
-Total	2 (28.6)	2 (28.6)	0
Headache	1 (14.3)	1 (14.3)	0
Seizure	1 (14.3)	1 (14.3)	0

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=7 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Psychiatric disorders			
-Total	1 (14.3)	1 (14.3)	0
Mental status changes	1 (14.3)	1 (14.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183o
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (86.8)	25 (36.8)	30 (44.1)
Blood and lymphatic system disorders			
-Total	34 (50.0)	29 (42.6)	5 (7.4)
Febrile neutropenia	30 (44.1)	30 (44.1)	0
Neutropenia	3 (4.4)	0	3 (4.4)
Pancytopenia	3 (4.4)	1 (1.5)	2 (2.9)
Disseminated intravascular coagulation	2 (2.9)	0	0
Eosinophilia	1 (1.5)	1 (1.5)	0
Cardiac disorders			
-Total	3 (4.4)	0	1 (1.5)
Atrioventricular block second degree	1 (1.5)	0	0
Cardiovascular insufficiency	1 (1.5)	0	1 (1.5)

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ventricular tachycardia	1 (1.5)	0	0
Eye disorders			
-Total	2 (2.9)	0	0
Papilloedema	1 (1.5)	0	0
Vision blurred	1 (1.5)	0	0
Gastrointestinal disorders			
-Total	13 (19.1)	10 (14.7)	0
Abdominal pain	3 (4.4)	2 (2.9)	0
Colitis	3 (4.4)	3 (4.4)	0
Stomatitis	3 (4.4)	2 (2.9)	0
Diarrhoea	2 (2.9)	0	0
Ascites	1 (1.5)	1 (1.5)	0
Enterocolitis	1 (1.5)	1 (1.5)	0
Intestinal obstruction	1 (1.5)	1 (1.5)	0
Pancreatitis	1 (1.5)	1 (1.5)	0
Vomiting	1 (1.5)	1 (1.5)	0
General disorders and administration site conditions			
-Total	15 (22.1)	4 (5.9)	3 (4.4)

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	10 (14.7)	2 (2.9)	0
Multiple organ dysfunction syndrome	3 (4.4)	0	3 (4.4)
Physical deconditioning	2 (2.9)	2 (2.9)	0
Hepatobiliary disorders			
-Total	3 (4.4)	2 (2.9)	1 (1.5)
Cholecystitis	1 (1.5)	1 (1.5)	0
Hepatic failure	1 (1.5)	0	1 (1.5)
Hyperbilirubinaemia	1 (1.5)	1 (1.5)	0
Immune system disorders			
-Total	38 (55.9)	8 (11.8)	9 (13.2)
Cytokine release syndrome	38 (55.9)	8 (11.8)	9 (13.2)
Graft versus host disease in gastrointestinal tract	1 (1.5)	0	0
Infections and infestations			
-Total	30 (44.1)	17 (25.0)	10 (14.7)
Pneumonia	4 (5.9)	1 (1.5)	1 (1.5)
Clostridium difficile infection	3 (4.4)	1 (1.5)	0
Clostridium difficile colitis	2 (2.9)	0	0
Device related infection	2 (2.9)	2 (2.9)	0

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Parainfluenzae virus infection	2 (2.9)	1 (1.5)	0
Respiratory syncytial virus infection	2 (2.9)	1 (1.5)	0
Sepsis	2 (2.9)	0	2 (2.9)
Staphylococcal bacteraemia	2 (2.9)	2 (2.9)	0
Staphylococcal infection	2 (2.9)	1 (1.5)	1 (1.5)
Urinary tract infection	2 (2.9)	1 (1.5)	0
Abscess limb	1 (1.5)	1 (1.5)	0
Bacteraemia	1 (1.5)	1 (1.5)	0
Bacterial sepsis	1 (1.5)	0	1 (1.5)
Bronchitis	1 (1.5)	0	0
Bronchopulmonary aspergillosis	1 (1.5)	1 (1.5)	0
Campylobacter infection	1 (1.5)	1 (1.5)	0
Candida sepsis	1 (1.5)	0	1 (1.5)
Catheter site infection	1 (1.5)	1 (1.5)	0
Cellulitis	1 (1.5)	1 (1.5)	0
Cellulitis of male external genital organ	1 (1.5)	1 (1.5)	0
Cholecystitis infective	1 (1.5)	1 (1.5)	0
Corona virus infection	1 (1.5)	1 (1.5)	0

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterovirus infection	1 (1.5)	1 (1.5)	0
Escherichia bacteraemia	1 (1.5)	1 (1.5)	0
Escherichia sepsis	1 (1.5)	0	1 (1.5)
Escherichia urinary tract infection	1 (1.5)	1 (1.5)	0
Gastroenteritis	1 (1.5)	1 (1.5)	0
Gastroenteritis norovirus	1 (1.5)	0	0
Herpes zoster	1 (1.5)	1 (1.5)	0
Klebsiella sepsis	1 (1.5)	0	1 (1.5)
Necrotising fasciitis	1 (1.5)	1 (1.5)	0
Pneumonia fungal	1 (1.5)	0	0
Respiratory syncytial virus bronchitis	1 (1.5)	1 (1.5)	0
Respiratory tract infection	1 (1.5)	0	1 (1.5)
Respiratory tract infection viral	1 (1.5)	1 (1.5)	0
Rhinovirus infection	1 (1.5)	0	0
Rotavirus infection	1 (1.5)	1 (1.5)	0
Septic embolus	1 (1.5)	0	1 (1.5)
Staphylococcal scalded skin syndrome	1 (1.5)	0	0
Staphylococcal sepsis	1 (1.5)	0	1 (1.5)

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal bacteraemia	1 (1.5)	1 (1.5)	0
Upper respiratory tract infection	1 (1.5)	1 (1.5)	0
Vascular device infection	1 (1.5)	1 (1.5)	0
Vulvovaginal candidiasis	1 (1.5)	0	0
Injury, poisoning and procedural complications			
-Total	2 (2.9)	0	1 (1.5)
Subdural haematoma	1 (1.5)	0	0
Transfusion related complication	1 (1.5)	0	1 (1.5)
Investigations			
-Total	4 (5.9)	3 (4.4)	1 (1.5)
Alanine aminotransferase increased	1 (1.5)	1 (1.5)	0
Electrocardiogram qt prolonged	1 (1.5)	1 (1.5)	0
Transaminases increased	1 (1.5)	1 (1.5)	0
White blood cell count decreased	1 (1.5)	0	1 (1.5)
Metabolism and nutrition disorders			
-Total	6 (8.8)	4 (5.9)	1 (1.5)
Hypocalcaemia	2 (2.9)	0	0
Tumour lysis syndrome	2 (2.9)	2 (2.9)	0

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acidosis	1 (1.5)	0	0
Decreased appetite	1 (1.5)	1 (1.5)	0
Dehydration	1 (1.5)	1 (1.5)	0
Hypernatraemia	1 (1.5)	0	1 (1.5)
Hypophosphataemia	1 (1.5)	1 (1.5)	0
Musculoskeletal and connective tissue disorders			
-Total	5 (7.4)	2 (2.9)	0
Back pain	1 (1.5)	1 (1.5)	0
Flank pain	1 (1.5)	0	0
Myopathy	1 (1.5)	1 (1.5)	0
Myositis	1 (1.5)	1 (1.5)	0
Osteonecrosis	1 (1.5)	0	0
Pain in extremity	1 (1.5)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (1.5)	0	0
Myelodysplastic syndrome	1 (1.5)	0	0
Nervous system disorders			

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (14.7)	4 (5.9)	1 (1.5)
Encephalopathy	4 (5.9)	2 (2.9)	0
Seizure	3 (4.4)	1 (1.5)	0
Headache	2 (2.9)	2 (2.9)	0
Embolic stroke	1 (1.5)	0	1 (1.5)
Idiopathic intracranial hypertension	1 (1.5)	0	0
Psychiatric disorders			
-Total	1 (1.5)	0	0
Delirium	1 (1.5)	0	0
Renal and urinary disorders			
-Total	7 (10.3)	3 (4.4)	3 (4.4)
Acute kidney injury	6 (8.8)	3 (4.4)	2 (2.9)
Renal failure	1 (1.5)	0	1 (1.5)
Reproductive system and breast disorders			
-Total	2 (2.9)	1 (1.5)	0
Scrotal pain	1 (1.5)	0	0
Vaginal haemorrhage	1 (1.5)	1 (1.5)	0

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	16 (23.5)	3 (4.4)	9 (13.2)
Hypoxia	6 (8.8)	2 (2.9)	1 (1.5)
Respiratory failure	4 (5.9)	0	4 (5.9)
Pulmonary oedema	3 (4.4)	1 (1.5)	2 (2.9)
Pleural effusion	2 (2.9)	1 (1.5)	0
Acute respiratory failure	1 (1.5)	0	1 (1.5)
Aspiration	1 (1.5)	0	1 (1.5)
Epistaxis	1 (1.5)	1 (1.5)	0
Idiopathic pneumonia syndrome	1 (1.5)	0	1 (1.5)
Pulmonary mass	1 (1.5)	0	0
Respiratory distress	1 (1.5)	0	1 (1.5)
Skin and subcutaneous tissue disorders			
-Total	1 (1.5)	1 (1.5)	0
Ecchymosis	1 (1.5)	1 (1.5)	0
Vascular disorders			
-Total	12 (17.6)	7 (10.3)	5 (7.4)

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=68 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypotension	11 (16.2)	6 (8.8)	5 (7.4)
Embolism	1 (1.5)	1 (1.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183p
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	3 (75.0)	0
Blood and lymphatic system disorders			
-Total	2 (50.0)	2 (50.0)	0
Febrile neutropenia	2 (50.0)	2 (50.0)	0
Gastrointestinal disorders			
-Total	2 (50.0)	2 (50.0)	0
Enterocolitis	1 (25.0)	1 (25.0)	0
Stomatitis	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
-Total	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0

Down syndrome: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Immune system disorders			
-Total	2 (50.0)	0	0
Cytokine release syndrome	2 (50.0)	0	0
Infections and infestations			
-Total	1 (25.0)	1 (25.0)	0
Corona virus infection	1 (25.0)	1 (25.0)	0
Respiratory syncytial virus infection	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	0
Vascular disorders			
-Total	1 (25.0)	1 (25.0)	0
Hypotension	1 (25.0)	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183p
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	61 (85.9)	24 (33.8)	33 (46.5)
Blood and lymphatic system disorders			
-Total	35 (49.3)	29 (40.8)	6 (8.5)
Febrile neutropenia	31 (43.7)	30 (42.3)	1 (1.4)
Neutropenia	3 (4.2)	0	3 (4.2)
Pancytopenia	3 (4.2)	1 (1.4)	2 (2.8)
Disseminated intravascular coagulation	2 (2.8)	0	0
Eosinophilia	1 (1.4)	1 (1.4)	0
Cardiac disorders			
-Total	3 (4.2)	0	1 (1.4)
Atrioventricular block second degree	1 (1.4)	0	0

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiovascular insufficiency	1 (1.4)	0	1 (1.4)
Ventricular tachycardia	1 (1.4)	0	0
Eye disorders			
-Total	2 (2.8)	0	0
Papilloedema	1 (1.4)	0	0
Vision blurred	1 (1.4)	0	0
Gastrointestinal disorders			
-Total	11 (15.5)	8 (11.3)	0
Abdominal pain	3 (4.2)	2 (2.8)	0
Colitis	3 (4.2)	3 (4.2)	0
Diarrhoea	2 (2.8)	0	0
Stomatitis	2 (2.8)	1 (1.4)	0
Ascites	1 (1.4)	1 (1.4)	0
Intestinal obstruction	1 (1.4)	1 (1.4)	0
Pancreatitis	1 (1.4)	1 (1.4)	0
Vomiting	1 (1.4)	1 (1.4)	0
General disorders and administration site conditions			

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (21.1)	3 (4.2)	3 (4.2)
Pyrexia	9 (12.7)	1 (1.4)	0
Multiple organ dysfunction syndrome	3 (4.2)	0	3 (4.2)
Physical deconditioning	2 (2.8)	2 (2.8)	0
Malaise	1 (1.4)	0	0
Hepatobiliary disorders			
-Total	3 (4.2)	2 (2.8)	1 (1.4)
Cholecystitis	1 (1.4)	1 (1.4)	0
Hepatic failure	1 (1.4)	0	1 (1.4)
Hyperbilirubinaemia	1 (1.4)	1 (1.4)	0
Immune system disorders			
-Total	39 (54.9)	8 (11.3)	10 (14.1)
Cytokine release syndrome	39 (54.9)	8 (11.3)	10 (14.1)
Graft versus host disease in gastrointestinal tract	1 (1.4)	0	0
Infections and infestations			
-Total	30 (42.3)	17 (23.9)	10 (14.1)
Pneumonia	4 (5.6)	1 (1.4)	1 (1.4)

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	3 (4.2)	1 (1.4)	0
Device related infection	3 (4.2)	3 (4.2)	0
Clostridium difficile colitis	2 (2.8)	0	0
Parainfluenzae virus infection	2 (2.8)	1 (1.4)	0
Sepsis	2 (2.8)	0	2 (2.8)
Staphylococcal bacteraemia	2 (2.8)	2 (2.8)	0
Staphylococcal infection	2 (2.8)	1 (1.4)	1 (1.4)
Urinary tract infection	2 (2.8)	1 (1.4)	0
Abscess limb	1 (1.4)	1 (1.4)	0
Bacteraemia	1 (1.4)	1 (1.4)	0
Bacterial sepsis	1 (1.4)	0	1 (1.4)
Bronchitis	1 (1.4)	0	0
Bronchopulmonary aspergillosis	1 (1.4)	1 (1.4)	0
Campylobacter infection	1 (1.4)	1 (1.4)	0
Candida sepsis	1 (1.4)	0	1 (1.4)
Catheter site infection	1 (1.4)	1 (1.4)	0
Cellulitis	1 (1.4)	1 (1.4)	0

Down syndrome: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Cellulitis of male external genital organ	1 (1.4)	1 (1.4)	0
Cholecystitis infective	1 (1.4)	1 (1.4)	0
Enterovirus infection	1 (1.4)	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Escherichia sepsis	1 (1.4)	0	1 (1.4)
Escherichia urinary tract infection	1 (1.4)	1 (1.4)	0
Gastroenteritis	1 (1.4)	1 (1.4)	0
Gastroenteritis norovirus	1 (1.4)	0	0
Herpes zoster	1 (1.4)	1 (1.4)	0
Klebsiella sepsis	1 (1.4)	0	1 (1.4)
Necrotising fasciitis	1 (1.4)	1 (1.4)	0
Pneumonia fungal	1 (1.4)	0	0
Respiratory syncytial virus bronchitis	1 (1.4)	1 (1.4)	0
Respiratory syncytial virus infection	1 (1.4)	0	0
Respiratory tract infection	1 (1.4)	0	1 (1.4)
Respiratory tract infection viral	1 (1.4)	1 (1.4)	0
Rhinovirus infection	1 (1.4)	0	0

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rotavirus infection	1 (1.4)	1 (1.4)	0
Septic embolus	1 (1.4)	0	1 (1.4)
Staphylococcal scalded skin syndrome	1 (1.4)	0	0
Staphylococcal sepsis	1 (1.4)	0	1 (1.4)
Streptococcal bacteraemia	1 (1.4)	1 (1.4)	0
Upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Vascular device infection	1 (1.4)	1 (1.4)	0
Viral upper respiratory tract infection	1 (1.4)	1 (1.4)	0
Vulvovaginal candidiasis	1 (1.4)	0	0
Injury, poisoning and procedural complications			
-Total	4 (5.6)	2 (2.8)	1 (1.4)
Subdural haematoma	2 (2.8)	1 (1.4)	0
Extradural haematoma	1 (1.4)	1 (1.4)	0
Procedural pain	1 (1.4)	1 (1.4)	0
Transfusion related complication	1 (1.4)	0	1 (1.4)
Investigations			
-Total	4 (5.6)	3 (4.2)	1 (1.4)

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (1.4)	1 (1.4)	0
Electrocardiogram qt prolonged	1 (1.4)	1 (1.4)	0
Transaminases increased	1 (1.4)	1 (1.4)	0
White blood cell count decreased	1 (1.4)	0	1 (1.4)
Metabolism and nutrition disorders			
-Total	7 (9.9)	4 (5.6)	1 (1.4)
Hypocalcaemia	2 (2.8)	0	0
Tumour lysis syndrome	2 (2.8)	2 (2.8)	0
Acidosis	1 (1.4)	0	0
Decreased appetite	1 (1.4)	1 (1.4)	0
Dehydration	1 (1.4)	1 (1.4)	0
Hypernatraemia	1 (1.4)	0	1 (1.4)
Hypophosphataemia	1 (1.4)	1 (1.4)	0
Malnutrition	1 (1.4)	0	0
Musculoskeletal and connective tissue disorders			
-Total	5 (7.0)	2 (2.8)	0
Back pain	1 (1.4)	1 (1.4)	0

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flank pain	1 (1.4)	0	0
Myopathy	1 (1.4)	1 (1.4)	0
Myositis	1 (1.4)	1 (1.4)	0
Osteonecrosis	1 (1.4)	0	0
Pain in extremity	1 (1.4)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (2.8)	0	1 (1.4)
Glioblastoma multiforme	1 (1.4)	0	1 (1.4)
Myelodysplastic syndrome	1 (1.4)	0	0
Nervous system disorders			
-Total	12 (16.9)	6 (8.5)	1 (1.4)
Encephalopathy	4 (5.6)	2 (2.8)	0
Seizure	4 (5.6)	2 (2.8)	0
Headache	3 (4.2)	3 (4.2)	0
Embolic stroke	1 (1.4)	0	1 (1.4)
Idiopathic intracranial hypertension	1 (1.4)	0	0
Psychiatric disorders			

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (2.8)	1 (1.4)	0
Delirium	1 (1.4)	0	0
Mental status changes	1 (1.4)	1 (1.4)	0
Renal and urinary disorders			
-Total	7 (9.9)	3 (4.2)	3 (4.2)
Acute kidney injury	6 (8.5)	3 (4.2)	2 (2.8)
Renal failure	1 (1.4)	0	1 (1.4)
Reproductive system and breast disorders			
-Total	2 (2.8)	1 (1.4)	0
Scrotal pain	1 (1.4)	0	0
Vaginal haemorrhage	1 (1.4)	1 (1.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	15 (21.1)	3 (4.2)	9 (12.7)
Hypoxia	5 (7.0)	2 (2.8)	1 (1.4)
Respiratory failure	4 (5.6)	0	4 (5.6)
Pulmonary oedema	3 (4.2)	1 (1.4)	2 (2.8)
Pleural effusion	2 (2.8)	1 (1.4)	0

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute respiratory failure	1 (1.4)	0	1 (1.4)
Aspiration	1 (1.4)	0	1 (1.4)
Epistaxis	1 (1.4)	1 (1.4)	0
Idiopathic pneumonia syndrome	1 (1.4)	0	1 (1.4)
Pulmonary mass	1 (1.4)	0	0
Respiratory distress	1 (1.4)	0	1 (1.4)
Skin and subcutaneous tissue disorders			
-Total	1 (1.4)	1 (1.4)	0
Ecchymosis	1 (1.4)	1 (1.4)	0
Vascular disorders			
-Total	11 (15.5)	6 (8.5)	5 (7.0)
Hypotension	10 (14.1)	5 (7.0)	5 (7.0)
Embolism	1 (1.4)	1 (1.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183q
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (90.6)	15 (46.9)	12 (37.5)
Blood and lymphatic system disorders			
-Total	18 (56.3)	15 (46.9)	3 (9.4)
Febrile neutropenia	16 (50.0)	15 (46.9)	1 (3.1)
Pancytopenia	2 (6.3)	1 (3.1)	1 (3.1)
Neutropenia	1 (3.1)	0	1 (3.1)
Cardiac disorders			
-Total	1 (3.1)	0	0
Atrioventricular block second degree	1 (3.1)	0	0
Eye disorders			
-Total	1 (3.1)	0	0
Vision blurred	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	5 (15.6)	5 (15.6)	0
Stomatitis	2 (6.3)	2 (6.3)	0
Colitis	1 (3.1)	1 (3.1)	0
Intestinal obstruction	1 (3.1)	1 (3.1)	0
Vomiting	1 (3.1)	1 (3.1)	0
General disorders and administration site conditions			
-Total	6 (18.8)	2 (6.3)	0
Pyrexia	4 (12.5)	1 (3.1)	0
Malaise	1 (3.1)	0	0
Physical deconditioning	1 (3.1)	1 (3.1)	0
Hepatobiliary disorders			
-Total	2 (6.3)	2 (6.3)	0
Cholecystitis	1 (3.1)	1 (3.1)	0
Hyperbilirubinaemia	1 (3.1)	1 (3.1)	0
Immune system disorders			
-Total	19 (59.4)	2 (6.3)	4 (12.5)
Cytokine release syndrome	19 (59.4)	2 (6.3)	4 (12.5)

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Graft versus host disease in gastrointestinal tract	1 (3.1)	0	0
Infections and infestations			
-Total	15 (46.9)	9 (28.1)	4 (12.5)
Clostridium difficile infection	3 (9.4)	1 (3.1)	0
Device related infection	3 (9.4)	3 (9.4)	0
Parainfluenzae virus infection	2 (6.3)	1 (3.1)	0
Pneumonia	2 (6.3)	0	0
Abscess limb	1 (3.1)	1 (3.1)	0
Bacteraemia	1 (3.1)	1 (3.1)	0
Bacterial sepsis	1 (3.1)	0	1 (3.1)
Campylobacter infection	1 (3.1)	1 (3.1)	0
Catheter site infection	1 (3.1)	1 (3.1)	0
Enterovirus infection	1 (3.1)	1 (3.1)	0
Escherichia bacteraemia	1 (3.1)	1 (3.1)	0
Escherichia urinary tract infection	1 (3.1)	1 (3.1)	0
Gastroenteritis norovirus	1 (3.1)	0	0
Pneumonia fungal	1 (3.1)	0	0
Respiratory syncytial virus bronchitis	1 (3.1)	1 (3.1)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (3.1)	0	0
Respiratory tract infection	1 (3.1)	0	1 (3.1)
Respiratory tract infection viral	1 (3.1)	1 (3.1)	0
Rhinovirus infection	1 (3.1)	0	0
Rotavirus infection	1 (3.1)	1 (3.1)	0
Sepsis	1 (3.1)	0	1 (3.1)
Septic embolus	1 (3.1)	0	1 (3.1)
Staphylococcal bacteraemia	1 (3.1)	1 (3.1)	0
Staphylococcal infection	1 (3.1)	1 (3.1)	0
Staphylococcal scalded skin syndrome	1 (3.1)	0	0
Staphylococcal sepsis	1 (3.1)	0	1 (3.1)
Streptococcal bacteraemia	1 (3.1)	1 (3.1)	0
Urinary tract infection	1 (3.1)	0	0
Viral upper respiratory tract infection	1 (3.1)	1 (3.1)	0
Vulvovaginal candidiasis	1 (3.1)	0	0
Injury, poisoning and procedural complications			
-Total	3 (9.4)	2 (6.3)	1 (3.1)

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Extradural haematoma	1 (3.1)	1 (3.1)	0
Procedural pain	1 (3.1)	1 (3.1)	0
Subdural haematoma	1 (3.1)	1 (3.1)	0
Transfusion related complication	1 (3.1)	0	1 (3.1)
Investigations			
-Total	3 (9.4)	2 (6.3)	1 (3.1)
Electrocardiogram qt prolonged	1 (3.1)	1 (3.1)	0
Transaminases increased	1 (3.1)	1 (3.1)	0
White blood cell count decreased	1 (3.1)	0	1 (3.1)
Metabolism and nutrition disorders			
-Total	2 (6.3)	0	0
Hypocalcaemia	1 (3.1)	0	0
Malnutrition	1 (3.1)	0	0
Musculoskeletal and connective tissue disorders			
-Total	3 (9.4)	1 (3.1)	0
Flank pain	1 (3.1)	0	0
Myopathy	1 (3.1)	1 (3.1)	0
Myositis	1 (3.1)	1 (3.1)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	1 (3.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (3.1)	0	0
Myelodysplastic syndrome	1 (3.1)	0	0
Nervous system disorders			
-Total	4 (12.5)	3 (9.4)	1 (3.1)
Embolic stroke	1 (3.1)	0	1 (3.1)
Encephalopathy	1 (3.1)	1 (3.1)	0
Headache	1 (3.1)	1 (3.1)	0
Seizure	1 (3.1)	1 (3.1)	0
Psychiatric disorders			
-Total	1 (3.1)	1 (3.1)	0
Mental status changes	1 (3.1)	1 (3.1)	0
Renal and urinary disorders			
-Total	2 (6.3)	1 (3.1)	0
Acute kidney injury	2 (6.3)	1 (3.1)	0
Reproductive system and breast disorders			

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=32 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	1 (3.1)	1 (3.1)	0
Vaginal haemorrhage	1 (3.1)	1 (3.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (15.6)	1 (3.1)	2 (6.3)
Hypoxia	2 (6.3)	0	0
Acute respiratory failure	1 (3.1)	0	1 (3.1)
Epistaxis	1 (3.1)	1 (3.1)	0
Idiopathic pneumonia syndrome	1 (3.1)	0	1 (3.1)
Pulmonary mass	1 (3.1)	0	0
Vascular disorders			
-Total	3 (9.4)	3 (9.4)	0
Hypotension	2 (6.3)	2 (6.3)	0
Embolism	1 (3.1)	1 (3.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183q
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (87.5)	12 (37.5)	14 (43.8)
Blood and lymphatic system disorders			
-Total	17 (53.1)	14 (43.8)	3 (9.4)
Febrile neutropenia	15 (46.9)	15 (46.9)	0
Disseminated intravascular coagulation	2 (6.3)	0	0
Neutropenia	2 (6.3)	0	2 (6.3)
Eosinophilia	1 (3.1)	1 (3.1)	0
Pancytopenia	1 (3.1)	0	1 (3.1)
Cardiac disorders			
-Total	1 (3.1)	0	0
Ventricular tachycardia	1 (3.1)	0	0
Eye disorders			

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.1)	0	0
Papilloedema	1 (3.1)	0	0
Gastrointestinal disorders			
-Total	6 (18.8)	3 (9.4)	0
Abdominal pain	2 (6.3)	1 (3.1)	0
Diarrhoea	2 (6.3)	0	0
Enterocolitis	1 (3.1)	1 (3.1)	0
Pancreatitis	1 (3.1)	1 (3.1)	0
Stomatitis	1 (3.1)	0	0
General disorders and administration site conditions			
-Total	5 (15.6)	1 (3.1)	0
Pyrexia	4 (12.5)	0	0
Physical deconditioning	1 (3.1)	1 (3.1)	0
Immune system disorders			
-Total	22 (68.8)	6 (18.8)	6 (18.8)
Cytokine release syndrome	22 (68.8)	6 (18.8)	6 (18.8)
Infections and infestations			
-Total	11 (34.4)	9 (28.1)	1 (3.1)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	2 (6.3)	0	0
Bronchopulmonary aspergillosis	1 (3.1)	1 (3.1)	0
Cellulitis	1 (3.1)	1 (3.1)	0
Cellulitis of male external genital organ	1 (3.1)	1 (3.1)	0
Cholecystitis infective	1 (3.1)	1 (3.1)	0
Corona virus infection	1 (3.1)	1 (3.1)	0
Escherichia sepsis	1 (3.1)	0	1 (3.1)
Gastroenteritis	1 (3.1)	1 (3.1)	0
Herpes zoster	1 (3.1)	1 (3.1)	0
Necrotising fasciitis	1 (3.1)	1 (3.1)	0
Pneumonia	1 (3.1)	1 (3.1)	0
Respiratory syncytial virus infection	1 (3.1)	1 (3.1)	0
Upper respiratory tract infection	1 (3.1)	1 (3.1)	0
Urinary tract infection	1 (3.1)	1 (3.1)	0
Vascular device infection	1 (3.1)	1 (3.1)	0
Injury, poisoning and procedural complications			
-Total	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Subdural haematoma	1 (3.1)	0	0
Investigations			
-Total	1 (3.1)	1 (3.1)	0
Alanine aminotransferase increased	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			
-Total	4 (12.5)	4 (12.5)	0
Tumour lysis syndrome	2 (6.3)	2 (6.3)	0
Acidosis	1 (3.1)	0	0
Decreased appetite	1 (3.1)	1 (3.1)	0
Dehydration	1 (3.1)	1 (3.1)	0
Hypocalcaemia	1 (3.1)	0	0
Hypophosphataemia	1 (3.1)	1 (3.1)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (6.3)	1 (3.1)	0
Back pain	1 (3.1)	1 (3.1)	0
Osteonecrosis	1 (3.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.1)	0	1 (3.1)
Glioblastoma multiforme	1 (3.1)	0	1 (3.1)
Nervous system disorders			
-Total	7 (21.9)	2 (6.3)	0
Encephalopathy	3 (9.4)	1 (3.1)	0
Seizure	3 (9.4)	1 (3.1)	0
Headache	1 (3.1)	1 (3.1)	0
Idiopathic intracranial hypertension	1 (3.1)	0	0
Psychiatric disorders			
-Total	1 (3.1)	0	0
Delirium	1 (3.1)	0	0
Renal and urinary disorders			
-Total	4 (12.5)	2 (6.3)	2 (6.3)
Acute kidney injury	3 (9.4)	2 (6.3)	1 (3.1)
Renal failure	1 (3.1)	0	1 (3.1)
Reproductive system and breast disorders			
-Total	1 (3.1)	0	0
Scrotal pain	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	8 (25.0)	2 (6.3)	4 (12.5)
Hypoxia	3 (9.4)	1 (3.1)	1 (3.1)
Respiratory failure	3 (9.4)	0	3 (9.4)
Pleural effusion	2 (6.3)	1 (3.1)	0
Pulmonary oedema	2 (6.3)	1 (3.1)	1 (3.1)
Skin and subcutaneous tissue disorders			
-Total	1 (3.1)	1 (3.1)	0
Ecchymosis	1 (3.1)	1 (3.1)	0
Vascular disorders			
-Total	6 (18.8)	3 (9.4)	3 (9.4)
Hypotension	6 (18.8)	3 (9.4)	3 (9.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183q
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (63.6)	0	7 (63.6)
Blood and lymphatic system disorders			
-Total	2 (18.2)	2 (18.2)	0
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Cardiac disorders			
-Total	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Gastrointestinal disorders			
-Total	2 (18.2)	2 (18.2)	0
Colitis	2 (18.2)	2 (18.2)	0
Abdominal pain	1 (9.1)	1 (9.1)	0
Ascites	1 (9.1)	1 (9.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	5 (45.5)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Pyrexia	2 (18.2)	1 (9.1)	0
Hepatobiliary disorders			
-Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	5 (45.5)	0	5 (45.5)
Bronchitis	1 (9.1)	0	0
Candida sepsis	1 (9.1)	0	1 (9.1)
Klebsiella sepsis	1 (9.1)	0	1 (9.1)
Pneumonia	1 (9.1)	0	1 (9.1)
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	1 (9.1)	0	1 (9.1)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Headache	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	1 (9.1)	0	1 (9.1)
Acute kidney injury	1 (9.1)	0	1 (9.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (27.3)	0	3 (27.3)
Aspiration	1 (9.1)	0	1 (9.1)
Hypoxia	1 (9.1)	1 (9.1)	0
Pulmonary oedema	1 (9.1)	0	1 (9.1)
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Vascular disorders			
-Total	3 (27.3)	1 (9.1)	2 (18.2)
Hypotension	3 (27.3)	1 (9.1)	2 (18.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183r
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (87.5)	3 (37.5)	4 (50.0)
Blood and lymphatic system disorders			
-Total	3 (37.5)	3 (37.5)	0
Febrile neutropenia	3 (37.5)	3 (37.5)	0
Gastrointestinal disorders			
-Total	1 (12.5)	1 (12.5)	0
Enterocolitis	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	2 (25.0)	1 (12.5)	0
Pyrexia	2 (25.0)	1 (12.5)	0
Immune system disorders			

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (62.5)	0	3 (37.5)
Cytokine release syndrome	5 (62.5)	0	3 (37.5)
Infections and infestations			
-Total	3 (37.5)	2 (25.0)	1 (12.5)
Cellulitis	1 (12.5)	1 (12.5)	0
Corona virus infection	1 (12.5)	1 (12.5)	0
Pneumonia	1 (12.5)	0	1 (12.5)
Respiratory syncytial virus infection	1 (12.5)	1 (12.5)	0
Renal and urinary disorders			
-Total	1 (12.5)	0	1 (12.5)
Renal failure	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (25.0)	0	2 (25.0)
Aspiration	1 (12.5)	0	1 (12.5)
Hypoxia	1 (12.5)	1 (12.5)	0
Respiratory failure	1 (12.5)	0	1 (12.5)
Vascular disorders			

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (37.5)	2 (25.0)	1 (12.5)
Hypotension	3 (37.5)	2 (25.0)	1 (12.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183r
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (82.6)	8 (34.8)	9 (39.1)
Blood and lymphatic system disorders			
-Total	12 (52.2)	10 (43.5)	2 (8.7)
Febrile neutropenia	11 (47.8)	11 (47.8)	0
Pancytopenia	2 (8.7)	0	2 (8.7)
Disseminated intravascular coagulation	1 (4.3)	0	0
Cardiac disorders			
-Total	1 (4.3)	0	0
Ventricular tachycardia	1 (4.3)	0	0
Gastrointestinal disorders			
-Total	4 (17.4)	3 (13.0)	0

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (4.3)	1 (4.3)	0
Diarrhoea	1 (4.3)	0	0
Stomatitis	1 (4.3)	1 (4.3)	0
Vomiting	1 (4.3)	1 (4.3)	0
General disorders and administration site conditions			
-Total	4 (17.4)	3 (13.0)	0
Physical deconditioning	2 (8.7)	2 (8.7)	0
Pyrexia	2 (8.7)	1 (4.3)	0
Hepatobiliary disorders			
-Total	1 (4.3)	1 (4.3)	0
Hyperbilirubinaemia	1 (4.3)	1 (4.3)	0
Immune system disorders			
-Total	14 (60.9)	2 (8.7)	4 (17.4)
Cytokine release syndrome	14 (60.9)	2 (8.7)	4 (17.4)
Graft versus host disease in gastrointestinal tract	1 (4.3)	0	0
Infections and infestations			
-Total	9 (39.1)	7 (30.4)	1 (4.3)

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (8.7)	2 (8.7)	0
Pneumonia	2 (8.7)	1 (4.3)	0
Abscess limb	1 (4.3)	1 (4.3)	0
Bronchopulmonary aspergillosis	1 (4.3)	1 (4.3)	0
Clostridium difficile infection	1 (4.3)	0	0
Escherichia bacteraemia	1 (4.3)	1 (4.3)	0
Escherichia urinary tract infection	1 (4.3)	1 (4.3)	0
Gastroenteritis	1 (4.3)	1 (4.3)	0
Gastroenteritis norovirus	1 (4.3)	0	0
Herpes zoster	1 (4.3)	1 (4.3)	0
Parainfluenzae virus infection	1 (4.3)	0	0
Pneumonia fungal	1 (4.3)	0	0
Respiratory syncytial virus bronchitis	1 (4.3)	1 (4.3)	0
Respiratory syncytial virus infection	1 (4.3)	0	0
Sepsis	1 (4.3)	0	1 (4.3)
Staphylococcal bacteraemia	1 (4.3)	1 (4.3)	0
Staphylococcal infection	1 (4.3)	1 (4.3)	0

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal scalded skin syndrome	1 (4.3)	0	0
Staphylococcal sepsis	1 (4.3)	0	1 (4.3)
Viral upper respiratory tract infection	1 (4.3)	1 (4.3)	0
Injury, poisoning and procedural complications			
-Total	1 (4.3)	0	1 (4.3)
Transfusion related complication	1 (4.3)	0	1 (4.3)
Investigations			
-Total	1 (4.3)	1 (4.3)	0
Transaminases increased	1 (4.3)	1 (4.3)	0
Metabolism and nutrition disorders			
-Total	4 (17.4)	2 (8.7)	0
Acidosis	1 (4.3)	0	0
Dehydration	1 (4.3)	1 (4.3)	0
Hypocalcaemia	1 (4.3)	0	0
Malnutrition	1 (4.3)	0	0
Tumour lysis syndrome	1 (4.3)	1 (4.3)	0

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	4 (17.4)	2 (8.7)	0
Back pain	1 (4.3)	1 (4.3)	0
Flank pain	1 (4.3)	0	0
Myopathy	1 (4.3)	1 (4.3)	0
Myositis	1 (4.3)	1 (4.3)	0
Osteonecrosis	1 (4.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	2 (8.7)	0	1 (4.3)
Glioblastoma multiforme	1 (4.3)	0	1 (4.3)
Myelodysplastic syndrome	1 (4.3)	0	0
Nervous system disorders			
-Total	5 (21.7)	3 (13.0)	0
Encephalopathy	2 (8.7)	1 (4.3)	0
Seizure	2 (8.7)	1 (4.3)	0
Headache	1 (4.3)	1 (4.3)	0
Psychiatric disorders			

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.3)	0	0
Delirium	1 (4.3)	0	0
Renal and urinary disorders			
-Total	3 (13.0)	2 (8.7)	0
Acute kidney injury	3 (13.0)	2 (8.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (30.4)	3 (13.0)	3 (13.0)
Hypoxia	2 (8.7)	1 (4.3)	0
Pulmonary oedema	2 (8.7)	1 (4.3)	1 (4.3)
Acute respiratory failure	1 (4.3)	0	1 (4.3)
Epistaxis	1 (4.3)	1 (4.3)	0
Pulmonary mass	1 (4.3)	0	0
Respiratory distress	1 (4.3)	0	1 (4.3)
Respiratory failure	1 (4.3)	0	1 (4.3)
Skin and subcutaneous tissue disorders			
-Total	1 (4.3)	1 (4.3)	0
Ecchymosis	1 (4.3)	1 (4.3)	0

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	2 (8.7)	1 (4.3)	1 (4.3)
Hypotension	2 (8.7)	1 (4.3)	1 (4.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183r
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (87.5)	8 (33.3)	11 (45.8)
Blood and lymphatic system disorders			
-Total	13 (54.2)	10 (41.7)	3 (12.5)
Febrile neutropenia	11 (45.8)	10 (41.7)	1 (4.2)
Neutropenia	2 (8.3)	0	2 (8.3)
Disseminated intravascular coagulation	1 (4.2)	0	0
Pancytopenia	1 (4.2)	1 (4.2)	0
Cardiac disorders			
-Total	1 (4.2)	0	0
Atrioventricular block second degree	1 (4.2)	0	0

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders			
-Total	1 (4.2)	0	0
Vision blurred	1 (4.2)	0	0
Gastrointestinal disorders			
-Total	3 (12.5)	2 (8.3)	0
Abdominal pain	1 (4.2)	0	0
Intestinal obstruction	1 (4.2)	1 (4.2)	0
Pancreatitis	1 (4.2)	1 (4.2)	0
Stomatitis	1 (4.2)	0	0
General disorders and administration site conditions			
-Total	3 (12.5)	0	0
Pyrexia	3 (12.5)	0	0
Immune system disorders			
-Total	14 (58.3)	4 (16.7)	1 (4.2)
Cytokine release syndrome	14 (58.3)	4 (16.7)	1 (4.2)
Infections and infestations			
-Total	9 (37.5)	2 (8.3)	5 (20.8)

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacterial sepsis	1 (4.2)	0	1 (4.2)
Candida sepsis	1 (4.2)	0	1 (4.2)
Catheter site infection	1 (4.2)	1 (4.2)	0
Cholecystitis infective	1 (4.2)	1 (4.2)	0
Clostridium difficile colitis	1 (4.2)	0	0
Clostridium difficile infection	1 (4.2)	0	0
Escherichia sepsis	1 (4.2)	0	1 (4.2)
Parainfluenzae virus infection	1 (4.2)	1 (4.2)	0
Pneumonia	1 (4.2)	0	0
Respiratory tract infection	1 (4.2)	0	1 (4.2)
Rhinovirus infection	1 (4.2)	0	0
Septic embolus	1 (4.2)	0	1 (4.2)
Injury, poisoning and procedural complications			
-Total	1 (4.2)	1 (4.2)	0
Procedural pain	1 (4.2)	1 (4.2)	0
Investigations			
-Total	1 (4.2)	0	1 (4.2)

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (4.2)	0	1 (4.2)
Metabolism and nutrition disorders			
-Total	3 (12.5)	2 (8.3)	1 (4.2)
Decreased appetite	1 (4.2)	1 (4.2)	0
Hypernatraemia	1 (4.2)	0	1 (4.2)
Hypocalcaemia	1 (4.2)	0	0
Hypophosphataemia	1 (4.2)	1 (4.2)	0
Tumour lysis syndrome	1 (4.2)	1 (4.2)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (4.2)	0	0
Pain in extremity	1 (4.2)	0	0
Nervous system disorders			
-Total	3 (12.5)	1 (4.2)	1 (4.2)
Embolic stroke	1 (4.2)	0	1 (4.2)
Encephalopathy	1 (4.2)	1 (4.2)	0
Headache	1 (4.2)	1 (4.2)	0
Seizure	1 (4.2)	0	0

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	3 (12.5)	1 (4.2)	2 (8.3)
Acute kidney injury	3 (12.5)	1 (4.2)	2 (8.3)
Reproductive system and breast disorders			
-Total	1 (4.2)	1 (4.2)	0
Vaginal haemorrhage	1 (4.2)	1 (4.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (16.7)	0	3 (12.5)
Hypoxia	2 (8.3)	0	1 (4.2)
Respiratory failure	2 (8.3)	0	2 (8.3)
Pleural effusion	1 (4.2)	1 (4.2)	0
Pulmonary oedema	1 (4.2)	0	1 (4.2)
Vascular disorders			
-Total	3 (12.5)	1 (4.2)	2 (8.3)
Hypotension	3 (12.5)	1 (4.2)	2 (8.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 183r
Serious adverse events at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (85.0)	8 (40.0)	9 (45.0)
Blood and lymphatic system disorders			
-Total	9 (45.0)	8 (40.0)	1 (5.0)
Febrile neutropenia	8 (40.0)	8 (40.0)	0
Eosinophilia	1 (5.0)	1 (5.0)	0
Neutropenia	1 (5.0)	0	1 (5.0)
Cardiac disorders			
-Total	1 (5.0)	0	1 (5.0)
Cardiovascular insufficiency	1 (5.0)	0	1 (5.0)
Eye disorders			
-Total	1 (5.0)	0	0

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Papilloedema	1 (5.0)	0	0
Gastrointestinal disorders			
-Total	5 (25.0)	4 (20.0)	0
Colitis	3 (15.0)	3 (15.0)	0
Abdominal pain	1 (5.0)	1 (5.0)	0
Ascites	1 (5.0)	1 (5.0)	0
Diarrhoea	1 (5.0)	0	0
Stomatitis	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	7 (35.0)	0	3 (15.0)
Multiple organ dysfunction syndrome	3 (15.0)	0	3 (15.0)
Pyrexia	3 (15.0)	0	0
Malaise	1 (5.0)	0	0
Hepatobiliary disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Cholecystitis	1 (5.0)	1 (5.0)	0
Hepatic failure	1 (5.0)	0	1 (5.0)

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	8 (40.0)	2 (10.0)	2 (10.0)
Cytokine release syndrome	8 (40.0)	2 (10.0)	2 (10.0)
Infections and infestations			
-Total	10 (50.0)	7 (35.0)	3 (15.0)
Urinary tract infection	2 (10.0)	1 (5.0)	0
Bacteraemia	1 (5.0)	1 (5.0)	0
Bronchitis	1 (5.0)	0	0
Campylobacter infection	1 (5.0)	1 (5.0)	0
Cellulitis of male external genital organ	1 (5.0)	1 (5.0)	0
Clostridium difficile colitis	1 (5.0)	0	0
Clostridium difficile infection	1 (5.0)	1 (5.0)	0
Device related infection	1 (5.0)	1 (5.0)	0
Enterovirus infection	1 (5.0)	1 (5.0)	0
Klebsiella sepsis	1 (5.0)	0	1 (5.0)
Necrotising fasciitis	1 (5.0)	1 (5.0)	0
Respiratory tract infection viral	1 (5.0)	1 (5.0)	0

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rotavirus infection	1 (5.0)	1 (5.0)	0
Sepsis	1 (5.0)	0	1 (5.0)
Staphylococcal bacteraemia	1 (5.0)	1 (5.0)	0
Staphylococcal infection	1 (5.0)	0	1 (5.0)
Streptococcal bacteraemia	1 (5.0)	1 (5.0)	0
Upper respiratory tract infection	1 (5.0)	1 (5.0)	0
Vascular device infection	1 (5.0)	1 (5.0)	0
Vulvovaginal candidiasis	1 (5.0)	0	0
Injury, poisoning and procedural complications			
-Total	2 (10.0)	1 (5.0)	0
Subdural haematoma	2 (10.0)	1 (5.0)	0
Extradural haematoma	1 (5.0)	1 (5.0)	0
Investigations			
-Total	2 (10.0)	2 (10.0)	0
Alanine aminotransferase increased	1 (5.0)	1 (5.0)	0
Electrocardiogram qt prolonged	1 (5.0)	1 (5.0)	0
Nervous system disorders			

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (20.0)	2 (10.0)	0
Encephalopathy	1 (5.0)	0	0
Headache	1 (5.0)	1 (5.0)	0
Idiopathic intracranial hypertension	1 (5.0)	0	0
Seizure	1 (5.0)	1 (5.0)	0
Psychiatric disorders			
-Total	1 (5.0)	1 (5.0)	0
Mental status changes	1 (5.0)	1 (5.0)	0
Reproductive system and breast disorders			
-Total	1 (5.0)	0	0
Scrotal pain	1 (5.0)	0	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (15.0)	0	1 (5.0)
Hypoxia	1 (5.0)	0	0
Idiopathic pneumonia syndrome	1 (5.0)	0	1 (5.0)
Pleural effusion	1 (5.0)	0	0
Vascular disorders			

Number of previous relapses: >=3

Group term Preferred term	All patients N=20 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	4 (20.0)	3 (15.0)	1 (5.0)
Hypotension	3 (15.0)	2 (10.0)	1 (5.0)
Embolism	1 (5.0)	1 (5.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: <10 years

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (95.0)	1 (5.0)	5 (25.0)	2 (10.0)	11 (55.0)
Blood and lymphatic system disorders					
-Total	10 (50.0)	1 (5.0)	0	8 (40.0)	1 (5.0)
Anaemia	6 (30.0)	2 (10.0)	0	4 (20.0)	0
Febrile neutropenia	6 (30.0)	0	0	6 (30.0)	0
Thrombocytopenia	1 (5.0)	0	0	0	1 (5.0)
Cardiac disorders					
-Total	5 (25.0)	3 (15.0)	2 (10.0)	0	0
Sinus tachycardia	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Tachycardia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Eye disorders					
-Total	2 (10.0)	2 (10.0)	0	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctival haemorrhage	2 (10.0)	2 (10.0)	0	0	0
Periorbital oedema	2 (10.0)	2 (10.0)	0	0	0
Gastrointestinal disorders					
-Total	11 (55.0)	4 (20.0)	4 (20.0)	3 (15.0)	0
Nausea	8 (40.0)	3 (15.0)	3 (15.0)	2 (10.0)	0
Vomiting	7 (35.0)	5 (25.0)	2 (10.0)	0	0
Diarrhoea	6 (30.0)	4 (20.0)	2 (10.0)	0	0
Abdominal pain	4 (20.0)	3 (15.0)	1 (5.0)	0	0
Constipation	3 (15.0)	3 (15.0)	0	0	0
Pancreatitis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions					
-Total	8 (40.0)	2 (10.0)	3 (15.0)	3 (15.0)	0
Pyrexia	4 (20.0)	0	2 (10.0)	2 (10.0)	0
Fatigue	3 (15.0)	3 (15.0)	0	0	0
Catheter site pain	2 (10.0)	0	2 (10.0)	0	0
Oedema peripheral	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Chills	1 (5.0)	1 (5.0)	0	0	0
Immune system disorders					

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	19 (95.0)	1 (5.0)	12 (60.0)	3 (15.0)	3 (15.0)
Cytokine release syndrome	16 (80.0)	2 (10.0)	8 (40.0)	3 (15.0)	3 (15.0)
Hypogammaglobulinaemia	8 (40.0)	1 (5.0)	6 (30.0)	1 (5.0)	0
Infections and infestations					
-Total	9 (45.0)	3 (15.0)	4 (20.0)	2 (10.0)	0
Clostridium difficile infection	3 (15.0)	0	3 (15.0)	0	0
Rhinovirus infection	3 (15.0)	3 (15.0)	0	0	0
Clostridium difficile colitis	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Gastroenteritis	1 (5.0)	0	1 (5.0)	0	0
Pneumonia	1 (5.0)	0	0	1 (5.0)	0
Viral upper respiratory tract infection	1 (5.0)	0	1 (5.0)	0	0
Vulvovaginal candidiasis	1 (5.0)	1 (5.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Procedural pain	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Infusion related reaction	1 (5.0)	0	1 (5.0)	0	0
Transfusion reaction	1 (5.0)	1 (5.0)	0	0	0
Investigations					
-Total	14 (70.0)	0	1 (5.0)	3 (15.0)	10 (50.0)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	9 (45.0)	2 (10.0)	0	2 (10.0)	5 (25.0)
Neutrophil count decreased	8 (40.0)	0	1 (5.0)	1 (5.0)	6 (30.0)
Aspartate aminotransferase increased	7 (35.0)	1 (5.0)	1 (5.0)	3 (15.0)	2 (10.0)
Alanine aminotransferase increased	6 (30.0)	1 (5.0)	1 (5.0)	4 (20.0)	0
Lymphocyte count decreased	4 (20.0)	1 (5.0)	1 (5.0)	1 (5.0)	1 (5.0)
Blood bilirubin increased	3 (15.0)	0	2 (10.0)	1 (5.0)	0
Platelet count decreased	3 (15.0)	0	0	0	3 (15.0)
Blood fibrinogen decreased	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Blood urea increased	2 (10.0)	1 (5.0)	0	1 (5.0)	0
International normalised ratio increased	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Lipase increased	2 (10.0)	0	0	0	2 (10.0)
Prothrombin time prolonged	2 (10.0)	2 (10.0)	0	0	0
Activated partial thromboplastin time prolonged	1 (5.0)	1 (5.0)	0	0	0
Blood creatinine increased	1 (5.0)	0	0	1 (5.0)	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Transaminases increased	1 (5.0)	1 (5.0)	0	0	0
Metabolism and nutrition disorders					
-Total	12 (60.0)	2 (10.0)	4 (20.0)	5 (25.0)	1 (5.0)
Hypokalaemia	7 (35.0)	0	2 (10.0)	5 (25.0)	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	6 (30.0)	2 (10.0)	1 (5.0)	3 (15.0)	0
Hypophosphataemia	5 (25.0)	2 (10.0)	0	2 (10.0)	1 (5.0)
Hypertriglyceridaemia	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Hypoalbuminaemia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Hypocalcaemia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Fluid overload	1 (5.0)	1 (5.0)	0	0	0
Hyperglycaemia	1 (5.0)	0	1 (5.0)	0	0
Hyperphosphataemia	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Pain in extremity	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Nervous system disorders					
-Total	7 (35.0)	6 (30.0)	0	1 (5.0)	0
Headache	7 (35.0)	7 (35.0)	0	0	0
Dizziness	1 (5.0)	1 (5.0)	0	0	0
Seizure	1 (5.0)	0	0	1 (5.0)	0
Psychiatric disorders					
-Total	4 (20.0)	2 (10.0)	2 (10.0)	0	0
Confusional state	2 (10.0)	1 (5.0)	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	1 (5.0)	1 (5.0)	0	0	0
Delirium	1 (5.0)	0	1 (5.0)	0	0
Renal and urinary disorders					
-Total	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Acute kidney injury	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Reproductive system and breast disorders					
-Total	2 (10.0)	2 (10.0)	0	0	0
Vulvovaginal adhesion	2 (10.0)	2 (10.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (40.0)	2 (10.0)	1 (5.0)	5 (25.0)	0
Cough	4 (20.0)	4 (20.0)	0	0	0
Hypoxia	4 (20.0)	0	1 (5.0)	3 (15.0)	0
Pleural effusion	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0
Epistaxis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Pulmonary oedema	2 (10.0)	0	0	2 (10.0)	0
Tachypnoea	1 (5.0)	0	1 (5.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (40.0)	7 (35.0)	1 (5.0)	0	0
Hyperhidrosis	2 (10.0)	2 (10.0)	0	0	0

Timing: within 8 weeks post infusion, Age: <10 years

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	2 (10.0)	2 (10.0)	0	0	0
Rash maculo-papular	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Rash papular	2 (10.0)	2 (10.0)	0	0	0
Erythema	1 (5.0)	1 (5.0)	0	0	0
Petechiae	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	8 (40.0)	2 (10.0)	2 (10.0)	1 (5.0)	3 (15.0)
Hypertension	5 (25.0)	2 (10.0)	3 (15.0)	0	0
Hypotension	5 (25.0)	1 (5.0)	0	1 (5.0)	3 (15.0)
Flushing	2 (10.0)	2 (10.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

			All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (100)	1 (2.9)	3 (8.8)	8 (23.5)	22 (64.7)
Blood and lymphatic system disorders					
-Total	24 (70.6)	0	2 (5.9)	16 (47.1)	6 (17.6)
Anaemia	18 (52.9)	1 (2.9)	5 (14.7)	11 (32.4)	1 (2.9)
Febrile neutropenia	14 (41.2)	0	0	14 (41.2)	0
Neutropenia	5 (14.7)	0	0	1 (2.9)	4 (11.8)
Thrombocytopenia	4 (11.8)	0	0	2 (5.9)	2 (5.9)
Lymphopenia	2 (5.9)	0	0	1 (2.9)	1 (2.9)
Cardiac disorders					
-Total	10 (29.4)	6 (17.6)	3 (8.8)	1 (2.9)	0
Tachycardia	9 (26.5)	6 (17.6)	2 (5.9)	1 (2.9)	0
Sinus tachycardia	2 (5.9)	1 (2.9)	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Periorbital oedema	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Conjunctival haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Uveitis	1 (2.9)	0	1 (2.9)	0	0
Gastrointestinal disorders					
-Total	18 (52.9)	7 (20.6)	8 (23.5)	3 (8.8)	0
Vomiting	12 (35.3)	8 (23.5)	2 (5.9)	2 (5.9)	0
Nausea	9 (26.5)	3 (8.8)	6 (17.6)	0	0
Diarrhoea	8 (23.5)	5 (14.7)	2 (5.9)	1 (2.9)	0
Abdominal pain	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Constipation	3 (8.8)	3 (8.8)	0	0	0
Abdominal pain upper	1 (2.9)	0	1 (2.9)	0	0
General disorders and administration site conditions					
-Total	18 (52.9)	9 (26.5)	5 (14.7)	3 (8.8)	1 (2.9)
Fatigue	8 (23.5)	7 (20.6)	0	1 (2.9)	0
Pyrexia	8 (23.5)	2 (5.9)	4 (11.8)	1 (2.9)	1 (2.9)
Chills	4 (11.8)	4 (11.8)	0	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	3 (8.8)	0	1 (2.9)	2 (5.9)	0
Malaise	2 (5.9)	0	2 (5.9)	0	0
Catheter site pain	1 (2.9)	1 (2.9)	0	0	0
Hepatobiliary disorders					
-Total	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Hepatomegaly	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Immune system disorders					
-Total	29 (85.3)	3 (8.8)	13 (38.2)	8 (23.5)	5 (14.7)
Cytokine release syndrome	26 (76.5)	4 (11.8)	12 (35.3)	5 (14.7)	5 (14.7)
Hypogammaglobulinaemia	14 (41.2)	2 (5.9)	9 (26.5)	3 (8.8)	0
Infections and infestations					
-Total	6 (17.6)	1 (2.9)	4 (11.8)	1 (2.9)	0
Clostridium difficile colitis	2 (5.9)	0	2 (5.9)	0	0
Clostridium difficile infection	1 (2.9)	0	1 (2.9)	0	0
Gastroenteritis	1 (2.9)	0	0	1 (2.9)	0
Influenza	1 (2.9)	1 (2.9)	0	0	0
Upper respiratory tract infection	1 (2.9)	0	1 (2.9)	0	0
Injury, poisoning and procedural complications					

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Infusion related reaction	1 (2.9)	0	1 (2.9)	0	0
Procedural pain	1 (2.9)	0	1 (2.9)	0	0
Transfusion reaction	1 (2.9)	1 (2.9)	0	0	0
Investigations					
-Total	27 (79.4)	2 (5.9)	3 (8.8)	5 (14.7)	17 (50.0)
White blood cell count decreased	17 (50.0)	1 (2.9)	1 (2.9)	6 (17.6)	9 (26.5)
Neutrophil count decreased	16 (47.1)	0	1 (2.9)	3 (8.8)	12 (35.3)
Platelet count decreased	13 (38.2)	2 (5.9)	1 (2.9)	2 (5.9)	8 (23.5)
Alanine aminotransferase increased	12 (35.3)	3 (8.8)	2 (5.9)	7 (20.6)	0
Aspartate aminotransferase increased	9 (26.5)	1 (2.9)	3 (8.8)	4 (11.8)	1 (2.9)
Lymphocyte count decreased	9 (26.5)	0	1 (2.9)	5 (14.7)	3 (8.8)
Blood creatinine increased	8 (23.5)	5 (14.7)	2 (5.9)	1 (2.9)	0
International normalised ratio increased	6 (17.6)	6 (17.6)	0	0	0
Activated partial thromboplastin time prolonged	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Blood bilirubin increased	4 (11.8)	2 (5.9)	1 (2.9)	1 (2.9)	0
Prothrombin time prolonged	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Blood immunoglobulin m decreased	2 (5.9)	2 (5.9)	0	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood urea increased	1 (2.9)	0	1 (2.9)	0	0
Haemoglobin decreased	1 (2.9)	0	0	1 (2.9)	0
Transaminases increased	1 (2.9)	1 (2.9)	0	0	0
Metabolism and nutrition disorders					
-Total	17 (50.0)	3 (8.8)	4 (11.8)	10 (29.4)	0
Decreased appetite	10 (29.4)	2 (5.9)	2 (5.9)	6 (17.6)	0
Hyperphosphataemia	6 (17.6)	6 (17.6)	0	0	0
Hypokalaemia	6 (17.6)	1 (2.9)	3 (8.8)	2 (5.9)	0
Hypoalbuminaemia	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Hypophosphataemia	3 (8.8)	0	0	3 (8.8)	0
Dehydration	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Hyperuricaemia	2 (5.9)	2 (5.9)	0	0	0
Fluid overload	1 (2.9)	0	1 (2.9)	0	0
Hyperglycaemia	1 (2.9)	0	1 (2.9)	0	0
Hypocalcaemia	1 (2.9)	0	0	1 (2.9)	0
Musculoskeletal and connective tissue disorders					
-Total	9 (26.5)	6 (17.6)	2 (5.9)	1 (2.9)	0
Myalgia	5 (14.7)	4 (11.8)	1 (2.9)	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	4 (11.8)	3 (8.8)	0	1 (2.9)	0
Musculoskeletal pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Pain in extremity	1 (2.9)	1 (2.9)	0	0	0
Nervous system disorders					
-Total	19 (55.9)	9 (26.5)	7 (20.6)	3 (8.8)	0
Headache	15 (44.1)	8 (23.5)	5 (14.7)	2 (5.9)	0
Encephalopathy	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Seizure	2 (5.9)	0	2 (5.9)	0	0
Dizziness	1 (2.9)	1 (2.9)	0	0	0
Psychiatric disorders					
-Total	7 (20.6)	3 (8.8)	4 (11.8)	0	0
Anxiety	4 (11.8)	1 (2.9)	3 (8.8)	0	0
Confusional state	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Delirium	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Renal and urinary disorders					
-Total	4 (11.8)	1 (2.9)	0	1 (2.9)	2 (5.9)
Acute kidney injury	3 (8.8)	1 (2.9)	0	1 (2.9)	1 (2.9)
Haematuria	2 (5.9)	0	1 (2.9)	0	1 (2.9)

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	14 (41.2)	7 (20.6)	2 (5.9)	2 (5.9)	3 (8.8)
Epistaxis	4 (11.8)	1 (2.9)	0	2 (5.9)	1 (2.9)
Hypoxia	4 (11.8)	0	2 (5.9)	1 (2.9)	1 (2.9)
Tachypnoea	4 (11.8)	3 (8.8)	0	1 (2.9)	0
Cough	3 (8.8)	3 (8.8)	0	0	0
Pulmonary oedema	3 (8.8)	1 (2.9)	0	1 (2.9)	1 (2.9)
Oropharyngeal pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Pleural effusion	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Dyspnoea	1 (2.9)	0	0	1 (2.9)	0
Nasal congestion	1 (2.9)	1 (2.9)	0	0	0
Rhinitis allergic	1 (2.9)	1 (2.9)	0	0	0
Rhinorrhoea	1 (2.9)	1 (2.9)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (23.5)	7 (20.6)	1 (2.9)	0	0
Dry skin	4 (11.8)	4 (11.8)	0	0	0
Erythema	2 (5.9)	2 (5.9)	0	0	0
Hyperhidrosis	1 (2.9)	1 (2.9)	0	0	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ingrowing nail	1 (2.9)	0	1 (2.9)	0	0
Petechiae	1 (2.9)	1 (2.9)	0	0	0
Pruritus	1 (2.9)	1 (2.9)	0	0	0
Rash	1 (2.9)	1 (2.9)	0	0	0
Vascular disorders					
-Total	10 (29.4)	0	1 (2.9)	5 (14.7)	4 (11.8)
Hypotension	9 (26.5)	0	0	5 (14.7)	4 (11.8)
Hypertension	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Orthostatic hypotension	1 (2.9)	0	1 (2.9)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=18

			All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (100)	0	0	4 (40.0)	6 (60.0)
Blood and lymphatic system disorders					
-Total	7 (70.0)	0	0	3 (30.0)	4 (40.0)
Anaemia	3 (30.0)	0	0	3 (30.0)	0
Neutropenia	3 (30.0)	0	0	2 (20.0)	1 (10.0)
Thrombocytopenia	3 (30.0)	0	0	0	3 (30.0)
Febrile neutropenia	2 (20.0)	0	0	2 (20.0)	0
Lymphopenia	1 (10.0)	0	1 (10.0)	0	0
Pancytopenia	1 (10.0)	0	0	0	1 (10.0)
Cardiac disorders					
-Total	4 (40.0)	1 (10.0)	2 (20.0)	1 (10.0)	0
Tachycardia	4 (40.0)	1 (10.0)	2 (20.0)	1 (10.0)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (10.0)	0	0	1 (10.0)	0
Ear and labyrinth disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Hypoacusis	1 (10.0)	0	1 (10.0)	0	0
Eye disorders					
-Total	2 (20.0)	0	2 (20.0)	0	0
Papilloedema	1 (10.0)	0	1 (10.0)	0	0
Uveitis	1 (10.0)	0	1 (10.0)	0	0
Visual impairment	1 (10.0)	0	1 (10.0)	0	0
Gastrointestinal disorders					
-Total	5 (50.0)	1 (10.0)	2 (20.0)	2 (20.0)	0
Diarrhoea	4 (40.0)	2 (20.0)	2 (20.0)	0	0
Nausea	4 (40.0)	0	3 (30.0)	1 (10.0)	0
Vomiting	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Abdominal discomfort	1 (10.0)	1 (10.0)	0	0	0
Abdominal pain	1 (10.0)	0	0	1 (10.0)	0
Abdominal pain upper	1 (10.0)	0	1 (10.0)	0	0
Constipation	1 (10.0)	0	1 (10.0)	0	0
Dyspepsia	1 (10.0)	0	1 (10.0)	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Intestinal obstruction	1 (10.0)	0	0	1 (10.0)	0
General disorders and administration site conditions					
-Total	5 (50.0)	1 (10.0)	2 (20.0)	2 (20.0)	0
Pyrexia	4 (40.0)	1 (10.0)	1 (10.0)	2 (20.0)	0
Chills	3 (30.0)	3 (30.0)	0	0	0
Fatigue	2 (20.0)	0	2 (20.0)	0	0
Asthenia	1 (10.0)	1 (10.0)	0	0	0
Facial pain	1 (10.0)	0	1 (10.0)	0	0
Malaise	1 (10.0)	0	1 (10.0)	0	0
Hepatobiliary disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Hepatomegaly	1 (10.0)	0	1 (10.0)	0	0
Immune system disorders					
-Total	8 (80.0)	0	5 (50.0)	0	3 (30.0)
Cytokine release syndrome	8 (80.0)	0	5 (50.0)	0	3 (30.0)
Hypogammaglobulinaemia	3 (30.0)	0	3 (30.0)	0	0
Infections and infestations					
-Total	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Folliculitis	1 (10.0)	0	1 (10.0)	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Human herpesvirus 6 infection	1 (10.0)	0	1 (10.0)	0	0
Pneumonia	1 (10.0)	0	1 (10.0)	0	0
Urinary tract infection enterococcal	1 (10.0)	0	0	1 (10.0)	0
Injury, poisoning and procedural complications					
-Total	3 (30.0)	1 (10.0)	1 (10.0)	1 (10.0)	0
Incision site pain	1 (10.0)	1 (10.0)	0	0	0
Limb injury	1 (10.0)	1 (10.0)	0	0	0
Tracheal haemorrhage	1 (10.0)	0	0	1 (10.0)	0
Transfusion reaction	1 (10.0)	0	1 (10.0)	0	0
Investigations					
-Total	8 (80.0)	0	0	4 (40.0)	4 (40.0)
White blood cell count decreased	4 (40.0)	0	0	2 (20.0)	2 (20.0)
Platelet count decreased	3 (30.0)	1 (10.0)	1 (10.0)	0	1 (10.0)
Prothrombin time prolonged	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Aspartate aminotransferase increased	2 (20.0)	1 (10.0)	0	0	1 (10.0)
Blood fibrinogen decreased	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Alanine aminotransferase increased	1 (10.0)	1 (10.0)	0	0	0
Blood immunoglobulin m decreased	1 (10.0)	1 (10.0)	0	0	0
C-reactive protein increased	1 (10.0)	0	0	1 (10.0)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic enzyme increased	1 (10.0)	0	1 (10.0)	0	0
International normalised ratio increased	1 (10.0)	1 (10.0)	0	0	0
Lymphocyte count decreased	1 (10.0)	0	0	0	1 (10.0)
Neutrophil count decreased	1 (10.0)	0	0	0	1 (10.0)
Metabolism and nutrition disorders					
-Total	7 (70.0)	0	2 (20.0)	4 (40.0)	1 (10.0)
Decreased appetite	4 (40.0)	0	1 (10.0)	3 (30.0)	0
Hypokalaemia	3 (30.0)	2 (20.0)	1 (10.0)	0	0
Dehydration	1 (10.0)	0	0	1 (10.0)	0
Fluid overload	1 (10.0)	0	1 (10.0)	0	0
Hyperglycaemia	1 (10.0)	0	0	1 (10.0)	0
Hyperphosphataemia	1 (10.0)	1 (10.0)	0	0	0
Hyperuricaemia	1 (10.0)	0	0	0	1 (10.0)
Hypophosphataemia	1 (10.0)	0	0	1 (10.0)	0
Metabolic acidosis	1 (10.0)	0	1 (10.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Limb discomfort	1 (10.0)	1 (10.0)	0	0	0
Musculoskeletal pain	1 (10.0)	1 (10.0)	0	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	1 (10.0)	0	1 (10.0)	0	0
Nervous system disorders					
-Total	4 (40.0)	2 (20.0)	2 (20.0)	0	0
Dizziness	2 (20.0)	2 (20.0)	0	0	0
Headache	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Idiopathic intracranial hypertension	1 (10.0)	0	1 (10.0)	0	0
Psychiatric disorders					
-Total	4 (40.0)	2 (20.0)	1 (10.0)	1 (10.0)	0
Anxiety	1 (10.0)	0	0	1 (10.0)	0
Confusional state	1 (10.0)	1 (10.0)	0	0	0
Delirium	1 (10.0)	1 (10.0)	0	0	0
Panic attack	1 (10.0)	0	1 (10.0)	0	0
Renal and urinary disorders					
-Total	2 (20.0)	0	0	0	2 (20.0)
Acute kidney injury	2 (20.0)	0	0	0	2 (20.0)
Haematuria	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Reproductive system and breast disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Oedema genital	1 (10.0)	0	1 (10.0)	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	3 (30.0)	0	1 (10.0)	0	2 (20.0)
Hypoxia	2 (20.0)	0	0	0	2 (20.0)
Pleural effusion	2 (20.0)	0	2 (20.0)	0	0
Cough	1 (10.0)	1 (10.0)	0	0	0
Dyspnoea	1 (10.0)	0	0	0	1 (10.0)
Epistaxis	1 (10.0)	1 (10.0)	0	0	0
Interstitial lung disease	1 (10.0)	0	0	0	1 (10.0)
Pulmonary oedema	1 (10.0)	0	0	0	1 (10.0)
Skin and subcutaneous tissue disorders					
-Total	3 (30.0)	1 (10.0)	1 (10.0)	1 (10.0)	0
Ingrowing nail	1 (10.0)	0	1 (10.0)	0	0
Petechiae	1 (10.0)	0	1 (10.0)	0	0
Pruritus	1 (10.0)	1 (10.0)	0	0	0
Rash	1 (10.0)	1 (10.0)	0	0	0
Rash maculo-papular	1 (10.0)	0	0	1 (10.0)	0
Vascular disorders					
-Total	5 (50.0)	1 (10.0)	2 (20.0)	1 (10.0)	1 (10.0)
Hypertension	3 (30.0)	0	3 (30.0)	0	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	2 (20.0)	0	0	1 (10.0)	1 (10.0)
Orthostatic hypotension	1 (10.0)	1 (10.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

			All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (72.2)	2 (11.1)	7 (38.9)	4 (22.2)	0
Blood and lymphatic system disorders					
-Total	1 (5.6)	0	1 (5.6)	0	0
Thrombocytopenia	1 (5.6)	0	1 (5.6)	0	0
Gastrointestinal disorders					
-Total	5 (27.8)	2 (11.1)	3 (16.7)	0	0
Vomiting	4 (22.2)	2 (11.1)	2 (11.1)	0	0
Diarrhoea	3 (16.7)	3 (16.7)	0	0	0
Nausea	2 (11.1)	0	2 (11.1)	0	0
Abdominal pain	1 (5.6)	1 (5.6)	0	0	0
General disorders and administration site conditions					

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (33.3)	6 (33.3)	0	0	0
Pyrexia	5 (27.8)	5 (27.8)	0	0	0
Fatigue	1 (5.6)	1 (5.6)	0	0	0
Malaise	1 (5.6)	1 (5.6)	0	0	0
Immune system disorders					
-Total	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Hypogammaglobulinaemia	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Infections and infestations					
-Total	8 (44.4)	3 (16.7)	5 (27.8)	0	0
Upper respiratory tract infection	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Ear infection	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Gastroenteritis	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Otitis media acute	1 (5.6)	0	1 (5.6)	0	0
Sinusitis	1 (5.6)	0	1 (5.6)	0	0
Urinary tract infection	1 (5.6)	0	1 (5.6)	0	0
Viral upper respiratory tract infection	1 (5.6)	1 (5.6)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (5.6)	1 (5.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infusion related reaction	1 (5.6)	1 (5.6)	0	0	0
Procedural pain	1 (5.6)	1 (5.6)	0	0	0
Investigations					
-Total	4 (22.2)	1 (5.6)	1 (5.6)	2 (11.1)	0
Blood urea increased	1 (5.6)	1 (5.6)	0	0	0
Neutrophil count decreased	1 (5.6)	0	0	1 (5.6)	0
Weight decreased	1 (5.6)	0	1 (5.6)	0	0
White blood cell count decreased	1 (5.6)	0	0	1 (5.6)	0
Metabolism and nutrition disorders					
-Total	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Decreased appetite	1 (5.6)	0	1 (5.6)	0	0
Dehydration	1 (5.6)	0	0	1 (5.6)	0
Musculoskeletal and connective tissue disorders					
-Total	6 (33.3)	4 (22.2)	2 (11.1)	0	0
Pain in extremity	6 (33.3)	4 (22.2)	2 (11.1)	0	0
Nervous system disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Dizziness	2 (11.1)	2 (11.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (5.6)	0	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (27.8)	3 (16.7)	2 (11.1)	0	0
Cough	2 (11.1)	2 (11.1)	0	0	0
Rhinorrhoea	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Nasal congestion	1 (5.6)	1 (5.6)	0	0	0
Oropharyngeal pain	1 (5.6)	1 (5.6)	0	0	0
Rhinitis allergic	1 (5.6)	0	1 (5.6)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (5.6)	0	1 (5.6)	0	0
Pruritus	1 (5.6)	1 (5.6)	0	0	0
Rash	1 (5.6)	0	1 (5.6)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (77.4)	1 (3.2)	8 (25.8)	10 (32.3)	5 (16.1)
Blood and lymphatic system disorders					
-Total	8 (25.8)	1 (3.2)	1 (3.2)	3 (9.7)	3 (9.7)
Neutropenia	4 (12.9)	0	0	1 (3.2)	3 (9.7)
Febrile neutropenia	3 (9.7)	0	0	3 (9.7)	0
Anaemia	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Lymphopenia	1 (3.2)	0	1 (3.2)	0	0
Thrombocytopenia	1 (3.2)	0	0	1 (3.2)	0
Cardiac disorders					
-Total	1 (3.2)	0	1 (3.2)	0	0
Sinus tachycardia	1 (3.2)	0	1 (3.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	8 (25.8)	7 (22.6)	0	1 (3.2)	0
Diarrhoea	4 (12.9)	3 (9.7)	1 (3.2)	0	0
Vomiting	3 (9.7)	2 (6.5)	0	1 (3.2)	0
Abdominal pain	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Nausea	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Abdominal pain upper	1 (3.2)	1 (3.2)	0	0	0
General disorders and administration site conditions					
-Total	7 (22.6)	4 (12.9)	2 (6.5)	1 (3.2)	0
Pyrexia	3 (9.7)	1 (3.2)	1 (3.2)	1 (3.2)	0
Catheter site pain	1 (3.2)	0	1 (3.2)	0	0
Chills	1 (3.2)	1 (3.2)	0	0	0
Fatigue	1 (3.2)	1 (3.2)	0	0	0
Influenza like illness	1 (3.2)	1 (3.2)	0	0	0
Oedema peripheral	1 (3.2)	1 (3.2)	0	0	0
Pain	1 (3.2)	1 (3.2)	0	0	0
Immune system disorders					
-Total	5 (16.1)	0	5 (16.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	5 (16.1)	0	5 (16.1)	0	0
Infections and infestations					
-Total	12 (38.7)	3 (9.7)	5 (16.1)	4 (12.9)	0
Upper respiratory tract infection	4 (12.9)	1 (3.2)	2 (6.5)	1 (3.2)	0
Urinary tract infection	3 (9.7)	0	1 (3.2)	2 (6.5)	0
Rhinovirus infection	2 (6.5)	2 (6.5)	0	0	0
Gastroenteritis	1 (3.2)	0	1 (3.2)	0	0
Influenza	1 (3.2)	0	1 (3.2)	0	0
Sinusitis	1 (3.2)	0	1 (3.2)	0	0
Viral upper respiratory tract infection	1 (3.2)	0	0	1 (3.2)	0
Injury, poisoning and procedural complications					
-Total	2 (6.5)	0	2 (6.5)	0	0
Infusion related reaction	1 (3.2)	0	1 (3.2)	0	0
Procedural pain	1 (3.2)	0	1 (3.2)	0	0
Investigations					
-Total	12 (38.7)	2 (6.5)	1 (3.2)	6 (19.4)	3 (9.7)
Neutrophil count decreased	6 (19.4)	2 (6.5)	0	2 (6.5)	2 (6.5)
White blood cell count decreased	3 (9.7)	1 (3.2)	1 (3.2)	0	1 (3.2)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	2 (6.5)	0	0	2 (6.5)	0
Aspartate aminotransferase increased	2 (6.5)	0	0	2 (6.5)	0
Lymphocyte count decreased	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Platelet count decreased	2 (6.5)	2 (6.5)	0	0	0
Blood bilirubin increased	1 (3.2)	0	0	1 (3.2)	0
Blood creatinine increased	1 (3.2)	1 (3.2)	0	0	0
Haemoglobin decreased	1 (3.2)	1 (3.2)	0	0	0
Weight decreased	1 (3.2)	1 (3.2)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (12.9)	3 (9.7)	0	0	1 (3.2)
Hyperphosphataemia	2 (6.5)	2 (6.5)	0	0	0
Hypokalaemia	2 (6.5)	1 (3.2)	0	0	1 (3.2)
Decreased appetite	1 (3.2)	1 (3.2)	0	0	0
Hyperglycaemia	1 (3.2)	0	0	1 (3.2)	0
Hypophosphataemia	1 (3.2)	0	0	1 (3.2)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (9.7)	3 (9.7)	0	0	0
Pain in extremity	2 (6.5)	2 (6.5)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	1 (3.2)	1 (3.2)	0	0	0
Nervous system disorders					
-Total	4 (12.9)	4 (12.9)	0	0	0
Headache	3 (9.7)	3 (9.7)	0	0	0
Peroneal nerve palsy	1 (3.2)	1 (3.2)	0	0	0
Psychiatric disorders					
-Total	1 (3.2)	1 (3.2)	0	0	0
Anxiety	1 (3.2)	1 (3.2)	0	0	0
Renal and urinary disorders					
-Total	2 (6.5)	0	0	2 (6.5)	0
Acute kidney injury	1 (3.2)	0	0	1 (3.2)	0
Haematuria	1 (3.2)	0	0	1 (3.2)	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (32.3)	6 (19.4)	2 (6.5)	2 (6.5)	0
Cough	5 (16.1)	3 (9.7)	2 (6.5)	0	0
Nasal congestion	3 (9.7)	3 (9.7)	0	0	0
Epistaxis	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Oropharyngeal pain	2 (6.5)	1 (3.2)	1 (3.2)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	2 (6.5)	2 (6.5)	0	0	0
Pulmonary oedema	1 (3.2)	0	0	1 (3.2)	0
Rhinitis allergic	1 (3.2)	1 (3.2)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (29.0)	7 (22.6)	2 (6.5)	0	0
Rash	3 (9.7)	1 (3.2)	2 (6.5)	0	0
Rash maculo-papular	2 (6.5)	2 (6.5)	0	0	0
Dry skin	1 (3.2)	1 (3.2)	0	0	0
Erythema	1 (3.2)	1 (3.2)	0	0	0
Ingrowing nail	1 (3.2)	1 (3.2)	0	0	0
Petechiae	1 (3.2)	1 (3.2)	0	0	0
Vascular disorders					
-Total	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Hypertension	2 (6.5)	1 (3.2)	1 (3.2)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

		All patients N=7			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	1 (14.3)	2 (28.6)	1 (14.3)	3 (42.9)
Gastrointestinal disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Nausea	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Vomiting	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Abdominal pain	1 (14.3)	0	0	1 (14.3)	0
Diarrhoea	1 (14.3)	0	0	1 (14.3)	0
General disorders and administration site conditions					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Pyrexia	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Influenza like illness	1 (14.3)	1 (14.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Hypogammaglobulinaemia	1 (14.3)	0	1 (14.3)	0	0
Infections and infestations					
-Total	5 (71.4)	0	2 (28.6)	1 (14.3)	2 (28.6)
Influenza	2 (28.6)	0	2 (28.6)	0	0
Bacterial sepsis	1 (14.3)	0	0	0	1 (14.3)
Cholecystitis infective	1 (14.3)	0	0	1 (14.3)	0
Sepsis	1 (14.3)	0	0	0	1 (14.3)
Injury, poisoning and procedural complications					
-Total	1 (14.3)	0	1 (14.3)	0	0
Foot fracture	1 (14.3)	0	1 (14.3)	0	0
Investigations					
-Total	4 (57.1)	2 (28.6)	1 (14.3)	0	1 (14.3)
Weight decreased	2 (28.6)	0	2 (28.6)	0	0
Aspartate aminotransferase increased	1 (14.3)	1 (14.3)	0	0	0
Haemoglobin decreased	1 (14.3)	1 (14.3)	0	0	0
Neutrophil count decreased	1 (14.3)	0	0	0	1 (14.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (14.3)	1 (14.3)	0	0	0
Transaminases increased	1 (14.3)	1 (14.3)	0	0	0
White blood cell count decreased	1 (14.3)	1 (14.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Arthralgia	1 (14.3)	0	1 (14.3)	0	0
Nervous system disorders					
-Total	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Dizziness	1 (14.3)	1 (14.3)	0	0	0
Headache	1 (14.3)	1 (14.3)	0	0	0
Peroneal nerve palsy	1 (14.3)	0	1 (14.3)	0	0
Reproductive system and breast disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Vaginal haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Rhinitis allergic	1 (14.3)	1 (14.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Erythema	1 (14.3)	1 (14.3)	0	0	0
Hyperhidrosis	1 (14.3)	1 (14.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: <10 years

			All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (27.3)	0	1 (9.1)	2 (18.2)	0
Gastrointestinal disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Abdominal pain	1 (9.1)	0	1 (9.1)	0	0
Diarrhoea	1 (9.1)	0	1 (9.1)	0	0
Infections and infestations					
-Total	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Otitis media acute	2 (18.2)	0	2 (18.2)	0	0
Clostridium difficile infection	1 (9.1)	0	0	1 (9.1)	0
Pneumonia	1 (9.1)	0	1 (9.1)	0	0
Sinusitis	1 (9.1)	0	1 (9.1)	0	0
Urinary tract infection	1 (9.1)	0	1 (9.1)	0	0

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal candidiasis	1 (9.1)	0	1 (9.1)	0	0
Nervous system disorders					
-Total	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Dizziness	1 (9.1)	1 (9.1)	0	0	0
Headache	1 (9.1)	0	1 (9.1)	0	0
Seizure	1 (9.1)	0	0	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Oropharyngeal pain	1 (9.1)	1 (9.1)	0	0	0
Rhinorrhoea	1 (9.1)	1 (9.1)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

			All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (54.5)	4 (18.2)	2 (9.1)	4 (18.2)	2 (9.1)
Blood and lymphatic system disorders					
-Total	2 (9.1)	1 (4.5)	0	0	1 (4.5)
Febrile neutropenia	1 (4.5)	0	0	0	1 (4.5)
Thrombocytopenia	1 (4.5)	1 (4.5)	0	0	0
Gastrointestinal disorders					
-Total	2 (9.1)	0	2 (9.1)	0	0
Diarrhoea	1 (4.5)	0	1 (4.5)	0	0
Nausea	1 (4.5)	0	1 (4.5)	0	0
General disorders and administration site conditions					
-Total	1 (4.5)	0	1 (4.5)	0	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	1 (4.5)	0	1 (4.5)	0	0
Pyrexia	1 (4.5)	0	1 (4.5)	0	0
Infections and infestations					
-Total	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Pneumonia	1 (4.5)	0	1 (4.5)	0	0
Sinusitis	1 (4.5)	0	1 (4.5)	0	0
Upper respiratory tract infection	1 (4.5)	1 (4.5)	0	0	0
Urinary tract infection	1 (4.5)	0	0	1 (4.5)	0
Injury, poisoning and procedural complications					
-Total	1 (4.5)	0	0	1 (4.5)	0
Procedural pain	1 (4.5)	0	0	1 (4.5)	0
Investigations					
-Total	7 (31.8)	1 (4.5)	2 (9.1)	3 (13.6)	1 (4.5)
White blood cell count decreased	4 (18.2)	1 (4.5)	0	2 (9.1)	1 (4.5)
Lymphocyte count decreased	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Alanine aminotransferase increased	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Neutrophil count decreased	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Aspartate aminotransferase increased	1 (4.5)	1 (4.5)	0	0	0

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

			All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	1 (4.5)	1 (4.5)	0	0	0
Platelet count decreased	1 (4.5)	0	0	1 (4.5)	0
Metabolism and nutrition disorders					
-Total	1 (4.5)	0	0	1 (4.5)	0
Hypokalaemia	1 (4.5)	0	0	1 (4.5)	0
Renal and urinary disorders					
-Total	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Acute kidney injury	1 (4.5)	0	0	1 (4.5)	0
Haematuria	1 (4.5)	1 (4.5)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (13.6)	3 (13.6)	0	0	0
Cough	2 (9.1)	2 (9.1)	0	0	0
Epistaxis	1 (4.5)	1 (4.5)	0	0	0
Rhinitis allergic	1 (4.5)	1 (4.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Pruritus	1 (4.5)	1 (4.5)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=18

		All patients N=1			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Infections and infestations					
-Total	1 (100)	0	1 (100)	0	0
Sinusitis	1 (100)	0	1 (100)	0	0
Upper respiratory tract infection	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	0	0	1 (100)	0
Alanine aminotransferase increased	1 (100)	0	0	1 (100)	0
Aspartate aminotransferase increased	1 (100)	0	0	1 (100)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: <10 years

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (100)	1 (5.0)	4 (20.0)	4 (20.0)	11 (55.0)
Blood and lymphatic system disorders					
-Total	11 (55.0)	1 (5.0)	1 (5.0)	8 (40.0)	1 (5.0)
Anaemia	6 (30.0)	2 (10.0)	0	4 (20.0)	0
Febrile neutropenia	6 (30.0)	0	0	6 (30.0)	0
Thrombocytopenia	2 (10.0)	0	1 (5.0)	0	1 (5.0)
Cardiac disorders					
-Total	5 (25.0)	3 (15.0)	2 (10.0)	0	0
Sinus tachycardia	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Tachycardia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Eye disorders					
-Total	2 (10.0)	2 (10.0)	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctival haemorrhage	2 (10.0)	2 (10.0)	0	0	0
Periorbital oedema	2 (10.0)	2 (10.0)	0	0	0
Gastrointestinal disorders					
-Total	12 (60.0)	3 (15.0)	6 (30.0)	3 (15.0)	0
Nausea	9 (45.0)	2 (10.0)	5 (25.0)	2 (10.0)	0
Vomiting	9 (45.0)	5 (25.0)	4 (20.0)	0	0
Diarrhoea	8 (40.0)	5 (25.0)	3 (15.0)	0	0
Abdominal pain	4 (20.0)	2 (10.0)	2 (10.0)	0	0
Constipation	3 (15.0)	3 (15.0)	0	0	0
Pancreatitis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions					
-Total	11 (55.0)	5 (25.0)	3 (15.0)	3 (15.0)	0
Pyrexia	7 (35.0)	3 (15.0)	2 (10.0)	2 (10.0)	0
Fatigue	4 (20.0)	4 (20.0)	0	0	0
Catheter site pain	2 (10.0)	0	2 (10.0)	0	0
Oedema peripheral	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Chills	1 (5.0)	1 (5.0)	0	0	0
Malaise	1 (5.0)	1 (5.0)	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	19 (95.0)	1 (5.0)	12 (60.0)	3 (15.0)	3 (15.0)
Cytokine release syndrome	16 (80.0)	2 (10.0)	8 (40.0)	3 (15.0)	3 (15.0)
Hypogammaglobulinaemia	10 (50.0)	1 (5.0)	7 (35.0)	2 (10.0)	0
Infections and infestations					
-Total	14 (70.0)	4 (20.0)	7 (35.0)	3 (15.0)	0
Clostridium difficile infection	4 (20.0)	0	3 (15.0)	1 (5.0)	0
Gastroenteritis	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Rhinovirus infection	3 (15.0)	3 (15.0)	0	0	0
Upper respiratory tract infection	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Clostridium difficile colitis	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Ear infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Otitis media acute	2 (10.0)	0	2 (10.0)	0	0
Pneumonia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Sinusitis	2 (10.0)	0	2 (10.0)	0	0
Urinary tract infection	2 (10.0)	0	2 (10.0)	0	0
Viral upper respiratory tract infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Vulvovaginal candidiasis	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Injury, poisoning and procedural complications					

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (20.0)	3 (15.0)	1 (5.0)	0	0
Procedural pain	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Infusion related reaction	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Transfusion reaction	1 (5.0)	1 (5.0)	0	0	0
Investigations					
-Total	15 (75.0)	0	1 (5.0)	4 (20.0)	10 (50.0)
White blood cell count decreased	10 (50.0)	2 (10.0)	0	3 (15.0)	5 (25.0)
Neutrophil count decreased	8 (40.0)	0	1 (5.0)	1 (5.0)	6 (30.0)
Aspartate aminotransferase increased	7 (35.0)	1 (5.0)	1 (5.0)	3 (15.0)	2 (10.0)
Alanine aminotransferase increased	6 (30.0)	1 (5.0)	1 (5.0)	4 (20.0)	0
Lymphocyte count decreased	4 (20.0)	1 (5.0)	1 (5.0)	1 (5.0)	1 (5.0)
Blood bilirubin increased	3 (15.0)	0	2 (10.0)	1 (5.0)	0
Platelet count decreased	3 (15.0)	0	0	0	3 (15.0)
Blood fibrinogen decreased	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Blood urea increased	2 (10.0)	1 (5.0)	0	1 (5.0)	0
International normalised ratio increased	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Lipase increased	2 (10.0)	0	0	0	2 (10.0)
Prothrombin time prolonged	2 (10.0)	2 (10.0)	0	0	0
Activated partial thromboplastin time prolonged	1 (5.0)	1 (5.0)	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	1 (5.0)	0	0	1 (5.0)	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Transaminases increased	1 (5.0)	1 (5.0)	0	0	0
Weight decreased	1 (5.0)	0	1 (5.0)	0	0
Metabolism and nutrition disorders					
-Total	12 (60.0)	2 (10.0)	3 (15.0)	6 (30.0)	1 (5.0)
Decreased appetite	7 (35.0)	2 (10.0)	2 (10.0)	3 (15.0)	0
Hypokalaemia	7 (35.0)	0	2 (10.0)	5 (25.0)	0
Hypophosphataemia	5 (25.0)	2 (10.0)	0	2 (10.0)	1 (5.0)
Hypertriglyceridaemia	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Hypoalbuminaemia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Hypocalcaemia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Dehydration	1 (5.0)	0	0	1 (5.0)	0
Fluid overload	1 (5.0)	1 (5.0)	0	0	0
Hyperglycaemia	1 (5.0)	0	1 (5.0)	0	0
Hyperphosphataemia	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (35.0)	4 (20.0)	3 (15.0)	0	0
Pain in extremity	7 (35.0)	4 (20.0)	3 (15.0)	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	9 (45.0)	7 (35.0)	0	2 (10.0)	0
Headache	7 (35.0)	6 (30.0)	1 (5.0)	0	0
Dizziness	2 (10.0)	2 (10.0)	0	0	0
Seizure	2 (10.0)	0	0	2 (10.0)	0
Psychiatric disorders					
-Total	4 (20.0)	2 (10.0)	2 (10.0)	0	0
Confusional state	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Anxiety	1 (5.0)	1 (5.0)	0	0	0
Delirium	1 (5.0)	0	1 (5.0)	0	0
Renal and urinary disorders					
-Total	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Acute kidney injury	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Reproductive system and breast disorders					
-Total	2 (10.0)	2 (10.0)	0	0	0
Vulvovaginal adhesion	2 (10.0)	2 (10.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (55.0)	3 (15.0)	3 (15.0)	5 (25.0)	0
Cough	5 (25.0)	5 (25.0)	0	0	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	4 (20.0)	0	1 (5.0)	3 (15.0)	0
Pleural effusion	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0
Rhinorrhoea	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Epistaxis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Oropharyngeal pain	2 (10.0)	2 (10.0)	0	0	0
Pulmonary oedema	2 (10.0)	0	0	2 (10.0)	0
Nasal congestion	1 (5.0)	1 (5.0)	0	0	0
Rhinitis allergic	1 (5.0)	0	1 (5.0)	0	0
Tachypnoea	1 (5.0)	0	1 (5.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (45.0)	7 (35.0)	2 (10.0)	0	0
Rash	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Hyperhidrosis	2 (10.0)	2 (10.0)	0	0	0
Rash maculo-papular	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Rash papular	2 (10.0)	2 (10.0)	0	0	0
Erythema	1 (5.0)	1 (5.0)	0	0	0
Petechiae	1 (5.0)	1 (5.0)	0	0	0
Pruritus	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (40.0)	2 (10.0)	2 (10.0)	1 (5.0)	3 (15.0)
Hypertension	5 (25.0)	2 (10.0)	3 (15.0)	0	0
Hypotension	5 (25.0)	1 (5.0)	0	1 (5.0)	3 (15.0)
Flushing	2 (10.0)	2 (10.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

			All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (100)	0	2 (5.9)	7 (20.6)	25 (73.5)
Blood and lymphatic system disorders					
-Total	27 (79.4)	0	1 (2.9)	16 (47.1)	10 (29.4)
Anaemia	18 (52.9)	1 (2.9)	4 (11.8)	12 (35.3)	1 (2.9)
Febrile neutropenia	16 (47.1)	0	0	15 (44.1)	1 (2.9)
Neutropenia	8 (23.5)	0	0	1 (2.9)	7 (20.6)
Thrombocytopenia	5 (14.7)	0	0	3 (8.8)	2 (5.9)
Lymphopenia	3 (8.8)	0	1 (2.9)	1 (2.9)	1 (2.9)
Cardiac disorders					
-Total	11 (32.4)	6 (17.6)	4 (11.8)	1 (2.9)	0
Tachycardia	9 (26.5)	6 (17.6)	2 (5.9)	1 (2.9)	0
Sinus tachycardia	3 (8.8)	1 (2.9)	2 (5.9)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Periorbital oedema	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Conjunctival haemorrhage	1 (2.9)	1 (2.9)	0	0	0
Uveitis	1 (2.9)	0	1 (2.9)	0	0
Gastrointestinal disorders					
-Total	24 (70.6)	11 (32.4)	10 (29.4)	3 (8.8)	0
Vomiting	14 (41.2)	10 (29.4)	2 (5.9)	2 (5.9)	0
Nausea	12 (35.3)	4 (11.8)	7 (20.6)	1 (2.9)	0
Diarrhoea	11 (32.4)	6 (17.6)	4 (11.8)	1 (2.9)	0
Abdominal pain	6 (17.6)	4 (11.8)	2 (5.9)	0	0
Constipation	3 (8.8)	3 (8.8)	0	0	0
Abdominal pain upper	2 (5.9)	1 (2.9)	1 (2.9)	0	0
General disorders and administration site conditions					
-Total	22 (64.7)	9 (26.5)	8 (23.5)	4 (11.8)	1 (2.9)
Pyrexia	12 (35.3)	3 (8.8)	6 (17.6)	2 (5.9)	1 (2.9)
Fatigue	9 (26.5)	8 (23.5)	0	1 (2.9)	0
Chills	6 (17.6)	5 (14.7)	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Catheter site pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Malaise	2 (5.9)	0	2 (5.9)	0	0
Influenza like illness	1 (2.9)	1 (2.9)	0	0	0
Oedema peripheral	1 (2.9)	1 (2.9)	0	0	0
Hepatobiliary disorders					
-Total	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Hepatomegaly	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Immune system disorders					
-Total	30 (88.2)	3 (8.8)	14 (41.2)	8 (23.5)	5 (14.7)
Cytokine release syndrome	26 (76.5)	4 (11.8)	12 (35.3)	5 (14.7)	5 (14.7)
Hypogammaglobulinaemia	19 (55.9)	2 (5.9)	14 (41.2)	3 (8.8)	0
Infections and infestations					
-Total	15 (44.1)	3 (8.8)	7 (20.6)	5 (14.7)	0
Upper respiratory tract infection	5 (14.7)	2 (5.9)	2 (5.9)	1 (2.9)	0
Urinary tract infection	3 (8.8)	0	1 (2.9)	2 (5.9)	0
Clostridium difficile colitis	2 (5.9)	0	2 (5.9)	0	0
Gastroenteritis	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Influenza	2 (5.9)	1 (2.9)	1 (2.9)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	2 (5.9)	2 (5.9)	0	0	0
Clostridium difficile infection	1 (2.9)	0	1 (2.9)	0	0
Pneumonia	1 (2.9)	0	1 (2.9)	0	0
Sinusitis	1 (2.9)	0	1 (2.9)	0	0
Viral upper respiratory tract infection	1 (2.9)	0	0	1 (2.9)	0
Injury, poisoning and procedural complications					
-Total	5 (14.7)	1 (2.9)	3 (8.8)	1 (2.9)	0
Infusion related reaction	2 (5.9)	0	2 (5.9)	0	0
Procedural pain	2 (5.9)	0	1 (2.9)	1 (2.9)	0
Transfusion reaction	1 (2.9)	1 (2.9)	0	0	0
Investigations					
-Total	30 (88.2)	1 (2.9)	4 (11.8)	6 (17.6)	19 (55.9)
White blood cell count decreased	21 (61.8)	2 (5.9)	1 (2.9)	7 (20.6)	11 (32.4)
Neutrophil count decreased	18 (52.9)	1 (2.9)	1 (2.9)	3 (8.8)	13 (38.2)
Platelet count decreased	14 (41.2)	2 (5.9)	1 (2.9)	3 (8.8)	8 (23.5)
Alanine aminotransferase increased	13 (38.2)	3 (8.8)	1 (2.9)	9 (26.5)	0
Lymphocyte count decreased	11 (32.4)	0	2 (5.9)	6 (17.6)	3 (8.8)
Aspartate aminotransferase increased	10 (29.4)	2 (5.9)	3 (8.8)	4 (11.8)	1 (2.9)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	8 (23.5)	5 (14.7)	2 (5.9)	1 (2.9)	0
International normalised ratio increased	6 (17.6)	6 (17.6)	0	0	0
Blood bilirubin increased	5 (14.7)	2 (5.9)	1 (2.9)	2 (5.9)	0
Activated partial thromboplastin time prolonged	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Prothrombin time prolonged	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Blood immunoglobulin m decreased	2 (5.9)	2 (5.9)	0	0	0
Haemoglobin decreased	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Blood urea increased	1 (2.9)	0	1 (2.9)	0	0
C-reactive protein increased	1 (2.9)	1 (2.9)	0	0	0
Transaminases increased	1 (2.9)	1 (2.9)	0	0	0
Weight decreased	1 (2.9)	1 (2.9)	0	0	0
Metabolism and nutrition disorders					
-Total	19 (55.9)	4 (11.8)	3 (8.8)	11 (32.4)	1 (2.9)
Decreased appetite	11 (32.4)	3 (8.8)	2 (5.9)	6 (17.6)	0
Hypokalaemia	9 (26.5)	2 (5.9)	3 (8.8)	3 (8.8)	1 (2.9)
Hyperphosphataemia	6 (17.6)	6 (17.6)	0	0	0
Hypophosphataemia	4 (11.8)	0	0	4 (11.8)	0
Hypoalbuminaemia	3 (8.8)	1 (2.9)	2 (5.9)	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Hyperuricaemia	2 (5.9)	2 (5.9)	0	0	0
Fluid overload	1 (2.9)	0	1 (2.9)	0	0
Hyperglycaemia	1 (2.9)	0	0	1 (2.9)	0
Hypocalcaemia	1 (2.9)	0	0	1 (2.9)	0
Musculoskeletal and connective tissue disorders					
-Total	10 (29.4)	7 (20.6)	2 (5.9)	1 (2.9)	0
Myalgia	5 (14.7)	4 (11.8)	1 (2.9)	0	0
Arthralgia	4 (11.8)	3 (8.8)	0	1 (2.9)	0
Pain in extremity	3 (8.8)	3 (8.8)	0	0	0
Musculoskeletal pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Nervous system disorders					
-Total	19 (55.9)	9 (26.5)	7 (20.6)	3 (8.8)	0
Headache	15 (44.1)	8 (23.5)	5 (14.7)	2 (5.9)	0
Encephalopathy	4 (11.8)	1 (2.9)	1 (2.9)	2 (5.9)	0
Seizure	2 (5.9)	0	2 (5.9)	0	0
Dizziness	1 (2.9)	1 (2.9)	0	0	0
Peroneal nerve palsy	1 (2.9)	1 (2.9)	0	0	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	7 (20.6)	3 (8.8)	4 (11.8)	0	0
Anxiety	5 (14.7)	2 (5.9)	3 (8.8)	0	0
Confusional state	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Delirium	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Renal and urinary disorders					
-Total	7 (20.6)	1 (2.9)	0	4 (11.8)	2 (5.9)
Acute kidney injury	5 (14.7)	1 (2.9)	0	3 (8.8)	1 (2.9)
Haematuria	3 (8.8)	0	1 (2.9)	1 (2.9)	1 (2.9)
Respiratory, thoracic and mediastinal disorders					
-Total	20 (58.8)	10 (29.4)	3 (8.8)	4 (11.8)	3 (8.8)
Cough	8 (23.5)	6 (17.6)	2 (5.9)	0	0
Epistaxis	7 (20.6)	3 (8.8)	0	3 (8.8)	1 (2.9)
Hypoxia	4 (11.8)	0	2 (5.9)	1 (2.9)	1 (2.9)
Nasal congestion	4 (11.8)	4 (11.8)	0	0	0
Oropharyngeal pain	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Pulmonary oedema	4 (11.8)	1 (2.9)	0	2 (5.9)	1 (2.9)
Tachypnoea	4 (11.8)	3 (8.8)	0	1 (2.9)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	3 (8.8)	3 (8.8)	0	0	0
Pleural effusion	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Rhinitis allergic	2 (5.9)	2 (5.9)	0	0	0
Dyspnoea	1 (2.9)	0	0	1 (2.9)	0
Skin and subcutaneous tissue disorders					
-Total	15 (44.1)	12 (35.3)	3 (8.8)	0	0
Dry skin	5 (14.7)	5 (14.7)	0	0	0
Rash	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Erythema	3 (8.8)	3 (8.8)	0	0	0
Ingrowing nail	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Petechiae	2 (5.9)	2 (5.9)	0	0	0
Pruritus	2 (5.9)	2 (5.9)	0	0	0
Rash maculo-papular	2 (5.9)	2 (5.9)	0	0	0
Hyperhidrosis	1 (2.9)	1 (2.9)	0	0	0
Vascular disorders					
-Total	11 (32.4)	0	2 (5.9)	5 (14.7)	4 (11.8)
Hypotension	9 (26.5)	0	0	5 (14.7)	4 (11.8)
Hypertension	4 (11.8)	1 (2.9)	2 (5.9)	1 (2.9)	0
Orthostatic hypotension	1 (2.9)	0	1 (2.9)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184a
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=18

		All patients N=10			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (100)	0	0	2 (20.0)	8 (80.0)
Blood and lymphatic system disorders					
-Total	7 (70.0)	0	0	3 (30.0)	4 (40.0)
Anaemia	3 (30.0)	0	0	3 (30.0)	0
Neutropenia	3 (30.0)	0	0	2 (20.0)	1 (10.0)
Thrombocytopenia	3 (30.0)	0	0	0	3 (30.0)
Febrile neutropenia	2 (20.0)	0	0	2 (20.0)	0
Lymphopenia	1 (10.0)	0	1 (10.0)	0	0
Pancytopenia	1 (10.0)	0	0	0	1 (10.0)
Cardiac disorders					
-Total	4 (40.0)	1 (10.0)	2 (20.0)	1 (10.0)	0
Tachycardia	4 (40.0)	1 (10.0)	2 (20.0)	1 (10.0)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (10.0)	0	0	1 (10.0)	0
Ear and labyrinth disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Hypoacusis	1 (10.0)	0	1 (10.0)	0	0
Eye disorders					
-Total	2 (20.0)	0	2 (20.0)	0	0
Papilloedema	1 (10.0)	0	1 (10.0)	0	0
Uveitis	1 (10.0)	0	1 (10.0)	0	0
Visual impairment	1 (10.0)	0	1 (10.0)	0	0
Gastrointestinal disorders					
-Total	5 (50.0)	1 (10.0)	2 (20.0)	2 (20.0)	0
Diarrhoea	5 (50.0)	2 (20.0)	2 (20.0)	1 (10.0)	0
Nausea	4 (40.0)	0	2 (20.0)	2 (20.0)	0
Vomiting	4 (40.0)	1 (10.0)	2 (20.0)	1 (10.0)	0
Abdominal discomfort	1 (10.0)	1 (10.0)	0	0	0
Abdominal pain	1 (10.0)	0	0	1 (10.0)	0
Abdominal pain upper	1 (10.0)	0	1 (10.0)	0	0
Constipation	1 (10.0)	0	1 (10.0)	0	0
Dyspepsia	1 (10.0)	0	1 (10.0)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Intestinal obstruction	1 (10.0)	0	0	1 (10.0)	0
General disorders and administration site conditions					
-Total	7 (70.0)	2 (20.0)	3 (30.0)	2 (20.0)	0
Pyrexia	6 (60.0)	2 (20.0)	2 (20.0)	2 (20.0)	0
Chills	3 (30.0)	3 (30.0)	0	0	0
Fatigue	2 (20.0)	0	2 (20.0)	0	0
Asthenia	1 (10.0)	1 (10.0)	0	0	0
Facial pain	1 (10.0)	0	1 (10.0)	0	0
Influenza like illness	1 (10.0)	1 (10.0)	0	0	0
Malaise	1 (10.0)	0	1 (10.0)	0	0
Hepatobiliary disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Hepatomegaly	1 (10.0)	0	1 (10.0)	0	0
Immune system disorders					
-Total	8 (80.0)	0	5 (50.0)	0	3 (30.0)
Cytokine release syndrome	8 (80.0)	0	5 (50.0)	0	3 (30.0)
Hypogammaglobulinaemia	3 (30.0)	0	3 (30.0)	0	0
Infections and infestations					

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (70.0)	0	4 (40.0)	1 (10.0)	2 (20.0)
Influenza	2 (20.0)	0	2 (20.0)	0	0
Bacterial sepsis	1 (10.0)	0	0	0	1 (10.0)
Cholecystitis infective	1 (10.0)	0	0	1 (10.0)	0
Folliculitis	1 (10.0)	0	1 (10.0)	0	0
Human herpesvirus 6 infection	1 (10.0)	0	1 (10.0)	0	0
Pneumonia	1 (10.0)	0	1 (10.0)	0	0
Sepsis	1 (10.0)	0	0	0	1 (10.0)
Sinusitis	1 (10.0)	0	1 (10.0)	0	0
Upper respiratory tract infection	1 (10.0)	0	1 (10.0)	0	0
Urinary tract infection enterococcal	1 (10.0)	0	0	1 (10.0)	0
Injury, poisoning and procedural complications					
-Total	4 (40.0)	1 (10.0)	2 (20.0)	1 (10.0)	0
Foot fracture	1 (10.0)	0	1 (10.0)	0	0
Incision site pain	1 (10.0)	1 (10.0)	0	0	0
Limb injury	1 (10.0)	1 (10.0)	0	0	0
Tracheal haemorrhage	1 (10.0)	0	0	1 (10.0)	0
Transfusion reaction	1 (10.0)	0	1 (10.0)	0	0
Investigations					

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (90.0)	0	0	4 (40.0)	5 (50.0)
White blood cell count decreased	4 (40.0)	0	0	2 (20.0)	2 (20.0)
Aspartate aminotransferase increased	3 (30.0)	1 (10.0)	0	1 (10.0)	1 (10.0)
Platelet count decreased	3 (30.0)	1 (10.0)	1 (10.0)	0	1 (10.0)
Prothrombin time prolonged	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Alanine aminotransferase increased	2 (20.0)	1 (10.0)	0	1 (10.0)	0
Blood fibrinogen decreased	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Neutrophil count decreased	2 (20.0)	0	0	0	2 (20.0)
Weight decreased	2 (20.0)	0	2 (20.0)	0	0
Blood immunoglobulin m decreased	1 (10.0)	1 (10.0)	0	0	0
C-reactive protein increased	1 (10.0)	0	0	1 (10.0)	0
Haemoglobin decreased	1 (10.0)	1 (10.0)	0	0	0
Hepatic enzyme increased	1 (10.0)	0	1 (10.0)	0	0
International normalised ratio increased	1 (10.0)	1 (10.0)	0	0	0
Lymphocyte count decreased	1 (10.0)	0	0	0	1 (10.0)
Transaminases increased	1 (10.0)	1 (10.0)	0	0	0
Metabolism and nutrition disorders					
-Total	7 (70.0)	0	2 (20.0)	4 (40.0)	1 (10.0)
Decreased appetite	4 (40.0)	0	1 (10.0)	3 (30.0)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	3 (30.0)	2 (20.0)	1 (10.0)	0	0
Dehydration	1 (10.0)	0	0	1 (10.0)	0
Fluid overload	1 (10.0)	0	1 (10.0)	0	0
Hyperglycaemia	1 (10.0)	0	0	1 (10.0)	0
Hyperphosphataemia	1 (10.0)	1 (10.0)	0	0	0
Hyperuricaemia	1 (10.0)	0	0	0	1 (10.0)
Hypophosphataemia	1 (10.0)	0	0	1 (10.0)	0
Metabolic acidosis	1 (10.0)	0	1 (10.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Arthralgia	1 (10.0)	0	1 (10.0)	0	0
Limb discomfort	1 (10.0)	1 (10.0)	0	0	0
Musculoskeletal pain	1 (10.0)	1 (10.0)	0	0	0
Pain in extremity	1 (10.0)	0	1 (10.0)	0	0
Nervous system disorders					
-Total	5 (50.0)	2 (20.0)	3 (30.0)	0	0
Dizziness	3 (30.0)	3 (30.0)	0	0	0
Headache	2 (20.0)	1 (10.0)	1 (10.0)	0	0
Idiopathic intracranial hypertension	1 (10.0)	0	1 (10.0)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

			All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Peroneal nerve palsy	1 (10.0)	0	1 (10.0)	0	0
Psychiatric disorders					
-Total	4 (40.0)	2 (20.0)	1 (10.0)	1 (10.0)	0
Anxiety	1 (10.0)	0	0	1 (10.0)	0
Confusional state	1 (10.0)	1 (10.0)	0	0	0
Delirium	1 (10.0)	1 (10.0)	0	0	0
Panic attack	1 (10.0)	0	1 (10.0)	0	0
Renal and urinary disorders					
-Total	2 (20.0)	0	0	0	2 (20.0)
Acute kidney injury	2 (20.0)	0	0	0	2 (20.0)
Haematuria	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Reproductive system and breast disorders					
-Total	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Oedema genital	1 (10.0)	0	1 (10.0)	0	0
Vaginal haemorrhage	1 (10.0)	0	0	1 (10.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (40.0)	1 (10.0)	1 (10.0)	0	2 (20.0)
Hypoxia	2 (20.0)	0	0	0	2 (20.0)
Pleural effusion	2 (20.0)	0	2 (20.0)	0	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	1 (10.0)	1 (10.0)	0	0	0
Dyspnoea	1 (10.0)	0	0	0	1 (10.0)
Epistaxis	1 (10.0)	1 (10.0)	0	0	0
Interstitial lung disease	1 (10.0)	0	0	0	1 (10.0)
Pulmonary oedema	1 (10.0)	0	0	0	1 (10.0)
Rhinitis allergic	1 (10.0)	1 (10.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (30.0)	1 (10.0)	1 (10.0)	1 (10.0)	0
Erythema	1 (10.0)	1 (10.0)	0	0	0
Hyperhidrosis	1 (10.0)	1 (10.0)	0	0	0
Ingrowing nail	1 (10.0)	0	1 (10.0)	0	0
Petechiae	1 (10.0)	0	1 (10.0)	0	0
Pruritus	1 (10.0)	1 (10.0)	0	0	0
Rash	1 (10.0)	1 (10.0)	0	0	0
Rash maculo-papular	1 (10.0)	0	0	1 (10.0)	0
Vascular disorders					
-Total	5 (50.0)	1 (10.0)	2 (20.0)	1 (10.0)	1 (10.0)
Hypertension	3 (30.0)	0	3 (30.0)	0	0
Hypotension	2 (20.0)	0	0	1 (10.0)	1 (10.0)

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Orthostatic hypotension	1 (10.0)	1 (10.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184b
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Male

			All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (96.7)	2 (6.7)	4 (13.3)	7 (23.3)	16 (53.3)
Blood and lymphatic system disorders					
-Total	18 (60.0)	1 (3.3)	0	13 (43.3)	4 (13.3)
Anaemia	13 (43.3)	3 (10.0)	2 (6.7)	8 (26.7)	0
Febrile neutropenia	10 (33.3)	0	0	10 (33.3)	0
Neutropenia	4 (13.3)	0	0	2 (6.7)	2 (6.7)
Thrombocytopenia	4 (13.3)	0	0	1 (3.3)	3 (10.0)
Cardiac disorders					
-Total	7 (23.3)	3 (10.0)	2 (6.7)	2 (6.7)	0
Tachycardia	7 (23.3)	3 (10.0)	2 (6.7)	2 (6.7)	0
Gastrointestinal disorders					
-Total	11 (36.7)	5 (16.7)	5 (16.7)	1 (3.3)	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	7 (23.3)	5 (16.7)	2 (6.7)	0	0
Diarrhoea	6 (20.0)	3 (10.0)	3 (10.0)	0	0
Nausea	5 (16.7)	2 (6.7)	2 (6.7)	1 (3.3)	0
Abdominal pain	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Constipation	1 (3.3)	1 (3.3)	0	0	0
General disorders and administration site conditions					
-Total	10 (33.3)	2 (6.7)	3 (10.0)	5 (16.7)	0
Pyrexia	6 (20.0)	0	3 (10.0)	3 (10.0)	0
Chills	4 (13.3)	4 (13.3)	0	0	0
Fatigue	3 (10.0)	2 (6.7)	0	1 (3.3)	0
Pain	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Hepatobiliary disorders					
-Total	5 (16.7)	1 (3.3)	2 (6.7)	2 (6.7)	0
Hepatomegaly	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Hyperbilirubinaemia	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Immune system disorders					
-Total	25 (83.3)	3 (10.0)	12 (40.0)	4 (13.3)	6 (20.0)
Cytokine release syndrome	23 (76.7)	4 (13.3)	10 (33.3)	3 (10.0)	6 (20.0)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	12 (40.0)	1 (3.3)	10 (33.3)	1 (3.3)	0
Infections and infestations					
-Total	4 (13.3)	0	3 (10.0)	1 (3.3)	0
Clostridium difficile infection	1 (3.3)	0	1 (3.3)	0	0
Gastroenteritis	1 (3.3)	0	0	1 (3.3)	0
Upper respiratory tract infection	1 (3.3)	0	1 (3.3)	0	0
Viral infection	1 (3.3)	0	1 (3.3)	0	0
Investigations					
-Total	19 (63.3)	1 (3.3)	2 (6.7)	3 (10.0)	13 (43.3)
White blood cell count decreased	12 (40.0)	2 (6.7)	0	4 (13.3)	6 (20.0)
Neutrophil count decreased	11 (36.7)	0	1 (3.3)	2 (6.7)	8 (26.7)
Aspartate aminotransferase increased	8 (26.7)	0	2 (6.7)	3 (10.0)	3 (10.0)
Platelet count decreased	8 (26.7)	2 (6.7)	1 (3.3)	1 (3.3)	4 (13.3)
Alanine aminotransferase increased	7 (23.3)	2 (6.7)	0	5 (16.7)	0
Lymphocyte count decreased	5 (16.7)	1 (3.3)	1 (3.3)	1 (3.3)	2 (6.7)
Blood creatinine increased	4 (13.3)	2 (6.7)	0	2 (6.7)	0
International normalised ratio increased	4 (13.3)	4 (13.3)	0	0	0
Activated partial thromboplastin time prolonged	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Blood bilirubin increased	3 (10.0)	2 (6.7)	0	1 (3.3)	0

Timing: within 8 weeks post infusion, Gender: Male

			All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prothrombin time prolonged	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Metabolism and nutrition disorders					
-Total	12 (40.0)	2 (6.7)	1 (3.3)	9 (30.0)	0
Decreased appetite	9 (30.0)	2 (6.7)	1 (3.3)	6 (20.0)	0
Hypokalaemia	7 (23.3)	3 (10.0)	1 (3.3)	3 (10.0)	0
Hypophosphataemia	5 (16.7)	1 (3.3)	0	4 (13.3)	0
Hyperphosphataemia	2 (6.7)	2 (6.7)	0	0	0
Nervous system disorders					
-Total	12 (40.0)	9 (30.0)	2 (6.7)	1 (3.3)	0
Headache	11 (36.7)	8 (26.7)	2 (6.7)	1 (3.3)	0
Dizziness	1 (3.3)	1 (3.3)	0	0	0
Psychiatric disorders					
-Total	5 (16.7)	3 (10.0)	2 (6.7)	0	0
Confusional state	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Anxiety	2 (6.7)	0	2 (6.7)	0	0
Renal and urinary disorders					
-Total	3 (10.0)	0	1 (3.3)	0	2 (6.7)
Acute kidney injury	3 (10.0)	0	1 (3.3)	0	2 (6.7)
Respiratory, thoracic and mediastinal disorders					

Timing: within 8 weeks post infusion, Gender: Male

			All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (33.3)	4 (13.3)	2 (6.7)	2 (6.7)	2 (6.7)
Hypoxia	5 (16.7)	0	2 (6.7)	1 (3.3)	2 (6.7)
Pleural effusion	5 (16.7)	1 (3.3)	3 (10.0)	1 (3.3)	0
Cough	4 (13.3)	4 (13.3)	0	0	0
Epistaxis	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Pulmonary oedema	3 (10.0)	0	0	2 (6.7)	1 (3.3)
Nasal congestion	1 (3.3)	1 (3.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (23.3)	6 (20.0)	0	1 (3.3)	0
Erythema	2 (6.7)	2 (6.7)	0	0	0
Rash	2 (6.7)	2 (6.7)	0	0	0
Rash maculo-papular	2 (6.7)	1 (3.3)	0	1 (3.3)	0
Dry skin	1 (3.3)	1 (3.3)	0	0	0
Vascular disorders					
-Total	10 (33.3)	0	1 (3.3)	5 (16.7)	4 (13.3)
Hypotension	9 (30.0)	0	0	5 (16.7)	4 (13.3)
Hypertension	6 (20.0)	1 (3.3)	4 (13.3)	1 (3.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184b
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Female

			All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (100)	0	4 (11.8)	7 (20.6)	23 (67.6)
Blood and lymphatic system disorders					
-Total	22 (64.7)	0	2 (5.9)	15 (44.1)	5 (14.7)
Anaemia	14 (41.2)	0	3 (8.8)	10 (29.4)	1 (2.9)
Febrile neutropenia	12 (35.3)	0	0	12 (35.3)	0
Neutropenia	4 (11.8)	0	0	1 (2.9)	3 (8.8)
Thrombocytopenia	4 (11.8)	0	0	1 (2.9)	3 (8.8)
Cardiac disorders					
-Total	12 (35.3)	7 (20.6)	5 (14.7)	0	0
Tachycardia	8 (23.5)	5 (14.7)	3 (8.8)	0	0
Sinus tachycardia	5 (14.7)	3 (8.8)	2 (5.9)	0	0
Gastrointestinal disorders					

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	22 (64.7)	7 (20.6)	9 (26.5)	6 (17.6)	0
Nausea	16 (47.1)	4 (11.8)	10 (29.4)	2 (5.9)	0
Vomiting	15 (44.1)	8 (23.5)	4 (11.8)	3 (8.8)	0
Diarrhoea	12 (35.3)	8 (23.5)	3 (8.8)	1 (2.9)	0
Abdominal pain	7 (20.6)	5 (14.7)	1 (2.9)	1 (2.9)	0
Constipation	6 (17.6)	5 (14.7)	1 (2.9)	0	0
General disorders and administration site conditions					
-Total	18 (52.9)	10 (29.4)	5 (14.7)	2 (5.9)	1 (2.9)
Fatigue	10 (29.4)	8 (23.5)	2 (5.9)	0	0
Pyrexia	10 (29.4)	3 (8.8)	4 (11.8)	2 (5.9)	1 (2.9)
Chills	4 (11.8)	4 (11.8)	0	0	0
Immune system disorders					
-Total	31 (91.2)	1 (2.9)	18 (52.9)	7 (20.6)	5 (14.7)
Cytokine release syndrome	27 (79.4)	2 (5.9)	15 (44.1)	5 (14.7)	5 (14.7)
Hypogammaglobulinaemia	13 (38.2)	2 (5.9)	8 (23.5)	3 (8.8)	0
Infections and infestations					
-Total	6 (17.6)	2 (5.9)	4 (11.8)	0	0
Clostridium difficile infection	3 (8.8)	0	3 (8.8)	0	0

Timing: within 8 weeks post infusion, Gender: Female

			All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	3 (8.8)	3 (8.8)	0	0	0
Gastroenteritis	1 (2.9)	0	1 (2.9)	0	0
Injury, poisoning and procedural complications					
-Total	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Procedural pain	3 (8.8)	1 (2.9)	2 (5.9)	0	0
Investigations					
-Total	28 (82.4)	0	2 (5.9)	8 (23.5)	18 (52.9)
White blood cell count decreased	18 (52.9)	1 (2.9)	1 (2.9)	6 (17.6)	10 (29.4)
Neutrophil count decreased	14 (41.2)	0	1 (2.9)	2 (5.9)	11 (32.4)
Alanine aminotransferase increased	12 (35.3)	3 (8.8)	3 (8.8)	6 (17.6)	0
Platelet count decreased	11 (32.4)	1 (2.9)	1 (2.9)	1 (2.9)	8 (23.5)
Aspartate aminotransferase increased	10 (29.4)	3 (8.8)	2 (5.9)	4 (11.8)	1 (2.9)
Lymphocyte count decreased	9 (26.5)	0	1 (2.9)	5 (14.7)	3 (8.8)
Prothrombin time prolonged	7 (20.6)	4 (11.8)	2 (5.9)	1 (2.9)	0
Blood creatinine increased	5 (14.7)	3 (8.8)	2 (5.9)	0	0
International normalised ratio increased	5 (14.7)	4 (11.8)	0	1 (2.9)	0
Blood bilirubin increased	4 (11.8)	0	3 (8.8)	1 (2.9)	0
Activated partial thromboplastin time prolonged	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Metabolism and nutrition disorders					

Timing: within 8 weeks post infusion, Gender: Female

			All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	21 (61.8)	5 (14.7)	7 (20.6)	8 (23.5)	1 (2.9)
Decreased appetite	11 (32.4)	2 (5.9)	3 (8.8)	6 (17.6)	0
Hypokalaemia	9 (26.5)	0	5 (14.7)	4 (11.8)	0
Hyperphosphataemia	6 (17.6)	6 (17.6)	0	0	0
Hypophosphataemia	4 (11.8)	1 (2.9)	0	2 (5.9)	1 (2.9)
Musculoskeletal and connective tissue disorders					
-Total	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Pain in extremity	4 (11.8)	2 (5.9)	2 (5.9)	0	0
Nervous system disorders					
-Total	14 (41.2)	9 (26.5)	4 (11.8)	1 (2.9)	0
Headache	13 (38.2)	8 (23.5)	4 (11.8)	1 (2.9)	0
Dizziness	3 (8.8)	3 (8.8)	0	0	0
Psychiatric disorders					
-Total	6 (17.6)	2 (5.9)	3 (8.8)	1 (2.9)	0
Anxiety	4 (11.8)	2 (5.9)	1 (2.9)	1 (2.9)	0
Confusional state	2 (5.9)	0	2 (5.9)	0	0
Renal and urinary disorders					
-Total	4 (11.8)	1 (2.9)	0	2 (5.9)	1 (2.9)
Acute kidney injury	4 (11.8)	1 (2.9)	0	2 (5.9)	1 (2.9)

Timing: within 8 weeks post infusion, Gender: Female

			All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	14 (41.2)	5 (14.7)	2 (5.9)	4 (11.8)	3 (8.8)
Hypoxia	5 (14.7)	0	1 (2.9)	3 (8.8)	1 (2.9)
Cough	4 (11.8)	4 (11.8)	0	0	0
Epistaxis	3 (8.8)	1 (2.9)	0	1 (2.9)	1 (2.9)
Pleural effusion	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Pulmonary oedema	3 (8.8)	1 (2.9)	0	1 (2.9)	1 (2.9)
Oropharyngeal pain	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Rhinorrhoea	1 (2.9)	1 (2.9)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (23.5)	6 (17.6)	2 (5.9)	0	0
Dry skin	3 (8.8)	3 (8.8)	0	0	0
Petechiae	3 (8.8)	2 (5.9)	1 (2.9)	0	0
Rash	2 (5.9)	2 (5.9)	0	0	0
Erythema	1 (2.9)	1 (2.9)	0	0	0
Rash maculo-papular	1 (2.9)	0	1 (2.9)	0	0
Vascular disorders					
-Total	11 (32.4)	2 (5.9)	3 (8.8)	2 (5.9)	4 (11.8)
Hypotension	7 (20.6)	1 (2.9)	0	2 (5.9)	4 (11.8)

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	4 (11.8)	1 (2.9)	3 (8.8)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184b
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (63.0)	2 (7.4)	7 (25.9)	5 (18.5)	3 (11.1)
Blood and lymphatic system disorders					
-Total	6 (22.2)	1 (3.7)	0	2 (7.4)	3 (11.1)
Neutropenia	4 (14.8)	0	0	1 (3.7)	3 (11.1)
Febrile neutropenia	2 (7.4)	0	0	2 (7.4)	0
Anaemia	1 (3.7)	1 (3.7)	0	0	0
Thrombocytopenia	1 (3.7)	0	0	1 (3.7)	0
Cardiac disorders					
-Total	1 (3.7)	0	1 (3.7)	0	0
Sinus tachycardia	1 (3.7)	0	1 (3.7)	0	0
Gastrointestinal disorders					
-Total	4 (14.8)	3 (11.1)	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	3 (11.1)	3 (11.1)	0	0	0
Abdominal pain	1 (3.7)	1 (3.7)	0	0	0
Diarrhoea	1 (3.7)	1 (3.7)	0	0	0
Nausea	1 (3.7)	0	1 (3.7)	0	0
General disorders and administration site conditions					
-Total	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Pyrexia	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Chills	1 (3.7)	1 (3.7)	0	0	0
Fatigue	1 (3.7)	1 (3.7)	0	0	0
Pain	1 (3.7)	1 (3.7)	0	0	0
Immune system disorders					
-Total	4 (14.8)	0	3 (11.1)	1 (3.7)	0
Hypogammaglobulinaemia	4 (14.8)	0	3 (11.1)	1 (3.7)	0
Infections and infestations					
-Total	8 (29.6)	2 (7.4)	5 (18.5)	1 (3.7)	0
Upper respiratory tract infection	4 (14.8)	2 (7.4)	2 (7.4)	0	0
Gastroenteritis	2 (7.4)	0	2 (7.4)	0	0
Otitis media	1 (3.7)	0	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (3.7)	1 (3.7)	0	0	0
Urinary tract infection	1 (3.7)	0	0	1 (3.7)	0
Viral infection	1 (3.7)	1 (3.7)	0	0	0
Investigations					
-Total	7 (25.9)	1 (3.7)	1 (3.7)	3 (11.1)	2 (7.4)
Neutrophil count decreased	3 (11.1)	1 (3.7)	0	1 (3.7)	1 (3.7)
White blood cell count decreased	3 (11.1)	2 (7.4)	0	0	1 (3.7)
Alanine aminotransferase increased	1 (3.7)	0	0	1 (3.7)	0
Blood bilirubin increased	1 (3.7)	0	0	1 (3.7)	0
Lymphocyte count decreased	1 (3.7)	0	1 (3.7)	0	0
Platelet count decreased	1 (3.7)	1 (3.7)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (3.7)	1 (3.7)	0	0	0
Hyperphosphataemia	1 (3.7)	1 (3.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Pain in extremity	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Nervous system disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (11.1)	3 (11.1)	0	0	0
Headache	3 (11.1)	3 (11.1)	0	0	0
Psychiatric disorders					
-Total	1 (3.7)	1 (3.7)	0	0	0
Anxiety	1 (3.7)	1 (3.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (22.2)	1 (3.7)	3 (11.1)	2 (7.4)	0
Cough	2 (7.4)	0	2 (7.4)	0	0
Nasal congestion	2 (7.4)	2 (7.4)	0	0	0
Rhinorrhoea	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Epistaxis	1 (3.7)	0	0	1 (3.7)	0
Oropharyngeal pain	1 (3.7)	0	1 (3.7)	0	0
Pulmonary oedema	1 (3.7)	0	0	1 (3.7)	0
Skin and subcutaneous tissue disorders					
-Total	5 (18.5)	4 (14.8)	1 (3.7)	0	0
Erythema	2 (7.4)	2 (7.4)	0	0	0
Rash maculo-papular	2 (7.4)	2 (7.4)	0	0	0
Rash	1 (3.7)	0	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Hypertension	2 (7.4)	1 (3.7)	1 (3.7)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184b
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

			All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (82.8)	6 (20.7)	7 (24.1)	8 (27.6)	3 (10.3)
Blood and lymphatic system disorders					
-Total	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Anaemia	1 (3.4)	0	0	1 (3.4)	0
Febrile neutropenia	1 (3.4)	0	0	1 (3.4)	0
Thrombocytopenia	1 (3.4)	0	1 (3.4)	0	0
Gastrointestinal disorders					
-Total	10 (34.5)	5 (17.2)	3 (10.3)	2 (6.9)	0
Diarrhoea	7 (24.1)	5 (17.2)	1 (3.4)	1 (3.4)	0
Vomiting	6 (20.7)	2 (6.9)	2 (6.9)	2 (6.9)	0
Nausea	5 (17.2)	1 (3.4)	2 (6.9)	2 (6.9)	0
Abdominal pain	3 (10.3)	1 (3.4)	1 (3.4)	1 (3.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	8 (27.6)	6 (20.7)	1 (3.4)	1 (3.4)	0
Pyrexia	8 (27.6)	6 (20.7)	1 (3.4)	1 (3.4)	0
Fatigue	1 (3.4)	1 (3.4)	0	0	0
Immune system disorders					
-Total	4 (13.8)	0	4 (13.8)	0	0
Hypogammaglobulinaemia	4 (13.8)	0	4 (13.8)	0	0
Infections and infestations					
-Total	8 (27.6)	3 (10.3)	3 (10.3)	2 (6.9)	0
Upper respiratory tract infection	3 (10.3)	1 (3.4)	1 (3.4)	1 (3.4)	0
Urinary tract infection	3 (10.3)	0	2 (6.9)	1 (3.4)	0
Gastroenteritis	1 (3.4)	1 (3.4)	0	0	0
Rhinovirus infection	1 (3.4)	1 (3.4)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Procedural pain	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Investigations					

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (31.0)	2 (6.9)	0	5 (17.2)	2 (6.9)
Neutrophil count decreased	5 (17.2)	1 (3.4)	0	2 (6.9)	2 (6.9)
Aspartate aminotransferase increased	3 (10.3)	1 (3.4)	0	2 (6.9)	0
Platelet count decreased	2 (6.9)	2 (6.9)	0	0	0
White blood cell count decreased	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Alanine aminotransferase increased	1 (3.4)	0	0	1 (3.4)	0
Blood creatinine increased	1 (3.4)	1 (3.4)	0	0	0
Lymphocyte count decreased	1 (3.4)	1 (3.4)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (13.8)	2 (6.9)	1 (3.4)	0	1 (3.4)
Decreased appetite	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Hypokalaemia	2 (6.9)	1 (3.4)	0	0	1 (3.4)
Hyperphosphataemia	1 (3.4)	1 (3.4)	0	0	0
Hypophosphataemia	1 (3.4)	0	0	1 (3.4)	0
Musculoskeletal and connective tissue disorders					
-Total	6 (20.7)	5 (17.2)	1 (3.4)	0	0
Pain in extremity	6 (20.7)	5 (17.2)	1 (3.4)	0	0
Nervous system disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (10.3)	2 (6.9)	1 (3.4)	0	0
Dizziness	3 (10.3)	3 (10.3)	0	0	0
Headache	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Renal and urinary disorders					
-Total	1 (3.4)	0	0	1 (3.4)	0
Acute kidney injury	1 (3.4)	0	0	1 (3.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (27.6)	8 (27.6)	0	0	0
Cough	5 (17.2)	5 (17.2)	0	0	0
Nasal congestion	2 (6.9)	2 (6.9)	0	0	0
Oropharyngeal pain	2 (6.9)	2 (6.9)	0	0	0
Rhinorrhoea	2 (6.9)	2 (6.9)	0	0	0
Epistaxis	1 (3.4)	1 (3.4)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (17.2)	3 (10.3)	2 (6.9)	0	0
Rash	3 (10.3)	1 (3.4)	2 (6.9)	0	0
Dry skin	1 (3.4)	1 (3.4)	0	0	0
Petechiae	1 (3.4)	1 (3.4)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184b
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Male

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (45.0)	2 (10.0)	1 (5.0)	5 (25.0)	1 (5.0)
Blood and lymphatic system disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Thrombocytopenia	1 (5.0)	1 (5.0)	0	0	0
Gastrointestinal disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Diarrhoea	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0
Otitis media	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Upper respiratory tract infection	1 (5.0)	0	1 (5.0)	0	0
Urinary tract infection	1 (5.0)	0	0	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Gender: Male

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=20 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Viral infection	1 (5.0)	1 (5.0)	0	0	0
Investigations					
-Total	6 (30.0)	1 (5.0)	1 (5.0)	3 (15.0)	1 (5.0)
Alanine aminotransferase increased	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Lymphocyte count decreased	2 (10.0)	1 (5.0)	0	1 (5.0)	0
White blood cell count decreased	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Aspartate aminotransferase increased	1 (5.0)	0	0	1 (5.0)	0
Neutrophil count decreased	1 (5.0)	1 (5.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184b
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Female

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (42.9)	1 (7.1)	2 (14.3)	2 (14.3)	1 (7.1)
Blood and lymphatic system disorders					
-Total	1 (7.1)	0	0	0	1 (7.1)
Febrile neutropenia	1 (7.1)	0	0	0	1 (7.1)
Gastrointestinal disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Abdominal pain	1 (7.1)	0	1 (7.1)	0	0
Diarrhoea	1 (7.1)	0	1 (7.1)	0	0
Nausea	1 (7.1)	0	1 (7.1)	0	0
General disorders and administration site conditions					
-Total	1 (7.1)	0	1 (7.1)	0	0

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	1 (7.1)	0	1 (7.1)	0	0
Pyrexia	1 (7.1)	0	1 (7.1)	0	0
Infections and infestations					
-Total	3 (21.4)	1 (7.1)	1 (7.1)	1 (7.1)	0
Clostridium difficile infection	1 (7.1)	0	0	1 (7.1)	0
Otitis media	1 (7.1)	0	1 (7.1)	0	0
Upper respiratory tract infection	1 (7.1)	1 (7.1)	0	0	0
Urinary tract infection	1 (7.1)	0	1 (7.1)	0	0
Injury, poisoning and procedural complications					
-Total	1 (7.1)	0	0	1 (7.1)	0
Procedural pain	1 (7.1)	0	0	1 (7.1)	0
Investigations					
-Total	2 (14.3)	0	1 (7.1)	1 (7.1)	0
White blood cell count decreased	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Alanine aminotransferase increased	1 (7.1)	0	0	1 (7.1)	0
Aspartate aminotransferase increased	1 (7.1)	1 (7.1)	0	0	0
Lymphocyte count decreased	1 (7.1)	1 (7.1)	0	0	0
Neutrophil count decreased	1 (7.1)	0	1 (7.1)	0	0
Platelet count decreased	1 (7.1)	0	0	1 (7.1)	0

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	1 (7.1)	0	0	1 (7.1)	0
Hypokalaemia	1 (7.1)	0	0	1 (7.1)	0
Nervous system disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0
Dizziness	1 (7.1)	1 (7.1)	0	0	0
Headache	1 (7.1)	0	1 (7.1)	0	0
Renal and urinary disorders					
-Total	1 (7.1)	0	0	1 (7.1)	0
Acute kidney injury	1 (7.1)	0	0	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (28.6)	4 (28.6)	0	0	0
Cough	2 (14.3)	2 (14.3)	0	0	0
Epistaxis	1 (7.1)	1 (7.1)	0	0	0
Oropharyngeal pain	1 (7.1)	1 (7.1)	0	0	0
Rhinorrhoea	1 (7.1)	1 (7.1)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184b
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Male

			All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (100)	1 (3.3)	3 (10.0)	7 (23.3)	19 (63.3)
Blood and lymphatic system disorders					
-Total	21 (70.0)	1 (3.3)	0	13 (43.3)	7 (23.3)
Anaemia	13 (43.3)	3 (10.0)	2 (6.7)	8 (26.7)	0
Febrile neutropenia	10 (33.3)	0	0	10 (33.3)	0
Neutropenia	7 (23.3)	0	0	2 (6.7)	5 (16.7)
Thrombocytopenia	5 (16.7)	0	0	2 (6.7)	3 (10.0)
Cardiac disorders					
-Total	8 (26.7)	3 (10.0)	3 (10.0)	2 (6.7)	0
Tachycardia	7 (23.3)	3 (10.0)	2 (6.7)	2 (6.7)	0
Sinus tachycardia	1 (3.3)	0	1 (3.3)	0	0
Gastrointestinal disorders					

Timing: Any time post CTL019 infusion, Gender: Male

			All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (50.0)	7 (23.3)	7 (23.3)	1 (3.3)	0
Vomiting	10 (33.3)	8 (26.7)	2 (6.7)	0	0
Diarrhoea	7 (23.3)	3 (10.0)	4 (13.3)	0	0
Nausea	6 (20.0)	2 (6.7)	3 (10.0)	1 (3.3)	0
Abdominal pain	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Constipation	1 (3.3)	1 (3.3)	0	0	0
General disorders and administration site conditions					
-Total	12 (40.0)	3 (10.0)	4 (13.3)	5 (16.7)	0
Pyrexia	8 (26.7)	1 (3.3)	4 (13.3)	3 (10.0)	0
Chills	5 (16.7)	5 (16.7)	0	0	0
Fatigue	4 (13.3)	3 (10.0)	0	1 (3.3)	0
Pain	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Hepatobiliary disorders					
-Total	5 (16.7)	1 (3.3)	2 (6.7)	2 (6.7)	0
Hepatomegaly	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Hyperbilirubinaemia	3 (10.0)	0	1 (3.3)	2 (6.7)	0
Immune system disorders					
-Total	26 (86.7)	3 (10.0)	13 (43.3)	4 (13.3)	6 (20.0)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	23 (76.7)	4 (13.3)	10 (33.3)	3 (10.0)	6 (20.0)
Hypogammaglobulinaemia	16 (53.3)	1 (3.3)	13 (43.3)	2 (6.7)	0
Infections and infestations					
-Total	13 (43.3)	2 (6.7)	8 (26.7)	3 (10.0)	0
Upper respiratory tract infection	5 (16.7)	2 (6.7)	3 (10.0)	0	0
Gastroenteritis	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Otitis media	3 (10.0)	0	2 (6.7)	1 (3.3)	0
Viral infection	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Clostridium difficile infection	1 (3.3)	0	1 (3.3)	0	0
Rhinovirus infection	1 (3.3)	1 (3.3)	0	0	0
Urinary tract infection	1 (3.3)	0	0	1 (3.3)	0
Investigations					
-Total	23 (76.7)	0	3 (10.0)	5 (16.7)	15 (50.0)
White blood cell count decreased	15 (50.0)	3 (10.0)	0	4 (13.3)	8 (26.7)
Neutrophil count decreased	13 (43.3)	1 (3.3)	1 (3.3)	2 (6.7)	9 (30.0)
Aspartate aminotransferase increased	9 (30.0)	0	2 (6.7)	4 (13.3)	3 (10.0)
Alanine aminotransferase increased	8 (26.7)	2 (6.7)	0	6 (20.0)	0
Platelet count decreased	8 (26.7)	2 (6.7)	1 (3.3)	1 (3.3)	4 (13.3)
Lymphocyte count decreased	7 (23.3)	1 (3.3)	2 (6.7)	2 (6.7)	2 (6.7)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	4 (13.3)	2 (6.7)	0	2 (6.7)	0
Blood creatinine increased	4 (13.3)	2 (6.7)	0	2 (6.7)	0
International normalised ratio increased	4 (13.3)	4 (13.3)	0	0	0
Activated partial thromboplastin time prolonged	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Prothrombin time prolonged	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Metabolism and nutrition disorders					
-Total	12 (40.0)	2 (6.7)	1 (3.3)	9 (30.0)	0
Decreased appetite	9 (30.0)	2 (6.7)	1 (3.3)	6 (20.0)	0
Hypokalaemia	7 (23.3)	3 (10.0)	1 (3.3)	3 (10.0)	0
Hypophosphataemia	5 (16.7)	1 (3.3)	0	4 (13.3)	0
Hyperphosphataemia	2 (6.7)	2 (6.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Pain in extremity	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Nervous system disorders					
-Total	12 (40.0)	9 (30.0)	2 (6.7)	1 (3.3)	0
Headache	11 (36.7)	8 (26.7)	2 (6.7)	1 (3.3)	0
Dizziness	1 (3.3)	1 (3.3)	0	0	0
Psychiatric disorders					

Timing: Any time post CTL019 infusion, Gender: Male

			All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (20.0)	4 (13.3)	2 (6.7)	0	0
Confusional state	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Anxiety	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Renal and urinary disorders					
-Total	3 (10.0)	0	1 (3.3)	0	2 (6.7)
Acute kidney injury	3 (10.0)	0	1 (3.3)	0	2 (6.7)
Respiratory, thoracic and mediastinal disorders					
-Total	14 (46.7)	4 (13.3)	4 (13.3)	4 (13.3)	2 (6.7)
Cough	6 (20.0)	4 (13.3)	2 (6.7)	0	0
Epistaxis	5 (16.7)	1 (3.3)	1 (3.3)	3 (10.0)	0
Hypoxia	5 (16.7)	0	2 (6.7)	1 (3.3)	2 (6.7)
Pleural effusion	5 (16.7)	1 (3.3)	3 (10.0)	1 (3.3)	0
Pulmonary oedema	4 (13.3)	0	0	3 (10.0)	1 (3.3)
Nasal congestion	3 (10.0)	3 (10.0)	0	0	0
Rhinorrhoea	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Oropharyngeal pain	1 (3.3)	0	1 (3.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (36.7)	9 (30.0)	1 (3.3)	1 (3.3)	0
Erythema	4 (13.3)	4 (13.3)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash maculo-papular	4 (13.3)	3 (10.0)	0	1 (3.3)	0
Rash	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Dry skin	1 (3.3)	1 (3.3)	0	0	0
Vascular disorders					
-Total	11 (36.7)	0	2 (6.7)	5 (16.7)	4 (13.3)
Hypotension	9 (30.0)	0	0	5 (16.7)	4 (13.3)
Hypertension	8 (26.7)	2 (6.7)	5 (16.7)	1 (3.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184b
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Female

			All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (100)	0	3 (8.8)	7 (20.6)	24 (70.6)
Blood and lymphatic system disorders					
-Total	23 (67.6)	0	2 (5.9)	15 (44.1)	6 (17.6)
Anaemia	14 (41.2)	0	2 (5.9)	11 (32.4)	1 (2.9)
Febrile neutropenia	14 (41.2)	0	0	13 (38.2)	1 (2.9)
Thrombocytopenia	5 (14.7)	0	1 (2.9)	1 (2.9)	3 (8.8)
Neutropenia	4 (11.8)	0	0	1 (2.9)	3 (8.8)
Cardiac disorders					
-Total	12 (35.3)	7 (20.6)	5 (14.7)	0	0
Tachycardia	8 (23.5)	5 (14.7)	3 (8.8)	0	0
Sinus tachycardia	5 (14.7)	3 (8.8)	2 (5.9)	0	0
Gastrointestinal disorders					

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	24 (70.6)	7 (20.6)	11 (32.4)	6 (17.6)	0
Nausea	19 (55.9)	4 (11.8)	11 (32.4)	4 (11.8)	0
Diarrhoea	17 (50.0)	10 (29.4)	5 (14.7)	2 (5.9)	0
Vomiting	17 (50.0)	8 (23.5)	6 (17.6)	3 (8.8)	0
Abdominal pain	8 (23.5)	4 (11.8)	3 (8.8)	1 (2.9)	0
Constipation	6 (17.6)	5 (14.7)	1 (2.9)	0	0
General disorders and administration site conditions					
-Total	23 (67.6)	12 (35.3)	7 (20.6)	3 (8.8)	1 (2.9)
Pyrexia	17 (50.0)	7 (20.6)	6 (17.6)	3 (8.8)	1 (2.9)
Fatigue	11 (32.4)	9 (26.5)	2 (5.9)	0	0
Chills	5 (14.7)	4 (11.8)	1 (2.9)	0	0
Immune system disorders					
-Total	31 (91.2)	1 (2.9)	18 (52.9)	7 (20.6)	5 (14.7)
Cytokine release syndrome	27 (79.4)	2 (5.9)	15 (44.1)	5 (14.7)	5 (14.7)
Hypogammaglobulinaemia	16 (47.1)	2 (5.9)	11 (32.4)	3 (8.8)	0
Infections and infestations					
-Total	13 (38.2)	4 (11.8)	6 (17.6)	3 (8.8)	0
Clostridium difficile infection	4 (11.8)	0	3 (8.8)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	4 (11.8)	4 (11.8)	0	0	0
Upper respiratory tract infection	4 (11.8)	2 (5.9)	1 (2.9)	1 (2.9)	0
Urinary tract infection	4 (11.8)	0	3 (8.8)	1 (2.9)	0
Gastroenteritis	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Otitis media	1 (2.9)	0	1 (2.9)	0	0
Injury, poisoning and procedural complications					
-Total	5 (14.7)	2 (5.9)	2 (5.9)	1 (2.9)	0
Procedural pain	5 (14.7)	2 (5.9)	2 (5.9)	1 (2.9)	0
Investigations					
-Total	29 (85.3)	0	2 (5.9)	8 (23.5)	19 (55.9)
White blood cell count decreased	20 (58.8)	1 (2.9)	1 (2.9)	8 (23.5)	10 (29.4)
Neutrophil count decreased	15 (44.1)	0	1 (2.9)	2 (5.9)	12 (35.3)
Alanine aminotransferase increased	13 (38.2)	3 (8.8)	2 (5.9)	8 (23.5)	0
Platelet count decreased	12 (35.3)	1 (2.9)	1 (2.9)	2 (5.9)	8 (23.5)
Aspartate aminotransferase increased	11 (32.4)	4 (11.8)	2 (5.9)	4 (11.8)	1 (2.9)
Lymphocyte count decreased	9 (26.5)	0	1 (2.9)	5 (14.7)	3 (8.8)
Prothrombin time prolonged	7 (20.6)	4 (11.8)	2 (5.9)	1 (2.9)	0
Blood creatinine increased	5 (14.7)	3 (8.8)	2 (5.9)	0	0
International normalised ratio increased	5 (14.7)	4 (11.8)	0	1 (2.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	4 (11.8)	0	3 (8.8)	1 (2.9)	0
Activated partial thromboplastin time prolonged	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Metabolism and nutrition disorders					
-Total	23 (67.6)	5 (14.7)	7 (20.6)	9 (26.5)	2 (5.9)
Decreased appetite	13 (38.2)	3 (8.8)	4 (11.8)	6 (17.6)	0
Hypokalaemia	12 (35.3)	1 (2.9)	5 (14.7)	5 (14.7)	1 (2.9)
Hyperphosphataemia	6 (17.6)	6 (17.6)	0	0	0
Hypophosphataemia	5 (14.7)	1 (2.9)	0	3 (8.8)	1 (2.9)
Musculoskeletal and connective tissue disorders					
-Total	9 (26.5)	6 (17.6)	3 (8.8)	0	0
Pain in extremity	9 (26.5)	6 (17.6)	3 (8.8)	0	0
Nervous system disorders					
-Total	15 (44.1)	9 (26.5)	5 (14.7)	1 (2.9)	0
Headache	13 (38.2)	7 (20.6)	5 (14.7)	1 (2.9)	0
Dizziness	5 (14.7)	5 (14.7)	0	0	0
Psychiatric disorders					
-Total	6 (17.6)	2 (5.9)	3 (8.8)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	4 (11.8)	2 (5.9)	1 (2.9)	1 (2.9)	0
Confusional state	2 (5.9)	0	2 (5.9)	0	0
Renal and urinary disorders					
-Total	6 (17.6)	1 (2.9)	0	4 (11.8)	1 (2.9)
Acute kidney injury	6 (17.6)	1 (2.9)	0	4 (11.8)	1 (2.9)
Respiratory, thoracic and mediastinal disorders					
-Total	19 (55.9)	10 (29.4)	2 (5.9)	4 (11.8)	3 (8.8)
Cough	8 (23.5)	8 (23.5)	0	0	0
Epistaxis	5 (14.7)	3 (8.8)	0	1 (2.9)	1 (2.9)
Hypoxia	5 (14.7)	0	1 (2.9)	3 (8.8)	1 (2.9)
Oropharyngeal pain	5 (14.7)	4 (11.8)	1 (2.9)	0	0
Rhinorrhoea	4 (11.8)	4 (11.8)	0	0	0
Pleural effusion	3 (8.8)	1 (2.9)	1 (2.9)	1 (2.9)	0
Pulmonary oedema	3 (8.8)	1 (2.9)	0	1 (2.9)	1 (2.9)
Nasal congestion	2 (5.9)	2 (5.9)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	12 (35.3)	8 (23.5)	4 (11.8)	0	0
Rash	5 (14.7)	3 (8.8)	2 (5.9)	0	0
Dry skin	4 (11.8)	4 (11.8)	0	0	0

Timing: Any time post CTL019 infusion, Gender: Female

Group term Preferred term	All patients N=34 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Petechiae	4 (11.8)	3 (8.8)	1 (2.9)	0	0
Erythema	1 (2.9)	1 (2.9)	0	0	0
Rash maculo-papular	1 (2.9)	0	1 (2.9)	0	0
Vascular disorders					
-Total	11 (32.4)	2 (5.9)	3 (8.8)	2 (5.9)	4 (11.8)
Hypotension	7 (20.6)	1 (2.9)	0	2 (5.9)	4 (11.8)
Hypertension	4 (11.8)	1 (2.9)	3 (8.8)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: White

			All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (98.1)	2 (3.8)	6 (11.5)	10 (19.2)	33 (63.5)
Blood and lymphatic system disorders					
-Total	33 (63.5)	1 (1.9)	0	23 (44.2)	9 (17.3)
Anaemia	21 (40.4)	3 (5.8)	3 (5.8)	14 (26.9)	1 (1.9)
Febrile neutropenia	19 (36.5)	0	0	19 (36.5)	0
Neutropenia	8 (15.4)	0	0	3 (5.8)	5 (9.6)
Thrombocytopenia	8 (15.4)	0	0	2 (3.8)	6 (11.5)
Disseminated intravascular coagulation	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Lymphopenia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Cardiac disorders					
-Total	16 (30.8)	7 (13.5)	7 (13.5)	2 (3.8)	0
Tachycardia	12 (23.1)	5 (9.6)	5 (9.6)	2 (3.8)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	5 (9.6)	3 (5.8)	2 (3.8)	0	0
Eye disorders					
-Total	6 (11.5)	3 (5.8)	3 (5.8)	0	0
Periorbital oedema	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Conjunctival haemorrhage	2 (3.8)	2 (3.8)	0	0	0
Vision blurred	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Uveitis	1 (1.9)	0	1 (1.9)	0	0
Gastrointestinal disorders					
-Total	27 (51.9)	10 (19.2)	9 (17.3)	8 (15.4)	0
Vomiting	17 (32.7)	8 (15.4)	6 (11.5)	3 (5.8)	0
Diarrhoea	16 (30.8)	11 (21.2)	4 (7.7)	1 (1.9)	0
Nausea	16 (30.8)	4 (7.7)	9 (17.3)	3 (5.8)	0
Abdominal pain	8 (15.4)	5 (9.6)	2 (3.8)	1 (1.9)	0
Constipation	6 (11.5)	5 (9.6)	1 (1.9)	0	0
Abdominal pain upper	1 (1.9)	0	1 (1.9)	0	0
Dysphagia	1 (1.9)	0	0	1 (1.9)	0
General disorders and administration site conditions					
-Total	23 (44.2)	8 (15.4)	7 (13.5)	7 (13.5)	1 (1.9)

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	14 (26.9)	2 (3.8)	6 (11.5)	5 (9.6)	1 (1.9)
Fatigue	9 (17.3)	6 (11.5)	2 (3.8)	1 (1.9)	0
Chills	8 (15.4)	8 (15.4)	0	0	0
Catheter site pain	2 (3.8)	0	2 (3.8)	0	0
Malaise	2 (3.8)	0	2 (3.8)	0	0
Pain	2 (3.8)	0	0	2 (3.8)	0
Immune system disorders					
-Total	45 (86.5)	3 (5.8)	22 (42.3)	10 (19.2)	10 (19.2)
Cytokine release syndrome	40 (76.9)	4 (7.7)	19 (36.5)	7 (13.5)	10 (19.2)
Hypogammaglobulinaemia	20 (38.5)	1 (1.9)	15 (28.8)	4 (7.7)	0
Infections and infestations					
-Total	8 (15.4)	1 (1.9)	6 (11.5)	1 (1.9)	0
Clostridium difficile colitis	3 (5.8)	1 (1.9)	1 (1.9)	1 (1.9)	0
Clostridium difficile infection	3 (5.8)	0	3 (5.8)	0	0
Gastroenteritis	1 (1.9)	0	1 (1.9)	0	0
Upper respiratory tract infection	1 (1.9)	0	1 (1.9)	0	0
Viral infection	1 (1.9)	0	1 (1.9)	0	0
Injury, poisoning and procedural complications					
-Total	4 (7.7)	2 (3.8)	2 (3.8)	0	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural pain	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Transfusion reaction	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Investigations					
-Total	39 (75.0)	1 (1.9)	3 (5.8)	9 (17.3)	26 (50.0)
White blood cell count decreased	23 (44.2)	3 (5.8)	0	7 (13.5)	13 (25.0)
Neutrophil count decreased	20 (38.5)	0	1 (1.9)	4 (7.7)	15 (28.8)
Platelet count decreased	17 (32.7)	3 (5.8)	2 (3.8)	2 (3.8)	10 (19.2)
Alanine aminotransferase increased	16 (30.8)	4 (7.7)	2 (3.8)	10 (19.2)	0
Aspartate aminotransferase increased	14 (26.9)	2 (3.8)	3 (5.8)	5 (9.6)	4 (7.7)
Lymphocyte count decreased	11 (21.2)	1 (1.9)	1 (1.9)	5 (9.6)	4 (7.7)
Blood bilirubin increased	7 (13.5)	2 (3.8)	3 (5.8)	2 (3.8)	0
Blood creatinine increased	7 (13.5)	4 (7.7)	1 (1.9)	2 (3.8)	0
International normalised ratio increased	7 (13.5)	6 (11.5)	0	1 (1.9)	0
Prothrombin time prolonged	7 (13.5)	4 (7.7)	2 (3.8)	1 (1.9)	0
Activated partial thromboplastin time prolonged	4 (7.7)	2 (3.8)	2 (3.8)	0	0
Blood immunoglobulin m decreased	3 (5.8)	3 (5.8)	0	0	0
Blood immunoglobulin a decreased	1 (1.9)	1 (1.9)	0	0	0
Blood uric acid increased	1 (1.9)	1 (1.9)	0	0	0
C-reactive protein increased	1 (1.9)	0	0	1 (1.9)	0

Timing: within 8 weeks post infusion, Race: White

			All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	32 (61.5)	4 (7.7)	8 (15.4)	17 (32.7)	3 (5.8)
Decreased appetite	18 (34.6)	3 (5.8)	4 (7.7)	11 (21.2)	0
Hypokalaemia	16 (30.8)	3 (5.8)	6 (11.5)	7 (13.5)	0
Hypophosphataemia	9 (17.3)	2 (3.8)	0	6 (11.5)	1 (1.9)
Hyperphosphataemia	6 (11.5)	6 (11.5)	0	0	0
Hypernatraemia	3 (5.8)	0	2 (3.8)	0	1 (1.9)
Dehydration	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Hyperuricaemia	2 (3.8)	1 (1.9)	0	0	1 (1.9)
Acidosis	1 (1.9)	0	0	1 (1.9)	0
Musculoskeletal and connective tissue disorders					
-Total	8 (15.4)	4 (7.7)	3 (5.8)	1 (1.9)	0
Arthralgia	3 (5.8)	2 (3.8)	0	1 (1.9)	0
Myalgia	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Pain in extremity	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Muscular weakness	1 (1.9)	0	1 (1.9)	0	0
Musculoskeletal chest pain	1 (1.9)	1 (1.9)	0	0	0
Nervous system disorders					
-Total	25 (48.1)	15 (28.8)	6 (11.5)	4 (7.7)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	19 (36.5)	14 (26.9)	3 (5.8)	2 (3.8)	0
Dizziness	4 (7.7)	4 (7.7)	0	0	0
Encephalopathy	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Seizure	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Dysarthria	1 (1.9)	0	1 (1.9)	0	0
Tremor	1 (1.9)	1 (1.9)	0	0	0
Psychiatric disorders					
-Total	13 (25.0)	7 (13.5)	5 (9.6)	1 (1.9)	0
Confusional state	6 (11.5)	3 (5.8)	3 (5.8)	0	0
Anxiety	5 (9.6)	2 (3.8)	2 (3.8)	1 (1.9)	0
Delirium	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Agitation	1 (1.9)	0	1 (1.9)	0	0
Renal and urinary disorders					
-Total	6 (11.5)	1 (1.9)	1 (1.9)	1 (1.9)	3 (5.8)
Acute kidney injury	5 (9.6)	0	1 (1.9)	1 (1.9)	3 (5.8)
Dysuria	1 (1.9)	1 (1.9)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	22 (42.3)	9 (17.3)	4 (7.7)	4 (7.7)	5 (9.6)
Hypoxia	10 (19.2)	0	3 (5.8)	4 (7.7)	3 (5.8)

Timing: within 8 weeks post infusion, Race: White

			All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	8 (15.4)	8 (15.4)	0	0	0
Pleural effusion	8 (15.4)	2 (3.8)	4 (7.7)	2 (3.8)	0
Epistaxis	6 (11.5)	2 (3.8)	1 (1.9)	2 (3.8)	1 (1.9)
Pulmonary oedema	5 (9.6)	1 (1.9)	0	3 (5.8)	1 (1.9)
Respiratory failure	2 (3.8)	0	0	0	2 (3.8)
Haemoptysis	1 (1.9)	0	0	0	1 (1.9)
Nasal congestion	1 (1.9)	1 (1.9)	0	0	0
Oropharyngeal pain	1 (1.9)	1 (1.9)	0	0	0
Rhinitis allergic	1 (1.9)	1 (1.9)	0	0	0
Rhinorrhoea	1 (1.9)	1 (1.9)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (21.2)	11 (21.2)	0	0	0
Rash	4 (7.7)	4 (7.7)	0	0	0
Dry skin	2 (3.8)	2 (3.8)	0	0	0
Erythema	2 (3.8)	2 (3.8)	0	0	0
Hyperhidrosis	2 (3.8)	2 (3.8)	0	0	0
Pruritus	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					
-Total	20 (38.5)	3 (5.8)	3 (5.8)	7 (13.5)	7 (13.5)

Timing: within 8 weeks post infusion, Race: White

Group term Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	15 (28.8)	1 (1.9)	0	7 (13.5)	7 (13.5)
Hypertension	9 (17.3)	2 (3.8)	6 (11.5)	1 (1.9)	0
Orthostatic hypotension	1 (1.9)	1 (1.9)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Asian

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	0	2 (40.0)	2 (40.0)	1 (20.0)
Blood and lymphatic system disorders					
-Total	3 (60.0)	0	1 (20.0)	2 (40.0)	0
Anaemia	3 (60.0)	0	1 (20.0)	2 (40.0)	0
Febrile neutropenia	1 (20.0)	0	0	1 (20.0)	0
Cardiac disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Atrioventricular block second degree	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Diarrhoea	1 (20.0)	0	1 (20.0)	0	0
Nausea	1 (20.0)	1 (20.0)	0	0	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (20.0)	1 (20.0)	0	0	0
General disorders and administration site conditions					
-Total	4 (80.0)	2 (40.0)	2 (40.0)	0	0
Fatigue	3 (60.0)	3 (60.0)	0	0	0
Pain	1 (20.0)	0	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	1 (20.0)	0	0
Immune system disorders					
-Total	5 (100)	0	5 (100)	0	0
Cytokine release syndrome	4 (80.0)	0	4 (80.0)	0	0
Hypogammaglobulinaemia	3 (60.0)	1 (20.0)	2 (40.0)	0	0
Infections and infestations					
-Total	2 (40.0)	0	1 (20.0)	1 (20.0)	0
Gastroenteritis	1 (20.0)	0	0	1 (20.0)	0
Pharyngitis	1 (20.0)	0	1 (20.0)	0	0
Streptococcal infection	1 (20.0)	0	1 (20.0)	0	0
Viral upper respiratory tract infection	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	3 (60.0)	0	1 (20.0)	1 (20.0)	1 (20.0)

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (40.0)	0	1 (20.0)	0	1 (20.0)
White blood cell count decreased	2 (40.0)	0	1 (20.0)	1 (20.0)	0
Aspartate aminotransferase increased	1 (20.0)	0	0	1 (20.0)	0
Blood immunoglobulin a decreased	1 (20.0)	1 (20.0)	0	0	0
International normalised ratio increased	1 (20.0)	1 (20.0)	0	0	0
Lymphocyte count decreased	1 (20.0)	0	1 (20.0)	0	0
Metabolism and nutrition disorders					
-Total	3 (60.0)	2 (40.0)	0	1 (20.0)	0
Decreased appetite	1 (20.0)	1 (20.0)	0	0	0
Dehydration	1 (20.0)	0	0	1 (20.0)	0
Hyperphosphataemia	1 (20.0)	1 (20.0)	0	0	0
Hyperuricaemia	1 (20.0)	1 (20.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Pain in extremity	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Arthralgia	1 (20.0)	1 (20.0)	0	0	0
Myalgia	1 (20.0)	1 (20.0)	0	0	0
Nervous system disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	2 (40.0)	2 (40.0)	0	0	0
Renal and urinary disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Dysuria	1 (20.0)	0	1 (20.0)	0	0
Pollakiuria	1 (20.0)	1 (20.0)	0	0	0
Vascular disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Embolism	1 (20.0)	0	0	1 (20.0)	0
Hypertension	1 (20.0)	0	1 (20.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Other

		All patients N=7			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	0	2 (28.6)	5 (71.4)
Blood and lymphatic system disorders					
-Total	5 (71.4)	0	2 (28.6)	2 (28.6)	1 (14.3)
Anaemia	3 (42.9)	0	1 (14.3)	2 (28.6)	0
Febrile neutropenia	2 (28.6)	0	0	2 (28.6)	0
Disseminated intravascular coagulation	1 (14.3)	0	1 (14.3)	0	0
Lymphopenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Tachycardia	3 (42.9)	3 (42.9)	0	0	0
Ventricular tachycardia	1 (14.3)	0	1 (14.3)	0	0
Endocrine disorders					

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (14.3)	0	1 (14.3)	0	0
Adrenal insufficiency	1 (14.3)	0	1 (14.3)	0	0
Eye disorders					
-Total	2 (28.6)	0	2 (28.6)	0	0
Conjunctival haemorrhage	1 (14.3)	1 (14.3)	0	0	0
Periorbital oedema	1 (14.3)	1 (14.3)	0	0	0
Uveitis	1 (14.3)	0	1 (14.3)	0	0
Vision blurred	1 (14.3)	0	1 (14.3)	0	0
Gastrointestinal disorders					
-Total	5 (71.4)	1 (14.3)	4 (57.1)	0	0
Nausea	4 (57.1)	1 (14.3)	3 (42.9)	0	0
Vomiting	4 (57.1)	4 (57.1)	0	0	0
Abdominal pain	1 (14.3)	1 (14.3)	0	0	0
Abdominal pain upper	1 (14.3)	0	1 (14.3)	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Diarrhoea	1 (14.3)	0	1 (14.3)	0	0
Dysphagia	1 (14.3)	0	1 (14.3)	0	0
Flatulence	1 (14.3)	1 (14.3)	0	0	0
Lip pain	1 (14.3)	0	1 (14.3)	0	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	4 (57.1)	2 (28.6)	1 (14.3)	1 (14.3)	0
Catheter site haemorrhage	1 (14.3)	1 (14.3)	0	0	0
Catheter site pain	1 (14.3)	1 (14.3)	0	0	0
Fatigue	1 (14.3)	1 (14.3)	0	0	0
Injection site haematoma	1 (14.3)	1 (14.3)	0	0	0
Malaise	1 (14.3)	0	1 (14.3)	0	0
Physical deconditioning	1 (14.3)	0	0	1 (14.3)	0
Pyrexia	1 (14.3)	1 (14.3)	0	0	0
Hepatobiliary disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Gallbladder enlargement	1 (14.3)	1 (14.3)	0	0	0
Immune system disorders					
-Total	6 (85.7)	1 (14.3)	3 (42.9)	1 (14.3)	1 (14.3)
Cytokine release syndrome	6 (85.7)	2 (28.6)	2 (28.6)	1 (14.3)	1 (14.3)
Hypogammaglobulinaemia	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Infections and infestations					
-Total	3 (42.9)	1 (14.3)	2 (28.6)	0	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site cellulitis	1 (14.3)	1 (14.3)	0	0	0
Clostridium difficile colitis	1 (14.3)	0	1 (14.3)	0	0
Clostridium difficile infection	1 (14.3)	0	1 (14.3)	0	0
Cytomegalovirus infection	1 (14.3)	1 (14.3)	0	0	0
Herpes simplex	1 (14.3)	1 (14.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (42.9)	1 (14.3)	1 (14.3)	0	1 (14.3)
Post procedural haemorrhage	1 (14.3)	1 (14.3)	0	0	0
Procedural pain	1 (14.3)	0	1 (14.3)	0	0
Transfusion reaction	1 (14.3)	1 (14.3)	0	0	0
Transfusion related complication	1 (14.3)	0	0	0	1 (14.3)
Investigations					
-Total	6 (85.7)	0	0	2 (28.6)	4 (57.1)
White blood cell count decreased	5 (71.4)	0	0	2 (28.6)	3 (42.9)
Alanine aminotransferase increased	3 (42.9)	1 (14.3)	1 (14.3)	1 (14.3)	0
Aspartate aminotransferase increased	3 (42.9)	1 (14.3)	1 (14.3)	1 (14.3)	0
Neutrophil count decreased	3 (42.9)	0	0	0	3 (42.9)
Blood creatinine increased	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Lymphocyte count decreased	2 (28.6)	0	0	1 (14.3)	1 (14.3)

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	2 (28.6)	0	0	0	2 (28.6)
Prothrombin time prolonged	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0	0	0
Blood immunoglobulin a decreased	1 (14.3)	1 (14.3)	0	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0
Culture stool positive	1 (14.3)	1 (14.3)	0	0	0
Haemoglobin decreased	1 (14.3)	0	0	1 (14.3)	0
Hepatic enzyme increased	1 (14.3)	0	1 (14.3)	0	0
International normalised ratio increased	1 (14.3)	1 (14.3)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (42.9)	1 (14.3)	0	2 (28.6)	0
Acidosis	1 (14.3)	1 (14.3)	0	0	0
Decreased appetite	1 (14.3)	0	0	1 (14.3)	0
Hypernatraemia	1 (14.3)	1 (14.3)	0	0	0
Hyperphosphataemia	1 (14.3)	1 (14.3)	0	0	0
Tumour lysis syndrome	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Coccydynia	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	1 (14.3)	1 (14.3)	0	0	0
Nervous system disorders					
-Total	4 (57.1)	1 (14.3)	3 (42.9)	0	0
Headache	3 (42.9)	0	3 (42.9)	0	0
Asterixis	1 (14.3)	1 (14.3)	0	0	0
Ataxia	1 (14.3)	0	1 (14.3)	0	0
Dysarthria	1 (14.3)	1 (14.3)	0	0	0
Encephalopathy	1 (14.3)	1 (14.3)	0	0	0
Myoclonus	1 (14.3)	1 (14.3)	0	0	0
Neuropathy peripheral	1 (14.3)	0	1 (14.3)	0	0
Pleocytosis	1 (14.3)	1 (14.3)	0	0	0
Seizure	1 (14.3)	0	1 (14.3)	0	0
Tremor	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Adjustment disorder	1 (14.3)	0	1 (14.3)	0	0
Agitation	1 (14.3)	0	1 (14.3)	0	0
Anxiety	1 (14.3)	0	1 (14.3)	0	0
Delirium	1 (14.3)	0	1 (14.3)	0	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Suicidal ideation	1 (14.3)	1 (14.3)	0	0	0
Renal and urinary disorders					
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Acute kidney injury	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Epistaxis	1 (14.3)	0	0	1 (14.3)	0
Haemoptysis	1 (14.3)	1 (14.3)	0	0	0
Oropharyngeal pain	1 (14.3)	0	1 (14.3)	0	0
Pulmonary oedema	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Skin and subcutaneous tissue disorders					
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Dry skin	2 (28.6)	2 (28.6)	0	0	0
Ecchymosis	1 (14.3)	0	0	1 (14.3)	0
Erythema	1 (14.3)	1 (14.3)	0	0	0
Hyperhidrosis	1 (14.3)	1 (14.3)	0	0	0
Pruritus	1 (14.3)	1 (14.3)	0	0	0
Rash vesicular	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Race: Other

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin exfoliation	1 (14.3)	1 (14.3)	0	0	0
Skin fissures	1 (14.3)	1 (14.3)	0	0	0
Vascular disorders					
-Total	3 (42.9)	0	2 (28.6)	0	1 (14.3)
Hypotension	1 (14.3)	0	0	0	1 (14.3)
Orthostatic hypotension	1 (14.3)	0	1 (14.3)	0	0
Secondary hypertension	1 (14.3)	0	1 (14.3)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

			All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (72.7)	4 (9.1)	9 (20.5)	15 (34.1)	4 (9.1)
Blood and lymphatic system disorders					
-Total	6 (13.6)	1 (2.3)	1 (2.3)	2 (4.5)	2 (4.5)
Neutropenia	3 (6.8)	0	0	1 (2.3)	2 (4.5)
Thrombocytopenia	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Anaemia	1 (2.3)	1 (2.3)	0	0	0
Febrile neutropenia	1 (2.3)	0	0	1 (2.3)	0
Cardiac disorders					
-Total	1 (2.3)	0	1 (2.3)	0	0
Sinus tachycardia	1 (2.3)	0	1 (2.3)	0	0
Endocrine disorders					
-Total	1 (2.3)	1 (2.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

		All patients N=44			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	1 (2.3)	1 (2.3)	0	0	0
Eye disorders					
-Total	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Dry eye	1 (2.3)	0	1 (2.3)	0	0
Vision blurred	1 (2.3)	1 (2.3)	0	0	0
Gastrointestinal disorders					
-Total	13 (29.5)	7 (15.9)	4 (9.1)	2 (4.5)	0
Vomiting	9 (20.5)	5 (11.4)	2 (4.5)	2 (4.5)	0
Diarrhoea	7 (15.9)	5 (11.4)	1 (2.3)	1 (2.3)	0
Nausea	5 (11.4)	0	3 (6.8)	2 (4.5)	0
Abdominal pain	4 (9.1)	2 (4.5)	1 (2.3)	1 (2.3)	0
Abdominal pain upper	1 (2.3)	1 (2.3)	0	0	0
General disorders and administration site conditions					
-Total	10 (22.7)	6 (13.6)	3 (6.8)	1 (2.3)	0
Pyrexia	7 (15.9)	4 (9.1)	2 (4.5)	1 (2.3)	0
Fatigue	2 (4.5)	2 (4.5)	0	0	0
Catheter site pain	1 (2.3)	0	1 (2.3)	0	0
Chills	1 (2.3)	1 (2.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

			All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	1 (2.3)	1 (2.3)	0	0	0
Pain	1 (2.3)	1 (2.3)	0	0	0
Immune system disorders					
-Total	8 (18.2)	1 (2.3)	6 (13.6)	1 (2.3)	0
Hypogammaglobulinaemia	7 (15.9)	0	6 (13.6)	1 (2.3)	0
Seasonal allergy	1 (2.3)	1 (2.3)	0	0	0
Infections and infestations					
-Total	15 (34.1)	5 (11.4)	6 (13.6)	4 (9.1)	0
Upper respiratory tract infection	7 (15.9)	3 (6.8)	3 (6.8)	1 (2.3)	0
Gastroenteritis	3 (6.8)	1 (2.3)	2 (4.5)	0	0
Urinary tract infection	3 (6.8)	0	1 (2.3)	2 (4.5)	0
Viral upper respiratory tract infection	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Cytomegalovirus infection	1 (2.3)	1 (2.3)	0	0	0
Otitis media	1 (2.3)	0	1 (2.3)	0	0
Viral infection	1 (2.3)	1 (2.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (2.3)	1 (2.3)	0	0	0
Procedural pain	1 (2.3)	1 (2.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	12 (27.3)	1 (2.3)	1 (2.3)	8 (18.2)	2 (4.5)
Neutrophil count decreased	5 (11.4)	1 (2.3)	0	3 (6.8)	1 (2.3)
White blood cell count decreased	5 (11.4)	2 (4.5)	1 (2.3)	1 (2.3)	1 (2.3)
Aspartate aminotransferase increased	3 (6.8)	1 (2.3)	0	2 (4.5)	0
Platelet count decreased	3 (6.8)	3 (6.8)	0	0	0
Alanine aminotransferase increased	2 (4.5)	0	0	2 (4.5)	0
Blood bilirubin increased	1 (2.3)	0	0	1 (2.3)	0
Haemoglobin decreased	1 (2.3)	1 (2.3)	0	0	0
Lymphocyte count decreased	1 (2.3)	0	1 (2.3)	0	0
Metabolism and nutrition disorders					
-Total	5 (11.4)	1 (2.3)	1 (2.3)	2 (4.5)	1 (2.3)
Hyperphosphataemia	2 (4.5)	2 (4.5)	0	0	0
Decreased appetite	1 (2.3)	0	1 (2.3)	0	0
Dehydration	1 (2.3)	0	0	1 (2.3)	0
Hypokalaemia	1 (2.3)	0	0	0	1 (2.3)
Hypophosphataemia	1 (2.3)	0	0	1 (2.3)	0
Tumour lysis syndrome	1 (2.3)	0	0	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	8 (18.2)	5 (11.4)	3 (6.8)	0	0
Pain in extremity	5 (11.4)	3 (6.8)	2 (4.5)	0	0
Arthralgia	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Joint range of motion decreased	1 (2.3)	1 (2.3)	0	0	0
Muscular weakness	1 (2.3)	1 (2.3)	0	0	0
Nervous system disorders					
-Total	6 (13.6)	5 (11.4)	1 (2.3)	0	0
Headache	5 (11.4)	4 (9.1)	1 (2.3)	0	0
Dizziness	3 (6.8)	3 (6.8)	0	0	0
Psychiatric disorders					
-Total	1 (2.3)	1 (2.3)	0	0	0
Anxiety	1 (2.3)	1 (2.3)	0	0	0
Renal and urinary disorders					
-Total	1 (2.3)	0	0	1 (2.3)	0
Acute kidney injury	1 (2.3)	0	0	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

		All patients N=44			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (25.0)	6 (13.6)	4 (9.1)	1 (2.3)	0
Cough	4 (9.1)	2 (4.5)	2 (4.5)	0	0
Nasal congestion	3 (6.8)	3 (6.8)	0	0	0
Oropharyngeal pain	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Rhinorrhoea	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Epistaxis	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Rhinitis allergic	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Erythema	2 (4.5)	2 (4.5)	0	0	0
Hyperhidrosis	1 (2.3)	1 (2.3)	0	0	0
Pruritus	1 (2.3)	1 (2.3)	0	0	0
Rash	1 (2.3)	0	1 (2.3)	0	0
Vascular disorders					
-Total	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Hypertension	2 (4.5)	1 (2.3)	1 (2.3)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	2 (40.0)	1 (20.0)	0	1 (20.0)
Blood and lymphatic system disorders					
-Total	2 (40.0)	0	1 (20.0)	0	1 (20.0)
Febrile neutropenia	1 (20.0)	0	0	1 (20.0)	0
Lymphopenia	1 (20.0)	0	1 (20.0)	0	0
Neutropenia	1 (20.0)	0	0	0	1 (20.0)
General disorders and administration site conditions					
-Total	2 (40.0)	2 (40.0)	0	0	0
Pyrexia	2 (40.0)	2 (40.0)	0	0	0
Infections and infestations					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Herpes zoster	1 (20.0)	0	0	1 (20.0)	0
Molluscum contagiosum	1 (20.0)	1 (20.0)	0	0	0
Investigations					
-Total	2 (40.0)	1 (20.0)	0	0	1 (20.0)
Neutrophil count decreased	2 (40.0)	1 (20.0)	0	0	1 (20.0)
Blood uric acid increased	1 (20.0)	1 (20.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (60.0)	2 (40.0)	1 (20.0)	0	0
Joint range of motion decreased	1 (20.0)	1 (20.0)	0	0	0
Osteonecrosis	1 (20.0)	0	1 (20.0)	0	0
Pain in extremity	1 (20.0)	1 (20.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Pulmonary oedema	1 (20.0)	0	0	1 (20.0)	0
Skin and subcutaneous tissue disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Rash	1 (20.0)	0	1 (20.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	3 (42.9)	1 (14.3)	2 (28.6)
Blood and lymphatic system disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Anaemia	1 (14.3)	0	0	1 (14.3)	0
Febrile neutropenia	1 (14.3)	0	0	1 (14.3)	0
Lymphadenopathy	1 (14.3)	0	1 (14.3)	0	0
Eye disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Dry eye	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Diarrhoea	1 (14.3)	1 (14.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (14.3)	1 (14.3)	0	0	0
General disorders and administration site conditions					
-Total	1 (14.3)	1 (14.3)	0	0	0
Pyrexia	1 (14.3)	1 (14.3)	0	0	0
Immune system disorders					
-Total	4 (57.1)	1 (14.3)	3 (42.9)	0	0
Immunodeficiency common variable	2 (28.6)	0	2 (28.6)	0	0
Hypogammaglobulinaemia	1 (14.3)	0	1 (14.3)	0	0
Seasonal allergy	1 (14.3)	1 (14.3)	0	0	0
Infections and infestations					
-Total	5 (71.4)	0	3 (42.9)	1 (14.3)	1 (14.3)
Oral herpes	1 (14.3)	0	1 (14.3)	0	0
Rhinitis	1 (14.3)	1 (14.3)	0	0	0
Sepsis	1 (14.3)	0	0	0	1 (14.3)
Urinary tract infection	1 (14.3)	0	1 (14.3)	0	0
Vascular device infection	1 (14.3)	0	0	1 (14.3)	0
Vulvovaginal mycotic infection	1 (14.3)	0	1 (14.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	1 (14.3)	0	1 (14.3)	0	0
Arthropod bite	1 (14.3)	1 (14.3)	0	0	0
Procedural pain	1 (14.3)	0	1 (14.3)	0	0
Investigations					
-Total	2 (28.6)	1 (14.3)	0	0	1 (14.3)
Blood creatinine increased	1 (14.3)	1 (14.3)	0	0	0
Haemoglobin decreased	1 (14.3)	1 (14.3)	0	0	0
Lymphocyte count decreased	1 (14.3)	1 (14.3)	0	0	0
Neutrophil count decreased	1 (14.3)	0	0	0	1 (14.3)
Metabolism and nutrition disorders					
-Total	2 (28.6)	2 (28.6)	0	0	0
Decreased appetite	1 (14.3)	1 (14.3)	0	0	0
Hypokalaemia	1 (14.3)	1 (14.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (42.9)	3 (42.9)	0	0	0
Pain in extremity	2 (28.6)	2 (28.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	1 (14.3)	1 (14.3)	0	0	0
Musculoskeletal chest pain	1 (14.3)	1 (14.3)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (14.3)	0	1 (14.3)	0	0
Myelodysplastic syndrome	1 (14.3)	0	1 (14.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (57.1)	4 (57.1)	0	0	0
Cough	3 (42.9)	3 (42.9)	0	0	0
Nasal congestion	1 (14.3)	1 (14.3)	0	0	0
Rhinitis allergic	1 (14.3)	1 (14.3)	0	0	0
Rhinorrhoea	1 (14.3)	1 (14.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (71.4)	4 (57.1)	1 (14.3)	0	0
Rash	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Dermatitis	1 (14.3)	1 (14.3)	0	0	0
Dermatitis atopic	1 (14.3)	1 (14.3)	0	0	0
Dry skin	1 (14.3)	1 (14.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eczema	1 (14.3)	1 (14.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: White

		All patients N=28			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (35.7)	2 (7.1)	1 (3.6)	6 (21.4)	1 (3.6)
Blood and lymphatic system disorders					
-Total	1 (3.6)	1 (3.6)	0	0	0
Thrombocytopenia	1 (3.6)	1 (3.6)	0	0	0
Gastrointestinal disorders					
-Total	2 (7.1)	0	2 (7.1)	0	0
Diarrhoea	2 (7.1)	0	2 (7.1)	0	0
Abdominal pain	1 (3.6)	0	1 (3.6)	0	0
Infections and infestations					
-Total	4 (14.3)	0	1 (3.6)	3 (10.7)	0
Otitis media	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Urinary tract infection	2 (7.1)	0	1 (3.6)	1 (3.6)	0

Timing: >1 year post-CTL019 infusion, Race: White

		All patients N=28			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (3.6)	0	0	1 (3.6)	0
Upper respiratory tract infection	1 (3.6)	0	1 (3.6)	0	0
Investigations					
-Total	5 (17.9)	1 (3.6)	1 (3.6)	2 (7.1)	1 (3.6)
Alanine aminotransferase increased	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Lymphocyte count decreased	2 (7.1)	1 (3.6)	0	1 (3.6)	0
Aspartate aminotransferase increased	1 (3.6)	0	0	1 (3.6)	0
Neutrophil count decreased	1 (3.6)	1 (3.6)	0	0	0
White blood cell count decreased	1 (3.6)	0	0	0	1 (3.6)
Metabolism and nutrition disorders					
-Total	1 (3.6)	0	0	1 (3.6)	0
Hypokalaemia	1 (3.6)	0	0	1 (3.6)	0
Nervous system disorders					
-Total	2 (7.1)	0	1 (3.6)	1 (3.6)	0
Dizziness	1 (3.6)	1 (3.6)	0	0	0
Headache	1 (3.6)	0	1 (3.6)	0	0
Seizure	1 (3.6)	0	0	1 (3.6)	0
Renal and urinary disorders					
-Total	1 (3.6)	0	0	1 (3.6)	0

Timing: >1 year post-CTL019 infusion, Race: White

		All patients N=28			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (3.6)	0	0	1 (3.6)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (3.6)	1 (3.6)	0	0	0
Oropharyngeal pain	1 (3.6)	1 (3.6)	0	0	0
Rhinorrhoea	1 (3.6)	1 (3.6)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Asian

		All patients N=2			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Infections and infestations					
-Total	2 (100)	1 (50.0)	0	0	1 (50.0)
Gingivitis	1 (50.0)	1 (50.0)	0	0	0
Respiratory tract infection	1 (50.0)	0	0	0	1 (50.0)
Viral infection	1 (50.0)	1 (50.0)	0	0	0
Investigations					
-Total	1 (50.0)	0	0	1 (50.0)	0
White blood cell count decreased	1 (50.0)	0	0	1 (50.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Other

		All patients N=4			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	2 (50.0)	1 (25.0)	1 (25.0)
Blood and lymphatic system disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Febrile neutropenia	1 (25.0)	0	0	0	1 (25.0)
Gastrointestinal disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Nausea	1 (25.0)	0	1 (25.0)	0	0
General disorders and administration site conditions					
-Total	1 (25.0)	0	1 (25.0)	0	0
Chills	1 (25.0)	0	1 (25.0)	0	0
Pyrexia	1 (25.0)	0	1 (25.0)	0	0

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Immunodeficiency	1 (25.0)	0	1 (25.0)	0	0
Infections and infestations					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Meningitis aseptic	1 (25.0)	0	1 (25.0)	0	0
Otitis media	1 (25.0)	0	1 (25.0)	0	0
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (25.0)	0	0	1 (25.0)	0
Procedural pain	1 (25.0)	0	0	1 (25.0)	0
Investigations					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
White blood cell count decreased	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Alanine aminotransferase increased	1 (25.0)	0	0	1 (25.0)	0
Aspartate aminotransferase increased	1 (25.0)	1 (25.0)	0	0	0
Blood alkaline phosphatase increased	1 (25.0)	1 (25.0)	0	0	0
Blood lactate dehydrogenase increased	1 (25.0)	1 (25.0)	0	0	0
C-reactive protein increased	1 (25.0)	1 (25.0)	0	0	0

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (25.0)	1 (25.0)	0	0	0
Neutrophil count decreased	1 (25.0)	0	1 (25.0)	0	0
Platelet count decreased	1 (25.0)	0	0	1 (25.0)	0
Reproductive system and breast disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Ovarian failure	1 (25.0)	0	0	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (75.0)	3 (75.0)	0	0	0
Cough	2 (50.0)	2 (50.0)	0	0	0
Epistaxis	1 (25.0)	1 (25.0)	0	0	0
Rhinitis allergic	1 (25.0)	1 (25.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Pruritus	1 (25.0)	1 (25.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: White

		All patients N=52			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (100)	1 (1.9)	4 (7.7)	11 (21.2)	36 (69.2)
Blood and lymphatic system disorders					
-Total	37 (71.2)	1 (1.9)	1 (1.9)	24 (46.2)	11 (21.2)
Anaemia	21 (40.4)	3 (5.8)	3 (5.8)	14 (26.9)	1 (1.9)
Febrile neutropenia	19 (36.5)	0	0	19 (36.5)	0
Neutropenia	10 (19.2)	0	0	3 (5.8)	7 (13.5)
Thrombocytopenia	10 (19.2)	0	1 (1.9)	3 (5.8)	6 (11.5)
Disseminated intravascular coagulation	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Lymphopenia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Cardiac disorders					
-Total	17 (32.7)	7 (13.5)	8 (15.4)	2 (3.8)	0
Tachycardia	12 (23.1)	5 (9.6)	5 (9.6)	2 (3.8)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	6 (11.5)	3 (5.8)	3 (5.8)	0	0
Endocrine disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Adrenal insufficiency	1 (1.9)	1 (1.9)	0	0	0
Eye disorders					
-Total	8 (15.4)	4 (7.7)	4 (7.7)	0	0
Periorbital oedema	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Vision blurred	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Conjunctival haemorrhage	2 (3.8)	2 (3.8)	0	0	0
Dry eye	1 (1.9)	0	1 (1.9)	0	0
Uveitis	1 (1.9)	0	1 (1.9)	0	0
Gastrointestinal disorders					
-Total	33 (63.5)	13 (25.0)	12 (23.1)	8 (15.4)	0
Vomiting	22 (42.3)	11 (21.2)	8 (15.4)	3 (5.8)	0
Diarrhoea	21 (40.4)	12 (23.1)	7 (13.5)	2 (3.8)	0
Nausea	18 (34.6)	3 (5.8)	10 (19.2)	5 (9.6)	0
Abdominal pain	10 (19.2)	5 (9.6)	4 (7.7)	1 (1.9)	0
Constipation	6 (11.5)	5 (9.6)	1 (1.9)	0	0
Abdominal pain upper	2 (3.8)	1 (1.9)	1 (1.9)	0	0

Timing: Any time post CTL019 infusion, Race: White

		All patients N=52			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphagia	1 (1.9)	0	0	1 (1.9)	0
General disorders and administration site conditions					
-Total	29 (55.8)	10 (19.2)	10 (19.2)	8 (15.4)	1 (1.9)
Pyrexia	20 (38.5)	5 (9.6)	8 (15.4)	6 (11.5)	1 (1.9)
Fatigue	11 (21.2)	8 (15.4)	2 (3.8)	1 (1.9)	0
Chills	9 (17.3)	9 (17.3)	0	0	0
Catheter site pain	3 (5.8)	0	3 (5.8)	0	0
Malaise	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Pain	3 (5.8)	1 (1.9)	0	2 (3.8)	0
Immune system disorders					
-Total	46 (88.5)	3 (5.8)	23 (44.2)	10 (19.2)	10 (19.2)
Cytokine release syndrome	40 (76.9)	4 (7.7)	19 (36.5)	7 (13.5)	10 (19.2)
Hypogammaglobulinaemia	26 (50.0)	1 (1.9)	20 (38.5)	5 (9.6)	0
Seasonal allergy	1 (1.9)	1 (1.9)	0	0	0
Infections and infestations					
-Total	22 (42.3)	4 (7.7)	11 (21.2)	7 (13.5)	0
Upper respiratory tract infection	8 (15.4)	3 (5.8)	4 (7.7)	1 (1.9)	0
Clostridium difficile infection	4 (7.7)	0	3 (5.8)	1 (1.9)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	4 (7.7)	1 (1.9)	3 (5.8)	0	0
Urinary tract infection	4 (7.7)	0	2 (3.8)	2 (3.8)	0
Clostridium difficile colitis	3 (5.8)	1 (1.9)	1 (1.9)	1 (1.9)	0
Otitis media	3 (5.8)	0	2 (3.8)	1 (1.9)	0
Viral infection	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Viral upper respiratory tract infection	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Cytomegalovirus infection	1 (1.9)	1 (1.9)	0	0	0
Injury, poisoning and procedural complications					
-Total	5 (9.6)	3 (5.8)	2 (3.8)	0	0
Procedural pain	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Transfusion reaction	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Investigations					
-Total	43 (82.7)	0	4 (7.7)	11 (21.2)	28 (53.8)
White blood cell count decreased	26 (50.0)	4 (7.7)	0	7 (13.5)	15 (28.8)
Neutrophil count decreased	22 (42.3)	1 (1.9)	1 (1.9)	4 (7.7)	16 (30.8)
Alanine aminotransferase increased	17 (32.7)	4 (7.7)	1 (1.9)	12 (23.1)	0
Platelet count decreased	17 (32.7)	3 (5.8)	2 (3.8)	2 (3.8)	10 (19.2)
Aspartate aminotransferase increased	15 (28.8)	2 (3.8)	3 (5.8)	6 (11.5)	4 (7.7)
Lymphocyte count decreased	13 (25.0)	1 (1.9)	2 (3.8)	6 (11.5)	4 (7.7)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	8 (15.4)	2 (3.8)	3 (5.8)	3 (5.8)	0
Blood creatinine increased	7 (13.5)	4 (7.7)	1 (1.9)	2 (3.8)	0
International normalised ratio increased	7 (13.5)	6 (11.5)	0	1 (1.9)	0
Prothrombin time prolonged	7 (13.5)	4 (7.7)	2 (3.8)	1 (1.9)	0
Activated partial thromboplastin time prolonged	4 (7.7)	2 (3.8)	2 (3.8)	0	0
Blood immunoglobulin m decreased	3 (5.8)	3 (5.8)	0	0	0
Blood immunoglobulin a decreased	1 (1.9)	1 (1.9)	0	0	0
Blood uric acid increased	1 (1.9)	1 (1.9)	0	0	0
C-reactive protein increased	1 (1.9)	0	0	1 (1.9)	0
Haemoglobin decreased	1 (1.9)	1 (1.9)	0	0	0
Metabolism and nutrition disorders					
-Total	33 (63.5)	2 (3.8)	8 (15.4)	19 (36.5)	4 (7.7)
Decreased appetite	19 (36.5)	3 (5.8)	5 (9.6)	11 (21.2)	0
Hypokalaemia	18 (34.6)	3 (5.8)	6 (11.5)	8 (15.4)	1 (1.9)
Hypophosphataemia	10 (19.2)	2 (3.8)	0	7 (13.5)	1 (1.9)
Hyperphosphataemia	6 (11.5)	6 (11.5)	0	0	0
Dehydration	3 (5.8)	1 (1.9)	0	2 (3.8)	0
Hypernatraemia	3 (5.8)	0	2 (3.8)	0	1 (1.9)
Hyperuricaemia	2 (3.8)	1 (1.9)	0	0	1 (1.9)

Timing: Any time post CTL019 infusion, Race: White

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=52 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acidosis	1 (1.9)	0	0	1 (1.9)	0
Tumour lysis syndrome	1 (1.9)	0	0	1 (1.9)	0
Musculoskeletal and connective tissue disorders					
-Total	13 (25.0)	7 (13.5)	5 (9.6)	1 (1.9)	0
Pain in extremity	6 (11.5)	3 (5.8)	3 (5.8)	0	0
Arthralgia	4 (7.7)	2 (3.8)	1 (1.9)	1 (1.9)	0
Myalgia	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Muscular weakness	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Joint range of motion decreased	1 (1.9)	1 (1.9)	0	0	0
Musculoskeletal chest pain	1 (1.9)	1 (1.9)	0	0	0
Nervous system disorders					
-Total	27 (51.9)	16 (30.8)	6 (11.5)	5 (9.6)	0
Headache	19 (36.5)	13 (25.0)	4 (7.7)	2 (3.8)	0
Dizziness	6 (11.5)	6 (11.5)	0	0	0
Encephalopathy	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Seizure	3 (5.8)	0	1 (1.9)	2 (3.8)	0
Dysarthria	1 (1.9)	0	1 (1.9)	0	0
Tremor	1 (1.9)	1 (1.9)	0	0	0
Psychiatric disorders					

Timing: Any time post CTL019 infusion, Race: White

		All patients N=52			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (25.0)	7 (13.5)	5 (9.6)	1 (1.9)	0
Anxiety	6 (11.5)	3 (5.8)	2 (3.8)	1 (1.9)	0
Confusional state	6 (11.5)	3 (5.8)	3 (5.8)	0	0
Delirium	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Agitation	1 (1.9)	0	1 (1.9)	0	0
Renal and urinary disorders					
-Total	8 (15.4)	1 (1.9)	1 (1.9)	3 (5.8)	3 (5.8)
Acute kidney injury	7 (13.5)	0	1 (1.9)	3 (5.8)	3 (5.8)
Dysuria	1 (1.9)	1 (1.9)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	29 (55.8)	12 (23.1)	7 (13.5)	5 (9.6)	5 (9.6)
Cough	11 (21.2)	9 (17.3)	2 (3.8)	0	0
Hypoxia	10 (19.2)	0	3 (5.8)	4 (7.7)	3 (5.8)
Epistaxis	8 (15.4)	3 (5.8)	1 (1.9)	3 (5.8)	1 (1.9)
Pleural effusion	8 (15.4)	2 (3.8)	4 (7.7)	2 (3.8)	0
Oropharyngeal pain	5 (9.6)	4 (7.7)	1 (1.9)	0	0
Pulmonary oedema	5 (9.6)	1 (1.9)	0	3 (5.8)	1 (1.9)
Rhinorrhoea	5 (9.6)	4 (7.7)	1 (1.9)	0	0
Nasal congestion	4 (7.7)	4 (7.7)	0	0	0

Timing: Any time post CTL019 infusion, Race: White

Group term Preferred term	All patients N=52 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rhinitis allergic	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Respiratory failure	2 (3.8)	0	0	0	2 (3.8)
Haemoptysis	1 (1.9)	0	0	0	1 (1.9)
Skin and subcutaneous tissue disorders					
-Total	14 (26.9)	13 (25.0)	1 (1.9)	0	0
Rash	5 (9.6)	4 (7.7)	1 (1.9)	0	0
Erythema	4 (7.7)	4 (7.7)	0	0	0
Hyperhidrosis	3 (5.8)	3 (5.8)	0	0	0
Dry skin	2 (3.8)	2 (3.8)	0	0	0
Pruritus	2 (3.8)	2 (3.8)	0	0	0
Vascular disorders					
-Total	21 (40.4)	3 (5.8)	4 (7.7)	7 (13.5)	7 (13.5)
Hypotension	15 (28.8)	1 (1.9)	0	7 (13.5)	7 (13.5)
Hypertension	11 (21.2)	3 (5.8)	7 (13.5)	1 (1.9)	0
Orthostatic hypotension	1 (1.9)	1 (1.9)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Asian

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	0	1 (20.0)	1 (20.0)	3 (60.0)
Blood and lymphatic system disorders					
-Total	3 (60.0)	0	1 (20.0)	1 (20.0)	1 (20.0)
Anaemia	3 (60.0)	0	1 (20.0)	2 (40.0)	0
Febrile neutropenia	1 (20.0)	0	0	1 (20.0)	0
Lymphopenia	1 (20.0)	0	1 (20.0)	0	0
Neutropenia	1 (20.0)	0	0	0	1 (20.0)
Cardiac disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Atrioventricular block second degree	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (20.0)	0	1 (20.0)	0	0
Nausea	1 (20.0)	1 (20.0)	0	0	0
Vomiting	1 (20.0)	1 (20.0)	0	0	0
General disorders and administration site conditions					
-Total	5 (100)	3 (60.0)	2 (40.0)	0	0
Fatigue	3 (60.0)	3 (60.0)	0	0	0
Pyrexia	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Pain	1 (20.0)	0	1 (20.0)	0	0
Immune system disorders					
-Total	5 (100)	0	5 (100)	0	0
Cytokine release syndrome	4 (80.0)	0	4 (80.0)	0	0
Hypogammaglobulinaemia	3 (60.0)	1 (20.0)	2 (40.0)	0	0
Infections and infestations					
-Total	3 (60.0)	0	1 (20.0)	1 (20.0)	1 (20.0)
Gastroenteritis	1 (20.0)	0	0	1 (20.0)	0
Gingivitis	1 (20.0)	1 (20.0)	0	0	0
Herpes zoster	1 (20.0)	0	0	1 (20.0)	0
Molluscum contagiosum	1 (20.0)	1 (20.0)	0	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngitis	1 (20.0)	0	1 (20.0)	0	0
Respiratory tract infection	1 (20.0)	0	0	0	1 (20.0)
Streptococcal infection	1 (20.0)	0	1 (20.0)	0	0
Viral infection	1 (20.0)	1 (20.0)	0	0	0
Viral upper respiratory tract infection	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	4 (80.0)	0	1 (20.0)	1 (20.0)	2 (40.0)
Neutrophil count decreased	3 (60.0)	0	1 (20.0)	0	2 (40.0)
White blood cell count decreased	3 (60.0)	0	1 (20.0)	2 (40.0)	0
Aspartate aminotransferase increased	1 (20.0)	0	0	1 (20.0)	0
Blood immunoglobulin a decreased	1 (20.0)	1 (20.0)	0	0	0
Blood uric acid increased	1 (20.0)	1 (20.0)	0	0	0
International normalised ratio increased	1 (20.0)	1 (20.0)	0	0	0
Lymphocyte count decreased	1 (20.0)	0	1 (20.0)	0	0
Metabolism and nutrition disorders					
-Total	3 (60.0)	2 (40.0)	0	1 (20.0)	0
Decreased appetite	1 (20.0)	1 (20.0)	0	0	0
Dehydration	1 (20.0)	0	0	1 (20.0)	0
Hyperphosphataemia	1 (20.0)	1 (20.0)	0	0	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	1 (20.0)	1 (20.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (80.0)	2 (40.0)	2 (40.0)	0	0
Pain in extremity	3 (60.0)	2 (40.0)	1 (20.0)	0	0
Arthralgia	1 (20.0)	1 (20.0)	0	0	0
Joint range of motion decreased	1 (20.0)	1 (20.0)	0	0	0
Myalgia	1 (20.0)	1 (20.0)	0	0	0
Osteonecrosis	1 (20.0)	0	1 (20.0)	0	0
Nervous system disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0
Headache	2 (40.0)	2 (40.0)	0	0	0
Renal and urinary disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Dysuria	1 (20.0)	0	1 (20.0)	0	0
Pollakiuria	1 (20.0)	1 (20.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Pulmonary oedema	1 (20.0)	0	0	1 (20.0)	0
Skin and subcutaneous tissue disorders					

Timing: Any time post CTL019 infusion, Race: Asian

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (20.0)	0	1 (20.0)	0	0
Rash	1 (20.0)	0	1 (20.0)	0	0
Vascular disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Embolism	1 (20.0)	0	0	1 (20.0)	0
Hypertension	1 (20.0)	0	1 (20.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184c
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Other

		All patients N=7			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	0	1 (14.3)	6 (85.7)
Blood and lymphatic system disorders					
-Total	5 (71.4)	0	1 (14.3)	2 (28.6)	2 (28.6)
Febrile neutropenia	4 (57.1)	0	0	3 (42.9)	1 (14.3)
Anaemia	3 (42.9)	0	0	3 (42.9)	0
Disseminated intravascular coagulation	1 (14.3)	0	1 (14.3)	0	0
Lymphadenopathy	1 (14.3)	0	1 (14.3)	0	0
Lymphopenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Tachycardia	3 (42.9)	3 (42.9)	0	0	0
Ventricular tachycardia	1 (14.3)	0	1 (14.3)	0	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Adrenal insufficiency	1 (14.3)	0	1 (14.3)	0	0
Eye disorders					
-Total	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Conjunctival haemorrhage	1 (14.3)	1 (14.3)	0	0	0
Dry eye	1 (14.3)	1 (14.3)	0	0	0
Periorbital oedema	1 (14.3)	1 (14.3)	0	0	0
Uveitis	1 (14.3)	0	1 (14.3)	0	0
Vision blurred	1 (14.3)	0	1 (14.3)	0	0
Gastrointestinal disorders					
-Total	6 (85.7)	1 (14.3)	5 (71.4)	0	0
Nausea	6 (85.7)	2 (28.6)	4 (57.1)	0	0
Vomiting	4 (57.1)	4 (57.1)	0	0	0
Diarrhoea	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Abdominal pain	1 (14.3)	1 (14.3)	0	0	0
Abdominal pain upper	1 (14.3)	0	1 (14.3)	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Dysphagia	1 (14.3)	0	1 (14.3)	0	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flatulence	1 (14.3)	1 (14.3)	0	0	0
Lip pain	1 (14.3)	0	1 (14.3)	0	0
General disorders and administration site conditions					
-Total	5 (71.4)	2 (28.6)	2 (28.6)	1 (14.3)	0
Pyrexia	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Catheter site haemorrhage	1 (14.3)	1 (14.3)	0	0	0
Catheter site pain	1 (14.3)	1 (14.3)	0	0	0
Chills	1 (14.3)	0	1 (14.3)	0	0
Fatigue	1 (14.3)	1 (14.3)	0	0	0
Injection site haematoma	1 (14.3)	1 (14.3)	0	0	0
Malaise	1 (14.3)	0	1 (14.3)	0	0
Physical deconditioning	1 (14.3)	0	0	1 (14.3)	0
Hepatobiliary disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Gallbladder enlargement	1 (14.3)	1 (14.3)	0	0	0
Immune system disorders					
-Total	6 (85.7)	1 (14.3)	3 (42.9)	1 (14.3)	1 (14.3)
Cytokine release syndrome	6 (85.7)	2 (28.6)	2 (28.6)	1 (14.3)	1 (14.3)

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Immunodeficiency common variable	2 (28.6)	0	2 (28.6)	0	0
Immunodeficiency	1 (14.3)	0	1 (14.3)	0	0
Seasonal allergy	1 (14.3)	1 (14.3)	0	0	0
Infections and infestations					
-Total	5 (71.4)	0	3 (42.9)	1 (14.3)	1 (14.3)
Catheter site cellulitis	1 (14.3)	1 (14.3)	0	0	0
Clostridium difficile colitis	1 (14.3)	0	1 (14.3)	0	0
Clostridium difficile infection	1 (14.3)	0	1 (14.3)	0	0
Cytomegalovirus infection	1 (14.3)	1 (14.3)	0	0	0
Herpes simplex	1 (14.3)	1 (14.3)	0	0	0
Meningitis aseptic	1 (14.3)	0	1 (14.3)	0	0
Oral herpes	1 (14.3)	0	1 (14.3)	0	0
Otitis media	1 (14.3)	0	1 (14.3)	0	0
Rhinitis	1 (14.3)	1 (14.3)	0	0	0
Sepsis	1 (14.3)	0	0	0	1 (14.3)
Upper respiratory tract infection	1 (14.3)	1 (14.3)	0	0	0
Urinary tract infection	1 (14.3)	0	1 (14.3)	0	0
Vascular device infection	1 (14.3)	0	0	1 (14.3)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vulvovaginal mycotic infection	1 (14.3)	0	1 (14.3)	0	0
Injury, poisoning and procedural complications					
-Total	4 (57.1)	1 (14.3)	1 (14.3)	1 (14.3)	1 (14.3)
Procedural pain	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Arthropod bite	1 (14.3)	1 (14.3)	0	0	0
Post procedural haemorrhage	1 (14.3)	1 (14.3)	0	0	0
Transfusion reaction	1 (14.3)	1 (14.3)	0	0	0
Transfusion related complication	1 (14.3)	0	0	0	1 (14.3)
Investigations					
-Total	6 (85.7)	0	0	2 (28.6)	4 (57.1)
White blood cell count decreased	6 (85.7)	0	0	3 (42.9)	3 (42.9)
Alanine aminotransferase increased	4 (57.1)	1 (14.3)	1 (14.3)	2 (28.6)	0
Aspartate aminotransferase increased	4 (57.1)	2 (28.6)	1 (14.3)	1 (14.3)	0
Neutrophil count decreased	3 (42.9)	0	0	0	3 (42.9)
Platelet count decreased	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Blood creatinine increased	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Haemoglobin decreased	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Lymphocyte count decreased	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Prothrombin time prolonged	2 (28.6)	1 (14.3)	1 (14.3)	0	0

Timing: Any time post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0	0	0
Blood alkaline phosphatase increased	1 (14.3)	1 (14.3)	0	0	0
Blood immunoglobulin a decreased	1 (14.3)	1 (14.3)	0	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0
Blood lactate dehydrogenase increased	1 (14.3)	1 (14.3)	0	0	0
C-reactive protein increased	1 (14.3)	1 (14.3)	0	0	0
Culture stool positive	1 (14.3)	1 (14.3)	0	0	0
Hepatic enzyme increased	1 (14.3)	0	1 (14.3)	0	0
International normalised ratio increased	1 (14.3)	1 (14.3)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (57.1)	2 (28.6)	0	2 (28.6)	0
Decreased appetite	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Acidosis	1 (14.3)	1 (14.3)	0	0	0
Hypernatraemia	1 (14.3)	1 (14.3)	0	0	0
Hyperphosphataemia	1 (14.3)	1 (14.3)	0	0	0
Hypokalaemia	1 (14.3)	1 (14.3)	0	0	0
Tumour lysis syndrome	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (42.9)	3 (42.9)	0	0	0

Timing: Any time post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain in extremity	2 (28.6)	2 (28.6)	0	0	0
Coccydynia	1 (14.3)	1 (14.3)	0	0	0
Muscular weakness	1 (14.3)	1 (14.3)	0	0	0
Musculoskeletal chest pain	1 (14.3)	1 (14.3)	0	0	0
Myalgia	1 (14.3)	1 (14.3)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (14.3)	0	1 (14.3)	0	0
Myelodysplastic syndrome	1 (14.3)	0	1 (14.3)	0	0
Nervous system disorders					
-Total	4 (57.1)	1 (14.3)	3 (42.9)	0	0
Headache	3 (42.9)	0	3 (42.9)	0	0
Asterixis	1 (14.3)	1 (14.3)	0	0	0
Ataxia	1 (14.3)	0	1 (14.3)	0	0
Dysarthria	1 (14.3)	1 (14.3)	0	0	0
Encephalopathy	1 (14.3)	1 (14.3)	0	0	0
Myoclonus	1 (14.3)	1 (14.3)	0	0	0
Neuropathy peripheral	1 (14.3)	0	1 (14.3)	0	0
Pleocytosis	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (14.3)	0	1 (14.3)	0	0
Tremor	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Adjustment disorder	1 (14.3)	0	1 (14.3)	0	0
Agitation	1 (14.3)	0	1 (14.3)	0	0
Anxiety	1 (14.3)	0	1 (14.3)	0	0
Delirium	1 (14.3)	0	1 (14.3)	0	0
Suicidal ideation	1 (14.3)	1 (14.3)	0	0	0
Renal and urinary disorders					
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Acute kidney injury	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Reproductive system and breast disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Ovarian failure	1 (14.3)	0	0	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (71.4)	3 (42.9)	0	1 (14.3)	1 (14.3)
Cough	3 (42.9)	3 (42.9)	0	0	0
Epistaxis	2 (28.6)	1 (14.3)	0	1 (14.3)	0

Timing: Any time post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemoptysis	1 (14.3)	1 (14.3)	0	0	0
Nasal congestion	1 (14.3)	1 (14.3)	0	0	0
Oropharyngeal pain	1 (14.3)	0	1 (14.3)	0	0
Pulmonary oedema	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Rhinitis allergic	1 (14.3)	1 (14.3)	0	0	0
Rhinorrhoea	1 (14.3)	1 (14.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (71.4)	3 (42.9)	1 (14.3)	1 (14.3)	0
Dry skin	3 (42.9)	3 (42.9)	0	0	0
Pruritus	2 (28.6)	2 (28.6)	0	0	0
Rash	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Dermatitis	1 (14.3)	1 (14.3)	0	0	0
Dermatitis atopic	1 (14.3)	1 (14.3)	0	0	0
Ecchymosis	1 (14.3)	0	0	1 (14.3)	0
Eczema	1 (14.3)	1 (14.3)	0	0	0
Erythema	1 (14.3)	1 (14.3)	0	0	0
Hyperhidrosis	1 (14.3)	1 (14.3)	0	0	0
Rash vesicular	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin exfoliation	1 (14.3)	1 (14.3)	0	0	0
Skin fissures	1 (14.3)	1 (14.3)	0	0	0
Vascular disorders					
-Total	3 (42.9)	0	2 (28.6)	0	1 (14.3)
Hypotension	1 (14.3)	0	0	0	1 (14.3)
Orthostatic hypotension	1 (14.3)	0	1 (14.3)	0	0
Secondary hypertension	1 (14.3)	0	1 (14.3)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184d
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (100)	1 (4.0)	2 (8.0)	5 (20.0)	17 (68.0)
Blood and lymphatic system disorders					
-Total	18 (72.0)	0	1 (4.0)	15 (60.0)	2 (8.0)
Febrile neutropenia	14 (56.0)	0	0	14 (56.0)	0
Anaemia	11 (44.0)	2 (8.0)	3 (12.0)	6 (24.0)	0
Neutropenia	2 (8.0)	0	0	2 (8.0)	0
Thrombocytopenia	2 (8.0)	0	0	0	2 (8.0)
Cardiac disorders					
-Total	8 (32.0)	6 (24.0)	2 (8.0)	0	0
Tachycardia	7 (28.0)	6 (24.0)	1 (4.0)	0	0
Sinus tachycardia	1 (4.0)	0	1 (4.0)	0	0
Gastrointestinal disorders					

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (44.0)	3 (12.0)	6 (24.0)	2 (8.0)	0
Nausea	7 (28.0)	1 (4.0)	6 (24.0)	0	0
Vomiting	6 (24.0)	4 (16.0)	1 (4.0)	1 (4.0)	0
Diarrhoea	5 (20.0)	3 (12.0)	1 (4.0)	1 (4.0)	0
Abdominal pain	3 (12.0)	3 (12.0)	0	0	0
Constipation	2 (8.0)	2 (8.0)	0	0	0
General disorders and administration site conditions					
-Total	6 (24.0)	4 (16.0)	0	2 (8.0)	0
Pyrexia	3 (12.0)	1 (4.0)	0	2 (8.0)	0
Chills	2 (8.0)	2 (8.0)	0	0	0
Fatigue	2 (8.0)	2 (8.0)	0	0	0
Immune system disorders					
-Total	22 (88.0)	1 (4.0)	14 (56.0)	4 (16.0)	3 (12.0)
Cytokine release syndrome	20 (80.0)	2 (8.0)	12 (48.0)	3 (12.0)	3 (12.0)
Hypogammaglobulinaemia	12 (48.0)	0	11 (44.0)	1 (4.0)	0
Infections and infestations					
-Total	1 (4.0)	1 (4.0)	0	0	0
Influenza	1 (4.0)	1 (4.0)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Procedural pain	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Investigations					
-Total	20 (80.0)	1 (4.0)	0	4 (16.0)	15 (60.0)
White blood cell count decreased	15 (60.0)	0	0	6 (24.0)	9 (36.0)
Neutrophil count decreased	13 (52.0)	0	0	2 (8.0)	11 (44.0)
Platelet count decreased	9 (36.0)	3 (12.0)	2 (8.0)	0	4 (16.0)
Alanine aminotransferase increased	7 (28.0)	1 (4.0)	0	6 (24.0)	0
Lymphocyte count decreased	7 (28.0)	1 (4.0)	0	4 (16.0)	2 (8.0)
Aspartate aminotransferase increased	4 (16.0)	1 (4.0)	0	3 (12.0)	0
Blood creatinine increased	4 (16.0)	4 (16.0)	0	0	0
Activated partial thromboplastin time prolonged	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Blood bilirubin increased	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Prothrombin time prolonged	2 (8.0)	1 (4.0)	1 (4.0)	0	0
International normalised ratio increased	1 (4.0)	1 (4.0)	0	0	0
Metabolism and nutrition disorders					

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (48.0)	2 (8.0)	5 (20.0)	4 (16.0)	1 (4.0)
Decreased appetite	7 (28.0)	1 (4.0)	3 (12.0)	3 (12.0)	0
Hypokalaemia	6 (24.0)	1 (4.0)	3 (12.0)	2 (8.0)	0
Hyperphosphataemia	4 (16.0)	4 (16.0)	0	0	0
Hypoalbuminaemia	1 (4.0)	0	0	1 (4.0)	0
Hypophosphataemia	1 (4.0)	0	0	0	1 (4.0)
Nervous system disorders					
-Total	10 (40.0)	6 (24.0)	4 (16.0)	0	0
Headache	10 (40.0)	6 (24.0)	4 (16.0)	0	0
Dizziness	1 (4.0)	1 (4.0)	0	0	0
Psychiatric disorders					
-Total	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Anxiety	1 (4.0)	0	1 (4.0)	0	0
Confusional state	1 (4.0)	1 (4.0)	0	0	0
Renal and urinary disorders					
-Total	2 (8.0)	0	0	2 (8.0)	0
Acute kidney injury	2 (8.0)	0	0	2 (8.0)	0
Respiratory, thoracic and mediastinal disorders					

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (36.0)	6 (24.0)	1 (4.0)	1 (4.0)	1 (4.0)
Pulmonary oedema	3 (12.0)	1 (4.0)	0	1 (4.0)	1 (4.0)
Tachypnoea	3 (12.0)	3 (12.0)	0	0	0
Cough	1 (4.0)	1 (4.0)	0	0	0
Epistaxis	1 (4.0)	1 (4.0)	0	0	0
Hypoxia	1 (4.0)	0	1 (4.0)	0	0
Nasal congestion	1 (4.0)	1 (4.0)	0	0	0
Oropharyngeal pain	1 (4.0)	0	1 (4.0)	0	0
Pleural effusion	1 (4.0)	0	0	1 (4.0)	0
Rhinorrhoea	1 (4.0)	1 (4.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (16.0)	4 (16.0)	0	0	0
Dry skin	2 (8.0)	2 (8.0)	0	0	0
Erythema	1 (4.0)	1 (4.0)	0	0	0
Rash	1 (4.0)	1 (4.0)	0	0	0
Vascular disorders					
-Total	7 (28.0)	0	2 (8.0)	4 (16.0)	1 (4.0)
Hypotension	5 (20.0)	0	0	4 (16.0)	1 (4.0)
Hypertension	2 (8.0)	0	2 (8.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184d
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Other

			All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (97.4)	1 (2.6)	6 (15.4)	9 (23.1)	22 (56.4)
Blood and lymphatic system disorders					
-Total	22 (56.4)	1 (2.6)	1 (2.6)	13 (33.3)	7 (17.9)
Anaemia	16 (41.0)	1 (2.6)	2 (5.1)	12 (30.8)	1 (2.6)
Febrile neutropenia	8 (20.5)	0	0	8 (20.5)	0
Neutropenia	6 (15.4)	0	0	1 (2.6)	5 (12.8)
Thrombocytopenia	6 (15.4)	0	0	2 (5.1)	4 (10.3)
Cardiac disorders					
-Total	11 (28.2)	4 (10.3)	5 (12.8)	2 (5.1)	0
Tachycardia	8 (20.5)	2 (5.1)	4 (10.3)	2 (5.1)	0
Sinus tachycardia	4 (10.3)	3 (7.7)	1 (2.6)	0	0
Gastrointestinal disorders					

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	22 (56.4)	9 (23.1)	8 (20.5)	5 (12.8)	0
Vomiting	16 (41.0)	9 (23.1)	5 (12.8)	2 (5.1)	0
Nausea	14 (35.9)	5 (12.8)	6 (15.4)	3 (7.7)	0
Diarrhoea	13 (33.3)	8 (20.5)	5 (12.8)	0	0
Abdominal pain	6 (15.4)	3 (7.7)	2 (5.1)	1 (2.6)	0
Constipation	5 (12.8)	4 (10.3)	1 (2.6)	0	0
General disorders and administration site conditions					
-Total	22 (56.4)	9 (23.1)	8 (20.5)	4 (10.3)	1 (2.6)
Pyrexia	13 (33.3)	2 (5.1)	7 (17.9)	3 (7.7)	1 (2.6)
Fatigue	11 (28.2)	8 (20.5)	2 (5.1)	1 (2.6)	0
Chills	6 (15.4)	6 (15.4)	0	0	0
Immune system disorders					
-Total	34 (87.2)	3 (7.7)	16 (41.0)	7 (17.9)	8 (20.5)
Cytokine release syndrome	30 (76.9)	4 (10.3)	13 (33.3)	5 (12.8)	8 (20.5)
Hypogammaglobulinaemia	13 (33.3)	3 (7.7)	7 (17.9)	3 (7.7)	0
Infections and infestations					
-Total	9 (23.1)	3 (7.7)	4 (10.3)	2 (5.1)	0
Clostridium difficile colitis	4 (10.3)	1 (2.6)	2 (5.1)	1 (2.6)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

			All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	3 (7.7)	3 (7.7)	0	0	0
Pneumonia	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Upper respiratory tract infection	1 (2.6)	0	1 (2.6)	0	0
Injury, poisoning and procedural complications					
-Total	1 (2.6)	0	1 (2.6)	0	0
Procedural pain	1 (2.6)	0	1 (2.6)	0	0
Investigations					
-Total	27 (69.2)	0	4 (10.3)	7 (17.9)	16 (41.0)
White blood cell count decreased	15 (38.5)	3 (7.7)	1 (2.6)	4 (10.3)	7 (17.9)
Aspartate aminotransferase increased	14 (35.9)	2 (5.1)	4 (10.3)	4 (10.3)	4 (10.3)
Alanine aminotransferase increased	12 (30.8)	4 (10.3)	3 (7.7)	5 (12.8)	0
Neutrophil count decreased	12 (30.8)	0	2 (5.1)	2 (5.1)	8 (20.5)
Platelet count decreased	10 (25.6)	0	0	2 (5.1)	8 (20.5)
International normalised ratio increased	8 (20.5)	7 (17.9)	0	1 (2.6)	0
Lymphocyte count decreased	7 (17.9)	0	2 (5.1)	2 (5.1)	3 (7.7)
Prothrombin time prolonged	7 (17.9)	4 (10.3)	2 (5.1)	1 (2.6)	0
Blood bilirubin increased	5 (12.8)	1 (2.6)	2 (5.1)	2 (5.1)	0
Blood creatinine increased	5 (12.8)	1 (2.6)	2 (5.1)	2 (5.1)	0
Activated partial thromboplastin time prolonged	2 (5.1)	1 (2.6)	1 (2.6)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	21 (53.8)	5 (12.8)	3 (7.7)	13 (33.3)	0
Decreased appetite	13 (33.3)	3 (7.7)	1 (2.6)	9 (23.1)	0
Hypokalaemia	10 (25.6)	2 (5.1)	3 (7.7)	5 (12.8)	0
Hypophosphataemia	8 (20.5)	2 (5.1)	0	6 (15.4)	0
Hyperphosphataemia	4 (10.3)	4 (10.3)	0	0	0
Hypoalbuminaemia	4 (10.3)	1 (2.6)	3 (7.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	8 (20.5)	5 (12.8)	3 (7.7)	0	0
Myalgia	5 (12.8)	4 (10.3)	1 (2.6)	0	0
Pain in extremity	4 (10.3)	2 (5.1)	2 (5.1)	0	0
Nervous system disorders					
-Total	16 (41.0)	12 (30.8)	2 (5.1)	2 (5.1)	0
Headache	14 (35.9)	10 (25.6)	2 (5.1)	2 (5.1)	0
Dizziness	3 (7.7)	3 (7.7)	0	0	0
Psychiatric disorders					
-Total	9 (23.1)	4 (10.3)	4 (10.3)	1 (2.6)	0
Anxiety	5 (12.8)	2 (5.1)	2 (5.1)	1 (2.6)	0
Confusional state	5 (12.8)	2 (5.1)	3 (7.7)	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	6 (15.4)	1 (2.6)	1 (2.6)	0	4 (10.3)
Acute kidney injury	5 (12.8)	1 (2.6)	1 (2.6)	0	3 (7.7)
Haematuria	4 (10.3)	0	2 (5.1)	1 (2.6)	1 (2.6)
Respiratory, thoracic and mediastinal disorders					
-Total	16 (41.0)	3 (7.7)	3 (7.7)	6 (15.4)	4 (10.3)
Hypoxia	9 (23.1)	0	2 (5.1)	4 (10.3)	3 (7.7)
Cough	7 (17.9)	7 (17.9)	0	0	0
Pleural effusion	7 (17.9)	2 (5.1)	4 (10.3)	1 (2.6)	0
Epistaxis	6 (15.4)	1 (2.6)	1 (2.6)	3 (7.7)	1 (2.6)
Pulmonary oedema	3 (7.7)	0	0	2 (5.1)	1 (2.6)
Tachypnoea	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Oropharyngeal pain	1 (2.6)	1 (2.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (20.5)	8 (20.5)	0	0	0
Hyperhidrosis	3 (7.7)	3 (7.7)	0	0	0
Rash	3 (7.7)	3 (7.7)	0	0	0
Dry skin	2 (5.1)	2 (5.1)	0	0	0
Erythema	2 (5.1)	2 (5.1)	0	0	0

Timing: within 8 weeks post infusion, Ethnicity: Other

Group term Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	14 (35.9)	2 (5.1)	2 (5.1)	3 (7.7)	7 (17.9)
Hypotension	11 (28.2)	1 (2.6)	0	3 (7.7)	7 (17.9)
Hypertension	8 (20.5)	2 (5.1)	5 (12.8)	1 (2.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184d
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (91.3)	2 (8.7)	10 (43.5)	6 (26.1)	3 (13.0)
Blood and lymphatic system disorders					
-Total	4 (17.4)	1 (4.3)	0	2 (8.7)	1 (4.3)
Anaemia	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Febrile neutropenia	2 (8.7)	0	0	2 (8.7)	0
Neutropenia	2 (8.7)	0	0	1 (4.3)	1 (4.3)
Cardiac disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Sinus tachycardia	1 (4.3)	0	1 (4.3)	0	0
Gastrointestinal disorders					
-Total	8 (34.8)	4 (17.4)	3 (13.0)	1 (4.3)	0
Vomiting	6 (26.1)	4 (17.4)	1 (4.3)	1 (4.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	3 (13.0)	2 (8.7)	1 (4.3)	0	0
Nausea	3 (13.0)	0	2 (8.7)	1 (4.3)	0
Abdominal pain	1 (4.3)	0	1 (4.3)	0	0
General disorders and administration site conditions					
-Total	3 (13.0)	2 (8.7)	1 (4.3)	0	0
Pyrexia	3 (13.0)	2 (8.7)	1 (4.3)	0	0
Chills	1 (4.3)	1 (4.3)	0	0	0
Fatigue	1 (4.3)	1 (4.3)	0	0	0
Immune system disorders					
-Total	4 (17.4)	0	4 (17.4)	0	0
Hypogammaglobulinaemia	4 (17.4)	0	4 (17.4)	0	0
Infections and infestations					
-Total	12 (52.2)	2 (8.7)	8 (34.8)	2 (8.7)	0
Upper respiratory tract infection	4 (17.4)	2 (8.7)	2 (8.7)	0	0
Urinary tract infection	4 (17.4)	0	2 (8.7)	2 (8.7)	0
Influenza	3 (13.0)	0	3 (13.0)	0	0
Otitis media	1 (4.3)	0	1 (4.3)	0	0
Rhinovirus infection	1 (4.3)	1 (4.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	1 (4.3)	0	1 (4.3)	0	0
Procedural pain	1 (4.3)	0	1 (4.3)	0	0
Investigations					
-Total	8 (34.8)	1 (4.3)	1 (4.3)	5 (21.7)	1 (4.3)
Neutrophil count decreased	5 (21.7)	1 (4.3)	0	3 (13.0)	1 (4.3)
Aspartate aminotransferase increased	3 (13.0)	1 (4.3)	0	2 (8.7)	0
Platelet count decreased	3 (13.0)	3 (13.0)	0	0	0
White blood cell count decreased	3 (13.0)	2 (8.7)	1 (4.3)	0	0
Alanine aminotransferase increased	1 (4.3)	0	0	1 (4.3)	0
Lymphocyte count decreased	1 (4.3)	0	1 (4.3)	0	0
Metabolism and nutrition disorders					
-Total	4 (17.4)	2 (8.7)	1 (4.3)	0	1 (4.3)
Hyperphosphataemia	2 (8.7)	2 (8.7)	0	0	0
Hypokalaemia	2 (8.7)	1 (4.3)	0	0	1 (4.3)
Decreased appetite	1 (4.3)	0	1 (4.3)	0	0
Hypophosphataemia	1 (4.3)	0	0	1 (4.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	3 (13.0)	3 (13.0)	0	0	0
Pain in extremity	3 (13.0)	3 (13.0)	0	0	0
Nervous system disorders					
-Total	3 (13.0)	3 (13.0)	0	0	0
Headache	3 (13.0)	3 (13.0)	0	0	0
Dizziness	1 (4.3)	1 (4.3)	0	0	0
Renal and urinary disorders					
-Total	2 (8.7)	0	0	2 (8.7)	0
Acute kidney injury	1 (4.3)	0	0	1 (4.3)	0
Haematuria	1 (4.3)	0	0	1 (4.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (39.1)	6 (26.1)	3 (13.0)	0	0
Cough	4 (17.4)	2 (8.7)	2 (8.7)	0	0
Nasal congestion	4 (17.4)	4 (17.4)	0	0	0
Rhinorrhoea	4 (17.4)	3 (13.0)	1 (4.3)	0	0
Oropharyngeal pain	2 (8.7)	2 (8.7)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	1 (4.3)	1 (4.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Dry skin	1 (4.3)	1 (4.3)	0	0	0
Rash	1 (4.3)	0	1 (4.3)	0	0
Vascular disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Hypertension	1 (4.3)	0	1 (4.3)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184d
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (60.6)	6 (18.2)	4 (12.1)	7 (21.2)	3 (9.1)
Blood and lymphatic system disorders					
-Total	4 (12.1)	0	1 (3.0)	1 (3.0)	2 (6.1)
Neutropenia	2 (6.1)	0	0	0	2 (6.1)
Thrombocytopenia	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Febrile neutropenia	1 (3.0)	0	0	1 (3.0)	0
Gastrointestinal disorders					
-Total	6 (18.2)	4 (12.1)	1 (3.0)	1 (3.0)	0
Diarrhoea	5 (15.2)	4 (12.1)	0	1 (3.0)	0
Abdominal pain	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Nausea	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Vomiting	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	8 (24.2)	6 (18.2)	1 (3.0)	1 (3.0)	0
Pyrexia	7 (21.2)	5 (15.2)	1 (3.0)	1 (3.0)	0
Fatigue	1 (3.0)	1 (3.0)	0	0	0
Immune system disorders					
-Total	4 (12.1)	0	3 (9.1)	1 (3.0)	0
Hypogammaglobulinaemia	4 (12.1)	0	3 (9.1)	1 (3.0)	0
Infections and infestations					
-Total	4 (12.1)	2 (6.1)	1 (3.0)	1 (3.0)	0
Upper respiratory tract infection	3 (9.1)	1 (3.0)	1 (3.0)	1 (3.0)	0
Rhinovirus infection	1 (3.0)	1 (3.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (3.0)	1 (3.0)	0	0	0
Procedural pain	1 (3.0)	1 (3.0)	0	0	0
Investigations					
-Total	8 (24.2)	2 (6.1)	0	3 (9.1)	3 (9.1)
Neutrophil count decreased	3 (9.1)	1 (3.0)	0	0	2 (6.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Alanine aminotransferase increased	1 (3.0)	0	0	1 (3.0)	0
Blood bilirubin increased	1 (3.0)	0	0	1 (3.0)	0
Blood creatinine increased	1 (3.0)	1 (3.0)	0	0	0
Lymphocyte count decreased	1 (3.0)	1 (3.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (3.0)	1 (3.0)	0	0	0
Decreased appetite	1 (3.0)	1 (3.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (15.2)	3 (9.1)	2 (6.1)	0	0
Pain in extremity	5 (15.2)	3 (9.1)	2 (6.1)	0	0
Nervous system disorders					
-Total	3 (9.1)	2 (6.1)	1 (3.0)	0	0
Dizziness	2 (6.1)	2 (6.1)	0	0	0
Headache	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Psychiatric disorders					
-Total	1 (3.0)	1 (3.0)	0	0	0
Anxiety	1 (3.0)	1 (3.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	5 (15.2)	3 (9.1)	0	2 (6.1)	0
Cough	3 (9.1)	3 (9.1)	0	0	0
Epistaxis	1 (3.0)	0	0	1 (3.0)	0
Oropharyngeal pain	1 (3.0)	0	1 (3.0)	0	0
Pulmonary oedema	1 (3.0)	0	0	1 (3.0)	0
Skin and subcutaneous tissue disorders					
-Total	5 (15.2)	3 (9.1)	2 (6.1)	0	0
Rash	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Erythema	2 (6.1)	2 (6.1)	0	0	0
Hyperhidrosis	1 (3.0)	1 (3.0)	0	0	0
Vascular disorders					
-Total	1 (3.0)	1 (3.0)	0	0	0
Hypertension	1 (3.0)	1 (3.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184d
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (47.1)	3 (17.6)	2 (11.8)	1 (5.9)	2 (11.8)
Blood and lymphatic system disorders					
-Total	1 (5.9)	0	0	0	1 (5.9)
Febrile neutropenia	1 (5.9)	0	0	0	1 (5.9)
Gastrointestinal disorders					
-Total	2 (11.8)	0	2 (11.8)	0	0
Diarrhoea	1 (5.9)	0	1 (5.9)	0	0
Nausea	1 (5.9)	0	1 (5.9)	0	0
General disorders and administration site conditions					
-Total	1 (5.9)	0	1 (5.9)	0	0
Chills	1 (5.9)	0	1 (5.9)	0	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (5.9)	0	1 (5.9)	0	0
Infections and infestations					
-Total	2 (11.8)	0	1 (5.9)	1 (5.9)	0
Otitis media	2 (11.8)	0	2 (11.8)	0	0
Urinary tract infection	1 (5.9)	0	0	1 (5.9)	0
Injury, poisoning and procedural complications					
-Total	1 (5.9)	0	0	1 (5.9)	0
Procedural pain	1 (5.9)	0	0	1 (5.9)	0
Investigations					
-Total	4 (23.5)	1 (5.9)	1 (5.9)	1 (5.9)	1 (5.9)
Alanine aminotransferase increased	2 (11.8)	0	1 (5.9)	1 (5.9)	0
White blood cell count decreased	2 (11.8)	0	0	1 (5.9)	1 (5.9)
Aspartate aminotransferase increased	1 (5.9)	1 (5.9)	0	0	0
Lymphocyte count decreased	1 (5.9)	1 (5.9)	0	0	0
Neutrophil count decreased	1 (5.9)	1 (5.9)	0	0	0
Platelet count decreased	1 (5.9)	0	0	1 (5.9)	0
Renal and urinary disorders					
-Total	1 (5.9)	1 (5.9)	0	0	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	1 (5.9)	1 (5.9)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (11.8)	2 (11.8)	0	0	0
Cough	1 (5.9)	1 (5.9)	0	0	0
Epistaxis	1 (5.9)	1 (5.9)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184d
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

			All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (47.1)	1 (5.9)	2 (11.8)	5 (29.4)	0
Blood and lymphatic system disorders					
-Total	1 (5.9)	1 (5.9)	0	0	0
Thrombocytopenia	1 (5.9)	1 (5.9)	0	0	0
Gastrointestinal disorders					
-Total	1 (5.9)	0	1 (5.9)	0	0
Abdominal pain	1 (5.9)	0	1 (5.9)	0	0
Diarrhoea	1 (5.9)	0	1 (5.9)	0	0
Infections and infestations					
-Total	5 (29.4)	1 (5.9)	3 (17.6)	1 (5.9)	0
Pneumonia	2 (11.8)	0	2 (11.8)	0	0
Upper respiratory tract infection	2 (11.8)	1 (5.9)	1 (5.9)	0	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (5.9)	0	0	1 (5.9)	0
Urinary tract infection	1 (5.9)	0	1 (5.9)	0	0
Investigations					
-Total	4 (23.5)	0	1 (5.9)	3 (17.6)	0
Lymphocyte count decreased	2 (11.8)	1 (5.9)	0	1 (5.9)	0
White blood cell count decreased	2 (11.8)	1 (5.9)	0	1 (5.9)	0
Alanine aminotransferase increased	1 (5.9)	0	0	1 (5.9)	0
Aspartate aminotransferase increased	1 (5.9)	0	0	1 (5.9)	0
Neutrophil count decreased	1 (5.9)	0	1 (5.9)	0	0
Metabolism and nutrition disorders					
-Total	1 (5.9)	0	0	1 (5.9)	0
Hypokalaemia	1 (5.9)	0	0	1 (5.9)	0
Nervous system disorders					
-Total	1 (5.9)	0	1 (5.9)	0	0
Dizziness	1 (5.9)	1 (5.9)	0	0	0
Headache	1 (5.9)	0	1 (5.9)	0	0
Renal and urinary disorders					
-Total	1 (5.9)	0	0	1 (5.9)	0
Acute kidney injury	1 (5.9)	0	0	1 (5.9)	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=17				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	2 (11.8)	2 (11.8)	0	0	0
Cough	1 (5.9)	1 (5.9)	0	0	0
Oropharyngeal pain	1 (5.9)	1 (5.9)	0	0	0
Rhinorrhoea	1 (5.9)	1 (5.9)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184d
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (100)	0	2 (8.0)	4 (16.0)	19 (76.0)
Blood and lymphatic system disorders					
-Total	19 (76.0)	0	0	15 (60.0)	4 (16.0)
Febrile neutropenia	16 (64.0)	0	0	15 (60.0)	1 (4.0)
Anaemia	11 (44.0)	2 (8.0)	2 (8.0)	7 (28.0)	0
Neutropenia	3 (12.0)	0	0	2 (8.0)	1 (4.0)
Thrombocytopenia	2 (8.0)	0	0	0	2 (8.0)
Cardiac disorders					
-Total	9 (36.0)	6 (24.0)	3 (12.0)	0	0
Tachycardia	7 (28.0)	6 (24.0)	1 (4.0)	0	0
Sinus tachycardia	2 (8.0)	0	2 (8.0)	0	0
Gastrointestinal disorders					

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	16 (64.0)	5 (20.0)	9 (36.0)	2 (8.0)	0
Vomiting	11 (44.0)	8 (32.0)	2 (8.0)	1 (4.0)	0
Nausea	10 (40.0)	1 (4.0)	8 (32.0)	1 (4.0)	0
Diarrhoea	8 (32.0)	4 (16.0)	3 (12.0)	1 (4.0)	0
Abdominal pain	4 (16.0)	3 (12.0)	1 (4.0)	0	0
Constipation	2 (8.0)	2 (8.0)	0	0	0
General disorders and administration site conditions					
-Total	10 (40.0)	6 (24.0)	2 (8.0)	2 (8.0)	0
Pyrexia	7 (28.0)	3 (12.0)	2 (8.0)	2 (8.0)	0
Chills	4 (16.0)	3 (12.0)	1 (4.0)	0	0
Fatigue	3 (12.0)	3 (12.0)	0	0	0
Immune system disorders					
-Total	23 (92.0)	1 (4.0)	15 (60.0)	4 (16.0)	3 (12.0)
Cytokine release syndrome	20 (80.0)	2 (8.0)	12 (48.0)	3 (12.0)	3 (12.0)
Hypogammaglobulinaemia	15 (60.0)	0	14 (56.0)	1 (4.0)	0
Infections and infestations					
-Total	13 (52.0)	2 (8.0)	9 (36.0)	2 (8.0)	0
Influenza	4 (16.0)	1 (4.0)	3 (12.0)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	4 (16.0)	2 (8.0)	2 (8.0)	0	0
Urinary tract infection	4 (16.0)	0	2 (8.0)	2 (8.0)	0
Otitis media	3 (12.0)	0	3 (12.0)	0	0
Rhinovirus infection	1 (4.0)	1 (4.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (12.0)	1 (4.0)	1 (4.0)	1 (4.0)	0
Procedural pain	3 (12.0)	1 (4.0)	1 (4.0)	1 (4.0)	0
Investigations					
-Total	20 (80.0)	0	1 (4.0)	3 (12.0)	16 (64.0)
White blood cell count decreased	17 (68.0)	1 (4.0)	0	6 (24.0)	10 (40.0)
Neutrophil count decreased	15 (60.0)	1 (4.0)	0	2 (8.0)	12 (48.0)
Platelet count decreased	10 (40.0)	3 (12.0)	2 (8.0)	1 (4.0)	4 (16.0)
Alanine aminotransferase increased	8 (32.0)	1 (4.0)	0	7 (28.0)	0
Lymphocyte count decreased	8 (32.0)	1 (4.0)	1 (4.0)	4 (16.0)	2 (8.0)
Aspartate aminotransferase increased	5 (20.0)	2 (8.0)	0	3 (12.0)	0
Blood creatinine increased	4 (16.0)	4 (16.0)	0	0	0
Activated partial thromboplastin time prolonged	3 (12.0)	2 (8.0)	1 (4.0)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Prothrombin time prolonged	2 (8.0)	1 (4.0)	1 (4.0)	0	0
International normalised ratio increased	1 (4.0)	1 (4.0)	0	0	0
Metabolism and nutrition disorders					
-Total	13 (52.0)	2 (8.0)	5 (20.0)	4 (16.0)	2 (8.0)
Decreased appetite	8 (32.0)	1 (4.0)	4 (16.0)	3 (12.0)	0
Hypokalaemia	8 (32.0)	2 (8.0)	3 (12.0)	2 (8.0)	1 (4.0)
Hyperphosphataemia	4 (16.0)	4 (16.0)	0	0	0
Hypophosphataemia	2 (8.0)	0	0	1 (4.0)	1 (4.0)
Hypoalbuminaemia	1 (4.0)	0	0	1 (4.0)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (12.0)	3 (12.0)	0	0	0
Pain in extremity	3 (12.0)	3 (12.0)	0	0	0
Nervous system disorders					
-Total	10 (40.0)	6 (24.0)	4 (16.0)	0	0
Headache	10 (40.0)	6 (24.0)	4 (16.0)	0	0
Dizziness	2 (8.0)	2 (8.0)	0	0	0
Psychiatric disorders					

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Anxiety	1 (4.0)	0	1 (4.0)	0	0
Confusional state	1 (4.0)	1 (4.0)	0	0	0
Renal and urinary disorders					
-Total	4 (16.0)	0	0	4 (16.0)	0
Acute kidney injury	3 (12.0)	0	0	3 (12.0)	0
Haematuria	1 (4.0)	0	0	1 (4.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	15 (60.0)	10 (40.0)	3 (12.0)	1 (4.0)	1 (4.0)
Cough	5 (20.0)	3 (12.0)	2 (8.0)	0	0
Nasal congestion	5 (20.0)	5 (20.0)	0	0	0
Rhinorrhoea	5 (20.0)	4 (16.0)	1 (4.0)	0	0
Epistaxis	3 (12.0)	3 (12.0)	0	0	0
Oropharyngeal pain	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Pulmonary oedema	3 (12.0)	1 (4.0)	0	1 (4.0)	1 (4.0)
Tachypnoea	3 (12.0)	3 (12.0)	0	0	0
Hypoxia	1 (4.0)	0	1 (4.0)	0	0
Pleural effusion	1 (4.0)	0	0	1 (4.0)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	6 (24.0)	5 (20.0)	1 (4.0)	0	0
Dry skin	3 (12.0)	3 (12.0)	0	0	0
Rash	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Erythema	1 (4.0)	1 (4.0)	0	0	0
Vascular disorders					
-Total	8 (32.0)	0	3 (12.0)	4 (16.0)	1 (4.0)
Hypotension	5 (20.0)	0	0	4 (16.0)	1 (4.0)
Hypertension	3 (12.0)	0	3 (12.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184d
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Other

			All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (100)	1 (2.6)	4 (10.3)	10 (25.6)	24 (61.5)
Blood and lymphatic system disorders					
-Total	25 (64.1)	1 (2.6)	2 (5.1)	13 (33.3)	9 (23.1)
Anaemia	16 (41.0)	1 (2.6)	2 (5.1)	12 (30.8)	1 (2.6)
Febrile neutropenia	8 (20.5)	0	0	8 (20.5)	0
Neutropenia	8 (20.5)	0	0	1 (2.6)	7 (17.9)
Thrombocytopenia	8 (20.5)	0	1 (2.6)	3 (7.7)	4 (10.3)
Cardiac disorders					
-Total	11 (28.2)	4 (10.3)	5 (12.8)	2 (5.1)	0
Tachycardia	8 (20.5)	2 (5.1)	4 (10.3)	2 (5.1)	0
Sinus tachycardia	4 (10.3)	3 (7.7)	1 (2.6)	0	0
Gastrointestinal disorders					

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	23 (59.0)	9 (23.1)	9 (23.1)	5 (12.8)	0
Diarrhoea	16 (41.0)	9 (23.1)	6 (15.4)	1 (2.6)	0
Vomiting	16 (41.0)	8 (20.5)	6 (15.4)	2 (5.1)	0
Nausea	15 (38.5)	5 (12.8)	6 (15.4)	4 (10.3)	0
Abdominal pain	7 (17.9)	3 (7.7)	3 (7.7)	1 (2.6)	0
Constipation	5 (12.8)	4 (10.3)	1 (2.6)	0	0
General disorders and administration site conditions					
-Total	25 (64.1)	10 (25.6)	9 (23.1)	5 (12.8)	1 (2.6)
Pyrexia	18 (46.2)	5 (12.8)	8 (20.5)	4 (10.3)	1 (2.6)
Fatigue	12 (30.8)	9 (23.1)	2 (5.1)	1 (2.6)	0
Chills	6 (15.4)	6 (15.4)	0	0	0
Immune system disorders					
-Total	34 (87.2)	3 (7.7)	16 (41.0)	7 (17.9)	8 (20.5)
Cytokine release syndrome	30 (76.9)	4 (10.3)	13 (33.3)	5 (12.8)	8 (20.5)
Hypogammaglobulinaemia	17 (43.6)	3 (7.7)	10 (25.6)	4 (10.3)	0
Infections and infestations					
-Total	16 (41.0)	5 (12.8)	7 (17.9)	4 (10.3)	0
Upper respiratory tract infection	5 (12.8)	2 (5.1)	2 (5.1)	1 (2.6)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile colitis	4 (10.3)	1 (2.6)	2 (5.1)	1 (2.6)	0
Pneumonia	4 (10.3)	0	3 (7.7)	1 (2.6)	0
Rhinovirus infection	4 (10.3)	4 (10.3)	0	0	0
Otitis media	1 (2.6)	0	0	1 (2.6)	0
Urinary tract infection	1 (2.6)	0	1 (2.6)	0	0
Injury, poisoning and procedural complications					
-Total	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Procedural pain	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Investigations					
-Total	32 (82.1)	0	4 (10.3)	10 (25.6)	18 (46.2)
White blood cell count decreased	18 (46.2)	3 (7.7)	1 (2.6)	6 (15.4)	8 (20.5)
Aspartate aminotransferase increased	15 (38.5)	2 (5.1)	4 (10.3)	5 (12.8)	4 (10.3)
Alanine aminotransferase increased	13 (33.3)	4 (10.3)	2 (5.1)	7 (17.9)	0
Neutrophil count decreased	13 (33.3)	0	2 (5.1)	2 (5.1)	9 (23.1)
Platelet count decreased	10 (25.6)	0	0	2 (5.1)	8 (20.5)
International normalised ratio increased	8 (20.5)	7 (17.9)	0	1 (2.6)	0
Lymphocyte count decreased	8 (20.5)	0	2 (5.1)	3 (7.7)	3 (7.7)
Prothrombin time prolonged	7 (17.9)	4 (10.3)	2 (5.1)	1 (2.6)	0
Blood bilirubin increased	6 (15.4)	1 (2.6)	2 (5.1)	3 (7.7)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	5 (12.8)	1 (2.6)	2 (5.1)	2 (5.1)	0
Activated partial thromboplastin time prolonged	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Metabolism and nutrition disorders					
-Total	22 (56.4)	5 (12.8)	3 (7.7)	14 (35.9)	0
Decreased appetite	14 (35.9)	4 (10.3)	1 (2.6)	9 (23.1)	0
Hypokalaemia	11 (28.2)	2 (5.1)	3 (7.7)	6 (15.4)	0
Hypophosphataemia	8 (20.5)	2 (5.1)	0	6 (15.4)	0
Hyperphosphataemia	4 (10.3)	4 (10.3)	0	0	0
Hypoalbuminaemia	4 (10.3)	1 (2.6)	3 (7.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	11 (28.2)	6 (15.4)	5 (12.8)	0	0
Pain in extremity	8 (20.5)	4 (10.3)	4 (10.3)	0	0
Myalgia	5 (12.8)	4 (10.3)	1 (2.6)	0	0
Nervous system disorders					
-Total	17 (43.6)	12 (30.8)	3 (7.7)	2 (5.1)	0
Headache	14 (35.9)	9 (23.1)	3 (7.7)	2 (5.1)	0
Dizziness	4 (10.3)	4 (10.3)	0	0	0
Psychiatric disorders					
-Total	10 (25.6)	5 (12.8)	4 (10.3)	1 (2.6)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	6 (15.4)	3 (7.7)	2 (5.1)	1 (2.6)	0
Confusional state	5 (12.8)	2 (5.1)	3 (7.7)	0	0
Renal and urinary disorders					
-Total	7 (17.9)	1 (2.6)	1 (2.6)	1 (2.6)	4 (10.3)
Acute kidney injury	6 (15.4)	1 (2.6)	1 (2.6)	1 (2.6)	3 (7.7)
Haematuria	4 (10.3)	0	2 (5.1)	1 (2.6)	1 (2.6)
Respiratory, thoracic and mediastinal disorders					
-Total	18 (46.2)	3 (7.7)	3 (7.7)	8 (20.5)	4 (10.3)
Cough	9 (23.1)	9 (23.1)	0	0	0
Hypoxia	9 (23.1)	0	2 (5.1)	4 (10.3)	3 (7.7)
Epistaxis	7 (17.9)	1 (2.6)	1 (2.6)	4 (10.3)	1 (2.6)
Pleural effusion	7 (17.9)	2 (5.1)	4 (10.3)	1 (2.6)	0
Pulmonary oedema	4 (10.3)	0	0	3 (7.7)	1 (2.6)
Oropharyngeal pain	3 (7.7)	2 (5.1)	1 (2.6)	0	0
Tachypnoea	2 (5.1)	0	1 (2.6)	1 (2.6)	0
Rhinorrhoea	1 (2.6)	1 (2.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	12 (30.8)	10 (25.6)	2 (5.1)	0	0
Rash	6 (15.4)	4 (10.3)	2 (5.1)	0	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	4 (10.3)	4 (10.3)	0	0	0
Hyperhidrosis	4 (10.3)	4 (10.3)	0	0	0
Dry skin	2 (5.1)	2 (5.1)	0	0	0
Vascular disorders					
-Total	14 (35.9)	2 (5.1)	2 (5.1)	3 (7.7)	7 (17.9)
Hypotension	11 (28.2)	1 (2.6)	0	3 (7.7)	7 (17.9)
Hypertension	9 (23.1)	3 (7.7)	5 (12.8)	1 (2.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184e
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	1 (14.3)	0	6 (85.7)
Blood and lymphatic system disorders					
-Total	5 (71.4)	1 (14.3)	0	2 (28.6)	2 (28.6)
Anaemia	4 (57.1)	2 (28.6)	0	1 (14.3)	1 (14.3)
Febrile neutropenia	2 (28.6)	0	0	2 (28.6)	0
Neutropenia	2 (28.6)	0	0	0	2 (28.6)
Thrombocytopenia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Cardiac disorders					
-Total	3 (42.9)	2 (28.6)	0	1 (14.3)	0
Tachycardia	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Palpitations	1 (14.3)	1 (14.3)	0	0	0
Pericardial effusion	1 (14.3)	1 (14.3)	0	0	0
Eye disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Eye pain	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal disorders					
-Total	4 (57.1)	2 (28.6)	1 (14.3)	1 (14.3)	0
Diarrhoea	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Nausea	3 (42.9)	1 (14.3)	1 (14.3)	1 (14.3)	0
Vomiting	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
General disorders and administration site conditions					
-Total	3 (42.9)	0	0	2 (28.6)	1 (14.3)
Pyrexia	3 (42.9)	0	1 (14.3)	1 (14.3)	1 (14.3)
Asthenia	1 (14.3)	1 (14.3)	0	0	0
Chills	1 (14.3)	1 (14.3)	0	0	0
Pain	1 (14.3)	0	0	1 (14.3)	0
Hepatobiliary disorders					

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (14.3)	0	1 (14.3)	0	0
Hepatomegaly	1 (14.3)	0	1 (14.3)	0	0
Immune system disorders					
-Total	7 (100)	0	4 (57.1)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)	0	0
Infections and infestations					
-Total	2 (28.6)	0	2 (28.6)	0	0
Gastroenteritis	1 (14.3)	0	1 (14.3)	0	0
Viral infection	1 (14.3)	0	1 (14.3)	0	0
Injury, poisoning and procedural complications					
-Total	1 (14.3)	0	0	1 (14.3)	0
Tracheal haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Investigations					
-Total	7 (100)	1 (14.3)	1 (14.3)	1 (14.3)	4 (57.1)
Neutrophil count decreased	4 (57.1)	0	1 (14.3)	0	3 (42.9)
White blood cell count decreased	4 (57.1)	1 (14.3)	0	1 (14.3)	2 (28.6)
Lymphocyte count decreased	2 (28.6)	1 (14.3)	1 (14.3)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0	0	0
Aspartate aminotransferase increased	1 (14.3)	0	0	0	1 (14.3)
Blood creatinine increased	1 (14.3)	0	1 (14.3)	0	0
Blood fibrinogen decreased	1 (14.3)	0	1 (14.3)	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0
Blood magnesium decreased	1 (14.3)	0	0	1 (14.3)	0
Blood phosphorus increased	1 (14.3)	1 (14.3)	0	0	0
Blood uric acid increased	1 (14.3)	1 (14.3)	0	0	0
Cardiac murmur	1 (14.3)	1 (14.3)	0	0	0
Fibrin d dimer increased	1 (14.3)	1 (14.3)	0	0	0
International normalised ratio increased	1 (14.3)	1 (14.3)	0	0	0
Prothrombin time prolonged	1 (14.3)	0	1 (14.3)	0	0
Metabolism and nutrition disorders					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Decreased appetite	3 (42.9)	1 (14.3)	1 (14.3)	1 (14.3)	0
Hypokalaemia	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Hypernatraemia	1 (14.3)	0	1 (14.3)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	1 (14.3)	1 (14.3)	0	0	0
Hypophosphataemia	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Arthralgia	1 (14.3)	0	0	1 (14.3)	0
Nervous system disorders					
-Total	4 (57.1)	4 (57.1)	0	0	0
Headache	3 (42.9)	3 (42.9)	0	0	0
Dizziness	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Confusional state	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Delirium	1 (14.3)	1 (14.3)	0	0	0
Renal and urinary disorders					
-Total	2 (28.6)	0	0	0	2 (28.6)
Haematuria	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Acute kidney injury	1 (14.3)	0	0	0	1 (14.3)
Oliguria	1 (14.3)	0	0	1 (14.3)	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal failure	1 (14.3)	0	0	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders					
-Total	3 (42.9)	1 (14.3)	0	0	2 (28.6)
Cough	2 (28.6)	2 (28.6)	0	0	0
Hypoxia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Dyspnoea	1 (14.3)	0	0	0	1 (14.3)
Epistaxis	1 (14.3)	0	0	0	1 (14.3)
Haemoptysis	1 (14.3)	0	0	0	1 (14.3)
Interstitial lung disease	1 (14.3)	0	0	0	1 (14.3)
Pleural effusion	1 (14.3)	0	1 (14.3)	0	0
Pulmonary oedema	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Skin and subcutaneous tissue disorders					
-Total	4 (57.1)	4 (57.1)	0	0	0
Dermatitis diaper	1 (14.3)	1 (14.3)	0	0	0
Dry skin	1 (14.3)	1 (14.3)	0	0	0
Erythema	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Livedo reticularis	1 (14.3)	1 (14.3)	0	0	0
Rash maculo-papular	1 (14.3)	1 (14.3)	0	0	0
Vascular disorders					
-Total	4 (57.1)	0	0	2 (28.6)	2 (28.6)
Hypotension	4 (57.1)	0	0	2 (28.6)	2 (28.6)
Haematoma	1 (14.3)	0	1 (14.3)	0	0
Hypertension	1 (14.3)	0	1 (14.3)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184e
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (98.2)	2 (3.5)	7 (12.3)	14 (24.6)	33 (57.9)
Blood and lymphatic system disorders					
-Total	35 (61.4)	0	2 (3.5)	26 (45.6)	7 (12.3)
Anaemia	23 (40.4)	1 (1.8)	5 (8.8)	17 (29.8)	0
Febrile neutropenia	20 (35.1)	0	0	20 (35.1)	0
Neutropenia	6 (10.5)	0	0	3 (5.3)	3 (5.3)
Thrombocytopenia	6 (10.5)	0	0	1 (1.8)	5 (8.8)
Cardiac disorders					
-Total	18 (31.6)	9 (15.8)	8 (14.0)	1 (1.8)	0
Tachycardia	13 (22.8)	7 (12.3)	5 (8.8)	1 (1.8)	0
Sinus tachycardia	5 (8.8)	3 (5.3)	2 (3.5)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

			All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pericardial effusion	1 (1.8)	0	1 (1.8)	0	0
Endocrine disorders					
-Total	1 (1.8)	0	1 (1.8)	0	0
Adrenal insufficiency	1 (1.8)	0	1 (1.8)	0	0
Eye disorders					
-Total	2 (3.5)	0	2 (3.5)	0	0
Eye pain	2 (3.5)	0	2 (3.5)	0	0
Gastrointestinal disorders					
-Total	29 (50.9)	10 (17.5)	13 (22.8)	6 (10.5)	0
Vomiting	19 (33.3)	12 (21.1)	4 (7.0)	3 (5.3)	0
Nausea	18 (31.6)	5 (8.8)	11 (19.3)	2 (3.5)	0
Diarrhoea	15 (26.3)	9 (15.8)	5 (8.8)	1 (1.8)	0
Abdominal pain	9 (15.8)	6 (10.5)	2 (3.5)	1 (1.8)	0
Constipation	6 (10.5)	5 (8.8)	1 (1.8)	0	0
General disorders and administration site conditions					
-Total	26 (45.6)	12 (21.1)	9 (15.8)	5 (8.8)	0
Fatigue	13 (22.8)	10 (17.5)	2 (3.5)	1 (1.8)	0
Pyrexia	13 (22.8)	3 (5.3)	6 (10.5)	4 (7.0)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	7 (12.3)	7 (12.3)	0	0	0
Catheter site pain	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Pain	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Hepatobiliary disorders					
-Total	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Hepatomegaly	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Immune system disorders					
-Total	49 (86.0)	4 (7.0)	26 (45.6)	11 (19.3)	8 (14.0)
Cytokine release syndrome	45 (78.9)	6 (10.5)	23 (40.4)	8 (14.0)	8 (14.0)
Hypogammaglobulinaemia	21 (36.8)	3 (5.3)	14 (24.6)	4 (7.0)	0
Infections and infestations					
-Total	6 (10.5)	3 (5.3)	2 (3.5)	1 (1.8)	0
Rhinovirus infection	3 (5.3)	3 (5.3)	0	0	0
Gastroenteritis	1 (1.8)	0	0	1 (1.8)	0
Skin infection	1 (1.8)	0	1 (1.8)	0	0
Upper respiratory tract infection	1 (1.8)	0	1 (1.8)	0	0
Injury, poisoning and procedural complications					
-Total	3 (5.3)	1 (1.8)	2 (3.5)	0	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infusion related reaction	2 (3.5)	0	2 (3.5)	0	0
Contusion	1 (1.8)	1 (1.8)	0	0	0
Investigations					
-Total	41 (71.9)	1 (1.8)	2 (3.5)	11 (19.3)	27 (47.4)
White blood cell count decreased	26 (45.6)	2 (3.5)	1 (1.8)	9 (15.8)	14 (24.6)
Neutrophil count decreased	21 (36.8)	0	1 (1.8)	4 (7.0)	16 (28.1)
Alanine aminotransferase increased	19 (33.3)	5 (8.8)	3 (5.3)	11 (19.3)	0
Platelet count decreased	19 (33.3)	3 (5.3)	2 (3.5)	2 (3.5)	12 (21.1)
Aspartate aminotransferase increased	17 (29.8)	3 (5.3)	4 (7.0)	7 (12.3)	3 (5.3)
Lymphocyte count decreased	12 (21.1)	0	1 (1.8)	6 (10.5)	5 (8.8)
Blood creatinine increased	8 (14.0)	5 (8.8)	1 (1.8)	2 (3.5)	0
International normalised ratio increased	8 (14.0)	7 (12.3)	0	1 (1.8)	0
Prothrombin time prolonged	8 (14.0)	5 (8.8)	2 (3.5)	1 (1.8)	0
Blood bilirubin increased	7 (12.3)	2 (3.5)	3 (5.3)	2 (3.5)	0
Activated partial thromboplastin time prolonged	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Blood fibrinogen decreased	3 (5.3)	0	0	2 (3.5)	1 (1.8)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	3 (5.3)	3 (5.3)	0	0	0
Blood phosphorus increased	1 (1.8)	1 (1.8)	0	0	0
Metabolism and nutrition disorders					
-Total	31 (54.4)	7 (12.3)	6 (10.5)	16 (28.1)	2 (3.5)
Decreased appetite	17 (29.8)	3 (5.3)	3 (5.3)	11 (19.3)	0
Hypokalaemia	14 (24.6)	2 (3.5)	5 (8.8)	7 (12.3)	0
Hyperphosphataemia	8 (14.0)	8 (14.0)	0	0	0
Hypophosphataemia	8 (14.0)	2 (3.5)	0	5 (8.8)	1 (1.8)
Hypoalbuminaemia	4 (7.0)	0	3 (5.3)	1 (1.8)	0
Hypernatraemia	3 (5.3)	1 (1.8)	1 (1.8)	0	1 (1.8)
Musculoskeletal and connective tissue disorders					
-Total	6 (10.5)	3 (5.3)	3 (5.3)	0	0
Pain in extremity	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Arthralgia	3 (5.3)	3 (5.3)	0	0	0
Muscular weakness	1 (1.8)	0	1 (1.8)	0	0
Nervous system disorders					
-Total	22 (38.6)	14 (24.6)	6 (10.5)	2 (3.5)	0
Headache	21 (36.8)	13 (22.8)	6 (10.5)	2 (3.5)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dizziness	3 (5.3)	3 (5.3)	0	0	0
Psychiatric disorders					
-Total	11 (19.3)	5 (8.8)	5 (8.8)	1 (1.8)	0
Anxiety	6 (10.5)	2 (3.5)	3 (5.3)	1 (1.8)	0
Confusional state	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Delirium	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Renal and urinary disorders					
-Total	6 (10.5)	1 (1.8)	1 (1.8)	2 (3.5)	2 (3.5)
Acute kidney injury	6 (10.5)	1 (1.8)	1 (1.8)	2 (3.5)	2 (3.5)
Haematuria	2 (3.5)	0	2 (3.5)	0	0
Oliguria	1 (1.8)	0	0	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders					
-Total	21 (36.8)	8 (14.0)	4 (7.0)	5 (8.8)	4 (7.0)
Hypoxia	8 (14.0)	0	3 (5.3)	3 (5.3)	2 (3.5)
Pleural effusion	7 (12.3)	2 (3.5)	3 (5.3)	2 (3.5)	0
Cough	6 (10.5)	6 (10.5)	0	0	0
Epistaxis	6 (10.5)	2 (3.5)	1 (1.8)	3 (5.3)	0
Pulmonary oedema	5 (8.8)	1 (1.8)	0	3 (5.3)	1 (1.8)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Respiratory failure	2 (3.5)	0	0	0	2 (3.5)
Dyspnoea	1 (1.8)	0	0	1 (1.8)	0
Haemoptysis	1 (1.8)	1 (1.8)	0	0	0
Nasal congestion	1 (1.8)	1 (1.8)	0	0	0
Rhinorrhoea	1 (1.8)	1 (1.8)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (19.3)	9 (15.8)	1 (1.8)	1 (1.8)	0
Rash	4 (7.0)	4 (7.0)	0	0	0
Dry skin	3 (5.3)	3 (5.3)	0	0	0
Erythema	2 (3.5)	2 (3.5)	0	0	0
Rash maculo-papular	2 (3.5)	0	1 (1.8)	1 (1.8)	0
Rash erythematous	1 (1.8)	1 (1.8)	0	0	0
Vascular disorders					
-Total	17 (29.8)	2 (3.5)	4 (7.0)	5 (8.8)	6 (10.5)
Hypotension	12 (21.1)	1 (1.8)	0	5 (8.8)	6 (10.5)
Hypertension	9 (15.8)	2 (3.5)	6 (10.5)	1 (1.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184e
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	2 (40.0)	2 (40.0)	0
Endocrine disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Adrenal insufficiency	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal disorders					
-Total	4 (80.0)	2 (40.0)	0	2 (40.0)	0
Diarrhoea	2 (40.0)	2 (40.0)	0	0	0
Oral pain	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Vomiting	2 (40.0)	2 (40.0)	0	0	0
Abdominal pain	1 (20.0)	1 (20.0)	0	0	0
Enterocolitis	1 (20.0)	0	0	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (20.0)	0	1 (20.0)	0	0
General disorders and administration site conditions					
-Total	3 (60.0)	2 (40.0)	1 (20.0)	0	0
Catheter site pain	1 (20.0)	0	1 (20.0)	0	0
Fatigue	1 (20.0)	1 (20.0)	0	0	0
Pyrexia	1 (20.0)	1 (20.0)	0	0	0
Immune system disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Graft versus host disease	1 (20.0)	0	1 (20.0)	0	0
Infections and infestations					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Upper respiratory tract infection	2 (40.0)	0	2 (40.0)	0	0
Corona virus infection	1 (20.0)	0	0	1 (20.0)	0
Ear infection	1 (20.0)	1 (20.0)	0	0	0
Respiratory syncytial virus infection	1 (20.0)	0	0	1 (20.0)	0
Rhinovirus infection	1 (20.0)	1 (20.0)	0	0	0
Tinea capitis	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	1 (20.0)	1 (20.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (20.0)	0	1 (20.0)	0	0
Contusion	1 (20.0)	1 (20.0)	0	0	0
Infusion related reaction	1 (20.0)	0	1 (20.0)	0	0
Procedural nausea	1 (20.0)	0	1 (20.0)	0	0
Sunburn	1 (20.0)	1 (20.0)	0	0	0
Investigations					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Blood bilirubin increased	1 (20.0)	0	0	1 (20.0)	0
Blood magnesium decreased	1 (20.0)	1 (20.0)	0	0	0
Weight decreased	1 (20.0)	1 (20.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (60.0)	3 (60.0)	0	0	0
Pain in extremity	2 (40.0)	2 (40.0)	0	0	0
Arthralgia	1 (20.0)	1 (20.0)	0	0	0
Muscular weakness	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in jaw	1 (20.0)	1 (20.0)	0	0	0
Nervous system disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0
Headache	1 (20.0)	1 (20.0)	0	0	0
Peroneal nerve palsy	1 (20.0)	1 (20.0)	0	0	0
Psychiatric disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Anxiety	1 (20.0)	1 (20.0)	0	0	0
Depression	1 (20.0)	1 (20.0)	0	0	0
Sleep disorder	1 (20.0)	0	1 (20.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (80.0)	2 (40.0)	1 (20.0)	1 (20.0)	0
Rhinorrhoea	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Cough	1 (20.0)	1 (20.0)	0	0	0
Epistaxis	1 (20.0)	0	0	1 (20.0)	0
Nasal congestion	1 (20.0)	1 (20.0)	0	0	0
Oropharyngeal pain	1 (20.0)	0	1 (20.0)	0	0
Pharyngeal erythema	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngeal lesion	1 (20.0)	0	0	1 (20.0)	0
Skin and subcutaneous tissue disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Alopecia	1 (20.0)	0	1 (20.0)	0	0
Erythema	1 (20.0)	1 (20.0)	0	0	0
Rash erythematous	1 (20.0)	0	1 (20.0)	0	0
Vascular disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Hypertension	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Hot flush	1 (20.0)	1 (20.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184e
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (74.5)	7 (13.7)	13 (25.5)	12 (23.5)	6 (11.8)
Blood and lymphatic system disorders					
-Total	8 (15.7)	1 (2.0)	1 (2.0)	3 (5.9)	3 (5.9)
Neutropenia	4 (7.8)	0	0	1 (2.0)	3 (5.9)
Febrile neutropenia	3 (5.9)	0	0	3 (5.9)	0
Anaemia	2 (3.9)	1 (2.0)	0	1 (2.0)	0
Thrombocytopenia	2 (3.9)	0	1 (2.0)	1 (2.0)	0
Cardiac disorders					
-Total	1 (2.0)	0	1 (2.0)	0	0
Sinus tachycardia	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	10 (19.6)	5 (9.8)	3 (5.9)	2 (3.9)	0
Vomiting	7 (13.7)	3 (5.9)	2 (3.9)	2 (3.9)	0
Diarrhoea	6 (11.8)	4 (7.8)	1 (2.0)	1 (2.0)	0
Nausea	5 (9.8)	1 (2.0)	2 (3.9)	2 (3.9)	0
Abdominal pain	3 (5.9)	1 (2.0)	1 (2.0)	1 (2.0)	0
General disorders and administration site conditions					
-Total	9 (17.6)	6 (11.8)	2 (3.9)	1 (2.0)	0
Pyrexia	9 (17.6)	6 (11.8)	2 (3.9)	1 (2.0)	0
Chills	1 (2.0)	1 (2.0)	0	0	0
Fatigue	1 (2.0)	1 (2.0)	0	0	0
Pain	1 (2.0)	1 (2.0)	0	0	0
Immune system disorders					
-Total	9 (17.6)	1 (2.0)	7 (13.7)	1 (2.0)	0
Hypogammaglobulinaemia	8 (15.7)	0	7 (13.7)	1 (2.0)	0
Graft versus host disease	1 (2.0)	1 (2.0)	0	0	0
Infections and infestations					
-Total	10 (19.6)	5 (9.8)	4 (7.8)	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	5 (9.8)	3 (5.9)	1 (2.0)	1 (2.0)	0
Gastroenteritis	3 (5.9)	1 (2.0)	2 (3.9)	0	0
Ear infection	1 (2.0)	0	1 (2.0)	0	0
Rhinovirus infection	1 (2.0)	1 (2.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (3.9)	2 (3.9)	0	0	0
Contusion	1 (2.0)	1 (2.0)	0	0	0
Infusion related reaction	1 (2.0)	1 (2.0)	0	0	0
Investigations					
-Total	17 (33.3)	3 (5.9)	3 (5.9)	7 (13.7)	4 (7.8)
Neutrophil count decreased	8 (15.7)	2 (3.9)	0	3 (5.9)	3 (5.9)
White blood cell count decreased	5 (9.8)	2 (3.9)	1 (2.0)	1 (2.0)	1 (2.0)
Aspartate aminotransferase increased	3 (5.9)	1 (2.0)	0	2 (3.9)	0
Platelet count decreased	3 (5.9)	3 (5.9)	0	0	0
Weight decreased	3 (5.9)	0	3 (5.9)	0	0
Alanine aminotransferase increased	2 (3.9)	0	0	2 (3.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Blood creatinine increased	1 (2.0)	1 (2.0)	0	0	0
Blood uric acid increased	1 (2.0)	1 (2.0)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (9.8)	3 (5.9)	1 (2.0)	0	1 (2.0)
Decreased appetite	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Hyperphosphataemia	2 (3.9)	2 (3.9)	0	0	0
Hypokalaemia	2 (3.9)	1 (2.0)	0	0	1 (2.0)
Hypophosphataemia	1 (2.0)	0	0	1 (2.0)	0
Musculoskeletal and connective tissue disorders					
-Total	8 (15.7)	5 (9.8)	3 (5.9)	0	0
Pain in extremity	6 (11.8)	4 (7.8)	2 (3.9)	0	0
Arthralgia	1 (2.0)	0	1 (2.0)	0	0
Muscular weakness	1 (2.0)	1 (2.0)	0	0	0
Nervous system disorders					
-Total	6 (11.8)	4 (7.8)	2 (3.9)	0	0
Headache	4 (7.8)	3 (5.9)	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dizziness	3 (5.9)	3 (5.9)	0	0	0
Peroneal nerve palsy	1 (2.0)	0	1 (2.0)	0	0
Psychiatric disorders					
-Total	1 (2.0)	1 (2.0)	0	0	0
Depression	1 (2.0)	1 (2.0)	0	0	0
Renal and urinary disorders					
-Total	2 (3.9)	0	0	2 (3.9)	0
Acute kidney injury	1 (2.0)	0	0	1 (2.0)	0
Haematuria	1 (2.0)	0	0	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (19.6)	7 (13.7)	2 (3.9)	1 (2.0)	0
Cough	6 (11.8)	4 (7.8)	2 (3.9)	0	0
Nasal congestion	3 (5.9)	3 (5.9)	0	0	0
Oropharyngeal pain	2 (3.9)	2 (3.9)	0	0	0
Rhinorrhoea	2 (3.9)	2 (3.9)	0	0	0
Epistaxis	1 (2.0)	1 (2.0)	0	0	0
Pulmonary oedema	1 (2.0)	0	0	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	8 (15.7)	5 (9.8)	3 (5.9)	0	0
Rash	4 (7.8)	1 (2.0)	3 (5.9)	0	0
Rash maculo-papular	2 (3.9)	2 (3.9)	0	0	0
Dry skin	1 (2.0)	1 (2.0)	0	0	0
Erythema	1 (2.0)	1 (2.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184e
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (40.0)	0	1 (20.0)	0	1 (20.0)
Infections and infestations					
-Total	1 (20.0)	0	1 (20.0)	0	0
Skin infection	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	1 (20.0)	0	0	0	1 (20.0)
White blood cell count decreased	1 (20.0)	0	0	0	1 (20.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184e
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (44.8)	4 (13.8)	4 (13.8)	4 (13.8)	1 (3.4)
Blood and lymphatic system disorders					
-Total	2 (6.9)	1 (3.4)	0	0	1 (3.4)
Febrile neutropenia	1 (3.4)	0	0	0	1 (3.4)
Thrombocytopenia	1 (3.4)	1 (3.4)	0	0	0
Gastrointestinal disorders					
-Total	3 (10.3)	0	3 (10.3)	0	0
Diarrhoea	2 (6.9)	0	2 (6.9)	0	0
Abdominal pain	1 (3.4)	0	1 (3.4)	0	0
Nausea	1 (3.4)	0	1 (3.4)	0	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	1 (3.4)	0	1 (3.4)	0	0
Chills	1 (3.4)	0	1 (3.4)	0	0
Pyrexia	1 (3.4)	0	1 (3.4)	0	0
Infections and infestations					
-Total	3 (10.3)	2 (6.9)	1 (3.4)	0	0
Upper respiratory tract infection	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Viral infection	1 (3.4)	1 (3.4)	0	0	0
Investigations					
-Total	7 (24.1)	1 (3.4)	2 (6.9)	4 (13.8)	0
Alanine aminotransferase increased	3 (10.3)	0	1 (3.4)	2 (6.9)	0
Lymphocyte count decreased	3 (10.3)	2 (6.9)	0	1 (3.4)	0
White blood cell count decreased	3 (10.3)	1 (3.4)	0	2 (6.9)	0
Aspartate aminotransferase increased	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Neutrophil count decreased	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Platelet count decreased	1 (3.4)	0	0	1 (3.4)	0
Metabolism and nutrition disorders					

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.4)	0	0	1 (3.4)	0
Hypokalaemia	1 (3.4)	0	0	1 (3.4)	0
Nervous system disorders					
-Total	1 (3.4)	0	1 (3.4)	0	0
Dizziness	1 (3.4)	1 (3.4)	0	0	0
Headache	1 (3.4)	0	1 (3.4)	0	0
Renal and urinary disorders					
-Total	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Acute kidney injury	1 (3.4)	0	0	1 (3.4)	0
Haematuria	1 (3.4)	1 (3.4)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (13.8)	4 (13.8)	0	0	0
Cough	2 (6.9)	2 (6.9)	0	0	0
Epistaxis	1 (3.4)	1 (3.4)	0	0	0
Oropharyngeal pain	1 (3.4)	1 (3.4)	0	0	0
Rhinorrhoea	1 (3.4)	1 (3.4)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184e
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	1 (14.3)	0	6 (85.7)
Blood and lymphatic system disorders					
-Total	5 (71.4)	1 (14.3)	0	2 (28.6)	2 (28.6)
Anaemia	4 (57.1)	2 (28.6)	0	1 (14.3)	1 (14.3)
Febrile neutropenia	2 (28.6)	0	0	2 (28.6)	0
Neutropenia	2 (28.6)	0	0	0	2 (28.6)
Thrombocytopenia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Cardiac disorders					
-Total	3 (42.9)	2 (28.6)	0	1 (14.3)	0
Tachycardia	2 (28.6)	1 (14.3)	0	1 (14.3)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0
Palpitations	1 (14.3)	1 (14.3)	0	0	0
Pericardial effusion	1 (14.3)	1 (14.3)	0	0	0
Endocrine disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Adrenal insufficiency	1 (14.3)	1 (14.3)	0	0	0
Eye disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Eye pain	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal disorders					
-Total	6 (85.7)	2 (28.6)	1 (14.3)	3 (42.9)	0
Vomiting	5 (71.4)	3 (42.9)	2 (28.6)	0	0
Diarrhoea	4 (57.1)	3 (42.9)	1 (14.3)	0	0
Nausea	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Oral pain	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Abdominal pain	1 (14.3)	1 (14.3)	0	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Enterocolitis	1 (14.3)	0	0	1 (14.3)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	5 (71.4)	1 (14.3)	1 (14.3)	2 (28.6)	1 (14.3)
Pyrexia	4 (57.1)	1 (14.3)	1 (14.3)	1 (14.3)	1 (14.3)
Asthenia	1 (14.3)	1 (14.3)	0	0	0
Catheter site pain	1 (14.3)	0	1 (14.3)	0	0
Chills	1 (14.3)	1 (14.3)	0	0	0
Fatigue	1 (14.3)	1 (14.3)	0	0	0
Pain	1 (14.3)	0	0	1 (14.3)	0
Hepatobiliary disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Hepatomegaly	1 (14.3)	0	1 (14.3)	0	0
Immune system disorders					
-Total	7 (100)	0	4 (57.1)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)	0	0
Graft versus host disease	1 (14.3)	0	1 (14.3)	0	0
Infections and infestations					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	2 (28.6)	0	2 (28.6)	0	0
Viral infection	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Corona virus infection	1 (14.3)	0	0	1 (14.3)	0
Ear infection	1 (14.3)	1 (14.3)	0	0	0
Gastroenteritis	1 (14.3)	0	1 (14.3)	0	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	1 (14.3)	0	0	0
Skin infection	1 (14.3)	0	1 (14.3)	0	0
Tinea capitis	1 (14.3)	1 (14.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Contusion	1 (14.3)	1 (14.3)	0	0	0
Infusion related reaction	1 (14.3)	0	1 (14.3)	0	0
Procedural nausea	1 (14.3)	0	1 (14.3)	0	0
Sunburn	1 (14.3)	1 (14.3)	0	0	0
Tracheal haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Investigations					

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (100)	0	1 (14.3)	2 (28.6)	4 (57.1)
Neutrophil count decreased	4 (57.1)	0	1 (14.3)	0	3 (42.9)
White blood cell count decreased	4 (57.1)	1 (14.3)	0	0	3 (42.9)
Blood magnesium decreased	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Lymphocyte count decreased	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0	0	0
Aspartate aminotransferase increased	1 (14.3)	0	0	0	1 (14.3)
Blood bilirubin increased	1 (14.3)	0	0	1 (14.3)	0
Blood creatinine increased	1 (14.3)	0	1 (14.3)	0	0
Blood fibrinogen decreased	1 (14.3)	0	1 (14.3)	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0
Blood phosphorus increased	1 (14.3)	1 (14.3)	0	0	0
Blood uric acid increased	1 (14.3)	1 (14.3)	0	0	0
Cardiac murmur	1 (14.3)	1 (14.3)	0	0	0
Fibrin d dimer increased	1 (14.3)	1 (14.3)	0	0	0
International normalised ratio increased	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prothrombin time prolonged	1 (14.3)	0	1 (14.3)	0	0
Weight decreased	1 (14.3)	1 (14.3)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Decreased appetite	3 (42.9)	1 (14.3)	1 (14.3)	1 (14.3)	0
Hypokalaemia	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Hypernatraemia	1 (14.3)	0	1 (14.3)	0	0
Hypoalbuminaemia	1 (14.3)	1 (14.3)	0	0	0
Hypophosphataemia	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (42.9)	2 (28.6)	0	1 (14.3)	0
Pain in extremity	2 (28.6)	2 (28.6)	0	0	0
Arthralgia	1 (14.3)	0	0	1 (14.3)	0
Muscular weakness	1 (14.3)	1 (14.3)	0	0	0
Pain in jaw	1 (14.3)	1 (14.3)	0	0	0
Nervous system disorders					
-Total	4 (57.1)	4 (57.1)	0	0	0
Headache	3 (42.9)	3 (42.9)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dizziness	1 (14.3)	1 (14.3)	0	0	0
Peroneal nerve palsy	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Confusional state	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Anxiety	1 (14.3)	1 (14.3)	0	0	0
Delirium	1 (14.3)	1 (14.3)	0	0	0
Depression	1 (14.3)	1 (14.3)	0	0	0
Sleep disorder	1 (14.3)	0	1 (14.3)	0	0
Renal and urinary disorders					
-Total	2 (28.6)	0	0	0	2 (28.6)
Haematuria	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Acute kidney injury	1 (14.3)	0	0	0	1 (14.3)
Oliguria	1 (14.3)	0	0	1 (14.3)	0
Renal failure	1 (14.3)	0	0	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders					
-Total	6 (85.7)	2 (28.6)	1 (14.3)	1 (14.3)	2 (28.6)
Cough	3 (42.9)	3 (42.9)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Hypoxia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Rhinorrhoea	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Dyspnoea	1 (14.3)	0	0	0	1 (14.3)
Haemoptysis	1 (14.3)	0	0	0	1 (14.3)
Interstitial lung disease	1 (14.3)	0	0	0	1 (14.3)
Nasal congestion	1 (14.3)	1 (14.3)	0	0	0
Oropharyngeal pain	1 (14.3)	0	1 (14.3)	0	0
Pharyngeal erythema	1 (14.3)	1 (14.3)	0	0	0
Pharyngeal lesion	1 (14.3)	0	0	1 (14.3)	0
Pleural effusion	1 (14.3)	0	1 (14.3)	0	0
Pulmonary oedema	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Skin and subcutaneous tissue disorders					
-Total	4 (57.1)	3 (42.9)	1 (14.3)	0	0
Erythema	2 (28.6)	2 (28.6)	0	0	0
Alopecia	1 (14.3)	0	1 (14.3)	0	0
Dermatitis diaper	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	1 (14.3)	1 (14.3)	0	0	0
Livedo reticularis	1 (14.3)	1 (14.3)	0	0	0
Rash erythematous	1 (14.3)	0	1 (14.3)	0	0
Rash maculo-papular	1 (14.3)	1 (14.3)	0	0	0
Vascular disorders					
-Total	5 (71.4)	0	1 (14.3)	2 (28.6)	2 (28.6)
Hypotension	4 (57.1)	0	0	2 (28.6)	2 (28.6)
Hypertension	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Haematoma	1 (14.3)	0	1 (14.3)	0	0
Hot flush	1 (14.3)	1 (14.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184e
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

			All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (98.2)	1 (1.8)	5 (8.8)	13 (22.8)	37 (64.9)
Blood and lymphatic system disorders					
-Total	39 (68.4)	0	2 (3.5)	26 (45.6)	11 (19.3)
Anaemia	23 (40.4)	1 (1.8)	4 (7.0)	18 (31.6)	0
Febrile neutropenia	22 (38.6)	0	0	21 (36.8)	1 (1.8)
Neutropenia	9 (15.8)	0	0	3 (5.3)	6 (10.5)
Thrombocytopenia	8 (14.0)	0	1 (1.8)	2 (3.5)	5 (8.8)
Cardiac disorders					
-Total	19 (33.3)	9 (15.8)	9 (15.8)	1 (1.8)	0
Tachycardia	13 (22.8)	7 (12.3)	5 (8.8)	1 (1.8)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	6 (10.5)	3 (5.3)	3 (5.3)	0	0
Pericardial effusion	1 (1.8)	0	1 (1.8)	0	0
Endocrine disorders					
-Total	1 (1.8)	0	1 (1.8)	0	0
Adrenal insufficiency	1 (1.8)	0	1 (1.8)	0	0
Eye disorders					
-Total	2 (3.5)	0	2 (3.5)	0	0
Eye pain	2 (3.5)	0	2 (3.5)	0	0
Gastrointestinal disorders					
-Total	33 (57.9)	11 (19.3)	16 (28.1)	6 (10.5)	0
Vomiting	22 (38.6)	13 (22.8)	6 (10.5)	3 (5.3)	0
Nausea	21 (36.8)	5 (8.8)	12 (21.1)	4 (7.0)	0
Diarrhoea	20 (35.1)	10 (17.5)	8 (14.0)	2 (3.5)	0
Abdominal pain	10 (17.5)	5 (8.8)	4 (7.0)	1 (1.8)	0
Constipation	6 (10.5)	5 (8.8)	1 (1.8)	0	0
General disorders and administration site conditions					
-Total	32 (56.1)	14 (24.6)	12 (21.1)	6 (10.5)	0
Pyrexia	21 (36.8)	7 (12.3)	9 (15.8)	5 (8.8)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	14 (24.6)	11 (19.3)	2 (3.5)	1 (1.8)	0
Chills	9 (15.8)	8 (14.0)	1 (1.8)	0	0
Catheter site pain	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Pain	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)	0
Hepatobiliary disorders					
-Total	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Hepatomegaly	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Immune system disorders					
-Total	51 (89.5)	5 (8.8)	27 (47.4)	11 (19.3)	8 (14.0)
Cytokine release syndrome	45 (78.9)	6 (10.5)	23 (40.4)	8 (14.0)	8 (14.0)
Hypogammaglobulinaemia	28 (49.1)	3 (5.3)	20 (35.1)	5 (8.8)	0
Graft versus host disease	1 (1.8)	1 (1.8)	0	0	0
Infections and infestations					
-Total	16 (28.1)	8 (14.0)	6 (10.5)	2 (3.5)	0
Upper respiratory tract infection	7 (12.3)	4 (7.0)	2 (3.5)	1 (1.8)	0
Gastroenteritis	4 (7.0)	1 (1.8)	2 (3.5)	1 (1.8)	0
Rhinovirus infection	4 (7.0)	4 (7.0)	0	0	0
Ear infection	1 (1.8)	0	1 (1.8)	0	0
Skin infection	1 (1.8)	0	1 (1.8)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	1 (1.8)	1 (1.8)	0	0	0
Injury, poisoning and procedural complications					
-Total	5 (8.8)	3 (5.3)	2 (3.5)	0	0
Infusion related reaction	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Contusion	2 (3.5)	2 (3.5)	0	0	0
Investigations					
-Total	45 (78.9)	0	3 (5.3)	12 (21.1)	30 (52.6)
White blood cell count decreased	31 (54.4)	3 (5.3)	1 (1.8)	12 (21.1)	15 (26.3)
Neutrophil count decreased	24 (42.1)	1 (1.8)	1 (1.8)	4 (7.0)	18 (31.6)
Alanine aminotransferase increased	21 (36.8)	5 (8.8)	2 (3.5)	14 (24.6)	0
Platelet count decreased	20 (35.1)	3 (5.3)	2 (3.5)	3 (5.3)	12 (21.1)
Aspartate aminotransferase increased	19 (33.3)	4 (7.0)	4 (7.0)	8 (14.0)	3 (5.3)
Lymphocyte count decreased	14 (24.6)	0	2 (3.5)	7 (12.3)	5 (8.8)
Blood creatinine increased	8 (14.0)	5 (8.8)	1 (1.8)	2 (3.5)	0
International normalised ratio increased	8 (14.0)	7 (12.3)	0	1 (1.8)	0
Prothrombin time prolonged	8 (14.0)	5 (8.8)	2 (3.5)	1 (1.8)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	7 (12.3)	2 (3.5)	3 (5.3)	2 (3.5)	0
Activated partial thromboplastin time prolonged	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Blood fibrinogen decreased	3 (5.3)	0	0	2 (3.5)	1 (1.8)
Blood immunoglobulin m decreased	3 (5.3)	3 (5.3)	0	0	0
Weight decreased	3 (5.3)	0	3 (5.3)	0	0
Blood phosphorus increased	1 (1.8)	1 (1.8)	0	0	0
Blood uric acid increased	1 (1.8)	1 (1.8)	0	0	0
Metabolism and nutrition disorders					
-Total	33 (57.9)	7 (12.3)	6 (10.5)	17 (29.8)	3 (5.3)
Decreased appetite	19 (33.3)	4 (7.0)	4 (7.0)	11 (19.3)	0
Hypokalaemia	17 (29.8)	3 (5.3)	5 (8.8)	8 (14.0)	1 (1.8)
Hypophosphataemia	9 (15.8)	2 (3.5)	0	6 (10.5)	1 (1.8)
Hyperphosphataemia	8 (14.0)	8 (14.0)	0	0	0
Hypoalbuminaemia	4 (7.0)	0	3 (5.3)	1 (1.8)	0
Hypernatraemia	3 (5.3)	1 (1.8)	1 (1.8)	0	1 (1.8)
Musculoskeletal and connective tissue disorders					
-Total	12 (21.1)	7 (12.3)	5 (8.8)	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	9 (15.8)	5 (8.8)	4 (7.0)	0	0
Arthralgia	4 (7.0)	3 (5.3)	1 (1.8)	0	0
Muscular weakness	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Nervous system disorders					
-Total	24 (42.1)	14 (24.6)	8 (14.0)	2 (3.5)	0
Headache	21 (36.8)	12 (21.1)	7 (12.3)	2 (3.5)	0
Dizziness	5 (8.8)	5 (8.8)	0	0	0
Peroneal nerve palsy	1 (1.8)	0	1 (1.8)	0	0
Psychiatric disorders					
-Total	12 (21.1)	6 (10.5)	5 (8.8)	1 (1.8)	0
Anxiety	6 (10.5)	2 (3.5)	3 (5.3)	1 (1.8)	0
Confusional state	4 (7.0)	2 (3.5)	2 (3.5)	0	0
Delirium	3 (5.3)	1 (1.8)	2 (3.5)	0	0
Depression	1 (1.8)	1 (1.8)	0	0	0
Renal and urinary disorders					
-Total	9 (15.8)	1 (1.8)	1 (1.8)	5 (8.8)	2 (3.5)
Acute kidney injury	8 (14.0)	1 (1.8)	1 (1.8)	4 (7.0)	2 (3.5)
Haematuria	3 (5.3)	0	2 (3.5)	1 (1.8)	0
Oliguria	1 (1.8)	0	0	1 (1.8)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	27 (47.4)	12 (21.1)	5 (8.8)	6 (10.5)	4 (7.0)
Cough	11 (19.3)	9 (15.8)	2 (3.5)	0	0
Epistaxis	8 (14.0)	4 (7.0)	1 (1.8)	3 (5.3)	0
Hypoxia	8 (14.0)	0	3 (5.3)	3 (5.3)	2 (3.5)
Pleural effusion	7 (12.3)	2 (3.5)	3 (5.3)	2 (3.5)	0
Pulmonary oedema	6 (10.5)	1 (1.8)	0	4 (7.0)	1 (1.8)
Oropharyngeal pain	5 (8.8)	4 (7.0)	1 (1.8)	0	0
Nasal congestion	4 (7.0)	4 (7.0)	0	0	0
Rhinorrhoea	4 (7.0)	4 (7.0)	0	0	0
Respiratory failure	2 (3.5)	0	0	0	2 (3.5)
Dyspnoea	1 (1.8)	0	0	1 (1.8)	0
Haemoptysis	1 (1.8)	1 (1.8)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	17 (29.8)	12 (21.1)	4 (7.0)	1 (1.8)	0
Rash	8 (14.0)	5 (8.8)	3 (5.3)	0	0
Dry skin	4 (7.0)	4 (7.0)	0	0	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash maculo-papular	4 (7.0)	2 (3.5)	1 (1.8)	1 (1.8)	0
Erythema	3 (5.3)	3 (5.3)	0	0	0
Rash erythematous	1 (1.8)	1 (1.8)	0	0	0
Vascular disorders					
-Total	17 (29.8)	2 (3.5)	4 (7.0)	5 (8.8)	6 (10.5)
Hypotension	12 (21.1)	1 (1.8)	0	5 (8.8)	6 (10.5)
Hypertension	9 (15.8)	2 (3.5)	6 (10.5)	1 (1.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184f
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	1 (50.0)	1 (50.0)	0	0
Blood and lymphatic system disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Anaemia	1 (50.0)	0	1 (50.0)	0	0
General disorders and administration site conditions					
-Total	1 (50.0)	1 (50.0)	0	0	0
Fatigue	1 (50.0)	1 (50.0)	0	0	0
Immune system disorders					
-Total	2 (100)	1 (50.0)	1 (50.0)	0	0
Graft versus host disease in skin	1 (50.0)	1 (50.0)	0	0	0
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	1 (50.0)	1 (50.0)	0	0	0
Skin abrasion	1 (50.0)	1 (50.0)	0	0	0
Investigations					
-Total	1 (50.0)	0	1 (50.0)	0	0
Blood immunoglobulin a decreased	1 (50.0)	1 (50.0)	0	0	0
International normalised ratio increased	1 (50.0)	1 (50.0)	0	0	0
Lymphocyte count decreased	1 (50.0)	0	1 (50.0)	0	0
Neutrophil count decreased	1 (50.0)	0	1 (50.0)	0	0
White blood cell count decreased	1 (50.0)	0	1 (50.0)	0	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Hyperphosphataemia	1 (50.0)	1 (50.0)	0	0	0
Hyperuricaemia	1 (50.0)	1 (50.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Arthralgia	1 (50.0)	1 (50.0)	0	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	1 (50.0)	1 (50.0)	0	0	0
Pain in extremity	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					
-Total	2 (100)	2 (100)	0	0	0
Headache	2 (100)	2 (100)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Cough	1 (50.0)	1 (50.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Skin irritation	1 (50.0)	1 (50.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184f
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	61 (98.4)	1 (1.6)	7 (11.3)	14 (22.6)	39 (62.9)
Blood and lymphatic system disorders					
-Total	39 (62.9)	1 (1.6)	1 (1.6)	27 (43.5)	10 (16.1)
Anaemia	26 (41.9)	3 (4.8)	4 (6.5)	18 (29.0)	1 (1.6)
Febrile neutropenia	22 (35.5)	0	0	22 (35.5)	0
Neutropenia	8 (12.9)	0	0	3 (4.8)	5 (8.1)
Thrombocytopenia	8 (12.9)	0	0	2 (3.2)	6 (9.7)
Lymphopenia	3 (4.8)	0	1 (1.6)	1 (1.6)	1 (1.6)
Cardiac disorders					
-Total	19 (30.6)	10 (16.1)	7 (11.3)	2 (3.2)	0
Tachycardia	15 (24.2)	8 (12.9)	5 (8.1)	2 (3.2)	0
Sinus tachycardia	5 (8.1)	3 (4.8)	2 (3.2)	0	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	33 (53.2)	12 (19.4)	14 (22.6)	7 (11.3)	0
Vomiting	22 (35.5)	13 (21.0)	6 (9.7)	3 (4.8)	0
Nausea	21 (33.9)	6 (9.7)	12 (19.4)	3 (4.8)	0
Diarrhoea	18 (29.0)	11 (17.7)	6 (9.7)	1 (1.6)	0
Abdominal pain	9 (14.5)	6 (9.7)	2 (3.2)	1 (1.6)	0
Constipation	7 (11.3)	6 (9.7)	1 (1.6)	0	0
General disorders and administration site conditions					
-Total	27 (43.5)	11 (17.7)	8 (12.9)	7 (11.3)	1 (1.6)
Pyrexia	16 (25.8)	3 (4.8)	7 (11.3)	5 (8.1)	1 (1.6)
Fatigue	12 (19.4)	9 (14.5)	2 (3.2)	1 (1.6)	0
Chills	8 (12.9)	8 (12.9)	0	0	0
Pain	3 (4.8)	0	1 (1.6)	2 (3.2)	0
Immune system disorders					
-Total	55 (88.7)	4 (6.5)	29 (46.8)	11 (17.7)	11 (17.7)
Cytokine release syndrome	50 (80.6)	6 (9.7)	25 (40.3)	8 (12.9)	11 (17.7)
Hypogammaglobulinaemia	24 (38.7)	3 (4.8)	17 (27.4)	4 (6.5)	0
Infections and infestations					

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.6)	0	1 (1.6)	0	0
Upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Investigations					
-Total	46 (74.2)	1 (1.6)	3 (4.8)	11 (17.7)	31 (50.0)
White blood cell count decreased	29 (46.8)	3 (4.8)	0	10 (16.1)	16 (25.8)
Neutrophil count decreased	24 (38.7)	0	1 (1.6)	4 (6.5)	19 (30.6)
Alanine aminotransferase increased	19 (30.6)	5 (8.1)	3 (4.8)	11 (17.7)	0
Platelet count decreased	19 (30.6)	3 (4.8)	2 (3.2)	2 (3.2)	12 (19.4)
Aspartate aminotransferase increased	18 (29.0)	3 (4.8)	4 (6.5)	7 (11.3)	4 (6.5)
Lymphocyte count decreased	13 (21.0)	1 (1.6)	1 (1.6)	6 (9.7)	5 (8.1)
Blood creatinine increased	9 (14.5)	5 (8.1)	2 (3.2)	2 (3.2)	0
Prothrombin time prolonged	9 (14.5)	5 (8.1)	3 (4.8)	1 (1.6)	0
International normalised ratio increased	8 (12.9)	7 (11.3)	0	1 (1.6)	0
Blood bilirubin increased	7 (11.3)	2 (3.2)	3 (4.8)	2 (3.2)	0
Blood immunoglobulin a decreased	2 (3.2)	2 (3.2)	0	0	0
Blood uric acid increased	1 (1.6)	1 (1.6)	0	0	0
Metabolism and nutrition disorders					

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	33 (53.2)	6 (9.7)	8 (12.9)	17 (27.4)	2 (3.2)
Decreased appetite	20 (32.3)	4 (6.5)	4 (6.5)	12 (19.4)	0
Hypokalaemia	16 (25.8)	3 (4.8)	6 (9.7)	7 (11.3)	0
Hypophosphataemia	9 (14.5)	2 (3.2)	0	6 (9.7)	1 (1.6)
Hyperphosphataemia	7 (11.3)	7 (11.3)	0	0	0
Hyperuricaemia	2 (3.2)	1 (1.6)	0	0	1 (1.6)
Musculoskeletal and connective tissue disorders					
-Total	10 (16.1)	6 (9.7)	3 (4.8)	1 (1.6)	0
Myalgia	4 (6.5)	3 (4.8)	1 (1.6)	0	0
Arthralgia	3 (4.8)	2 (3.2)	0	1 (1.6)	0
Pain in extremity	3 (4.8)	1 (1.6)	2 (3.2)	0	0
Muscle spasms	1 (1.6)	1 (1.6)	0	0	0
Nervous system disorders					
-Total	22 (35.5)	14 (22.6)	6 (9.7)	2 (3.2)	0
Headache	22 (35.5)	14 (22.6)	6 (9.7)	2 (3.2)	0
Psychiatric disorders					
-Total	6 (9.7)	2 (3.2)	3 (4.8)	1 (1.6)	0
Anxiety	6 (9.7)	2 (3.2)	3 (4.8)	1 (1.6)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	7 (11.3)	1 (1.6)	1 (1.6)	2 (3.2)	3 (4.8)
Acute kidney injury	7 (11.3)	1 (1.6)	1 (1.6)	2 (3.2)	3 (4.8)
Respiratory, thoracic and mediastinal disorders					
-Total	20 (32.3)	5 (8.1)	4 (6.5)	6 (9.7)	5 (8.1)
Hypoxia	10 (16.1)	0	3 (4.8)	4 (6.5)	3 (4.8)
Pleural effusion	8 (12.9)	2 (3.2)	4 (6.5)	2 (3.2)	0
Cough	7 (11.3)	7 (11.3)	0	0	0
Epistaxis	7 (11.3)	2 (3.2)	1 (1.6)	3 (4.8)	1 (1.6)
Pulmonary oedema	6 (9.7)	1 (1.6)	0	3 (4.8)	2 (3.2)
Skin and subcutaneous tissue disorders					
-Total	8 (12.9)	6 (9.7)	1 (1.6)	1 (1.6)	0
Rash	4 (6.5)	4 (6.5)	0	0	0
Rash maculo-papular	3 (4.8)	1 (1.6)	1 (1.6)	1 (1.6)	0
Macule	1 (1.6)	1 (1.6)	0	0	0
Vascular disorders					
-Total	21 (33.9)	2 (3.2)	4 (6.5)	7 (11.3)	8 (12.9)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	16 (25.8)	1 (1.6)	0	7 (11.3)	8 (12.9)
Hypertension	10 (16.1)	2 (3.2)	7 (11.3)	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184f
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	1 (50.0)	0	1 (50.0)
Blood and lymphatic system disorders					
-Total	2 (100)	0	1 (50.0)	0	1 (50.0)
Eosinophilia	1 (50.0)	0	0	1 (50.0)	0
Lymphopenia	1 (50.0)	0	1 (50.0)	0	0
Neutropenia	1 (50.0)	0	0	0	1 (50.0)
Cardiac disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Sinus tachycardia	1 (50.0)	0	1 (50.0)	0	0
Gastrointestinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	1 (50.0)	0	0	0
Pigmentation lip	1 (50.0)	1 (50.0)	0	0	0
General disorders and administration site conditions					
-Total	1 (50.0)	0	1 (50.0)	0	0
Chills	1 (50.0)	1 (50.0)	0	0	0
Pain	1 (50.0)	1 (50.0)	0	0	0
Pyrexia	1 (50.0)	0	1 (50.0)	0	0
Immune system disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Graft versus host disease	1 (50.0)	1 (50.0)	0	0	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	0	0	1 (50.0)	0
Urinary tract infection	1 (50.0)	0	0	1 (50.0)	0
Investigations					
-Total	1 (50.0)	1 (50.0)	0	0	0
Blood uric acid increased	1 (50.0)	1 (50.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	1 (50.0)	1 (50.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Vitamin d deficiency	1 (50.0)	1 (50.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (100)	2 (100)	0	0	0
Joint range of motion decreased	2 (100)	2 (100)	0	0	0
Back pain	1 (50.0)	1 (50.0)	0	0	0
Muscle spasms	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Headache	1 (50.0)	1 (50.0)	0	0	0
Reproductive system and breast disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Scrotal pain	1 (50.0)	0	1 (50.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Macule	1 (50.0)	1 (50.0)	0	0	0
Rash maculo-papular	1 (50.0)	1 (50.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184f
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (68.5)	6 (11.1)	13 (24.1)	13 (24.1)	5 (9.3)
Blood and lymphatic system disorders					
-Total	7 (13.0)	1 (1.9)	1 (1.9)	3 (5.6)	2 (3.7)
Febrile neutropenia	3 (5.6)	0	0	3 (5.6)	0
Neutropenia	3 (5.6)	0	0	1 (1.9)	2 (3.7)
Anaemia	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Thrombocytopenia	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders					
-Total	14 (25.9)	8 (14.8)	4 (7.4)	2 (3.7)	0
Vomiting	9 (16.7)	5 (9.3)	2 (3.7)	2 (3.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	8 (14.8)	6 (11.1)	1 (1.9)	1 (1.9)	0
Nausea	6 (11.1)	1 (1.9)	3 (5.6)	2 (3.7)	0
Abdominal pain	4 (7.4)	2 (3.7)	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions					
-Total	10 (18.5)	8 (14.8)	1 (1.9)	1 (1.9)	0
Pyrexia	9 (16.7)	7 (13.0)	1 (1.9)	1 (1.9)	0
Fatigue	2 (3.7)	2 (3.7)	0	0	0
Immune system disorders					
-Total	9 (16.7)	0	8 (14.8)	1 (1.9)	0
Hypogammaglobulinaemia	8 (14.8)	0	7 (13.0)	1 (1.9)	0
Graft versus host disease	1 (1.9)	0	1 (1.9)	0	0
Infections and infestations					
-Total	10 (18.5)	2 (3.7)	6 (11.1)	2 (3.7)	0
Upper respiratory tract infection	7 (13.0)	3 (5.6)	3 (5.6)	1 (1.9)	0
Urinary tract infection	3 (5.6)	0	2 (3.7)	1 (1.9)	0
Otitis media	1 (1.9)	0	1 (1.9)	0	0
Injury, poisoning and procedural complications					

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.9)	1 (1.9)	0	0	0
Skin abrasion	1 (1.9)	1 (1.9)	0	0	0
Investigations					
-Total	15 (27.8)	2 (3.7)	1 (1.9)	8 (14.8)	4 (7.4)
Neutrophil count decreased	7 (13.0)	1 (1.9)	0	3 (5.6)	3 (5.6)
White blood cell count decreased	5 (9.3)	2 (3.7)	1 (1.9)	1 (1.9)	1 (1.9)
Aspartate aminotransferase increased	3 (5.6)	1 (1.9)	0	2 (3.7)	0
Platelet count decreased	3 (5.6)	3 (5.6)	0	0	0
Alanine aminotransferase increased	2 (3.7)	0	0	2 (3.7)	0
Lymphocyte count decreased	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Blood bilirubin increased	1 (1.9)	0	0	1 (1.9)	0
Blood creatinine increased	1 (1.9)	1 (1.9)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (9.3)	3 (5.6)	1 (1.9)	0	1 (1.9)
Decreased appetite	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Hyperphosphataemia	2 (3.7)	2 (3.7)	0	0	0
Hypokalaemia	2 (3.7)	1 (1.9)	0	0	1 (1.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	1 (1.9)	0	0	1 (1.9)	0
Musculoskeletal and connective tissue disorders					
-Total	10 (18.5)	7 (13.0)	3 (5.6)	0	0
Pain in extremity	8 (14.8)	6 (11.1)	2 (3.7)	0	0
Arthralgia	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Nervous system disorders					
-Total	4 (7.4)	3 (5.6)	1 (1.9)	0	0
Headache	4 (7.4)	3 (5.6)	1 (1.9)	0	0
Psychiatric disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Anxiety	1 (1.9)	1 (1.9)	0	0	0
Renal and urinary disorders					
-Total	1 (1.9)	0	0	1 (1.9)	0
Acute kidney injury	1 (1.9)	0	0	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (18.5)	6 (11.1)	2 (3.7)	2 (3.7)	0
Cough	7 (13.0)	5 (9.3)	2 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Pulmonary oedema	1 (1.9)	0	0	1 (1.9)	0
Skin and subcutaneous tissue disorders					
-Total	5 (9.3)	2 (3.7)	3 (5.6)	0	0
Rash	4 (7.4)	1 (1.9)	3 (5.6)	0	0
Rash maculo-papular	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					
-Total	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Hypertension	2 (3.7)	1 (1.9)	1 (1.9)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184f
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=1			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Diarrhoea	1 (100)	0	1 (100)	0	0
Infections and infestations					
-Total	1 (100)	0	0	1 (100)	0
Cellulitis of male external genital organ	1 (100)	0	0	1 (100)	0
Otitis media	1 (100)	0	1 (100)	0	0
Urinary tract infection	1 (100)	0	0	1 (100)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184f
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (45.5)	4 (12.1)	4 (12.1)	5 (15.2)	2 (6.1)
Blood and lymphatic system disorders					
-Total	2 (6.1)	1 (3.0)	0	0	1 (3.0)
Febrile neutropenia	1 (3.0)	0	0	0	1 (3.0)
Thrombocytopenia	1 (3.0)	1 (3.0)	0	0	0
Gastrointestinal disorders					
-Total	2 (6.1)	0	2 (6.1)	0	0
Abdominal pain	1 (3.0)	0	1 (3.0)	0	0
Diarrhoea	1 (3.0)	0	1 (3.0)	0	0
Nausea	1 (3.0)	0	1 (3.0)	0	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	1 (3.0)	0	1 (3.0)	0	0
Chills	1 (3.0)	0	1 (3.0)	0	0
Pyrexia	1 (3.0)	0	1 (3.0)	0	0
Infections and infestations					
-Total	5 (15.2)	1 (3.0)	3 (9.1)	1 (3.0)	0
Otitis media	2 (6.1)	0	1 (3.0)	1 (3.0)	0
Upper respiratory tract infection	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Urinary tract infection	1 (3.0)	0	1 (3.0)	0	0
Investigations					
-Total	8 (24.2)	1 (3.0)	2 (6.1)	4 (12.1)	1 (3.0)
White blood cell count decreased	4 (12.1)	1 (3.0)	0	2 (6.1)	1 (3.0)
Alanine aminotransferase increased	3 (9.1)	0	1 (3.0)	2 (6.1)	0
Lymphocyte count decreased	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Aspartate aminotransferase increased	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Neutrophil count decreased	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Platelet count decreased	1 (3.0)	0	0	1 (3.0)	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Hypokalaemia	1 (3.0)	0	0	1 (3.0)	0
Vitamin d deficiency	1 (3.0)	1 (3.0)	0	0	0
Nervous system disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Headache	1 (3.0)	0	1 (3.0)	0	0
Renal and urinary disorders					
-Total	1 (3.0)	0	0	1 (3.0)	0
Acute kidney injury	1 (3.0)	0	0	1 (3.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (9.1)	3 (9.1)	0	0	0
Cough	2 (6.1)	2 (6.1)	0	0	0
Epistaxis	1 (3.0)	1 (3.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184f
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	1 (50.0)	0	1 (50.0)
Blood and lymphatic system disorders					
-Total	2 (100)	0	1 (50.0)	0	1 (50.0)
Anaemia	1 (50.0)	0	1 (50.0)	0	0
Eosinophilia	1 (50.0)	0	0	1 (50.0)	0
Lymphopenia	1 (50.0)	0	1 (50.0)	0	0
Neutropenia	1 (50.0)	0	0	0	1 (50.0)
Cardiac disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Sinus tachycardia	1 (50.0)	0	1 (50.0)	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Diarrhoea	1 (50.0)	0	1 (50.0)	0	0
Pigmentation lip	1 (50.0)	1 (50.0)	0	0	0
General disorders and administration site conditions					
-Total	2 (100)	1 (50.0)	1 (50.0)	0	0
Chills	1 (50.0)	1 (50.0)	0	0	0
Fatigue	1 (50.0)	1 (50.0)	0	0	0
Pain	1 (50.0)	1 (50.0)	0	0	0
Pyrexia	1 (50.0)	0	1 (50.0)	0	0
Immune system disorders					
-Total	2 (100)	1 (50.0)	1 (50.0)	0	0
Graft versus host disease	1 (50.0)	1 (50.0)	0	0	0
Graft versus host disease in skin	1 (50.0)	1 (50.0)	0	0	0
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis of male external genital organ	1 (50.0)	0	0	1 (50.0)	0
Otitis media	1 (50.0)	0	1 (50.0)	0	0
Urinary tract infection	1 (50.0)	0	0	1 (50.0)	0
Injury, poisoning and procedural complications					
-Total	1 (50.0)	1 (50.0)	0	0	0
Skin abrasion	1 (50.0)	1 (50.0)	0	0	0
Investigations					
-Total	1 (50.0)	0	1 (50.0)	0	0
Blood immunoglobulin a decreased	1 (50.0)	1 (50.0)	0	0	0
Blood uric acid increased	1 (50.0)	1 (50.0)	0	0	0
International normalised ratio increased	1 (50.0)	1 (50.0)	0	0	0
Lymphocyte count decreased	1 (50.0)	0	1 (50.0)	0	0
Neutrophil count decreased	1 (50.0)	0	1 (50.0)	0	0
White blood cell count decreased	1 (50.0)	0	1 (50.0)	0	0
Metabolism and nutrition disorders					
-Total	2 (100)	2 (100)	0	0	0
Hyperphosphataemia	1 (50.0)	1 (50.0)	0	0	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	1 (50.0)	1 (50.0)	0	0	0
Vitamin d deficiency	1 (50.0)	1 (50.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (100)	2 (100)	0	0	0
Joint range of motion decreased	2 (100)	2 (100)	0	0	0
Arthralgia	1 (50.0)	1 (50.0)	0	0	0
Back pain	1 (50.0)	1 (50.0)	0	0	0
Muscle spasms	1 (50.0)	1 (50.0)	0	0	0
Myalgia	1 (50.0)	1 (50.0)	0	0	0
Pain in extremity	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					
-Total	2 (100)	2 (100)	0	0	0
Headache	2 (100)	2 (100)	0	0	0
Reproductive system and breast disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Scrotal pain	1 (50.0)	0	1 (50.0)	0	0
Respiratory, thoracic and mediastinal disorders					

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	1 (50.0)	0	0	0
Cough	1 (50.0)	1 (50.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Macule	1 (50.0)	1 (50.0)	0	0	0
Rash maculo-papular	1 (50.0)	1 (50.0)	0	0	0
Skin irritation	1 (50.0)	1 (50.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184f
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	62 (100)	1 (1.6)	5 (8.1)	14 (22.6)	42 (67.7)
Blood and lymphatic system disorders					
-Total	42 (67.7)	1 (1.6)	1 (1.6)	27 (43.5)	13 (21.0)
Anaemia	26 (41.9)	3 (4.8)	3 (4.8)	19 (30.6)	1 (1.6)
Febrile neutropenia	24 (38.7)	0	0	23 (37.1)	1 (1.6)
Neutropenia	10 (16.1)	0	0	3 (4.8)	7 (11.3)
Thrombocytopenia	10 (16.1)	0	1 (1.6)	3 (4.8)	6 (9.7)
Lymphopenia	3 (4.8)	0	1 (1.6)	1 (1.6)	1 (1.6)
Cardiac disorders					
-Total	19 (30.6)	10 (16.1)	7 (11.3)	2 (3.2)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	15 (24.2)	8 (12.9)	5 (8.1)	2 (3.2)	0
Sinus tachycardia	5 (8.1)	3 (4.8)	2 (3.2)	0	0
Gastrointestinal disorders					
-Total	38 (61.3)	14 (22.6)	17 (27.4)	7 (11.3)	0
Vomiting	27 (43.5)	16 (25.8)	8 (12.9)	3 (4.8)	0
Nausea	25 (40.3)	6 (9.7)	14 (22.6)	5 (8.1)	0
Diarrhoea	23 (37.1)	13 (21.0)	8 (12.9)	2 (3.2)	0
Abdominal pain	11 (17.7)	6 (9.7)	4 (6.5)	1 (1.6)	0
Constipation	7 (11.3)	6 (9.7)	1 (1.6)	0	0
General disorders and administration site conditions					
-Total	33 (53.2)	14 (22.6)	10 (16.1)	8 (12.9)	1 (1.6)
Pyrexia	24 (38.7)	8 (12.9)	9 (14.5)	6 (9.7)	1 (1.6)
Fatigue	14 (22.6)	11 (17.7)	2 (3.2)	1 (1.6)	0
Chills	9 (14.5)	8 (12.9)	1 (1.6)	0	0
Pain	3 (4.8)	0	1 (1.6)	2 (3.2)	0
Immune system disorders					
-Total	56 (90.3)	4 (6.5)	30 (48.4)	11 (17.7)	11 (17.7)
Cytokine release syndrome	50 (80.6)	6 (9.7)	25 (40.3)	8 (12.9)	11 (17.7)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	31 (50.0)	3 (4.8)	23 (37.1)	5 (8.1)	0
Graft versus host disease	1 (1.6)	0	1 (1.6)	0	0
Infections and infestations					
-Total	15 (24.2)	3 (4.8)	9 (14.5)	3 (4.8)	0
Upper respiratory tract infection	9 (14.5)	4 (6.5)	4 (6.5)	1 (1.6)	0
Urinary tract infection	4 (6.5)	0	3 (4.8)	1 (1.6)	0
Otitis media	3 (4.8)	0	2 (3.2)	1 (1.6)	0
Injury, poisoning and procedural complications					
-Total	1 (1.6)	1 (1.6)	0	0	0
Skin abrasion	1 (1.6)	1 (1.6)	0	0	0
Investigations					
-Total	51 (82.3)	0	4 (6.5)	13 (21.0)	34 (54.8)
White blood cell count decreased	34 (54.8)	4 (6.5)	0	12 (19.4)	18 (29.0)
Neutrophil count decreased	27 (43.5)	1 (1.6)	1 (1.6)	4 (6.5)	21 (33.9)
Alanine aminotransferase increased	21 (33.9)	5 (8.1)	2 (3.2)	14 (22.6)	0
Aspartate aminotransferase increased	20 (32.3)	4 (6.5)	4 (6.5)	8 (12.9)	4 (6.5)
Platelet count decreased	20 (32.3)	3 (4.8)	2 (3.2)	3 (4.8)	12 (19.4)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	15 (24.2)	1 (1.6)	2 (3.2)	7 (11.3)	5 (8.1)
Blood creatinine increased	9 (14.5)	5 (8.1)	2 (3.2)	2 (3.2)	0
Prothrombin time prolonged	9 (14.5)	5 (8.1)	3 (4.8)	1 (1.6)	0
Blood bilirubin increased	8 (12.9)	2 (3.2)	3 (4.8)	3 (4.8)	0
International normalised ratio increased	8 (12.9)	7 (11.3)	0	1 (1.6)	0
Blood immunoglobulin a decreased	2 (3.2)	2 (3.2)	0	0	0
Blood uric acid increased	1 (1.6)	1 (1.6)	0	0	0
Metabolism and nutrition disorders					
-Total	36 (58.1)	7 (11.3)	8 (12.9)	18 (29.0)	3 (4.8)
Decreased appetite	22 (35.5)	5 (8.1)	5 (8.1)	12 (19.4)	0
Hypokalaemia	19 (30.6)	4 (6.5)	6 (9.7)	8 (12.9)	1 (1.6)
Hypophosphataemia	10 (16.1)	2 (3.2)	0	7 (11.3)	1 (1.6)
Hyperphosphataemia	7 (11.3)	7 (11.3)	0	0	0
Hyperuricaemia	2 (3.2)	1 (1.6)	0	0	1 (1.6)
Vitamin d deficiency	1 (1.6)	1 (1.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	16 (25.8)	10 (16.1)	5 (8.1)	1 (1.6)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

			All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	10 (16.1)	6 (9.7)	4 (6.5)	0	0
Arthralgia	4 (6.5)	2 (3.2)	1 (1.6)	1 (1.6)	0
Myalgia	4 (6.5)	3 (4.8)	1 (1.6)	0	0
Muscle spasms	1 (1.6)	1 (1.6)	0	0	0
Nervous system disorders					
-Total	22 (35.5)	13 (21.0)	7 (11.3)	2 (3.2)	0
Headache	22 (35.5)	13 (21.0)	7 (11.3)	2 (3.2)	0
Psychiatric disorders					
-Total	7 (11.3)	3 (4.8)	3 (4.8)	1 (1.6)	0
Anxiety	7 (11.3)	3 (4.8)	3 (4.8)	1 (1.6)	0
Renal and urinary disorders					
-Total	9 (14.5)	1 (1.6)	1 (1.6)	4 (6.5)	3 (4.8)
Acute kidney injury	9 (14.5)	1 (1.6)	1 (1.6)	4 (6.5)	3 (4.8)
Respiratory, thoracic and mediastinal disorders					
-Total	27 (43.5)	9 (14.5)	5 (8.1)	8 (12.9)	5 (8.1)
Cough	13 (21.0)	11 (17.7)	2 (3.2)	0	0
Epistaxis	10 (16.1)	4 (6.5)	1 (1.6)	4 (6.5)	1 (1.6)
Hypoxia	10 (16.1)	0	3 (4.8)	4 (6.5)	3 (4.8)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	8 (12.9)	2 (3.2)	4 (6.5)	2 (3.2)	0
Pulmonary oedema	7 (11.3)	1 (1.6)	0	4 (6.5)	2 (3.2)
Skin and subcutaneous tissue disorders					
-Total	13 (21.0)	8 (12.9)	4 (6.5)	1 (1.6)	0
Rash	8 (12.9)	5 (8.1)	3 (4.8)	0	0
Rash maculo-papular	4 (6.5)	2 (3.2)	1 (1.6)	1 (1.6)	0
Macule	1 (1.6)	1 (1.6)	0	0	0
Vascular disorders					
-Total	22 (35.5)	2 (3.2)	5 (8.1)	7 (11.3)	8 (12.9)
Hypotension	16 (25.8)	1 (1.6)	0	7 (11.3)	8 (12.9)
Hypertension	12 (19.4)	3 (4.8)	8 (12.9)	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184g
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Anaemia	2 (66.7)	0	0	2 (66.7)	0
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	0	0	1 (33.3)
Cardiac disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Bradycardia	1 (33.3)	0	1 (33.3)	0	0
Left ventricular dysfunction	1 (33.3)	0	0	1 (33.3)	0
Pericardial effusion	1 (33.3)	0	1 (33.3)	0	0
Tachycardia	1 (33.3)	0	0	1 (33.3)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Conjunctival haemorrhage	1 (33.3)	1 (33.3)	0	0	0
Periorbital oedema	1 (33.3)	1 (33.3)	0	0	0
Gastrointestinal disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Diarrhoea	1 (33.3)	0	1 (33.3)	0	0
Dysphagia	1 (33.3)	0	0	1 (33.3)	0
Nausea	1 (33.3)	0	0	1 (33.3)	0
Vomiting	1 (33.3)	0	1 (33.3)	0	0
General disorders and administration site conditions					
-Total	2 (66.7)	0	0	2 (66.7)	0
Asthenia	1 (33.3)	1 (33.3)	0	0	0
Chills	1 (33.3)	1 (33.3)	0	0	0
Face oedema	1 (33.3)	0	0	1 (33.3)	0
Localised oedema	1 (33.3)	0	0	1 (33.3)	0
Mucosal haemorrhage	1 (33.3)	0	1 (33.3)	0	0
Multiple organ dysfunction syndrome	1 (33.3)	0	0	1 (33.3)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	1 (33.3)	0	0	1 (33.3)	0
Pyrexia	1 (33.3)	0	0	1 (33.3)	0
Hepatobiliary disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Hepatomegaly	1 (33.3)	0	1 (33.3)	0	0
Hyperbilirubinaemia	1 (33.3)	0	0	1 (33.3)	0
Immune system disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	0	0	2 (66.7)
Injury, poisoning and procedural complications					
-Total	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Procedural complication	1 (33.3)	1 (33.3)	0	0	0
Tracheal haemorrhage	1 (33.3)	0	0	1 (33.3)	0
Investigations					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Aspartate aminotransferase increased	2 (66.7)	0	0	0	2 (66.7)
Blood fibrinogen decreased	2 (66.7)	0	1 (33.3)	0	1 (33.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (33.3)	0	0	1 (33.3)	0
Blood creatinine increased	1 (33.3)	0	0	1 (33.3)	0
Blood phosphorus decreased	1 (33.3)	1 (33.3)	0	0	0
Blood urea increased	1 (33.3)	0	0	1 (33.3)	0
International normalised ratio increased	1 (33.3)	1 (33.3)	0	0	0
Neutrophil count decreased	1 (33.3)	0	0	1 (33.3)	0
Platelet count decreased	1 (33.3)	0	0	1 (33.3)	0
Protein total decreased	1 (33.3)	0	0	1 (33.3)	0
Prothrombin time prolonged	1 (33.3)	0	1 (33.3)	0	0
White blood cell count decreased	1 (33.3)	0	0	1 (33.3)	0
Metabolism and nutrition disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Hypokalaemia	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Hypophosphataemia	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Acidosis	1 (33.3)	0	0	1 (33.3)	0
Decreased appetite	1 (33.3)	0	0	1 (33.3)	0
Hyperalbuminaemia	1 (33.3)	1 (33.3)	0	0	0
Hypercalcaemia	1 (33.3)	1 (33.3)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperchloraemia	1 (33.3)	1 (33.3)	0	0	0
Hypermagnesaemia	1 (33.3)	1 (33.3)	0	0	0
Hypernatraemia	1 (33.3)	0	1 (33.3)	0	0
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)	0	0
Metabolic alkalosis	1 (33.3)	1 (33.3)	0	0	0
Nervous system disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Dizziness	1 (33.3)	1 (33.3)	0	0	0
Psychiatric disorders					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Confusional state	1 (33.3)	1 (33.3)	0	0	0
Delirium	1 (33.3)	0	1 (33.3)	0	0
Insomnia	1 (33.3)	0	1 (33.3)	0	0
Irritability	1 (33.3)	1 (33.3)	0	0	0
Renal and urinary disorders					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Acute kidney injury	1 (33.3)	0	0	0	1 (33.3)
Haematuria	1 (33.3)	0	0	1 (33.3)	0
Renal impairment	1 (33.3)	0	0	1 (33.3)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Pleural effusion	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Pulmonary oedema	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Cough	1 (33.3)	1 (33.3)	0	0	0
Dyspnoea	1 (33.3)	0	0	0	1 (33.3)
Epistaxis	1 (33.3)	0	1 (33.3)	0	0
Hypoxia	1 (33.3)	0	0	0	1 (33.3)
Interstitial lung disease	1 (33.3)	0	0	0	1 (33.3)
Respiratory distress	1 (33.3)	0	0	0	1 (33.3)
Skin and subcutaneous tissue disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Hyperhidrosis	1 (33.3)	1 (33.3)	0	0	0
Rash papular	1 (33.3)	1 (33.3)	0	0	0
Vascular disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Hypertension	2 (66.7)	0	2 (66.7)	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	2 (66.7)	0	0	0	2 (66.7)
Capillary leak syndrome	1 (33.3)	0	0	0	1 (33.3)
Flushing	1 (33.3)	1 (33.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184g
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	60 (98.4)	2 (3.3)	8 (13.1)	13 (21.3)	37 (60.7)
Blood and lymphatic system disorders					
-Total	38 (62.3)	1 (1.6)	2 (3.3)	27 (44.3)	8 (13.1)
Anaemia	25 (41.0)	3 (4.9)	5 (8.2)	16 (26.2)	1 (1.6)
Febrile neutropenia	22 (36.1)	0	0	22 (36.1)	0
Neutropenia	7 (11.5)	0	0	3 (4.9)	4 (6.6)
Thrombocytopenia	7 (11.5)	0	0	2 (3.3)	5 (8.2)
Cardiac disorders					
-Total	14 (23.0)	8 (13.1)	5 (8.2)	1 (1.6)	0
Tachycardia	14 (23.0)	8 (13.1)	5 (8.2)	1 (1.6)	0
Pericardial effusion	1 (1.6)	1 (1.6)	0	0	0
Eye disorders					

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Periorbital oedema	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Conjunctival haemorrhage	2 (3.3)	2 (3.3)	0	0	0
Gastrointestinal disorders					
-Total	32 (52.5)	12 (19.7)	14 (23.0)	6 (9.8)	0
Vomiting	21 (34.4)	13 (21.3)	5 (8.2)	3 (4.9)	0
Nausea	20 (32.8)	6 (9.8)	12 (19.7)	2 (3.3)	0
Diarrhoea	17 (27.9)	11 (18.0)	5 (8.2)	1 (1.6)	0
Abdominal pain	9 (14.8)	6 (9.8)	2 (3.3)	1 (1.6)	0
Constipation	7 (11.5)	6 (9.8)	1 (1.6)	0	0
Dysphagia	1 (1.6)	0	1 (1.6)	0	0
General disorders and administration site conditions					
-Total	27 (44.3)	13 (21.3)	8 (13.1)	5 (8.2)	1 (1.6)
Pyrexia	15 (24.6)	3 (4.9)	7 (11.5)	4 (6.6)	1 (1.6)
Fatigue	13 (21.3)	10 (16.4)	2 (3.3)	1 (1.6)	0
Chills	7 (11.5)	7 (11.5)	0	0	0
Face oedema	1 (1.6)	0	1 (1.6)	0	0
Oedema peripheral	1 (1.6)	1 (1.6)	0	0	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	3 (4.9)	1 (1.6)	1 (1.6)	1 (1.6)	0
Hepatomegaly	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Hyperbilirubinaemia	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Immune system disorders					
-Total	54 (88.5)	4 (6.6)	30 (49.2)	11 (18.0)	9 (14.8)
Cytokine release syndrome	48 (78.7)	6 (9.8)	25 (41.0)	8 (13.1)	9 (14.8)
Hypogammaglobulinaemia	25 (41.0)	3 (4.9)	18 (29.5)	4 (6.6)	0
Infections and infestations					
-Total	1 (1.6)	0	1 (1.6)	0	0
Upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Investigations					
-Total	44 (72.1)	1 (1.6)	4 (6.6)	10 (16.4)	29 (47.5)
White blood cell count decreased	29 (47.5)	3 (4.9)	1 (1.6)	9 (14.8)	16 (26.2)
Neutrophil count decreased	24 (39.3)	0	2 (3.3)	3 (4.9)	19 (31.1)
Alanine aminotransferase increased	18 (29.5)	5 (8.2)	3 (4.9)	10 (16.4)	0
Platelet count decreased	18 (29.5)	3 (4.9)	2 (3.3)	1 (1.6)	12 (19.7)
Aspartate aminotransferase increased	16 (26.2)	3 (4.9)	4 (6.6)	7 (11.5)	2 (3.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	14 (23.0)	1 (1.6)	2 (3.3)	6 (9.8)	5 (8.2)
Blood creatinine increased	8 (13.1)	5 (8.2)	2 (3.3)	1 (1.6)	0
International normalised ratio increased	8 (13.1)	7 (11.5)	0	1 (1.6)	0
Prothrombin time prolonged	8 (13.1)	5 (8.2)	2 (3.3)	1 (1.6)	0
Blood bilirubin increased	7 (11.5)	2 (3.3)	3 (4.9)	2 (3.3)	0
Blood fibrinogen decreased	2 (3.3)	0	0	2 (3.3)	0
Blood urea increased	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Metabolism and nutrition disorders					
-Total	33 (54.1)	8 (13.1)	8 (13.1)	15 (24.6)	2 (3.3)
Decreased appetite	19 (31.1)	4 (6.6)	4 (6.6)	11 (18.0)	0
Hypokalaemia	14 (23.0)	2 (3.3)	6 (9.8)	6 (9.8)	0
Hyperphosphataemia	8 (13.1)	8 (13.1)	0	0	0
Hypophosphataemia	7 (11.5)	1 (1.6)	0	5 (8.2)	1 (1.6)
Hypoalbuminaemia	4 (6.6)	1 (1.6)	2 (3.3)	1 (1.6)	0
Hypernatraemia	3 (4.9)	1 (1.6)	1 (1.6)	0	1 (1.6)
Acidosis	1 (1.6)	1 (1.6)	0	0	0
Musculoskeletal and connective tissue disorders					

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (6.6)	2 (3.3)	2 (3.3)	0	0
Pain in extremity	4 (6.6)	2 (3.3)	2 (3.3)	0	0
Nervous system disorders					
-Total	25 (41.0)	17 (27.9)	6 (9.8)	2 (3.3)	0
Headache	24 (39.3)	16 (26.2)	6 (9.8)	2 (3.3)	0
Dizziness	3 (4.9)	3 (4.9)	0	0	0
Psychiatric disorders					
-Total	12 (19.7)	6 (9.8)	5 (8.2)	1 (1.6)	0
Anxiety	6 (9.8)	2 (3.3)	3 (4.9)	1 (1.6)	0
Confusional state	5 (8.2)	2 (3.3)	3 (4.9)	0	0
Delirium	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Irritability	1 (1.6)	1 (1.6)	0	0	0
Renal and urinary disorders					
-Total	7 (11.5)	1 (1.6)	1 (1.6)	2 (3.3)	3 (4.9)
Acute kidney injury	6 (9.8)	1 (1.6)	1 (1.6)	2 (3.3)	2 (3.3)
Haematuria	3 (4.9)	0	2 (3.3)	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders					
-Total	19 (31.1)	6 (9.8)	4 (6.6)	5 (8.2)	4 (6.6)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	9 (14.8)	0	3 (4.9)	4 (6.6)	2 (3.3)
Cough	7 (11.5)	7 (11.5)	0	0	0
Epistaxis	6 (9.8)	2 (3.3)	0	3 (4.9)	1 (1.6)
Pleural effusion	6 (9.8)	2 (3.3)	3 (4.9)	1 (1.6)	0
Pulmonary oedema	4 (6.6)	1 (1.6)	0	2 (3.3)	1 (1.6)
Dyspnoea	1 (1.6)	0	0	1 (1.6)	0
Skin and subcutaneous tissue disorders					
-Total	7 (11.5)	7 (11.5)	0	0	0
Rash	4 (6.6)	4 (6.6)	0	0	0
Hyperhidrosis	2 (3.3)	2 (3.3)	0	0	0
Rash papular	1 (1.6)	1 (1.6)	0	0	0
Vascular disorders					
-Total	19 (31.1)	2 (3.3)	4 (6.6)	7 (11.5)	6 (9.8)
Hypotension	14 (23.0)	1 (1.6)	0	7 (11.5)	6 (9.8)
Hypertension	8 (13.1)	2 (3.3)	5 (8.2)	1 (1.6)	0
Flushing	1 (1.6)	1 (1.6)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184g
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	0	0	1 (50.0)
Blood and lymphatic system disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Leukopenia	1 (50.0)	0	0	0	1 (50.0)
Immune system disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Hypogammaglobulinaemia	1 (50.0)	0	0	1 (50.0)	0
Infections and infestations					
-Total	1 (50.0)	1 (50.0)	0	0	0
Upper respiratory tract infection	1 (50.0)	1 (50.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	1 (50.0)	1 (50.0)	0	0	0
Blood urea increased	1 (50.0)	1 (50.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Hyperalbuminaemia	1 (50.0)	1 (50.0)	0	0	0
Hypercalcaemia	1 (50.0)	1 (50.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Papule	1 (50.0)	1 (50.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184g
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (70.4)	8 (14.8)	12 (22.2)	12 (22.2)	6 (11.1)
Blood and lymphatic system disorders					
-Total	8 (14.8)	1 (1.9)	1 (1.9)	3 (5.6)	3 (5.6)
Neutropenia	4 (7.4)	0	0	1 (1.9)	3 (5.6)
Febrile neutropenia	3 (5.6)	0	0	3 (5.6)	0
Anaemia	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Thrombocytopenia	2 (3.7)	0	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders					
-Total	14 (25.9)	8 (14.8)	4 (7.4)	2 (3.7)	0
Vomiting	9 (16.7)	5 (9.3)	2 (3.7)	2 (3.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	8 (14.8)	6 (11.1)	1 (1.9)	1 (1.9)	0
Nausea	6 (11.1)	1 (1.9)	3 (5.6)	2 (3.7)	0
Abdominal pain	4 (7.4)	2 (3.7)	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions					
-Total	12 (22.2)	9 (16.7)	2 (3.7)	1 (1.9)	0
Pyrexia	10 (18.5)	7 (13.0)	2 (3.7)	1 (1.9)	0
Fatigue	2 (3.7)	2 (3.7)	0	0	0
Chills	1 (1.9)	1 (1.9)	0	0	0
Oedema peripheral	1 (1.9)	1 (1.9)	0	0	0
Immune system disorders					
-Total	7 (13.0)	0	7 (13.0)	0	0
Hypogammaglobulinaemia	7 (13.0)	0	7 (13.0)	0	0
Infections and infestations					
-Total	6 (11.1)	2 (3.7)	3 (5.6)	1 (1.9)	0
Upper respiratory tract infection	6 (11.1)	2 (3.7)	3 (5.6)	1 (1.9)	0
Investigations					
-Total	16 (29.6)	3 (5.6)	1 (1.9)	8 (14.8)	4 (7.4)
Neutrophil count decreased	8 (14.8)	2 (3.7)	0	3 (5.6)	3 (5.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	5 (9.3)	2 (3.7)	1 (1.9)	1 (1.9)	1 (1.9)
Aspartate aminotransferase increased	3 (5.6)	1 (1.9)	0	2 (3.7)	0
Platelet count decreased	3 (5.6)	3 (5.6)	0	0	0
Alanine aminotransferase increased	2 (3.7)	0	0	2 (3.7)	0
Lymphocyte count decreased	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Blood bilirubin increased	1 (1.9)	0	0	1 (1.9)	0
Blood creatinine increased	1 (1.9)	1 (1.9)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (9.3)	3 (5.6)	1 (1.9)	0	1 (1.9)
Decreased appetite	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Hyperphosphataemia	2 (3.7)	2 (3.7)	0	0	0
Hypokalaemia	2 (3.7)	1 (1.9)	0	0	1 (1.9)
Hypophosphataemia	1 (1.9)	0	0	1 (1.9)	0
Musculoskeletal and connective tissue disorders					
-Total	8 (14.8)	6 (11.1)	2 (3.7)	0	0
Pain in extremity	8 (14.8)	6 (11.1)	2 (3.7)	0	0
Nervous system disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (11.1)	5 (9.3)	1 (1.9)	0	0
Headache	5 (9.3)	4 (7.4)	1 (1.9)	0	0
Dizziness	3 (5.6)	3 (5.6)	0	0	0
Psychiatric disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Anxiety	1 (1.9)	1 (1.9)	0	0	0
Renal and urinary disorders					
-Total	2 (3.7)	0	0	2 (3.7)	0
Acute kidney injury	1 (1.9)	0	0	1 (1.9)	0
Haematuria	1 (1.9)	0	0	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (18.5)	6 (11.1)	2 (3.7)	2 (3.7)	0
Cough	7 (13.0)	5 (9.3)	2 (3.7)	0	0
Epistaxis	2 (3.7)	1 (1.9)	0	1 (1.9)	0
Pulmonary oedema	1 (1.9)	0	0	1 (1.9)	0
Skin and subcutaneous tissue disorders					
-Total	5 (9.3)	2 (3.7)	3 (5.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	4 (7.4)	1 (1.9)	3 (5.6)	0	0
Hyperhidrosis	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					
-Total	2 (3.7)	1 (1.9)	1 (1.9)	0	0
Hypertension	2 (3.7)	1 (1.9)	1 (1.9)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184g
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (45.5)	5 (15.2)	4 (12.1)	4 (12.1)	2 (6.1)
Blood and lymphatic system disorders					
-Total	2 (6.1)	1 (3.0)	0	0	1 (3.0)
Febrile neutropenia	1 (3.0)	0	0	0	1 (3.0)
Thrombocytopenia	1 (3.0)	1 (3.0)	0	0	0
Gastrointestinal disorders					
-Total	3 (9.1)	0	3 (9.1)	0	0
Diarrhoea	2 (6.1)	0	2 (6.1)	0	0
Abdominal pain	1 (3.0)	0	1 (3.0)	0	0
Nausea	1 (3.0)	0	1 (3.0)	0	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	1 (3.0)	0	1 (3.0)	0	0
Chills	1 (3.0)	0	1 (3.0)	0	0
Pyrexia	1 (3.0)	0	1 (3.0)	0	0
Infections and infestations					
-Total	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Upper respiratory tract infection	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Investigations					
-Total	8 (24.2)	1 (3.0)	2 (6.1)	4 (12.1)	1 (3.0)
White blood cell count decreased	4 (12.1)	1 (3.0)	0	2 (6.1)	1 (3.0)
Alanine aminotransferase increased	3 (9.1)	0	1 (3.0)	2 (6.1)	0
Lymphocyte count decreased	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Aspartate aminotransferase increased	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Neutrophil count decreased	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Platelet count decreased	1 (3.0)	0	0	1 (3.0)	0
Metabolism and nutrition disorders					
-Total	1 (3.0)	0	0	1 (3.0)	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	1 (3.0)	0	0	1 (3.0)	0
Nervous system disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0
Dizziness	1 (3.0)	1 (3.0)	0	0	0
Headache	1 (3.0)	0	1 (3.0)	0	0
Renal and urinary disorders					
-Total	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Acute kidney injury	1 (3.0)	0	0	1 (3.0)	0
Haematuria	1 (3.0)	1 (3.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (9.1)	3 (9.1)	0	0	0
Cough	2 (6.1)	2 (6.1)	0	0	0
Epistaxis	1 (3.0)	1 (3.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (3.0)	1 (3.0)	0	0	0
Papule	1 (3.0)	1 (3.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184g
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

			All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Anaemia	2 (66.7)	0	0	2 (66.7)	0
Leukopenia	1 (33.3)	0	0	0	1 (33.3)
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	0	0	1 (33.3)
Cardiac disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Bradycardia	1 (33.3)	0	1 (33.3)	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (33.3)	0	0	1 (33.3)	0
Pericardial effusion	1 (33.3)	0	1 (33.3)	0	0
Tachycardia	1 (33.3)	0	0	1 (33.3)	0
Eye disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Conjunctival haemorrhage	1 (33.3)	1 (33.3)	0	0	0
Periorbital oedema	1 (33.3)	1 (33.3)	0	0	0
Gastrointestinal disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Diarrhoea	1 (33.3)	0	1 (33.3)	0	0
Dysphagia	1 (33.3)	0	0	1 (33.3)	0
Nausea	1 (33.3)	0	0	1 (33.3)	0
Vomiting	1 (33.3)	0	1 (33.3)	0	0
General disorders and administration site conditions					
-Total	2 (66.7)	0	0	2 (66.7)	0
Asthenia	1 (33.3)	1 (33.3)	0	0	0
Chills	1 (33.3)	1 (33.3)	0	0	0
Face oedema	1 (33.3)	0	0	1 (33.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Localised oedema	1 (33.3)	0	0	1 (33.3)	0
Mucosal haemorrhage	1 (33.3)	0	1 (33.3)	0	0
Multiple organ dysfunction syndrome	1 (33.3)	0	0	1 (33.3)	0
Oedema peripheral	1 (33.3)	0	0	1 (33.3)	0
Pyrexia	1 (33.3)	0	0	1 (33.3)	0
Hepatobiliary disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Hepatomegaly	1 (33.3)	0	1 (33.3)	0	0
Hyperbilirubinaemia	1 (33.3)	0	0	1 (33.3)	0
Immune system disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	0	0	2 (66.7)
Hypogammaglobulinaemia	1 (33.3)	0	0	1 (33.3)	0
Infections and infestations					
-Total	1 (33.3)	1 (33.3)	0	0	0
Upper respiratory tract infection	1 (33.3)	1 (33.3)	0	0	0
Injury, poisoning and procedural complications					

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Procedural complication	1 (33.3)	1 (33.3)	0	0	0
Tracheal haemorrhage	1 (33.3)	0	0	1 (33.3)	0
Investigations					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Aspartate aminotransferase increased	2 (66.7)	0	0	0	2 (66.7)
Blood fibrinogen decreased	2 (66.7)	0	1 (33.3)	0	1 (33.3)
Alanine aminotransferase increased	1 (33.3)	0	0	1 (33.3)	0
Blood creatinine increased	1 (33.3)	0	0	1 (33.3)	0
Blood phosphorus decreased	1 (33.3)	1 (33.3)	0	0	0
Blood urea increased	1 (33.3)	0	0	1 (33.3)	0
International normalised ratio increased	1 (33.3)	1 (33.3)	0	0	0
Neutrophil count decreased	1 (33.3)	0	0	1 (33.3)	0
Platelet count decreased	1 (33.3)	0	0	1 (33.3)	0
Protein total decreased	1 (33.3)	0	0	1 (33.3)	0
Prothrombin time prolonged	1 (33.3)	0	1 (33.3)	0	0
White blood cell count decreased	1 (33.3)	0	0	1 (33.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Hypokalaemia	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Hypophosphataemia	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Acidosis	1 (33.3)	0	0	1 (33.3)	0
Decreased appetite	1 (33.3)	0	0	1 (33.3)	0
Hyperalbuminaemia	1 (33.3)	1 (33.3)	0	0	0
Hypercalcaemia	1 (33.3)	1 (33.3)	0	0	0
Hyperchloraemia	1 (33.3)	1 (33.3)	0	0	0
Hypermagnesaemia	1 (33.3)	1 (33.3)	0	0	0
Hypernatraemia	1 (33.3)	0	1 (33.3)	0	0
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)	0	0
Metabolic alkalosis	1 (33.3)	1 (33.3)	0	0	0
Nervous system disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Dizziness	1 (33.3)	1 (33.3)	0	0	0
Psychiatric disorders					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Confusional state	1 (33.3)	1 (33.3)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	1 (33.3)	0	1 (33.3)	0	0
Insomnia	1 (33.3)	0	1 (33.3)	0	0
Irritability	1 (33.3)	1 (33.3)	0	0	0
Renal and urinary disorders					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Acute kidney injury	1 (33.3)	0	0	0	1 (33.3)
Haematuria	1 (33.3)	0	0	1 (33.3)	0
Renal impairment	1 (33.3)	0	0	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Pleural effusion	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Pulmonary oedema	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Cough	1 (33.3)	1 (33.3)	0	0	0
Dyspnoea	1 (33.3)	0	0	0	1 (33.3)
Epistaxis	1 (33.3)	0	1 (33.3)	0	0
Hypoxia	1 (33.3)	0	0	0	1 (33.3)
Interstitial lung disease	1 (33.3)	0	0	0	1 (33.3)
Respiratory distress	1 (33.3)	0	0	0	1 (33.3)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Hyperhidrosis	1 (33.3)	1 (33.3)	0	0	0
Papule	1 (33.3)	1 (33.3)	0	0	0
Rash papular	1 (33.3)	1 (33.3)	0	0	0
Vascular disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Hypertension	2 (66.7)	0	2 (66.7)	0	0
Hypotension	2 (66.7)	0	0	0	2 (66.7)
Capillary leak syndrome	1 (33.3)	0	0	0	1 (33.3)
Flushing	1 (33.3)	1 (33.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184g
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

			All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	60 (98.4)	1 (1.6)	6 (9.8)	12 (19.7)	41 (67.2)
Blood and lymphatic system disorders					
-Total	42 (68.9)	1 (1.6)	2 (3.3)	27 (44.3)	12 (19.7)
Anaemia	25 (41.0)	3 (4.9)	4 (6.6)	17 (27.9)	1 (1.6)
Febrile neutropenia	24 (39.3)	0	0	23 (37.7)	1 (1.6)
Neutropenia	10 (16.4)	0	0	3 (4.9)	7 (11.5)
Thrombocytopenia	9 (14.8)	0	1 (1.6)	3 (4.9)	5 (8.2)
Cardiac disorders					
-Total	14 (23.0)	8 (13.1)	5 (8.2)	1 (1.6)	0
Tachycardia	14 (23.0)	8 (13.1)	5 (8.2)	1 (1.6)	0
Pericardial effusion	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Periorbital oedema	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Conjunctival haemorrhage	2 (3.3)	2 (3.3)	0	0	0
Gastrointestinal disorders					
-Total	38 (62.3)	14 (23.0)	18 (29.5)	6 (9.8)	0
Vomiting	26 (42.6)	16 (26.2)	7 (11.5)	3 (4.9)	0
Nausea	24 (39.3)	6 (9.8)	14 (23.0)	4 (6.6)	0
Diarrhoea	23 (37.7)	13 (21.3)	8 (13.1)	2 (3.3)	0
Abdominal pain	11 (18.0)	6 (9.8)	4 (6.6)	1 (1.6)	0
Constipation	7 (11.5)	6 (9.8)	1 (1.6)	0	0
Dysphagia	1 (1.6)	0	1 (1.6)	0	0
General disorders and administration site conditions					
-Total	34 (55.7)	16 (26.2)	11 (18.0)	6 (9.8)	1 (1.6)
Pyrexia	24 (39.3)	8 (13.1)	10 (16.4)	5 (8.2)	1 (1.6)
Fatigue	15 (24.6)	12 (19.7)	2 (3.3)	1 (1.6)	0
Chills	9 (14.8)	8 (13.1)	1 (1.6)	0	0
Oedema peripheral	2 (3.3)	2 (3.3)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	1 (1.6)	0	1 (1.6)	0	0
Hepatobiliary disorders					
-Total	3 (4.9)	1 (1.6)	1 (1.6)	1 (1.6)	0
Hepatomegaly	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Hyperbilirubinaemia	2 (3.3)	0	1 (1.6)	1 (1.6)	0
Immune system disorders					
-Total	55 (90.2)	4 (6.6)	31 (50.8)	11 (18.0)	9 (14.8)
Cytokine release syndrome	48 (78.7)	6 (9.8)	25 (41.0)	8 (13.1)	9 (14.8)
Hypogammaglobulinaemia	31 (50.8)	3 (4.9)	24 (39.3)	4 (6.6)	0
Infections and infestations					
-Total	8 (13.1)	3 (4.9)	4 (6.6)	1 (1.6)	0
Upper respiratory tract infection	8 (13.1)	3 (4.9)	4 (6.6)	1 (1.6)	0
Investigations					
-Total	49 (80.3)	0	5 (8.2)	12 (19.7)	32 (52.5)
White blood cell count decreased	34 (55.7)	4 (6.6)	1 (1.6)	11 (18.0)	18 (29.5)
Neutrophil count decreased	27 (44.3)	1 (1.6)	2 (3.3)	3 (4.9)	21 (34.4)
Alanine aminotransferase increased	20 (32.8)	5 (8.2)	2 (3.3)	13 (21.3)	0
Platelet count decreased	19 (31.1)	3 (4.9)	2 (3.3)	2 (3.3)	12 (19.7)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	18 (29.5)	4 (6.6)	4 (6.6)	8 (13.1)	2 (3.3)
Lymphocyte count decreased	16 (26.2)	1 (1.6)	3 (4.9)	7 (11.5)	5 (8.2)
Blood bilirubin increased	8 (13.1)	2 (3.3)	3 (4.9)	3 (4.9)	0
Blood creatinine increased	8 (13.1)	5 (8.2)	2 (3.3)	1 (1.6)	0
International normalised ratio increased	8 (13.1)	7 (11.5)	0	1 (1.6)	0
Prothrombin time prolonged	8 (13.1)	5 (8.2)	2 (3.3)	1 (1.6)	0
Blood fibrinogen decreased	2 (3.3)	0	0	2 (3.3)	0
Blood urea increased	2 (3.3)	1 (1.6)	1 (1.6)	0	0
Metabolism and nutrition disorders					
-Total	35 (57.4)	8 (13.1)	8 (13.1)	16 (26.2)	3 (4.9)
Decreased appetite	21 (34.4)	5 (8.2)	5 (8.2)	11 (18.0)	0
Hypokalaemia	17 (27.9)	3 (4.9)	6 (9.8)	7 (11.5)	1 (1.6)
Hyperphosphataemia	8 (13.1)	8 (13.1)	0	0	0
Hypophosphataemia	8 (13.1)	1 (1.6)	0	6 (9.8)	1 (1.6)
Hypoalbuminaemia	4 (6.6)	1 (1.6)	2 (3.3)	1 (1.6)	0
Hypernatraemia	3 (4.9)	1 (1.6)	1 (1.6)	0	1 (1.6)
Acidosis	1 (1.6)	1 (1.6)	0	0	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	11 (18.0)	7 (11.5)	4 (6.6)	0	0
Pain in extremity	11 (18.0)	7 (11.5)	4 (6.6)	0	0
Nervous system disorders					
-Total	26 (42.6)	17 (27.9)	7 (11.5)	2 (3.3)	0
Headache	24 (39.3)	15 (24.6)	7 (11.5)	2 (3.3)	0
Dizziness	5 (8.2)	5 (8.2)	0	0	0
Psychiatric disorders					
-Total	12 (19.7)	6 (9.8)	5 (8.2)	1 (1.6)	0
Anxiety	7 (11.5)	3 (4.9)	3 (4.9)	1 (1.6)	0
Confusional state	5 (8.2)	2 (3.3)	3 (4.9)	0	0
Delirium	3 (4.9)	2 (3.3)	1 (1.6)	0	0
Irritability	1 (1.6)	1 (1.6)	0	0	0
Renal and urinary disorders					
-Total	10 (16.4)	1 (1.6)	1 (1.6)	5 (8.2)	3 (4.9)
Acute kidney injury	8 (13.1)	1 (1.6)	1 (1.6)	4 (6.6)	2 (3.3)
Haematuria	4 (6.6)	0	2 (3.3)	1 (1.6)	1 (1.6)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	26 (42.6)	10 (16.4)	5 (8.2)	7 (11.5)	4 (6.6)
Cough	13 (21.3)	11 (18.0)	2 (3.3)	0	0
Epistaxis	9 (14.8)	4 (6.6)	0	4 (6.6)	1 (1.6)
Hypoxia	9 (14.8)	0	3 (4.9)	4 (6.6)	2 (3.3)
Pleural effusion	6 (9.8)	2 (3.3)	3 (4.9)	1 (1.6)	0
Pulmonary oedema	5 (8.2)	1 (1.6)	0	3 (4.9)	1 (1.6)
Dyspnoea	1 (1.6)	0	0	1 (1.6)	0
Skin and subcutaneous tissue disorders					
-Total	12 (19.7)	9 (14.8)	3 (4.9)	0	0
Rash	8 (13.1)	5 (8.2)	3 (4.9)	0	0
Hyperhidrosis	3 (4.9)	3 (4.9)	0	0	0
Papule	1 (1.6)	1 (1.6)	0	0	0
Rash papular	1 (1.6)	1 (1.6)	0	0	0
Vascular disorders					
-Total	20 (32.8)	2 (3.3)	5 (8.2)	7 (11.5)	6 (9.8)
Hypotension	14 (23.0)	1 (1.6)	0	7 (11.5)	6 (9.8)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	10 (16.4)	3 (4.9)	6 (9.8)	1 (1.6)	0
Flushing	1 (1.6)	1 (1.6)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184h
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

		All patients N=1			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Blood and lymphatic system disorders					
-Total	1 (100)	0	0	1 (100)	0
Anaemia	1 (100)	0	0	1 (100)	0
Febrile neutropenia	1 (100)	0	0	1 (100)	0
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Haematemesis	1 (100)	1 (100)	0	0	0
Nausea	1 (100)	0	1 (100)	0	0
Vomiting	1 (100)	0	1 (100)	0	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	0	0	1 (100)	0
Activated partial thromboplastin time prolonged	1 (100)	0	1 (100)	0	0
Aspartate aminotransferase increased	1 (100)	0	1 (100)	0	0
Blood phosphorus increased	1 (100)	1 (100)	0	0	0
International normalised ratio increased	1 (100)	1 (100)	0	0	0
Neutrophil count decreased	1 (100)	0	0	1 (100)	0
Platelet count decreased	1 (100)	0	0	1 (100)	0
White blood cell count decreased	1 (100)	1 (100)	0	0	0
Nervous system disorders					
-Total	1 (100)	0	1 (100)	0	0
Encephalopathy	1 (100)	0	1 (100)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184h
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: No

			All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	62 (98.4)	2 (3.2)	8 (12.7)	13 (20.6)	39 (61.9)
Blood and lymphatic system disorders					
-Total	39 (61.9)	1 (1.6)	2 (3.2)	27 (42.9)	9 (14.3)
Anaemia	26 (41.3)	3 (4.8)	5 (7.9)	17 (27.0)	1 (1.6)
Febrile neutropenia	21 (33.3)	0	0	21 (33.3)	0
Neutropenia	8 (12.7)	0	0	3 (4.8)	5 (7.9)
Thrombocytopenia	8 (12.7)	0	0	2 (3.2)	6 (9.5)
Cardiac disorders					
-Total	15 (23.8)	8 (12.7)	5 (7.9)	2 (3.2)	0
Tachycardia	15 (23.8)	8 (12.7)	5 (7.9)	2 (3.2)	0
Gastrointestinal disorders					
-Total	32 (50.8)	12 (19.0)	13 (20.6)	7 (11.1)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	21 (33.3)	13 (20.6)	5 (7.9)	3 (4.8)	0
Nausea	20 (31.7)	6 (9.5)	11 (17.5)	3 (4.8)	0
Diarrhoea	18 (28.6)	11 (17.5)	6 (9.5)	1 (1.6)	0
Abdominal pain	9 (14.3)	6 (9.5)	2 (3.2)	1 (1.6)	0
Constipation	7 (11.1)	6 (9.5)	1 (1.6)	0	0
Haematemesis	1 (1.6)	1 (1.6)	0	0	0
General disorders and administration site conditions					
-Total	28 (44.4)	13 (20.6)	8 (12.7)	6 (9.5)	1 (1.6)
Pyrexia	16 (25.4)	3 (4.8)	7 (11.1)	5 (7.9)	1 (1.6)
Fatigue	13 (20.6)	10 (15.9)	2 (3.2)	1 (1.6)	0
Chills	8 (12.7)	8 (12.7)	0	0	0
Immune system disorders					
-Total	55 (87.3)	4 (6.3)	29 (46.0)	11 (17.5)	11 (17.5)
Cytokine release syndrome	49 (77.8)	6 (9.5)	24 (38.1)	8 (12.7)	11 (17.5)
Hypogammaglobulinaemia	25 (39.7)	3 (4.8)	18 (28.6)	4 (6.3)	0
Infections and infestations					
-Total	1 (1.6)	0	1 (1.6)	0	0
Upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	46 (73.0)	1 (1.6)	4 (6.3)	10 (15.9)	31 (49.2)
White blood cell count decreased	29 (46.0)	2 (3.2)	1 (1.6)	10 (15.9)	16 (25.4)
Neutrophil count decreased	24 (38.1)	0	2 (3.2)	3 (4.8)	19 (30.2)
Alanine aminotransferase increased	19 (30.2)	5 (7.9)	3 (4.8)	11 (17.5)	0
Platelet count decreased	18 (28.6)	3 (4.8)	2 (3.2)	1 (1.6)	12 (19.0)
Aspartate aminotransferase increased	17 (27.0)	3 (4.8)	3 (4.8)	7 (11.1)	4 (6.3)
Lymphocyte count decreased	14 (22.2)	1 (1.6)	2 (3.2)	6 (9.5)	5 (7.9)
Blood creatinine increased	9 (14.3)	5 (7.9)	2 (3.2)	2 (3.2)	0
Prothrombin time prolonged	9 (14.3)	5 (7.9)	3 (4.8)	1 (1.6)	0
International normalised ratio increased	8 (12.7)	7 (11.1)	0	1 (1.6)	0
Blood bilirubin increased	7 (11.1)	2 (3.2)	3 (4.8)	2 (3.2)	0
Activated partial thromboplastin time prolonged	4 (6.3)	3 (4.8)	1 (1.6)	0	0
Blood phosphorus increased	1 (1.6)	1 (1.6)	0	0	0
Metabolism and nutrition disorders					
-Total	33 (52.4)	7 (11.1)	8 (12.7)	17 (27.0)	1 (1.6)
Decreased appetite	20 (31.7)	4 (6.3)	4 (6.3)	12 (19.0)	0
Hypokalaemia	16 (25.4)	3 (4.8)	6 (9.5)	7 (11.1)	0
Hypophosphataemia	9 (14.3)	2 (3.2)	0	6 (9.5)	1 (1.6)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	8 (12.7)	8 (12.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (6.3)	2 (3.2)	2 (3.2)	0	0
Pain in extremity	4 (6.3)	2 (3.2)	2 (3.2)	0	0
Nervous system disorders					
-Total	26 (41.3)	17 (27.0)	6 (9.5)	3 (4.8)	0
Headache	24 (38.1)	16 (25.4)	6 (9.5)	2 (3.2)	0
Encephalopathy	3 (4.8)	1 (1.6)	0	2 (3.2)	0
Psychiatric disorders					
-Total	6 (9.5)	2 (3.2)	3 (4.8)	1 (1.6)	0
Anxiety	6 (9.5)	2 (3.2)	3 (4.8)	1 (1.6)	0
Renal and urinary disorders					
-Total	7 (11.1)	1 (1.6)	1 (1.6)	2 (3.2)	3 (4.8)
Acute kidney injury	7 (11.1)	1 (1.6)	1 (1.6)	2 (3.2)	3 (4.8)
Respiratory, thoracic and mediastinal disorders					
-Total	21 (33.3)	6 (9.5)	4 (6.3)	6 (9.5)	5 (7.9)
Hypoxia	10 (15.9)	0	3 (4.8)	4 (6.3)	3 (4.8)
Cough	8 (12.7)	8 (12.7)	0	0	0
Pleural effusion	8 (12.7)	2 (3.2)	4 (6.3)	2 (3.2)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	7 (11.1)	2 (3.2)	1 (1.6)	3 (4.8)	1 (1.6)
Pulmonary oedema	6 (9.5)	1 (1.6)	0	3 (4.8)	2 (3.2)
Skin and subcutaneous tissue disorders					
-Total	4 (6.3)	4 (6.3)	0	0	0
Rash	4 (6.3)	4 (6.3)	0	0	0
Vascular disorders					
-Total	21 (33.3)	2 (3.2)	4 (6.3)	7 (11.1)	8 (12.7)
Hypotension	16 (25.4)	1 (1.6)	0	7 (11.1)	8 (12.7)
Hypertension	10 (15.9)	2 (3.2)	7 (11.1)	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184h
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

			All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (70.9)	8 (14.5)	12 (21.8)	13 (23.6)	6 (10.9)
Blood and lymphatic system disorders					
-Total	8 (14.5)	1 (1.8)	1 (1.8)	3 (5.5)	3 (5.5)
Neutropenia	4 (7.3)	0	0	1 (1.8)	3 (5.5)
Febrile neutropenia	3 (5.5)	0	0	3 (5.5)	0
Anaemia	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Thrombocytopenia	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Gastrointestinal disorders					
-Total	14 (25.5)	8 (14.5)	4 (7.3)	2 (3.6)	0
Vomiting	9 (16.4)	5 (9.1)	2 (3.6)	2 (3.6)	0
Diarrhoea	8 (14.5)	6 (10.9)	1 (1.8)	1 (1.8)	0
Nausea	6 (10.9)	1 (1.8)	3 (5.5)	2 (3.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	4 (7.3)	2 (3.6)	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions					
-Total	11 (20.0)	8 (14.5)	2 (3.6)	1 (1.8)	0
Pyrexia	10 (18.2)	7 (12.7)	2 (3.6)	1 (1.8)	0
Fatigue	2 (3.6)	2 (3.6)	0	0	0
Chills	1 (1.8)	1 (1.8)	0	0	0
Immune system disorders					
-Total	8 (14.5)	0	7 (12.7)	1 (1.8)	0
Hypogammaglobulinaemia	8 (14.5)	0	7 (12.7)	1 (1.8)	0
Infections and infestations					
-Total	7 (12.7)	3 (5.5)	3 (5.5)	1 (1.8)	0
Upper respiratory tract infection	7 (12.7)	3 (5.5)	3 (5.5)	1 (1.8)	0
Investigations					
-Total	16 (29.1)	3 (5.5)	1 (1.8)	8 (14.5)	4 (7.3)
Neutrophil count decreased	8 (14.5)	2 (3.6)	0	3 (5.5)	3 (5.5)
White blood cell count decreased	5 (9.1)	2 (3.6)	1 (1.8)	1 (1.8)	1 (1.8)
Aspartate aminotransferase increased	3 (5.5)	1 (1.8)	0	2 (3.6)	0
Platelet count decreased	3 (5.5)	3 (5.5)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	2 (3.6)	0	0	2 (3.6)	0
Lymphocyte count decreased	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Blood bilirubin increased	1 (1.8)	0	0	1 (1.8)	0
Blood creatinine increased	1 (1.8)	1 (1.8)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (9.1)	3 (5.5)	1 (1.8)	0	1 (1.8)
Decreased appetite	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Hyperphosphataemia	2 (3.6)	2 (3.6)	0	0	0
Hypokalaemia	2 (3.6)	1 (1.8)	0	0	1 (1.8)
Hypophosphataemia	1 (1.8)	0	0	1 (1.8)	0
Musculoskeletal and connective tissue disorders					
-Total	8 (14.5)	6 (10.9)	2 (3.6)	0	0
Pain in extremity	8 (14.5)	6 (10.9)	2 (3.6)	0	0
Nervous system disorders					
-Total	5 (9.1)	4 (7.3)	1 (1.8)	0	0
Headache	5 (9.1)	4 (7.3)	1 (1.8)	0	0
Psychiatric disorders					
-Total	1 (1.8)	1 (1.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	1 (1.8)	1 (1.8)	0	0	0
Renal and urinary disorders					
-Total	1 (1.8)	0	0	1 (1.8)	0
Acute kidney injury	1 (1.8)	0	0	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (18.2)	6 (10.9)	2 (3.6)	2 (3.6)	0
Cough	7 (12.7)	5 (9.1)	2 (3.6)	0	0
Epistaxis	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Pulmonary oedema	1 (1.8)	0	0	1 (1.8)	0
Skin and subcutaneous tissue disorders					
-Total	4 (7.3)	1 (1.8)	3 (5.5)	0	0
Rash	4 (7.3)	1 (1.8)	3 (5.5)	0	0
Vascular disorders					
-Total	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Hypertension	2 (3.6)	1 (1.8)	1 (1.8)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184h
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

		All patients N=33			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (39.4)	3 (9.1)	4 (12.1)	4 (12.1)	2 (6.1)
Blood and lymphatic system disorders					
-Total	2 (6.1)	1 (3.0)	0	0	1 (3.0)
Febrile neutropenia	1 (3.0)	0	0	0	1 (3.0)
Thrombocytopenia	1 (3.0)	1 (3.0)	0	0	0
Gastrointestinal disorders					
-Total	3 (9.1)	0	3 (9.1)	0	0
Diarrhoea	2 (6.1)	0	2 (6.1)	0	0
Abdominal pain	1 (3.0)	0	1 (3.0)	0	0
Nausea	1 (3.0)	0	1 (3.0)	0	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.0)	0	1 (3.0)	0	0
Chills	1 (3.0)	0	1 (3.0)	0	0
Pyrexia	1 (3.0)	0	1 (3.0)	0	0
Infections and infestations					
-Total	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Upper respiratory tract infection	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Investigations					
-Total	8 (24.2)	1 (3.0)	2 (6.1)	4 (12.1)	1 (3.0)
White blood cell count decreased	4 (12.1)	1 (3.0)	0	2 (6.1)	1 (3.0)
Alanine aminotransferase increased	3 (9.1)	0	1 (3.0)	2 (6.1)	0
Lymphocyte count decreased	3 (9.1)	2 (6.1)	0	1 (3.0)	0
Aspartate aminotransferase increased	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Neutrophil count decreased	2 (6.1)	1 (3.0)	1 (3.0)	0	0
Platelet count decreased	1 (3.0)	0	0	1 (3.0)	0
Metabolism and nutrition disorders					
-Total	1 (3.0)	0	0	1 (3.0)	0
Hypokalaemia	1 (3.0)	0	0	1 (3.0)	0
Nervous system disorders					
-Total	1 (3.0)	0	1 (3.0)	0	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=33 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Headache	1 (3.0)	0	1 (3.0)	0	0
Renal and urinary disorders					
-Total	1 (3.0)	0	0	1 (3.0)	0
Acute kidney injury	1 (3.0)	0	0	1 (3.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (9.1)	3 (9.1)	0	0	0
Cough	2 (6.1)	2 (6.1)	0	0	0
Epistaxis	1 (3.0)	1 (3.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184h
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

		All patients N=1			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Blood and lymphatic system disorders					
-Total	1 (100)	0	0	1 (100)	0
Anaemia	1 (100)	0	0	1 (100)	0
Febrile neutropenia	1 (100)	0	0	1 (100)	0
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Haematemesis	1 (100)	1 (100)	0	0	0
Nausea	1 (100)	0	1 (100)	0	0
Vomiting	1 (100)	0	1 (100)	0	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	0	0	1 (100)	0
Activated partial thromboplastin time prolonged	1 (100)	0	1 (100)	0	0
Aspartate aminotransferase increased	1 (100)	0	1 (100)	0	0
Blood phosphorus increased	1 (100)	1 (100)	0	0	0
International normalised ratio increased	1 (100)	1 (100)	0	0	0
Neutrophil count decreased	1 (100)	0	0	1 (100)	0
Platelet count decreased	1 (100)	0	0	1 (100)	0
White blood cell count decreased	1 (100)	1 (100)	0	0	0
Nervous system disorders					
-Total	1 (100)	0	1 (100)	0	0
Encephalopathy	1 (100)	0	1 (100)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184h
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: No

		All patients N=63			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	62 (98.4)	1 (1.6)	6 (9.5)	12 (19.0)	43 (68.3)
Blood and lymphatic system disorders					
-Total	43 (68.3)	1 (1.6)	2 (3.2)	27 (42.9)	13 (20.6)
Anaemia	26 (41.3)	3 (4.8)	4 (6.3)	18 (28.6)	1 (1.6)
Febrile neutropenia	23 (36.5)	0	0	22 (34.9)	1 (1.6)
Neutropenia	11 (17.5)	0	0	3 (4.8)	8 (12.7)
Thrombocytopenia	10 (15.9)	0	1 (1.6)	3 (4.8)	6 (9.5)
Cardiac disorders					
-Total	15 (23.8)	8 (12.7)	5 (7.9)	2 (3.2)	0
Tachycardia	15 (23.8)	8 (12.7)	5 (7.9)	2 (3.2)	0
Gastrointestinal disorders					
-Total	38 (60.3)	14 (22.2)	17 (27.0)	7 (11.1)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	26 (41.3)	16 (25.4)	7 (11.1)	3 (4.8)	0
Diarrhoea	24 (38.1)	13 (20.6)	9 (14.3)	2 (3.2)	0
Nausea	24 (38.1)	6 (9.5)	13 (20.6)	5 (7.9)	0
Abdominal pain	11 (17.5)	6 (9.5)	4 (6.3)	1 (1.6)	0
Constipation	7 (11.1)	6 (9.5)	1 (1.6)	0	0
Haematemesis	1 (1.6)	1 (1.6)	0	0	0
General disorders and administration site conditions					
-Total	35 (55.6)	16 (25.4)	11 (17.5)	7 (11.1)	1 (1.6)
Pyrexia	25 (39.7)	8 (12.7)	10 (15.9)	6 (9.5)	1 (1.6)
Fatigue	15 (23.8)	12 (19.0)	2 (3.2)	1 (1.6)	0
Chills	10 (15.9)	9 (14.3)	1 (1.6)	0	0
Immune system disorders					
-Total	56 (88.9)	4 (6.3)	30 (47.6)	11 (17.5)	11 (17.5)
Cytokine release syndrome	49 (77.8)	6 (9.5)	24 (38.1)	8 (12.7)	11 (17.5)
Hypogammaglobulinaemia	32 (50.8)	3 (4.8)	24 (38.1)	5 (7.9)	0
Infections and infestations					
-Total	9 (14.3)	4 (6.3)	4 (6.3)	1 (1.6)	0
Upper respiratory tract infection	9 (14.3)	4 (6.3)	4 (6.3)	1 (1.6)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	51 (81.0)	0	5 (7.9)	12 (19.0)	34 (54.0)
White blood cell count decreased	34 (54.0)	3 (4.8)	1 (1.6)	12 (19.0)	18 (28.6)
Neutrophil count decreased	27 (42.9)	1 (1.6)	2 (3.2)	3 (4.8)	21 (33.3)
Alanine aminotransferase increased	21 (33.3)	5 (7.9)	2 (3.2)	14 (22.2)	0
Aspartate aminotransferase increased	19 (30.2)	4 (6.3)	3 (4.8)	8 (12.7)	4 (6.3)
Platelet count decreased	19 (30.2)	3 (4.8)	2 (3.2)	2 (3.2)	12 (19.0)
Lymphocyte count decreased	16 (25.4)	1 (1.6)	3 (4.8)	7 (11.1)	5 (7.9)
Blood creatinine increased	9 (14.3)	5 (7.9)	2 (3.2)	2 (3.2)	0
Prothrombin time prolonged	9 (14.3)	5 (7.9)	3 (4.8)	1 (1.6)	0
Blood bilirubin increased	8 (12.7)	2 (3.2)	3 (4.8)	3 (4.8)	0
International normalised ratio increased	8 (12.7)	7 (11.1)	0	1 (1.6)	0
Activated partial thromboplastin time prolonged	4 (6.3)	3 (4.8)	1 (1.6)	0	0
Blood phosphorus increased	1 (1.6)	1 (1.6)	0	0	0
Metabolism and nutrition disorders					
-Total	35 (55.6)	7 (11.1)	8 (12.7)	18 (28.6)	2 (3.2)
Decreased appetite	22 (34.9)	5 (7.9)	5 (7.9)	12 (19.0)	0
Hypokalaemia	19 (30.2)	4 (6.3)	6 (9.5)	8 (12.7)	1 (1.6)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	10 (15.9)	2 (3.2)	0	7 (11.1)	1 (1.6)
Hyperphosphataemia	8 (12.7)	8 (12.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	11 (17.5)	7 (11.1)	4 (6.3)	0	0
Pain in extremity	11 (17.5)	7 (11.1)	4 (6.3)	0	0
Nervous system disorders					
-Total	26 (41.3)	16 (25.4)	7 (11.1)	3 (4.8)	0
Headache	24 (38.1)	15 (23.8)	7 (11.1)	2 (3.2)	0
Encephalopathy	3 (4.8)	1 (1.6)	0	2 (3.2)	0
Psychiatric disorders					
-Total	7 (11.1)	3 (4.8)	3 (4.8)	1 (1.6)	0
Anxiety	7 (11.1)	3 (4.8)	3 (4.8)	1 (1.6)	0
Renal and urinary disorders					
-Total	9 (14.3)	1 (1.6)	1 (1.6)	4 (6.3)	3 (4.8)
Acute kidney injury	9 (14.3)	1 (1.6)	1 (1.6)	4 (6.3)	3 (4.8)
Respiratory, thoracic and mediastinal disorders					
-Total	28 (44.4)	10 (15.9)	5 (7.9)	8 (12.7)	5 (7.9)
Cough	14 (22.2)	12 (19.0)	2 (3.2)	0	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

Group term Preferred term	All patients N=63 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Epistaxis	10 (15.9)	4 (6.3)	1 (1.6)	4 (6.3)	1 (1.6)
Hypoxia	10 (15.9)	0	3 (4.8)	4 (6.3)	3 (4.8)
Pleural effusion	8 (12.7)	2 (3.2)	4 (6.3)	2 (3.2)	0
Pulmonary oedema	7 (11.1)	1 (1.6)	0	4 (6.3)	2 (3.2)
Skin and subcutaneous tissue disorders					
-Total	8 (12.7)	5 (7.9)	3 (4.8)	0	0
Rash	8 (12.7)	5 (7.9)	3 (4.8)	0	0
Vascular disorders					
-Total	22 (34.9)	2 (3.2)	5 (7.9)	7 (11.1)	8 (12.7)
Hypotension	16 (25.4)	1 (1.6)	0	7 (11.1)	8 (12.7)
Hypertension	12 (19.0)	3 (4.8)	8 (12.7)	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184i
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	2 (50.0)	1 (25.0)	1 (25.0)
Blood and lymphatic system disorders					
-Total	3 (75.0)	0	1 (25.0)	2 (50.0)	0
Anaemia	3 (75.0)	0	2 (50.0)	1 (25.0)	0
Febrile neutropenia	2 (50.0)	0	0	2 (50.0)	0
Cardiac disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Cardiac dysfunction	1 (25.0)	1 (25.0)	0	0	0
Sinus tachycardia	1 (25.0)	0	1 (25.0)	0	0
Tachycardia	1 (25.0)	1 (25.0)	0	0	0
Gastrointestinal disorders					
-Total	3 (75.0)	1 (25.0)	2 (50.0)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	3 (75.0)	2 (50.0)	1 (25.0)	0	0
Abdominal pain	2 (50.0)	2 (50.0)	0	0	0
Nausea	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Abdominal distension	1 (25.0)	0	1 (25.0)	0	0
Abdominal tenderness	1 (25.0)	1 (25.0)	0	0	0
Constipation	1 (25.0)	1 (25.0)	0	0	0
Gastrooesophageal reflux disease	1 (25.0)	1 (25.0)	0	0	0
Vomiting	1 (25.0)	1 (25.0)	0	0	0
General disorders and administration site conditions					
-Total	3 (75.0)	2 (50.0)	1 (25.0)	0	0
Fatigue	3 (75.0)	3 (75.0)	0	0	0
Pain	1 (25.0)	0	1 (25.0)	0	0
Immune system disorders					
-Total	4 (100)	0	3 (75.0)	1 (25.0)	0
Hypogammaglobulinaemia	4 (100)	0	4 (100)	0	0
Cytokine release syndrome	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Infections and infestations					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	1 (25.0)	0	1 (25.0)	0	0
Gastroenteritis	1 (25.0)	0	0	1 (25.0)	0
Pharyngitis	1 (25.0)	0	1 (25.0)	0	0
Streptococcal infection	1 (25.0)	0	1 (25.0)	0	0
Injury, poisoning and procedural complications					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Contusion	1 (25.0)	1 (25.0)	0	0	0
Infusion related reaction	1 (25.0)	0	1 (25.0)	0	0
Procedural pain	1 (25.0)	0	1 (25.0)	0	0
Procedural site reaction	1 (25.0)	1 (25.0)	0	0	0
Investigations					
-Total	3 (75.0)	0	2 (50.0)	0	1 (25.0)
International normalised ratio increased	2 (50.0)	2 (50.0)	0	0	0
Lymphocyte count decreased	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Neutrophil count decreased	2 (50.0)	0	1 (25.0)	0	1 (25.0)
White blood cell count decreased	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Activated partial thromboplastin time prolonged	1 (25.0)	1 (25.0)	0	0	0
Alanine aminotransferase increased	1 (25.0)	0	0	1 (25.0)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (25.0)	0	0	1 (25.0)	0
Blood bilirubin increased	1 (25.0)	0	1 (25.0)	0	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0
Platelet count decreased	1 (25.0)	0	1 (25.0)	0	0
Pulmonary function test decreased	1 (25.0)	0	1 (25.0)	0	0
Metabolism and nutrition disorders					
-Total	4 (100)	1 (25.0)	1 (25.0)	2 (50.0)	0
Hyperphosphataemia	2 (50.0)	2 (50.0)	0	0	0
Decreased appetite	1 (25.0)	0	0	1 (25.0)	0
Dehydration	1 (25.0)	0	0	1 (25.0)	0
Hyperuricaemia	1 (25.0)	1 (25.0)	0	0	0
Hypokalaemia	1 (25.0)	0	1 (25.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Arthralgia	2 (50.0)	2 (50.0)	0	0	0
Musculoskeletal chest pain	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal pain	1 (25.0)	0	1 (25.0)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	1 (25.0)	1 (25.0)	0	0	0
Pain in extremity	1 (25.0)	1 (25.0)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (25.0)	0	1 (25.0)	0	0
Skin papilloma	1 (25.0)	0	1 (25.0)	0	0
Nervous system disorders					
-Total	3 (75.0)	3 (75.0)	0	0	0
Headache	3 (75.0)	3 (75.0)	0	0	0
Dizziness	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Rhinorrhoea	1 (25.0)	1 (25.0)	0	0	0
Tachypnoea	1 (25.0)	1 (25.0)	0	0	0
Wheezing	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (50.0)	2 (50.0)	0	0	0
Petechiae	1 (25.0)	1 (25.0)	0	0	0
Rash follicular	1 (25.0)	1 (25.0)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash papular	1 (25.0)	1 (25.0)	0	0	0
Vascular disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Hypotension	1 (25.0)	0	0	0	1 (25.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184i
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

			All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (98.3)	2 (3.3)	6 (10.0)	13 (21.7)	38 (63.3)
Blood and lymphatic system disorders					
-Total	37 (61.7)	1 (1.7)	1 (1.7)	25 (41.7)	10 (16.7)
Anaemia	24 (40.0)	3 (5.0)	3 (5.0)	17 (28.3)	1 (1.7)
Febrile neutropenia	20 (33.3)	0	0	20 (33.3)	0
Neutropenia	8 (13.3)	0	0	3 (5.0)	5 (8.3)
Thrombocytopenia	8 (13.3)	0	0	2 (3.3)	6 (10.0)
Lymphopenia	3 (5.0)	0	1 (1.7)	1 (1.7)	1 (1.7)
Cardiac disorders					
-Total	17 (28.3)	9 (15.0)	6 (10.0)	2 (3.3)	0
Tachycardia	14 (23.3)	7 (11.7)	5 (8.3)	2 (3.3)	0
Sinus tachycardia	4 (6.7)	3 (5.0)	1 (1.7)	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	30 (50.0)	11 (18.3)	12 (20.0)	7 (11.7)	0
Vomiting	21 (35.0)	12 (20.0)	6 (10.0)	3 (5.0)	0
Nausea	19 (31.7)	5 (8.3)	11 (18.3)	3 (5.0)	0
Diarrhoea	15 (25.0)	9 (15.0)	5 (8.3)	1 (1.7)	0
Abdominal pain	7 (11.7)	4 (6.7)	2 (3.3)	1 (1.7)	0
Constipation	6 (10.0)	5 (8.3)	1 (1.7)	0	0
Abdominal distension	1 (1.7)	0	1 (1.7)	0	0
General disorders and administration site conditions					
-Total	25 (41.7)	10 (16.7)	7 (11.7)	7 (11.7)	1 (1.7)
Pyrexia	16 (26.7)	3 (5.0)	7 (11.7)	5 (8.3)	1 (1.7)
Fatigue	10 (16.7)	7 (11.7)	2 (3.3)	1 (1.7)	0
Chills	8 (13.3)	8 (13.3)	0	0	0
Pain	2 (3.3)	0	0	2 (3.3)	0
Immune system disorders					
-Total	52 (86.7)	4 (6.7)	27 (45.0)	10 (16.7)	11 (18.3)
Cytokine release syndrome	48 (80.0)	6 (10.0)	24 (40.0)	7 (11.7)	11 (18.3)
Hypogammaglobulinaemia	21 (35.0)	3 (5.0)	14 (23.3)	4 (6.7)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	6 (10.0)	0	6 (10.0)	0	0
Clostridium difficile infection	3 (5.0)	0	3 (5.0)	0	0
Cytomegalovirus infection	1 (1.7)	1 (1.7)	0	0	0
Gastroenteritis	1 (1.7)	0	1 (1.7)	0	0
Upper respiratory tract infection	1 (1.7)	0	1 (1.7)	0	0
Viral infection	1 (1.7)	0	1 (1.7)	0	0
Injury, poisoning and procedural complications					
-Total	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Procedural pain	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Infusion related reaction	1 (1.7)	0	1 (1.7)	0	0
Investigations					
-Total	45 (75.0)	1 (1.7)	3 (5.0)	11 (18.3)	30 (50.0)
White blood cell count decreased	28 (46.7)	3 (5.0)	0	9 (15.0)	16 (26.7)
Neutrophil count decreased	23 (38.3)	0	1 (1.7)	4 (6.7)	18 (30.0)
Alanine aminotransferase increased	18 (30.0)	5 (8.3)	3 (5.0)	10 (16.7)	0
Platelet count decreased	18 (30.0)	3 (5.0)	1 (1.7)	2 (3.3)	12 (20.0)
Aspartate aminotransferase increased	17 (28.3)	3 (5.0)	4 (6.7)	6 (10.0)	4 (6.7)
Lymphocyte count decreased	12 (20.0)	1 (1.7)	1 (1.7)	5 (8.3)	5 (8.3)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prothrombin time prolonged	9 (15.0)	5 (8.3)	3 (5.0)	1 (1.7)	0
Blood creatinine increased	8 (13.3)	4 (6.7)	2 (3.3)	2 (3.3)	0
International normalised ratio increased	7 (11.7)	6 (10.0)	0	1 (1.7)	0
Blood bilirubin increased	6 (10.0)	2 (3.3)	2 (3.3)	2 (3.3)	0
Activated partial thromboplastin time prolonged	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Blood immunoglobulin a decreased	2 (3.3)	2 (3.3)	0	0	0
Blood uric acid increased	1 (1.7)	1 (1.7)	0	0	0
Metabolism and nutrition disorders					
-Total	32 (53.3)	6 (10.0)	7 (11.7)	17 (28.3)	2 (3.3)
Decreased appetite	19 (31.7)	4 (6.7)	4 (6.7)	11 (18.3)	0
Hypokalaemia	15 (25.0)	3 (5.0)	5 (8.3)	7 (11.7)	0
Hypophosphataemia	9 (15.0)	2 (3.3)	0	6 (10.0)	1 (1.7)
Hyperphosphataemia	6 (10.0)	6 (10.0)	0	0	0
Dehydration	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Hyperuricaemia	2 (3.3)	1 (1.7)	0	0	1 (1.7)
Musculoskeletal and connective tissue disorders					
-Total	11 (18.3)	7 (11.7)	3 (5.0)	1 (1.7)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	4 (6.7)	3 (5.0)	1 (1.7)	0	0
Pain in extremity	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Arthralgia	2 (3.3)	1 (1.7)	0	1 (1.7)	0
Musculoskeletal pain	2 (3.3)	2 (3.3)	0	0	0
Nervous system disorders					
-Total	23 (38.3)	15 (25.0)	6 (10.0)	2 (3.3)	0
Headache	21 (35.0)	13 (21.7)	6 (10.0)	2 (3.3)	0
Dizziness	3 (5.0)	3 (5.0)	0	0	0
Psychiatric disorders					
-Total	11 (18.3)	5 (8.3)	5 (8.3)	1 (1.7)	0
Anxiety	6 (10.0)	2 (3.3)	3 (5.0)	1 (1.7)	0
Confusional state	6 (10.0)	3 (5.0)	3 (5.0)	0	0
Renal and urinary disorders					
-Total	7 (11.7)	1 (1.7)	1 (1.7)	2 (3.3)	3 (5.0)
Acute kidney injury	7 (11.7)	1 (1.7)	1 (1.7)	2 (3.3)	3 (5.0)
Respiratory, thoracic and mediastinal disorders					
-Total	23 (38.3)	7 (11.7)	4 (6.7)	7 (11.7)	5 (8.3)
Hypoxia	10 (16.7)	0	3 (5.0)	4 (6.7)	3 (5.0)
Cough	8 (13.3)	8 (13.3)	0	0	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	8 (13.3)	2 (3.3)	4 (6.7)	2 (3.3)	0
Epistaxis	7 (11.7)	2 (3.3)	1 (1.7)	3 (5.0)	1 (1.7)
Pulmonary oedema	6 (10.0)	1 (1.7)	0	3 (5.0)	2 (3.3)
Tachypnoea	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Oropharyngeal pain	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	6 (10.0)	5 (8.3)	1 (1.7)	0	0
Rash	4 (6.7)	4 (6.7)	0	0	0
Petechiae	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Rash papular	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					
-Total	20 (33.3)	2 (3.3)	4 (6.7)	7 (11.7)	7 (11.7)
Hypotension	15 (25.0)	1 (1.7)	0	7 (11.7)	7 (11.7)
Hypertension	10 (16.7)	2 (3.3)	7 (11.7)	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184i
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

		All patients N=4			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	2 (50.0)	1 (25.0)	1 (25.0)
Blood and lymphatic system disorders					
-Total	2 (50.0)	0	1 (25.0)	0	1 (25.0)
Febrile neutropenia	1 (25.0)	0	0	1 (25.0)	0
Lymphopenia	1 (25.0)	0	1 (25.0)	0	0
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
Eye disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Dry eye	1 (25.0)	0	1 (25.0)	0	0
Gastrointestinal disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Vomiting	1 (25.0)	0	1 (25.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	1 (25.0)	1 (25.0)	0	0	0
Fatigue	1 (25.0)	1 (25.0)	0	0	0
Pyrexia	1 (25.0)	1 (25.0)	0	0	0
Infections and infestations					
-Total	3 (75.0)	1 (25.0)	1 (25.0)	1 (25.0)	0
Cytomegalovirus infection	1 (25.0)	1 (25.0)	0	0	0
Herpes zoster	1 (25.0)	0	0	1 (25.0)	0
Otitis media acute	1 (25.0)	0	1 (25.0)	0	0
Parainfluenzae virus infection	1 (25.0)	1 (25.0)	0	0	0
Sinusitis	1 (25.0)	0	1 (25.0)	0	0
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0
Investigations					
-Total	3 (75.0)	1 (25.0)	0	1 (25.0)	1 (25.0)
Neutrophil count decreased	3 (75.0)	1 (25.0)	0	1 (25.0)	1 (25.0)
Aspartate aminotransferase increased	1 (25.0)	0	0	1 (25.0)	0
Blood uric acid increased	1 (25.0)	1 (25.0)	0	0	0
Platelet count decreased	1 (25.0)	1 (25.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (25.0)	0	1 (25.0)	0	0
Metabolism and nutrition disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Decreased appetite	1 (25.0)	0	1 (25.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Joint range of motion decreased	1 (25.0)	1 (25.0)	0	0	0
Osteonecrosis	1 (25.0)	0	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Pulmonary oedema	1 (25.0)	0	0	1 (25.0)	0
Skin and subcutaneous tissue disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Rash	1 (25.0)	0	1 (25.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184i
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (69.2)	6 (11.5)	12 (23.1)	13 (25.0)	5 (9.6)
Blood and lymphatic system disorders					
-Total	7 (13.5)	1 (1.9)	1 (1.9)	3 (5.8)	2 (3.8)
Neutropenia	3 (5.8)	0	0	1 (1.9)	2 (3.8)
Anaemia	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Febrile neutropenia	2 (3.8)	0	0	2 (3.8)	0
Thrombocytopenia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Cardiac disorders					
-Total	1 (1.9)	0	1 (1.9)	0	0
Sinus tachycardia	1 (1.9)	0	1 (1.9)	0	0
Eye disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry eye	1 (1.9)	1 (1.9)	0	0	0
Gastrointestinal disorders					
-Total	13 (25.0)	8 (15.4)	3 (5.8)	2 (3.8)	0
Diarrhoea	8 (15.4)	6 (11.5)	1 (1.9)	1 (1.9)	0
Vomiting	8 (15.4)	5 (9.6)	1 (1.9)	2 (3.8)	0
Nausea	6 (11.5)	1 (1.9)	3 (5.8)	2 (3.8)	0
Abdominal pain	4 (7.7)	2 (3.8)	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions					
-Total	10 (19.2)	7 (13.5)	2 (3.8)	1 (1.9)	0
Pyrexia	9 (17.3)	6 (11.5)	2 (3.8)	1 (1.9)	0
Chills	1 (1.9)	1 (1.9)	0	0	0
Fatigue	1 (1.9)	1 (1.9)	0	0	0
Pain	1 (1.9)	1 (1.9)	0	0	0
Immune system disorders					
-Total	8 (15.4)	0	7 (13.5)	1 (1.9)	0
Hypogammaglobulinaemia	8 (15.4)	0	7 (13.5)	1 (1.9)	0
Infections and infestations					
-Total	12 (23.1)	4 (7.7)	6 (11.5)	2 (3.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	6 (11.5)	2 (3.8)	3 (5.8)	1 (1.9)	0
Gastroenteritis	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Parainfluenzae virus infection	1 (1.9)	0	0	1 (1.9)	0
Sinusitis	1 (1.9)	0	1 (1.9)	0	0
Viral infection	1 (1.9)	1 (1.9)	0	0	0
Injury, poisoning and procedural complications					
-Total	4 (7.7)	2 (3.8)	2 (3.8)	0	0
Contusion	2 (3.8)	2 (3.8)	0	0	0
Infusion related reaction	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Procedural pain	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Investigations					
-Total	13 (25.0)	2 (3.8)	1 (1.9)	7 (13.5)	3 (5.8)
Neutrophil count decreased	5 (9.6)	1 (1.9)	0	2 (3.8)	2 (3.8)
White blood cell count decreased	4 (7.7)	2 (3.8)	0	1 (1.9)	1 (1.9)
Alanine aminotransferase increased	2 (3.8)	0	0	2 (3.8)	0
Aspartate aminotransferase increased	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Lymphocyte count decreased	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Platelet count decreased	2 (3.8)	2 (3.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

		All patients N=52			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (1.9)	0	0	1 (1.9)	0
Blood creatinine increased	1 (1.9)	1 (1.9)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (9.6)	3 (5.8)	0	1 (1.9)	1 (1.9)
Hyperphosphataemia	2 (3.8)	2 (3.8)	0	0	0
Hypokalaemia	2 (3.8)	1 (1.9)	0	0	1 (1.9)
Decreased appetite	1 (1.9)	1 (1.9)	0	0	0
Dehydration	1 (1.9)	0	0	1 (1.9)	0
Hypophosphataemia	1 (1.9)	0	0	1 (1.9)	0
Musculoskeletal and connective tissue disorders					
-Total	11 (21.2)	8 (15.4)	3 (5.8)	0	0
Pain in extremity	8 (15.4)	6 (11.5)	2 (3.8)	0	0
Arthralgia	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Joint range of motion decreased	1 (1.9)	1 (1.9)	0	0	0
Musculoskeletal chest pain	1 (1.9)	1 (1.9)	0	0	0
Nervous system disorders					
-Total	6 (11.5)	5 (9.6)	1 (1.9)	0	0
Headache	5 (9.6)	4 (7.7)	1 (1.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

			All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dizziness	3 (5.8)	3 (5.8)	0	0	0
Psychiatric disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Anxiety	1 (1.9)	1 (1.9)	0	0	0
Renal and urinary disorders					
-Total	1 (1.9)	0	0	1 (1.9)	0
Acute kidney injury	1 (1.9)	0	0	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (21.2)	7 (13.5)	3 (5.8)	1 (1.9)	0
Cough	7 (13.5)	5 (9.6)	2 (3.8)	0	0
Rhinorrhoea	4 (7.7)	3 (5.8)	1 (1.9)	0	0
Oropharyngeal pain	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Epistaxis	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Skin and subcutaneous tissue disorders					
-Total	4 (7.7)	2 (3.8)	2 (3.8)	0	0
Rash	3 (5.8)	1 (1.9)	2 (3.8)	0	0
Petechiae	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Hypertension	2 (3.8)	1 (1.9)	1 (1.9)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184i
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: Yes

		All patients N=3			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	0	2 (66.7)	0
General disorders and administration site conditions					
-Total	1 (33.3)	0	0	1 (33.3)	0
Cyst	1 (33.3)	0	0	1 (33.3)	0
Infections and infestations					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Gingivitis	1 (33.3)	1 (33.3)	0	0	0
Otitis media acute	1 (33.3)	0	1 (33.3)	0	0
Viral infection	1 (33.3)	1 (33.3)	0	0	0
Investigations					
-Total	1 (33.3)	0	0	1 (33.3)	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (33.3)	0	0	1 (33.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184i
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

			All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (41.9)	3 (9.7)	4 (12.9)	4 (12.9)	2 (6.5)
Blood and lymphatic system disorders					
-Total	2 (6.5)	1 (3.2)	0	0	1 (3.2)
Febrile neutropenia	1 (3.2)	0	0	0	1 (3.2)
Thrombocytopenia	1 (3.2)	1 (3.2)	0	0	0
Gastrointestinal disorders					
-Total	3 (9.7)	0	3 (9.7)	0	0
Diarrhoea	2 (6.5)	0	2 (6.5)	0	0
Abdominal pain	1 (3.2)	0	1 (3.2)	0	0
Nausea	1 (3.2)	0	1 (3.2)	0	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

		All patients N=31			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.2)	0	1 (3.2)	0	0
Chills	1 (3.2)	0	1 (3.2)	0	0
Pyrexia	1 (3.2)	0	1 (3.2)	0	0
Infections and infestations					
-Total	5 (16.1)	1 (3.2)	3 (9.7)	1 (3.2)	0
Sinusitis	3 (9.7)	0	3 (9.7)	0	0
Upper respiratory tract infection	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Clostridium difficile infection	1 (3.2)	0	0	1 (3.2)	0
Otitis media acute	1 (3.2)	0	1 (3.2)	0	0
Injury, poisoning and procedural complications					
-Total	1 (3.2)	0	0	1 (3.2)	0
Procedural pain	1 (3.2)	0	0	1 (3.2)	0
Investigations					
-Total	7 (22.6)	1 (3.2)	2 (6.5)	3 (9.7)	1 (3.2)
Alanine aminotransferase increased	3 (9.7)	0	1 (3.2)	2 (6.5)	0
Lymphocyte count decreased	3 (9.7)	2 (6.5)	0	1 (3.2)	0
White blood cell count decreased	3 (9.7)	1 (3.2)	0	1 (3.2)	1 (3.2)
Aspartate aminotransferase increased	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Neutrophil count decreased	2 (6.5)	1 (3.2)	1 (3.2)	0	0

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (3.2)	0	0	1 (3.2)	0
Metabolism and nutrition disorders					
-Total	1 (3.2)	0	0	1 (3.2)	0
Hypokalaemia	1 (3.2)	0	0	1 (3.2)	0
Nervous system disorders					
-Total	1 (3.2)	0	1 (3.2)	0	0
Dizziness	1 (3.2)	1 (3.2)	0	0	0
Headache	1 (3.2)	0	1 (3.2)	0	0
Renal and urinary disorders					
-Total	1 (3.2)	0	0	1 (3.2)	0
Acute kidney injury	1 (3.2)	0	0	1 (3.2)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (12.9)	4 (12.9)	0	0	0
Cough	2 (6.5)	2 (6.5)	0	0	0
Epistaxis	1 (3.2)	1 (3.2)	0	0	0
Oropharyngeal pain	1 (3.2)	1 (3.2)	0	0	0
Rhinorrhoea	1 (3.2)	1 (3.2)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184i
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

		All patients N=4			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	1 (25.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders					
-Total	3 (75.0)	0	1 (25.0)	1 (25.0)	1 (25.0)
Anaemia	3 (75.0)	0	2 (50.0)	1 (25.0)	0
Febrile neutropenia	2 (50.0)	0	0	2 (50.0)	0
Lymphopenia	1 (25.0)	0	1 (25.0)	0	0
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
Cardiac disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Cardiac dysfunction	1 (25.0)	1 (25.0)	0	0	0
Sinus tachycardia	1 (25.0)	0	1 (25.0)	0	0
Tachycardia	1 (25.0)	1 (25.0)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Dry eye	1 (25.0)	0	1 (25.0)	0	0
Gastrointestinal disorders					
-Total	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Diarrhoea	3 (75.0)	2 (50.0)	1 (25.0)	0	0
Abdominal pain	2 (50.0)	2 (50.0)	0	0	0
Nausea	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Vomiting	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Abdominal distension	1 (25.0)	0	1 (25.0)	0	0
Abdominal tenderness	1 (25.0)	1 (25.0)	0	0	0
Constipation	1 (25.0)	1 (25.0)	0	0	0
Gastrooesophageal reflux disease	1 (25.0)	1 (25.0)	0	0	0
General disorders and administration site conditions					
-Total	4 (100)	2 (50.0)	1 (25.0)	1 (25.0)	0
Fatigue	4 (100)	4 (100)	0	0	0
Cyst	1 (25.0)	0	0	1 (25.0)	0
Pain	1 (25.0)	0	1 (25.0)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (25.0)	1 (25.0)	0	0	0
Immune system disorders					
-Total	4 (100)	0	3 (75.0)	1 (25.0)	0
Hypogammaglobulinaemia	4 (100)	0	4 (100)	0	0
Cytokine release syndrome	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Infections and infestations					
-Total	3 (75.0)	1 (25.0)	1 (25.0)	1 (25.0)	0
Clostridium difficile infection	1 (25.0)	0	1 (25.0)	0	0
Cytomegalovirus infection	1 (25.0)	1 (25.0)	0	0	0
Gastroenteritis	1 (25.0)	0	0	1 (25.0)	0
Gingivitis	1 (25.0)	1 (25.0)	0	0	0
Herpes zoster	1 (25.0)	0	0	1 (25.0)	0
Otitis media acute	1 (25.0)	0	1 (25.0)	0	0
Parainfluenzae virus infection	1 (25.0)	1 (25.0)	0	0	0
Pharyngitis	1 (25.0)	0	1 (25.0)	0	0
Sinusitis	1 (25.0)	0	1 (25.0)	0	0
Streptococcal infection	1 (25.0)	0	1 (25.0)	0	0
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0
Viral infection	1 (25.0)	1 (25.0)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Contusion	1 (25.0)	1 (25.0)	0	0	0
Infusion related reaction	1 (25.0)	0	1 (25.0)	0	0
Procedural pain	1 (25.0)	0	1 (25.0)	0	0
Procedural site reaction	1 (25.0)	1 (25.0)	0	0	0
Investigations					
-Total	4 (100)	0	2 (50.0)	0	2 (50.0)
Neutrophil count decreased	3 (75.0)	0	1 (25.0)	0	2 (50.0)
White blood cell count decreased	3 (75.0)	0	1 (25.0)	2 (50.0)	0
International normalised ratio increased	2 (50.0)	2 (50.0)	0	0	0
Lymphocyte count decreased	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Activated partial thromboplastin time prolonged	1 (25.0)	1 (25.0)	0	0	0
Alanine aminotransferase increased	1 (25.0)	0	0	1 (25.0)	0
Aspartate aminotransferase increased	1 (25.0)	0	0	1 (25.0)	0
Blood bilirubin increased	1 (25.0)	0	1 (25.0)	0	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0
Blood uric acid increased	1 (25.0)	1 (25.0)	0	0	0
Platelet count decreased	1 (25.0)	0	1 (25.0)	0	0
Pulmonary function test decreased	1 (25.0)	0	1 (25.0)	0	0
Metabolism and nutrition disorders					
-Total	4 (100)	1 (25.0)	1 (25.0)	2 (50.0)	0
Decreased appetite	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Hyperphosphataemia	2 (50.0)	2 (50.0)	0	0	0
Dehydration	1 (25.0)	0	0	1 (25.0)	0
Hyperuricaemia	1 (25.0)	1 (25.0)	0	0	0
Hypokalaemia	1 (25.0)	0	1 (25.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Arthralgia	2 (50.0)	2 (50.0)	0	0	0
Joint range of motion decreased	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal chest pain	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal pain	1 (25.0)	0	1 (25.0)	0	0
Myalgia	1 (25.0)	1 (25.0)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Osteonecrosis	1 (25.0)	0	1 (25.0)	0	0
Pain in extremity	1 (25.0)	1 (25.0)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (25.0)	0	1 (25.0)	0	0
Skin papilloma	1 (25.0)	0	1 (25.0)	0	0
Nervous system disorders					
-Total	3 (75.0)	3 (75.0)	0	0	0
Headache	3 (75.0)	3 (75.0)	0	0	0
Dizziness	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (75.0)	1 (25.0)	1 (25.0)	1 (25.0)	0
Pulmonary oedema	1 (25.0)	0	0	1 (25.0)	0
Rhinorrhoea	1 (25.0)	1 (25.0)	0	0	0
Tachypnoea	1 (25.0)	1 (25.0)	0	0	0
Wheezing	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (75.0)	2 (50.0)	1 (25.0)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Petechiae	1 (25.0)	1 (25.0)	0	0	0
Rash	1 (25.0)	0	1 (25.0)	0	0
Rash follicular	1 (25.0)	1 (25.0)	0	0	0
Rash papular	1 (25.0)	1 (25.0)	0	0	0
Vascular disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Hypotension	1 (25.0)	0	0	0	1 (25.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184i
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	60 (100)	1 (1.7)	5 (8.3)	13 (21.7)	41 (68.3)
Blood and lymphatic system disorders					
-Total	41 (68.3)	1 (1.7)	1 (1.7)	26 (43.3)	13 (21.7)
Anaemia	24 (40.0)	3 (5.0)	2 (3.3)	18 (30.0)	1 (1.7)
Febrile neutropenia	22 (36.7)	0	0	21 (35.0)	1 (1.7)
Neutropenia	10 (16.7)	0	0	3 (5.0)	7 (11.7)
Thrombocytopenia	10 (16.7)	0	1 (1.7)	3 (5.0)	6 (10.0)
Lymphopenia	3 (5.0)	0	1 (1.7)	1 (1.7)	1 (1.7)
Cardiac disorders					
-Total	18 (30.0)	9 (15.0)	7 (11.7)	2 (3.3)	0
Tachycardia	14 (23.3)	7 (11.7)	5 (8.3)	2 (3.3)	0
Sinus tachycardia	5 (8.3)	3 (5.0)	2 (3.3)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	1 (1.7)	1 (1.7)	0	0	0
Dry eye	1 (1.7)	1 (1.7)	0	0	0
Gastrointestinal disorders					
-Total	36 (60.0)	13 (21.7)	16 (26.7)	7 (11.7)	0
Vomiting	25 (41.7)	15 (25.0)	7 (11.7)	3 (5.0)	0
Nausea	23 (38.3)	5 (8.3)	13 (21.7)	5 (8.3)	0
Diarrhoea	21 (35.0)	11 (18.3)	8 (13.3)	2 (3.3)	0
Abdominal pain	9 (15.0)	4 (6.7)	4 (6.7)	1 (1.7)	0
Constipation	6 (10.0)	5 (8.3)	1 (1.7)	0	0
Abdominal distension	1 (1.7)	0	1 (1.7)	0	0
General disorders and administration site conditions					
-Total	31 (51.7)	12 (20.0)	10 (16.7)	8 (13.3)	1 (1.7)
Pyrexia	24 (40.0)	7 (11.7)	10 (16.7)	6 (10.0)	1 (1.7)
Fatigue	11 (18.3)	8 (13.3)	2 (3.3)	1 (1.7)	0
Chills	10 (16.7)	9 (15.0)	1 (1.7)	0	0
Pain	3 (5.0)	1 (1.7)	0	2 (3.3)	0
Immune system disorders					

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	53 (88.3)	4 (6.7)	28 (46.7)	10 (16.7)	11 (18.3)
Cytokine release syndrome	48 (80.0)	6 (10.0)	24 (40.0)	7 (11.7)	11 (18.3)
Hypogammaglobulinaemia	28 (46.7)	3 (5.0)	20 (33.3)	5 (8.3)	0
Infections and infestations					
-Total	20 (33.3)	5 (8.3)	12 (20.0)	3 (5.0)	0
Upper respiratory tract infection	8 (13.3)	3 (5.0)	4 (6.7)	1 (1.7)	0
Clostridium difficile infection	4 (6.7)	0	3 (5.0)	1 (1.7)	0
Gastroenteritis	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Sinusitis	3 (5.0)	0	3 (5.0)	0	0
Viral infection	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Cytomegalovirus infection	1 (1.7)	1 (1.7)	0	0	0
Otitis media acute	1 (1.7)	0	1 (1.7)	0	0
Parainfluenzae virus infection	1 (1.7)	0	0	1 (1.7)	0
Injury, poisoning and procedural complications					
-Total	7 (11.7)	3 (5.0)	3 (5.0)	1 (1.7)	0
Procedural pain	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Infusion related reaction	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Contusion	2 (3.3)	2 (3.3)	0	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	49 (81.7)	0	4 (6.7)	13 (21.7)	32 (53.3)
White blood cell count decreased	32 (53.3)	4 (6.7)	0	10 (16.7)	18 (30.0)
Neutrophil count decreased	25 (41.7)	1 (1.7)	1 (1.7)	4 (6.7)	19 (31.7)
Alanine aminotransferase increased	20 (33.3)	5 (8.3)	2 (3.3)	13 (21.7)	0
Aspartate aminotransferase increased	19 (31.7)	4 (6.7)	4 (6.7)	7 (11.7)	4 (6.7)
Platelet count decreased	19 (31.7)	3 (5.0)	1 (1.7)	3 (5.0)	12 (20.0)
Lymphocyte count decreased	14 (23.3)	1 (1.7)	2 (3.3)	6 (10.0)	5 (8.3)
Prothrombin time prolonged	9 (15.0)	5 (8.3)	3 (5.0)	1 (1.7)	0
Blood creatinine increased	8 (13.3)	4 (6.7)	2 (3.3)	2 (3.3)	0
Blood bilirubin increased	7 (11.7)	2 (3.3)	2 (3.3)	3 (5.0)	0
International normalised ratio increased	7 (11.7)	6 (10.0)	0	1 (1.7)	0
Activated partial thromboplastin time prolonged	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Blood immunoglobulin a decreased	2 (3.3)	2 (3.3)	0	0	0
Blood uric acid increased	1 (1.7)	1 (1.7)	0	0	0
Metabolism and nutrition disorders					
-Total	34 (56.7)	5 (8.3)	7 (11.7)	19 (31.7)	3 (5.0)
Decreased appetite	20 (33.3)	5 (8.3)	4 (6.7)	11 (18.3)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Group term Preferred term	All grades n (%)	Grade 1 n (%)	All patients N=60 Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypokalaemia	18 (30.0)	4 (6.7)	5 (8.3)	8 (13.3)	1 (1.7)
Hypophosphataemia	10 (16.7)	2 (3.3)	0	7 (11.7)	1 (1.7)
Hyperphosphataemia	6 (10.0)	6 (10.0)	0	0	0
Dehydration	3 (5.0)	1 (1.7)	0	2 (3.3)	0
Hyperuricaemia	2 (3.3)	1 (1.7)	0	0	1 (1.7)
Musculoskeletal and connective tissue disorders					
-Total	18 (30.0)	12 (20.0)	5 (8.3)	1 (1.7)	0
Pain in extremity	10 (16.7)	6 (10.0)	4 (6.7)	0	0
Myalgia	4 (6.7)	3 (5.0)	1 (1.7)	0	0
Arthralgia	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Musculoskeletal pain	2 (3.3)	2 (3.3)	0	0	0
Joint range of motion decreased	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal chest pain	1 (1.7)	1 (1.7)	0	0	0
Nervous system disorders					
-Total	24 (40.0)	15 (25.0)	7 (11.7)	2 (3.3)	0
Headache	21 (35.0)	12 (20.0)	7 (11.7)	2 (3.3)	0
Dizziness	5 (8.3)	5 (8.3)	0	0	0
Psychiatric disorders					

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (20.0)	6 (10.0)	5 (8.3)	1 (1.7)	0
Anxiety	7 (11.7)	3 (5.0)	3 (5.0)	1 (1.7)	0
Confusional state	6 (10.0)	3 (5.0)	3 (5.0)	0	0
Renal and urinary disorders					
-Total	9 (15.0)	1 (1.7)	1 (1.7)	4 (6.7)	3 (5.0)
Acute kidney injury	9 (15.0)	1 (1.7)	1 (1.7)	4 (6.7)	3 (5.0)
Respiratory, thoracic and mediastinal disorders					
-Total	29 (48.3)	10 (16.7)	6 (10.0)	8 (13.3)	5 (8.3)
Cough	14 (23.3)	12 (20.0)	2 (3.3)	0	0
Epistaxis	10 (16.7)	4 (6.7)	1 (1.7)	4 (6.7)	1 (1.7)
Hypoxia	10 (16.7)	0	3 (5.0)	4 (6.7)	3 (5.0)
Pleural effusion	8 (13.3)	2 (3.3)	4 (6.7)	2 (3.3)	0
Oropharyngeal pain	6 (10.0)	4 (6.7)	2 (3.3)	0	0
Pulmonary oedema	6 (10.0)	1 (1.7)	0	3 (5.0)	2 (3.3)
Rhinorrhoea	5 (8.3)	4 (6.7)	1 (1.7)	0	0
Tachypnoea	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Skin and subcutaneous tissue disorders					
-Total	10 (16.7)	7 (11.7)	3 (5.0)	0	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	7 (11.7)	5 (8.3)	2 (3.3)	0	0
Petechiae	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Rash papular	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					
-Total	21 (35.0)	2 (3.3)	5 (8.3)	7 (11.7)	7 (11.7)
Hypotension	15 (25.0)	1 (1.7)	0	7 (11.7)	7 (11.7)
Hypertension	12 (20.0)	3 (5.0)	8 (13.3)	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184j
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (100)	1 (5.3)	2 (10.5)	4 (21.1)	12 (63.2)
Blood and lymphatic system disorders					
-Total	11 (57.9)	0	0	9 (47.4)	2 (10.5)
Febrile neutropenia	8 (42.1)	0	0	8 (42.1)	0
Anaemia	7 (36.8)	1 (5.3)	0	6 (31.6)	0
Thrombocytopenia	2 (10.5)	0	0	0	2 (10.5)
Neutropenia	1 (5.3)	0	0	1 (5.3)	0
Cardiac disorders					
-Total	6 (31.6)	3 (15.8)	2 (10.5)	1 (5.3)	0
Tachycardia	4 (21.1)	2 (10.5)	1 (5.3)	1 (5.3)	0
Sinus tachycardia	2 (10.5)	1 (5.3)	1 (5.3)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	6 (31.6)	4 (21.1)	2 (10.5)	0	0
Periorbital oedema	3 (15.8)	2 (10.5)	1 (5.3)	0	0
Conjunctival haemorrhage	2 (10.5)	2 (10.5)	0	0	0
Photophobia	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Vision blurred	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Gastrointestinal disorders					
-Total	12 (63.2)	3 (15.8)	5 (26.3)	4 (21.1)	0
Vomiting	10 (52.6)	6 (31.6)	2 (10.5)	2 (10.5)	0
Diarrhoea	8 (42.1)	4 (21.1)	3 (15.8)	1 (5.3)	0
Nausea	7 (36.8)	2 (10.5)	4 (21.1)	1 (5.3)	0
Abdominal pain	5 (26.3)	3 (15.8)	1 (5.3)	1 (5.3)	0
Constipation	3 (15.8)	2 (10.5)	1 (5.3)	0	0
General disorders and administration site conditions					
-Total	11 (57.9)	2 (10.5)	5 (26.3)	4 (21.1)	0
Pyrexia	7 (36.8)	1 (5.3)	4 (21.1)	2 (10.5)	0
Fatigue	5 (26.3)	3 (15.8)	1 (5.3)	1 (5.3)	0
Chills	2 (10.5)	2 (10.5)	0	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Malaise	2 (10.5)	0	2 (10.5)	0	0
Oedema peripheral	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Pain	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Hepatobiliary disorders					
-Total	3 (15.8)	0	1 (5.3)	2 (10.5)	0
Hyperbilirubinaemia	3 (15.8)	0	1 (5.3)	2 (10.5)	0
Immune system disorders					
-Total	18 (94.7)	0	9 (47.4)	4 (21.1)	5 (26.3)
Cytokine release syndrome	18 (94.7)	1 (5.3)	9 (47.4)	3 (15.8)	5 (26.3)
Hypogammaglobulinaemia	9 (47.4)	2 (10.5)	5 (26.3)	2 (10.5)	0
Infections and infestations					
-Total	6 (31.6)	1 (5.3)	4 (21.1)	1 (5.3)	0
Clostridium difficile colitis	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Gastroenteritis	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Rhinovirus infection	2 (10.5)	2 (10.5)	0	0	0
Clostridium difficile infection	1 (5.3)	0	1 (5.3)	0	0
Upper respiratory tract infection	1 (5.3)	0	1 (5.3)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	3 (15.8)	3 (15.8)	0	0	0
Transfusion reaction	2 (10.5)	2 (10.5)	0	0	0
Skin abrasion	1 (5.3)	1 (5.3)	0	0	0
Investigations					
-Total	14 (73.7)	1 (5.3)	0	3 (15.8)	10 (52.6)
Alanine aminotransferase increased	8 (42.1)	2 (10.5)	1 (5.3)	5 (26.3)	0
White blood cell count decreased	7 (36.8)	0	0	0	7 (36.8)
Aspartate aminotransferase increased	6 (31.6)	2 (10.5)	1 (5.3)	1 (5.3)	2 (10.5)
Neutrophil count decreased	6 (31.6)	0	0	1 (5.3)	5 (26.3)
Platelet count decreased	6 (31.6)	1 (5.3)	0	0	5 (26.3)
Blood creatinine increased	5 (26.3)	2 (10.5)	1 (5.3)	2 (10.5)	0
Prothrombin time prolonged	4 (21.1)	2 (10.5)	1 (5.3)	1 (5.3)	0
Blood bilirubin increased	3 (15.8)	1 (5.3)	1 (5.3)	1 (5.3)	0
International normalised ratio increased	3 (15.8)	2 (10.5)	0	1 (5.3)	0
Blood fibrinogen decreased	2 (10.5)	0	0	1 (5.3)	1 (5.3)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	2 (10.5)	2 (10.5)	0	0	0
Blood immunoglobulin m decreased	2 (10.5)	2 (10.5)	0	0	0
Blood urea increased	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Lymphocyte count decreased	2 (10.5)	0	0	2 (10.5)	0
Haemoglobin decreased	1 (5.3)	0	0	1 (5.3)	0
Metabolism and nutrition disorders					
-Total	15 (78.9)	2 (10.5)	4 (21.1)	8 (42.1)	1 (5.3)
Decreased appetite	7 (36.8)	1 (5.3)	2 (10.5)	4 (21.1)	0
Hypokalaemia	4 (21.1)	1 (5.3)	1 (5.3)	2 (10.5)	0
Hypophosphataemia	4 (21.1)	2 (10.5)	0	2 (10.5)	0
Dehydration	2 (10.5)	0	0	2 (10.5)	0
Fluid overload	2 (10.5)	0	2 (10.5)	0	0
Hypernatraemia	2 (10.5)	0	1 (5.3)	0	1 (5.3)
Hyperphosphataemia	2 (10.5)	2 (10.5)	0	0	0
Hypoalbuminaemia	2 (10.5)	0	2 (10.5)	0	0
Hypocalcaemia	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Musculoskeletal and connective tissue disorders					

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (21.1)	2 (10.5)	2 (10.5)	0	0
Myalgia	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Pain in extremity	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Muscle spasms	1 (5.3)	1 (5.3)	0	0	0
Nervous system disorders					
-Total	9 (47.4)	6 (31.6)	1 (5.3)	2 (10.5)	0
Headache	7 (36.8)	5 (26.3)	1 (5.3)	1 (5.3)	0
Encephalopathy	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Dizziness	1 (5.3)	1 (5.3)	0	0	0
Psychiatric disorders					
-Total	7 (36.8)	3 (15.8)	4 (21.1)	0	0
Anxiety	3 (15.8)	1 (5.3)	2 (10.5)	0	0
Confusional state	2 (10.5)	0	2 (10.5)	0	0
Delirium	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Hallucination	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Irritability	2 (10.5)	2 (10.5)	0	0	0
Renal and urinary disorders					
-Total	3 (15.8)	1 (5.3)	0	0	2 (10.5)
Acute kidney injury	3 (15.8)	1 (5.3)	0	0	2 (10.5)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	2 (10.5)	0	2 (10.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (52.6)	4 (21.1)	1 (5.3)	3 (15.8)	2 (10.5)
Cough	4 (21.1)	4 (21.1)	0	0	0
Epistaxis	4 (21.1)	1 (5.3)	1 (5.3)	2 (10.5)	0
Hypoxia	4 (21.1)	0	1 (5.3)	1 (5.3)	2 (10.5)
Pulmonary oedema	3 (15.8)	1 (5.3)	0	2 (10.5)	0
Pleural effusion	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Skin and subcutaneous tissue disorders					
-Total	5 (26.3)	4 (21.1)	1 (5.3)	0	0
Erythema	2 (10.5)	2 (10.5)	0	0	0
Hyperhidrosis	2 (10.5)	2 (10.5)	0	0	0
Pruritus	1 (5.3)	1 (5.3)	0	0	0
Rash	1 (5.3)	1 (5.3)	0	0	0
Rash maculo-papular	1 (5.3)	0	1 (5.3)	0	0
Vascular disorders					
-Total	8 (42.1)	2 (10.5)	0	2 (10.5)	4 (21.1)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	7 (36.8)	1 (5.3)	0	2 (10.5)	4 (21.1)
Hypertension	3 (15.8)	1 (5.3)	1 (5.3)	1 (5.3)	0
Flushing	2 (10.5)	2 (10.5)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184j
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	44 (97.8)	1 (2.2)	6 (13.3)	10 (22.2)	27 (60.0)
Blood and lymphatic system disorders					
-Total	29 (64.4)	1 (2.2)	2 (4.4)	19 (42.2)	7 (15.6)
Anaemia	20 (44.4)	2 (4.4)	5 (11.1)	12 (26.7)	1 (2.2)
Febrile neutropenia	14 (31.1)	0	0	14 (31.1)	0
Neutropenia	7 (15.6)	0	0	2 (4.4)	5 (11.1)
Thrombocytopenia	6 (13.3)	0	0	2 (4.4)	4 (8.9)
Cardiac disorders					
-Total	13 (28.9)	7 (15.6)	5 (11.1)	1 (2.2)	0
Tachycardia	11 (24.4)	6 (13.3)	4 (8.9)	1 (2.2)	0
Sinus tachycardia	3 (6.7)	2 (4.4)	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	1 (2.2)	0	1 (2.2)	0	0
Conjunctival haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Periorbital oedema	1 (2.2)	1 (2.2)	0	0	0
Vision blurred	1 (2.2)	0	1 (2.2)	0	0
Gastrointestinal disorders					
-Total	21 (46.7)	9 (20.0)	9 (20.0)	3 (6.7)	0
Nausea	14 (31.1)	4 (8.9)	8 (17.8)	2 (4.4)	0
Vomiting	12 (26.7)	7 (15.6)	4 (8.9)	1 (2.2)	0
Diarrhoea	10 (22.2)	7 (15.6)	3 (6.7)	0	0
Abdominal pain	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Constipation	4 (8.9)	4 (8.9)	0	0	0
General disorders and administration site conditions					
-Total	19 (42.2)	10 (22.2)	4 (8.9)	4 (8.9)	1 (2.2)
Pyrexia	9 (20.0)	2 (4.4)	3 (6.7)	3 (6.7)	1 (2.2)
Fatigue	8 (17.8)	7 (15.6)	1 (2.2)	0	0
Chills	6 (13.3)	6 (13.3)	0	0	0
Malaise	1 (2.2)	0	1 (2.2)	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	1 (2.2)	0	0	1 (2.2)	0
Immune system disorders					
-Total	38 (84.4)	4 (8.9)	21 (46.7)	7 (15.6)	6 (13.3)
Cytokine release syndrome	32 (71.1)	5 (11.1)	16 (35.6)	5 (11.1)	6 (13.3)
Hypogammaglobulinaemia	16 (35.6)	1 (2.2)	13 (28.9)	2 (4.4)	0
Infections and infestations					
-Total	5 (11.1)	1 (2.2)	3 (6.7)	1 (2.2)	0
Clostridium difficile infection	3 (6.7)	0	3 (6.7)	0	0
Clostridium difficile colitis	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Rhinovirus infection	1 (2.2)	1 (2.2)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (2.2)	0	1 (2.2)	0	0
Transfusion reaction	1 (2.2)	0	1 (2.2)	0	0
Investigations					
-Total	33 (73.3)	0	4 (8.9)	8 (17.8)	21 (46.7)
White blood cell count decreased	23 (51.1)	3 (6.7)	1 (2.2)	10 (22.2)	9 (20.0)
Neutrophil count decreased	19 (42.2)	0	2 (4.4)	3 (6.7)	14 (31.1)
Platelet count decreased	13 (28.9)	2 (4.4)	2 (4.4)	2 (4.4)	7 (15.6)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	12 (26.7)	1 (2.2)	3 (6.7)	6 (13.3)	2 (4.4)
Lymphocyte count decreased	12 (26.7)	1 (2.2)	2 (4.4)	4 (8.9)	5 (11.1)
Alanine aminotransferase increased	11 (24.4)	3 (6.7)	2 (4.4)	6 (13.3)	0
International normalised ratio increased	6 (13.3)	6 (13.3)	0	0	0
Prothrombin time prolonged	5 (11.1)	3 (6.7)	2 (4.4)	0	0
Blood bilirubin increased	4 (8.9)	1 (2.2)	2 (4.4)	1 (2.2)	0
Blood creatinine increased	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Blood fibrinogen decreased	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Blood immunoglobulin m decreased	2 (4.4)	2 (4.4)	0	0	0
Blood immunoglobulin a decreased	1 (2.2)	1 (2.2)	0	0	0
Blood urea increased	1 (2.2)	1 (2.2)	0	0	0
Metabolism and nutrition disorders					
-Total	22 (48.9)	5 (11.1)	5 (11.1)	11 (24.4)	1 (2.2)
Decreased appetite	13 (28.9)	3 (6.7)	2 (4.4)	8 (17.8)	0
Hypokalaemia	12 (26.7)	2 (4.4)	5 (11.1)	5 (11.1)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	6 (13.3)	6 (13.3)	0	0	0
Hypophosphataemia	5 (11.1)	0	0	4 (8.9)	1 (2.2)
Hypoalbuminaemia	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Hypernatraemia	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Dehydration	1 (2.2)	1 (2.2)	0	0	0
Fluid overload	1 (2.2)	1 (2.2)	0	0	0
Hypocalcaemia	1 (2.2)	1 (2.2)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Myalgia	3 (6.7)	3 (6.7)	0	0	0
Pain in extremity	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Nervous system disorders					
-Total	20 (44.4)	13 (28.9)	6 (13.3)	1 (2.2)	0
Headache	17 (37.8)	11 (24.4)	5 (11.1)	1 (2.2)	0
Dizziness	3 (6.7)	3 (6.7)	0	0	0
Encephalopathy	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Psychiatric disorders					
-Total	8 (17.8)	5 (11.1)	2 (4.4)	1 (2.2)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Anxiety	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Delirium	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Renal and urinary disorders					
-Total	5 (11.1)	0	1 (2.2)	2 (4.4)	2 (4.4)
Acute kidney injury	4 (8.9)	0	1 (2.2)	2 (4.4)	1 (2.2)
Haematuria	2 (4.4)	0	0	1 (2.2)	1 (2.2)
Respiratory, thoracic and mediastinal disorders					
-Total	13 (28.9)	4 (8.9)	3 (6.7)	3 (6.7)	3 (6.7)
Hypoxia	6 (13.3)	0	2 (4.4)	3 (6.7)	1 (2.2)
Pleural effusion	6 (13.3)	2 (4.4)	3 (6.7)	1 (2.2)	0
Cough	4 (8.9)	4 (8.9)	0	0	0
Epistaxis	3 (6.7)	1 (2.2)	0	1 (2.2)	1 (2.2)
Pulmonary oedema	3 (6.7)	0	0	1 (2.2)	2 (4.4)
Oropharyngeal pain	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Rhinitis allergic	1 (2.2)	1 (2.2)	0	0	0
Rhinorrhoea	1 (2.2)	1 (2.2)	0	0	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	8 (17.8)	7 (15.6)	0	1 (2.2)	0
Rash	3 (6.7)	3 (6.7)	0	0	0
Rash maculo-papular	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Erythema	1 (2.2)	1 (2.2)	0	0	0
Hyperhidrosis	1 (2.2)	1 (2.2)	0	0	0
Pruritus	1 (2.2)	1 (2.2)	0	0	0
Vascular disorders					
-Total	13 (28.9)	0	4 (8.9)	5 (11.1)	4 (8.9)
Hypotension	9 (20.0)	0	0	5 (11.1)	4 (8.9)
Hypertension	7 (15.6)	1 (2.2)	6 (13.3)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184j
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (88.9)	1 (5.6)	6 (33.3)	5 (27.8)	4 (22.2)
Blood and lymphatic system disorders					
-Total	4 (22.2)	1 (5.6)	0	0	3 (16.7)
Neutropenia	3 (16.7)	0	0	0	3 (16.7)
Anaemia	1 (5.6)	1 (5.6)	0	0	0
Febrile neutropenia	1 (5.6)	0	0	1 (5.6)	0
Cardiac disorders					
-Total	1 (5.6)	0	1 (5.6)	0	0
Sinus tachycardia	1 (5.6)	0	1 (5.6)	0	0
Eye disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.6)	1 (5.6)	0	0	0
Vision blurred	1 (5.6)	1 (5.6)	0	0	0
Gastrointestinal disorders					
-Total	6 (33.3)	4 (22.2)	1 (5.6)	1 (5.6)	0
Diarrhoea	4 (22.2)	3 (16.7)	0	1 (5.6)	0
Vomiting	4 (22.2)	2 (11.1)	1 (5.6)	1 (5.6)	0
Nausea	3 (16.7)	1 (5.6)	1 (5.6)	1 (5.6)	0
Abdominal pain	2 (11.1)	1 (5.6)	0	1 (5.6)	0
General disorders and administration site conditions					
-Total	6 (33.3)	4 (22.2)	2 (11.1)	0	0
Pyrexia	6 (33.3)	4 (22.2)	2 (11.1)	0	0
Chills	1 (5.6)	1 (5.6)	0	0	0
Pain	1 (5.6)	1 (5.6)	0	0	0
Immune system disorders					
-Total	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Hypogammaglobulinaemia	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Infections and infestations					
-Total	8 (44.4)	3 (16.7)	4 (22.2)	1 (5.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Ear infection	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Gastroenteritis	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Rhinovirus infection	1 (5.6)	1 (5.6)	0	0	0
Urinary tract infection	1 (5.6)	0	0	1 (5.6)	0
Injury, poisoning and procedural complications					
-Total	1 (5.6)	1 (5.6)	0	0	0
Skin abrasion	1 (5.6)	1 (5.6)	0	0	0
Investigations					
-Total	9 (50.0)	2 (11.1)	3 (16.7)	1 (5.6)	3 (16.7)
Neutrophil count decreased	4 (22.2)	1 (5.6)	0	1 (5.6)	2 (11.1)
Lymphocyte count decreased	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Weight decreased	2 (11.1)	0	2 (11.1)	0	0
White blood cell count decreased	2 (11.1)	1 (5.6)	0	0	1 (5.6)
Blood creatinine increased	1 (5.6)	1 (5.6)	0	0	0
Blood urea increased	1 (5.6)	1 (5.6)	0	0	0
Haemoglobin decreased	1 (5.6)	1 (5.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (5.6)	1 (5.6)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (22.2)	3 (16.7)	0	1 (5.6)	0
Decreased appetite	1 (5.6)	1 (5.6)	0	0	0
Dehydration	1 (5.6)	0	0	1 (5.6)	0
Hyperphosphataemia	1 (5.6)	1 (5.6)	0	0	0
Vitamin d deficiency	1 (5.6)	1 (5.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (38.9)	5 (27.8)	2 (11.1)	0	0
Pain in extremity	6 (33.3)	4 (22.2)	2 (11.1)	0	0
Muscle spasms	1 (5.6)	1 (5.6)	0	0	0
Nervous system disorders					
-Total	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Headache	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Dizziness	1 (5.6)	1 (5.6)	0	0	0
Renal and urinary disorders					
-Total	1 (5.6)	0	0	1 (5.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (5.6)	0	0	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (38.9)	4 (22.2)	2 (11.1)	1 (5.6)	0
Cough	5 (27.8)	4 (22.2)	1 (5.6)	0	0
Rhinitis allergic	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pulmonary oedema	1 (5.6)	0	0	1 (5.6)	0
Rhinorrhoea	1 (5.6)	1 (5.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (27.8)	3 (16.7)	2 (11.1)	0	0
Rash	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Rash maculo-papular	2 (11.1)	2 (11.1)	0	0	0
Pruritus	1 (5.6)	1 (5.6)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184j
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (65.8)	5 (13.2)	9 (23.7)	9 (23.7)	2 (5.3)
Blood and lymphatic system disorders					
-Total	4 (10.5)	0	1 (2.6)	3 (7.9)	0
Febrile neutropenia	2 (5.3)	0	0	2 (5.3)	0
Thrombocytopenia	2 (5.3)	0	1 (2.6)	1 (2.6)	0
Anaemia	1 (2.6)	0	0	1 (2.6)	0
Neutropenia	1 (2.6)	0	0	1 (2.6)	0
Gastrointestinal disorders					
-Total	8 (21.1)	4 (10.5)	3 (7.9)	1 (2.6)	0
Vomiting	5 (13.2)	3 (7.9)	1 (2.6)	1 (2.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=38				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	4 (10.5)	3 (7.9)	1 (2.6)	0	0
Nausea	3 (7.9)	0	2 (5.3)	1 (2.6)	0
Abdominal pain	2 (5.3)	1 (2.6)	1 (2.6)	0	0
General disorders and administration site conditions					
-Total	7 (18.4)	6 (15.8)	0	1 (2.6)	0
Pyrexia	4 (10.5)	3 (7.9)	0	1 (2.6)	0
Fatigue	2 (5.3)	2 (5.3)	0	0	0
Malaise	1 (2.6)	1 (2.6)	0	0	0
Oedema peripheral	1 (2.6)	1 (2.6)	0	0	0
Immune system disorders					
-Total	5 (13.2)	0	5 (13.2)	0	0
Hypogammaglobulinaemia	5 (13.2)	0	5 (13.2)	0	0
Infections and infestations					
-Total	9 (23.7)	3 (7.9)	4 (10.5)	2 (5.3)	0
Upper respiratory tract infection	4 (10.5)	2 (5.3)	1 (2.6)	1 (2.6)	0
Urinary tract infection	3 (7.9)	0	2 (5.3)	1 (2.6)	0
Gastroenteritis	1 (2.6)	0	1 (2.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=38				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (2.6)	1 (2.6)	0	0	0
Investigations					
-Total	10 (26.3)	2 (5.3)	0	7 (18.4)	1 (2.6)
Neutrophil count decreased	4 (10.5)	1 (2.6)	0	2 (5.3)	1 (2.6)
Aspartate aminotransferase increased	3 (7.9)	1 (2.6)	0	2 (5.3)	0
White blood cell count decreased	3 (7.9)	1 (2.6)	1 (2.6)	1 (2.6)	0
Alanine aminotransferase increased	2 (5.3)	0	0	2 (5.3)	0
Platelet count decreased	2 (5.3)	2 (5.3)	0	0	0
Weight decreased	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Blood bilirubin increased	1 (2.6)	0	0	1 (2.6)	0
Haemoglobin decreased	1 (2.6)	1 (2.6)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (7.9)	1 (2.6)	1 (2.6)	0	1 (2.6)
Hypokalaemia	2 (5.3)	1 (2.6)	0	0	1 (2.6)
Decreased appetite	1 (2.6)	0	1 (2.6)	0	0
Hyperphosphataemia	1 (2.6)	1 (2.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	1 (2.6)	0	0	1 (2.6)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (5.3)	2 (5.3)	0	0	0
Pain in extremity	2 (5.3)	2 (5.3)	0	0	0
Nervous system disorders					
-Total	3 (7.9)	3 (7.9)	0	0	0
Dizziness	2 (5.3)	2 (5.3)	0	0	0
Headache	2 (5.3)	2 (5.3)	0	0	0
Psychiatric disorders					
-Total	1 (2.6)	1 (2.6)	0	0	0
Anxiety	1 (2.6)	1 (2.6)	0	0	0
Renal and urinary disorders					
-Total	1 (2.6)	0	0	1 (2.6)	0
Haematuria	1 (2.6)	0	0	1 (2.6)	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (18.4)	4 (10.5)	2 (5.3)	1 (2.6)	0
Oropharyngeal pain	3 (7.9)	2 (5.3)	1 (2.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=38				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	3 (7.9)	2 (5.3)	1 (2.6)	0	0
Cough	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Epistaxis	2 (5.3)	1 (2.6)	0	1 (2.6)	0
Rhinitis allergic	1 (2.6)	1 (2.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (7.9)	2 (5.3)	1 (2.6)	0	0
Erythema	2 (5.3)	2 (5.3)	0	0	0
Hyperhidrosis	1 (2.6)	1 (2.6)	0	0	0
Rash	1 (2.6)	0	1 (2.6)	0	0
Vascular disorders					
-Total	2 (5.3)	1 (2.6)	1 (2.6)	0	0
Hypertension	2 (5.3)	1 (2.6)	1 (2.6)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184j
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (63.6)	2 (18.2)	1 (9.1)	4 (36.4)	0
Gastrointestinal disorders					
-Total	2 (18.2)	0	2 (18.2)	0	0
Diarrhoea	2 (18.2)	0	2 (18.2)	0	0
Abdominal pain	1 (9.1)	0	1 (9.1)	0	0
Infections and infestations					
-Total	3 (27.3)	1 (9.1)	0	2 (18.2)	0
Urinary tract infection	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Clostridium difficile infection	1 (9.1)	0	0	1 (9.1)	0
Upper respiratory tract infection	1 (9.1)	1 (9.1)	0	0	0
Investigations					

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (36.4)	1 (9.1)	1 (9.1)	2 (18.2)	0
Lymphocyte count decreased	3 (27.3)	2 (18.2)	0	1 (9.1)	0
Neutrophil count decreased	2 (18.2)	1 (9.1)	1 (9.1)	0	0
White blood cell count decreased	2 (18.2)	1 (9.1)	0	1 (9.1)	0
Metabolism and nutrition disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Vitamin d deficiency	1 (9.1)	1 (9.1)	0	0	0
Nervous system disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Dizziness	1 (9.1)	1 (9.1)	0	0	0
Headache	1 (9.1)	0	1 (9.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (18.2)	2 (18.2)	0	0	0
Cough	1 (9.1)	1 (9.1)	0	0	0
Oropharyngeal pain	1 (9.1)	1 (9.1)	0	0	0
Rhinitis allergic	1 (9.1)	1 (9.1)	0	0	0
Rhinorrhoea	1 (9.1)	1 (9.1)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184j
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (34.8)	3 (13.0)	1 (4.3)	2 (8.7)	2 (8.7)
Blood and lymphatic system disorders					
-Total	2 (8.7)	1 (4.3)	0	0	1 (4.3)
Febrile neutropenia	1 (4.3)	0	0	0	1 (4.3)
Thrombocytopenia	1 (4.3)	1 (4.3)	0	0	0
Gastrointestinal disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Nausea	1 (4.3)	0	1 (4.3)	0	0
General disorders and administration site conditions					
-Total	1 (4.3)	0	1 (4.3)	0	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	1 (4.3)	0	1 (4.3)	0	0
Pyrexia	1 (4.3)	0	1 (4.3)	0	0
Infections and infestations					
-Total	1 (4.3)	0	1 (4.3)	0	0
Upper respiratory tract infection	1 (4.3)	0	1 (4.3)	0	0
Investigations					
-Total	4 (17.4)	0	1 (4.3)	2 (8.7)	1 (4.3)
Alanine aminotransferase increased	3 (13.0)	0	1 (4.3)	2 (8.7)	0
Aspartate aminotransferase increased	2 (8.7)	1 (4.3)	0	1 (4.3)	0
White blood cell count decreased	2 (8.7)	0	0	1 (4.3)	1 (4.3)
Platelet count decreased	1 (4.3)	0	0	1 (4.3)	0
Metabolism and nutrition disorders					
-Total	1 (4.3)	0	0	1 (4.3)	0
Hypokalaemia	1 (4.3)	0	0	1 (4.3)	0
Renal and urinary disorders					
-Total	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Acute kidney injury	1 (4.3)	0	0	1 (4.3)	0

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	1 (4.3)	1 (4.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (8.7)	2 (8.7)	0	0	0
Cough	1 (4.3)	1 (4.3)	0	0	0
Epistaxis	1 (4.3)	1 (4.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (4.3)	1 (4.3)	0	0	0
Pruritus	1 (4.3)	1 (4.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184j
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (100)	0	2 (10.5)	2 (10.5)	15 (78.9)
Blood and lymphatic system disorders					
-Total	13 (68.4)	0	0	8 (42.1)	5 (26.3)
Febrile neutropenia	8 (42.1)	0	0	8 (42.1)	0
Anaemia	7 (36.8)	1 (5.3)	0	6 (31.6)	0
Neutropenia	4 (21.1)	0	0	1 (5.3)	3 (15.8)
Thrombocytopenia	2 (10.5)	0	0	0	2 (10.5)
Cardiac disorders					
-Total	7 (36.8)	3 (15.8)	3 (15.8)	1 (5.3)	0
Tachycardia	4 (21.1)	2 (10.5)	1 (5.3)	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	3 (15.8)	1 (5.3)	2 (10.5)	0	0
Eye disorders					
-Total	7 (36.8)	5 (26.3)	2 (10.5)	0	0
Periorbital oedema	3 (15.8)	2 (10.5)	1 (5.3)	0	0
Vision blurred	3 (15.8)	2 (10.5)	1 (5.3)	0	0
Conjunctival haemorrhage	2 (10.5)	2 (10.5)	0	0	0
Photophobia	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Gastrointestinal disorders					
-Total	14 (73.7)	3 (15.8)	7 (36.8)	4 (21.1)	0
Diarrhoea	12 (63.2)	5 (26.3)	5 (26.3)	2 (10.5)	0
Vomiting	11 (57.9)	6 (31.6)	3 (15.8)	2 (10.5)	0
Nausea	8 (42.1)	2 (10.5)	4 (21.1)	2 (10.5)	0
Abdominal pain	5 (26.3)	2 (10.5)	2 (10.5)	1 (5.3)	0
Constipation	3 (15.8)	2 (10.5)	1 (5.3)	0	0
General disorders and administration site conditions					
-Total	14 (73.7)	3 (15.8)	7 (36.8)	4 (21.1)	0
Pyrexia	11 (57.9)	3 (15.8)	6 (31.6)	2 (10.5)	0
Fatigue	5 (26.3)	3 (15.8)	1 (5.3)	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

			All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	3 (15.8)	3 (15.8)	0	0	0
Pain	3 (15.8)	1 (5.3)	1 (5.3)	1 (5.3)	0
Face oedema	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Malaise	2 (10.5)	0	2 (10.5)	0	0
Oedema peripheral	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Hepatobiliary disorders					
-Total	3 (15.8)	0	1 (5.3)	2 (10.5)	0
Hyperbilirubinaemia	3 (15.8)	0	1 (5.3)	2 (10.5)	0
Immune system disorders					
-Total	18 (94.7)	0	9 (47.4)	4 (21.1)	5 (26.3)
Cytokine release syndrome	18 (94.7)	1 (5.3)	9 (47.4)	3 (15.8)	5 (26.3)
Hypogammaglobulinaemia	12 (63.2)	2 (10.5)	7 (36.8)	3 (15.8)	0
Infections and infestations					
-Total	11 (57.9)	3 (15.8)	5 (26.3)	3 (15.8)	0
Gastroenteritis	4 (21.1)	1 (5.3)	2 (10.5)	1 (5.3)	0
Upper respiratory tract infection	4 (21.1)	2 (10.5)	2 (10.5)	0	0
Rhinovirus infection	3 (15.8)	3 (15.8)	0	0	0
Clostridium difficile colitis	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Clostridium difficile infection	2 (10.5)	0	1 (5.3)	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Urinary tract infection	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Injury, poisoning and procedural complications					
-Total	4 (21.1)	4 (21.1)	0	0	0
Skin abrasion	2 (10.5)	2 (10.5)	0	0	0
Transfusion reaction	2 (10.5)	2 (10.5)	0	0	0
Investigations					
-Total	16 (84.2)	0	1 (5.3)	3 (15.8)	12 (63.2)
White blood cell count decreased	10 (52.6)	1 (5.3)	0	1 (5.3)	8 (42.1)
Alanine aminotransferase increased	8 (42.1)	2 (10.5)	1 (5.3)	5 (26.3)	0
Neutrophil count decreased	8 (42.1)	1 (5.3)	0	1 (5.3)	6 (31.6)
Aspartate aminotransferase increased	6 (31.6)	2 (10.5)	1 (5.3)	1 (5.3)	2 (10.5)
Platelet count decreased	6 (31.6)	1 (5.3)	0	0	5 (26.3)
Blood creatinine increased	5 (26.3)	2 (10.5)	1 (5.3)	2 (10.5)	0
Lymphocyte count decreased	4 (21.1)	0	1 (5.3)	3 (15.8)	0
Prothrombin time prolonged	4 (21.1)	2 (10.5)	1 (5.3)	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	3 (15.8)	1 (5.3)	1 (5.3)	1 (5.3)	0
International normalised ratio increased	3 (15.8)	2 (10.5)	0	1 (5.3)	0
Blood fibrinogen decreased	2 (10.5)	0	0	1 (5.3)	1 (5.3)
Blood immunoglobulin a decreased	2 (10.5)	2 (10.5)	0	0	0
Blood immunoglobulin m decreased	2 (10.5)	2 (10.5)	0	0	0
Blood urea increased	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Haemoglobin decreased	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Weight decreased	2 (10.5)	0	2 (10.5)	0	0
Metabolism and nutrition disorders					
-Total	17 (89.5)	4 (21.1)	3 (15.8)	9 (47.4)	1 (5.3)
Decreased appetite	8 (42.1)	2 (10.5)	2 (10.5)	4 (21.1)	0
Hypokalaemia	4 (21.1)	1 (5.3)	1 (5.3)	2 (10.5)	0
Hypophosphataemia	4 (21.1)	2 (10.5)	0	2 (10.5)	0
Dehydration	3 (15.8)	0	0	3 (15.8)	0
Fluid overload	2 (10.5)	0	2 (10.5)	0	0
Hypernatraemia	2 (10.5)	0	1 (5.3)	0	1 (5.3)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	2 (10.5)	2 (10.5)	0	0	0
Hypoalbuminaemia	2 (10.5)	0	2 (10.5)	0	0
Hypocalcaemia	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Vitamin d deficiency	2 (10.5)	2 (10.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	9 (47.4)	5 (26.3)	4 (21.1)	0	0
Pain in extremity	7 (36.8)	4 (21.1)	3 (15.8)	0	0
Muscle spasms	2 (10.5)	2 (10.5)	0	0	0
Myalgia	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Nervous system disorders					
-Total	9 (47.4)	5 (26.3)	2 (10.5)	2 (10.5)	0
Headache	7 (36.8)	4 (21.1)	2 (10.5)	1 (5.3)	0
Encephalopathy	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Dizziness	1 (5.3)	1 (5.3)	0	0	0
Psychiatric disorders					
-Total	7 (36.8)	3 (15.8)	4 (21.1)	0	0
Anxiety	3 (15.8)	1 (5.3)	2 (10.5)	0	0
Confusional state	2 (10.5)	0	2 (10.5)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Hallucination	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Irritability	2 (10.5)	2 (10.5)	0	0	0
Renal and urinary disorders					
-Total	4 (21.1)	1 (5.3)	0	1 (5.3)	2 (10.5)
Acute kidney injury	4 (21.1)	1 (5.3)	0	1 (5.3)	2 (10.5)
Haematuria	2 (10.5)	0	2 (10.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	14 (73.7)	6 (31.6)	2 (10.5)	4 (21.1)	2 (10.5)
Cough	8 (42.1)	7 (36.8)	1 (5.3)	0	0
Epistaxis	4 (21.1)	1 (5.3)	1 (5.3)	2 (10.5)	0
Hypoxia	4 (21.1)	0	1 (5.3)	1 (5.3)	2 (10.5)
Pulmonary oedema	4 (21.1)	1 (5.3)	0	3 (15.8)	0
Pleural effusion	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Rhinitis allergic	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Rhinorrhoea	2 (10.5)	2 (10.5)	0	0	0
Oropharyngeal pain	1 (5.3)	1 (5.3)	0	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	9 (47.4)	6 (31.6)	3 (15.8)	0	0
Rash	4 (21.1)	2 (10.5)	2 (10.5)	0	0
Rash maculo-papular	3 (15.8)	2 (10.5)	1 (5.3)	0	0
Erythema	2 (10.5)	2 (10.5)	0	0	0
Hyperhidrosis	2 (10.5)	2 (10.5)	0	0	0
Pruritus	2 (10.5)	2 (10.5)	0	0	0
Vascular disorders					
-Total	8 (42.1)	2 (10.5)	0	2 (10.5)	4 (21.1)
Hypotension	7 (36.8)	1 (5.3)	0	2 (10.5)	4 (21.1)
Hypertension	3 (15.8)	1 (5.3)	1 (5.3)	1 (5.3)	0
Flushing	2 (10.5)	2 (10.5)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184j
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	44 (97.8)	1 (2.2)	4 (8.9)	11 (24.4)	28 (62.2)
Blood and lymphatic system disorders					
-Total	31 (68.9)	1 (2.2)	2 (4.4)	20 (44.4)	8 (17.8)
Anaemia	20 (44.4)	2 (4.4)	4 (8.9)	13 (28.9)	1 (2.2)
Febrile neutropenia	16 (35.6)	0	0	15 (33.3)	1 (2.2)
Thrombocytopenia	8 (17.8)	0	1 (2.2)	3 (6.7)	4 (8.9)
Neutropenia	7 (15.6)	0	0	2 (4.4)	5 (11.1)
Cardiac disorders					
-Total	13 (28.9)	7 (15.6)	5 (11.1)	1 (2.2)	0
Tachycardia	11 (24.4)	6 (13.3)	4 (8.9)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	3 (6.7)	2 (4.4)	1 (2.2)	0	0
Eye disorders					
-Total	1 (2.2)	0	1 (2.2)	0	0
Conjunctival haemorrhage	1 (2.2)	1 (2.2)	0	0	0
Periorbital oedema	1 (2.2)	1 (2.2)	0	0	0
Vision blurred	1 (2.2)	0	1 (2.2)	0	0
Gastrointestinal disorders					
-Total	25 (55.6)	11 (24.4)	11 (24.4)	3 (6.7)	0
Nausea	17 (37.8)	4 (8.9)	10 (22.2)	3 (6.7)	0
Vomiting	16 (35.6)	10 (22.2)	5 (11.1)	1 (2.2)	0
Diarrhoea	12 (26.7)	8 (17.8)	4 (8.9)	0	0
Abdominal pain	6 (13.3)	4 (8.9)	2 (4.4)	0	0
Constipation	4 (8.9)	4 (8.9)	0	0	0
General disorders and administration site conditions					
-Total	24 (53.3)	13 (28.9)	5 (11.1)	5 (11.1)	1 (2.2)
Pyrexia	14 (31.1)	5 (11.1)	4 (8.9)	4 (8.9)	1 (2.2)
Fatigue	10 (22.2)	9 (20.0)	1 (2.2)	0	0
Chills	7 (15.6)	6 (13.3)	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Oedema peripheral	1 (2.2)	1 (2.2)	0	0	0
Pain	1 (2.2)	0	0	1 (2.2)	0
Immune system disorders					
-Total	39 (86.7)	4 (8.9)	22 (48.9)	7 (15.6)	6 (13.3)
Cytokine release syndrome	32 (71.1)	5 (11.1)	16 (35.6)	5 (11.1)	6 (13.3)
Hypogammaglobulinaemia	20 (44.4)	1 (2.2)	17 (37.8)	2 (4.4)	0
Infections and infestations					
-Total	13 (28.9)	3 (6.7)	7 (15.6)	3 (6.7)	0
Upper respiratory tract infection	5 (11.1)	2 (4.4)	2 (4.4)	1 (2.2)	0
Clostridium difficile infection	3 (6.7)	0	3 (6.7)	0	0
Urinary tract infection	3 (6.7)	0	2 (4.4)	1 (2.2)	0
Clostridium difficile colitis	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Rhinovirus infection	2 (4.4)	2 (4.4)	0	0	0
Gastroenteritis	1 (2.2)	0	1 (2.2)	0	0
Injury, poisoning and procedural complications					
-Total	1 (2.2)	0	1 (2.2)	0	0
Transfusion reaction	1 (2.2)	0	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	36 (80.0)	0	4 (8.9)	10 (22.2)	22 (48.9)
White blood cell count decreased	25 (55.6)	3 (6.7)	1 (2.2)	11 (24.4)	10 (22.2)
Neutrophil count decreased	20 (44.4)	0	2 (4.4)	3 (6.7)	15 (33.3)
Aspartate aminotransferase increased	14 (31.1)	2 (4.4)	3 (6.7)	7 (15.6)	2 (4.4)
Platelet count decreased	14 (31.1)	2 (4.4)	2 (4.4)	3 (6.7)	7 (15.6)
Alanine aminotransferase increased	13 (28.9)	3 (6.7)	1 (2.2)	9 (20.0)	0
Lymphocyte count decreased	12 (26.7)	1 (2.2)	2 (4.4)	4 (8.9)	5 (11.1)
International normalised ratio increased	6 (13.3)	6 (13.3)	0	0	0
Blood bilirubin increased	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Prothrombin time prolonged	5 (11.1)	3 (6.7)	2 (4.4)	0	0
Blood creatinine increased	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Blood fibrinogen decreased	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Blood immunoglobulin m decreased	2 (4.4)	2 (4.4)	0	0	0
Weight decreased	2 (4.4)	1 (2.2)	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (2.2)	1 (2.2)	0	0	0
Blood urea increased	1 (2.2)	1 (2.2)	0	0	0
Haemoglobin decreased	1 (2.2)	1 (2.2)	0	0	0
Metabolism and nutrition disorders					
-Total	24 (53.3)	5 (11.1)	5 (11.1)	12 (26.7)	2 (4.4)
Hypokalaemia	15 (33.3)	3 (6.7)	5 (11.1)	6 (13.3)	1 (2.2)
Decreased appetite	14 (31.1)	3 (6.7)	3 (6.7)	8 (17.8)	0
Hyperphosphataemia	6 (13.3)	6 (13.3)	0	0	0
Hypophosphataemia	6 (13.3)	0	0	5 (11.1)	1 (2.2)
Hypoalbuminaemia	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)	0
Hypernatraemia	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Dehydration	1 (2.2)	1 (2.2)	0	0	0
Fluid overload	1 (2.2)	1 (2.2)	0	0	0
Hypocalcaemia	1 (2.2)	1 (2.2)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	6 (13.3)	5 (11.1)	1 (2.2)	0	0
Pain in extremity	4 (8.9)	3 (6.7)	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	3 (6.7)	3 (6.7)	0	0	0
Nervous system disorders					
-Total	21 (46.7)	14 (31.1)	6 (13.3)	1 (2.2)	0
Headache	17 (37.8)	11 (24.4)	5 (11.1)	1 (2.2)	0
Dizziness	5 (11.1)	5 (11.1)	0	0	0
Encephalopathy	2 (4.4)	0	1 (2.2)	1 (2.2)	0
Psychiatric disorders					
-Total	8 (17.8)	5 (11.1)	2 (4.4)	1 (2.2)	0
Anxiety	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
Confusional state	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Delirium	2 (4.4)	1 (2.2)	1 (2.2)	0	0
Renal and urinary disorders					
-Total	7 (15.6)	0	1 (2.2)	4 (8.9)	2 (4.4)
Acute kidney injury	5 (11.1)	0	1 (2.2)	3 (6.7)	1 (2.2)
Haematuria	3 (6.7)	0	0	2 (4.4)	1 (2.2)
Respiratory, thoracic and mediastinal disorders					
-Total	19 (42.2)	7 (15.6)	5 (11.1)	4 (8.9)	3 (6.7)
Cough	6 (13.3)	5 (11.1)	1 (2.2)	0	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

			All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	6 (13.3)	3 (6.7)	0	2 (4.4)	1 (2.2)
Hypoxia	6 (13.3)	0	2 (4.4)	3 (6.7)	1 (2.2)
Pleural effusion	6 (13.3)	2 (4.4)	3 (6.7)	1 (2.2)	0
Oropharyngeal pain	5 (11.1)	3 (6.7)	2 (4.4)	0	0
Rhinorrhoea	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Pulmonary oedema	3 (6.7)	0	0	1 (2.2)	2 (4.4)
Rhinitis allergic	2 (4.4)	2 (4.4)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	10 (22.2)	8 (17.8)	1 (2.2)	1 (2.2)	0
Rash	4 (8.9)	3 (6.7)	1 (2.2)	0	0
Erythema	3 (6.7)	3 (6.7)	0	0	0
Hyperhidrosis	2 (4.4)	2 (4.4)	0	0	0
Pruritus	2 (4.4)	2 (4.4)	0	0	0
Rash maculo-papular	2 (4.4)	1 (2.2)	0	1 (2.2)	0
Vascular disorders					
-Total	14 (31.1)	0	5 (11.1)	5 (11.1)	4 (8.9)
Hypertension	9 (20.0)	2 (4.4)	7 (15.6)	0	0
Hypotension	9 (20.0)	0	0	5 (11.1)	4 (8.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184k
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: US

			All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	63 (98.4)	2 (3.1)	8 (12.5)	14 (21.9)	39 (60.9)
Blood and lymphatic system disorders					
-Total	40 (62.5)	1 (1.6)	2 (3.1)	28 (43.8)	9 (14.1)
Anaemia	27 (42.2)	3 (4.7)	5 (7.8)	18 (28.1)	1 (1.6)
Febrile neutropenia	22 (34.4)	0	0	22 (34.4)	0
Neutropenia	8 (12.5)	0	0	3 (4.7)	5 (7.8)
Thrombocytopenia	8 (12.5)	0	0	2 (3.1)	6 (9.4)
Cardiac disorders					
-Total	15 (23.4)	8 (12.5)	5 (7.8)	2 (3.1)	0
Tachycardia	15 (23.4)	8 (12.5)	5 (7.8)	2 (3.1)	0
Gastrointestinal disorders					
-Total	33 (51.6)	12 (18.8)	14 (21.9)	7 (10.9)	0

Timing: within 8 weeks post infusion, Region: US

			All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	22 (34.4)	13 (20.3)	6 (9.4)	3 (4.7)	0
Nausea	21 (32.8)	6 (9.4)	12 (18.8)	3 (4.7)	0
Diarrhoea	18 (28.1)	11 (17.2)	6 (9.4)	1 (1.6)	0
Abdominal pain	9 (14.1)	6 (9.4)	2 (3.1)	1 (1.6)	0
Constipation	7 (10.9)	6 (9.4)	1 (1.6)	0	0
General disorders and administration site conditions					
-Total	28 (43.8)	13 (20.3)	8 (12.5)	6 (9.4)	1 (1.6)
Pyrexia	16 (25.0)	3 (4.7)	7 (10.9)	5 (7.8)	1 (1.6)
Fatigue	13 (20.3)	10 (15.6)	2 (3.1)	1 (1.6)	0
Chills	8 (12.5)	8 (12.5)	0	0	0
Immune system disorders					
-Total	56 (87.5)	4 (6.3)	30 (46.9)	11 (17.2)	11 (17.2)
Cytokine release syndrome	50 (78.1)	6 (9.4)	25 (39.1)	8 (12.5)	11 (17.2)
Hypogammaglobulinaemia	25 (39.1)	3 (4.7)	18 (28.1)	4 (6.3)	0
Infections and infestations					
-Total	1 (1.6)	0	1 (1.6)	0	0
Upper respiratory tract infection	1 (1.6)	0	1 (1.6)	0	0
Investigations					

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	47 (73.4)	1 (1.6)	4 (6.3)	11 (17.2)	31 (48.4)
White blood cell count decreased	30 (46.9)	3 (4.7)	1 (1.6)	10 (15.6)	16 (25.0)
Neutrophil count decreased	25 (39.1)	0	2 (3.1)	4 (6.3)	19 (29.7)
Alanine aminotransferase increased	19 (29.7)	5 (7.8)	3 (4.7)	11 (17.2)	0
Platelet count decreased	19 (29.7)	3 (4.7)	2 (3.1)	2 (3.1)	12 (18.8)
Aspartate aminotransferase increased	18 (28.1)	3 (4.7)	4 (6.3)	7 (10.9)	4 (6.3)
Lymphocyte count decreased	14 (21.9)	1 (1.6)	2 (3.1)	6 (9.4)	5 (7.8)
Blood creatinine increased	9 (14.1)	5 (7.8)	2 (3.1)	2 (3.1)	0
International normalised ratio increased	9 (14.1)	8 (12.5)	0	1 (1.6)	0
Prothrombin time prolonged	9 (14.1)	5 (7.8)	3 (4.7)	1 (1.6)	0
Blood bilirubin increased	7 (10.9)	2 (3.1)	3 (4.7)	2 (3.1)	0
Metabolism and nutrition disorders					
-Total	33 (51.6)	7 (10.9)	8 (12.5)	17 (26.6)	1 (1.6)
Decreased appetite	20 (31.3)	4 (6.3)	4 (6.3)	12 (18.8)	0
Hypokalaemia	16 (25.0)	3 (4.7)	6 (9.4)	7 (10.9)	0
Hypophosphataemia	9 (14.1)	2 (3.1)	0	6 (9.4)	1 (1.6)
Hyperphosphataemia	8 (12.5)	8 (12.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (6.3)	2 (3.1)	2 (3.1)	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	4 (6.3)	2 (3.1)	2 (3.1)	0	0
Nervous system disorders					
-Total	24 (37.5)	16 (25.0)	6 (9.4)	2 (3.1)	0
Headache	24 (37.5)	16 (25.0)	6 (9.4)	2 (3.1)	0
Psychiatric disorders					
-Total	6 (9.4)	2 (3.1)	3 (4.7)	1 (1.6)	0
Anxiety	6 (9.4)	2 (3.1)	3 (4.7)	1 (1.6)	0
Renal and urinary disorders					
-Total	7 (10.9)	1 (1.6)	1 (1.6)	2 (3.1)	3 (4.7)
Acute kidney injury	7 (10.9)	1 (1.6)	1 (1.6)	2 (3.1)	3 (4.7)
Respiratory, thoracic and mediastinal disorders					
-Total	21 (32.8)	6 (9.4)	4 (6.3)	6 (9.4)	5 (7.8)
Hypoxia	10 (15.6)	0	3 (4.7)	4 (6.3)	3 (4.7)
Cough	8 (12.5)	8 (12.5)	0	0	0
Pleural effusion	8 (12.5)	2 (3.1)	4 (6.3)	2 (3.1)	0
Epistaxis	7 (10.9)	2 (3.1)	1 (1.6)	3 (4.7)	1 (1.6)
Pulmonary oedema	6 (9.4)	1 (1.6)	0	3 (4.7)	2 (3.1)
Skin and subcutaneous tissue disorders					
-Total	4 (6.3)	4 (6.3)	0	0	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	4 (6.3)	4 (6.3)	0	0	0
Vascular disorders					
-Total	21 (32.8)	2 (3.1)	4 (6.3)	7 (10.9)	8 (12.5)
Hypotension	16 (25.0)	1 (1.6)	0	7 (10.9)	8 (12.5)
Hypertension	10 (15.6)	2 (3.1)	7 (10.9)	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184k
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

			All patients N=56		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (69.6)	8 (14.3)	12 (21.4)	13 (23.2)	6 (10.7)
Blood and lymphatic system disorders					
-Total	8 (14.3)	1 (1.8)	1 (1.8)	3 (5.4)	3 (5.4)
Neutropenia	4 (7.1)	0	0	1 (1.8)	3 (5.4)
Febrile neutropenia	3 (5.4)	0	0	3 (5.4)	0
Anaemia	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Thrombocytopenia	2 (3.6)	0	1 (1.8)	1 (1.8)	0
Gastrointestinal disorders					
-Total	14 (25.0)	8 (14.3)	4 (7.1)	2 (3.6)	0
Vomiting	9 (16.1)	5 (8.9)	2 (3.6)	2 (3.6)	0
Diarrhoea	8 (14.3)	6 (10.7)	1 (1.8)	1 (1.8)	0
Nausea	6 (10.7)	1 (1.8)	3 (5.4)	2 (3.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	4 (7.1)	2 (3.6)	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions					
-Total	11 (19.6)	8 (14.3)	2 (3.6)	1 (1.8)	0
Pyrexia	10 (17.9)	7 (12.5)	2 (3.6)	1 (1.8)	0
Fatigue	2 (3.6)	2 (3.6)	0	0	0
Chills	1 (1.8)	1 (1.8)	0	0	0
Immune system disorders					
-Total	8 (14.3)	0	7 (12.5)	1 (1.8)	0
Hypogammaglobulinaemia	8 (14.3)	0	7 (12.5)	1 (1.8)	0
Infections and infestations					
-Total	7 (12.5)	3 (5.4)	3 (5.4)	1 (1.8)	0
Upper respiratory tract infection	7 (12.5)	3 (5.4)	3 (5.4)	1 (1.8)	0
Investigations					
-Total	16 (28.6)	3 (5.4)	1 (1.8)	8 (14.3)	4 (7.1)
Neutrophil count decreased	8 (14.3)	2 (3.6)	0	3 (5.4)	3 (5.4)
White blood cell count decreased	5 (8.9)	2 (3.6)	1 (1.8)	1 (1.8)	1 (1.8)
Aspartate aminotransferase increased	3 (5.4)	1 (1.8)	0	2 (3.6)	0
Platelet count decreased	3 (5.4)	3 (5.4)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	2 (3.6)	0	0	2 (3.6)	0
Lymphocyte count decreased	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Blood bilirubin increased	1 (1.8)	0	0	1 (1.8)	0
Blood creatinine increased	1 (1.8)	1 (1.8)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (8.9)	3 (5.4)	1 (1.8)	0	1 (1.8)
Decreased appetite	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Hyperphosphataemia	2 (3.6)	2 (3.6)	0	0	0
Hypokalaemia	2 (3.6)	1 (1.8)	0	0	1 (1.8)
Hypophosphataemia	1 (1.8)	0	0	1 (1.8)	0
Musculoskeletal and connective tissue disorders					
-Total	8 (14.3)	6 (10.7)	2 (3.6)	0	0
Pain in extremity	8 (14.3)	6 (10.7)	2 (3.6)	0	0
Nervous system disorders					
-Total	5 (8.9)	4 (7.1)	1 (1.8)	0	0
Headache	5 (8.9)	4 (7.1)	1 (1.8)	0	0
Psychiatric disorders					
-Total	1 (1.8)	1 (1.8)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	1 (1.8)	1 (1.8)	0	0	0
Renal and urinary disorders					
-Total	1 (1.8)	0	0	1 (1.8)	0
Acute kidney injury	1 (1.8)	0	0	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (17.9)	6 (10.7)	2 (3.6)	2 (3.6)	0
Cough	7 (12.5)	5 (8.9)	2 (3.6)	0	0
Epistaxis	2 (3.6)	1 (1.8)	0	1 (1.8)	0
Pulmonary oedema	1 (1.8)	0	0	1 (1.8)	0
Skin and subcutaneous tissue disorders					
-Total	4 (7.1)	1 (1.8)	3 (5.4)	0	0
Rash	4 (7.1)	1 (1.8)	3 (5.4)	0	0
Vascular disorders					
-Total	2 (3.6)	1 (1.8)	1 (1.8)	0	0
Hypertension	2 (3.6)	1 (1.8)	1 (1.8)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184k
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: US

			All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (38.2)	3 (8.8)	4 (11.8)	4 (11.8)	2 (5.9)
Blood and lymphatic system disorders					
-Total	2 (5.9)	1 (2.9)	0	0	1 (2.9)
Febrile neutropenia	1 (2.9)	0	0	0	1 (2.9)
Thrombocytopenia	1 (2.9)	1 (2.9)	0	0	0
Gastrointestinal disorders					
-Total	3 (8.8)	0	3 (8.8)	0	0
Diarrhoea	2 (5.9)	0	2 (5.9)	0	0
Abdominal pain	1 (2.9)	0	1 (2.9)	0	0
Nausea	1 (2.9)	0	1 (2.9)	0	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, Region: US

		All patients N=34			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.9)	0	1 (2.9)	0	0
Chills	1 (2.9)	0	1 (2.9)	0	0
Pyrexia	1 (2.9)	0	1 (2.9)	0	0
Infections and infestations					
-Total	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Upper respiratory tract infection	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Investigations					
-Total	8 (23.5)	1 (2.9)	2 (5.9)	4 (11.8)	1 (2.9)
White blood cell count decreased	4 (11.8)	1 (2.9)	0	2 (5.9)	1 (2.9)
Alanine aminotransferase increased	3 (8.8)	0	1 (2.9)	2 (5.9)	0
Lymphocyte count decreased	3 (8.8)	2 (5.9)	0	1 (2.9)	0
Aspartate aminotransferase increased	2 (5.9)	1 (2.9)	0	1 (2.9)	0
Neutrophil count decreased	2 (5.9)	1 (2.9)	1 (2.9)	0	0
Platelet count decreased	1 (2.9)	0	0	1 (2.9)	0
Metabolism and nutrition disorders					
-Total	1 (2.9)	0	0	1 (2.9)	0
Hypokalaemia	1 (2.9)	0	0	1 (2.9)	0
Nervous system disorders					
-Total	1 (2.9)	0	1 (2.9)	0	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=34				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (2.9)	0	1 (2.9)	0	0
Renal and urinary disorders					
-Total	1 (2.9)	0	0	1 (2.9)	0
Acute kidney injury	1 (2.9)	0	0	1 (2.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (8.8)	3 (8.8)	0	0	0
Cough	2 (5.9)	2 (5.9)	0	0	0
Epistaxis	1 (2.9)	1 (2.9)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184k
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: US

			All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	63 (98.4)	1 (1.6)	6 (9.4)	13 (20.3)	43 (67.2)
Blood and lymphatic system disorders					
-Total	44 (68.8)	1 (1.6)	2 (3.1)	28 (43.8)	13 (20.3)
Anaemia	27 (42.2)	3 (4.7)	4 (6.3)	19 (29.7)	1 (1.6)
Febrile neutropenia	24 (37.5)	0	0	23 (35.9)	1 (1.6)
Neutropenia	11 (17.2)	0	0	3 (4.7)	8 (12.5)
Thrombocytopenia	10 (15.6)	0	1 (1.6)	3 (4.7)	6 (9.4)
Cardiac disorders					
-Total	15 (23.4)	8 (12.5)	5 (7.8)	2 (3.1)	0
Tachycardia	15 (23.4)	8 (12.5)	5 (7.8)	2 (3.1)	0
Gastrointestinal disorders					
-Total	39 (60.9)	14 (21.9)	18 (28.1)	7 (10.9)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	27 (42.2)	16 (25.0)	8 (12.5)	3 (4.7)	0
Nausea	25 (39.1)	6 (9.4)	14 (21.9)	5 (7.8)	0
Diarrhoea	24 (37.5)	13 (20.3)	9 (14.1)	2 (3.1)	0
Abdominal pain	11 (17.2)	6 (9.4)	4 (6.3)	1 (1.6)	0
Constipation	7 (10.9)	6 (9.4)	1 (1.6)	0	0
General disorders and administration site conditions					
-Total	35 (54.7)	16 (25.0)	11 (17.2)	7 (10.9)	1 (1.6)
Pyrexia	25 (39.1)	8 (12.5)	10 (15.6)	6 (9.4)	1 (1.6)
Fatigue	15 (23.4)	12 (18.8)	2 (3.1)	1 (1.6)	0
Chills	10 (15.6)	9 (14.1)	1 (1.6)	0	0
Immune system disorders					
-Total	57 (89.1)	4 (6.3)	31 (48.4)	11 (17.2)	11 (17.2)
Cytokine release syndrome	50 (78.1)	6 (9.4)	25 (39.1)	8 (12.5)	11 (17.2)
Hypogammaglobulinaemia	32 (50.0)	3 (4.7)	24 (37.5)	5 (7.8)	0
Infections and infestations					
-Total	9 (14.1)	4 (6.3)	4 (6.3)	1 (1.6)	0
Upper respiratory tract infection	9 (14.1)	4 (6.3)	4 (6.3)	1 (1.6)	0
Investigations					

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	52 (81.3)	0	5 (7.8)	13 (20.3)	34 (53.1)
White blood cell count decreased	35 (54.7)	4 (6.3)	1 (1.6)	12 (18.8)	18 (28.1)
Neutrophil count decreased	28 (43.8)	1 (1.6)	2 (3.1)	4 (6.3)	21 (32.8)
Alanine aminotransferase increased	21 (32.8)	5 (7.8)	2 (3.1)	14 (21.9)	0
Aspartate aminotransferase increased	20 (31.3)	4 (6.3)	4 (6.3)	8 (12.5)	4 (6.3)
Platelet count decreased	20 (31.3)	3 (4.7)	2 (3.1)	3 (4.7)	12 (18.8)
Lymphocyte count decreased	16 (25.0)	1 (1.6)	3 (4.7)	7 (10.9)	5 (7.8)
Blood creatinine increased	9 (14.1)	5 (7.8)	2 (3.1)	2 (3.1)	0
International normalised ratio increased	9 (14.1)	8 (12.5)	0	1 (1.6)	0
Prothrombin time prolonged	9 (14.1)	5 (7.8)	3 (4.7)	1 (1.6)	0
Blood bilirubin increased	8 (12.5)	2 (3.1)	3 (4.7)	3 (4.7)	0
Metabolism and nutrition disorders					
-Total	35 (54.7)	7 (10.9)	8 (12.5)	18 (28.1)	2 (3.1)
Decreased appetite	22 (34.4)	5 (7.8)	5 (7.8)	12 (18.8)	0
Hypokalaemia	19 (29.7)	4 (6.3)	6 (9.4)	8 (12.5)	1 (1.6)
Hypophosphataemia	10 (15.6)	2 (3.1)	0	7 (10.9)	1 (1.6)
Hyperphosphataemia	8 (12.5)	8 (12.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	11 (17.2)	7 (10.9)	4 (6.3)	0	0

Timing: Any time post CTL019 infusion, Region: US

			All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	11 (17.2)	7 (10.9)	4 (6.3)	0	0
Nervous system disorders					
-Total	24 (37.5)	15 (23.4)	7 (10.9)	2 (3.1)	0
Headache	24 (37.5)	15 (23.4)	7 (10.9)	2 (3.1)	0
Psychiatric disorders					
-Total	7 (10.9)	3 (4.7)	3 (4.7)	1 (1.6)	0
Anxiety	7 (10.9)	3 (4.7)	3 (4.7)	1 (1.6)	0
Renal and urinary disorders					
-Total	9 (14.1)	1 (1.6)	1 (1.6)	4 (6.3)	3 (4.7)
Acute kidney injury	9 (14.1)	1 (1.6)	1 (1.6)	4 (6.3)	3 (4.7)
Respiratory, thoracic and mediastinal disorders					
-Total	28 (43.8)	10 (15.6)	5 (7.8)	8 (12.5)	5 (7.8)
Cough	14 (21.9)	12 (18.8)	2 (3.1)	0	0
Epistaxis	10 (15.6)	4 (6.3)	1 (1.6)	4 (6.3)	1 (1.6)
Hypoxia	10 (15.6)	0	3 (4.7)	4 (6.3)	3 (4.7)
Pleural effusion	8 (12.5)	2 (3.1)	4 (6.3)	2 (3.1)	0
Pulmonary oedema	7 (10.9)	1 (1.6)	0	4 (6.3)	2 (3.1)
Skin and subcutaneous tissue disorders					
-Total	8 (12.5)	5 (7.8)	3 (4.7)	0	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	8 (12.5)	5 (7.8)	3 (4.7)	0	0
Vascular disorders					
-Total	22 (34.4)	2 (3.1)	5 (7.8)	7 (10.9)	8 (12.5)
Hypotension	16 (25.0)	1 (1.6)	0	7 (10.9)	8 (12.5)
Hypertension	12 (18.8)	3 (4.7)	8 (12.5)	1 (1.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184l
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

			All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (96.4)	1 (3.6)	4 (14.3)	8 (28.6)	14 (50.0)
Blood and lymphatic system disorders					
-Total	18 (64.3)	0	2 (7.1)	13 (46.4)	3 (10.7)
Anaemia	14 (50.0)	1 (3.6)	4 (14.3)	9 (32.1)	0
Febrile neutropenia	9 (32.1)	0	0	9 (32.1)	0
Lymphopenia	2 (7.1)	0	1 (3.6)	0	1 (3.6)
Thrombocytopenia	2 (7.1)	0	0	1 (3.6)	1 (3.6)
Neutropenia	1 (3.6)	0	0	0	1 (3.6)
Cardiac disorders					
-Total	10 (35.7)	4 (14.3)	5 (17.9)	1 (3.6)	0
Tachycardia	7 (25.0)	3 (10.7)	3 (10.7)	1 (3.6)	0
Sinus tachycardia	4 (14.3)	2 (7.1)	2 (7.1)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	16 (57.1)	6 (21.4)	7 (25.0)	3 (10.7)	0
Nausea	12 (42.9)	5 (17.9)	6 (21.4)	1 (3.6)	0
Diarrhoea	10 (35.7)	7 (25.0)	3 (10.7)	0	0
Vomiting	10 (35.7)	8 (28.6)	0	2 (7.1)	0
Abdominal pain	7 (25.0)	5 (17.9)	2 (7.1)	0	0
Constipation	2 (7.1)	2 (7.1)	0	0	0
General disorders and administration site conditions					
-Total	13 (46.4)	8 (28.6)	3 (10.7)	2 (7.1)	0
Fatigue	8 (28.6)	6 (21.4)	1 (3.6)	1 (3.6)	0
Pyrexia	6 (21.4)	3 (10.7)	2 (7.1)	1 (3.6)	0
Chills	3 (10.7)	3 (10.7)	0	0	0
Immune system disorders					
-Total	22 (78.6)	3 (10.7)	12 (42.9)	5 (17.9)	2 (7.1)
Cytokine release syndrome	20 (71.4)	3 (10.7)	11 (39.3)	4 (14.3)	2 (7.1)
Hypogammaglobulinaemia	9 (32.1)	2 (7.1)	6 (21.4)	1 (3.6)	0
Infections and infestations					
-Total	3 (10.7)	0	3 (10.7)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Clostridium difficile infection	3 (10.7)	0	3 (10.7)	0	0
Rhinovirus infection	1 (3.6)	1 (3.6)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Transfusion reaction	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Investigations					
-Total	21 (75.0)	1 (3.6)	2 (7.1)	5 (17.9)	13 (46.4)
White blood cell count decreased	15 (53.6)	0	1 (3.6)	7 (25.0)	7 (25.0)
Alanine aminotransferase increased	12 (42.9)	4 (14.3)	2 (7.1)	6 (21.4)	0
Aspartate aminotransferase increased	12 (42.9)	3 (10.7)	2 (7.1)	5 (17.9)	2 (7.1)
Neutrophil count decreased	12 (42.9)	0	1 (3.6)	1 (3.6)	10 (35.7)
Platelet count decreased	11 (39.3)	2 (7.1)	1 (3.6)	1 (3.6)	7 (25.0)
Blood bilirubin increased	6 (21.4)	2 (7.1)	2 (7.1)	2 (7.1)	0
Blood creatinine increased	6 (21.4)	4 (14.3)	1 (3.6)	1 (3.6)	0
Lymphocyte count decreased	6 (21.4)	0	1 (3.6)	4 (14.3)	1 (3.6)
Prothrombin time prolonged	6 (21.4)	4 (14.3)	2 (7.1)	0	0
International normalised ratio increased	5 (17.9)	5 (17.9)	0	0	0
Blood immunoglobulin a decreased	3 (10.7)	3 (10.7)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	3 (10.7)	3 (10.7)	0	0	0
Haemoglobin decreased	1 (3.6)	0	0	1 (3.6)	0
Metabolism and nutrition disorders					
-Total	17 (60.7)	5 (17.9)	5 (17.9)	7 (25.0)	0
Decreased appetite	9 (32.1)	2 (7.1)	2 (7.1)	5 (17.9)	0
Hyperphosphataemia	7 (25.0)	7 (25.0)	0	0	0
Hypokalaemia	7 (25.0)	1 (3.6)	3 (10.7)	3 (10.7)	0
Hypophosphataemia	4 (14.3)	1 (3.6)	0	3 (10.7)	0
Musculoskeletal and connective tissue disorders					
-Total	7 (25.0)	5 (17.9)	2 (7.1)	0	0
Myalgia	5 (17.9)	4 (14.3)	1 (3.6)	0	0
Pain in extremity	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Nervous system disorders					
-Total	13 (46.4)	7 (25.0)	4 (14.3)	2 (7.1)	0
Headache	12 (42.9)	6 (21.4)	4 (14.3)	2 (7.1)	0
Dizziness	3 (10.7)	3 (10.7)	0	0	0
Psychiatric disorders					
-Total	4 (14.3)	1 (3.6)	2 (7.1)	1 (3.6)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Confusional state	2 (7.1)	0	2 (7.1)	0	0
Renal and urinary disorders					
-Total	2 (7.1)	1 (3.6)	0	0	1 (3.6)
Acute kidney injury	2 (7.1)	1 (3.6)	0	0	1 (3.6)
Respiratory, thoracic and mediastinal disorders					
-Total	12 (42.9)	5 (17.9)	4 (14.3)	2 (7.1)	1 (3.6)
Hypoxia	5 (17.9)	0	3 (10.7)	1 (3.6)	1 (3.6)
Cough	4 (14.3)	4 (14.3)	0	0	0
Epistaxis	3 (10.7)	1 (3.6)	0	2 (7.1)	0
Pleural effusion	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Oropharyngeal pain	1 (3.6)	1 (3.6)	0	0	0
Pulmonary oedema	1 (3.6)	0	0	1 (3.6)	0
Rhinitis allergic	1 (3.6)	1 (3.6)	0	0	0
Rhinorrhoea	1 (3.6)	1 (3.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (14.3)	2 (7.1)	1 (3.6)	1 (3.6)	0
Petechiae	2 (7.1)	1 (3.6)	1 (3.6)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	2 (7.1)	2 (7.1)	0	0	0
Rash maculo-papular	1 (3.6)	0	0	1 (3.6)	0
Vascular disorders					
-Total	9 (32.1)	2 (7.1)	2 (7.1)	2 (7.1)	3 (10.7)
Hypotension	6 (21.4)	1 (3.6)	0	2 (7.1)	3 (10.7)
Hypertension	5 (17.9)	1 (3.6)	3 (10.7)	1 (3.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184l
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (100)	1 (2.8)	4 (11.1)	6 (16.7)	25 (69.4)
Blood and lymphatic system disorders					
-Total	22 (61.1)	1 (2.8)	0	14 (38.9)	7 (19.4)
Anaemia	13 (36.1)	2 (5.6)	1 (2.8)	9 (25.0)	1 (2.8)
Febrile neutropenia	13 (36.1)	0	0	13 (36.1)	0
Neutropenia	7 (19.4)	0	0	3 (8.3)	4 (11.1)
Thrombocytopenia	6 (16.7)	0	0	1 (2.8)	5 (13.9)
Lymphopenia	1 (2.8)	0	0	1 (2.8)	0
Cardiac disorders					
-Total	9 (25.0)	6 (16.7)	2 (5.6)	1 (2.8)	0
Tachycardia	8 (22.2)	5 (13.9)	2 (5.6)	1 (2.8)	0
Sinus tachycardia	1 (2.8)	1 (2.8)	0	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	17 (47.2)	6 (16.7)	7 (19.4)	4 (11.1)	0
Vomiting	12 (33.3)	5 (13.9)	6 (16.7)	1 (2.8)	0
Nausea	9 (25.0)	1 (2.8)	6 (16.7)	2 (5.6)	0
Diarrhoea	8 (22.2)	4 (11.1)	3 (8.3)	1 (2.8)	0
Constipation	5 (13.9)	4 (11.1)	1 (2.8)	0	0
Abdominal pain	2 (5.6)	1 (2.8)	0	1 (2.8)	0
General disorders and administration site conditions					
-Total	15 (41.7)	5 (13.9)	5 (13.9)	4 (11.1)	1 (2.8)
Pyrexia	10 (27.8)	0	5 (13.9)	4 (11.1)	1 (2.8)
Chills	5 (13.9)	5 (13.9)	0	0	0
Fatigue	5 (13.9)	4 (11.1)	1 (2.8)	0	0
Immune system disorders					
-Total	34 (94.4)	1 (2.8)	18 (50.0)	6 (16.7)	9 (25.0)
Cytokine release syndrome	30 (83.3)	3 (8.3)	14 (38.9)	4 (11.1)	9 (25.0)
Hypogammaglobulinaemia	16 (44.4)	1 (2.8)	12 (33.3)	3 (8.3)	0
Infections and infestations					
-Total	6 (16.7)	2 (5.6)	3 (8.3)	1 (2.8)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Rhinovirus infection	2 (5.6)	2 (5.6)	0	0	0
Clostridium difficile infection	1 (2.8)	0	1 (2.8)	0	0
Upper respiratory tract infection	1 (2.8)	0	1 (2.8)	0	0
Investigations					
-Total	26 (72.2)	0	2 (5.6)	6 (16.7)	18 (50.0)
White blood cell count decreased	15 (41.7)	3 (8.3)	0	3 (8.3)	9 (25.0)
Neutrophil count decreased	13 (36.1)	0	1 (2.8)	3 (8.3)	9 (25.0)
Lymphocyte count decreased	8 (22.2)	1 (2.8)	1 (2.8)	2 (5.6)	4 (11.1)
Platelet count decreased	8 (22.2)	1 (2.8)	1 (2.8)	1 (2.8)	5 (13.9)
Alanine aminotransferase increased	7 (19.4)	1 (2.8)	1 (2.8)	5 (13.9)	0
Aspartate aminotransferase increased	6 (16.7)	0	2 (5.6)	2 (5.6)	2 (5.6)
Blood fibrinogen decreased	4 (11.1)	0	1 (2.8)	2 (5.6)	1 (2.8)
International normalised ratio increased	4 (11.1)	3 (8.3)	0	1 (2.8)	0
Blood creatinine increased	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Prothrombin time prolonged	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Blood bilirubin increased	1 (2.8)	0	1 (2.8)	0	0
Blood immunoglobulin m decreased	1 (2.8)	1 (2.8)	0	0	0
Metabolism and nutrition disorders					

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	18 (50.0)	3 (8.3)	3 (8.3)	10 (27.8)	2 (5.6)
Decreased appetite	11 (30.6)	2 (5.6)	2 (5.6)	7 (19.4)	0
Hypokalaemia	9 (25.0)	2 (5.6)	3 (8.3)	4 (11.1)	0
Hypophosphataemia	5 (13.9)	1 (2.8)	0	3 (8.3)	1 (2.8)
Hypernatraemia	4 (11.1)	1 (2.8)	2 (5.6)	0	1 (2.8)
Hyperphosphataemia	1 (2.8)	1 (2.8)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (2.8)	0	1 (2.8)	0	0
Pain in extremity	1 (2.8)	0	1 (2.8)	0	0
Nervous system disorders					
-Total	13 (36.1)	11 (30.6)	2 (5.6)	0	0
Headache	12 (33.3)	10 (27.8)	2 (5.6)	0	0
Dizziness	1 (2.8)	1 (2.8)	0	0	0
Psychiatric disorders					
-Total	10 (27.8)	6 (16.7)	4 (11.1)	0	0
Confusional state	4 (11.1)	3 (8.3)	1 (2.8)	0	0
Delirium	4 (11.1)	2 (5.6)	2 (5.6)	0	0
Anxiety	3 (8.3)	1 (2.8)	2 (5.6)	0	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

			All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	5 (13.9)	0	1 (2.8)	2 (5.6)	2 (5.6)
Acute kidney injury	5 (13.9)	0	1 (2.8)	2 (5.6)	2 (5.6)
Respiratory, thoracic and mediastinal disorders					
-Total	12 (33.3)	4 (11.1)	0	4 (11.1)	4 (11.1)
Hypoxia	5 (13.9)	0	0	3 (8.3)	2 (5.6)
Pleural effusion	5 (13.9)	1 (2.8)	2 (5.6)	2 (5.6)	0
Pulmonary oedema	5 (13.9)	1 (2.8)	0	2 (5.6)	2 (5.6)
Cough	4 (11.1)	4 (11.1)	0	0	0
Epistaxis	4 (11.1)	1 (2.8)	1 (2.8)	1 (2.8)	1 (2.8)
Nasal congestion	1 (2.8)	1 (2.8)	0	0	0
Oropharyngeal pain	1 (2.8)	0	1 (2.8)	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (13.9)	4 (11.1)	1 (2.8)	0	0
Rash	2 (5.6)	2 (5.6)	0	0	0
Rash maculo-papular	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Petechiae	1 (2.8)	1 (2.8)	0	0	0
Vascular disorders					

Timing: within 8 weeks post infusion, Prior SCT therapy: No

Group term Preferred term	All patients N=36 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	12 (33.3)	0	2 (5.6)	5 (13.9)	5 (13.9)
Hypotension	10 (27.8)	0	0	5 (13.9)	5 (13.9)
Hypertension	5 (13.9)	1 (2.8)	4 (11.1)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184l
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

		All patients N=25			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (68.0)	2 (8.0)	7 (28.0)	4 (16.0)	4 (16.0)
Blood and lymphatic system disorders					
-Total	5 (20.0)	1 (4.0)	1 (4.0)	2 (8.0)	1 (4.0)
Anaemia	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Febrile neutropenia	1 (4.0)	0	0	1 (4.0)	0
Lymphopenia	1 (4.0)	0	1 (4.0)	0	0
Neutropenia	1 (4.0)	0	0	0	1 (4.0)
Thrombocytopenia	1 (4.0)	0	0	1 (4.0)	0
Cardiac disorders					
-Total	1 (4.0)	0	1 (4.0)	0	0
Sinus tachycardia	1 (4.0)	0	1 (4.0)	0	0
Gastrointestinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (28.0)	3 (12.0)	3 (12.0)	1 (4.0)	0
Vomiting	5 (20.0)	2 (8.0)	2 (8.0)	1 (4.0)	0
Nausea	4 (16.0)	1 (4.0)	2 (8.0)	1 (4.0)	0
Diarrhoea	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Abdominal pain	2 (8.0)	1 (4.0)	1 (4.0)	0	0
General disorders and administration site conditions					
-Total	6 (24.0)	5 (20.0)	1 (4.0)	0	0
Pyrexia	6 (24.0)	5 (20.0)	1 (4.0)	0	0
Chills	1 (4.0)	1 (4.0)	0	0	0
Fatigue	1 (4.0)	1 (4.0)	0	0	0
Immune system disorders					
-Total	5 (20.0)	0	5 (20.0)	0	0
Hypogammaglobulinaemia	5 (20.0)	0	5 (20.0)	0	0
Infections and infestations					
-Total	6 (24.0)	0	3 (12.0)	3 (12.0)	0
Upper respiratory tract infection	3 (12.0)	2 (8.0)	0	1 (4.0)	0
Urinary tract infection	3 (12.0)	0	1 (4.0)	2 (8.0)	0
Otitis media	1 (4.0)	0	1 (4.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinusitis	1 (4.0)	0	1 (4.0)	0	0
Investigations					
-Total	8 (32.0)	2 (8.0)	1 (4.0)	3 (12.0)	2 (8.0)
Neutrophil count decreased	5 (20.0)	2 (8.0)	0	1 (4.0)	2 (8.0)
Aspartate aminotransferase increased	3 (12.0)	1 (4.0)	0	2 (8.0)	0
Platelet count decreased	3 (12.0)	3 (12.0)	0	0	0
Haemoglobin decreased	2 (8.0)	2 (8.0)	0	0	0
Lymphocyte count decreased	2 (8.0)	1 (4.0)	1 (4.0)	0	0
White blood cell count decreased	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Alanine aminotransferase increased	1 (4.0)	0	0	1 (4.0)	0
Blood creatinine increased	1 (4.0)	1 (4.0)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (20.0)	3 (12.0)	1 (4.0)	0	1 (4.0)
Decreased appetite	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Hyperphosphataemia	2 (8.0)	2 (8.0)	0	0	0
Hypokalaemia	2 (8.0)	1 (4.0)	0	0	1 (4.0)
Hypophosphataemia	1 (4.0)	0	0	1 (4.0)	0
Musculoskeletal and connective tissue disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Pain in extremity	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Nervous system disorders					
-Total	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Headache	3 (12.0)	2 (8.0)	1 (4.0)	0	0
Dizziness	2 (8.0)	2 (8.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (24.0)	5 (20.0)	1 (4.0)	0	0
Cough	4 (16.0)	3 (12.0)	1 (4.0)	0	0
Rhinitis allergic	2 (8.0)	2 (8.0)	0	0	0
Epistaxis	1 (4.0)	1 (4.0)	0	0	0
Nasal congestion	1 (4.0)	1 (4.0)	0	0	0
Oropharyngeal pain	1 (4.0)	1 (4.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (20.0)	4 (16.0)	1 (4.0)	0	0
Rash	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Rash maculo-papular	2 (8.0)	2 (8.0)	0	0	0
Petechiae	1 (4.0)	1 (4.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184l
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

			All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (77.4)	4 (12.9)	9 (29.0)	9 (29.0)	2 (6.5)
Blood and lymphatic system disorders					
-Total	4 (12.9)	0	1 (3.2)	1 (3.2)	2 (6.5)
Neutropenia	3 (9.7)	0	0	1 (3.2)	2 (6.5)
Febrile neutropenia	2 (6.5)	0	0	2 (6.5)	0
Thrombocytopenia	1 (3.2)	0	1 (3.2)	0	0
Gastrointestinal disorders					
-Total	7 (22.6)	5 (16.1)	1 (3.2)	1 (3.2)	0
Diarrhoea	5 (16.1)	4 (12.9)	0	1 (3.2)	0
Vomiting	4 (12.9)	3 (9.7)	0	1 (3.2)	0
Abdominal pain	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Nausea	2 (6.5)	0	1 (3.2)	1 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	5 (16.1)	3 (9.7)	1 (3.2)	1 (3.2)	0
Pyrexia	4 (12.9)	2 (6.5)	1 (3.2)	1 (3.2)	0
Fatigue	1 (3.2)	1 (3.2)	0	0	0
Immune system disorders					
-Total	3 (9.7)	0	2 (6.5)	1 (3.2)	0
Hypogammaglobulinaemia	3 (9.7)	0	2 (6.5)	1 (3.2)	0
Infections and infestations					
-Total	11 (35.5)	4 (12.9)	7 (22.6)	0	0
Upper respiratory tract infection	4 (12.9)	1 (3.2)	3 (9.7)	0	0
Gastroenteritis	3 (9.7)	1 (3.2)	2 (6.5)	0	0
Rhinovirus infection	2 (6.5)	2 (6.5)	0	0	0
Sinusitis	1 (3.2)	0	1 (3.2)	0	0
Urinary tract infection	1 (3.2)	0	1 (3.2)	0	0
Investigations					
-Total	8 (25.8)	1 (3.2)	0	5 (16.1)	2 (6.5)
Neutrophil count decreased	3 (9.7)	0	0	2 (6.5)	1 (3.2)
White blood cell count decreased	3 (9.7)	1 (3.2)	0	1 (3.2)	1 (3.2)

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

			All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (3.2)	0	0	1 (3.2)	0
Blood bilirubin increased	1 (3.2)	0	0	1 (3.2)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (16.1)	4 (12.9)	1 (3.2)	0	0
Pain in extremity	5 (16.1)	4 (12.9)	1 (3.2)	0	0
Nervous system disorders					
-Total	3 (9.7)	3 (9.7)	0	0	0
Headache	2 (6.5)	2 (6.5)	0	0	0
Dizziness	1 (3.2)	1 (3.2)	0	0	0
Psychiatric disorders					
-Total	1 (3.2)	1 (3.2)	0	0	0
Anxiety	1 (3.2)	1 (3.2)	0	0	0
Renal and urinary disorders					
-Total	1 (3.2)	0	0	1 (3.2)	0
Acute kidney injury	1 (3.2)	0	0	1 (3.2)	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (32.3)	5 (16.1)	3 (9.7)	2 (6.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	4 (12.9)	3 (9.7)	1 (3.2)	0	0
Cough	3 (9.7)	2 (6.5)	1 (3.2)	0	0
Nasal congestion	3 (9.7)	3 (9.7)	0	0	0
Oropharyngeal pain	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Epistaxis	1 (3.2)	0	0	1 (3.2)	0
Pulmonary oedema	1 (3.2)	0	0	1 (3.2)	0
Rhinitis allergic	1 (3.2)	0	1 (3.2)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (6.5)	0	2 (6.5)	0	0
Rash	2 (6.5)	0	2 (6.5)	0	0
Vascular disorders					
-Total	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Hypertension	2 (6.5)	1 (3.2)	1 (3.2)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184l
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (57.1)	3 (21.4)	1 (7.1)	4 (28.6)	0
Blood and lymphatic system disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Thrombocytopenia	1 (7.1)	1 (7.1)	0	0	0
Gastrointestinal disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Diarrhoea	2 (14.3)	0	2 (14.3)	0	0
Abdominal pain	1 (7.1)	0	1 (7.1)	0	0
Infections and infestations					
-Total	5 (35.7)	1 (7.1)	1 (7.1)	3 (21.4)	0
Otitis media	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Sinusitis	2 (14.3)	0	2 (14.3)	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

		All patients N=14			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Urinary tract infection	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Clostridium difficile infection	1 (7.1)	0	0	1 (7.1)	0
Investigations					
-Total	3 (21.4)	1 (7.1)	1 (7.1)	1 (7.1)	0
Lymphocyte count decreased	2 (14.3)	2 (14.3)	0	0	0
Neutrophil count decreased	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Alanine aminotransferase increased	1 (7.1)	0	0	1 (7.1)	0
Aspartate aminotransferase increased	1 (7.1)	0	0	1 (7.1)	0
White blood cell count decreased	1 (7.1)	1 (7.1)	0	0	0
Nervous system disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0
Dizziness	1 (7.1)	1 (7.1)	0	0	0
Headache	1 (7.1)	0	1 (7.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (21.4)	3 (21.4)	0	0	0
Cough	1 (7.1)	1 (7.1)	0	0	0
Epistaxis	1 (7.1)	1 (7.1)	0	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	1 (7.1)	1 (7.1)	0	0	0
Rhinitis allergic	1 (7.1)	1 (7.1)	0	0	0
Rhinorrhoea	1 (7.1)	1 (7.1)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184l
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

		All patients N=20			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (35.0)	0	2 (10.0)	3 (15.0)	2 (10.0)
Blood and lymphatic system disorders					
-Total	1 (5.0)	0	0	0	1 (5.0)
Febrile neutropenia	1 (5.0)	0	0	0	1 (5.0)
Gastrointestinal disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Nausea	1 (5.0)	0	1 (5.0)	0	0
General disorders and administration site conditions					
-Total	1 (5.0)	0	1 (5.0)	0	0
Chills	1 (5.0)	0	1 (5.0)	0	0
Pyrexia	1 (5.0)	0	1 (5.0)	0	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	2 (10.0)	0	2 (10.0)	0	0
Otitis media	1 (5.0)	0	1 (5.0)	0	0
Sinusitis	1 (5.0)	0	1 (5.0)	0	0
Investigations					
-Total	5 (25.0)	0	1 (5.0)	3 (15.0)	1 (5.0)
White blood cell count decreased	3 (15.0)	0	0	2 (10.0)	1 (5.0)
Alanine aminotransferase increased	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Aspartate aminotransferase increased	1 (5.0)	1 (5.0)	0	0	0
Lymphocyte count decreased	1 (5.0)	0	0	1 (5.0)	0
Platelet count decreased	1 (5.0)	0	0	1 (5.0)	0
Metabolism and nutrition disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Hypokalaemia	1 (5.0)	0	0	1 (5.0)	0
Renal and urinary disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Acute kidney injury	1 (5.0)	0	0	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders					

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.0)	1 (5.0)	0	0	0
Cough	1 (5.0)	1 (5.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184l
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

			All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (100)	0	3 (10.7)	9 (32.1)	16 (57.1)
Blood and lymphatic system disorders					
-Total	20 (71.4)	0	1 (3.6)	15 (53.6)	4 (14.3)
Anaemia	14 (50.0)	1 (3.6)	3 (10.7)	10 (35.7)	0
Febrile neutropenia	10 (35.7)	0	0	10 (35.7)	0
Lymphopenia	3 (10.7)	0	2 (7.1)	0	1 (3.6)
Thrombocytopenia	3 (10.7)	0	0	2 (7.1)	1 (3.6)
Neutropenia	2 (7.1)	0	0	0	2 (7.1)
Cardiac disorders					
-Total	11 (39.3)	4 (14.3)	6 (21.4)	1 (3.6)	0
Tachycardia	7 (25.0)	3 (10.7)	3 (10.7)	1 (3.6)	0
Sinus tachycardia	5 (17.9)	2 (7.1)	3 (10.7)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	18 (64.3)	6 (21.4)	9 (32.1)	3 (10.7)	0
Nausea	14 (50.0)	5 (17.9)	7 (25.0)	2 (7.1)	0
Vomiting	13 (46.4)	9 (32.1)	2 (7.1)	2 (7.1)	0
Diarrhoea	12 (42.9)	6 (21.4)	6 (21.4)	0	0
Abdominal pain	8 (28.6)	4 (14.3)	4 (14.3)	0	0
Constipation	2 (7.1)	2 (7.1)	0	0	0
General disorders and administration site conditions					
-Total	17 (60.7)	11 (39.3)	4 (14.3)	2 (7.1)	0
Pyrexia	11 (39.3)	7 (25.0)	3 (10.7)	1 (3.6)	0
Fatigue	9 (32.1)	7 (25.0)	1 (3.6)	1 (3.6)	0
Chills	4 (14.3)	4 (14.3)	0	0	0
Immune system disorders					
-Total	23 (82.1)	3 (10.7)	13 (46.4)	5 (17.9)	2 (7.1)
Cytokine release syndrome	20 (71.4)	3 (10.7)	11 (39.3)	4 (14.3)	2 (7.1)
Hypogammaglobulinaemia	13 (46.4)	2 (7.1)	10 (35.7)	1 (3.6)	0
Infections and infestations					
-Total	11 (39.3)	1 (3.6)	5 (17.9)	5 (17.9)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	5 (17.9)	3 (10.7)	1 (3.6)	1 (3.6)	0
Clostridium difficile infection	4 (14.3)	0	3 (10.7)	1 (3.6)	0
Urinary tract infection	4 (14.3)	0	2 (7.1)	2 (7.1)	0
Otitis media	3 (10.7)	0	2 (7.1)	1 (3.6)	0
Sinusitis	3 (10.7)	0	3 (10.7)	0	0
Rhinovirus infection	1 (3.6)	1 (3.6)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Transfusion reaction	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Investigations					
-Total	22 (78.6)	0	3 (10.7)	5 (17.9)	14 (50.0)
White blood cell count decreased	16 (57.1)	1 (3.6)	1 (3.6)	7 (25.0)	7 (25.0)
Neutrophil count decreased	14 (50.0)	1 (3.6)	1 (3.6)	1 (3.6)	11 (39.3)
Alanine aminotransferase increased	13 (46.4)	4 (14.3)	1 (3.6)	8 (28.6)	0
Aspartate aminotransferase increased	13 (46.4)	3 (10.7)	2 (7.1)	6 (21.4)	2 (7.1)
Platelet count decreased	11 (39.3)	2 (7.1)	1 (3.6)	1 (3.6)	7 (25.0)
Lymphocyte count decreased	7 (25.0)	0	2 (7.1)	4 (14.3)	1 (3.6)
Blood bilirubin increased	6 (21.4)	2 (7.1)	2 (7.1)	2 (7.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	6 (21.4)	4 (14.3)	1 (3.6)	1 (3.6)	0
Prothrombin time prolonged	6 (21.4)	4 (14.3)	2 (7.1)	0	0
International normalised ratio increased	5 (17.9)	5 (17.9)	0	0	0
Blood immunoglobulin a decreased	3 (10.7)	3 (10.7)	0	0	0
Blood immunoglobulin m decreased	3 (10.7)	3 (10.7)	0	0	0
Haemoglobin decreased	3 (10.7)	2 (7.1)	0	1 (3.6)	0
Metabolism and nutrition disorders					
-Total	18 (64.3)	5 (17.9)	5 (17.9)	7 (25.0)	1 (3.6)
Decreased appetite	11 (39.3)	3 (10.7)	3 (10.7)	5 (17.9)	0
Hypokalaemia	9 (32.1)	2 (7.1)	3 (10.7)	3 (10.7)	1 (3.6)
Hyperphosphataemia	7 (25.0)	7 (25.0)	0	0	0
Hypophosphataemia	5 (17.9)	1 (3.6)	0	4 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	8 (28.6)	5 (17.9)	3 (10.7)	0	0
Myalgia	5 (17.9)	4 (14.3)	1 (3.6)	0	0
Pain in extremity	5 (17.9)	3 (10.7)	2 (7.1)	0	0
Nervous system disorders					
-Total	13 (46.4)	6 (21.4)	5 (17.9)	2 (7.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	12 (42.9)	5 (17.9)	5 (17.9)	2 (7.1)	0
Dizziness	4 (14.3)	4 (14.3)	0	0	0
Psychiatric disorders					
-Total	4 (14.3)	1 (3.6)	2 (7.1)	1 (3.6)	0
Anxiety	3 (10.7)	1 (3.6)	1 (3.6)	1 (3.6)	0
Confusional state	2 (7.1)	0	2 (7.1)	0	0
Renal and urinary disorders					
-Total	2 (7.1)	1 (3.6)	0	0	1 (3.6)
Acute kidney injury	2 (7.1)	1 (3.6)	0	0	1 (3.6)
Respiratory, thoracic and mediastinal disorders					
-Total	16 (57.1)	9 (32.1)	4 (14.3)	2 (7.1)	1 (3.6)
Cough	7 (25.0)	6 (21.4)	1 (3.6)	0	0
Epistaxis	5 (17.9)	3 (10.7)	0	2 (7.1)	0
Hypoxia	5 (17.9)	0	3 (10.7)	1 (3.6)	1 (3.6)
Oropharyngeal pain	3 (10.7)	3 (10.7)	0	0	0
Pleural effusion	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Rhinitis allergic	3 (10.7)	3 (10.7)	0	0	0
Rhinorrhoea	2 (7.1)	2 (7.1)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	1 (3.6)	1 (3.6)	0	0	0
Pulmonary oedema	1 (3.6)	0	0	1 (3.6)	0
Skin and subcutaneous tissue disorders					
-Total	9 (32.1)	6 (21.4)	2 (7.1)	1 (3.6)	0
Rash	4 (14.3)	3 (10.7)	1 (3.6)	0	0
Petechiae	3 (10.7)	2 (7.1)	1 (3.6)	0	0
Rash maculo-papular	3 (10.7)	2 (7.1)	0	1 (3.6)	0
Vascular disorders					
-Total	9 (32.1)	2 (7.1)	2 (7.1)	2 (7.1)	3 (10.7)
Hypotension	6 (21.4)	1 (3.6)	0	2 (7.1)	3 (10.7)
Hypertension	5 (17.9)	1 (3.6)	3 (10.7)	1 (3.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184l
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

		All patients N=36			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (100)	1 (2.8)	3 (8.3)	5 (13.9)	27 (75.0)
Blood and lymphatic system disorders					
-Total	24 (66.7)	1 (2.8)	1 (2.8)	12 (33.3)	10 (27.8)
Febrile neutropenia	14 (38.9)	0	0	13 (36.1)	1 (2.8)
Anaemia	13 (36.1)	2 (5.6)	1 (2.8)	9 (25.0)	1 (2.8)
Neutropenia	9 (25.0)	0	0	3 (8.3)	6 (16.7)
Thrombocytopenia	7 (19.4)	0	1 (2.8)	1 (2.8)	5 (13.9)
Lymphopenia	1 (2.8)	0	0	1 (2.8)	0
Cardiac disorders					
-Total	9 (25.0)	6 (16.7)	2 (5.6)	1 (2.8)	0
Tachycardia	8 (22.2)	5 (13.9)	2 (5.6)	1 (2.8)	0
Sinus tachycardia	1 (2.8)	1 (2.8)	0	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	21 (58.3)	8 (22.2)	9 (25.0)	4 (11.1)	0
Vomiting	14 (38.9)	7 (19.4)	6 (16.7)	1 (2.8)	0
Diarrhoea	12 (33.3)	7 (19.4)	3 (8.3)	2 (5.6)	0
Nausea	11 (30.6)	1 (2.8)	7 (19.4)	3 (8.3)	0
Constipation	5 (13.9)	4 (11.1)	1 (2.8)	0	0
Abdominal pain	3 (8.3)	2 (5.6)	0	1 (2.8)	0
General disorders and administration site conditions					
-Total	18 (50.0)	5 (13.9)	7 (19.4)	5 (13.9)	1 (2.8)
Pyrexia	14 (38.9)	1 (2.8)	7 (19.4)	5 (13.9)	1 (2.8)
Chills	6 (16.7)	5 (13.9)	1 (2.8)	0	0
Fatigue	6 (16.7)	5 (13.9)	1 (2.8)	0	0
Immune system disorders					
-Total	34 (94.4)	1 (2.8)	18 (50.0)	6 (16.7)	9 (25.0)
Cytokine release syndrome	30 (83.3)	3 (8.3)	14 (38.9)	4 (11.1)	9 (25.0)
Hypogammaglobulinaemia	19 (52.8)	1 (2.8)	14 (38.9)	4 (11.1)	0
Infections and infestations					
-Total	15 (41.7)	5 (13.9)	9 (25.0)	1 (2.8)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	5 (13.9)	1 (2.8)	3 (8.3)	1 (2.8)	0
Rhinovirus infection	4 (11.1)	4 (11.1)	0	0	0
Upper respiratory tract infection	4 (11.1)	1 (2.8)	3 (8.3)	0	0
Clostridium difficile infection	1 (2.8)	0	1 (2.8)	0	0
Otitis media	1 (2.8)	0	1 (2.8)	0	0
Sinusitis	1 (2.8)	0	1 (2.8)	0	0
Urinary tract infection	1 (2.8)	0	1 (2.8)	0	0
Investigations					
-Total	30 (83.3)	0	2 (5.6)	8 (22.2)	20 (55.6)
White blood cell count decreased	19 (52.8)	3 (8.3)	0	5 (13.9)	11 (30.6)
Neutrophil count decreased	14 (38.9)	0	1 (2.8)	3 (8.3)	10 (27.8)
Lymphocyte count decreased	9 (25.0)	1 (2.8)	1 (2.8)	3 (8.3)	4 (11.1)
Platelet count decreased	9 (25.0)	1 (2.8)	1 (2.8)	2 (5.6)	5 (13.9)
Alanine aminotransferase increased	8 (22.2)	1 (2.8)	1 (2.8)	6 (16.7)	0
Aspartate aminotransferase increased	7 (19.4)	1 (2.8)	2 (5.6)	2 (5.6)	2 (5.6)
Blood fibrinogen decreased	4 (11.1)	0	1 (2.8)	2 (5.6)	1 (2.8)
International normalised ratio increased	4 (11.1)	3 (8.3)	0	1 (2.8)	0
Blood creatinine increased	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Prothrombin time prolonged	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	2 (5.6)	0	1 (2.8)	1 (2.8)	0
Blood immunoglobulin m decreased	1 (2.8)	1 (2.8)	0	0	0
Metabolism and nutrition disorders					
-Total	19 (52.8)	3 (8.3)	3 (8.3)	11 (30.6)	2 (5.6)
Decreased appetite	11 (30.6)	2 (5.6)	2 (5.6)	7 (19.4)	0
Hypokalaemia	10 (27.8)	2 (5.6)	3 (8.3)	5 (13.9)	0
Hypophosphataemia	5 (13.9)	1 (2.8)	0	3 (8.3)	1 (2.8)
Hypernatraemia	4 (11.1)	1 (2.8)	2 (5.6)	0	1 (2.8)
Hyperphosphataemia	1 (2.8)	1 (2.8)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	6 (16.7)	4 (11.1)	2 (5.6)	0	0
Pain in extremity	6 (16.7)	4 (11.1)	2 (5.6)	0	0
Nervous system disorders					
-Total	14 (38.9)	12 (33.3)	2 (5.6)	0	0
Headache	12 (33.3)	10 (27.8)	2 (5.6)	0	0
Dizziness	2 (5.6)	2 (5.6)	0	0	0
Psychiatric disorders					
-Total	10 (27.8)	6 (16.7)	4 (11.1)	0	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	4 (11.1)	2 (5.6)	2 (5.6)	0	0
Confusional state	4 (11.1)	3 (8.3)	1 (2.8)	0	0
Delirium	4 (11.1)	2 (5.6)	2 (5.6)	0	0
Renal and urinary disorders					
-Total	7 (19.4)	0	1 (2.8)	4 (11.1)	2 (5.6)
Acute kidney injury	7 (19.4)	0	1 (2.8)	4 (11.1)	2 (5.6)
Respiratory, thoracic and mediastinal disorders					
-Total	19 (52.8)	6 (16.7)	3 (8.3)	6 (16.7)	4 (11.1)
Cough	7 (19.4)	6 (16.7)	1 (2.8)	0	0
Pulmonary oedema	6 (16.7)	1 (2.8)	0	3 (8.3)	2 (5.6)
Epistaxis	5 (13.9)	1 (2.8)	1 (2.8)	2 (5.6)	1 (2.8)
Hypoxia	5 (13.9)	0	0	3 (8.3)	2 (5.6)
Pleural effusion	5 (13.9)	1 (2.8)	2 (5.6)	2 (5.6)	0
Nasal congestion	4 (11.1)	4 (11.1)	0	0	0
Rhinorrhoea	4 (11.1)	3 (8.3)	1 (2.8)	0	0
Oropharyngeal pain	3 (8.3)	1 (2.8)	2 (5.6)	0	0
Rhinitis allergic	1 (2.8)	0	1 (2.8)	0	0
Skin and subcutaneous tissue disorders					

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

Group term Preferred term	All patients N=36 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	7 (19.4)	4 (11.1)	3 (8.3)	0	0
Rash	4 (11.1)	2 (5.6)	2 (5.6)	0	0
Rash maculo-papular	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Petechiae	1 (2.8)	1 (2.8)	0	0	0
Vascular disorders					
-Total	13 (36.1)	0	3 (8.3)	5 (13.9)	5 (13.9)
Hypotension	10 (27.8)	0	0	5 (13.9)	5 (13.9)
Hypertension	7 (19.4)	2 (5.6)	5 (13.9)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184m
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

		All patients N=14			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (100)	0	2 (14.3)	3 (21.4)	9 (64.3)
Blood and lymphatic system disorders					
-Total	11 (78.6)	0	1 (7.1)	8 (57.1)	2 (14.3)
Febrile neutropenia	9 (64.3)	0	0	9 (64.3)	0
Anaemia	5 (35.7)	2 (14.3)	1 (7.1)	2 (14.3)	0
Thrombocytopenia	2 (14.3)	0	0	0	2 (14.3)
Neutropenia	1 (7.1)	0	0	1 (7.1)	0
Cardiac disorders					
-Total	3 (21.4)	3 (21.4)	0	0	0
Tachycardia	2 (14.3)	2 (14.3)	0	0	0
Sinus tachycardia	1 (7.1)	1 (7.1)	0	0	0
Gastrointestinal disorders					

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (28.6)	1 (7.1)	1 (7.1)	2 (14.3)	0
Nausea	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Abdominal pain	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Constipation	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Vomiting	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Diarrhoea	1 (7.1)	1 (7.1)	0	0	0
General disorders and administration site conditions					
-Total	3 (21.4)	1 (7.1)	1 (7.1)	1 (7.1)	0
Pyrexia	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Chills	1 (7.1)	1 (7.1)	0	0	0
Fatigue	1 (7.1)	1 (7.1)	0	0	0
Immune system disorders					
-Total	14 (100)	0	10 (71.4)	3 (21.4)	1 (7.1)
Cytokine release syndrome	13 (92.9)	0	10 (71.4)	2 (14.3)	1 (7.1)
Hypogammaglobulinaemia	8 (57.1)	1 (7.1)	6 (42.9)	1 (7.1)	0
Injury, poisoning and procedural complications					
-Total	1 (7.1)	1 (7.1)	0	0	0
Procedural pain	1 (7.1)	1 (7.1)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	11 (78.6)	1 (7.1)	0	2 (14.3)	8 (57.1)
White blood cell count decreased	8 (57.1)	1 (7.1)	0	1 (7.1)	6 (42.9)
Neutrophil count decreased	7 (50.0)	0	0	2 (14.3)	5 (35.7)
Lymphocyte count decreased	5 (35.7)	1 (7.1)	0	2 (14.3)	2 (14.3)
Platelet count decreased	4 (28.6)	1 (7.1)	0	0	3 (21.4)
Alanine aminotransferase increased	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Blood bilirubin increased	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Aspartate aminotransferase increased	1 (7.1)	0	1 (7.1)	0	0
Blood creatinine increased	1 (7.1)	1 (7.1)	0	0	0
International normalised ratio increased	1 (7.1)	1 (7.1)	0	0	0
Prothrombin time prolonged	1 (7.1)	1 (7.1)	0	0	0
Metabolism and nutrition disorders					
-Total	6 (42.9)	1 (7.1)	1 (7.1)	3 (21.4)	1 (7.1)
Decreased appetite	4 (28.6)	1 (7.1)	1 (7.1)	2 (14.3)	0
Hypokalaemia	4 (28.6)	1 (7.1)	1 (7.1)	2 (14.3)	0
Hyperphosphataemia	2 (14.3)	2 (14.3)	0	0	0
Hypophosphataemia	1 (7.1)	0	0	0	1 (7.1)

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	2 (14.3)	0	2 (14.3)	0	0
Arthralgia	1 (7.1)	1 (7.1)	0	0	0
Muscular weakness	1 (7.1)	0	1 (7.1)	0	0
Pain in extremity	1 (7.1)	0	1 (7.1)	0	0
Nervous system disorders					
-Total	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Headache	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Renal and urinary disorders					
-Total	1 (7.1)	0	0	1 (7.1)	0
Acute kidney injury	1 (7.1)	0	0	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (28.6)	1 (7.1)	1 (7.1)	2 (14.3)	0
Hypoxia	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Pleural effusion	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Cough	1 (7.1)	1 (7.1)	0	0	0
Nasal congestion	1 (7.1)	1 (7.1)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	1 (7.1)	0	0	1 (7.1)	0
Skin and subcutaneous tissue disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Rash	1 (7.1)	1 (7.1)	0	0	0
Vascular disorders					
-Total	4 (28.6)	0	2 (14.3)	2 (14.3)	0
Hypertension	2 (14.3)	0	2 (14.3)	0	0
Hypotension	2 (14.3)	0	0	2 (14.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184m
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: No

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	49 (98.0)	2 (4.0)	6 (12.0)	11 (22.0)	30 (60.0)
Blood and lymphatic system disorders					
-Total	29 (58.0)	1 (2.0)	1 (2.0)	20 (40.0)	7 (14.0)
Anaemia	22 (44.0)	1 (2.0)	4 (8.0)	16 (32.0)	1 (2.0)
Febrile neutropenia	13 (26.0)	0	0	13 (26.0)	0
Neutropenia	7 (14.0)	0	0	2 (4.0)	5 (10.0)
Thrombocytopenia	6 (12.0)	0	0	2 (4.0)	4 (8.0)
Cardiac disorders					
-Total	16 (32.0)	7 (14.0)	7 (14.0)	2 (4.0)	0
Tachycardia	13 (26.0)	6 (12.0)	5 (10.0)	2 (4.0)	0
Sinus tachycardia	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Gastrointestinal disorders					

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	29 (58.0)	11 (22.0)	13 (26.0)	5 (10.0)	0
Vomiting	20 (40.0)	13 (26.0)	5 (10.0)	2 (4.0)	0
Nausea	18 (36.0)	6 (12.0)	10 (20.0)	2 (4.0)	0
Diarrhoea	17 (34.0)	10 (20.0)	6 (12.0)	1 (2.0)	0
Abdominal pain	7 (14.0)	5 (10.0)	2 (4.0)	0	0
Constipation	5 (10.0)	5 (10.0)	0	0	0
General disorders and administration site conditions					
-Total	25 (50.0)	12 (24.0)	7 (14.0)	5 (10.0)	1 (2.0)
Pyrexia	14 (28.0)	3 (6.0)	6 (12.0)	4 (8.0)	1 (2.0)
Fatigue	12 (24.0)	9 (18.0)	2 (4.0)	1 (2.0)	0
Chills	7 (14.0)	7 (14.0)	0	0	0
Immune system disorders					
-Total	42 (84.0)	4 (8.0)	20 (40.0)	8 (16.0)	10 (20.0)
Cytokine release syndrome	37 (74.0)	6 (12.0)	15 (30.0)	6 (12.0)	10 (20.0)
Hypogammaglobulinaemia	17 (34.0)	2 (4.0)	12 (24.0)	3 (6.0)	0
Infections and infestations					
-Total	3 (6.0)	1 (2.0)	2 (4.0)	0	0
Influenza	1 (2.0)	1 (2.0)	0	0	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (2.0)	0	1 (2.0)	0	0
Viral upper respiratory tract infection	1 (2.0)	0	1 (2.0)	0	0
Injury, poisoning and procedural complications					
-Total	2 (4.0)	0	2 (4.0)	0	0
Procedural pain	2 (4.0)	0	2 (4.0)	0	0
Investigations					
-Total	36 (72.0)	0	4 (8.0)	9 (18.0)	23 (46.0)
White blood cell count decreased	22 (44.0)	2 (4.0)	1 (2.0)	9 (18.0)	10 (20.0)
Neutrophil count decreased	18 (36.0)	0	2 (4.0)	2 (4.0)	14 (28.0)
Alanine aminotransferase increased	17 (34.0)	5 (10.0)	2 (4.0)	10 (20.0)	0
Aspartate aminotransferase increased	17 (34.0)	3 (6.0)	3 (6.0)	7 (14.0)	4 (8.0)
Platelet count decreased	15 (30.0)	2 (4.0)	2 (4.0)	2 (4.0)	9 (18.0)
Lymphocyte count decreased	9 (18.0)	0	2 (4.0)	4 (8.0)	3 (6.0)
Blood creatinine increased	8 (16.0)	4 (8.0)	2 (4.0)	2 (4.0)	0
International normalised ratio increased	8 (16.0)	7 (14.0)	0	1 (2.0)	0
Prothrombin time prolonged	8 (16.0)	4 (8.0)	3 (6.0)	1 (2.0)	0
Activated partial thromboplastin time prolonged	5 (10.0)	3 (6.0)	2 (4.0)	0	0
Blood bilirubin increased	5 (10.0)	1 (2.0)	2 (4.0)	2 (4.0)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	27 (54.0)	6 (12.0)	7 (14.0)	14 (28.0)	0
Decreased appetite	16 (32.0)	3 (6.0)	3 (6.0)	10 (20.0)	0
Hypokalaemia	12 (24.0)	2 (4.0)	5 (10.0)	5 (10.0)	0
Hypophosphataemia	8 (16.0)	2 (4.0)	0	6 (12.0)	0
Hyperphosphataemia	6 (12.0)	6 (12.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	9 (18.0)	6 (12.0)	2 (4.0)	1 (2.0)	0
Myalgia	5 (10.0)	4 (8.0)	1 (2.0)	0	0
Arthralgia	3 (6.0)	2 (4.0)	0	1 (2.0)	0
Pain in extremity	3 (6.0)	2 (4.0)	1 (2.0)	0	0
Nervous system disorders					
-Total	23 (46.0)	16 (32.0)	5 (10.0)	2 (4.0)	0
Headache	21 (42.0)	14 (28.0)	5 (10.0)	2 (4.0)	0
Dizziness	4 (8.0)	4 (8.0)	0	0	0
Psychiatric disorders					
-Total	11 (22.0)	5 (10.0)	5 (10.0)	1 (2.0)	0
Anxiety	6 (12.0)	2 (4.0)	3 (6.0)	1 (2.0)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	6 (12.0)	3 (6.0)	3 (6.0)	0	0
Renal and urinary disorders					
-Total	7 (14.0)	1 (2.0)	1 (2.0)	1 (2.0)	4 (8.0)
Acute kidney injury	6 (12.0)	1 (2.0)	1 (2.0)	1 (2.0)	3 (6.0)
Haematuria	4 (8.0)	0	2 (4.0)	1 (2.0)	1 (2.0)
Respiratory, thoracic and mediastinal disorders					
-Total	20 (40.0)	8 (16.0)	3 (6.0)	4 (8.0)	5 (10.0)
Hypoxia	8 (16.0)	0	2 (4.0)	3 (6.0)	3 (6.0)
Cough	7 (14.0)	7 (14.0)	0	0	0
Epistaxis	7 (14.0)	2 (4.0)	1 (2.0)	3 (6.0)	1 (2.0)
Pleural effusion	6 (12.0)	1 (2.0)	4 (8.0)	1 (2.0)	0
Pulmonary oedema	5 (10.0)	1 (2.0)	0	2 (4.0)	2 (4.0)
Oropharyngeal pain	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Rhinorrhoea	1 (2.0)	1 (2.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (6.0)	3 (6.0)	0	0	0
Rash	3 (6.0)	3 (6.0)	0	0	0
Vascular disorders					
-Total	17 (34.0)	2 (4.0)	2 (4.0)	5 (10.0)	8 (16.0)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	14 (28.0)	1 (2.0)	0	5 (10.0)	8 (16.0)
Hypertension	8 (16.0)	2 (4.0)	5 (10.0)	1 (2.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184m
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

		All patients N=12			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (100)	1 (8.3)	5 (41.7)	6 (50.0)	0
Blood and lymphatic system disorders					
-Total	3 (25.0)	1 (8.3)	1 (8.3)	1 (8.3)	0
Anaemia	2 (16.7)	1 (8.3)	0	1 (8.3)	0
Febrile neutropenia	1 (8.3)	0	0	1 (8.3)	0
Thrombocytopenia	1 (8.3)	0	1 (8.3)	0	0
Gastrointestinal disorders					
-Total	4 (33.3)	2 (16.7)	1 (8.3)	1 (8.3)	0
Vomiting	3 (25.0)	2 (16.7)	0	1 (8.3)	0
Diarrhoea	2 (16.7)	1 (8.3)	0	1 (8.3)	0
Nausea	2 (16.7)	0	1 (8.3)	1 (8.3)	0
Abdominal pain	1 (8.3)	0	0	1 (8.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=12				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	2 (16.7)	1 (8.3)	1 (8.3)	0	0
Pyrexia	2 (16.7)	1 (8.3)	1 (8.3)	0	0
Infections and infestations					
-Total	6 (50.0)	1 (8.3)	4 (33.3)	1 (8.3)	0
Influenza	2 (16.7)	0	2 (16.7)	0	0
Urinary tract infection	2 (16.7)	0	2 (16.7)	0	0
Viral upper respiratory tract infection	2 (16.7)	1 (8.3)	0	1 (8.3)	0
Injury, poisoning and procedural complications					
-Total	1 (8.3)	1 (8.3)	0	0	0
Procedural pain	1 (8.3)	1 (8.3)	0	0	0
Investigations					
-Total	4 (33.3)	0	1 (8.3)	3 (25.0)	0
Neutrophil count decreased	3 (25.0)	1 (8.3)	0	2 (16.7)	0
White blood cell count decreased	2 (16.7)	1 (8.3)	0	1 (8.3)	0
Lymphocyte count decreased	1 (8.3)	0	1 (8.3)	0	0
Platelet count decreased	1 (8.3)	1 (8.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=12				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	2 (16.7)	2 (16.7)	0	0	0
Hyperphosphataemia	1 (8.3)	1 (8.3)	0	0	0
Hypokalaemia	1 (8.3)	1 (8.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (41.7)	4 (33.3)	1 (8.3)	0	0
Pain in extremity	3 (25.0)	3 (25.0)	0	0	0
Arthralgia	1 (8.3)	0	1 (8.3)	0	0
Muscular weakness	1 (8.3)	1 (8.3)	0	0	0
Nervous system disorders					
-Total	1 (8.3)	1 (8.3)	0	0	0
Dizziness	1 (8.3)	1 (8.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (33.3)	1 (8.3)	3 (25.0)	0	0
Cough	2 (16.7)	0	2 (16.7)	0	0
Nasal congestion	2 (16.7)	2 (16.7)	0	0	0
Rhinorrhoea	2 (16.7)	1 (8.3)	1 (8.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=12				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	1 (8.3)	1 (8.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184m
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (68.2)	7 (15.9)	9 (20.5)	8 (18.2)	6 (13.6)
Blood and lymphatic system disorders					
-Total	5 (11.4)	0	0	2 (4.5)	3 (6.8)
Neutropenia	4 (9.1)	0	0	1 (2.3)	3 (6.8)
Febrile neutropenia	2 (4.5)	0	0	2 (4.5)	0
Thrombocytopenia	1 (2.3)	0	0	1 (2.3)	0
Cardiac disorders					
-Total	1 (2.3)	0	1 (2.3)	0	0
Sinus tachycardia	1 (2.3)	0	1 (2.3)	0	0
Gastrointestinal disorders					
-Total	10 (22.7)	6 (13.6)	3 (6.8)	1 (2.3)	0
Diarrhoea	6 (13.6)	5 (11.4)	1 (2.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	6 (13.6)	3 (6.8)	2 (4.5)	1 (2.3)	0
Nausea	4 (9.1)	1 (2.3)	2 (4.5)	1 (2.3)	0
Abdominal pain	3 (6.8)	2 (4.5)	1 (2.3)	0	0
General disorders and administration site conditions					
-Total	9 (20.5)	7 (15.9)	1 (2.3)	1 (2.3)	0
Pyrexia	8 (18.2)	6 (13.6)	1 (2.3)	1 (2.3)	0
Fatigue	2 (4.5)	2 (4.5)	0	0	0
Chills	1 (2.3)	1 (2.3)	0	0	0
Immune system disorders					
-Total	8 (18.2)	0	7 (15.9)	1 (2.3)	0
Hypogammaglobulinaemia	8 (18.2)	0	7 (15.9)	1 (2.3)	0
Infections and infestations					
-Total	10 (22.7)	3 (6.8)	4 (9.1)	3 (6.8)	0
Upper respiratory tract infection	7 (15.9)	3 (6.8)	3 (6.8)	1 (2.3)	0
Urinary tract infection	2 (4.5)	0	0	2 (4.5)	0
Influenza	1 (2.3)	0	1 (2.3)	0	0
Injury, poisoning and procedural complications					

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.3)	0	1 (2.3)	0	0
Procedural pain	1 (2.3)	0	1 (2.3)	0	0
Investigations					
-Total	12 (27.3)	3 (6.8)	0	5 (11.4)	4 (9.1)
Neutrophil count decreased	5 (11.4)	1 (2.3)	0	1 (2.3)	3 (6.8)
Aspartate aminotransferase increased	3 (6.8)	1 (2.3)	0	2 (4.5)	0
White blood cell count decreased	3 (6.8)	1 (2.3)	1 (2.3)	0	1 (2.3)
Alanine aminotransferase increased	2 (4.5)	0	0	2 (4.5)	0
Platelet count decreased	2 (4.5)	2 (4.5)	0	0	0
Blood bilirubin increased	1 (2.3)	0	0	1 (2.3)	0
Blood creatinine increased	1 (2.3)	1 (2.3)	0	0	0
Lymphocyte count decreased	1 (2.3)	1 (2.3)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (6.8)	1 (2.3)	1 (2.3)	0	1 (2.3)
Decreased appetite	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Hyperphosphataemia	1 (2.3)	1 (2.3)	0	0	0
Hypokalaemia	1 (2.3)	0	0	0	1 (2.3)
Hypophosphataemia	1 (2.3)	0	0	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

			All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	6 (13.6)	4 (9.1)	2 (4.5)	0	0
Pain in extremity	5 (11.4)	3 (6.8)	2 (4.5)	0	0
Arthralgia	1 (2.3)	1 (2.3)	0	0	0
Muscular weakness	1 (2.3)	1 (2.3)	0	0	0
Nervous system disorders					
-Total	5 (11.4)	4 (9.1)	1 (2.3)	0	0
Headache	5 (11.4)	4 (9.1)	1 (2.3)	0	0
Dizziness	2 (4.5)	2 (4.5)	0	0	0
Psychiatric disorders					
-Total	1 (2.3)	1 (2.3)	0	0	0
Anxiety	1 (2.3)	1 (2.3)	0	0	0
Renal and urinary disorders					
-Total	2 (4.5)	0	0	2 (4.5)	0
Acute kidney injury	1 (2.3)	0	0	1 (2.3)	0
Haematuria	1 (2.3)	0	0	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (22.7)	8 (18.2)	0	2 (4.5)	0
Cough	5 (11.4)	5 (11.4)	0	0	0
Epistaxis	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Nasal congestion	2 (4.5)	2 (4.5)	0	0	0
Oropharyngeal pain	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Rhinorrhoea	2 (4.5)	2 (4.5)	0	0	0
Pulmonary oedema	1 (2.3)	0	0	1 (2.3)	0
Skin and subcutaneous tissue disorders					
-Total	4 (9.1)	1 (2.3)	3 (6.8)	0	0
Rash	4 (9.1)	1 (2.3)	3 (6.8)	0	0
Vascular disorders					
-Total	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Hypertension	2 (4.5)	1 (2.3)	1 (2.3)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184m
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

			All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (22.2)	2 (22.2)	0	0	0
Investigations					
-Total	1 (11.1)	1 (11.1)	0	0	0
Lymphocyte count decreased	1 (11.1)	1 (11.1)	0	0	0
Neutrophil count decreased	1 (11.1)	1 (11.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (11.1)	1 (11.1)	0	0	0
Epistaxis	1 (11.1)	1 (11.1)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184m
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

			All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (48.0)	2 (8.0)	3 (12.0)	5 (20.0)	2 (8.0)
Blood and lymphatic system disorders					
-Total	2 (8.0)	1 (4.0)	0	0	1 (4.0)
Febrile neutropenia	1 (4.0)	0	0	0	1 (4.0)
Thrombocytopenia	1 (4.0)	1 (4.0)	0	0	0
Gastrointestinal disorders					
-Total	3 (12.0)	0	3 (12.0)	0	0
Diarrhoea	2 (8.0)	0	2 (8.0)	0	0
Abdominal pain	1 (4.0)	0	1 (4.0)	0	0
Nausea	1 (4.0)	0	1 (4.0)	0	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.0)	0	1 (4.0)	0	0
Chills	1 (4.0)	0	1 (4.0)	0	0
Pyrexia	1 (4.0)	0	1 (4.0)	0	0
Infections and infestations					
-Total	4 (16.0)	1 (4.0)	2 (8.0)	1 (4.0)	0
Upper respiratory tract infection	2 (8.0)	1 (4.0)	1 (4.0)	0	0
Urinary tract infection	2 (8.0)	0	1 (4.0)	1 (4.0)	0
Injury, poisoning and procedural complications					
-Total	1 (4.0)	0	0	1 (4.0)	0
Procedural pain	1 (4.0)	0	0	1 (4.0)	0
Investigations					
-Total	7 (28.0)	0	2 (8.0)	4 (16.0)	1 (4.0)
White blood cell count decreased	4 (16.0)	1 (4.0)	0	2 (8.0)	1 (4.0)
Alanine aminotransferase increased	3 (12.0)	0	1 (4.0)	2 (8.0)	0
Aspartate aminotransferase increased	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Lymphocyte count decreased	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Neutrophil count decreased	1 (4.0)	0	1 (4.0)	0	0
Platelet count decreased	1 (4.0)	0	0	1 (4.0)	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=25				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	1 (4.0)	0	0	1 (4.0)	0
Hypokalaemia	1 (4.0)	0	0	1 (4.0)	0
Nervous system disorders					
-Total	1 (4.0)	0	1 (4.0)	0	0
Dizziness	1 (4.0)	1 (4.0)	0	0	0
Headache	1 (4.0)	0	1 (4.0)	0	0
Renal and urinary disorders					
-Total	2 (8.0)	1 (4.0)	0	1 (4.0)	0
Acute kidney injury	1 (4.0)	0	0	1 (4.0)	0
Haematuria	1 (4.0)	1 (4.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (12.0)	3 (12.0)	0	0	0
Cough	2 (8.0)	2 (8.0)	0	0	0
Oropharyngeal pain	1 (4.0)	1 (4.0)	0	0	0
Rhinorrhoea	1 (4.0)	1 (4.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184m
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (100)	0	1 (7.1)	4 (28.6)	9 (64.3)
Blood and lymphatic system disorders					
-Total	12 (85.7)	0	1 (7.1)	9 (64.3)	2 (14.3)
Febrile neutropenia	10 (71.4)	0	0	10 (71.4)	0
Anaemia	5 (35.7)	2 (14.3)	0	3 (21.4)	0
Thrombocytopenia	3 (21.4)	0	1 (7.1)	0	2 (14.3)
Neutropenia	1 (7.1)	0	0	1 (7.1)	0
Cardiac disorders					
-Total	3 (21.4)	3 (21.4)	0	0	0
Tachycardia	2 (14.3)	2 (14.3)	0	0	0
Sinus tachycardia	1 (7.1)	1 (7.1)	0	0	0
Gastrointestinal disorders					

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (42.9)	2 (14.3)	2 (14.3)	2 (14.3)	0
Nausea	4 (28.6)	0	2 (14.3)	2 (14.3)	0
Vomiting	4 (28.6)	2 (14.3)	1 (7.1)	1 (7.1)	0
Diarrhoea	3 (21.4)	2 (14.3)	0	1 (7.1)	0
Abdominal pain	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Constipation	2 (14.3)	1 (7.1)	1 (7.1)	0	0
General disorders and administration site conditions					
-Total	4 (28.6)	1 (7.1)	2 (14.3)	1 (7.1)	0
Pyrexia	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Chills	1 (7.1)	1 (7.1)	0	0	0
Fatigue	1 (7.1)	1 (7.1)	0	0	0
Immune system disorders					
-Total	14 (100)	0	10 (71.4)	3 (21.4)	1 (7.1)
Cytokine release syndrome	13 (92.9)	0	10 (71.4)	2 (14.3)	1 (7.1)
Hypogammaglobulinaemia	8 (57.1)	1 (7.1)	6 (42.9)	1 (7.1)	0
Infections and infestations					
-Total	6 (42.9)	1 (7.1)	4 (28.6)	1 (7.1)	0
Influenza	2 (14.3)	0	2 (14.3)	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	2 (14.3)	0	2 (14.3)	0	0
Viral upper respiratory tract infection	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Injury, poisoning and procedural complications					
-Total	2 (14.3)	2 (14.3)	0	0	0
Procedural pain	2 (14.3)	2 (14.3)	0	0	0
Investigations					
-Total	12 (85.7)	0	1 (7.1)	3 (21.4)	8 (57.1)
White blood cell count decreased	10 (71.4)	2 (14.3)	0	2 (14.3)	6 (42.9)
Neutrophil count decreased	8 (57.1)	1 (7.1)	0	2 (14.3)	5 (35.7)
Lymphocyte count decreased	6 (42.9)	1 (7.1)	1 (7.1)	2 (14.3)	2 (14.3)
Platelet count decreased	4 (28.6)	1 (7.1)	0	0	3 (21.4)
Alanine aminotransferase increased	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Blood bilirubin increased	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Aspartate aminotransferase increased	1 (7.1)	0	1 (7.1)	0	0
Blood creatinine increased	1 (7.1)	1 (7.1)	0	0	0
International normalised ratio increased	1 (7.1)	1 (7.1)	0	0	0
Prothrombin time prolonged	1 (7.1)	1 (7.1)	0	0	0
Metabolism and nutrition disorders					

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (50.0)	2 (14.3)	1 (7.1)	3 (21.4)	1 (7.1)
Hypokalaemia	5 (35.7)	2 (14.3)	1 (7.1)	2 (14.3)	0
Decreased appetite	4 (28.6)	1 (7.1)	1 (7.1)	2 (14.3)	0
Hyperphosphataemia	2 (14.3)	2 (14.3)	0	0	0
Hypophosphataemia	1 (7.1)	0	0	0	1 (7.1)
Musculoskeletal and connective tissue disorders					
-Total	6 (42.9)	4 (28.6)	2 (14.3)	0	0
Pain in extremity	4 (28.6)	3 (21.4)	1 (7.1)	0	0
Arthralgia	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Muscular weakness	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Nervous system disorders					
-Total	4 (28.6)	3 (21.4)	1 (7.1)	0	0
Headache	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Dizziness	1 (7.1)	1 (7.1)	0	0	0
Renal and urinary disorders					
-Total	1 (7.1)	0	0	1 (7.1)	0
Acute kidney injury	1 (7.1)	0	0	1 (7.1)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	7 (50.0)	2 (14.3)	3 (21.4)	2 (14.3)	0
Cough	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Nasal congestion	3 (21.4)	3 (21.4)	0	0	0
Hypoxia	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Pleural effusion	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Rhinorrhoea	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Epistaxis	1 (7.1)	1 (7.1)	0	0	0
Oropharyngeal pain	1 (7.1)	1 (7.1)	0	0	0
Pulmonary oedema	1 (7.1)	0	0	1 (7.1)	0
Skin and subcutaneous tissue disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Rash	1 (7.1)	1 (7.1)	0	0	0
Vascular disorders					
-Total	4 (28.6)	0	2 (14.3)	2 (14.3)	0
Hypertension	2 (14.3)	0	2 (14.3)	0	0
Hypotension	2 (14.3)	0	0	2 (14.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184m
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

			All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	49 (98.0)	1 (2.0)	5 (10.0)	9 (18.0)	34 (68.0)
Blood and lymphatic system disorders					
-Total	32 (64.0)	1 (2.0)	1 (2.0)	19 (38.0)	11 (22.0)
Anaemia	22 (44.0)	1 (2.0)	4 (8.0)	16 (32.0)	1 (2.0)
Febrile neutropenia	14 (28.0)	0	0	13 (26.0)	1 (2.0)
Neutropenia	10 (20.0)	0	0	2 (4.0)	8 (16.0)
Thrombocytopenia	7 (14.0)	0	0	3 (6.0)	4 (8.0)
Cardiac disorders					
-Total	17 (34.0)	7 (14.0)	8 (16.0)	2 (4.0)	0
Tachycardia	13 (26.0)	6 (12.0)	5 (10.0)	2 (4.0)	0
Sinus tachycardia	5 (10.0)	2 (4.0)	3 (6.0)	0	0
Gastrointestinal disorders					

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	33 (66.0)	12 (24.0)	16 (32.0)	5 (10.0)	0
Vomiting	23 (46.0)	14 (28.0)	7 (14.0)	2 (4.0)	0
Diarrhoea	21 (42.0)	11 (22.0)	9 (18.0)	1 (2.0)	0
Nausea	21 (42.0)	6 (12.0)	12 (24.0)	3 (6.0)	0
Abdominal pain	9 (18.0)	5 (10.0)	4 (8.0)	0	0
Constipation	5 (10.0)	5 (10.0)	0	0	0
General disorders and administration site conditions					
-Total	31 (62.0)	15 (30.0)	9 (18.0)	6 (12.0)	1 (2.0)
Pyrexia	22 (44.0)	8 (16.0)	8 (16.0)	5 (10.0)	1 (2.0)
Fatigue	14 (28.0)	11 (22.0)	2 (4.0)	1 (2.0)	0
Chills	9 (18.0)	8 (16.0)	1 (2.0)	0	0
Immune system disorders					
-Total	43 (86.0)	4 (8.0)	21 (42.0)	8 (16.0)	10 (20.0)
Cytokine release syndrome	37 (74.0)	6 (12.0)	15 (30.0)	6 (12.0)	10 (20.0)
Hypogammaglobulinaemia	24 (48.0)	2 (4.0)	18 (36.0)	4 (8.0)	0
Infections and infestations					
-Total	14 (28.0)	4 (8.0)	7 (14.0)	3 (6.0)	0
Upper respiratory tract infection	9 (18.0)	4 (8.0)	4 (8.0)	1 (2.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	3 (6.0)	0	1 (2.0)	2 (4.0)	0
Influenza	2 (4.0)	1 (2.0)	1 (2.0)	0	0
Viral upper respiratory tract infection	1 (2.0)	0	1 (2.0)	0	0
Injury, poisoning and procedural complications					
-Total	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Procedural pain	3 (6.0)	0	2 (4.0)	1 (2.0)	0
Investigations					
-Total	40 (80.0)	0	4 (8.0)	10 (20.0)	26 (52.0)
White blood cell count decreased	25 (50.0)	2 (4.0)	1 (2.0)	10 (20.0)	12 (24.0)
Neutrophil count decreased	20 (40.0)	0	2 (4.0)	2 (4.0)	16 (32.0)
Alanine aminotransferase increased	19 (38.0)	5 (10.0)	1 (2.0)	13 (26.0)	0
Aspartate aminotransferase increased	19 (38.0)	4 (8.0)	3 (6.0)	8 (16.0)	4 (8.0)
Platelet count decreased	16 (32.0)	2 (4.0)	2 (4.0)	3 (6.0)	9 (18.0)
Lymphocyte count decreased	10 (20.0)	0	2 (4.0)	5 (10.0)	3 (6.0)
Blood creatinine increased	8 (16.0)	4 (8.0)	2 (4.0)	2 (4.0)	0
International normalised ratio increased	8 (16.0)	7 (14.0)	0	1 (2.0)	0
Prothrombin time prolonged	8 (16.0)	4 (8.0)	3 (6.0)	1 (2.0)	0
Blood bilirubin increased	6 (12.0)	1 (2.0)	2 (4.0)	3 (6.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	5 (10.0)	3 (6.0)	2 (4.0)	0	0
Metabolism and nutrition disorders					
-Total	28 (56.0)	5 (10.0)	7 (14.0)	15 (30.0)	1 (2.0)
Decreased appetite	18 (36.0)	4 (8.0)	4 (8.0)	10 (20.0)	0
Hypokalaemia	14 (28.0)	2 (4.0)	5 (10.0)	6 (12.0)	1 (2.0)
Hypophosphataemia	9 (18.0)	2 (4.0)	0	7 (14.0)	0
Hyperphosphataemia	6 (12.0)	6 (12.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	12 (24.0)	7 (14.0)	4 (8.0)	1 (2.0)	0
Pain in extremity	7 (14.0)	4 (8.0)	3 (6.0)	0	0
Myalgia	5 (10.0)	4 (8.0)	1 (2.0)	0	0
Arthralgia	3 (6.0)	2 (4.0)	0	1 (2.0)	0
Muscular weakness	1 (2.0)	1 (2.0)	0	0	0
Nervous system disorders					
-Total	23 (46.0)	15 (30.0)	6 (12.0)	2 (4.0)	0
Headache	21 (42.0)	13 (26.0)	6 (12.0)	2 (4.0)	0
Dizziness	5 (10.0)	5 (10.0)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	12 (24.0)	6 (12.0)	5 (10.0)	1 (2.0)	0
Anxiety	7 (14.0)	3 (6.0)	3 (6.0)	1 (2.0)	0
Confusional state	6 (12.0)	3 (6.0)	3 (6.0)	0	0
Renal and urinary disorders					
-Total	10 (20.0)	1 (2.0)	1 (2.0)	4 (8.0)	4 (8.0)
Acute kidney injury	8 (16.0)	1 (2.0)	1 (2.0)	3 (6.0)	3 (6.0)
Haematuria	5 (10.0)	0	2 (4.0)	2 (4.0)	1 (2.0)
Respiratory, thoracic and mediastinal disorders					
-Total	26 (52.0)	12 (24.0)	3 (6.0)	6 (12.0)	5 (10.0)
Cough	11 (22.0)	11 (22.0)	0	0	0
Epistaxis	9 (18.0)	3 (6.0)	1 (2.0)	4 (8.0)	1 (2.0)
Hypoxia	8 (16.0)	0	2 (4.0)	3 (6.0)	3 (6.0)
Pleural effusion	6 (12.0)	1 (2.0)	4 (8.0)	1 (2.0)	0
Pulmonary oedema	6 (12.0)	1 (2.0)	0	3 (6.0)	2 (4.0)
Oropharyngeal pain	5 (10.0)	3 (6.0)	2 (4.0)	0	0
Rhinorrhoea	4 (8.0)	4 (8.0)	0	0	0
Nasal congestion	2 (4.0)	2 (4.0)	0	0	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	7 (14.0)	4 (8.0)	3 (6.0)	0	0
Rash	7 (14.0)	4 (8.0)	3 (6.0)	0	0
Vascular disorders					
-Total	18 (36.0)	2 (4.0)	3 (6.0)	5 (10.0)	8 (16.0)
Hypotension	14 (28.0)	1 (2.0)	0	5 (10.0)	8 (16.0)
Hypertension	10 (20.0)	3 (6.0)	6 (12.0)	1 (2.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184n
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (95.0)	0	1 (5.0)	7 (35.0)	11 (55.0)
Blood and lymphatic system disorders					
-Total	13 (65.0)	0	0	12 (60.0)	1 (5.0)
Anaemia	9 (45.0)	2 (10.0)	2 (10.0)	5 (25.0)	0
Febrile neutropenia	9 (45.0)	0	0	9 (45.0)	0
Neutropenia	3 (15.0)	0	0	2 (10.0)	1 (5.0)
Cardiac disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Tachycardia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Eye disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Eye pain	2 (10.0)	1 (5.0)	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	11 (55.0)	5 (25.0)	5 (25.0)	1 (5.0)	0
Nausea	7 (35.0)	3 (15.0)	4 (20.0)	0	0
Vomiting	7 (35.0)	4 (20.0)	2 (10.0)	1 (5.0)	0
Abdominal pain	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Constipation	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Diarrhoea	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Abdominal pain upper	1 (5.0)	0	1 (5.0)	0	0
General disorders and administration site conditions					
-Total	7 (35.0)	4 (20.0)	1 (5.0)	2 (10.0)	0
Fatigue	4 (20.0)	4 (20.0)	0	0	0
Chills	2 (10.0)	2 (10.0)	0	0	0
Pain	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Pyrexia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Catheter site pain	1 (5.0)	1 (5.0)	0	0	0
Immune system disorders					
-Total	17 (85.0)	0	11 (55.0)	4 (20.0)	2 (10.0)
Cytokine release syndrome	16 (80.0)	0	11 (55.0)	3 (15.0)	2 (10.0)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	9 (45.0)	1 (5.0)	7 (35.0)	1 (5.0)	0
Infections and infestations					
-Total	4 (20.0)	0	3 (15.0)	1 (5.0)	0
Gastroenteritis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Upper respiratory tract infection	1 (5.0)	0	1 (5.0)	0	0
Viral infection	1 (5.0)	0	1 (5.0)	0	0
Investigations					
-Total	15 (75.0)	1 (5.0)	1 (5.0)	3 (15.0)	10 (50.0)
White blood cell count decreased	9 (45.0)	1 (5.0)	0	3 (15.0)	5 (25.0)
Neutrophil count decreased	8 (40.0)	0	0	2 (10.0)	6 (30.0)
Lymphocyte count decreased	6 (30.0)	1 (5.0)	0	2 (10.0)	3 (15.0)
Platelet count decreased	6 (30.0)	2 (10.0)	0	1 (5.0)	3 (15.0)
Aspartate aminotransferase increased	5 (25.0)	0	3 (15.0)	1 (5.0)	1 (5.0)
Alanine aminotransferase increased	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0
Blood bilirubin increased	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Blood creatinine increased	3 (15.0)	3 (15.0)	0	0	0
International normalised ratio increased	3 (15.0)	3 (15.0)	0	0	0
Prothrombin time prolonged	2 (10.0)	1 (5.0)	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	9 (45.0)	1 (5.0)	1 (5.0)	7 (35.0)	0
Decreased appetite	5 (25.0)	1 (5.0)	1 (5.0)	3 (15.0)	0
Dehydration	2 (10.0)	0	0	2 (10.0)	0
Hyperphosphataemia	2 (10.0)	2 (10.0)	0	0	0
Hypophosphataemia	2 (10.0)	0	0	2 (10.0)	0
Hypokalaemia	1 (5.0)	0	0	1 (5.0)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (25.0)	2 (10.0)	2 (10.0)	1 (5.0)	0
Myalgia	2 (10.0)	2 (10.0)	0	0	0
Pain in extremity	2 (10.0)	0	2 (10.0)	0	0
Arthralgia	1 (5.0)	0	0	1 (5.0)	0
Nervous system disorders					
-Total	9 (45.0)	5 (25.0)	3 (15.0)	1 (5.0)	0
Headache	6 (30.0)	4 (20.0)	1 (5.0)	1 (5.0)	0
Encephalopathy	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Seizure	1 (5.0)	0	1 (5.0)	0	0
Psychiatric disorders					

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Anxiety	1 (5.0)	0	1 (5.0)	0	0
Confusional state	1 (5.0)	1 (5.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (25.0)	2 (10.0)	3 (15.0)	0	0
Hypoxia	3 (15.0)	0	3 (15.0)	0	0
Cough	2 (10.0)	2 (10.0)	0	0	0
Nasal congestion	1 (5.0)	1 (5.0)	0	0	0
Pleural effusion	1 (5.0)	1 (5.0)	0	0	0
Rhinitis allergic	1 (5.0)	1 (5.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (25.0)	4 (20.0)	0	1 (5.0)	0
Dry skin	2 (10.0)	2 (10.0)	0	0	0
Erythema	2 (10.0)	2 (10.0)	0	0	0
Ingrowing nail	1 (5.0)	0	1 (5.0)	0	0
Rash maculo-papular	1 (5.0)	0	0	1 (5.0)	0
Vascular disorders					

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (25.0)	0	1 (5.0)	3 (15.0)	1 (5.0)
Hypotension	4 (20.0)	0	0	3 (15.0)	1 (5.0)
Hypertension	2 (10.0)	0	2 (10.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184n
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

			All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	44 (100)	2 (4.5)	7 (15.9)	7 (15.9)	28 (63.6)
Blood and lymphatic system disorders					
-Total	27 (61.4)	1 (2.3)	2 (4.5)	16 (36.4)	8 (18.2)
Anaemia	18 (40.9)	1 (2.3)	3 (6.8)	13 (29.5)	1 (2.3)
Febrile neutropenia	13 (29.5)	0	0	13 (29.5)	0
Thrombocytopenia	8 (18.2)	0	0	2 (4.5)	6 (13.6)
Neutropenia	5 (11.4)	0	0	1 (2.3)	4 (9.1)
Cardiac disorders					
-Total	17 (38.6)	9 (20.5)	6 (13.6)	2 (4.5)	0
Tachycardia	13 (29.5)	7 (15.9)	4 (9.1)	2 (4.5)	0
Sinus tachycardia	5 (11.4)	3 (6.8)	2 (4.5)	0	0
Eye disorders					

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.3)	0	1 (2.3)	0	0
Eye pain	1 (2.3)	0	1 (2.3)	0	0
Gastrointestinal disorders					
-Total	22 (50.0)	7 (15.9)	9 (20.5)	6 (13.6)	0
Diarrhoea	15 (34.1)	10 (22.7)	4 (9.1)	1 (2.3)	0
Vomiting	15 (34.1)	9 (20.5)	4 (9.1)	2 (4.5)	0
Nausea	14 (31.8)	3 (6.8)	8 (18.2)	3 (6.8)	0
Abdominal pain	6 (13.6)	5 (11.4)	1 (2.3)	0	0
Constipation	4 (9.1)	4 (9.1)	0	0	0
Abdominal pain upper	1 (2.3)	0	1 (2.3)	0	0
General disorders and administration site conditions					
-Total	22 (50.0)	8 (18.2)	8 (18.2)	5 (11.4)	1 (2.3)
Pyrexia	14 (31.8)	3 (6.8)	6 (13.6)	4 (9.1)	1 (2.3)
Fatigue	9 (20.5)	6 (13.6)	2 (4.5)	1 (2.3)	0
Chills	6 (13.6)	6 (13.6)	0	0	0
Catheter site pain	2 (4.5)	0	2 (4.5)	0	0
Pain	1 (2.3)	0	0	1 (2.3)	0
Immune system disorders					

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	39 (88.6)	4 (9.1)	19 (43.2)	7 (15.9)	9 (20.5)
Cytokine release syndrome	34 (77.3)	6 (13.6)	14 (31.8)	5 (11.4)	9 (20.5)
Hypogammaglobulinaemia	16 (36.4)	2 (4.5)	11 (25.0)	3 (6.8)	0
Infections and infestations					
-Total	5 (11.4)	1 (2.3)	4 (9.1)	0	0
Clostridium difficile infection	4 (9.1)	0	4 (9.1)	0	0
Influenza	1 (2.3)	1 (2.3)	0	0	0
Investigations					
-Total	32 (72.7)	0	3 (6.8)	8 (18.2)	21 (47.7)
White blood cell count decreased	21 (47.7)	2 (4.5)	1 (2.3)	7 (15.9)	11 (25.0)
Neutrophil count decreased	17 (38.6)	0	2 (4.5)	2 (4.5)	13 (29.5)
Alanine aminotransferase increased	15 (34.1)	4 (9.1)	2 (4.5)	9 (20.5)	0
Aspartate aminotransferase increased	13 (29.5)	3 (6.8)	1 (2.3)	6 (13.6)	3 (6.8)
Platelet count decreased	13 (29.5)	1 (2.3)	2 (4.5)	1 (2.3)	9 (20.5)
Lymphocyte count decreased	8 (18.2)	0	2 (4.5)	4 (9.1)	2 (4.5)
Prothrombin time prolonged	7 (15.9)	4 (9.1)	2 (4.5)	1 (2.3)	0
Blood creatinine increased	6 (13.6)	2 (4.5)	2 (4.5)	2 (4.5)	0
International normalised ratio increased	6 (13.6)	5 (11.4)	0	1 (2.3)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	4 (9.1)	0	3 (6.8)	1 (2.3)	0
Metabolism and nutrition disorders					
-Total	26 (59.1)	6 (13.6)	7 (15.9)	12 (27.3)	1 (2.3)
Decreased appetite	15 (34.1)	3 (6.8)	3 (6.8)	9 (20.5)	0
Hypokalaemia	15 (34.1)	3 (6.8)	6 (13.6)	6 (13.6)	0
Hypophosphataemia	7 (15.9)	2 (4.5)	0	4 (9.1)	1 (2.3)
Hyperphosphataemia	6 (13.6)	6 (13.6)	0	0	0
Hypoalbuminaemia	5 (11.4)	1 (2.3)	3 (6.8)	1 (2.3)	0
Dehydration	1 (2.3)	1 (2.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	6 (13.6)	5 (11.4)	1 (2.3)	0	0
Arthralgia	3 (6.8)	3 (6.8)	0	0	0
Myalgia	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Pain in extremity	2 (4.5)	2 (4.5)	0	0	0
Nervous system disorders					
-Total	21 (47.7)	13 (29.5)	5 (11.4)	3 (6.8)	0
Headache	18 (40.9)	12 (27.3)	5 (11.4)	1 (2.3)	0
Dizziness	4 (9.1)	4 (9.1)	0	0	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Encephalopathy	1 (2.3)	0	0	1 (2.3)	0
Psychiatric disorders					
-Total	9 (20.5)	4 (9.1)	4 (9.1)	1 (2.3)	0
Anxiety	5 (11.4)	2 (4.5)	2 (4.5)	1 (2.3)	0
Confusional state	5 (11.4)	2 (4.5)	3 (6.8)	0	0
Renal and urinary disorders					
-Total	8 (18.2)	1 (2.3)	1 (2.3)	2 (4.5)	4 (9.1)
Acute kidney injury	7 (15.9)	1 (2.3)	1 (2.3)	2 (4.5)	3 (6.8)
Haematuria	4 (9.1)	0	2 (4.5)	1 (2.3)	1 (2.3)
Respiratory, thoracic and mediastinal disorders					
-Total	20 (45.5)	7 (15.9)	1 (2.3)	7 (15.9)	5 (11.4)
Epistaxis	7 (15.9)	2 (4.5)	1 (2.3)	3 (6.8)	1 (2.3)
Hypoxia	7 (15.9)	0	0	4 (9.1)	3 (6.8)
Pleural effusion	7 (15.9)	1 (2.3)	4 (9.1)	2 (4.5)	0
Cough	6 (13.6)	6 (13.6)	0	0	0
Pulmonary oedema	6 (13.6)	1 (2.3)	0	3 (6.8)	2 (4.5)
Tachypnoea	5 (11.4)	3 (6.8)	1 (2.3)	1 (2.3)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Rhinorrhoea	1 (2.3)	1 (2.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (20.5)	7 (15.9)	2 (4.5)	0	0
Rash	4 (9.1)	4 (9.1)	0	0	0
Dry skin	2 (4.5)	2 (4.5)	0	0	0
Rash maculo-papular	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Erythema	1 (2.3)	1 (2.3)	0	0	0
Ingrowing nail	1 (2.3)	0	1 (2.3)	0	0
Vascular disorders					
-Total	16 (36.4)	2 (4.5)	3 (6.8)	4 (9.1)	7 (15.9)
Hypotension	12 (27.3)	1 (2.3)	0	4 (9.1)	7 (15.9)
Hypertension	8 (18.2)	2 (4.5)	5 (11.4)	1 (2.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184n
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (85.0)	1 (5.0)	7 (35.0)	6 (30.0)	3 (15.0)
Blood and lymphatic system disorders					
-Total	5 (25.0)	1 (5.0)	0	2 (10.0)	2 (10.0)
Neutropenia	3 (15.0)	0	0	1 (5.0)	2 (10.0)
Febrile neutropenia	2 (10.0)	0	0	2 (10.0)	0
Anaemia	1 (5.0)	1 (5.0)	0	0	0
Thrombocytopenia	1 (5.0)	0	0	1 (5.0)	0
Gastrointestinal disorders					
-Total	7 (35.0)	4 (20.0)	1 (5.0)	2 (10.0)	0
Vomiting	4 (20.0)	3 (15.0)	0	1 (5.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Abdominal pain	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Nausea	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Oral pain	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Abdominal pain upper	1 (5.0)	1 (5.0)	0	0	0
General disorders and administration site conditions					
-Total	8 (40.0)	5 (25.0)	2 (10.0)	1 (5.0)	0
Pyrexia	6 (30.0)	4 (20.0)	1 (5.0)	1 (5.0)	0
Catheter site pain	1 (5.0)	0	1 (5.0)	0	0
Fatigue	1 (5.0)	1 (5.0)	0	0	0
Immune system disorders					
-Total	3 (15.0)	0	3 (15.0)	0	0
Hypogammaglobulinaemia	3 (15.0)	0	3 (15.0)	0	0
Infections and infestations					
-Total	6 (30.0)	1 (5.0)	5 (25.0)	0	0
Upper respiratory tract infection	3 (15.0)	0	3 (15.0)	0	0
Influenza	2 (10.0)	0	2 (10.0)	0	0
Viral infection	1 (5.0)	1 (5.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	7 (35.0)	0	1 (5.0)	3 (15.0)	3 (15.0)
Neutrophil count decreased	4 (20.0)	1 (5.0)	0	1 (5.0)	2 (10.0)
Lymphocyte count decreased	2 (10.0)	1 (5.0)	1 (5.0)	0	0
White blood cell count decreased	2 (10.0)	1 (5.0)	0	0	1 (5.0)
Alanine aminotransferase increased	1 (5.0)	0	0	1 (5.0)	0
Blood bilirubin increased	1 (5.0)	0	0	1 (5.0)	0
Platelet count decreased	1 (5.0)	1 (5.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Hyperphosphataemia	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (25.0)	4 (20.0)	1 (5.0)	0	0
Pain in extremity	3 (15.0)	3 (15.0)	0	0	0
Arthralgia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Nervous system disorders					
-Total	4 (20.0)	3 (15.0)	1 (5.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	2 (10.0)	2 (10.0)	0	0	0
Peroneal nerve palsy	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Psychiatric disorders					
-Total	2 (10.0)	2 (10.0)	0	0	0
Depression	2 (10.0)	2 (10.0)	0	0	0
Anxiety	1 (5.0)	1 (5.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (35.0)	3 (15.0)	2 (10.0)	2 (10.0)	0
Cough	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Nasal congestion	2 (10.0)	2 (10.0)	0	0	0
Rhinorrhoea	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Epistaxis	1 (5.0)	0	0	1 (5.0)	0
Oropharyngeal pain	1 (5.0)	0	1 (5.0)	0	0
Pulmonary oedema	1 (5.0)	0	0	1 (5.0)	0
Rhinitis allergic	1 (5.0)	1 (5.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (25.0)	4 (20.0)	1 (5.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	2 (10.0)	2 (10.0)	0	0	0
Ingrowing nail	1 (5.0)	1 (5.0)	0	0	0
Rash	1 (5.0)	0	1 (5.0)	0	0
Rash maculo-papular	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Hypertension	2 (10.0)	1 (5.0)	1 (5.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184n
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (69.4)	5 (13.9)	9 (25.0)	8 (22.2)	3 (8.3)
Blood and lymphatic system disorders					
-Total	3 (8.3)	0	1 (2.8)	1 (2.8)	1 (2.8)
Anaemia	1 (2.8)	0	0	1 (2.8)	0
Febrile neutropenia	1 (2.8)	0	0	1 (2.8)	0
Neutropenia	1 (2.8)	0	0	0	1 (2.8)
Thrombocytopenia	1 (2.8)	0	1 (2.8)	0	0
Cardiac disorders					
-Total	1 (2.8)	0	1 (2.8)	0	0
Sinus tachycardia	1 (2.8)	0	1 (2.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	8 (22.2)	4 (11.1)	3 (8.3)	1 (2.8)	0
Diarrhoea	5 (13.9)	4 (11.1)	1 (2.8)	0	0
Vomiting	5 (13.9)	2 (5.6)	2 (5.6)	1 (2.8)	0
Nausea	4 (11.1)	1 (2.8)	2 (5.6)	1 (2.8)	0
Abdominal pain	2 (5.6)	1 (2.8)	1 (2.8)	0	0
General disorders and administration site conditions					
-Total	4 (11.1)	3 (8.3)	1 (2.8)	0	0
Pyrexia	4 (11.1)	3 (8.3)	1 (2.8)	0	0
Chills	1 (2.8)	1 (2.8)	0	0	0
Fatigue	1 (2.8)	1 (2.8)	0	0	0
Pain	1 (2.8)	1 (2.8)	0	0	0
Immune system disorders					
-Total	5 (13.9)	0	4 (11.1)	1 (2.8)	0
Hypogammaglobulinaemia	5 (13.9)	0	4 (11.1)	1 (2.8)	0
Infections and infestations					
-Total	13 (36.1)	3 (8.3)	7 (19.4)	3 (8.3)	0
Upper respiratory tract infection	4 (11.1)	3 (8.3)	0	1 (2.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	4 (11.1)	0	2 (5.6)	2 (5.6)	0
Gastroenteritis	3 (8.3)	1 (2.8)	2 (5.6)	0	0
Sinusitis	2 (5.6)	0	2 (5.6)	0	0
Influenza	1 (2.8)	0	1 (2.8)	0	0
Investigations					
-Total	9 (25.0)	3 (8.3)	0	5 (13.9)	1 (2.8)
Neutrophil count decreased	4 (11.1)	1 (2.8)	0	2 (5.6)	1 (2.8)
Aspartate aminotransferase increased	3 (8.3)	1 (2.8)	0	2 (5.6)	0
White blood cell count decreased	3 (8.3)	1 (2.8)	1 (2.8)	1 (2.8)	0
Platelet count decreased	2 (5.6)	2 (5.6)	0	0	0
Alanine aminotransferase increased	1 (2.8)	0	0	1 (2.8)	0
Blood creatinine increased	1 (2.8)	1 (2.8)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (13.9)	2 (5.6)	1 (2.8)	1 (2.8)	1 (2.8)
Decreased appetite	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Hypokalaemia	2 (5.6)	1 (2.8)	0	0	1 (2.8)
Dehydration	1 (2.8)	0	0	1 (2.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	1 (2.8)	1 (2.8)	0	0	0
Hypophosphataemia	1 (2.8)	0	0	1 (2.8)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (13.9)	3 (8.3)	2 (5.6)	0	0
Pain in extremity	5 (13.9)	3 (8.3)	2 (5.6)	0	0
Nervous system disorders					
-Total	4 (11.1)	3 (8.3)	1 (2.8)	0	0
Dizziness	3 (8.3)	3 (8.3)	0	0	0
Headache	3 (8.3)	2 (5.6)	1 (2.8)	0	0
Renal and urinary disorders					
-Total	2 (5.6)	0	0	2 (5.6)	0
Acute kidney injury	1 (2.8)	0	0	1 (2.8)	0
Haematuria	1 (2.8)	0	0	1 (2.8)	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (25.0)	7 (19.4)	2 (5.6)	0	0
Cough	4 (11.1)	3 (8.3)	1 (2.8)	0	0
Nasal congestion	2 (5.6)	2 (5.6)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	2 (5.6)	2 (5.6)	0	0	0
Rhinitis allergic	2 (5.6)	1 (2.8)	1 (2.8)	0	0
Rhinorrhoea	2 (5.6)	2 (5.6)	0	0	0
Epistaxis	1 (2.8)	1 (2.8)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (13.9)	3 (8.3)	2 (5.6)	0	0
Rash	3 (8.3)	1 (2.8)	2 (5.6)	0	0
Dry skin	1 (2.8)	1 (2.8)	0	0	0
Rash maculo-papular	1 (2.8)	1 (2.8)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184n
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (64.3)	2 (14.3)	2 (14.3)	4 (28.6)	1 (7.1)
Blood and lymphatic system disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Thrombocytopenia	1 (7.1)	1 (7.1)	0	0	0
Infections and infestations					
-Total	4 (28.6)	2 (14.3)	2 (14.3)	0	0
Sinusitis	2 (14.3)	0	2 (14.3)	0	0
Upper respiratory tract infection	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Viral infection	1 (7.1)	1 (7.1)	0	0	0
Investigations					
-Total	7 (50.0)	1 (7.1)	2 (14.3)	3 (21.4)	1 (7.1)

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	3 (21.4)	2 (14.3)	0	1 (7.1)	0
White blood cell count decreased	3 (21.4)	1 (7.1)	0	1 (7.1)	1 (7.1)
Alanine aminotransferase increased	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Neutrophil count decreased	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Aspartate aminotransferase increased	1 (7.1)	0	0	1 (7.1)	0
Nervous system disorders					
-Total	1 (7.1)	0	0	1 (7.1)	0
Seizure	1 (7.1)	0	0	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Cough	1 (7.1)	1 (7.1)	0	0	0
Rhinitis allergic	1 (7.1)	1 (7.1)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184n
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (30.0)	2 (10.0)	0	3 (15.0)	1 (5.0)
Blood and lymphatic system disorders					
-Total	1 (5.0)	0	0	0	1 (5.0)
Febrile neutropenia	1 (5.0)	0	0	0	1 (5.0)
Gastrointestinal disorders					
-Total	3 (15.0)	0	3 (15.0)	0	0
Diarrhoea	2 (10.0)	0	2 (10.0)	0	0
Abdominal pain	1 (5.0)	0	1 (5.0)	0	0
Nausea	1 (5.0)	0	1 (5.0)	0	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.0)	0	1 (5.0)	0	0
Chills	1 (5.0)	0	1 (5.0)	0	0
Pyrexia	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	3 (15.0)	0	1 (5.0)	2 (10.0)	0
Urinary tract infection	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Clostridium difficile infection	1 (5.0)	0	0	1 (5.0)	0
Sinusitis	1 (5.0)	0	1 (5.0)	0	0
Investigations					
-Total	1 (5.0)	0	0	1 (5.0)	0
Alanine aminotransferase increased	1 (5.0)	0	0	1 (5.0)	0
Aspartate aminotransferase increased	1 (5.0)	1 (5.0)	0	0	0
Platelet count decreased	1 (5.0)	0	0	1 (5.0)	0
White blood cell count decreased	1 (5.0)	0	0	1 (5.0)	0
Metabolism and nutrition disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Hypokalaemia	1 (5.0)	0	0	1 (5.0)	0
Nervous system disorders					

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.0)	0	1 (5.0)	0	0
Dizziness	1 (5.0)	1 (5.0)	0	0	0
Headache	1 (5.0)	0	1 (5.0)	0	0
Renal and urinary disorders					
-Total	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Acute kidney injury	1 (5.0)	0	0	1 (5.0)	0
Haematuria	1 (5.0)	1 (5.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (15.0)	3 (15.0)	0	0	0
Cough	1 (5.0)	1 (5.0)	0	0	0
Epistaxis	1 (5.0)	1 (5.0)	0	0	0
Oropharyngeal pain	1 (5.0)	1 (5.0)	0	0	0
Rhinorrhoea	1 (5.0)	1 (5.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184n
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (100)	0	0	7 (35.0)	13 (65.0)
Blood and lymphatic system disorders					
-Total	15 (75.0)	0	0	12 (60.0)	3 (15.0)
Anaemia	9 (45.0)	2 (10.0)	2 (10.0)	5 (25.0)	0
Febrile neutropenia	9 (45.0)	0	0	9 (45.0)	0
Neutropenia	5 (25.0)	0	0	2 (10.0)	3 (15.0)
Thrombocytopenia	1 (5.0)	0	0	1 (5.0)	0
Cardiac disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Tachycardia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Eye disorders					

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Eye pain	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Gastrointestinal disorders					
-Total	15 (75.0)	7 (35.0)	6 (30.0)	2 (10.0)	0
Vomiting	10 (50.0)	7 (35.0)	2 (10.0)	1 (5.0)	0
Nausea	8 (40.0)	3 (15.0)	4 (20.0)	1 (5.0)	0
Diarrhoea	5 (25.0)	2 (10.0)	2 (10.0)	1 (5.0)	0
Abdominal pain	4 (20.0)	2 (10.0)	1 (5.0)	1 (5.0)	0
Constipation	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Abdominal pain upper	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Oral pain	2 (10.0)	1 (5.0)	0	1 (5.0)	0
General disorders and administration site conditions					
-Total	12 (60.0)	6 (30.0)	3 (15.0)	3 (15.0)	0
Pyrexia	8 (40.0)	4 (20.0)	2 (10.0)	2 (10.0)	0
Fatigue	5 (25.0)	5 (25.0)	0	0	0
Catheter site pain	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Chills	2 (10.0)	2 (10.0)	0	0	0
Pain	2 (10.0)	0	1 (5.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	17 (85.0)	0	11 (55.0)	4 (20.0)	2 (10.0)
Cytokine release syndrome	16 (80.0)	0	11 (55.0)	3 (15.0)	2 (10.0)
Hypogammaglobulinaemia	12 (60.0)	1 (5.0)	10 (50.0)	1 (5.0)	0
Infections and infestations					
-Total	11 (55.0)	2 (10.0)	8 (40.0)	1 (5.0)	0
Upper respiratory tract infection	5 (25.0)	1 (5.0)	4 (20.0)	0	0
Viral infection	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Gastroenteritis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Influenza	2 (10.0)	0	2 (10.0)	0	0
Sinusitis	2 (10.0)	0	2 (10.0)	0	0
Investigations					
-Total	19 (95.0)	0	2 (10.0)	5 (25.0)	12 (60.0)
White blood cell count decreased	12 (60.0)	2 (10.0)	0	3 (15.0)	7 (35.0)
Neutrophil count decreased	10 (50.0)	1 (5.0)	0	2 (10.0)	7 (35.0)
Lymphocyte count decreased	8 (40.0)	1 (5.0)	1 (5.0)	3 (15.0)	3 (15.0)
Aspartate aminotransferase increased	6 (30.0)	0	3 (15.0)	2 (10.0)	1 (5.0)
Platelet count decreased	6 (30.0)	2 (10.0)	0	1 (5.0)	3 (15.0)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	5 (25.0)	1 (5.0)	1 (5.0)	3 (15.0)	0
Blood bilirubin increased	4 (20.0)	2 (10.0)	0	2 (10.0)	0
Blood creatinine increased	3 (15.0)	3 (15.0)	0	0	0
International normalised ratio increased	3 (15.0)	3 (15.0)	0	0	0
Prothrombin time prolonged	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Metabolism and nutrition disorders					
-Total	9 (45.0)	1 (5.0)	1 (5.0)	7 (35.0)	0
Decreased appetite	5 (25.0)	1 (5.0)	1 (5.0)	3 (15.0)	0
Dehydration	2 (10.0)	0	0	2 (10.0)	0
Hyperphosphataemia	2 (10.0)	2 (10.0)	0	0	0
Hypophosphataemia	2 (10.0)	0	0	2 (10.0)	0
Hypokalaemia	1 (5.0)	0	0	1 (5.0)	0
Musculoskeletal and connective tissue disorders					
-Total	7 (35.0)	4 (20.0)	2 (10.0)	1 (5.0)	0
Pain in extremity	5 (25.0)	3 (15.0)	2 (10.0)	0	0
Arthralgia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Myalgia	2 (10.0)	2 (10.0)	0	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	11 (55.0)	5 (25.0)	4 (20.0)	2 (10.0)	0
Headache	6 (30.0)	4 (20.0)	1 (5.0)	1 (5.0)	0
Encephalopathy	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Peroneal nerve palsy	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Seizure	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Psychiatric disorders					
-Total	4 (20.0)	3 (15.0)	1 (5.0)	0	0
Anxiety	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Depression	2 (10.0)	2 (10.0)	0	0	0
Confusional state	1 (5.0)	1 (5.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	10 (50.0)	4 (20.0)	4 (20.0)	2 (10.0)	0
Cough	5 (25.0)	4 (20.0)	1 (5.0)	0	0
Hypoxia	3 (15.0)	0	3 (15.0)	0	0
Nasal congestion	3 (15.0)	3 (15.0)	0	0	0
Rhinitis allergic	2 (10.0)	2 (10.0)	0	0	0
Rhinorrhoea	2 (10.0)	1 (5.0)	1 (5.0)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	1 (5.0)	0	0	1 (5.0)	0
Oropharyngeal pain	1 (5.0)	0	1 (5.0)	0	0
Pleural effusion	1 (5.0)	1 (5.0)	0	0	0
Pulmonary oedema	1 (5.0)	0	0	1 (5.0)	0
Skin and subcutaneous tissue disorders					
-Total	9 (45.0)	7 (35.0)	1 (5.0)	1 (5.0)	0
Erythema	4 (20.0)	4 (20.0)	0	0	0
Dry skin	2 (10.0)	2 (10.0)	0	0	0
Ingrowing nail	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Rash maculo-papular	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Rash	1 (5.0)	0	1 (5.0)	0	0
Vascular disorders					
-Total	6 (30.0)	0	2 (10.0)	3 (15.0)	1 (5.0)
Hypertension	4 (20.0)	1 (5.0)	3 (15.0)	0	0
Hypotension	4 (20.0)	0	0	3 (15.0)	1 (5.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184n
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

			All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	44 (100)	1 (2.3)	6 (13.6)	7 (15.9)	30 (68.2)
Blood and lymphatic system disorders					
-Total	29 (65.9)	1 (2.3)	2 (4.5)	16 (36.4)	10 (22.7)
Anaemia	18 (40.9)	1 (2.3)	2 (4.5)	14 (31.8)	1 (2.3)
Febrile neutropenia	15 (34.1)	0	0	14 (31.8)	1 (2.3)
Thrombocytopenia	9 (20.5)	0	1 (2.3)	2 (4.5)	6 (13.6)
Neutropenia	6 (13.6)	0	0	1 (2.3)	5 (11.4)
Cardiac disorders					
-Total	18 (40.9)	9 (20.5)	7 (15.9)	2 (4.5)	0
Tachycardia	13 (29.5)	7 (15.9)	4 (9.1)	2 (4.5)	0
Sinus tachycardia	6 (13.6)	3 (6.8)	3 (6.8)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	1 (2.3)	0	1 (2.3)	0	0
Eye pain	1 (2.3)	0	1 (2.3)	0	0
Gastrointestinal disorders					
-Total	25 (56.8)	7 (15.9)	12 (27.3)	6 (13.6)	0
Diarrhoea	19 (43.2)	11 (25.0)	7 (15.9)	1 (2.3)	0
Nausea	17 (38.6)	3 (6.8)	10 (22.7)	4 (9.1)	0
Vomiting	17 (38.6)	9 (20.5)	6 (13.6)	2 (4.5)	0
Abdominal pain	7 (15.9)	4 (9.1)	3 (6.8)	0	0
Constipation	4 (9.1)	4 (9.1)	0	0	0
Abdominal pain upper	1 (2.3)	0	1 (2.3)	0	0
General disorders and administration site conditions					
-Total	25 (56.8)	9 (20.5)	10 (22.7)	5 (11.4)	1 (2.3)
Pyrexia	17 (38.6)	4 (9.1)	8 (18.2)	4 (9.1)	1 (2.3)
Fatigue	10 (22.7)	7 (15.9)	2 (4.5)	1 (2.3)	0
Chills	8 (18.2)	7 (15.9)	1 (2.3)	0	0
Catheter site pain	2 (4.5)	0	2 (4.5)	0	0
Pain	2 (4.5)	1 (2.3)	0	1 (2.3)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	40 (90.9)	4 (9.1)	20 (45.5)	7 (15.9)	9 (20.5)
Cytokine release syndrome	34 (77.3)	6 (13.6)	14 (31.8)	5 (11.4)	9 (20.5)
Hypogammaglobulinaemia	20 (45.5)	2 (4.5)	14 (31.8)	4 (9.1)	0
Infections and infestations					
-Total	16 (36.4)	3 (6.8)	9 (20.5)	4 (9.1)	0
Clostridium difficile infection	5 (11.4)	0	4 (9.1)	1 (2.3)	0
Urinary tract infection	5 (11.4)	0	3 (6.8)	2 (4.5)	0
Upper respiratory tract infection	4 (9.1)	3 (6.8)	0	1 (2.3)	0
Gastroenteritis	3 (6.8)	1 (2.3)	2 (4.5)	0	0
Influenza	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Sinusitis	2 (4.5)	0	2 (4.5)	0	0
Investigations					
-Total	33 (75.0)	0	3 (6.8)	8 (18.2)	22 (50.0)
White blood cell count decreased	23 (52.3)	2 (4.5)	1 (2.3)	9 (20.5)	11 (25.0)
Neutrophil count decreased	18 (40.9)	0	2 (4.5)	2 (4.5)	14 (31.8)
Alanine aminotransferase increased	16 (36.4)	4 (9.1)	1 (2.3)	11 (25.0)	0
Aspartate aminotransferase increased	14 (31.8)	4 (9.1)	1 (2.3)	6 (13.6)	3 (6.8)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	14 (31.8)	1 (2.3)	2 (4.5)	2 (4.5)	9 (20.5)
Lymphocyte count decreased	8 (18.2)	0	2 (4.5)	4 (9.1)	2 (4.5)
Prothrombin time prolonged	7 (15.9)	4 (9.1)	2 (4.5)	1 (2.3)	0
Blood creatinine increased	6 (13.6)	2 (4.5)	2 (4.5)	2 (4.5)	0
International normalised ratio increased	6 (13.6)	5 (11.4)	0	1 (2.3)	0
Blood bilirubin increased	4 (9.1)	0	3 (6.8)	1 (2.3)	0
Metabolism and nutrition disorders					
-Total	28 (63.6)	5 (11.4)	7 (15.9)	14 (31.8)	2 (4.5)
Hypokalaemia	18 (40.9)	4 (9.1)	6 (13.6)	7 (15.9)	1 (2.3)
Decreased appetite	17 (38.6)	4 (9.1)	4 (9.1)	9 (20.5)	0
Hypophosphataemia	8 (18.2)	2 (4.5)	0	5 (11.4)	1 (2.3)
Hyperphosphataemia	6 (13.6)	6 (13.6)	0	0	0
Hypoalbuminaemia	5 (11.4)	1 (2.3)	3 (6.8)	1 (2.3)	0
Dehydration	2 (4.5)	1 (2.3)	0	1 (2.3)	0
Musculoskeletal and connective tissue disorders					
-Total	10 (22.7)	7 (15.9)	3 (6.8)	0	0
Pain in extremity	6 (13.6)	4 (9.1)	2 (4.5)	0	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	3 (6.8)	3 (6.8)	0	0	0
Myalgia	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Nervous system disorders					
-Total	22 (50.0)	14 (31.8)	5 (11.4)	3 (6.8)	0
Headache	18 (40.9)	11 (25.0)	6 (13.6)	1 (2.3)	0
Dizziness	6 (13.6)	6 (13.6)	0	0	0
Seizure	2 (4.5)	0	1 (2.3)	1 (2.3)	0
Encephalopathy	1 (2.3)	0	0	1 (2.3)	0
Psychiatric disorders					
-Total	9 (20.5)	4 (9.1)	4 (9.1)	1 (2.3)	0
Anxiety	5 (11.4)	2 (4.5)	2 (4.5)	1 (2.3)	0
Confusional state	5 (11.4)	2 (4.5)	3 (6.8)	0	0
Renal and urinary disorders					
-Total	11 (25.0)	1 (2.3)	1 (2.3)	5 (11.4)	4 (9.1)
Acute kidney injury	9 (20.5)	1 (2.3)	1 (2.3)	4 (9.1)	3 (6.8)
Haematuria	5 (11.4)	0	2 (4.5)	2 (4.5)	1 (2.3)
Respiratory, thoracic and mediastinal disorders					
-Total	25 (56.8)	10 (22.7)	3 (6.8)	7 (15.9)	5 (11.4)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	9 (20.5)	8 (18.2)	1 (2.3)	0	0
Epistaxis	9 (20.5)	4 (9.1)	1 (2.3)	3 (6.8)	1 (2.3)
Hypoxia	7 (15.9)	0	0	4 (9.1)	3 (6.8)
Pleural effusion	7 (15.9)	1 (2.3)	4 (9.1)	2 (4.5)	0
Pulmonary oedema	6 (13.6)	1 (2.3)	0	3 (6.8)	2 (4.5)
Oropharyngeal pain	5 (11.4)	4 (9.1)	1 (2.3)	0	0
Tachypnoea	5 (11.4)	3 (6.8)	1 (2.3)	1 (2.3)	0
Rhinorrhoea	4 (9.1)	4 (9.1)	0	0	0
Nasal congestion	2 (4.5)	2 (4.5)	0	0	0
Rhinitis allergic	2 (4.5)	1 (2.3)	1 (2.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	13 (29.5)	9 (20.5)	4 (9.1)	0	0
Rash	7 (15.9)	5 (11.4)	2 (4.5)	0	0
Dry skin	3 (6.8)	3 (6.8)	0	0	0
Rash maculo-papular	3 (6.8)	2 (4.5)	1 (2.3)	0	0
Erythema	1 (2.3)	1 (2.3)	0	0	0
Ingrowing nail	1 (2.3)	0	1 (2.3)	0	0
Vascular disorders					

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	16 (36.4)	2 (4.5)	3 (6.8)	4 (9.1)	7 (15.9)
Hypotension	12 (27.3)	1 (2.3)	0	4 (9.1)	7 (15.9)
Hypertension	8 (18.2)	2 (4.5)	5 (11.4)	1 (2.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184o
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	0	0	4 (80.0)
Blood and lymphatic system disorders					
-Total	2 (40.0)	0	0	2 (40.0)	0
Anaemia	2 (40.0)	0	0	2 (40.0)	0
Febrile neutropenia	1 (20.0)	0	0	1 (20.0)	0
Cardiac disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Bradycardia	1 (20.0)	0	1 (20.0)	0	0
Pericardial effusion	1 (20.0)	0	1 (20.0)	0	0
Tachycardia	1 (20.0)	1 (20.0)	0	0	0
Eye disorders					

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (20.0)	1 (20.0)	0	0	0
Conjunctival haemorrhage	1 (20.0)	1 (20.0)	0	0	0
Periorbital oedema	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal disorders					
-Total	3 (60.0)	1 (20.0)	1 (20.0)	1 (20.0)	0
Abdominal pain	1 (20.0)	1 (20.0)	0	0	0
Dysphagia	1 (20.0)	0	0	1 (20.0)	0
Nausea	1 (20.0)	0	1 (20.0)	0	0
Vomiting	1 (20.0)	1 (20.0)	0	0	0
General disorders and administration site conditions					
-Total	2 (40.0)	0	1 (20.0)	1 (20.0)	0
Face oedema	1 (20.0)	0	0	1 (20.0)	0
Localised oedema	1 (20.0)	0	0	1 (20.0)	0
Malaise	1 (20.0)	0	1 (20.0)	0	0
Mucosal haemorrhage	1 (20.0)	0	1 (20.0)	0	0
Multiple organ dysfunction syndrome	1 (20.0)	0	0	1 (20.0)	0
Oedema peripheral	1 (20.0)	0	0	1 (20.0)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Hyperbilirubinaemia	1 (20.0)	0	0	1 (20.0)	0
Immune system disorders					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	0	1 (20.0)
Cytokine release syndrome	4 (80.0)	2 (40.0)	1 (20.0)	0	1 (20.0)
Hypogammaglobulinaemia	2 (40.0)	0	2 (40.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (20.0)	1 (20.0)	0	0	0
Procedural complication	1 (20.0)	1 (20.0)	0	0	0
Investigations					
-Total	4 (80.0)	0	0	0	4 (80.0)
Alanine aminotransferase increased	2 (40.0)	0	0	2 (40.0)	0
Aspartate aminotransferase increased	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Neutrophil count decreased	2 (40.0)	0	0	0	2 (40.0)
White blood cell count decreased	2 (40.0)	0	0	0	2 (40.0)
Activated partial thromboplastin time prolonged	1 (20.0)	1 (20.0)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	1 (20.0)	0	0	1 (20.0)	0
Blood fibrinogen decreased	1 (20.0)	0	0	0	1 (20.0)
Blood phosphorus decreased	1 (20.0)	1 (20.0)	0	0	0
Blood urea increased	1 (20.0)	0	0	1 (20.0)	0
Lymphocyte count decreased	1 (20.0)	0	0	0	1 (20.0)
Platelet count decreased	1 (20.0)	0	0	0	1 (20.0)
Protein total decreased	1 (20.0)	0	0	1 (20.0)	0
Metabolism and nutrition disorders					
-Total	2 (40.0)	0	0	2 (40.0)	0
Hypokalaemia	2 (40.0)	0	0	2 (40.0)	0
Acidosis	1 (20.0)	0	0	1 (20.0)	0
Decreased appetite	1 (20.0)	0	1 (20.0)	0	0
Hyperalbuminaemia	1 (20.0)	1 (20.0)	0	0	0
Hypercalcaemia	1 (20.0)	1 (20.0)	0	0	0
Hyperchloraemia	1 (20.0)	1 (20.0)	0	0	0
Hypermagnesaemia	1 (20.0)	1 (20.0)	0	0	0
Hypernatraemia	1 (20.0)	0	1 (20.0)	0	0
Hypoalbuminaemia	1 (20.0)	0	1 (20.0)	0	0
Hypophosphataemia	1 (20.0)	1 (20.0)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic alkalosis	1 (20.0)	1 (20.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Arthralgia	1 (20.0)	1 (20.0)	0	0	0
Muscular weakness	1 (20.0)	0	1 (20.0)	0	0
Nervous system disorders					
-Total	2 (40.0)	0	2 (40.0)	0	0
Dysarthria	1 (20.0)	0	1 (20.0)	0	0
Headache	1 (20.0)	0	1 (20.0)	0	0
Somnolence	1 (20.0)	1 (20.0)	0	0	0
Psychiatric disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Delirium	1 (20.0)	0	1 (20.0)	0	0
Insomnia	1 (20.0)	0	1 (20.0)	0	0
Irritability	1 (20.0)	1 (20.0)	0	0	0
Renal and urinary disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Renal impairment	1 (20.0)	0	0	1 (20.0)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	2 (40.0)	1 (20.0)	0	0	1 (20.0)
Epistaxis	1 (20.0)	0	1 (20.0)	0	0
Oropharyngeal plaque	1 (20.0)	1 (20.0)	0	0	0
Pleural effusion	1 (20.0)	0	0	1 (20.0)	0
Pulmonary oedema	1 (20.0)	0	0	1 (20.0)	0
Respiratory distress	1 (20.0)	0	0	0	1 (20.0)
Skin and subcutaneous tissue disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Hyperhidrosis	1 (20.0)	1 (20.0)	0	0	0
Rash papular	1 (20.0)	1 (20.0)	0	0	0
Vascular disorders					
-Total	1 (20.0)	0	0	0	1 (20.0)
Capillary leak syndrome	1 (20.0)	0	0	0	1 (20.0)
Flushing	1 (20.0)	1 (20.0)	0	0	0
Hypertension	1 (20.0)	0	1 (20.0)	0	0
Hypotension	1 (20.0)	0	0	0	1 (20.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184o
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (100)	2 (3.4)	8 (13.6)	14 (23.7)	35 (59.3)
Blood and lymphatic system disorders					
-Total	38 (64.4)	1 (1.7)	2 (3.4)	26 (44.1)	9 (15.3)
Anaemia	25 (42.4)	3 (5.1)	5 (8.5)	16 (27.1)	1 (1.7)
Febrile neutropenia	21 (35.6)	0	0	21 (35.6)	0
Neutropenia	8 (13.6)	0	0	3 (5.1)	5 (8.5)
Thrombocytopenia	8 (13.6)	0	0	2 (3.4)	6 (10.2)
Cardiac disorders					
-Total	18 (30.5)	9 (15.3)	7 (11.9)	2 (3.4)	0
Tachycardia	14 (23.7)	7 (11.9)	5 (8.5)	2 (3.4)	0
Sinus tachycardia	5 (8.5)	3 (5.1)	2 (3.4)	0	0
Pericardial effusion	1 (1.7)	1 (1.7)	0	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Periorbital oedema	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Conjunctival haemorrhage	2 (3.4)	2 (3.4)	0	0	0
Gastrointestinal disorders					
-Total	31 (52.5)	11 (18.6)	13 (22.0)	7 (11.9)	0
Vomiting	21 (35.6)	12 (20.3)	6 (10.2)	3 (5.1)	0
Nausea	20 (33.9)	6 (10.2)	11 (18.6)	3 (5.1)	0
Diarrhoea	18 (30.5)	11 (18.6)	6 (10.2)	1 (1.7)	0
Abdominal pain	8 (13.6)	5 (8.5)	2 (3.4)	1 (1.7)	0
Constipation	7 (11.9)	6 (10.2)	1 (1.7)	0	0
Dysphagia	1 (1.7)	0	1 (1.7)	0	0
General disorders and administration site conditions					
-Total	28 (47.5)	13 (22.0)	8 (13.6)	6 (10.2)	1 (1.7)
Pyrexia	16 (27.1)	3 (5.1)	7 (11.9)	5 (8.5)	1 (1.7)
Fatigue	13 (22.0)	10 (16.9)	2 (3.4)	1 (1.7)	0
Chills	8 (13.6)	8 (13.6)	0	0	0
Malaise	2 (3.4)	0	2 (3.4)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Face oedema	1 (1.7)	0	1 (1.7)	0	0
Oedema peripheral	1 (1.7)	1 (1.7)	0	0	0
Hepatobiliary disorders					
-Total	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Hyperbilirubinaemia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Immune system disorders					
-Total	52 (88.1)	3 (5.1)	28 (47.5)	11 (18.6)	10 (16.9)
Cytokine release syndrome	46 (78.0)	4 (6.8)	24 (40.7)	8 (13.6)	10 (16.9)
Hypogammaglobulinaemia	23 (39.0)	3 (5.1)	16 (27.1)	4 (6.8)	0
Infections and infestations					
-Total	6 (10.2)	0	4 (6.8)	2 (3.4)	0
Gastroenteritis	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Pneumonia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Upper respiratory tract infection	1 (1.7)	0	1 (1.7)	0	0
Viral upper respiratory tract infection	1 (1.7)	0	1 (1.7)	0	0
Injury, poisoning and procedural complications					
-Total	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Procedural pain	3 (5.1)	1 (1.7)	2 (3.4)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	44 (74.6)	1 (1.7)	4 (6.8)	12 (20.3)	27 (45.8)
White blood cell count decreased	28 (47.5)	3 (5.1)	1 (1.7)	10 (16.9)	14 (23.7)
Neutrophil count decreased	23 (39.0)	0	2 (3.4)	4 (6.8)	17 (28.8)
Platelet count decreased	18 (30.5)	3 (5.1)	2 (3.4)	2 (3.4)	11 (18.6)
Alanine aminotransferase increased	17 (28.8)	5 (8.5)	3 (5.1)	9 (15.3)	0
Aspartate aminotransferase increased	16 (27.1)	3 (5.1)	4 (6.8)	6 (10.2)	3 (5.1)
Lymphocyte count decreased	13 (22.0)	1 (1.7)	2 (3.4)	6 (10.2)	4 (6.8)
International normalised ratio increased	9 (15.3)	8 (13.6)	0	1 (1.7)	0
Prothrombin time prolonged	9 (15.3)	5 (8.5)	3 (5.1)	1 (1.7)	0
Blood creatinine increased	8 (13.6)	5 (8.5)	2 (3.4)	1 (1.7)	0
Blood bilirubin increased	7 (11.9)	2 (3.4)	3 (5.1)	2 (3.4)	0
Activated partial thromboplastin time prolonged	4 (6.8)	2 (3.4)	2 (3.4)	0	0
Blood fibrinogen decreased	3 (5.1)	0	1 (1.7)	2 (3.4)	0
Blood urea increased	2 (3.4)	1 (1.7)	1 (1.7)	0	0
C-reactive protein increased	1 (1.7)	0	0	1 (1.7)	0
Serum ferritin increased	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	33 (55.9)	8 (13.6)	8 (13.6)	15 (25.4)	2 (3.4)
Decreased appetite	19 (32.2)	4 (6.8)	3 (5.1)	12 (20.3)	0
Hypokalaemia	14 (23.7)	3 (5.1)	6 (10.2)	5 (8.5)	0
Hyperphosphataemia	8 (13.6)	8 (13.6)	0	0	0
Hypophosphataemia	8 (13.6)	1 (1.7)	0	6 (10.2)	1 (1.7)
Hypoalbuminaemia	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Hypernatraemia	3 (5.1)	1 (1.7)	1 (1.7)	0	1 (1.7)
Acidosis	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	6 (10.2)	3 (5.1)	2 (3.4)	1 (1.7)	0
Pain in extremity	4 (6.8)	2 (3.4)	2 (3.4)	0	0
Arthralgia	3 (5.1)	2 (3.4)	0	1 (1.7)	0
Nervous system disorders					
-Total	26 (44.1)	17 (28.8)	6 (10.2)	3 (5.1)	0
Headache	23 (39.0)	16 (27.1)	5 (8.5)	2 (3.4)	0
Dizziness	4 (6.8)	4 (6.8)	0	0	0
Seizure	3 (5.1)	0	2 (3.4)	1 (1.7)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysarthria	1 (1.7)	1 (1.7)	0	0	0
Psychiatric disorders					
-Total	13 (22.0)	7 (11.9)	5 (8.5)	1 (1.7)	0
Anxiety	6 (10.2)	2 (3.4)	3 (5.1)	1 (1.7)	0
Confusional state	6 (10.2)	3 (5.1)	3 (5.1)	0	0
Delirium	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Irritability	1 (1.7)	1 (1.7)	0	0	0
Renal and urinary disorders					
-Total	7 (11.9)	1 (1.7)	1 (1.7)	2 (3.4)	3 (5.1)
Acute kidney injury	7 (11.9)	1 (1.7)	1 (1.7)	2 (3.4)	3 (5.1)
Respiratory, thoracic and mediastinal disorders					
-Total	22 (37.3)	8 (13.6)	4 (6.8)	5 (8.5)	5 (8.5)
Hypoxia	10 (16.9)	0	3 (5.1)	4 (6.8)	3 (5.1)
Cough	8 (13.6)	8 (13.6)	0	0	0
Pleural effusion	7 (11.9)	2 (3.4)	4 (6.8)	1 (1.7)	0
Epistaxis	6 (10.2)	2 (3.4)	0	3 (5.1)	1 (1.7)
Pulmonary oedema	5 (8.5)	1 (1.7)	0	2 (3.4)	2 (3.4)
Oropharyngeal pain	2 (3.4)	1 (1.7)	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinorrhoea	1 (1.7)	1 (1.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	8 (13.6)	8 (13.6)	0	0	0
Rash	4 (6.8)	4 (6.8)	0	0	0
Hyperhidrosis	2 (3.4)	2 (3.4)	0	0	0
Pruritus	2 (3.4)	2 (3.4)	0	0	0
Rash papular	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					
-Total	20 (33.9)	2 (3.4)	4 (6.8)	7 (11.9)	7 (11.9)
Hypotension	15 (25.4)	1 (1.7)	0	7 (11.9)	7 (11.9)
Hypertension	9 (15.3)	2 (3.4)	6 (10.2)	1 (1.7)	0
Flushing	1 (1.7)	1 (1.7)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184o
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=5			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	1 (20.0)	1 (20.0)	1 (20.0)	1 (20.0)
Blood and lymphatic system disorders					
-Total	2 (40.0)	0	1 (20.0)	0	1 (20.0)
Leukopenia	1 (20.0)	0	0	0	1 (20.0)
Lymphadenopathy	1 (20.0)	0	1 (20.0)	0	0
General disorders and administration site conditions					
-Total	1 (20.0)	1 (20.0)	0	0	0
Acquired gene mutation	1 (20.0)	1 (20.0)	0	0	0
Immune system disorders					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	1 (20.0)	0	0	1 (20.0)	0
Seasonal allergy	1 (20.0)	1 (20.0)	0	0	0
Infections and infestations					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Gastroenteritis	1 (20.0)	0	1 (20.0)	0	0
Subcutaneous abscess	1 (20.0)	0	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	1 (20.0)	0	0	0
Viral upper respiratory tract infection	1 (20.0)	0	0	1 (20.0)	0
Injury, poisoning and procedural complications					
-Total	1 (20.0)	0	1 (20.0)	0	0
Arthropod bite	1 (20.0)	1 (20.0)	0	0	0
Procedural pain	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Blood urea increased	1 (20.0)	1 (20.0)	0	0	0
Serum ferritin increased	1 (20.0)	0	1 (20.0)	0	0
Metabolism and nutrition disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Hyperalbuminaemia	1 (20.0)	1 (20.0)	0	0	0
Hypercalcaemia	1 (20.0)	1 (20.0)	0	0	0
Iron overload	1 (20.0)	0	0	1 (20.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Cough	1 (20.0)	1 (20.0)	0	0	0
Rhinorrhoea	1 (20.0)	1 (20.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Dermatitis	1 (20.0)	1 (20.0)	0	0	0
Papule	1 (20.0)	1 (20.0)	0	0	0
Rash	1 (20.0)	0	1 (20.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184o
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=51			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (72.5)	7 (13.7)	12 (23.5)	12 (23.5)	6 (11.8)
Blood and lymphatic system disorders					
-Total	8 (15.7)	1 (2.0)	1 (2.0)	3 (5.9)	3 (5.9)
Neutropenia	4 (7.8)	0	0	1 (2.0)	3 (5.9)
Febrile neutropenia	3 (5.9)	0	0	3 (5.9)	0
Anaemia	2 (3.9)	1 (2.0)	0	1 (2.0)	0
Thrombocytopenia	2 (3.9)	0	1 (2.0)	1 (2.0)	0
Cardiac disorders					
-Total	1 (2.0)	0	1 (2.0)	0	0
Sinus tachycardia	1 (2.0)	0	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	14 (27.5)	8 (15.7)	4 (7.8)	2 (3.9)	0
Vomiting	9 (17.6)	5 (9.8)	2 (3.9)	2 (3.9)	0
Diarrhoea	8 (15.7)	6 (11.8)	1 (2.0)	1 (2.0)	0
Nausea	6 (11.8)	1 (2.0)	3 (5.9)	2 (3.9)	0
Abdominal pain	4 (7.8)	2 (3.9)	1 (2.0)	1 (2.0)	0
General disorders and administration site conditions					
-Total	13 (25.5)	10 (19.6)	2 (3.9)	1 (2.0)	0
Pyrexia	10 (19.6)	7 (13.7)	2 (3.9)	1 (2.0)	0
Fatigue	2 (3.9)	2 (3.9)	0	0	0
Chills	1 (2.0)	1 (2.0)	0	0	0
Malaise	1 (2.0)	1 (2.0)	0	0	0
Oedema peripheral	1 (2.0)	1 (2.0)	0	0	0
Immune system disorders					
-Total	8 (15.7)	1 (2.0)	7 (13.7)	0	0
Hypogammaglobulinaemia	7 (13.7)	0	7 (13.7)	0	0
Seasonal allergy	1 (2.0)	1 (2.0)	0	0	0
Infections and infestations					

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (19.6)	2 (3.9)	7 (13.7)	1 (2.0)	0
Upper respiratory tract infection	6 (11.8)	2 (3.9)	3 (5.9)	1 (2.0)	0
Gastroenteritis	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Sinusitis	2 (3.9)	0	2 (3.9)	0	0
Otitis media	1 (2.0)	0	1 (2.0)	0	0
Otitis media acute	1 (2.0)	0	1 (2.0)	0	0
Viral upper respiratory tract infection	1 (2.0)	1 (2.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (2.0)	1 (2.0)	0	0	0
Procedural pain	1 (2.0)	1 (2.0)	0	0	0
Investigations					
-Total	16 (31.4)	3 (5.9)	1 (2.0)	8 (15.7)	4 (7.8)
Neutrophil count decreased	8 (15.7)	2 (3.9)	0	3 (5.9)	3 (5.9)
White blood cell count decreased	5 (9.8)	2 (3.9)	1 (2.0)	1 (2.0)	1 (2.0)
Aspartate aminotransferase increased	3 (5.9)	1 (2.0)	0	2 (3.9)	0
Platelet count decreased	3 (5.9)	3 (5.9)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	2 (3.9)	0	0	2 (3.9)	0
Lymphocyte count decreased	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Blood bilirubin increased	1 (2.0)	0	0	1 (2.0)	0
Blood creatinine increased	1 (2.0)	1 (2.0)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (9.8)	3 (5.9)	1 (2.0)	0	1 (2.0)
Decreased appetite	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Hyperphosphataemia	2 (3.9)	2 (3.9)	0	0	0
Hypokalaemia	2 (3.9)	1 (2.0)	0	0	1 (2.0)
Hypophosphataemia	1 (2.0)	0	0	1 (2.0)	0
Musculoskeletal and connective tissue disorders					
-Total	11 (21.6)	8 (15.7)	3 (5.9)	0	0
Pain in extremity	8 (15.7)	6 (11.8)	2 (3.9)	0	0
Arthralgia	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Muscular weakness	2 (3.9)	2 (3.9)	0	0	0
Nervous system disorders					
-Total	6 (11.8)	5 (9.8)	1 (2.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	5 (9.8)	4 (7.8)	1 (2.0)	0	0
Dizziness	3 (5.9)	3 (5.9)	0	0	0
Psychiatric disorders					
-Total	1 (2.0)	1 (2.0)	0	0	0
Anxiety	1 (2.0)	1 (2.0)	0	0	0
Renal and urinary disorders					
-Total	1 (2.0)	0	0	1 (2.0)	0
Acute kidney injury	1 (2.0)	0	0	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (21.6)	6 (11.8)	3 (5.9)	2 (3.9)	0
Cough	6 (11.8)	4 (7.8)	2 (3.9)	0	0
Oropharyngeal pain	3 (5.9)	2 (3.9)	1 (2.0)	0	0
Rhinorrhoea	3 (5.9)	2 (3.9)	1 (2.0)	0	0
Epistaxis	2 (3.9)	1 (2.0)	0	1 (2.0)	0
Pulmonary oedema	1 (2.0)	0	0	1 (2.0)	0
Skin and subcutaneous tissue disorders					
-Total	4 (7.8)	2 (3.9)	2 (3.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=51				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	3 (5.9)	1 (2.0)	2 (3.9)	0	0
Hyperhidrosis	1 (2.0)	1 (2.0)	0	0	0
Pruritus	1 (2.0)	1 (2.0)	0	0	0
Vascular disorders					
-Total	2 (3.9)	1 (2.0)	1 (2.0)	0	0
Hypertension	2 (3.9)	1 (2.0)	1 (2.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184o
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	0	0	2 (66.7)
Blood and lymphatic system disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Febrile neutropenia	1 (33.3)	0	0	0	1 (33.3)
Ear and labyrinth disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Tympanic membrane perforation	1 (33.3)	0	1 (33.3)	0	0
Gastrointestinal disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Nausea	1 (33.3)	0	1 (33.3)	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	1 (33.3)	0	1 (33.3)	0	0
Chills	1 (33.3)	0	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Immune system disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Immunodeficiency	1 (33.3)	0	1 (33.3)	0	0
Infections and infestations					
-Total	1 (33.3)	0	0	1 (33.3)	0
Haemophilus infection	1 (33.3)	0	1 (33.3)	0	0
Otitis media	1 (33.3)	0	0	1 (33.3)	0
Otitis media acute	1 (33.3)	0	1 (33.3)	0	0
Pneumonia	1 (33.3)	0	1 (33.3)	0	0
Sinusitis	1 (33.3)	0	1 (33.3)	0	0
Injury, poisoning and procedural complications					
-Total	1 (33.3)	0	0	1 (33.3)	0
Procedural pain	1 (33.3)	0	0	1 (33.3)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	1 (33.3)	0	0	1 (33.3)	0
Alanine aminotransferase increased	1 (33.3)	0	0	1 (33.3)	0
Aspartate aminotransferase increased	1 (33.3)	1 (33.3)	0	0	0
Blood alkaline phosphatase increased	1 (33.3)	1 (33.3)	0	0	0
Blood lactate dehydrogenase increased	1 (33.3)	1 (33.3)	0	0	0
C-reactive protein increased	1 (33.3)	1 (33.3)	0	0	0
Platelet count decreased	1 (33.3)	0	0	1 (33.3)	0
White blood cell count decreased	1 (33.3)	0	0	1 (33.3)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (33.3)	0	0	0	1 (33.3)
Glioblastoma multiforme	1 (33.3)	0	0	0	1 (33.3)
Nervous system disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Seizure	1 (33.3)	0	0	1 (33.3)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Cough	1 (33.3)	1 (33.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Pruritus	1 (33.3)	1 (33.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184o
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (48.4)	4 (12.9)	6 (19.4)	4 (12.9)	1 (3.2)
Blood and lymphatic system disorders					
-Total	1 (3.2)	1 (3.2)	0	0	0
Thrombocytopenia	1 (3.2)	1 (3.2)	0	0	0
Gastrointestinal disorders					
-Total	2 (6.5)	0	2 (6.5)	0	0
Diarrhoea	2 (6.5)	0	2 (6.5)	0	0
Abdominal pain	1 (3.2)	0	1 (3.2)	0	0
Infections and infestations					
-Total	6 (19.4)	1 (3.2)	5 (16.1)	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	2 (6.5)	0	2 (6.5)	0	0
Sinusitis	2 (6.5)	0	2 (6.5)	0	0
Upper respiratory tract infection	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Otitis media acute	1 (3.2)	0	1 (3.2)	0	0
Pneumonia	1 (3.2)	0	1 (3.2)	0	0
Investigations					
-Total	7 (22.6)	1 (3.2)	2 (6.5)	3 (9.7)	1 (3.2)
Lymphocyte count decreased	3 (9.7)	2 (6.5)	0	1 (3.2)	0
White blood cell count decreased	3 (9.7)	1 (3.2)	0	1 (3.2)	1 (3.2)
Alanine aminotransferase increased	2 (6.5)	0	1 (3.2)	1 (3.2)	0
Neutrophil count decreased	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Aspartate aminotransferase increased	1 (3.2)	0	0	1 (3.2)	0
Metabolism and nutrition disorders					
-Total	1 (3.2)	0	0	1 (3.2)	0
Hypokalaemia	1 (3.2)	0	0	1 (3.2)	0
Nervous system disorders					
-Total	1 (3.2)	0	1 (3.2)	0	0
Dizziness	1 (3.2)	1 (3.2)	0	0	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (3.2)	0	1 (3.2)	0	0
Renal and urinary disorders					
-Total	1 (3.2)	0	0	1 (3.2)	0
Acute kidney injury	1 (3.2)	0	0	1 (3.2)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (9.7)	3 (9.7)	0	0	0
Cough	1 (3.2)	1 (3.2)	0	0	0
Epistaxis	1 (3.2)	1 (3.2)	0	0	0
Oropharyngeal pain	1 (3.2)	1 (3.2)	0	0	0
Rhinorrhoea	1 (3.2)	1 (3.2)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (3.2)	1 (3.2)	0	0	0
Papule	1 (3.2)	1 (3.2)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184o
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	0	0	0	5 (100)
Blood and lymphatic system disorders					
-Total	3 (60.0)	0	0	1 (20.0)	2 (40.0)
Anaemia	2 (40.0)	0	0	2 (40.0)	0
Febrile neutropenia	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Leukopenia	1 (20.0)	0	0	0	1 (20.0)
Lymphadenopathy	1 (20.0)	0	1 (20.0)	0	0
Cardiac disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Bradycardia	1 (20.0)	0	1 (20.0)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pericardial effusion	1 (20.0)	0	1 (20.0)	0	0
Tachycardia	1 (20.0)	1 (20.0)	0	0	0
Ear and labyrinth disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Tympanic membrane perforation	1 (20.0)	0	1 (20.0)	0	0
Eye disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Conjunctival haemorrhage	1 (20.0)	1 (20.0)	0	0	0
Periorbital oedema	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal disorders					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Nausea	2 (40.0)	0	2 (40.0)	0	0
Abdominal pain	1 (20.0)	1 (20.0)	0	0	0
Dysphagia	1 (20.0)	0	0	1 (20.0)	0
Vomiting	1 (20.0)	1 (20.0)	0	0	0
General disorders and administration site conditions					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Acquired gene mutation	1 (20.0)	1 (20.0)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	1 (20.0)	0	1 (20.0)	0	0
Face oedema	1 (20.0)	0	0	1 (20.0)	0
Localised oedema	1 (20.0)	0	0	1 (20.0)	0
Malaise	1 (20.0)	0	1 (20.0)	0	0
Mucosal haemorrhage	1 (20.0)	0	1 (20.0)	0	0
Multiple organ dysfunction syndrome	1 (20.0)	0	0	1 (20.0)	0
Oedema peripheral	1 (20.0)	0	0	1 (20.0)	0
Pyrexia	1 (20.0)	0	1 (20.0)	0	0
Hepatobiliary disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Hyperbilirubinaemia	1 (20.0)	0	0	1 (20.0)	0
Immune system disorders					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	0	1 (20.0)
Cytokine release syndrome	4 (80.0)	2 (40.0)	1 (20.0)	0	1 (20.0)
Hypogammaglobulinaemia	3 (60.0)	0	2 (40.0)	1 (20.0)	0
Immunodeficiency	1 (20.0)	0	1 (20.0)	0	0
Seasonal allergy	1 (20.0)	1 (20.0)	0	0	0
Infections and infestations					

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (60.0)	1 (20.0)	0	2 (40.0)	0
Gastroenteritis	1 (20.0)	0	1 (20.0)	0	0
Haemophilus infection	1 (20.0)	0	1 (20.0)	0	0
Otitis media	1 (20.0)	0	0	1 (20.0)	0
Otitis media acute	1 (20.0)	0	1 (20.0)	0	0
Pneumonia	1 (20.0)	0	1 (20.0)	0	0
Sinusitis	1 (20.0)	0	1 (20.0)	0	0
Subcutaneous abscess	1 (20.0)	0	1 (20.0)	0	0
Upper respiratory tract infection	1 (20.0)	1 (20.0)	0	0	0
Viral upper respiratory tract infection	1 (20.0)	0	0	1 (20.0)	0
Injury, poisoning and procedural complications					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Arthropod bite	1 (20.0)	1 (20.0)	0	0	0
Procedural complication	1 (20.0)	1 (20.0)	0	0	0
Procedural pain	1 (20.0)	0	0	1 (20.0)	0
Investigations					
-Total	4 (80.0)	0	0	0	4 (80.0)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	3 (60.0)	0	0	3 (60.0)	0
Aspartate aminotransferase increased	3 (60.0)	1 (20.0)	0	1 (20.0)	1 (20.0)
White blood cell count decreased	3 (60.0)	0	0	1 (20.0)	2 (40.0)
Neutrophil count decreased	2 (40.0)	0	0	0	2 (40.0)
Platelet count decreased	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Activated partial thromboplastin time prolonged	1 (20.0)	1 (20.0)	0	0	0
Blood alkaline phosphatase increased	1 (20.0)	1 (20.0)	0	0	0
Blood creatinine increased	1 (20.0)	0	0	1 (20.0)	0
Blood fibrinogen decreased	1 (20.0)	0	0	0	1 (20.0)
Blood lactate dehydrogenase increased	1 (20.0)	1 (20.0)	0	0	0
Blood phosphorus decreased	1 (20.0)	1 (20.0)	0	0	0
Blood urea increased	1 (20.0)	0	0	1 (20.0)	0
C-reactive protein increased	1 (20.0)	1 (20.0)	0	0	0
Lymphocyte count decreased	1 (20.0)	0	0	0	1 (20.0)
Protein total decreased	1 (20.0)	0	0	1 (20.0)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Serum ferritin increased	1 (20.0)	0	1 (20.0)	0	0
Metabolism and nutrition disorders					
-Total	2 (40.0)	0	0	2 (40.0)	0
Hypokalaemia	2 (40.0)	0	0	2 (40.0)	0
Acidosis	1 (20.0)	0	0	1 (20.0)	0
Decreased appetite	1 (20.0)	0	1 (20.0)	0	0
Hyperalbuminaemia	1 (20.0)	1 (20.0)	0	0	0
Hypercalcaemia	1 (20.0)	1 (20.0)	0	0	0
Hyperchloraemia	1 (20.0)	1 (20.0)	0	0	0
Hypermagnesaemia	1 (20.0)	1 (20.0)	0	0	0
Hypernatraemia	1 (20.0)	0	1 (20.0)	0	0
Hypoalbuminaemia	1 (20.0)	0	1 (20.0)	0	0
Hypophosphataemia	1 (20.0)	1 (20.0)	0	0	0
Iron overload	1 (20.0)	0	0	1 (20.0)	0
Metabolic alkalosis	1 (20.0)	1 (20.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Arthralgia	1 (20.0)	1 (20.0)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Muscular weakness	1 (20.0)	0	1 (20.0)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (20.0)	0	0	0	1 (20.0)
Glioblastoma multiforme	1 (20.0)	0	0	0	1 (20.0)
Nervous system disorders					
-Total	3 (60.0)	0	2 (40.0)	1 (20.0)	0
Dysarthria	1 (20.0)	0	1 (20.0)	0	0
Headache	1 (20.0)	0	1 (20.0)	0	0
Seizure	1 (20.0)	0	0	1 (20.0)	0
Somnolence	1 (20.0)	1 (20.0)	0	0	0
Psychiatric disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Delirium	1 (20.0)	0	1 (20.0)	0	0
Insomnia	1 (20.0)	0	1 (20.0)	0	0
Irritability	1 (20.0)	1 (20.0)	0	0	0
Renal and urinary disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Renal impairment	1 (20.0)	0	0	1 (20.0)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	3 (60.0)	2 (40.0)	0	0	1 (20.0)
Cough	1 (20.0)	1 (20.0)	0	0	0
Epistaxis	1 (20.0)	0	1 (20.0)	0	0
Oropharyngeal plaque	1 (20.0)	1 (20.0)	0	0	0
Pleural effusion	1 (20.0)	0	0	1 (20.0)	0
Pulmonary oedema	1 (20.0)	0	0	1 (20.0)	0
Respiratory distress	1 (20.0)	0	0	0	1 (20.0)
Rhinorrhoea	1 (20.0)	1 (20.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Dermatitis	1 (20.0)	1 (20.0)	0	0	0
Hyperhidrosis	1 (20.0)	1 (20.0)	0	0	0
Papule	1 (20.0)	1 (20.0)	0	0	0
Pruritus	1 (20.0)	1 (20.0)	0	0	0
Rash	1 (20.0)	0	1 (20.0)	0	0
Rash papular	1 (20.0)	1 (20.0)	0	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	1 (20.0)	0	0	0	1 (20.0)
Capillary leak syndrome	1 (20.0)	0	0	0	1 (20.0)
Flushing	1 (20.0)	1 (20.0)	0	0	0
Hypertension	1 (20.0)	0	1 (20.0)	0	0
Hypotension	1 (20.0)	0	0	0	1 (20.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184o
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

			All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (100)	1 (1.7)	6 (10.2)	13 (22.0)	39 (66.1)
Blood and lymphatic system disorders					
-Total	42 (71.2)	1 (1.7)	2 (3.4)	27 (45.8)	12 (20.3)
Anaemia	25 (42.4)	3 (5.1)	4 (6.8)	17 (28.8)	1 (1.7)
Febrile neutropenia	22 (37.3)	0	0	22 (37.3)	0
Neutropenia	11 (18.6)	0	0	3 (5.1)	8 (13.6)
Thrombocytopenia	10 (16.9)	0	1 (1.7)	3 (5.1)	6 (10.2)
Cardiac disorders					
-Total	19 (32.2)	9 (15.3)	8 (13.6)	2 (3.4)	0
Tachycardia	14 (23.7)	7 (11.9)	5 (8.5)	2 (3.4)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	6 (10.2)	3 (5.1)	3 (5.1)	0	0
Pericardial effusion	1 (1.7)	1 (1.7)	0	0	0
Eye disorders					
-Total	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Periorbital oedema	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Conjunctival haemorrhage	2 (3.4)	2 (3.4)	0	0	0
Gastrointestinal disorders					
-Total	36 (61.0)	13 (22.0)	16 (27.1)	7 (11.9)	0
Vomiting	26 (44.1)	15 (25.4)	8 (13.6)	3 (5.1)	0
Diarrhoea	24 (40.7)	13 (22.0)	9 (15.3)	2 (3.4)	0
Nausea	23 (39.0)	6 (10.2)	12 (20.3)	5 (8.5)	0
Abdominal pain	10 (16.9)	5 (8.5)	4 (6.8)	1 (1.7)	0
Constipation	7 (11.9)	6 (10.2)	1 (1.7)	0	0
Dysphagia	1 (1.7)	0	1 (1.7)	0	0
General disorders and administration site conditions					
-Total	35 (59.3)	17 (28.8)	10 (16.9)	7 (11.9)	1 (1.7)
Pyrexia	24 (40.7)	8 (13.6)	9 (15.3)	6 (10.2)	1 (1.7)
Fatigue	15 (25.4)	12 (20.3)	2 (3.4)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	9 (15.3)	9 (15.3)	0	0	0
Malaise	3 (5.1)	1 (1.7)	2 (3.4)	0	0
Oedema peripheral	2 (3.4)	2 (3.4)	0	0	0
Face oedema	1 (1.7)	0	1 (1.7)	0	0
Hepatobiliary disorders					
-Total	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Hyperbilirubinaemia	2 (3.4)	0	1 (1.7)	1 (1.7)	0
Immune system disorders					
-Total	53 (89.8)	3 (5.1)	29 (49.2)	11 (18.6)	10 (16.9)
Cytokine release syndrome	46 (78.0)	4 (6.8)	24 (40.7)	8 (13.6)	10 (16.9)
Hypogammaglobulinaemia	29 (49.2)	3 (5.1)	22 (37.3)	4 (6.8)	0
Seasonal allergy	1 (1.7)	1 (1.7)	0	0	0
Infections and infestations					
-Total	18 (30.5)	3 (5.1)	12 (20.3)	3 (5.1)	0
Upper respiratory tract infection	8 (13.6)	3 (5.1)	4 (6.8)	1 (1.7)	0
Gastroenteritis	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Otitis media	3 (5.1)	0	3 (5.1)	0	0
Pneumonia	3 (5.1)	0	2 (3.4)	1 (1.7)	0
Sinusitis	3 (5.1)	0	3 (5.1)	0	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	2 (3.4)	1 (1.7)	1 (1.7)	0	0
Otitis media acute	1 (1.7)	0	1 (1.7)	0	0
Injury, poisoning and procedural complications					
-Total	4 (6.8)	2 (3.4)	2 (3.4)	0	0
Procedural pain	4 (6.8)	2 (3.4)	2 (3.4)	0	0
Investigations					
-Total	49 (83.1)	0	5 (8.5)	14 (23.7)	30 (50.8)
White blood cell count decreased	32 (54.2)	4 (6.8)	1 (1.7)	11 (18.6)	16 (27.1)
Neutrophil count decreased	26 (44.1)	1 (1.7)	2 (3.4)	4 (6.8)	19 (32.2)
Alanine aminotransferase increased	18 (30.5)	5 (8.5)	2 (3.4)	11 (18.6)	0
Platelet count decreased	18 (30.5)	3 (5.1)	2 (3.4)	2 (3.4)	11 (18.6)
Aspartate aminotransferase increased	17 (28.8)	3 (5.1)	4 (6.8)	7 (11.9)	3 (5.1)
Lymphocyte count decreased	15 (25.4)	1 (1.7)	3 (5.1)	7 (11.9)	4 (6.8)
International normalised ratio increased	9 (15.3)	8 (13.6)	0	1 (1.7)	0
Prothrombin time prolonged	9 (15.3)	5 (8.5)	3 (5.1)	1 (1.7)	0
Blood bilirubin increased	8 (13.6)	2 (3.4)	3 (5.1)	3 (5.1)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	8 (13.6)	5 (8.5)	2 (3.4)	1 (1.7)	0
Activated partial thromboplastin time prolonged	4 (6.8)	2 (3.4)	2 (3.4)	0	0
Blood fibrinogen decreased	3 (5.1)	0	1 (1.7)	2 (3.4)	0
Blood urea increased	2 (3.4)	1 (1.7)	1 (1.7)	0	0
C-reactive protein increased	1 (1.7)	0	0	1 (1.7)	0
Serum ferritin increased	1 (1.7)	0	1 (1.7)	0	0
Metabolism and nutrition disorders					
-Total	35 (59.3)	8 (13.6)	8 (13.6)	16 (27.1)	3 (5.1)
Decreased appetite	21 (35.6)	5 (8.5)	4 (6.8)	12 (20.3)	0
Hypokalaemia	17 (28.8)	4 (6.8)	6 (10.2)	6 (10.2)	1 (1.7)
Hypophosphataemia	9 (15.3)	1 (1.7)	0	7 (11.9)	1 (1.7)
Hyperphosphataemia	8 (13.6)	8 (13.6)	0	0	0
Hypoalbuminaemia	4 (6.8)	1 (1.7)	2 (3.4)	1 (1.7)	0
Hypernatraemia	3 (5.1)	1 (1.7)	1 (1.7)	0	1 (1.7)
Acidosis	1 (1.7)	1 (1.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	14 (23.7)	9 (15.3)	4 (6.8)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	11 (18.6)	7 (11.9)	4 (6.8)	0	0
Arthralgia	4 (6.8)	2 (3.4)	1 (1.7)	1 (1.7)	0
Muscular weakness	2 (3.4)	2 (3.4)	0	0	0
Nervous system disorders					
-Total	27 (45.8)	18 (30.5)	6 (10.2)	3 (5.1)	0
Headache	23 (39.0)	15 (25.4)	6 (10.2)	2 (3.4)	0
Dizziness	6 (10.2)	6 (10.2)	0	0	0
Seizure	3 (5.1)	0	2 (3.4)	1 (1.7)	0
Dysarthria	1 (1.7)	1 (1.7)	0	0	0
Psychiatric disorders					
-Total	13 (22.0)	7 (11.9)	5 (8.5)	1 (1.7)	0
Anxiety	7 (11.9)	3 (5.1)	3 (5.1)	1 (1.7)	0
Confusional state	6 (10.2)	3 (5.1)	3 (5.1)	0	0
Delirium	3 (5.1)	2 (3.4)	1 (1.7)	0	0
Irritability	1 (1.7)	1 (1.7)	0	0	0
Renal and urinary disorders					
-Total	9 (15.3)	1 (1.7)	1 (1.7)	4 (6.8)	3 (5.1)
Acute kidney injury	9 (15.3)	1 (1.7)	1 (1.7)	4 (6.8)	3 (5.1)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	29 (49.2)	11 (18.6)	6 (10.2)	7 (11.9)	5 (8.5)
Cough	13 (22.0)	11 (18.6)	2 (3.4)	0	0
Hypoxia	10 (16.9)	0	3 (5.1)	4 (6.8)	3 (5.1)
Epistaxis	9 (15.3)	4 (6.8)	0	4 (6.8)	1 (1.7)
Pleural effusion	7 (11.9)	2 (3.4)	4 (6.8)	1 (1.7)	0
Oropharyngeal pain	6 (10.2)	4 (6.8)	2 (3.4)	0	0
Pulmonary oedema	6 (10.2)	1 (1.7)	0	3 (5.1)	2 (3.4)
Rhinorrhoea	5 (8.5)	4 (6.8)	1 (1.7)	0	0
Skin and subcutaneous tissue disorders					
-Total	12 (20.3)	10 (16.9)	2 (3.4)	0	0
Rash	7 (11.9)	5 (8.5)	2 (3.4)	0	0
Hyperhidrosis	3 (5.1)	3 (5.1)	0	0	0
Pruritus	3 (5.1)	3 (5.1)	0	0	0
Papule	1 (1.7)	1 (1.7)	0	0	0
Rash papular	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	21 (35.6)	2 (3.4)	5 (8.5)	7 (11.9)	7 (11.9)
Hypotension	15 (25.4)	1 (1.7)	0	7 (11.9)	7 (11.9)
Hypertension	11 (18.6)	3 (5.1)	7 (11.9)	1 (1.7)	0
Flushing	1 (1.7)	1 (1.7)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184p
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: Yes

			All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	1 (25.0)	0	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders					
-Total	3 (75.0)	0	0	2 (50.0)	1 (25.0)
Anaemia	2 (50.0)	2 (50.0)	0	0	0
Febrile neutropenia	2 (50.0)	0	0	2 (50.0)	0
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
Gastrointestinal disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Constipation	1 (25.0)	1 (25.0)	0	0	0
General disorders and administration site conditions					
-Total	1 (25.0)	1 (25.0)	0	0	0
Fatigue	1 (25.0)	1 (25.0)	0	0	0

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Cytokine release syndrome	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Hypogammaglobulinaemia	1 (25.0)	0	1 (25.0)	0	0
Infections and infestations					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Fungal skin infection	1 (25.0)	1 (25.0)	0	0	0
Viral infection	1 (25.0)	0	1 (25.0)	0	0
Investigations					
-Total	3 (75.0)	1 (25.0)	0	0	2 (50.0)
Lymphocyte count decreased	2 (50.0)	1 (25.0)	0	0	1 (25.0)
Blood bilirubin increased	1 (25.0)	1 (25.0)	0	0	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0	0	0
Fibrin d dimer increased	1 (25.0)	1 (25.0)	0	0	0
Neutrophil count decreased	1 (25.0)	0	0	0	1 (25.0)
Platelet count decreased	1 (25.0)	1 (25.0)	0	0	0
White blood cell count decreased	1 (25.0)	0	0	0	1 (25.0)

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Decreased appetite	1 (25.0)	1 (25.0)	0	0	0
Hyperphosphataemia	1 (25.0)	1 (25.0)	0	0	0
Nervous system disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Headache	1 (25.0)	0	1 (25.0)	0	0
Tremor	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (50.0)	2 (50.0)	0	0	0
Dermatitis diaper	1 (25.0)	1 (25.0)	0	0	0
Dry skin	1 (25.0)	1 (25.0)	0	0	0
Erythema	1 (25.0)	1 (25.0)	0	0	0
Vascular disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Hypotension	1 (25.0)	0	0	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184p
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: No

			All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (98.3)	1 (1.7)	8 (13.3)	13 (21.7)	37 (61.7)
Blood and lymphatic system disorders					
-Total	37 (61.7)	1 (1.7)	2 (3.3)	26 (43.3)	8 (13.3)
Anaemia	25 (41.7)	1 (1.7)	5 (8.3)	18 (30.0)	1 (1.7)
Febrile neutropenia	20 (33.3)	0	0	20 (33.3)	0
Thrombocytopenia	8 (13.3)	0	0	2 (3.3)	6 (10.0)
Neutropenia	7 (11.7)	0	0	3 (5.0)	4 (6.7)
Cardiac disorders					
-Total	19 (31.7)	10 (16.7)	7 (11.7)	2 (3.3)	0
Tachycardia	15 (25.0)	8 (13.3)	5 (8.3)	2 (3.3)	0
Sinus tachycardia	5 (8.3)	3 (5.0)	2 (3.3)	0	0
Gastrointestinal disorders					

Timing: within 8 weeks post infusion, Down syndrome: No

			All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	32 (53.3)	11 (18.3)	14 (23.3)	7 (11.7)	0
Vomiting	22 (36.7)	13 (21.7)	6 (10.0)	3 (5.0)	0
Nausea	21 (35.0)	6 (10.0)	12 (20.0)	3 (5.0)	0
Diarrhoea	18 (30.0)	11 (18.3)	6 (10.0)	1 (1.7)	0
Abdominal pain	9 (15.0)	6 (10.0)	2 (3.3)	1 (1.7)	0
Constipation	6 (10.0)	5 (8.3)	1 (1.7)	0	0
General disorders and administration site conditions					
-Total	27 (45.0)	12 (20.0)	8 (13.3)	6 (10.0)	1 (1.7)
Pyrexia	16 (26.7)	3 (5.0)	7 (11.7)	5 (8.3)	1 (1.7)
Fatigue	12 (20.0)	9 (15.0)	2 (3.3)	1 (1.7)	0
Chills	8 (13.3)	8 (13.3)	0	0	0
Immune system disorders					
-Total	53 (88.3)	3 (5.0)	28 (46.7)	11 (18.3)	11 (18.3)
Cytokine release syndrome	47 (78.3)	5 (8.3)	23 (38.3)	8 (13.3)	11 (18.3)
Hypogammaglobulinaemia	24 (40.0)	3 (5.0)	17 (28.3)	4 (6.7)	0
Infections and infestations					
-Total	1 (1.7)	0	1 (1.7)	0	0
Upper respiratory tract infection	1 (1.7)	0	1 (1.7)	0	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	44 (73.3)	0	4 (6.7)	11 (18.3)	29 (48.3)
White blood cell count decreased	29 (48.3)	3 (5.0)	1 (1.7)	10 (16.7)	15 (25.0)
Neutrophil count decreased	24 (40.0)	0	2 (3.3)	4 (6.7)	18 (30.0)
Alanine aminotransferase increased	19 (31.7)	5 (8.3)	3 (5.0)	11 (18.3)	0
Aspartate aminotransferase increased	18 (30.0)	3 (5.0)	4 (6.7)	7 (11.7)	4 (6.7)
Platelet count decreased	18 (30.0)	2 (3.3)	2 (3.3)	2 (3.3)	12 (20.0)
Lymphocyte count decreased	12 (20.0)	0	2 (3.3)	6 (10.0)	4 (6.7)
International normalised ratio increased	9 (15.0)	8 (13.3)	0	1 (1.7)	0
Prothrombin time prolonged	9 (15.0)	5 (8.3)	3 (5.0)	1 (1.7)	0
Blood creatinine increased	8 (13.3)	4 (6.7)	2 (3.3)	2 (3.3)	0
Blood bilirubin increased	6 (10.0)	1 (1.7)	3 (5.0)	2 (3.3)	0
Blood immunoglobulin m decreased	3 (5.0)	3 (5.0)	0	0	0
Blood immunoglobulin a decreased	2 (3.3)	2 (3.3)	0	0	0
Metabolism and nutrition disorders					
-Total	32 (53.3)	6 (10.0)	8 (13.3)	17 (28.3)	1 (1.7)
Decreased appetite	19 (31.7)	3 (5.0)	4 (6.7)	12 (20.0)	0
Hypokalaemia	16 (26.7)	3 (5.0)	6 (10.0)	7 (11.7)	0
Hypophosphataemia	9 (15.0)	2 (3.3)	0	6 (10.0)	1 (1.7)

Timing: within 8 weeks post infusion, Down syndrome: No

			All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	7 (11.7)	7 (11.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Pain in extremity	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Nervous system disorders					
-Total	25 (41.7)	18 (30.0)	5 (8.3)	2 (3.3)	0
Headache	23 (38.3)	16 (26.7)	5 (8.3)	2 (3.3)	0
Dizziness	4 (6.7)	4 (6.7)	0	0	0
Tremor	1 (1.7)	1 (1.7)	0	0	0
Psychiatric disorders					
-Total	11 (18.3)	5 (8.3)	5 (8.3)	1 (1.7)	0
Anxiety	6 (10.0)	2 (3.3)	3 (5.0)	1 (1.7)	0
Confusional state	6 (10.0)	3 (5.0)	3 (5.0)	0	0
Renal and urinary disorders					
-Total	7 (11.7)	1 (1.7)	1 (1.7)	2 (3.3)	3 (5.0)
Acute kidney injury	7 (11.7)	1 (1.7)	1 (1.7)	2 (3.3)	3 (5.0)
Respiratory, thoracic and mediastinal disorders					
-Total	23 (38.3)	9 (15.0)	3 (5.0)	6 (10.0)	5 (8.3)

Timing: within 8 weeks post infusion, Down syndrome: No

			All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	9 (15.0)	0	2 (3.3)	4 (6.7)	3 (5.0)
Cough	8 (13.3)	8 (13.3)	0	0	0
Pleural effusion	8 (13.3)	2 (3.3)	4 (6.7)	2 (3.3)	0
Epistaxis	7 (11.7)	2 (3.3)	1 (1.7)	3 (5.0)	1 (1.7)
Pulmonary oedema	6 (10.0)	1 (1.7)	0	3 (5.0)	2 (3.3)
Oropharyngeal pain	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Nasal congestion	1 (1.7)	1 (1.7)	0	0	0
Rhinorrhoea	1 (1.7)	1 (1.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (18.3)	9 (15.0)	1 (1.7)	1 (1.7)	0
Rash	4 (6.7)	4 (6.7)	0	0	0
Dry skin	3 (5.0)	3 (5.0)	0	0	0
Rash maculo-papular	3 (5.0)	1 (1.7)	1 (1.7)	1 (1.7)	0
Erythema	2 (3.3)	2 (3.3)	0	0	0
Vascular disorders					
-Total	20 (33.3)	2 (3.3)	4 (6.7)	6 (10.0)	8 (13.3)
Hypotension	15 (25.0)	1 (1.7)	0	6 (10.0)	8 (13.3)
Hypertension	10 (16.7)	2 (3.3)	7 (11.7)	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184p
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

			All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	2 (50.0)	2 (50.0)	0
Blood and lymphatic system disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Anaemia	1 (25.0)	1 (25.0)	0	0	0
Eye disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Ocular hyperaemia	1 (25.0)	1 (25.0)	0	0	0
Gastrointestinal disorders					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Vomiting	2 (50.0)	2 (50.0)	0	0	0
Enterocolitis	1 (25.0)	0	0	1 (25.0)	0
Nausea	1 (25.0)	0	1 (25.0)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Influenza like illness	1 (25.0)	1 (25.0)	0	0	0
Pyrexia	1 (25.0)	0	0	1 (25.0)	0
Infections and infestations					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Corona virus infection	1 (25.0)	0	0	1 (25.0)	0
Rash pustular	1 (25.0)	0	1 (25.0)	0	0
Respiratory syncytial virus infection	1 (25.0)	0	0	1 (25.0)	0
Injury, poisoning and procedural complications					
-Total	1 (25.0)	0	1 (25.0)	0	0
Skin laceration	1 (25.0)	0	1 (25.0)	0	0
Investigations					
-Total	1 (25.0)	0	1 (25.0)	0	0
Lymphocyte count decreased	1 (25.0)	0	1 (25.0)	0	0
Neutrophil count decreased	1 (25.0)	1 (25.0)	0	0	0
Platelet count decreased	1 (25.0)	1 (25.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (25.0)	1 (25.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Hyperphosphataemia	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Pain in extremity	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (50.0)	0	2 (50.0)	0	0
Cough	1 (25.0)	0	1 (25.0)	0	0
Nasal congestion	1 (25.0)	1 (25.0)	0	0	0
Rhinorrhoea	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Rash maculo-papular	1 (25.0)	1 (25.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184p
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

			All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (71.2)	9 (17.3)	10 (19.2)	12 (23.1)	6 (11.5)
Blood and lymphatic system disorders					
-Total	7 (13.5)	0	1 (1.9)	3 (5.8)	3 (5.8)
Neutropenia	4 (7.7)	0	0	1 (1.9)	3 (5.8)
Febrile neutropenia	3 (5.8)	0	0	3 (5.8)	0
Thrombocytopenia	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Anaemia	1 (1.9)	0	0	1 (1.9)	0
Cardiac disorders					
-Total	1 (1.9)	0	1 (1.9)	0	0
Sinus tachycardia	1 (1.9)	0	1 (1.9)	0	0
Gastrointestinal disorders					
-Total	12 (23.1)	7 (13.5)	3 (5.8)	2 (3.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

			All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	8 (15.4)	6 (11.5)	1 (1.9)	1 (1.9)	0
Vomiting	7 (13.5)	3 (5.8)	2 (3.8)	2 (3.8)	0
Nausea	5 (9.6)	1 (1.9)	2 (3.8)	2 (3.8)	0
Abdominal pain	4 (7.7)	2 (3.8)	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions					
-Total	11 (21.2)	9 (17.3)	2 (3.8)	0	0
Pyrexia	9 (17.3)	7 (13.5)	2 (3.8)	0	0
Fatigue	2 (3.8)	2 (3.8)	0	0	0
Chills	1 (1.9)	1 (1.9)	0	0	0
Influenza like illness	1 (1.9)	1 (1.9)	0	0	0
Immune system disorders					
-Total	8 (15.4)	0	7 (13.5)	1 (1.9)	0
Hypogammaglobulinaemia	8 (15.4)	0	7 (13.5)	1 (1.9)	0
Infections and infestations					
-Total	8 (15.4)	4 (7.7)	3 (5.8)	1 (1.9)	0
Upper respiratory tract infection	7 (13.5)	3 (5.8)	3 (5.8)	1 (1.9)	0
Viral infection	1 (1.9)	1 (1.9)	0	0	0
Investigations					

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

			All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	15 (28.8)	3 (5.8)	0	8 (15.4)	4 (7.7)
Neutrophil count decreased	7 (13.5)	1 (1.9)	0	3 (5.8)	3 (5.8)
White blood cell count decreased	4 (7.7)	1 (1.9)	1 (1.9)	1 (1.9)	1 (1.9)
Aspartate aminotransferase increased	3 (5.8)	1 (1.9)	0	2 (3.8)	0
Alanine aminotransferase increased	2 (3.8)	0	0	2 (3.8)	0
Platelet count decreased	2 (3.8)	2 (3.8)	0	0	0
Blood bilirubin increased	1 (1.9)	0	0	1 (1.9)	0
Blood creatinine increased	1 (1.9)	1 (1.9)	0	0	0
Lymphocyte count decreased	1 (1.9)	1 (1.9)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (7.7)	2 (3.8)	1 (1.9)	0	1 (1.9)
Decreased appetite	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Hypokalaemia	2 (3.8)	1 (1.9)	0	0	1 (1.9)
Hyperphosphataemia	1 (1.9)	1 (1.9)	0	0	0
Hypophosphataemia	1 (1.9)	0	0	1 (1.9)	0
Musculoskeletal and connective tissue disorders					
-Total	7 (13.5)	5 (9.6)	2 (3.8)	0	0
Pain in extremity	7 (13.5)	5 (9.6)	2 (3.8)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	6 (11.5)	5 (9.6)	1 (1.9)	0	0
Headache	5 (9.6)	4 (7.7)	1 (1.9)	0	0
Dizziness	3 (5.8)	3 (5.8)	0	0	0
Psychiatric disorders					
-Total	1 (1.9)	1 (1.9)	0	0	0
Anxiety	1 (1.9)	1 (1.9)	0	0	0
Renal and urinary disorders					
-Total	1 (1.9)	0	0	1 (1.9)	0
Acute kidney injury	1 (1.9)	0	0	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders					
-Total	12 (23.1)	9 (17.3)	1 (1.9)	2 (3.8)	0
Cough	6 (11.5)	5 (9.6)	1 (1.9)	0	0
Nasal congestion	3 (5.8)	3 (5.8)	0	0	0
Oropharyngeal pain	3 (5.8)	2 (3.8)	1 (1.9)	0	0
Rhinorrhoea	3 (5.8)	3 (5.8)	0	0	0
Epistaxis	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Pulmonary oedema	1 (1.9)	0	0	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	8 (15.4)	5 (9.6)	3 (5.8)	0	0
Rash	4 (7.7)	1 (1.9)	3 (5.8)	0	0
Erythema	2 (3.8)	2 (3.8)	0	0	0
Dry skin	1 (1.9)	1 (1.9)	0	0	0
Rash maculo-papular	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					
-Total	2 (3.8)	1 (1.9)	1 (1.9)	0	0
Hypertension	2 (3.8)	1 (1.9)	1 (1.9)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184p
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: Yes

			All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (33.3)	1 (33.3)	0	0	0
Investigations					
-Total	1 (33.3)	1 (33.3)	0	0	0
Lymphocyte count decreased	1 (33.3)	1 (33.3)	0	0	0
Neutrophil count decreased	1 (33.3)	1 (33.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184p
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: No

			All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (38.7)	2 (6.5)	4 (12.9)	4 (12.9)	2 (6.5)
Blood and lymphatic system disorders					
-Total	2 (6.5)	1 (3.2)	0	0	1 (3.2)
Febrile neutropenia	1 (3.2)	0	0	0	1 (3.2)
Thrombocytopenia	1 (3.2)	1 (3.2)	0	0	0
Gastrointestinal disorders					
-Total	3 (9.7)	0	3 (9.7)	0	0
Diarrhoea	2 (6.5)	0	2 (6.5)	0	0
Abdominal pain	1 (3.2)	0	1 (3.2)	0	0
Nausea	1 (3.2)	0	1 (3.2)	0	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.2)	0	1 (3.2)	0	0
Chills	1 (3.2)	0	1 (3.2)	0	0
Pyrexia	1 (3.2)	0	1 (3.2)	0	0
Infections and infestations					
-Total	3 (9.7)	2 (6.5)	1 (3.2)	0	0
Upper respiratory tract infection	2 (6.5)	1 (3.2)	1 (3.2)	0	0
Viral infection	1 (3.2)	1 (3.2)	0	0	0
Investigations					
-Total	7 (22.6)	0	2 (6.5)	4 (12.9)	1 (3.2)
White blood cell count decreased	4 (12.9)	1 (3.2)	0	2 (6.5)	1 (3.2)
Alanine aminotransferase increased	3 (9.7)	0	1 (3.2)	2 (6.5)	0
Aspartate aminotransferase increased	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Lymphocyte count decreased	2 (6.5)	1 (3.2)	0	1 (3.2)	0
Neutrophil count decreased	1 (3.2)	0	1 (3.2)	0	0
Platelet count decreased	1 (3.2)	0	0	1 (3.2)	0
Metabolism and nutrition disorders					
-Total	1 (3.2)	0	0	1 (3.2)	0
Hypokalaemia	1 (3.2)	0	0	1 (3.2)	0
Nervous system disorders					

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.2)	0	1 (3.2)	0	0
Dizziness	1 (3.2)	1 (3.2)	0	0	0
Headache	1 (3.2)	0	1 (3.2)	0	0
Renal and urinary disorders					
-Total	1 (3.2)	0	0	1 (3.2)	0
Acute kidney injury	1 (3.2)	0	0	1 (3.2)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (12.9)	4 (12.9)	0	0	0
Cough	2 (6.5)	2 (6.5)	0	0	0
Epistaxis	1 (3.2)	1 (3.2)	0	0	0
Oropharyngeal pain	1 (3.2)	1 (3.2)	0	0	0
Rhinorrhoea	1 (3.2)	1 (3.2)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184p
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: Yes

		All patients N=4			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	1 (25.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders					
-Total	3 (75.0)	0	0	2 (50.0)	1 (25.0)
Anaemia	2 (50.0)	2 (50.0)	0	0	0
Febrile neutropenia	2 (50.0)	0	0	2 (50.0)	0
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
Eye disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Ocular hyperaemia	1 (25.0)	1 (25.0)	0	0	0
Gastrointestinal disorders					
-Total	3 (75.0)	2 (50.0)	0	1 (25.0)	0
Vomiting	2 (50.0)	2 (50.0)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (25.0)	1 (25.0)	0	0	0
Enterocolitis	1 (25.0)	0	0	1 (25.0)	0
Nausea	1 (25.0)	0	1 (25.0)	0	0
General disorders and administration site conditions					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Fatigue	1 (25.0)	1 (25.0)	0	0	0
Influenza like illness	1 (25.0)	1 (25.0)	0	0	0
Pyrexia	1 (25.0)	0	0	1 (25.0)	0
Immune system disorders					
-Total	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Cytokine release syndrome	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Hypogammaglobulinaemia	1 (25.0)	0	1 (25.0)	0	0
Infections and infestations					
-Total	3 (75.0)	1 (25.0)	1 (25.0)	1 (25.0)	0
Corona virus infection	1 (25.0)	0	0	1 (25.0)	0
Fungal skin infection	1 (25.0)	1 (25.0)	0	0	0
Rash pustular	1 (25.0)	0	1 (25.0)	0	0
Respiratory syncytial virus infection	1 (25.0)	0	0	1 (25.0)	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral infection	1 (25.0)	0	1 (25.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (25.0)	0	1 (25.0)	0	0
Skin laceration	1 (25.0)	0	1 (25.0)	0	0
Investigations					
-Total	3 (75.0)	0	1 (25.0)	0	2 (50.0)
Lymphocyte count decreased	3 (75.0)	1 (25.0)	1 (25.0)	0	1 (25.0)
Neutrophil count decreased	2 (50.0)	1 (25.0)	0	0	1 (25.0)
White blood cell count decreased	2 (50.0)	1 (25.0)	0	0	1 (25.0)
Blood bilirubin increased	1 (25.0)	1 (25.0)	0	0	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0	0	0
Fibrin d dimer increased	1 (25.0)	1 (25.0)	0	0	0
Platelet count decreased	1 (25.0)	1 (25.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Decreased appetite	1 (25.0)	1 (25.0)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Pain in extremity	1 (25.0)	1 (25.0)	0	0	0
Nervous system disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Headache	1 (25.0)	0	1 (25.0)	0	0
Tremor	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (50.0)	0	2 (50.0)	0	0
Cough	1 (25.0)	0	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	1 (25.0)	0	0
Nasal congestion	1 (25.0)	1 (25.0)	0	0	0
Rhinorrhoea	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (75.0)	3 (75.0)	0	0	0
Dermatitis diaper	1 (25.0)	1 (25.0)	0	0	0

Timing: Any time post CTL019 infusion, Down syndrome: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dry skin	1 (25.0)	1 (25.0)	0	0	0
Erythema	1 (25.0)	1 (25.0)	0	0	0
Rash maculo-papular	1 (25.0)	1 (25.0)	0	0	0
Vascular disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Hypotension	1 (25.0)	0	0	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184p
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: No

			All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	59 (98.3)	0	6 (10.0)	12 (20.0)	41 (68.3)
Blood and lymphatic system disorders					
-Total	41 (68.3)	1 (1.7)	2 (3.3)	26 (43.3)	12 (20.0)
Anaemia	25 (41.7)	1 (1.7)	4 (6.7)	19 (31.7)	1 (1.7)
Febrile neutropenia	22 (36.7)	0	0	21 (35.0)	1 (1.7)
Neutropenia	10 (16.7)	0	0	3 (5.0)	7 (11.7)
Thrombocytopenia	10 (16.7)	0	1 (1.7)	3 (5.0)	6 (10.0)
Cardiac disorders					
-Total	20 (33.3)	10 (16.7)	8 (13.3)	2 (3.3)	0
Tachycardia	15 (25.0)	8 (13.3)	5 (8.3)	2 (3.3)	0
Sinus tachycardia	6 (10.0)	3 (5.0)	3 (5.0)	0	0
Gastrointestinal disorders					

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	36 (60.0)	12 (20.0)	17 (28.3)	7 (11.7)	0
Vomiting	25 (41.7)	14 (23.3)	8 (13.3)	3 (5.0)	0
Diarrhoea	24 (40.0)	13 (21.7)	9 (15.0)	2 (3.3)	0
Nausea	24 (40.0)	6 (10.0)	13 (21.7)	5 (8.3)	0
Abdominal pain	11 (18.3)	6 (10.0)	4 (6.7)	1 (1.7)	0
Constipation	6 (10.0)	5 (8.3)	1 (1.7)	0	0
General disorders and administration site conditions					
-Total	34 (56.7)	16 (26.7)	11 (18.3)	6 (10.0)	1 (1.7)
Pyrexia	24 (40.0)	8 (13.3)	10 (16.7)	5 (8.3)	1 (1.7)
Fatigue	14 (23.3)	11 (18.3)	2 (3.3)	1 (1.7)	0
Chills	10 (16.7)	9 (15.0)	1 (1.7)	0	0
Influenza like illness	1 (1.7)	1 (1.7)	0	0	0
Immune system disorders					
-Total	54 (90.0)	3 (5.0)	29 (48.3)	11 (18.3)	11 (18.3)
Cytokine release syndrome	47 (78.3)	5 (8.3)	23 (38.3)	8 (13.3)	11 (18.3)
Hypogammaglobulinaemia	31 (51.7)	3 (5.0)	23 (38.3)	5 (8.3)	0
Infections and infestations					
-Total	11 (18.3)	6 (10.0)	4 (6.7)	1 (1.7)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	9 (15.0)	4 (6.7)	4 (6.7)	1 (1.7)	0
Viral infection	2 (3.3)	2 (3.3)	0	0	0
Investigations					
-Total	49 (81.7)	0	4 (6.7)	13 (21.7)	32 (53.3)
White blood cell count decreased	33 (55.0)	3 (5.0)	1 (1.7)	12 (20.0)	17 (28.3)
Neutrophil count decreased	26 (43.3)	0	2 (3.3)	4 (6.7)	20 (33.3)
Alanine aminotransferase increased	21 (35.0)	5 (8.3)	2 (3.3)	14 (23.3)	0
Aspartate aminotransferase increased	20 (33.3)	4 (6.7)	4 (6.7)	8 (13.3)	4 (6.7)
Platelet count decreased	19 (31.7)	2 (3.3)	2 (3.3)	3 (5.0)	12 (20.0)
Lymphocyte count decreased	13 (21.7)	0	2 (3.3)	7 (11.7)	4 (6.7)
International normalised ratio increased	9 (15.0)	8 (13.3)	0	1 (1.7)	0
Prothrombin time prolonged	9 (15.0)	5 (8.3)	3 (5.0)	1 (1.7)	0
Blood creatinine increased	8 (13.3)	4 (6.7)	2 (3.3)	2 (3.3)	0
Blood bilirubin increased	7 (11.7)	1 (1.7)	3 (5.0)	3 (5.0)	0
Blood immunoglobulin m decreased	3 (5.0)	3 (5.0)	0	0	0
Blood immunoglobulin a decreased	2 (3.3)	2 (3.3)	0	0	0
Metabolism and nutrition disorders					
-Total	34 (56.7)	6 (10.0)	8 (13.3)	18 (30.0)	2 (3.3)
Decreased appetite	21 (35.0)	4 (6.7)	5 (8.3)	12 (20.0)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	19 (31.7)	4 (6.7)	6 (10.0)	8 (13.3)	1 (1.7)
Hypophosphataemia	10 (16.7)	2 (3.3)	0	7 (11.7)	1 (1.7)
Hyperphosphataemia	7 (11.7)	7 (11.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	10 (16.7)	6 (10.0)	4 (6.7)	0	0
Pain in extremity	10 (16.7)	6 (10.0)	4 (6.7)	0	0
Nervous system disorders					
-Total	26 (43.3)	18 (30.0)	6 (10.0)	2 (3.3)	0
Headache	23 (38.3)	15 (25.0)	6 (10.0)	2 (3.3)	0
Dizziness	6 (10.0)	6 (10.0)	0	0	0
Tremor	1 (1.7)	1 (1.7)	0	0	0
Psychiatric disorders					
-Total	12 (20.0)	6 (10.0)	5 (8.3)	1 (1.7)	0
Anxiety	7 (11.7)	3 (5.0)	3 (5.0)	1 (1.7)	0
Confusional state	6 (10.0)	3 (5.0)	3 (5.0)	0	0
Renal and urinary disorders					
-Total	9 (15.0)	1 (1.7)	1 (1.7)	4 (6.7)	3 (5.0)
Acute kidney injury	9 (15.0)	1 (1.7)	1 (1.7)	4 (6.7)	3 (5.0)

Timing: Any time post CTL019 infusion, Down syndrome: No

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	31 (51.7)	14 (23.3)	4 (6.7)	8 (13.3)	5 (8.3)
Cough	13 (21.7)	12 (20.0)	1 (1.7)	0	0
Epistaxis	10 (16.7)	4 (6.7)	1 (1.7)	4 (6.7)	1 (1.7)
Hypoxia	9 (15.0)	0	2 (3.3)	4 (6.7)	3 (5.0)
Pleural effusion	8 (13.3)	2 (3.3)	4 (6.7)	2 (3.3)	0
Pulmonary oedema	7 (11.7)	1 (1.7)	0	4 (6.7)	2 (3.3)
Oropharyngeal pain	6 (10.0)	4 (6.7)	2 (3.3)	0	0
Rhinorrhoea	5 (8.3)	5 (8.3)	0	0	0
Nasal congestion	4 (6.7)	4 (6.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	17 (28.3)	12 (20.0)	4 (6.7)	1 (1.7)	0
Rash	8 (13.3)	5 (8.3)	3 (5.0)	0	0
Dry skin	4 (6.7)	4 (6.7)	0	0	0
Erythema	4 (6.7)	4 (6.7)	0	0	0
Rash maculo-papular	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Vascular disorders					
-Total	21 (35.0)	2 (3.3)	5 (8.3)	6 (10.0)	8 (13.3)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	15 (25.0)	1 (1.7)	0	6 (10.0)	8 (13.3)
Hypertension	12 (20.0)	3 (5.0)	8 (13.3)	1 (1.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184q
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	4 (12.5)	7 (21.9)	21 (65.6)
Blood and lymphatic system disorders					
-Total	19 (59.4)	0	1 (3.1)	16 (50.0)	2 (6.3)
Anaemia	11 (34.4)	1 (3.1)	1 (3.1)	9 (28.1)	0
Febrile neutropenia	10 (31.3)	0	0	10 (31.3)	0
Neutropenia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Thrombocytopenia	1 (3.1)	0	0	0	1 (3.1)
Cardiac disorders					
-Total	7 (21.9)	5 (15.6)	2 (6.3)	0	0
Tachycardia	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Sinus tachycardia	2 (6.3)	1 (3.1)	1 (3.1)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	17 (53.1)	6 (18.8)	6 (18.8)	5 (15.6)	0
Vomiting	11 (34.4)	7 (21.9)	1 (3.1)	3 (9.4)	0
Nausea	10 (31.3)	2 (6.3)	7 (21.9)	1 (3.1)	0
Diarrhoea	8 (25.0)	5 (15.6)	2 (6.3)	1 (3.1)	0
Abdominal pain	6 (18.8)	4 (12.5)	1 (3.1)	1 (3.1)	0
Constipation	5 (15.6)	4 (12.5)	1 (3.1)	0	0
General disorders and administration site conditions					
-Total	11 (34.4)	3 (9.4)	4 (12.5)	4 (12.5)	0
Pyrexia	9 (28.1)	1 (3.1)	4 (12.5)	4 (12.5)	0
Fatigue	3 (9.4)	3 (9.4)	0	0	0
Immune system disorders					
-Total	29 (90.6)	1 (3.1)	18 (56.3)	5 (15.6)	5 (15.6)
Cytokine release syndrome	25 (78.1)	3 (9.4)	15 (46.9)	2 (6.3)	5 (15.6)
Hypogammaglobulinaemia	15 (46.9)	1 (3.1)	11 (34.4)	3 (9.4)	0
Infections and infestations					
-Total	6 (18.8)	1 (3.1)	5 (15.6)	0	0
Clostridium difficile infection	4 (12.5)	0	4 (12.5)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	2 (6.3)	2 (6.3)	0	0	0
Upper respiratory tract infection	1 (3.1)	0	1 (3.1)	0	0
Investigations					
-Total	25 (78.1)	1 (3.1)	0	5 (15.6)	19 (59.4)
White blood cell count decreased	17 (53.1)	0	0	7 (21.9)	10 (31.3)
Neutrophil count decreased	14 (43.8)	0	0	3 (9.4)	11 (34.4)
Platelet count decreased	10 (31.3)	1 (3.1)	0	1 (3.1)	8 (25.0)
Alanine aminotransferase increased	7 (21.9)	3 (9.4)	0	4 (12.5)	0
Aspartate aminotransferase increased	7 (21.9)	2 (6.3)	0	4 (12.5)	1 (3.1)
Lymphocyte count decreased	6 (18.8)	0	0	3 (9.4)	3 (9.4)
Blood bilirubin increased	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Blood creatinine increased	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Prothrombin time prolonged	3 (9.4)	3 (9.4)	0	0	0
Metabolism and nutrition disorders					
-Total	14 (43.8)	4 (12.5)	4 (12.5)	6 (18.8)	0
Decreased appetite	7 (21.9)	1 (3.1)	3 (9.4)	3 (9.4)	0
Hypokalaemia	7 (21.9)	1 (3.1)	2 (6.3)	4 (12.5)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	4 (12.5)	1 (3.1)	0	3 (9.4)	0
Hyperphosphataemia	3 (9.4)	3 (9.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Pain in extremity	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Nervous system disorders					
-Total	13 (40.6)	9 (28.1)	3 (9.4)	1 (3.1)	0
Headache	13 (40.6)	9 (28.1)	3 (9.4)	1 (3.1)	0
Dizziness	1 (3.1)	1 (3.1)	0	0	0
Psychiatric disorders					
-Total	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Anxiety	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Confusional state	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Renal and urinary disorders					
-Total	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Acute kidney injury	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Respiratory, thoracic and mediastinal disorders					

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (28.1)	4 (12.5)	2 (6.3)	3 (9.4)	0
Hypoxia	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Cough	3 (9.4)	3 (9.4)	0	0	0
Epistaxis	3 (9.4)	1 (3.1)	0	2 (6.3)	0
Pleural effusion	1 (3.1)	0	1 (3.1)	0	0
Pulmonary oedema	1 (3.1)	1 (3.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (15.6)	5 (15.6)	0	0	0
Dry skin	3 (9.4)	3 (9.4)	0	0	0
Pruritus	2 (6.3)	2 (6.3)	0	0	0
Rash	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	8 (25.0)	2 (6.3)	2 (6.3)	3 (9.4)	1 (3.1)
Hypotension	5 (15.6)	1 (3.1)	0	3 (9.4)	1 (3.1)
Hypertension	4 (12.5)	2 (6.3)	2 (6.3)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184q
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (96.9)	2 (6.3)	4 (12.5)	7 (21.9)	18 (56.3)
Blood and lymphatic system disorders					
-Total	21 (65.6)	1 (3.1)	1 (3.1)	12 (37.5)	7 (21.9)
Anaemia	16 (50.0)	2 (6.3)	4 (12.5)	9 (28.1)	1 (3.1)
Febrile neutropenia	12 (37.5)	0	0	12 (37.5)	0
Thrombocytopenia	7 (21.9)	0	0	2 (6.3)	5 (15.6)
Neutropenia	6 (18.8)	0	0	2 (6.3)	4 (12.5)
Cardiac disorders					
-Total	12 (37.5)	5 (15.6)	5 (15.6)	2 (6.3)	0
Tachycardia	10 (31.3)	4 (12.5)	4 (12.5)	2 (6.3)	0
Sinus tachycardia	3 (9.4)	2 (6.3)	1 (3.1)	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Periorbital oedema	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Gastrointestinal disorders					
-Total	16 (50.0)	6 (18.8)	8 (25.0)	2 (6.3)	0
Nausea	11 (34.4)	4 (12.5)	5 (15.6)	2 (6.3)	0
Vomiting	11 (34.4)	6 (18.8)	5 (15.6)	0	0
Diarrhoea	10 (31.3)	6 (18.8)	4 (12.5)	0	0
Abdominal pain	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Constipation	2 (6.3)	2 (6.3)	0	0	0
General disorders and administration site conditions					
-Total	17 (53.1)	10 (31.3)	4 (12.5)	2 (6.3)	1 (3.1)
Fatigue	10 (31.3)	7 (21.9)	2 (6.3)	1 (3.1)	0
Chills	8 (25.0)	8 (25.0)	0	0	0
Pyrexia	7 (21.9)	2 (6.3)	3 (9.4)	1 (3.1)	1 (3.1)
Immune system disorders					
-Total	27 (84.4)	3 (9.4)	12 (37.5)	6 (18.8)	6 (18.8)
Cytokine release syndrome	25 (78.1)	3 (9.4)	10 (31.3)	6 (18.8)	6 (18.8)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	10 (31.3)	2 (6.3)	7 (21.9)	1 (3.1)	0
Infections and infestations					
-Total	1 (3.1)	1 (3.1)	0	0	0
Rhinovirus infection	1 (3.1)	1 (3.1)	0	0	0
Investigations					
-Total	22 (68.8)	0	4 (12.5)	6 (18.8)	12 (37.5)
White blood cell count decreased	13 (40.6)	3 (9.4)	1 (3.1)	3 (9.4)	6 (18.8)
Alanine aminotransferase increased	12 (37.5)	2 (6.3)	3 (9.4)	7 (21.9)	0
Aspartate aminotransferase increased	11 (34.4)	1 (3.1)	4 (12.5)	3 (9.4)	3 (9.4)
Neutrophil count decreased	11 (34.4)	0	2 (6.3)	1 (3.1)	8 (25.0)
International normalised ratio increased	9 (28.1)	8 (25.0)	0	1 (3.1)	0
Platelet count decreased	9 (28.1)	2 (6.3)	2 (6.3)	1 (3.1)	4 (12.5)
Lymphocyte count decreased	8 (25.0)	1 (3.1)	2 (6.3)	3 (9.4)	2 (6.3)
Blood creatinine increased	6 (18.8)	3 (9.4)	1 (3.1)	2 (6.3)	0
Prothrombin time prolonged	6 (18.8)	2 (6.3)	3 (9.4)	1 (3.1)	0
Blood bilirubin increased	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Blood fibrinogen decreased	4 (12.5)	0	1 (3.1)	2 (6.3)	1 (3.1)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	19 (59.4)	3 (9.4)	4 (12.5)	11 (34.4)	1 (3.1)
Decreased appetite	13 (40.6)	3 (9.4)	1 (3.1)	9 (28.1)	0
Hypokalaemia	9 (28.1)	2 (6.3)	4 (12.5)	3 (9.4)	0
Hyperphosphataemia	5 (15.6)	5 (15.6)	0	0	0
Hypoalbuminaemia	5 (15.6)	1 (3.1)	3 (9.4)	1 (3.1)	0
Hypophosphataemia	5 (15.6)	1 (3.1)	0	3 (9.4)	1 (3.1)
Musculoskeletal and connective tissue disorders					
-Total	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Myalgia	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Pain in extremity	1 (3.1)	1 (3.1)	0	0	0
Nervous system disorders					
-Total	13 (40.6)	9 (28.1)	3 (9.4)	1 (3.1)	0
Headache	11 (34.4)	7 (21.9)	3 (9.4)	1 (3.1)	0
Dizziness	3 (9.4)	3 (9.4)	0	0	0
Psychiatric disorders					
-Total	7 (21.9)	3 (9.4)	3 (9.4)	1 (3.1)	0
Anxiety	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Renal and urinary disorders					
-Total	6 (18.8)	0	0	2 (6.3)	4 (12.5)
Acute kidney injury	5 (15.6)	0	0	2 (6.3)	3 (9.4)
Haematuria	4 (12.5)	0	2 (6.3)	1 (3.1)	1 (3.1)
Respiratory, thoracic and mediastinal disorders					
-Total	12 (37.5)	2 (6.3)	2 (6.3)	3 (9.4)	5 (15.6)
Pleural effusion	7 (21.9)	2 (6.3)	3 (9.4)	2 (6.3)	0
Hypoxia	6 (18.8)	0	1 (3.1)	2 (6.3)	3 (9.4)
Cough	5 (15.6)	5 (15.6)	0	0	0
Pulmonary oedema	5 (15.6)	0	0	3 (9.4)	2 (6.3)
Epistaxis	4 (12.5)	1 (3.1)	1 (3.1)	1 (3.1)	1 (3.1)
Skin and subcutaneous tissue disorders					
-Total	7 (21.9)	5 (15.6)	1 (3.1)	1 (3.1)	0
Rash	3 (9.4)	3 (9.4)	0	0	0
Rash maculo-papular	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Dry skin	1 (3.1)	1 (3.1)	0	0	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	13 (40.6)	0	2 (6.3)	4 (12.5)	7 (21.9)
Hypotension	11 (34.4)	0	0	4 (12.5)	7 (21.9)
Hypertension	6 (18.8)	0	5 (15.6)	1 (3.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184q
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (75.9)	3 (10.3)	9 (31.0)	8 (27.6)	2 (6.9)
Blood and lymphatic system disorders					
-Total	4 (13.8)	1 (3.4)	1 (3.4)	1 (3.4)	1 (3.4)
Anaemia	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Febrile neutropenia	1 (3.4)	0	0	1 (3.4)	0
Neutropenia	1 (3.4)	0	0	0	1 (3.4)
Thrombocytopenia	1 (3.4)	0	1 (3.4)	0	0
Gastrointestinal disorders					
-Total	11 (37.9)	7 (24.1)	2 (6.9)	2 (6.9)	0
Diarrhoea	7 (24.1)	5 (17.2)	1 (3.4)	1 (3.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	6 (20.7)	2 (6.9)	2 (6.9)	2 (6.9)	0
Abdominal pain	4 (13.8)	2 (6.9)	1 (3.4)	1 (3.4)	0
Nausea	4 (13.8)	1 (3.4)	1 (3.4)	2 (6.9)	0
General disorders and administration site conditions					
-Total	8 (27.6)	6 (20.7)	1 (3.4)	1 (3.4)	0
Pyrexia	7 (24.1)	5 (17.2)	1 (3.4)	1 (3.4)	0
Fatigue	2 (6.9)	2 (6.9)	0	0	0
Immune system disorders					
-Total	4 (13.8)	0	4 (13.8)	0	0
Hypogammaglobulinaemia	4 (13.8)	0	4 (13.8)	0	0
Infections and infestations					
-Total	6 (20.7)	3 (10.3)	3 (10.3)	0	0
Upper respiratory tract infection	4 (13.8)	1 (3.4)	3 (10.3)	0	0
Rhinovirus infection	2 (6.9)	2 (6.9)	0	0	0
Investigations					
-Total	8 (27.6)	1 (3.4)	1 (3.4)	5 (17.2)	1 (3.4)
Neutrophil count decreased	3 (10.3)	1 (3.4)	0	2 (6.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	3 (10.3)	1 (3.4)	0	1 (3.4)	1 (3.4)
Aspartate aminotransferase increased	1 (3.4)	0	0	1 (3.4)	0
Blood bilirubin increased	1 (3.4)	0	0	1 (3.4)	0
Blood creatinine increased	1 (3.4)	1 (3.4)	0	0	0
Lymphocyte count decreased	1 (3.4)	0	1 (3.4)	0	0
Platelet count decreased	1 (3.4)	1 (3.4)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (17.2)	3 (10.3)	1 (3.4)	0	1 (3.4)
Decreased appetite	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Hyperphosphataemia	2 (6.9)	2 (6.9)	0	0	0
Hypokalaemia	2 (6.9)	1 (3.4)	0	0	1 (3.4)
Hypophosphataemia	1 (3.4)	0	0	1 (3.4)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (17.2)	3 (10.3)	2 (6.9)	0	0
Pain in extremity	5 (17.2)	3 (10.3)	2 (6.9)	0	0
Nervous system disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (13.8)	3 (10.3)	1 (3.4)	0	0
Headache	3 (10.3)	2 (6.9)	1 (3.4)	0	0
Dizziness	2 (6.9)	2 (6.9)	0	0	0
Psychiatric disorders					
-Total	1 (3.4)	1 (3.4)	0	0	0
Anxiety	1 (3.4)	1 (3.4)	0	0	0
Renal and urinary disorders					
-Total	2 (6.9)	0	0	2 (6.9)	0
Acute kidney injury	1 (3.4)	0	0	1 (3.4)	0
Haematuria	1 (3.4)	0	0	1 (3.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (24.1)	5 (17.2)	1 (3.4)	1 (3.4)	0
Cough	5 (17.2)	4 (13.8)	1 (3.4)	0	0
Epistaxis	2 (6.9)	1 (3.4)	0	1 (3.4)	0
Skin and subcutaneous tissue disorders					
-Total	5 (17.2)	3 (10.3)	2 (6.9)	0	0
Rash	3 (10.3)	1 (3.4)	2 (6.9)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry skin	1 (3.4)	1 (3.4)	0	0	0
Pruritus	1 (3.4)	1 (3.4)	0	0	0
Rash maculo-papular	1 (3.4)	1 (3.4)	0	0	0
Vascular disorders					
-Total	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Hypertension	2 (6.9)	1 (3.4)	1 (3.4)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184q
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (63.0)	5 (18.5)	3 (11.1)	5 (18.5)	4 (14.8)
Blood and lymphatic system disorders					
-Total	4 (14.8)	0	0	2 (7.4)	2 (7.4)
Neutropenia	3 (11.1)	0	0	1 (3.7)	2 (7.4)
Febrile neutropenia	2 (7.4)	0	0	2 (7.4)	0
Thrombocytopenia	1 (3.7)	0	0	1 (3.7)	0
Cardiac disorders					
-Total	1 (3.7)	0	1 (3.7)	0	0
Sinus tachycardia	1 (3.7)	0	1 (3.7)	0	0
Gastrointestinal disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (11.1)	1 (3.7)	2 (7.4)	0	0
Vomiting	3 (11.1)	3 (11.1)	0	0	0
Nausea	2 (7.4)	0	2 (7.4)	0	0
Diarrhoea	1 (3.7)	1 (3.7)	0	0	0
General disorders and administration site conditions					
-Total	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Pyrexia	3 (11.1)	2 (7.4)	1 (3.7)	0	0
Chills	1 (3.7)	1 (3.7)	0	0	0
Immune system disorders					
-Total	4 (14.8)	0	3 (11.1)	1 (3.7)	0
Hypogammaglobulinaemia	4 (14.8)	0	3 (11.1)	1 (3.7)	0
Infections and infestations					
-Total	3 (11.1)	1 (3.7)	1 (3.7)	1 (3.7)	0
Upper respiratory tract infection	3 (11.1)	2 (7.4)	0	1 (3.7)	0
Otitis media	1 (3.7)	0	1 (3.7)	0	0
Investigations					
-Total	8 (29.6)	2 (7.4)	0	3 (11.1)	3 (11.1)
Neutrophil count decreased	5 (18.5)	1 (3.7)	0	1 (3.7)	3 (11.1)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	2 (7.4)	0	0	2 (7.4)	0
Aspartate aminotransferase increased	2 (7.4)	1 (3.7)	0	1 (3.7)	0
Platelet count decreased	2 (7.4)	2 (7.4)	0	0	0
White blood cell count decreased	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Lymphocyte count decreased	1 (3.7)	1 (3.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (11.1)	3 (11.1)	0	0	0
Pain in extremity	3 (11.1)	3 (11.1)	0	0	0
Nervous system disorders					
-Total	2 (7.4)	2 (7.4)	0	0	0
Headache	2 (7.4)	2 (7.4)	0	0	0
Dizziness	1 (3.7)	1 (3.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (11.1)	1 (3.7)	1 (3.7)	1 (3.7)	0
Cough	2 (7.4)	1 (3.7)	1 (3.7)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=27				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	1 (3.7)	0	0	1 (3.7)	0
Skin and subcutaneous tissue disorders					
-Total	2 (7.4)	1 (3.7)	1 (3.7)	0	0
Rash	1 (3.7)	0	1 (3.7)	0	0
Rash maculo-papular	1 (3.7)	1 (3.7)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184q
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (44.4)	3 (16.7)	0	3 (16.7)	2 (11.1)
Blood and lymphatic system disorders					
-Total	1 (5.6)	0	0	0	1 (5.6)
Febrile neutropenia	1 (5.6)	0	0	0	1 (5.6)
Gastrointestinal disorders					
-Total	2 (11.1)	0	2 (11.1)	0	0
Abdominal pain	1 (5.6)	0	1 (5.6)	0	0
Diarrhoea	1 (5.6)	0	1 (5.6)	0	0
Nausea	1 (5.6)	0	1 (5.6)	0	0
General disorders and administration site conditions					

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (5.6)	0	1 (5.6)	0	0
Chills	1 (5.6)	0	1 (5.6)	0	0
Pyrexia	1 (5.6)	0	1 (5.6)	0	0
Infections and infestations					
-Total	1 (5.6)	0	0	1 (5.6)	0
Clostridium difficile infection	1 (5.6)	0	0	1 (5.6)	0
Investigations					
-Total	4 (22.2)	1 (5.6)	0	2 (11.1)	1 (5.6)
Lymphocyte count decreased	2 (11.1)	1 (5.6)	0	1 (5.6)	0
White blood cell count decreased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Alanine aminotransferase increased	1 (5.6)	0	0	1 (5.6)	0
Aspartate aminotransferase increased	1 (5.6)	1 (5.6)	0	0	0
Neutrophil count decreased	1 (5.6)	1 (5.6)	0	0	0
Platelet count decreased	1 (5.6)	0	0	1 (5.6)	0
Metabolism and nutrition disorders					
-Total	1 (5.6)	0	0	1 (5.6)	0
Hypokalaemia	1 (5.6)	0	0	1 (5.6)	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	1 (5.6)	0	1 (5.6)	0	0
Dizziness	1 (5.6)	1 (5.6)	0	0	0
Headache	1 (5.6)	0	1 (5.6)	0	0
Renal and urinary disorders					
-Total	2 (11.1)	1 (5.6)	0	1 (5.6)	0
Acute kidney injury	1 (5.6)	0	0	1 (5.6)	0
Haematuria	1 (5.6)	1 (5.6)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (11.1)	2 (11.1)	0	0	0
Cough	1 (5.6)	1 (5.6)	0	0	0
Epistaxis	1 (5.6)	1 (5.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (5.6)	1 (5.6)	0	0	0
Pruritus	1 (5.6)	1 (5.6)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184q
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (50.0)	1 (6.3)	4 (25.0)	3 (18.8)	0
Blood and lymphatic system disorders					
-Total	1 (6.3)	1 (6.3)	0	0	0
Thrombocytopenia	1 (6.3)	1 (6.3)	0	0	0
Gastrointestinal disorders					
-Total	1 (6.3)	0	1 (6.3)	0	0
Diarrhoea	1 (6.3)	0	1 (6.3)	0	0
Infections and infestations					
-Total	5 (31.3)	1 (6.3)	3 (18.8)	1 (6.3)	0
Otitis media	3 (18.8)	0	2 (12.5)	1 (6.3)	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Investigations					
-Total	4 (25.0)	0	2 (12.5)	2 (12.5)	0
Alanine aminotransferase increased	2 (12.5)	0	1 (6.3)	1 (6.3)	0
White blood cell count decreased	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Aspartate aminotransferase increased	1 (6.3)	0	0	1 (6.3)	0
Lymphocyte count decreased	1 (6.3)	1 (6.3)	0	0	0
Neutrophil count decreased	1 (6.3)	0	1 (6.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (6.3)	1 (6.3)	0	0	0
Cough	1 (6.3)	1 (6.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184q
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	3 (9.4)	7 (21.9)	22 (68.8)
Blood and lymphatic system disorders					
-Total	21 (65.6)	0	1 (3.1)	16 (50.0)	4 (12.5)
Febrile neutropenia	12 (37.5)	0	0	11 (34.4)	1 (3.1)
Anaemia	11 (34.4)	1 (3.1)	0	10 (31.3)	0
Neutropenia	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Thrombocytopenia	2 (6.3)	0	1 (3.1)	0	1 (3.1)
Cardiac disorders					
-Total	7 (21.9)	5 (15.6)	2 (6.3)	0	0
Tachycardia	5 (15.6)	4 (12.5)	1 (3.1)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Gastrointestinal disorders					
-Total	21 (65.6)	8 (25.0)	8 (25.0)	5 (15.6)	0
Vomiting	14 (43.8)	8 (25.0)	3 (9.4)	3 (9.4)	0
Nausea	13 (40.6)	2 (6.3)	8 (25.0)	3 (9.4)	0
Diarrhoea	12 (37.5)	6 (18.8)	4 (12.5)	2 (6.3)	0
Abdominal pain	8 (25.0)	4 (12.5)	3 (9.4)	1 (3.1)	0
Constipation	5 (15.6)	4 (12.5)	1 (3.1)	0	0
General disorders and administration site conditions					
-Total	16 (50.0)	5 (15.6)	6 (18.8)	5 (15.6)	0
Pyrexia	15 (46.9)	4 (12.5)	6 (18.8)	5 (15.6)	0
Fatigue	5 (15.6)	5 (15.6)	0	0	0
Chills	1 (3.1)	0	1 (3.1)	0	0
Immune system disorders					
-Total	29 (90.6)	1 (3.1)	18 (56.3)	5 (15.6)	5 (15.6)
Cytokine release syndrome	25 (78.1)	3 (9.4)	15 (46.9)	2 (6.3)	5 (15.6)
Hypogammaglobulinaemia	19 (59.4)	1 (3.1)	15 (46.9)	3 (9.4)	0
Infections and infestations					

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (34.4)	3 (9.4)	7 (21.9)	1 (3.1)	0
Clostridium difficile infection	5 (15.6)	0	4 (12.5)	1 (3.1)	0
Rhinovirus infection	4 (12.5)	4 (12.5)	0	0	0
Upper respiratory tract infection	4 (12.5)	1 (3.1)	3 (9.4)	0	0
Investigations					
-Total	28 (87.5)	0	1 (3.1)	7 (21.9)	20 (62.5)
White blood cell count decreased	21 (65.6)	1 (3.1)	0	8 (25.0)	12 (37.5)
Neutrophil count decreased	15 (46.9)	1 (3.1)	0	3 (9.4)	11 (34.4)
Platelet count decreased	11 (34.4)	1 (3.1)	0	2 (6.3)	8 (25.0)
Alanine aminotransferase increased	8 (25.0)	3 (9.4)	0	5 (15.6)	0
Aspartate aminotransferase increased	8 (25.0)	3 (9.4)	0	4 (12.5)	1 (3.1)
Lymphocyte count decreased	8 (25.0)	0	1 (3.1)	4 (12.5)	3 (9.4)
Blood bilirubin increased	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0
Blood creatinine increased	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Prothrombin time prolonged	3 (9.4)	3 (9.4)	0	0	0
Metabolism and nutrition disorders					
-Total	16 (50.0)	4 (12.5)	4 (12.5)	7 (21.9)	1 (3.1)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	10 (31.3)	2 (6.3)	2 (6.3)	5 (15.6)	1 (3.1)
Decreased appetite	9 (28.1)	2 (6.3)	4 (12.5)	3 (9.4)	0
Hypophosphataemia	5 (15.6)	1 (3.1)	0	4 (12.5)	0
Hyperphosphataemia	3 (9.4)	3 (9.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (21.9)	3 (9.4)	4 (12.5)	0	0
Pain in extremity	7 (21.9)	3 (9.4)	4 (12.5)	0	0
Nervous system disorders					
-Total	14 (43.8)	9 (28.1)	4 (12.5)	1 (3.1)	0
Headache	13 (40.6)	8 (25.0)	4 (12.5)	1 (3.1)	0
Dizziness	2 (6.3)	2 (6.3)	0	0	0
Psychiatric disorders					
-Total	5 (15.6)	3 (9.4)	2 (6.3)	0	0
Anxiety	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Confusional state	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Renal and urinary disorders					
-Total	5 (15.6)	1 (3.1)	1 (3.1)	3 (9.4)	0
Acute kidney injury	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	1 (3.1)	0	0	1 (3.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	13 (40.6)	7 (21.9)	2 (6.3)	4 (12.5)	0
Cough	7 (21.9)	6 (18.8)	1 (3.1)	0	0
Epistaxis	6 (18.8)	3 (9.4)	0	3 (9.4)	0
Hypoxia	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Pleural effusion	1 (3.1)	0	1 (3.1)	0	0
Pulmonary oedema	1 (3.1)	1 (3.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (28.1)	7 (21.9)	2 (6.3)	0	0
Dry skin	4 (12.5)	4 (12.5)	0	0	0
Pruritus	4 (12.5)	4 (12.5)	0	0	0
Rash	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Rash maculo-papular	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	9 (28.1)	2 (6.3)	3 (9.4)	3 (9.4)	1 (3.1)
Hypertension	6 (18.8)	3 (9.4)	3 (9.4)	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

			All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	5 (15.6)	1 (3.1)	0	3 (9.4)	1 (3.1)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184q
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	1 (3.1)	3 (9.4)	7 (21.9)	21 (65.6)
Blood and lymphatic system disorders					
-Total	23 (71.9)	1 (3.1)	1 (3.1)	12 (37.5)	9 (28.1)
Anaemia	16 (50.0)	2 (6.3)	4 (12.5)	9 (28.1)	1 (3.1)
Febrile neutropenia	12 (37.5)	0	0	12 (37.5)	0
Neutropenia	8 (25.0)	0	0	2 (6.3)	6 (18.8)
Thrombocytopenia	8 (25.0)	0	0	3 (9.4)	5 (15.6)
Cardiac disorders					
-Total	13 (40.6)	5 (15.6)	6 (18.8)	2 (6.3)	0
Tachycardia	10 (31.3)	4 (12.5)	4 (12.5)	2 (6.3)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Eye disorders					
-Total	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Periorbital oedema	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Gastrointestinal disorders					
-Total	18 (56.3)	6 (18.8)	10 (31.3)	2 (6.3)	0
Vomiting	13 (40.6)	8 (25.0)	5 (15.6)	0	0
Diarrhoea	12 (37.5)	7 (21.9)	5 (15.6)	0	0
Nausea	12 (37.5)	4 (12.5)	6 (18.8)	2 (6.3)	0
Abdominal pain	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Constipation	2 (6.3)	2 (6.3)	0	0	0
General disorders and administration site conditions					
-Total	19 (59.4)	11 (34.4)	5 (15.6)	2 (6.3)	1 (3.1)
Fatigue	10 (31.3)	7 (21.9)	2 (6.3)	1 (3.1)	0
Pyrexia	10 (31.3)	4 (12.5)	4 (12.5)	1 (3.1)	1 (3.1)
Chills	9 (28.1)	9 (28.1)	0	0	0
Immune system disorders					
-Total	28 (87.5)	3 (9.4)	13 (40.6)	6 (18.8)	6 (18.8)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	25 (78.1)	3 (9.4)	10 (31.3)	6 (18.8)	6 (18.8)
Hypogammaglobulinaemia	13 (40.6)	2 (6.3)	9 (28.1)	2 (6.3)	0
Infections and infestations					
-Total	9 (28.1)	3 (9.4)	4 (12.5)	2 (6.3)	0
Upper respiratory tract infection	5 (15.6)	3 (9.4)	1 (3.1)	1 (3.1)	0
Otitis media	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Rhinovirus infection	1 (3.1)	1 (3.1)	0	0	0
Investigations					
-Total	24 (75.0)	0	4 (12.5)	6 (18.8)	14 (43.8)
White blood cell count decreased	14 (43.8)	3 (9.4)	1 (3.1)	4 (12.5)	6 (18.8)
Alanine aminotransferase increased	13 (40.6)	2 (6.3)	2 (6.3)	9 (28.1)	0
Neutrophil count decreased	13 (40.6)	0	2 (6.3)	1 (3.1)	10 (31.3)
Aspartate aminotransferase increased	12 (37.5)	1 (3.1)	4 (12.5)	4 (12.5)	3 (9.4)
International normalised ratio increased	9 (28.1)	8 (25.0)	0	1 (3.1)	0
Platelet count decreased	9 (28.1)	2 (6.3)	2 (6.3)	1 (3.1)	4 (12.5)
Lymphocyte count decreased	8 (25.0)	1 (3.1)	2 (6.3)	3 (9.4)	2 (6.3)
Blood creatinine increased	6 (18.8)	3 (9.4)	1 (3.1)	2 (6.3)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

			All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prothrombin time prolonged	6 (18.8)	2 (6.3)	3 (9.4)	1 (3.1)	0
Blood bilirubin increased	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Blood fibrinogen decreased	4 (12.5)	0	1 (3.1)	2 (6.3)	1 (3.1)
Metabolism and nutrition disorders					
-Total	19 (59.4)	3 (9.4)	4 (12.5)	11 (34.4)	1 (3.1)
Decreased appetite	13 (40.6)	3 (9.4)	1 (3.1)	9 (28.1)	0
Hypokalaemia	9 (28.1)	2 (6.3)	4 (12.5)	3 (9.4)	0
Hyperphosphataemia	5 (15.6)	5 (15.6)	0	0	0
Hypoalbuminaemia	5 (15.6)	1 (3.1)	3 (9.4)	1 (3.1)	0
Hypophosphataemia	5 (15.6)	1 (3.1)	0	3 (9.4)	1 (3.1)
Musculoskeletal and connective tissue disorders					
-Total	7 (21.9)	6 (18.8)	1 (3.1)	0	0
Myalgia	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Pain in extremity	4 (12.5)	4 (12.5)	0	0	0
Nervous system disorders					
-Total	13 (40.6)	9 (28.1)	3 (9.4)	1 (3.1)	0
Headache	11 (34.4)	7 (21.9)	3 (9.4)	1 (3.1)	0
Dizziness	4 (12.5)	4 (12.5)	0	0	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	7 (21.9)	3 (9.4)	3 (9.4)	1 (3.1)	0
Anxiety	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Confusional state	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Renal and urinary disorders					
-Total	6 (18.8)	0	0	2 (6.3)	4 (12.5)
Acute kidney injury	5 (15.6)	0	0	2 (6.3)	3 (9.4)
Haematuria	4 (12.5)	0	2 (6.3)	1 (3.1)	1 (3.1)
Respiratory, thoracic and mediastinal disorders					
-Total	15 (46.9)	3 (9.4)	3 (9.4)	4 (12.5)	5 (15.6)
Cough	7 (21.9)	6 (18.8)	1 (3.1)	0	0
Pleural effusion	7 (21.9)	2 (6.3)	3 (9.4)	2 (6.3)	0
Hypoxia	6 (18.8)	0	1 (3.1)	2 (6.3)	3 (9.4)
Pulmonary oedema	6 (18.8)	0	0	4 (12.5)	2 (6.3)
Epistaxis	4 (12.5)	1 (3.1)	1 (3.1)	1 (3.1)	1 (3.1)
Skin and subcutaneous tissue disorders					
-Total	9 (28.1)	6 (18.8)	2 (6.3)	1 (3.1)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Rash maculo-papular	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Dry skin	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	13 (40.6)	0	2 (6.3)	4 (12.5)	7 (21.9)
Hypotension	11 (34.4)	0	0	4 (12.5)	7 (21.9)
Hypertension	6 (18.8)	0	5 (15.6)	1 (3.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 0

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	1 (14.3)	0	6 (85.7)
Blood and lymphatic system disorders					
-Total	5 (71.4)	1 (14.3)	0	2 (28.6)	2 (28.6)
Anaemia	4 (57.1)	2 (28.6)	0	1 (14.3)	1 (14.3)
Febrile neutropenia	2 (28.6)	0	0	2 (28.6)	0
Neutropenia	2 (28.6)	0	0	0	2 (28.6)
Thrombocytopenia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Cardiac disorders					
-Total	3 (42.9)	2 (28.6)	0	1 (14.3)	0
Tachycardia	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0
Palpitations	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pericardial effusion	1 (14.3)	1 (14.3)	0	0	0
Eye disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Eye pain	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal disorders					
-Total	4 (57.1)	2 (28.6)	1 (14.3)	1 (14.3)	0
Diarrhoea	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Nausea	3 (42.9)	1 (14.3)	1 (14.3)	1 (14.3)	0
Vomiting	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
General disorders and administration site conditions					
-Total	3 (42.9)	0	0	2 (28.6)	1 (14.3)
Pyrexia	3 (42.9)	0	1 (14.3)	1 (14.3)	1 (14.3)
Asthenia	1 (14.3)	1 (14.3)	0	0	0
Chills	1 (14.3)	1 (14.3)	0	0	0
Pain	1 (14.3)	0	0	1 (14.3)	0
Hepatobiliary disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatomegaly	1 (14.3)	0	1 (14.3)	0	0
Immune system disorders					
-Total	7 (100)	0	4 (57.1)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)	0	0
Infections and infestations					
-Total	2 (28.6)	0	2 (28.6)	0	0
Gastroenteritis	1 (14.3)	0	1 (14.3)	0	0
Viral infection	1 (14.3)	0	1 (14.3)	0	0
Injury, poisoning and procedural complications					
-Total	1 (14.3)	0	0	1 (14.3)	0
Tracheal haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Investigations					
-Total	7 (100)	1 (14.3)	1 (14.3)	1 (14.3)	4 (57.1)
Neutrophil count decreased	4 (57.1)	0	1 (14.3)	0	3 (42.9)
White blood cell count decreased	4 (57.1)	1 (14.3)	0	1 (14.3)	2 (28.6)
Lymphocyte count decreased	2 (28.6)	1 (14.3)	1 (14.3)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0	0	0
Aspartate aminotransferase increased	1 (14.3)	0	0	0	1 (14.3)
Blood creatinine increased	1 (14.3)	0	1 (14.3)	0	0
Blood fibrinogen decreased	1 (14.3)	0	1 (14.3)	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0
Blood magnesium decreased	1 (14.3)	0	0	1 (14.3)	0
Blood phosphorus increased	1 (14.3)	1 (14.3)	0	0	0
Blood uric acid increased	1 (14.3)	1 (14.3)	0	0	0
Cardiac murmur	1 (14.3)	1 (14.3)	0	0	0
Fibrin d dimer increased	1 (14.3)	1 (14.3)	0	0	0
International normalised ratio increased	1 (14.3)	1 (14.3)	0	0	0
Prothrombin time prolonged	1 (14.3)	0	1 (14.3)	0	0
Metabolism and nutrition disorders					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Decreased appetite	3 (42.9)	1 (14.3)	1 (14.3)	1 (14.3)	0
Hypokalaemia	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Hypernatraemia	1 (14.3)	0	1 (14.3)	0	0
Hypoalbuminaemia	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Arthralgia	1 (14.3)	0	0	1 (14.3)	0
Nervous system disorders					
-Total	4 (57.1)	4 (57.1)	0	0	0
Headache	3 (42.9)	3 (42.9)	0	0	0
Dizziness	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	3 (42.9)	2 (28.6)	1 (14.3)	0	0
Confusional state	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Delirium	1 (14.3)	1 (14.3)	0	0	0
Renal and urinary disorders					
-Total	2 (28.6)	0	0	0	2 (28.6)
Haematuria	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Acute kidney injury	1 (14.3)	0	0	0	1 (14.3)
Oliguria	1 (14.3)	0	0	1 (14.3)	0
Renal failure	1 (14.3)	0	0	0	1 (14.3)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	3 (42.9)	1 (14.3)	0	0	2 (28.6)
Cough	2 (28.6)	2 (28.6)	0	0	0
Hypoxia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Dyspnoea	1 (14.3)	0	0	0	1 (14.3)
Epistaxis	1 (14.3)	0	0	0	1 (14.3)
Haemoptysis	1 (14.3)	0	0	0	1 (14.3)
Interstitial lung disease	1 (14.3)	0	0	0	1 (14.3)
Pleural effusion	1 (14.3)	0	1 (14.3)	0	0
Pulmonary oedema	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Skin and subcutaneous tissue disorders					
-Total	4 (57.1)	4 (57.1)	0	0	0
Dermatitis diaper	1 (14.3)	1 (14.3)	0	0	0
Dry skin	1 (14.3)	1 (14.3)	0	0	0
Erythema	1 (14.3)	1 (14.3)	0	0	0
Livedo reticularis	1 (14.3)	1 (14.3)	0	0	0
Rash maculo-papular	1 (14.3)	1 (14.3)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	4 (57.1)	0	0	2 (28.6)	2 (28.6)
Hypotension	4 (57.1)	0	0	2 (28.6)	2 (28.6)
Haematoma	1 (14.3)	0	1 (14.3)	0	0
Hypertension	1 (14.3)	0	1 (14.3)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (95.0)	1 (5.0)	1 (5.0)	5 (25.0)	12 (60.0)
Blood and lymphatic system disorders					
-Total	14 (70.0)	0	2 (10.0)	11 (55.0)	1 (5.0)
Febrile neutropenia	9 (45.0)	0	0	9 (45.0)	0
Anaemia	8 (40.0)	0	2 (10.0)	6 (30.0)	0
Disseminated intravascular coagulation	3 (15.0)	0	1 (5.0)	2 (10.0)	0
Neutropenia	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Cardiac disorders					
-Total	6 (30.0)	3 (15.0)	3 (15.0)	0	0
Tachycardia	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Sinus tachycardia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Pericardial effusion	1 (5.0)	0	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Adrenal insufficiency	1 (5.0)	0	1 (5.0)	0	0
Eye disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Conjunctival haemorrhage	2 (10.0)	2 (10.0)	0	0	0
Periorbital oedema	2 (10.0)	2 (10.0)	0	0	0
Vision blurred	1 (5.0)	0	1 (5.0)	0	0
Gastrointestinal disorders					
-Total	13 (65.0)	4 (20.0)	5 (25.0)	4 (20.0)	0
Vomiting	7 (35.0)	4 (20.0)	2 (10.0)	1 (5.0)	0
Diarrhoea	6 (30.0)	3 (15.0)	2 (10.0)	1 (5.0)	0
Constipation	5 (25.0)	5 (25.0)	0	0	0
Nausea	5 (25.0)	1 (5.0)	3 (15.0)	1 (5.0)	0
Abdominal pain	2 (10.0)	2 (10.0)	0	0	0
Dysphagia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions					
-Total	11 (55.0)	5 (25.0)	2 (10.0)	4 (20.0)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	5 (25.0)	5 (25.0)	0	0	0
Pyrexia	5 (25.0)	1 (5.0)	1 (5.0)	3 (15.0)	0
Catheter site pain	1 (5.0)	0	1 (5.0)	0	0
Chills	1 (5.0)	1 (5.0)	0	0	0
Generalised oedema	1 (5.0)	0	1 (5.0)	0	0
Oedema peripheral	1 (5.0)	0	0	1 (5.0)	0
Pain	1 (5.0)	0	1 (5.0)	0	0
Immune system disorders					
-Total	16 (80.0)	1 (5.0)	7 (35.0)	3 (15.0)	5 (25.0)
Cytokine release syndrome	16 (80.0)	2 (10.0)	7 (35.0)	2 (10.0)	5 (25.0)
Hypogammaglobulinaemia	6 (30.0)	0	5 (25.0)	1 (5.0)	0
Infections and infestations					
-Total	6 (30.0)	1 (5.0)	2 (10.0)	3 (15.0)	0
Clostridium difficile infection	2 (10.0)	0	2 (10.0)	0	0
Staphylococcal infection	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Gastroenteritis	1 (5.0)	0	0	1 (5.0)	0
Influenza	1 (5.0)	1 (5.0)	0	0	0
Pneumonia	1 (5.0)	0	0	1 (5.0)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	1 (5.0)	1 (5.0)	0	0	0
Contusion	1 (5.0)	1 (5.0)	0	0	0
Investigations					
-Total	15 (75.0)	0	0	4 (20.0)	11 (55.0)
White blood cell count decreased	10 (50.0)	2 (10.0)	0	4 (20.0)	4 (20.0)
Platelet count decreased	9 (45.0)	0	2 (10.0)	1 (5.0)	6 (30.0)
Neutrophil count decreased	8 (40.0)	0	0	2 (10.0)	6 (30.0)
Alanine aminotransferase increased	7 (35.0)	2 (10.0)	1 (5.0)	4 (20.0)	0
Aspartate aminotransferase increased	7 (35.0)	1 (5.0)	2 (10.0)	3 (15.0)	1 (5.0)
Lymphocyte count decreased	6 (30.0)	0	0	3 (15.0)	3 (15.0)
Blood creatinine increased	4 (20.0)	2 (10.0)	1 (5.0)	1 (5.0)	0
Activated partial thromboplastin time prolonged	3 (15.0)	1 (5.0)	2 (10.0)	0	0
International normalised ratio increased	3 (15.0)	3 (15.0)	0	0	0
Prothrombin time prolonged	3 (15.0)	3 (15.0)	0	0	0
Blood bilirubin increased	2 (10.0)	0	2 (10.0)	0	0
Blood fibrinogen decreased	1 (5.0)	0	0	0	1 (5.0)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	1 (5.0)	1 (5.0)	0	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Blood phosphorus increased	1 (5.0)	1 (5.0)	0	0	0
Metabolism and nutrition disorders					
-Total	11 (55.0)	2 (10.0)	1 (5.0)	6 (30.0)	2 (10.0)
Decreased appetite	4 (20.0)	0	1 (5.0)	3 (15.0)	0
Hyperphosphataemia	4 (20.0)	4 (20.0)	0	0	0
Hypernatraemia	3 (15.0)	1 (5.0)	1 (5.0)	0	1 (5.0)
Hypokalaemia	3 (15.0)	0	0	3 (15.0)	0
Acidosis	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Dehydration	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Hyperglycaemia	2 (10.0)	0	2 (10.0)	0	0
Hyperuricaemia	2 (10.0)	1 (5.0)	0	0	1 (5.0)
Hypophosphataemia	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Hypoalbuminaemia	1 (5.0)	0	1 (5.0)	0	0
Hypocalcaemia	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	2 (10.0)	2 (10.0)	0	0	0
Muscular weakness	1 (5.0)	0	1 (5.0)	0	0
Musculoskeletal chest pain	1 (5.0)	1 (5.0)	0	0	0
Nervous system disorders					
-Total	12 (60.0)	6 (30.0)	5 (25.0)	1 (5.0)	0
Headache	9 (45.0)	6 (30.0)	3 (15.0)	0	0
Dysarthria	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Encephalopathy	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Tremor	2 (10.0)	2 (10.0)	0	0	0
Dizziness	1 (5.0)	1 (5.0)	0	0	0
Seizure	1 (5.0)	0	1 (5.0)	0	0
Psychiatric disorders					
-Total	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Delirium	2 (10.0)	0	2 (10.0)	0	0
Anxiety	1 (5.0)	0	1 (5.0)	0	0
Confusional state	1 (5.0)	1 (5.0)	0	0	0
Renal and urinary disorders					
-Total	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Acute kidney injury	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	8 (40.0)	3 (15.0)	0	4 (20.0)	1 (5.0)
Epistaxis	3 (15.0)	0	1 (5.0)	2 (10.0)	0
Pleural effusion	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Pulmonary oedema	3 (15.0)	1 (5.0)	0	1 (5.0)	1 (5.0)
Tachypnoea	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Hypoxia	2 (10.0)	0	0	2 (10.0)	0
Cough	1 (5.0)	1 (5.0)	0	0	0
Haemoptysis	1 (5.0)	1 (5.0)	0	0	0
Nasal congestion	1 (5.0)	1 (5.0)	0	0	0
Oropharyngeal pain	1 (5.0)	0	1 (5.0)	0	0
Respiratory failure	1 (5.0)	0	0	0	1 (5.0)
Rhinorrhoea	1 (5.0)	1 (5.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (35.0)	7 (35.0)	0	0	0
Dry skin	3 (15.0)	3 (15.0)	0	0	0
Hyperhidrosis	3 (15.0)	3 (15.0)	0	0	0
Petechiae	2 (10.0)	2 (10.0)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Erythema	1 (5.0)	1 (5.0)	0	0	0
Rash	1 (5.0)	1 (5.0)	0	0	0
Rash erythematous	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	4 (20.0)	0	0	1 (5.0)	3 (15.0)
Hypotension	4 (20.0)	0	0	1 (5.0)	3 (15.0)
Hypertension	2 (10.0)	1 (5.0)	1 (5.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 2

			All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (100)	0	2 (9.5)	7 (33.3)	12 (57.1)
Blood and lymphatic system disorders					
-Total	13 (61.9)	0	0	9 (42.9)	4 (19.0)
Febrile neutropenia	8 (38.1)	0	0	8 (38.1)	0
Anaemia	7 (33.3)	0	2 (9.5)	5 (23.8)	0
Thrombocytopenia	4 (19.0)	0	0	0	4 (19.0)
Neutropenia	3 (14.3)	0	0	2 (9.5)	1 (4.8)
Disseminated intravascular coagulation	1 (4.8)	0	1 (4.8)	0	0
Cardiac disorders					
-Total	6 (28.6)	2 (9.5)	4 (19.0)	0	0
Tachycardia	5 (23.8)	2 (9.5)	3 (14.3)	0	0
Sinus tachycardia	1 (4.8)	0	1 (4.8)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	4 (19.0)	2 (9.5)	2 (9.5)	0	0
Eye pain	2 (9.5)	0	2 (9.5)	0	0
Vision blurred	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Conjunctival haemorrhage	1 (4.8)	1 (4.8)	0	0	0
Periorbital oedema	1 (4.8)	1 (4.8)	0	0	0
Gastrointestinal disorders					
-Total	9 (42.9)	3 (14.3)	3 (14.3)	3 (14.3)	0
Nausea	7 (33.3)	1 (4.8)	5 (23.8)	1 (4.8)	0
Vomiting	7 (33.3)	3 (14.3)	2 (9.5)	2 (9.5)	0
Diarrhoea	4 (19.0)	2 (9.5)	2 (9.5)	0	0
Abdominal pain	2 (9.5)	1 (4.8)	0	1 (4.8)	0
Constipation	1 (4.8)	0	1 (4.8)	0	0
General disorders and administration site conditions					
-Total	9 (42.9)	4 (19.0)	5 (23.8)	0	0
Chills	5 (23.8)	5 (23.8)	0	0	0
Pyrexia	5 (23.8)	1 (4.8)	4 (19.0)	0	0
Fatigue	3 (14.3)	2 (9.5)	1 (4.8)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	2 (9.5)	0	2 (9.5)	0	0
Catheter site pain	1 (4.8)	0	1 (4.8)	0	0
Hepatobiliary disorders					
-Total	1 (4.8)	1 (4.8)	0	0	0
Hepatomegaly	1 (4.8)	1 (4.8)	0	0	0
Immune system disorders					
-Total	20 (95.2)	0	13 (61.9)	6 (28.6)	1 (4.8)
Cytokine release syndrome	18 (85.7)	1 (4.8)	12 (57.1)	4 (19.0)	1 (4.8)
Hypogammaglobulinaemia	10 (47.6)	1 (4.8)	6 (28.6)	3 (14.3)	0
Infections and infestations					
-Total	5 (23.8)	2 (9.5)	3 (14.3)	0	0
Rhinovirus infection	3 (14.3)	3 (14.3)	0	0	0
Clostridium difficile infection	1 (4.8)	0	1 (4.8)	0	0
Pneumonia	1 (4.8)	0	1 (4.8)	0	0
Upper respiratory tract infection	1 (4.8)	0	1 (4.8)	0	0
Injury, poisoning and procedural complications					
-Total	1 (4.8)	1 (4.8)	0	0	0
Procedural pain	1 (4.8)	1 (4.8)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	16 (76.2)	1 (4.8)	0	7 (33.3)	8 (38.1)
White blood cell count decreased	10 (47.6)	0	0	3 (14.3)	7 (33.3)
Alanine aminotransferase increased	7 (33.3)	2 (9.5)	0	5 (23.8)	0
Neutrophil count decreased	7 (33.3)	0	0	2 (9.5)	5 (23.8)
Platelet count decreased	5 (23.8)	2 (9.5)	0	1 (4.8)	2 (9.5)
Aspartate aminotransferase increased	4 (19.0)	1 (4.8)	0	3 (14.3)	0
Prothrombin time prolonged	4 (19.0)	2 (9.5)	1 (4.8)	1 (4.8)	0
Lymphocyte count decreased	3 (14.3)	0	0	1 (4.8)	2 (9.5)
Blood bilirubin increased	2 (9.5)	0	1 (4.8)	1 (4.8)	0
Blood fibrinogen decreased	2 (9.5)	0	0	2 (9.5)	0
International normalised ratio increased	2 (9.5)	1 (4.8)	0	1 (4.8)	0
Transaminases increased	2 (9.5)	2 (9.5)	0	0	0
Blood creatinine increased	1 (4.8)	1 (4.8)	0	0	0
Blood immunoglobulin m decreased	1 (4.8)	1 (4.8)	0	0	0
Metabolism and nutrition disorders					
-Total	13 (61.9)	1 (4.8)	3 (14.3)	8 (38.1)	1 (4.8)
Decreased appetite	9 (42.9)	1 (4.8)	2 (9.5)	6 (28.6)	0
Hypokalaemia	5 (23.8)	1 (4.8)	2 (9.5)	2 (9.5)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	4 (19.0)	0	0	3 (14.3)	1 (4.8)
Hyperphosphataemia	2 (9.5)	2 (9.5)	0	0	0
Dehydration	1 (4.8)	0	0	1 (4.8)	0
Fluid overload	1 (4.8)	0	1 (4.8)	0	0
Hyperglycaemia	1 (4.8)	0	0	1 (4.8)	0
Hypoalbuminaemia	1 (4.8)	0	0	1 (4.8)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Myalgia	1 (4.8)	1 (4.8)	0	0	0
Pain in extremity	1 (4.8)	0	1 (4.8)	0	0
Nervous system disorders					
-Total	7 (33.3)	3 (14.3)	2 (9.5)	2 (9.5)	0
Headache	6 (28.6)	3 (14.3)	1 (4.8)	2 (9.5)	0
Encephalopathy	1 (4.8)	0	0	1 (4.8)	0
Seizure	1 (4.8)	0	1 (4.8)	0	0
Psychiatric disorders					
-Total	5 (23.8)	3 (14.3)	2 (9.5)	0	0
Anxiety	2 (9.5)	1 (4.8)	1 (4.8)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Delirium	1 (4.8)	1 (4.8)	0	0	0
Renal and urinary disorders					
-Total	2 (9.5)	0	0	1 (4.8)	1 (4.8)
Acute kidney injury	2 (9.5)	0	0	1 (4.8)	1 (4.8)
Haematuria	1 (4.8)	0	1 (4.8)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (28.6)	2 (9.5)	1 (4.8)	1 (4.8)	2 (9.5)
Cough	3 (14.3)	3 (14.3)	0	0	0
Hypoxia	3 (14.3)	0	1 (4.8)	1 (4.8)	1 (4.8)
Pleural effusion	2 (9.5)	1 (4.8)	0	1 (4.8)	0
Epistaxis	1 (4.8)	1 (4.8)	0	0	0
Pulmonary oedema	1 (4.8)	0	0	1 (4.8)	0
Respiratory failure	1 (4.8)	0	0	0	1 (4.8)
Rhinitis allergic	1 (4.8)	1 (4.8)	0	0	0
Tachypnoea	1 (4.8)	1 (4.8)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (19.0)	2 (9.5)	1 (4.8)	1 (4.8)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash maculo-papular	2 (9.5)	0	1 (4.8)	1 (4.8)	0
Erythema	1 (4.8)	1 (4.8)	0	0	0
Rash	1 (4.8)	1 (4.8)	0	0	0
Vascular disorders					
-Total	7 (33.3)	1 (4.8)	2 (9.5)	3 (14.3)	1 (4.8)
Hypertension	4 (19.0)	1 (4.8)	3 (14.3)	0	0
Hypotension	4 (19.0)	0	0	3 (14.3)	1 (4.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

			All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (100)	1 (6.3)	4 (25.0)	2 (12.5)	9 (56.3)
Blood and lymphatic system disorders					
-Total	9 (56.3)	0	1 (6.3)	6 (37.5)	2 (12.5)
Anaemia	8 (50.0)	1 (6.3)	1 (6.3)	6 (37.5)	0
Febrile neutropenia	3 (18.8)	0	0	3 (18.8)	0
Thrombocytopenia	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Neutropenia	1 (6.3)	0	0	0	1 (6.3)
Cardiac disorders					
-Total	6 (37.5)	4 (25.0)	1 (6.3)	1 (6.3)	0
Tachycardia	5 (31.3)	3 (18.8)	1 (6.3)	1 (6.3)	0
Sinus tachycardia	2 (12.5)	2 (12.5)	0	0	0
Ear and labyrinth disorders					

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

			All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (12.5)	2 (12.5)	0	0	0
Ear pain	2 (12.5)	2 (12.5)	0	0	0
Eye disorders					
-Total	1 (6.3)	0	1 (6.3)	0	0
Periorbital oedema	1 (6.3)	0	1 (6.3)	0	0
Gastrointestinal disorders					
-Total	8 (50.0)	3 (18.8)	5 (31.3)	0	0
Nausea	6 (37.5)	3 (18.8)	3 (18.8)	0	0
Abdominal pain	5 (31.3)	3 (18.8)	2 (12.5)	0	0
Diarrhoea	5 (31.3)	4 (25.0)	1 (6.3)	0	0
Vomiting	5 (31.3)	5 (31.3)	0	0	0
Abdominal distension	2 (12.5)	0	2 (12.5)	0	0
General disorders and administration site conditions					
-Total	8 (50.0)	3 (18.8)	3 (18.8)	2 (12.5)	0
Fatigue	5 (31.3)	3 (18.8)	1 (6.3)	1 (6.3)	0
Pyrexia	3 (18.8)	1 (6.3)	1 (6.3)	1 (6.3)	0
Catheter site pain	1 (6.3)	1 (6.3)	0	0	0
Chills	1 (6.3)	1 (6.3)	0	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Generalised oedema	1 (6.3)	0	1 (6.3)	0	0
Malaise	1 (6.3)	0	1 (6.3)	0	0
Oedema peripheral	1 (6.3)	1 (6.3)	0	0	0
Pain	1 (6.3)	0	0	1 (6.3)	0
Hepatobiliary disorders					
-Total	1 (6.3)	0	1 (6.3)	0	0
Hepatomegaly	1 (6.3)	0	1 (6.3)	0	0
Immune system disorders					
-Total	13 (81.3)	3 (18.8)	6 (37.5)	2 (12.5)	2 (12.5)
Cytokine release syndrome	11 (68.8)	3 (18.8)	4 (25.0)	2 (12.5)	2 (12.5)
Hypogammaglobulinaemia	5 (31.3)	2 (12.5)	3 (18.8)	0	0
Infections and infestations					
-Total	3 (18.8)	1 (6.3)	2 (12.5)	0	0
Clostridium difficile infection	1 (6.3)	0	1 (6.3)	0	0
Skin infection	1 (6.3)	0	1 (6.3)	0	0
Vulvovaginal candidiasis	1 (6.3)	1 (6.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	3 (18.8)	0	3 (18.8)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

			All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infusion related reaction	2 (12.5)	0	2 (12.5)	0	0
Procedural pain	2 (12.5)	0	2 (12.5)	0	0
Investigations					
-Total	11 (68.8)	1 (6.3)	2 (12.5)	0	8 (50.0)
Aspartate aminotransferase increased	6 (37.5)	1 (6.3)	2 (12.5)	1 (6.3)	2 (12.5)
Neutrophil count decreased	6 (37.5)	0	1 (6.3)	0	5 (31.3)
White blood cell count decreased	6 (37.5)	0	1 (6.3)	2 (12.5)	3 (18.8)
Alanine aminotransferase increased	5 (31.3)	1 (6.3)	2 (12.5)	2 (12.5)	0
Platelet count decreased	5 (31.3)	1 (6.3)	0	0	4 (25.0)
Blood bilirubin increased	3 (18.8)	2 (12.5)	0	1 (6.3)	0
Blood creatinine increased	3 (18.8)	2 (12.5)	0	1 (6.3)	0
International normalised ratio increased	3 (18.8)	3 (18.8)	0	0	0
Lymphocyte count decreased	3 (18.8)	0	1 (6.3)	2 (12.5)	0
Blood immunoglobulin a decreased	2 (12.5)	2 (12.5)	0	0	0
Activated partial thromboplastin time prolonged	1 (6.3)	1 (6.3)	0	0	0
Blood immunoglobulin m decreased	1 (6.3)	1 (6.3)	0	0	0
Prothrombin time prolonged	1 (6.3)	0	1 (6.3)	0	0
Metabolism and nutrition disorders					

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

			All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (62.5)	2 (12.5)	4 (25.0)	4 (25.0)	0
Hypokalaemia	6 (37.5)	1 (6.3)	3 (18.8)	2 (12.5)	0
Decreased appetite	4 (25.0)	2 (12.5)	0	2 (12.5)	0
Fluid overload	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Hyperphosphataemia	2 (12.5)	2 (12.5)	0	0	0
Hypoalbuminaemia	2 (12.5)	0	2 (12.5)	0	0
Hypocalcaemia	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Hypophosphataemia	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Hyperuricaemia	1 (6.3)	1 (6.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	6 (37.5)	4 (25.0)	2 (12.5)	0	0
Myalgia	4 (25.0)	3 (18.8)	1 (6.3)	0	0
Pain in extremity	3 (18.8)	2 (12.5)	1 (6.3)	0	0
Arthralgia	1 (6.3)	1 (6.3)	0	0	0
Muscle spasms	1 (6.3)	1 (6.3)	0	0	0
Nervous system disorders					
-Total	8 (50.0)	5 (31.3)	2 (12.5)	1 (6.3)	0
Headache	6 (37.5)	4 (25.0)	2 (12.5)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dizziness	2 (12.5)	2 (12.5)	0	0	0
Encephalopathy	1 (6.3)	1 (6.3)	0	0	0
Seizure	1 (6.3)	0	0	1 (6.3)	0
Psychiatric disorders					
-Total	3 (18.8)	1 (6.3)	1 (6.3)	1 (6.3)	0
Anxiety	3 (18.8)	1 (6.3)	1 (6.3)	1 (6.3)	0
Confusional state	1 (6.3)	0	1 (6.3)	0	0
Renal and urinary disorders					
-Total	1 (6.3)	0	0	0	1 (6.3)
Acute kidney injury	1 (6.3)	0	0	0	1 (6.3)
Haematuria	1 (6.3)	0	1 (6.3)	0	0
Oliguria	1 (6.3)	0	0	1 (6.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (50.0)	3 (18.8)	3 (18.8)	1 (6.3)	1 (6.3)
Hypoxia	3 (18.8)	0	2 (12.5)	0	1 (6.3)
Cough	2 (12.5)	2 (12.5)	0	0	0
Epistaxis	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Pleural effusion	2 (12.5)	0	2 (12.5)	0	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	1 (6.3)	0	0	1 (6.3)	0
Oropharyngeal pain	1 (6.3)	1 (6.3)	0	0	0
Pulmonary oedema	1 (6.3)	0	0	1 (6.3)	0
Tachypnoea	1 (6.3)	0	0	1 (6.3)	0
Skin and subcutaneous tissue disorders					
-Total	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Rash	2 (12.5)	2 (12.5)	0	0	0
Petechiae	1 (6.3)	0	1 (6.3)	0	0
Vascular disorders					
-Total	6 (37.5)	1 (6.3)	2 (12.5)	1 (6.3)	2 (12.5)
Hypotension	4 (25.0)	1 (6.3)	0	1 (6.3)	2 (12.5)
Hypertension	3 (18.8)	0	2 (12.5)	1 (6.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

		All patients N=5			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	2 (40.0)	2 (40.0)	0
Endocrine disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Adrenal insufficiency	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal disorders					
-Total	4 (80.0)	2 (40.0)	0	2 (40.0)	0
Diarrhoea	2 (40.0)	2 (40.0)	0	0	0
Oral pain	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Vomiting	2 (40.0)	2 (40.0)	0	0	0
Abdominal pain	1 (20.0)	1 (20.0)	0	0	0
Enterocolitis	1 (20.0)	0	0	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (20.0)	0	1 (20.0)	0	0
General disorders and administration site conditions					
-Total	3 (60.0)	2 (40.0)	1 (20.0)	0	0
Catheter site pain	1 (20.0)	0	1 (20.0)	0	0
Fatigue	1 (20.0)	1 (20.0)	0	0	0
Pyrexia	1 (20.0)	1 (20.0)	0	0	0
Immune system disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Graft versus host disease	1 (20.0)	0	1 (20.0)	0	0
Infections and infestations					
-Total	4 (80.0)	1 (20.0)	2 (40.0)	1 (20.0)	0
Upper respiratory tract infection	2 (40.0)	0	2 (40.0)	0	0
Corona virus infection	1 (20.0)	0	0	1 (20.0)	0
Ear infection	1 (20.0)	1 (20.0)	0	0	0
Respiratory syncytial virus infection	1 (20.0)	0	0	1 (20.0)	0
Rhinovirus infection	1 (20.0)	1 (20.0)	0	0	0
Tinea capitis	1 (20.0)	1 (20.0)	0	0	0
Viral infection	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	1 (20.0)	0	1 (20.0)	0	0
Contusion	1 (20.0)	1 (20.0)	0	0	0
Infusion related reaction	1 (20.0)	0	1 (20.0)	0	0
Procedural nausea	1 (20.0)	0	1 (20.0)	0	0
Sunburn	1 (20.0)	1 (20.0)	0	0	0
Investigations					
-Total	2 (40.0)	1 (20.0)	0	1 (20.0)	0
Blood bilirubin increased	1 (20.0)	0	0	1 (20.0)	0
Blood magnesium decreased	1 (20.0)	1 (20.0)	0	0	0
Weight decreased	1 (20.0)	1 (20.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (60.0)	3 (60.0)	0	0	0
Pain in extremity	2 (40.0)	2 (40.0)	0	0	0
Arthralgia	1 (20.0)	1 (20.0)	0	0	0
Muscular weakness	1 (20.0)	1 (20.0)	0	0	0
Pain in jaw	1 (20.0)	1 (20.0)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	2 (40.0)	2 (40.0)	0	0	0
Headache	1 (20.0)	1 (20.0)	0	0	0
Peroneal nerve palsy	1 (20.0)	1 (20.0)	0	0	0
Psychiatric disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Anxiety	1 (20.0)	1 (20.0)	0	0	0
Depression	1 (20.0)	1 (20.0)	0	0	0
Sleep disorder	1 (20.0)	0	1 (20.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (80.0)	2 (40.0)	1 (20.0)	1 (20.0)	0
Rhinorrhoea	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Cough	1 (20.0)	1 (20.0)	0	0	0
Epistaxis	1 (20.0)	0	0	1 (20.0)	0
Nasal congestion	1 (20.0)	1 (20.0)	0	0	0
Oropharyngeal pain	1 (20.0)	0	1 (20.0)	0	0
Pharyngeal erythema	1 (20.0)	1 (20.0)	0	0	0
Pharyngeal lesion	1 (20.0)	0	0	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0
Alopecia	1 (20.0)	0	1 (20.0)	0	0
Erythema	1 (20.0)	1 (20.0)	0	0	0
Rash erythematous	1 (20.0)	0	1 (20.0)	0	0
Vascular disorders					
-Total	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Hypertension	2 (40.0)	1 (20.0)	1 (20.0)	0	0
Hot flush	1 (20.0)	1 (20.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

			All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (73.7)	1 (5.3)	5 (26.3)	6 (31.6)	2 (10.5)
Blood and lymphatic system disorders					
-Total	2 (10.5)	0	0	1 (5.3)	1 (5.3)
Febrile neutropenia	2 (10.5)	0	0	2 (10.5)	0
Anaemia	1 (5.3)	0	0	1 (5.3)	0
Neutropenia	1 (5.3)	0	0	0	1 (5.3)
Eye disorders					
-Total	1 (5.3)	1 (5.3)	0	0	0
Vision blurred	1 (5.3)	1 (5.3)	0	0	0
Gastrointestinal disorders					
-Total	3 (15.8)	2 (10.5)	0	1 (5.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Nausea	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Abdominal pain	1 (5.3)	0	1 (5.3)	0	0
Vomiting	1 (5.3)	0	0	1 (5.3)	0
General disorders and administration site conditions					
-Total	2 (10.5)	1 (5.3)	0	1 (5.3)	0
Generalised oedema	1 (5.3)	1 (5.3)	0	0	0
Oedema peripheral	1 (5.3)	1 (5.3)	0	0	0
Pyrexia	1 (5.3)	0	0	1 (5.3)	0
Immune system disorders					
-Total	5 (26.3)	0	4 (21.1)	1 (5.3)	0
Hypogammaglobulinaemia	3 (15.8)	0	2 (10.5)	1 (5.3)	0
Immunodeficiency common variable	2 (10.5)	0	2 (10.5)	0	0
Infections and infestations					
-Total	8 (42.1)	2 (10.5)	5 (26.3)	1 (5.3)	0
Gastroenteritis	2 (10.5)	0	2 (10.5)	0	0
Influenza	2 (10.5)	0	2 (10.5)	0	0
Urinary tract infection	2 (10.5)	0	1 (5.3)	1 (5.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (5.3)	1 (5.3)	0	0	0
Upper respiratory tract infection	1 (5.3)	1 (5.3)	0	0	0
Investigations					
-Total	6 (31.6)	2 (10.5)	0	3 (15.8)	1 (5.3)
Neutrophil count decreased	3 (15.8)	0	0	2 (10.5)	1 (5.3)
Aspartate aminotransferase increased	2 (10.5)	0	0	2 (10.5)	0
White blood cell count decreased	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Blood creatinine increased	1 (5.3)	1 (5.3)	0	0	0
Platelet count decreased	1 (5.3)	1 (5.3)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (15.8)	2 (10.5)	0	0	1 (5.3)
Hypokalaemia	2 (10.5)	1 (5.3)	0	0	1 (5.3)
Decreased appetite	1 (5.3)	1 (5.3)	0	0	0
Hyperglycaemia	1 (5.3)	0	0	1 (5.3)	0
Hyperphosphataemia	1 (5.3)	1 (5.3)	0	0	0
Hypophosphataemia	1 (5.3)	0	0	1 (5.3)	0
Musculoskeletal and connective tissue disorders					

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (15.8)	2 (10.5)	1 (5.3)	0	0
Pain in extremity	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Muscular weakness	1 (5.3)	1 (5.3)	0	0	0
Musculoskeletal chest pain	1 (5.3)	1 (5.3)	0	0	0
Psychiatric disorders					
-Total	1 (5.3)	1 (5.3)	0	0	0
Depression	1 (5.3)	1 (5.3)	0	0	0
Renal and urinary disorders					
-Total	2 (10.5)	0	0	2 (10.5)	0
Acute kidney injury	1 (5.3)	0	0	1 (5.3)	0
Haematuria	1 (5.3)	0	0	1 (5.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (21.1)	3 (15.8)	0	1 (5.3)	0
Cough	1 (5.3)	1 (5.3)	0	0	0
Epistaxis	1 (5.3)	1 (5.3)	0	0	0
Nasal congestion	1 (5.3)	1 (5.3)	0	0	0
Oropharyngeal pain	1 (5.3)	1 (5.3)	0	0	0
Pulmonary oedema	1 (5.3)	0	0	1 (5.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders					
-Total	5 (26.3)	4 (21.1)	1 (5.3)	0	0
Rash	2 (10.5)	1 (5.3)	1 (5.3)	0	0
Dry skin	1 (5.3)	1 (5.3)	0	0	0
Papule	1 (5.3)	1 (5.3)	0	0	0
Petechiae	1 (5.3)	1 (5.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

			All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (77.8)	2 (11.1)	6 (33.3)	4 (22.2)	2 (11.1)
Blood and lymphatic system disorders					
-Total	3 (16.7)	0	1 (5.6)	1 (5.6)	1 (5.6)
Neutropenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Febrile neutropenia	1 (5.6)	0	0	1 (5.6)	0
Thrombocytopenia	1 (5.6)	0	1 (5.6)	0	0
Gastrointestinal disorders					
-Total	4 (22.2)	2 (11.1)	1 (5.6)	1 (5.6)	0
Diarrhoea	3 (16.7)	2 (11.1)	0	1 (5.6)	0
Vomiting	3 (16.7)	2 (11.1)	0	1 (5.6)	0
Nausea	2 (11.1)	0	1 (5.6)	1 (5.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (5.6)	0	0	1 (5.6)	0
General disorders and administration site conditions					
-Total	4 (22.2)	3 (16.7)	1 (5.6)	0	0
Pyrexia	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Malaise	1 (5.6)	1 (5.6)	0	0	0
Immune system disorders					
-Total	3 (16.7)	0	3 (16.7)	0	0
Hypogammaglobulinaemia	3 (16.7)	0	3 (16.7)	0	0
Infections and infestations					
-Total	4 (22.2)	1 (5.6)	3 (16.7)	0	0
Gastroenteritis	1 (5.6)	1 (5.6)	0	0	0
Influenza	1 (5.6)	0	1 (5.6)	0	0
Upper respiratory tract infection	1 (5.6)	0	1 (5.6)	0	0
Urinary tract infection	1 (5.6)	0	1 (5.6)	0	0
Injury, poisoning and procedural complications					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Procedural pain	2 (11.1)	1 (5.6)	1 (5.6)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infusion related reaction	1 (5.6)	1 (5.6)	0	0	0
Investigations					
-Total	8 (44.4)	1 (5.6)	2 (11.1)	3 (16.7)	2 (11.1)
Weight decreased	3 (16.7)	0	3 (16.7)	0	0
Neutrophil count decreased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
White blood cell count decreased	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Alanine aminotransferase increased	1 (5.6)	0	0	1 (5.6)	0
Aspartate aminotransferase increased	1 (5.6)	1 (5.6)	0	0	0
Platelet count decreased	1 (5.6)	1 (5.6)	0	0	0
Transaminases increased	1 (5.6)	1 (5.6)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Pain in extremity	2 (11.1)	2 (11.1)	0	0	0
Arthralgia	1 (5.6)	0	1 (5.6)	0	0
Nervous system disorders					
-Total	4 (22.2)	3 (16.7)	1 (5.6)	0	0
Dizziness	2 (11.1)	2 (11.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	2 (11.1)	2 (11.1)	0	0	0
Peroneal nerve palsy	1 (5.6)	0	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (27.8)	3 (16.7)	2 (11.1)	0	0
Cough	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Rhinitis allergic	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Rhinorrhoea	2 (11.1)	2 (11.1)	0	0	0
Nasal congestion	1 (5.6)	1 (5.6)	0	0	0
Oropharyngeal pain	1 (5.6)	1 (5.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Erythema	1 (5.6)	1 (5.6)	0	0	0
Hyperhidrosis	1 (5.6)	1 (5.6)	0	0	0
Rash	1 (5.6)	0	1 (5.6)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (78.6)	2 (14.3)	4 (28.6)	3 (21.4)	2 (14.3)
Blood and lymphatic system disorders					
-Total	3 (21.4)	1 (7.1)	0	1 (7.1)	1 (7.1)
Anaemia	1 (7.1)	1 (7.1)	0	0	0
Neutropenia	1 (7.1)	0	0	0	1 (7.1)
Thrombocytopenia	1 (7.1)	0	0	1 (7.1)	0
Cardiac disorders					
-Total	1 (7.1)	0	1 (7.1)	0	0
Sinus tachycardia	1 (7.1)	0	1 (7.1)	0	0
Gastrointestinal disorders					
-Total	3 (21.4)	1 (7.1)	2 (14.3)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Abdominal pain	1 (7.1)	1 (7.1)	0	0	0
Diarrhoea	1 (7.1)	1 (7.1)	0	0	0
Nausea	1 (7.1)	0	1 (7.1)	0	0
General disorders and administration site conditions					
-Total	5 (35.7)	4 (28.6)	1 (7.1)	0	0
Pyrexia	5 (35.7)	4 (28.6)	1 (7.1)	0	0
Chills	1 (7.1)	1 (7.1)	0	0	0
Fatigue	1 (7.1)	1 (7.1)	0	0	0
Pain	1 (7.1)	1 (7.1)	0	0	0
Immune system disorders					
-Total	3 (21.4)	1 (7.1)	2 (14.3)	0	0
Hypogammaglobulinaemia	2 (14.3)	0	2 (14.3)	0	0
Graft versus host disease	1 (7.1)	1 (7.1)	0	0	0
Infections and infestations					
-Total	5 (35.7)	1 (7.1)	2 (14.3)	2 (14.3)	0
Upper respiratory tract infection	3 (21.4)	2 (14.3)	0	1 (7.1)	0
Ear infection	1 (7.1)	0	1 (7.1)	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (7.1)	0	1 (7.1)	0	0
Urinary tract infection	1 (7.1)	0	0	1 (7.1)	0
Injury, poisoning and procedural complications					
-Total	1 (7.1)	1 (7.1)	0	0	0
Contusion	1 (7.1)	1 (7.1)	0	0	0
Investigations					
-Total	4 (28.6)	1 (7.1)	1 (7.1)	1 (7.1)	1 (7.1)
Neutrophil count decreased	3 (21.4)	2 (14.3)	0	0	1 (7.1)
Lymphocyte count decreased	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Alanine aminotransferase increased	1 (7.1)	0	0	1 (7.1)	0
Blood uric acid increased	1 (7.1)	1 (7.1)	0	0	0
Platelet count decreased	1 (7.1)	1 (7.1)	0	0	0
White blood cell count decreased	1 (7.1)	1 (7.1)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (21.4)	1 (7.1)	1 (7.1)	1 (7.1)	0
Decreased appetite	1 (7.1)	0	1 (7.1)	0	0
Dehydration	1 (7.1)	0	0	1 (7.1)	0
Hyperphosphataemia	1 (7.1)	1 (7.1)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	4 (28.6)	3 (21.4)	1 (7.1)	0	0
Joint range of motion decreased	2 (14.3)	2 (14.3)	0	0	0
Pain in extremity	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Muscle spasms	1 (7.1)	1 (7.1)	0	0	0
Nervous system disorders					
-Total	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Headache	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Dizziness	1 (7.1)	1 (7.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Cough	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Nasal congestion	1 (7.1)	1 (7.1)	0	0	0
Rhinitis allergic	1 (7.1)	1 (7.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Rash maculo-papular	2 (14.3)	2 (14.3)	0	0	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

			All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash	1 (7.1)	0	1 (7.1)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

			All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (40.0)	0	1 (20.0)	0	1 (20.0)
Infections and infestations					
-Total	1 (20.0)	0	1 (20.0)	0	0
Skin infection	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	1 (20.0)	0	0	0	1 (20.0)
White blood cell count decreased	1 (20.0)	0	0	0	1 (20.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

			All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (54.5)	3 (27.3)	1 (9.1)	2 (18.2)	0
Infections and infestations					
-Total	3 (27.3)	1 (9.1)	1 (9.1)	1 (9.1)	0
Otitis media	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pneumonia	1 (9.1)	0	1 (9.1)	0	0
Viral infection	1 (9.1)	1 (9.1)	0	0	0
Investigations					
-Total	1 (9.1)	0	0	1 (9.1)	0
White blood cell count decreased	1 (9.1)	0	0	1 (9.1)	0
Nervous system disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Seizure	1 (9.1)	0	0	1 (9.1)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Haematuria	1 (9.1)	1 (9.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Epistaxis	1 (9.1)	1 (9.1)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (9.1)	1 (9.1)	0	0	0
Papule	1 (9.1)	1 (9.1)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

			All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (50.0)	0	1 (10.0)	3 (30.0)	1 (10.0)
Blood and lymphatic system disorders					
-Total	1 (10.0)	0	0	0	1 (10.0)
Febrile neutropenia	1 (10.0)	0	0	0	1 (10.0)
Gastrointestinal disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Nausea	1 (10.0)	0	1 (10.0)	0	0
General disorders and administration site conditions					
-Total	1 (10.0)	0	1 (10.0)	0	0
Chills	1 (10.0)	0	1 (10.0)	0	0
Pyrexia	1 (10.0)	0	1 (10.0)	0	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	2 (20.0)	0	2 (20.0)	0	0
Pneumonia	1 (10.0)	0	1 (10.0)	0	0
Upper respiratory tract infection	1 (10.0)	0	1 (10.0)	0	0
Injury, poisoning and procedural complications					
-Total	1 (10.0)	0	0	1 (10.0)	0
Procedural pain	1 (10.0)	0	0	1 (10.0)	0
Investigations					
-Total	4 (40.0)	0	1 (10.0)	3 (30.0)	0
Alanine aminotransferase increased	3 (30.0)	0	1 (10.0)	2 (20.0)	0
Aspartate aminotransferase increased	2 (20.0)	1 (10.0)	0	1 (10.0)	0
Lymphocyte count decreased	1 (10.0)	0	0	1 (10.0)	0
Platelet count decreased	1 (10.0)	0	0	1 (10.0)	0
White blood cell count decreased	1 (10.0)	0	0	1 (10.0)	0
Metabolism and nutrition disorders					
-Total	1 (10.0)	0	0	1 (10.0)	0
Hypokalaemia	1 (10.0)	0	0	1 (10.0)	0
Renal and urinary disorders					

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (10.0)	0	0	1 (10.0)	0
Acute kidney injury	1 (10.0)	0	0	1 (10.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (10.0)	1 (10.0)	0	0	0
Cough	1 (10.0)	1 (10.0)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

		All patients N=8			
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (62.5)	2 (25.0)	1 (12.5)	2 (25.0)	0
Blood and lymphatic system disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Thrombocytopenia	1 (12.5)	1 (12.5)	0	0	0
Gastrointestinal disorders					
-Total	2 (25.0)	0	2 (25.0)	0	0
Diarrhoea	2 (25.0)	0	2 (25.0)	0	0
Abdominal pain	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Urinary tract infection	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Clostridium difficile infection	1 (12.5)	0	0	1 (12.5)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (12.5)	0	1 (12.5)	0	0
Upper respiratory tract infection	1 (12.5)	1 (12.5)	0	0	0
Vulvovaginal candidiasis	1 (12.5)	0	1 (12.5)	0	0
Investigations					
-Total	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Lymphocyte count decreased	2 (25.0)	2 (25.0)	0	0	0
Neutrophil count decreased	2 (25.0)	1 (12.5)	1 (12.5)	0	0
White blood cell count decreased	1 (12.5)	1 (12.5)	0	0	0
Nervous system disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Dizziness	1 (12.5)	1 (12.5)	0	0	0
Headache	1 (12.5)	0	1 (12.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (25.0)	2 (25.0)	0	0	0
Cough	1 (12.5)	1 (12.5)	0	0	0
Oropharyngeal pain	1 (12.5)	1 (12.5)	0	0	0
Rhinitis allergic	1 (12.5)	1 (12.5)	0	0	0
Rhinorrhoea	1 (12.5)	1 (12.5)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

			All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	0	1 (14.3)	0	6 (85.7)
Blood and lymphatic system disorders					
-Total	5 (71.4)	1 (14.3)	0	2 (28.6)	2 (28.6)
Anaemia	4 (57.1)	2 (28.6)	0	1 (14.3)	1 (14.3)
Febrile neutropenia	2 (28.6)	0	0	2 (28.6)	0
Neutropenia	2 (28.6)	0	0	0	2 (28.6)
Thrombocytopenia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Cardiac disorders					
-Total	3 (42.9)	2 (28.6)	0	1 (14.3)	0
Tachycardia	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0
Palpitations	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pericardial effusion	1 (14.3)	1 (14.3)	0	0	0
Endocrine disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Adrenal insufficiency	1 (14.3)	1 (14.3)	0	0	0
Eye disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Eye pain	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal disorders					
-Total	6 (85.7)	2 (28.6)	1 (14.3)	3 (42.9)	0
Vomiting	5 (71.4)	3 (42.9)	2 (28.6)	0	0
Diarrhoea	4 (57.1)	3 (42.9)	1 (14.3)	0	0
Nausea	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Oral pain	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Abdominal pain	1 (14.3)	1 (14.3)	0	0	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Enterocolitis	1 (14.3)	0	0	1 (14.3)	0
General disorders and administration site conditions					
-Total	5 (71.4)	1 (14.3)	1 (14.3)	2 (28.6)	1 (14.3)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	4 (57.1)	1 (14.3)	1 (14.3)	1 (14.3)	1 (14.3)
Asthenia	1 (14.3)	1 (14.3)	0	0	0
Catheter site pain	1 (14.3)	0	1 (14.3)	0	0
Chills	1 (14.3)	1 (14.3)	0	0	0
Fatigue	1 (14.3)	1 (14.3)	0	0	0
Pain	1 (14.3)	0	0	1 (14.3)	0
Hepatobiliary disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Hepatomegaly	1 (14.3)	0	1 (14.3)	0	0
Immune system disorders					
-Total	7 (100)	0	4 (57.1)	0	3 (42.9)
Cytokine release syndrome	5 (71.4)	0	2 (28.6)	0	3 (42.9)
Hypogammaglobulinaemia	4 (57.1)	0	4 (57.1)	0	0
Graft versus host disease	1 (14.3)	0	1 (14.3)	0	0
Infections and infestations					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Upper respiratory tract infection	2 (28.6)	0	2 (28.6)	0	0
Viral infection	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Corona virus infection	1 (14.3)	0	0	1 (14.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	1 (14.3)	1 (14.3)	0	0	0
Gastroenteritis	1 (14.3)	0	1 (14.3)	0	0
Respiratory syncytial virus infection	1 (14.3)	0	0	1 (14.3)	0
Rhinovirus infection	1 (14.3)	1 (14.3)	0	0	0
Skin infection	1 (14.3)	0	1 (14.3)	0	0
Tinea capitis	1 (14.3)	1 (14.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Contusion	1 (14.3)	1 (14.3)	0	0	0
Infusion related reaction	1 (14.3)	0	1 (14.3)	0	0
Procedural nausea	1 (14.3)	0	1 (14.3)	0	0
Sunburn	1 (14.3)	1 (14.3)	0	0	0
Tracheal haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Investigations					
-Total	7 (100)	0	1 (14.3)	2 (28.6)	4 (57.1)
Neutrophil count decreased	4 (57.1)	0	1 (14.3)	0	3 (42.9)
White blood cell count decreased	4 (57.1)	1 (14.3)	0	0	3 (42.9)
Blood magnesium decreased	2 (28.6)	1 (14.3)	0	1 (14.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0	0	0
Aspartate aminotransferase increased	1 (14.3)	0	0	0	1 (14.3)
Blood bilirubin increased	1 (14.3)	0	0	1 (14.3)	0
Blood creatinine increased	1 (14.3)	0	1 (14.3)	0	0
Blood fibrinogen decreased	1 (14.3)	0	1 (14.3)	0	0
Blood immunoglobulin m decreased	1 (14.3)	1 (14.3)	0	0	0
Blood phosphorus increased	1 (14.3)	1 (14.3)	0	0	0
Blood uric acid increased	1 (14.3)	1 (14.3)	0	0	0
Cardiac murmur	1 (14.3)	1 (14.3)	0	0	0
Fibrin d dimer increased	1 (14.3)	1 (14.3)	0	0	0
International normalised ratio increased	1 (14.3)	1 (14.3)	0	0	0
Prothrombin time prolonged	1 (14.3)	0	1 (14.3)	0	0
Weight decreased	1 (14.3)	1 (14.3)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Decreased appetite	3 (42.9)	1 (14.3)	1 (14.3)	1 (14.3)	0
Hypokalaemia	2 (28.6)	1 (14.3)	1 (14.3)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	1 (14.3)	0	1 (14.3)	0	0
Hypoalbuminaemia	1 (14.3)	1 (14.3)	0	0	0
Hypophosphataemia	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (42.9)	2 (28.6)	0	1 (14.3)	0
Pain in extremity	2 (28.6)	2 (28.6)	0	0	0
Arthralgia	1 (14.3)	0	0	1 (14.3)	0
Muscular weakness	1 (14.3)	1 (14.3)	0	0	0
Pain in jaw	1 (14.3)	1 (14.3)	0	0	0
Nervous system disorders					
-Total	4 (57.1)	4 (57.1)	0	0	0
Headache	3 (42.9)	3 (42.9)	0	0	0
Dizziness	1 (14.3)	1 (14.3)	0	0	0
Peroneal nerve palsy	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Confusional state	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Anxiety	1 (14.3)	1 (14.3)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	1 (14.3)	1 (14.3)	0	0	0
Depression	1 (14.3)	1 (14.3)	0	0	0
Sleep disorder	1 (14.3)	0	1 (14.3)	0	0
Renal and urinary disorders					
-Total	2 (28.6)	0	0	0	2 (28.6)
Haematuria	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Acute kidney injury	1 (14.3)	0	0	0	1 (14.3)
Oliguria	1 (14.3)	0	0	1 (14.3)	0
Renal failure	1 (14.3)	0	0	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders					
-Total	6 (85.7)	2 (28.6)	1 (14.3)	1 (14.3)	2 (28.6)
Cough	3 (42.9)	3 (42.9)	0	0	0
Epistaxis	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Hypoxia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Rhinorrhoea	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Dyspnoea	1 (14.3)	0	0	0	1 (14.3)
Haemoptysis	1 (14.3)	0	0	0	1 (14.3)
Interstitial lung disease	1 (14.3)	0	0	0	1 (14.3)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	1 (14.3)	1 (14.3)	0	0	0
Oropharyngeal pain	1 (14.3)	0	1 (14.3)	0	0
Pharyngeal erythema	1 (14.3)	1 (14.3)	0	0	0
Pharyngeal lesion	1 (14.3)	0	0	1 (14.3)	0
Pleural effusion	1 (14.3)	0	1 (14.3)	0	0
Pulmonary oedema	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Skin and subcutaneous tissue disorders					
-Total	4 (57.1)	3 (42.9)	1 (14.3)	0	0
Erythema	2 (28.6)	2 (28.6)	0	0	0
Alopecia	1 (14.3)	0	1 (14.3)	0	0
Dermatitis diaper	1 (14.3)	1 (14.3)	0	0	0
Dry skin	1 (14.3)	1 (14.3)	0	0	0
Livedo reticularis	1 (14.3)	1 (14.3)	0	0	0
Rash erythematous	1 (14.3)	0	1 (14.3)	0	0
Rash maculo-papular	1 (14.3)	1 (14.3)	0	0	0
Vascular disorders					
-Total	5 (71.4)	0	1 (14.3)	2 (28.6)	2 (28.6)
Hypotension	4 (57.1)	0	0	2 (28.6)	2 (28.6)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Haematoma	1 (14.3)	0	1 (14.3)	0	0
Hot flush	1 (14.3)	1 (14.3)	0	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

			All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (100)	1 (5.0)	1 (5.0)	5 (25.0)	13 (65.0)
Blood and lymphatic system disorders					
-Total	14 (70.0)	0	1 (5.0)	11 (55.0)	2 (10.0)
Febrile neutropenia	10 (50.0)	0	0	10 (50.0)	0
Anaemia	8 (40.0)	0	1 (5.0)	7 (35.0)	0
Disseminated intravascular coagulation	3 (15.0)	0	1 (5.0)	2 (10.0)	0
Neutropenia	3 (15.0)	0	0	1 (5.0)	2 (10.0)
Cardiac disorders					
-Total	6 (30.0)	3 (15.0)	3 (15.0)	0	0
Tachycardia	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Sinus tachycardia	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Pericardial effusion	1 (5.0)	0	1 (5.0)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Endocrine disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Adrenal insufficiency	1 (5.0)	0	1 (5.0)	0	0
Eye disorders					
-Total	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Conjunctival haemorrhage	2 (10.0)	2 (10.0)	0	0	0
Periorbital oedema	2 (10.0)	2 (10.0)	0	0	0
Vision blurred	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Gastrointestinal disorders					
-Total	13 (65.0)	4 (20.0)	5 (25.0)	4 (20.0)	0
Diarrhoea	7 (35.0)	3 (15.0)	3 (15.0)	1 (5.0)	0
Nausea	7 (35.0)	2 (10.0)	3 (15.0)	2 (10.0)	0
Vomiting	7 (35.0)	4 (20.0)	2 (10.0)	1 (5.0)	0
Constipation	5 (25.0)	5 (25.0)	0	0	0
Abdominal pain	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Dysphagia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions					
-Total	11 (55.0)	4 (20.0)	2 (10.0)	5 (25.0)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	6 (30.0)	1 (5.0)	1 (5.0)	4 (20.0)	0
Fatigue	5 (25.0)	5 (25.0)	0	0	0
Generalised oedema	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Oedema peripheral	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Catheter site pain	1 (5.0)	0	1 (5.0)	0	0
Chills	1 (5.0)	1 (5.0)	0	0	0
Pain	1 (5.0)	0	1 (5.0)	0	0
Immune system disorders					
-Total	16 (80.0)	1 (5.0)	7 (35.0)	3 (15.0)	5 (25.0)
Cytokine release syndrome	16 (80.0)	2 (10.0)	7 (35.0)	2 (10.0)	5 (25.0)
Hypogammaglobulinaemia	9 (45.0)	0	7 (35.0)	2 (10.0)	0
Immunodeficiency common variable	2 (10.0)	0	2 (10.0)	0	0
Infections and infestations					
-Total	13 (65.0)	1 (5.0)	7 (35.0)	5 (25.0)	0
Gastroenteritis	3 (15.0)	0	2 (10.0)	1 (5.0)	0
Influenza	3 (15.0)	1 (5.0)	2 (10.0)	0	0
Clostridium difficile infection	2 (10.0)	0	2 (10.0)	0	0
Otitis media	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Pneumonia	2 (10.0)	0	1 (5.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Urinary tract infection	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Rhinovirus infection	1 (5.0)	1 (5.0)	0	0	0
Upper respiratory tract infection	1 (5.0)	1 (5.0)	0	0	0
Viral infection	1 (5.0)	1 (5.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (5.0)	1 (5.0)	0	0	0
Contusion	1 (5.0)	1 (5.0)	0	0	0
Investigations					
-Total	16 (80.0)	0	0	4 (20.0)	12 (60.0)
White blood cell count decreased	11 (55.0)	2 (10.0)	0	5 (25.0)	4 (20.0)
Neutrophil count decreased	9 (45.0)	0	0	2 (10.0)	7 (35.0)
Platelet count decreased	9 (45.0)	0	2 (10.0)	1 (5.0)	6 (30.0)
Alanine aminotransferase increased	7 (35.0)	2 (10.0)	1 (5.0)	4 (20.0)	0
Aspartate aminotransferase increased	7 (35.0)	1 (5.0)	2 (10.0)	3 (15.0)	1 (5.0)
Lymphocyte count decreased	6 (30.0)	0	0	3 (15.0)	3 (15.0)
Blood creatinine increased	4 (20.0)	2 (10.0)	1 (5.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	3 (15.0)	1 (5.0)	2 (10.0)	0	0
International normalised ratio increased	3 (15.0)	3 (15.0)	0	0	0
Prothrombin time prolonged	3 (15.0)	3 (15.0)	0	0	0
Blood bilirubin increased	2 (10.0)	0	2 (10.0)	0	0
Blood fibrinogen decreased	1 (5.0)	0	0	0	1 (5.0)
Blood immunoglobulin a decreased	1 (5.0)	1 (5.0)	0	0	0
Blood immunoglobulin m decreased	1 (5.0)	1 (5.0)	0	0	0
Blood phosphorus increased	1 (5.0)	1 (5.0)	0	0	0
Metabolism and nutrition disorders					
-Total	12 (60.0)	3 (15.0)	0	6 (30.0)	3 (15.0)
Decreased appetite	5 (25.0)	1 (5.0)	1 (5.0)	3 (15.0)	0
Hypokalaemia	5 (25.0)	1 (5.0)	0	3 (15.0)	1 (5.0)
Hyperphosphataemia	4 (20.0)	4 (20.0)	0	0	0
Hypernatraemia	3 (15.0)	1 (5.0)	1 (5.0)	0	1 (5.0)
Hypophosphataemia	3 (15.0)	1 (5.0)	0	2 (10.0)	0
Acidosis	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Dehydration	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Hyperglycaemia	2 (10.0)	0	1 (5.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	2 (10.0)	1 (5.0)	0	0	1 (5.0)
Hypoalbuminaemia	1 (5.0)	0	1 (5.0)	0	0
Hypocalcaemia	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (25.0)	3 (15.0)	2 (10.0)	0	0
Arthralgia	2 (10.0)	2 (10.0)	0	0	0
Muscular weakness	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Musculoskeletal chest pain	2 (10.0)	2 (10.0)	0	0	0
Pain in extremity	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Nervous system disorders					
-Total	13 (65.0)	6 (30.0)	5 (25.0)	2 (10.0)	0
Headache	9 (45.0)	6 (30.0)	3 (15.0)	0	0
Dysarthria	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Encephalopathy	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Seizure	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Tremor	2 (10.0)	2 (10.0)	0	0	0
Dizziness	1 (5.0)	1 (5.0)	0	0	0
Psychiatric disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (20.0)	2 (10.0)	2 (10.0)	0	0
Delirium	2 (10.0)	0	2 (10.0)	0	0
Anxiety	1 (5.0)	0	1 (5.0)	0	0
Confusional state	1 (5.0)	1 (5.0)	0	0	0
Depression	1 (5.0)	1 (5.0)	0	0	0
Renal and urinary disorders					
-Total	5 (25.0)	1 (5.0)	1 (5.0)	3 (15.0)	0
Acute kidney injury	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0
Haematuria	1 (5.0)	0	0	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (55.0)	5 (25.0)	0	5 (25.0)	1 (5.0)
Epistaxis	5 (25.0)	2 (10.0)	1 (5.0)	2 (10.0)	0
Pulmonary oedema	4 (20.0)	1 (5.0)	0	2 (10.0)	1 (5.0)
Pleural effusion	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Tachypnoea	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Cough	2 (10.0)	2 (10.0)	0	0	0
Hypoxia	2 (10.0)	0	0	2 (10.0)	0
Nasal congestion	2 (10.0)	2 (10.0)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Haemoptysis	1 (5.0)	1 (5.0)	0	0	0
Respiratory failure	1 (5.0)	0	0	0	1 (5.0)
Rhinorrhoea	1 (5.0)	1 (5.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (55.0)	10 (50.0)	1 (5.0)	0	0
Dry skin	4 (20.0)	4 (20.0)	0	0	0
Hyperhidrosis	3 (15.0)	3 (15.0)	0	0	0
Petechiae	3 (15.0)	3 (15.0)	0	0	0
Rash	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Papule	2 (10.0)	2 (10.0)	0	0	0
Erythema	1 (5.0)	1 (5.0)	0	0	0
Rash erythematous	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	4 (20.0)	0	0	1 (5.0)	3 (15.0)
Hypotension	4 (20.0)	0	0	1 (5.0)	3 (15.0)
Hypertension	2 (10.0)	1 (5.0)	1 (5.0)	0	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

			All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (100)	0	1 (4.8)	6 (28.6)	14 (66.7)
Blood and lymphatic system disorders					
-Total	15 (71.4)	0	1 (4.8)	8 (38.1)	6 (28.6)
Febrile neutropenia	9 (42.9)	0	0	8 (38.1)	1 (4.8)
Anaemia	7 (33.3)	0	2 (9.5)	5 (23.8)	0
Thrombocytopenia	5 (23.8)	0	1 (4.8)	0	4 (19.0)
Neutropenia	4 (19.0)	0	0	2 (9.5)	2 (9.5)
Disseminated intravascular coagulation	1 (4.8)	0	1 (4.8)	0	0
Cardiac disorders					
-Total	6 (28.6)	2 (9.5)	4 (19.0)	0	0
Tachycardia	5 (23.8)	2 (9.5)	3 (14.3)	0	0
Sinus tachycardia	1 (4.8)	0	1 (4.8)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eye disorders					
-Total	4 (19.0)	2 (9.5)	2 (9.5)	0	0
Eye pain	2 (9.5)	0	2 (9.5)	0	0
Vision blurred	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Conjunctival haemorrhage	1 (4.8)	1 (4.8)	0	0	0
Periorbital oedema	1 (4.8)	1 (4.8)	0	0	0
Gastrointestinal disorders					
-Total	11 (52.4)	4 (19.0)	4 (19.0)	3 (14.3)	0
Nausea	8 (38.1)	1 (4.8)	5 (23.8)	2 (9.5)	0
Vomiting	8 (38.1)	4 (19.0)	2 (9.5)	2 (9.5)	0
Diarrhoea	7 (33.3)	4 (19.0)	2 (9.5)	1 (4.8)	0
Abdominal pain	2 (9.5)	1 (4.8)	0	1 (4.8)	0
Constipation	1 (4.8)	0	1 (4.8)	0	0
General disorders and administration site conditions					
-Total	12 (57.1)	5 (23.8)	7 (33.3)	0	0
Pyrexia	8 (38.1)	2 (9.5)	6 (28.6)	0	0
Chills	6 (28.6)	5 (23.8)	1 (4.8)	0	0
Fatigue	3 (14.3)	2 (9.5)	1 (4.8)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Malaise	3 (14.3)	1 (4.8)	2 (9.5)	0	0
Catheter site pain	1 (4.8)	0	1 (4.8)	0	0
Hepatobiliary disorders					
-Total	1 (4.8)	1 (4.8)	0	0	0
Hepatomegaly	1 (4.8)	1 (4.8)	0	0	0
Immune system disorders					
-Total	20 (95.2)	0	13 (61.9)	6 (28.6)	1 (4.8)
Cytokine release syndrome	18 (85.7)	1 (4.8)	12 (57.1)	4 (19.0)	1 (4.8)
Hypogammaglobulinaemia	12 (57.1)	1 (4.8)	8 (38.1)	3 (14.3)	0
Infections and infestations					
-Total	9 (42.9)	2 (9.5)	7 (33.3)	0	0
Rhinovirus infection	3 (14.3)	3 (14.3)	0	0	0
Pneumonia	2 (9.5)	0	2 (9.5)	0	0
Upper respiratory tract infection	2 (9.5)	0	2 (9.5)	0	0
Clostridium difficile infection	1 (4.8)	0	1 (4.8)	0	0
Gastroenteritis	1 (4.8)	1 (4.8)	0	0	0
Influenza	1 (4.8)	0	1 (4.8)	0	0
Urinary tract infection	1 (4.8)	0	1 (4.8)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	3 (14.3)	2 (9.5)	0	1 (4.8)	0
Procedural pain	3 (14.3)	2 (9.5)	0	1 (4.8)	0
Infusion related reaction	1 (4.8)	1 (4.8)	0	0	0
Investigations					
-Total	19 (90.5)	1 (4.8)	0	8 (38.1)	10 (47.6)
White blood cell count decreased	13 (61.9)	0	0	5 (23.8)	8 (38.1)
Alanine aminotransferase increased	9 (42.9)	2 (9.5)	0	7 (33.3)	0
Neutrophil count decreased	8 (38.1)	0	0	2 (9.5)	6 (28.6)
Aspartate aminotransferase increased	6 (28.6)	2 (9.5)	0	4 (19.0)	0
Platelet count decreased	6 (28.6)	2 (9.5)	0	2 (9.5)	2 (9.5)
Lymphocyte count decreased	4 (19.0)	0	0	2 (9.5)	2 (9.5)
Prothrombin time prolonged	4 (19.0)	2 (9.5)	1 (4.8)	1 (4.8)	0
Transaminases increased	3 (14.3)	3 (14.3)	0	0	0
Weight decreased	3 (14.3)	0	3 (14.3)	0	0
Blood bilirubin increased	2 (9.5)	0	1 (4.8)	1 (4.8)	0
Blood fibrinogen decreased	2 (9.5)	0	0	2 (9.5)	0
International normalised ratio increased	2 (9.5)	1 (4.8)	0	1 (4.8)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	1 (4.8)	1 (4.8)	0	0	0
Blood immunoglobulin m decreased	1 (4.8)	1 (4.8)	0	0	0
Metabolism and nutrition disorders					
-Total	14 (66.7)	1 (4.8)	3 (14.3)	9 (42.9)	1 (4.8)
Decreased appetite	9 (42.9)	1 (4.8)	2 (9.5)	6 (28.6)	0
Hypokalaemia	6 (28.6)	1 (4.8)	2 (9.5)	3 (14.3)	0
Hypophosphataemia	4 (19.0)	0	0	3 (14.3)	1 (4.8)
Hyperphosphataemia	2 (9.5)	2 (9.5)	0	0	0
Dehydration	1 (4.8)	0	0	1 (4.8)	0
Fluid overload	1 (4.8)	0	1 (4.8)	0	0
Hyperglycaemia	1 (4.8)	0	0	1 (4.8)	0
Hypoalbuminaemia	1 (4.8)	0	0	1 (4.8)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (19.0)	3 (14.3)	1 (4.8)	0	0
Pain in extremity	3 (14.3)	2 (9.5)	1 (4.8)	0	0
Arthralgia	1 (4.8)	0	1 (4.8)	0	0
Myalgia	1 (4.8)	1 (4.8)	0	0	0
Nervous system disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (42.9)	4 (19.0)	3 (14.3)	2 (9.5)	0
Headache	6 (28.6)	3 (14.3)	1 (4.8)	2 (9.5)	0
Dizziness	2 (9.5)	2 (9.5)	0	0	0
Encephalopathy	1 (4.8)	0	0	1 (4.8)	0
Peroneal nerve palsy	1 (4.8)	0	1 (4.8)	0	0
Seizure	1 (4.8)	0	1 (4.8)	0	0
Psychiatric disorders					
-Total	5 (23.8)	3 (14.3)	2 (9.5)	0	0
Anxiety	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Confusional state	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Delirium	1 (4.8)	1 (4.8)	0	0	0
Renal and urinary disorders					
-Total	3 (14.3)	0	0	2 (9.5)	1 (4.8)
Acute kidney injury	3 (14.3)	0	0	2 (9.5)	1 (4.8)
Haematuria	1 (4.8)	0	1 (4.8)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (42.9)	3 (14.3)	3 (14.3)	1 (4.8)	2 (9.5)
Cough	5 (23.8)	4 (19.0)	1 (4.8)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	3 (14.3)	0	1 (4.8)	1 (4.8)	1 (4.8)
Rhinitis allergic	3 (14.3)	2 (9.5)	1 (4.8)	0	0
Pleural effusion	2 (9.5)	1 (4.8)	0	1 (4.8)	0
Rhinorrhoea	2 (9.5)	2 (9.5)	0	0	0
Epistaxis	1 (4.8)	1 (4.8)	0	0	0
Nasal congestion	1 (4.8)	1 (4.8)	0	0	0
Oropharyngeal pain	1 (4.8)	1 (4.8)	0	0	0
Pulmonary oedema	1 (4.8)	0	0	1 (4.8)	0
Respiratory failure	1 (4.8)	0	0	0	1 (4.8)
Tachypnoea	1 (4.8)	1 (4.8)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (23.8)	2 (9.5)	2 (9.5)	1 (4.8)	0
Erythema	2 (9.5)	2 (9.5)	0	0	0
Rash	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Rash maculo-papular	2 (9.5)	0	1 (4.8)	1 (4.8)	0
Hyperhidrosis	1 (4.8)	1 (4.8)	0	0	0
Vascular disorders					
-Total	7 (33.3)	1 (4.8)	2 (9.5)	3 (14.3)	1 (4.8)
Hypertension	4 (19.0)	1 (4.8)	3 (14.3)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	4 (19.0)	0	0	3 (14.3)	1 (4.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 184r
Adverse events post CTL019 infusion, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

			All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (100)	0	3 (18.8)	3 (18.8)	10 (62.5)
Blood and lymphatic system disorders					
-Total	11 (68.8)	0	1 (6.3)	7 (43.8)	3 (18.8)
Anaemia	8 (50.0)	1 (6.3)	1 (6.3)	6 (37.5)	0
Febrile neutropenia	3 (18.8)	0	0	3 (18.8)	0
Thrombocytopenia	3 (18.8)	0	0	2 (12.5)	1 (6.3)
Neutropenia	2 (12.5)	0	0	0	2 (12.5)
Cardiac disorders					
-Total	7 (43.8)	4 (25.0)	2 (12.5)	1 (6.3)	0
Tachycardia	5 (31.3)	3 (18.8)	1 (6.3)	1 (6.3)	0
Sinus tachycardia	3 (18.8)	2 (12.5)	1 (6.3)	0	0
Ear and labyrinth disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (12.5)	2 (12.5)	0	0	0
Ear pain	2 (12.5)	2 (12.5)	0	0	0
Eye disorders					
-Total	1 (6.3)	0	1 (6.3)	0	0
Periorbital oedema	1 (6.3)	0	1 (6.3)	0	0
Gastrointestinal disorders					
-Total	10 (62.5)	3 (18.8)	7 (43.8)	0	0
Vomiting	7 (43.8)	5 (31.3)	2 (12.5)	0	0
Diarrhoea	6 (37.5)	3 (18.8)	3 (18.8)	0	0
Nausea	6 (37.5)	2 (12.5)	4 (25.0)	0	0
Abdominal pain	5 (31.3)	2 (12.5)	3 (18.8)	0	0
Abdominal distension	2 (12.5)	0	2 (12.5)	0	0
General disorders and administration site conditions					
-Total	11 (68.8)	5 (31.3)	4 (25.0)	2 (12.5)	0
Pyrexia	7 (43.8)	4 (25.0)	2 (12.5)	1 (6.3)	0
Fatigue	6 (37.5)	4 (25.0)	1 (6.3)	1 (6.3)	0
Chills	2 (12.5)	2 (12.5)	0	0	0
Pain	2 (12.5)	1 (6.3)	0	1 (6.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site pain	1 (6.3)	1 (6.3)	0	0	0
Generalised oedema	1 (6.3)	0	1 (6.3)	0	0
Malaise	1 (6.3)	0	1 (6.3)	0	0
Oedema peripheral	1 (6.3)	1 (6.3)	0	0	0
Hepatobiliary disorders					
-Total	1 (6.3)	0	1 (6.3)	0	0
Hepatomegaly	1 (6.3)	0	1 (6.3)	0	0
Immune system disorders					
-Total	15 (93.8)	4 (25.0)	7 (43.8)	2 (12.5)	2 (12.5)
Cytokine release syndrome	11 (68.8)	3 (18.8)	4 (25.0)	2 (12.5)	2 (12.5)
Hypogammaglobulinaemia	7 (43.8)	2 (12.5)	5 (31.3)	0	0
Graft versus host disease	1 (6.3)	1 (6.3)	0	0	0
Infections and infestations					
-Total	8 (50.0)	2 (12.5)	3 (18.8)	3 (18.8)	0
Upper respiratory tract infection	4 (25.0)	3 (18.8)	0	1 (6.3)	0
Clostridium difficile infection	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Otitis media	2 (12.5)	0	2 (12.5)	0	0
Urinary tract infection	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Vulvovaginal candidiasis	2 (12.5)	1 (6.3)	1 (6.3)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ear infection	1 (6.3)	0	1 (6.3)	0	0
Skin infection	1 (6.3)	0	1 (6.3)	0	0
Injury, poisoning and procedural complications					
-Total	4 (25.0)	1 (6.3)	3 (18.8)	0	0
Infusion related reaction	2 (12.5)	0	2 (12.5)	0	0
Procedural pain	2 (12.5)	0	2 (12.5)	0	0
Contusion	1 (6.3)	1 (6.3)	0	0	0
Investigations					
-Total	11 (68.8)	0	3 (18.8)	0	8 (50.0)
Neutrophil count decreased	7 (43.8)	1 (6.3)	1 (6.3)	0	5 (31.3)
White blood cell count decreased	7 (43.8)	1 (6.3)	1 (6.3)	2 (12.5)	3 (18.8)
Aspartate aminotransferase increased	6 (37.5)	1 (6.3)	2 (12.5)	1 (6.3)	2 (12.5)
Alanine aminotransferase increased	5 (31.3)	1 (6.3)	1 (6.3)	3 (18.8)	0
Platelet count decreased	5 (31.3)	1 (6.3)	0	0	4 (25.0)
Lymphocyte count decreased	4 (25.0)	0	2 (12.5)	2 (12.5)	0
Blood bilirubin increased	3 (18.8)	2 (12.5)	0	1 (6.3)	0
Blood creatinine increased	3 (18.8)	2 (12.5)	0	1 (6.3)	0
International normalised ratio increased	3 (18.8)	3 (18.8)	0	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin a decreased	2 (12.5)	2 (12.5)	0	0	0
Activated partial thromboplastin time prolonged	1 (6.3)	1 (6.3)	0	0	0
Blood immunoglobulin m decreased	1 (6.3)	1 (6.3)	0	0	0
Blood uric acid increased	1 (6.3)	1 (6.3)	0	0	0
Prothrombin time prolonged	1 (6.3)	0	1 (6.3)	0	0
Metabolism and nutrition disorders					
-Total	10 (62.5)	2 (12.5)	3 (18.8)	5 (31.3)	0
Hypokalaemia	6 (37.5)	1 (6.3)	3 (18.8)	2 (12.5)	0
Decreased appetite	5 (31.3)	2 (12.5)	1 (6.3)	2 (12.5)	0
Fluid overload	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Hyperphosphataemia	2 (12.5)	2 (12.5)	0	0	0
Hypoalbuminaemia	2 (12.5)	0	2 (12.5)	0	0
Hypocalcaemia	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Hypophosphataemia	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Dehydration	1 (6.3)	0	0	1 (6.3)	0
Hyperuricaemia	1 (6.3)	1 (6.3)	0	0	0
Musculoskeletal and connective tissue disorders					

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (43.8)	4 (25.0)	3 (18.8)	0	0
Myalgia	4 (25.0)	3 (18.8)	1 (6.3)	0	0
Pain in extremity	4 (25.0)	2 (12.5)	2 (12.5)	0	0
Joint range of motion decreased	2 (12.5)	2 (12.5)	0	0	0
Muscle spasms	2 (12.5)	2 (12.5)	0	0	0
Arthralgia	1 (6.3)	1 (6.3)	0	0	0
Nervous system disorders					
-Total	8 (50.0)	5 (31.3)	2 (12.5)	1 (6.3)	0
Headache	6 (37.5)	3 (18.8)	3 (18.8)	0	0
Dizziness	2 (12.5)	2 (12.5)	0	0	0
Encephalopathy	1 (6.3)	1 (6.3)	0	0	0
Seizure	1 (6.3)	0	0	1 (6.3)	0
Psychiatric disorders					
-Total	3 (18.8)	1 (6.3)	1 (6.3)	1 (6.3)	0
Anxiety	3 (18.8)	1 (6.3)	1 (6.3)	1 (6.3)	0
Confusional state	1 (6.3)	0	1 (6.3)	0	0
Renal and urinary disorders					
-Total	1 (6.3)	0	0	0	1 (6.3)
Acute kidney injury	1 (6.3)	0	0	0	1 (6.3)

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	1 (6.3)	0	1 (6.3)	0	0
Oliguria	1 (6.3)	0	0	1 (6.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (56.3)	4 (25.0)	3 (18.8)	1 (6.3)	1 (6.3)
Cough	4 (25.0)	3 (18.8)	1 (6.3)	0	0
Hypoxia	3 (18.8)	0	2 (12.5)	0	1 (6.3)
Epistaxis	2 (12.5)	1 (6.3)	0	1 (6.3)	0
Oropharyngeal pain	2 (12.5)	2 (12.5)	0	0	0
Pleural effusion	2 (12.5)	0	2 (12.5)	0	0
Dyspnoea	1 (6.3)	0	0	1 (6.3)	0
Nasal congestion	1 (6.3)	1 (6.3)	0	0	0
Pulmonary oedema	1 (6.3)	0	0	1 (6.3)	0
Rhinitis allergic	1 (6.3)	1 (6.3)	0	0	0
Rhinorrhoea	1 (6.3)	1 (6.3)	0	0	0
Tachypnoea	1 (6.3)	0	0	1 (6.3)	0
Skin and subcutaneous tissue disorders					
-Total	5 (31.3)	3 (18.8)	2 (12.5)	0	0
Rash	3 (18.8)	2 (12.5)	1 (6.3)	0	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash maculo-papular	2 (12.5)	2 (12.5)	0	0	0
Petechiae	1 (6.3)	0	1 (6.3)	0	0
Vascular disorders					
-Total	6 (37.5)	1 (6.3)	2 (12.5)	1 (6.3)	2 (12.5)
Hypotension	4 (25.0)	1 (6.3)	0	1 (6.3)	2 (12.5)
Hypertension	3 (18.8)	0	2 (12.5)	1 (6.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185a
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (77.3)	1 (4.5)	3 (13.6)	5 (22.7)	8 (36.4)
Blood and lymphatic system disorders					
-Total	12 (54.5)	0	0	8 (36.4)	4 (18.2)
Anaemia	7 (31.8)	0	1 (4.5)	6 (27.3)	0
Febrile neutropenia	5 (22.7)	0	0	5 (22.7)	0
Thrombocytopenia	3 (13.6)	0	0	1 (4.5)	2 (9.1)
Neutropenia	2 (9.1)	0	0	0	2 (9.1)
Gastrointestinal disorders					
-Total	1 (4.5)	0	1 (4.5)	0	0
Nausea	1 (4.5)	0	1 (4.5)	0	0

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Catheter site pain	1 (4.5)	0	1 (4.5)	0	0
Pain	1 (4.5)	0	1 (4.5)	0	0
Pyrexia	1 (4.5)	1 (4.5)	0	0	0
Investigations					
-Total	7 (31.8)	1 (4.5)	0	1 (4.5)	5 (22.7)
Neutrophil count decreased	4 (18.2)	0	0	0	4 (18.2)
White blood cell count decreased	4 (18.2)	1 (4.5)	0	0	3 (13.6)
Platelet count decreased	3 (13.6)	0	0	0	3 (13.6)
Alanine aminotransferase increased	1 (4.5)	0	0	1 (4.5)	0
Aspartate aminotransferase increased	1 (4.5)	0	0	1 (4.5)	0
Metabolism and nutrition disorders					
-Total	4 (18.2)	0	1 (4.5)	2 (9.1)	1 (4.5)
Hyperuricaemia	4 (18.2)	2 (9.1)	0	1 (4.5)	1 (4.5)
Decreased appetite	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Hyperglycaemia	1 (4.5)	0	0	1 (4.5)	0

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal and connective tissue disorders					
-Total	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Pain in extremity	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (4.5)	0	1 (4.5)	0	0
Hypoxia	1 (4.5)	0	1 (4.5)	0	0
Pleural effusion	1 (4.5)	0	1 (4.5)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185a
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (69.2)	1 (2.6)	0	14 (35.9)	12 (30.8)
Blood and lymphatic system disorders					
-Total	20 (51.3)	0	0	17 (43.6)	3 (7.7)
Febrile neutropenia	12 (30.8)	0	0	12 (30.8)	0
Anaemia	9 (23.1)	0	1 (2.6)	8 (20.5)	0
Thrombocytopenia	4 (10.3)	0	0	1 (2.6)	3 (7.7)
Neutropenia	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Cardiac disorders					
-Total	1 (2.6)	0	1 (2.6)	0	0
Tachycardia	1 (2.6)	0	1 (2.6)	0	0
Gastrointestinal disorders					

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	16 (41.0)	5 (12.8)	6 (15.4)	4 (10.3)	1 (2.6)
Abdominal pain	6 (15.4)	0	4 (10.3)	2 (5.1)	0
Vomiting	6 (15.4)	4 (10.3)	2 (5.1)	0	0
Stomatitis	5 (12.8)	1 (2.6)	0	3 (7.7)	1 (2.6)
Constipation	3 (7.7)	1 (2.6)	2 (5.1)	0	0
Nausea	3 (7.7)	0	2 (5.1)	1 (2.6)	0
General disorders and administration site conditions					
-Total	10 (25.6)	6 (15.4)	3 (7.7)	1 (2.6)	0
Fatigue	5 (12.8)	3 (7.7)	1 (2.6)	1 (2.6)	0
Pyrexia	5 (12.8)	3 (7.7)	2 (5.1)	0	0
Catheter site pain	1 (2.6)	1 (2.6)	0	0	0
Hepatobiliary disorders					
-Total	1 (2.6)	0	1 (2.6)	0	0
Hyperbilirubinaemia	1 (2.6)	0	1 (2.6)	0	0
Investigations					
-Total	15 (38.5)	0	2 (5.1)	3 (7.7)	10 (25.6)
Platelet count decreased	6 (15.4)	0	0	1 (2.6)	5 (12.8)

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	6 (15.4)	0	1 (2.6)	1 (2.6)	4 (10.3)
Alanine aminotransferase increased	5 (12.8)	0	1 (2.6)	4 (10.3)	0
Aspartate aminotransferase increased	4 (10.3)	1 (2.6)	1 (2.6)	2 (5.1)	0
Neutrophil count decreased	4 (10.3)	0	0	0	4 (10.3)
Metabolism and nutrition disorders					
-Total	6 (15.4)	1 (2.6)	1 (2.6)	3 (7.7)	1 (2.6)
Decreased appetite	4 (10.3)	1 (2.6)	1 (2.6)	2 (5.1)	0
Hyperglycaemia	3 (7.7)	0	0	2 (5.1)	1 (2.6)
Musculoskeletal and connective tissue disorders					
-Total	4 (10.3)	1 (2.6)	1 (2.6)	2 (5.1)	0
Pain in extremity	4 (10.3)	1 (2.6)	1 (2.6)	2 (5.1)	0
Nervous system disorders					
-Total	7 (17.9)	2 (5.1)	2 (5.1)	3 (7.7)	0
Headache	7 (17.9)	2 (5.1)	2 (5.1)	3 (7.7)	0
Renal and urinary disorders					
-Total	1 (2.6)	0	0	0	1 (2.6)
Acute kidney injury	1 (2.6)	0	0	0	1 (2.6)

Age: >=10 years to <18 years

Group term Preferred term	All patients N=39 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	4 (10.3)	0	2 (5.1)	1 (2.6)	1 (2.6)
Hypoxia	3 (7.7)	0	2 (5.1)	0	1 (2.6)
Cough	1 (2.6)	1 (2.6)	0	0	0
Epistaxis	1 (2.6)	0	0	1 (2.6)	0
Vascular disorders					
-Total	6 (15.4)	1 (2.6)	0	4 (10.3)	1 (2.6)
Hypotension	5 (12.8)	0	0	4 (10.3)	1 (2.6)
Hypertension	1 (2.6)	1 (2.6)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185a
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (85.7)	0	1 (7.1)	6 (42.9)	5 (35.7)
Blood and lymphatic system disorders					
-Total	6 (42.9)	0	0	4 (28.6)	2 (14.3)
Anaemia	5 (35.7)	0	0	5 (35.7)	0
Thrombocytopenia	3 (21.4)	0	0	1 (7.1)	2 (14.3)
Neutropenia	2 (14.3)	0	0	0	2 (14.3)
Febrile neutropenia	1 (7.1)	0	0	1 (7.1)	0
Cardiac disorders					
-Total	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Pericardial effusion	2 (14.3)	0	2 (14.3)	0	0

Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Gastrointestinal disorders					
-Total	6 (42.9)	0	4 (28.6)	2 (14.3)	0
Nausea	6 (42.9)	0	4 (28.6)	2 (14.3)	0
Abdominal pain	3 (21.4)	1 (7.1)	1 (7.1)	1 (7.1)	0
Vomiting	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Constipation	2 (14.3)	2 (14.3)	0	0	0
General disorders and administration site conditions					
-Total	8 (57.1)	2 (14.3)	4 (28.6)	2 (14.3)	0
Pyrexia	6 (42.9)	2 (14.3)	2 (14.3)	2 (14.3)	0
Catheter site pain	2 (14.3)	0	2 (14.3)	0	0
Fatigue	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Pain	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Hepatobiliary disorders					
-Total	2 (14.3)	0	0	2 (14.3)	0
Hyperbilirubinaemia	2 (14.3)	0	0	2 (14.3)	0
Investigations					

Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (28.6)	0	0	1 (7.1)	3 (21.4)
Blood lactate dehydrogenase increased	2 (14.3)	0	0	2 (14.3)	0
White blood cell count decreased	2 (14.3)	0	0	0	2 (14.3)
Neutrophil count decreased	1 (7.1)	0	0	0	1 (7.1)
Platelet count decreased	1 (7.1)	0	0	0	1 (7.1)
Metabolism and nutrition disorders					
-Total	6 (42.9)	0	5 (35.7)	1 (7.1)	0
Hyperglycaemia	3 (21.4)	0	3 (21.4)	0	0
Decreased appetite	2 (14.3)	0	2 (14.3)	0	0
Fluid overload	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (21.4)	0	0	3 (21.4)	0
Pain in extremity	3 (21.4)	0	0	3 (21.4)	0
Nervous system disorders					
-Total	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Headache	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Psychiatric disorders					

Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (14.3)	0	2 (14.3)	0	0
Anxiety	2 (14.3)	0	2 (14.3)	0	0
Renal and urinary disorders					
-Total	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Acute kidney injury	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (28.6)	0	2 (14.3)	2 (14.3)	0
Hypoxia	3 (21.4)	0	1 (7.1)	2 (14.3)	0
Cough	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Epistaxis	2 (14.3)	0	2 (14.3)	0	0
Oropharyngeal pain	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Pleural effusion	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Vascular disorders					
-Total	4 (28.6)	1 (7.1)	0	1 (7.1)	2 (14.3)
Hypertension	3 (21.4)	1 (7.1)	1 (7.1)	1 (7.1)	0
Hypotension	2 (14.3)	0	0	0	2 (14.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185b
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (70.0)	0	2 (5.0)	14 (35.0)	12 (30.0)
Blood and lymphatic system disorders					
-Total	20 (50.0)	0	0	15 (37.5)	5 (12.5)
Anaemia	11 (27.5)	0	0	11 (27.5)	0
Febrile neutropenia	9 (22.5)	0	0	9 (22.5)	0
Thrombocytopenia	6 (15.0)	0	0	1 (2.5)	5 (12.5)
Gastrointestinal disorders					
-Total	13 (32.5)	4 (10.0)	6 (15.0)	3 (7.5)	0
Vomiting	8 (20.0)	4 (10.0)	3 (7.5)	1 (2.5)	0
Abdominal pain	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Nausea	5 (12.5)	0	3 (7.5)	2 (5.0)	0

Gender: Male

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Constipation	1 (2.5)	1 (2.5)	0	0	0
General disorders and administration site conditions					
-Total	10 (25.0)	5 (12.5)	3 (7.5)	2 (5.0)	0
Pyrexia	9 (22.5)	4 (10.0)	3 (7.5)	2 (5.0)	0
Fatigue	3 (7.5)	3 (7.5)	0	0	0
Investigations					
-Total	10 (25.0)	0	0	1 (2.5)	9 (22.5)
Neutrophil count decreased	4 (10.0)	0	0	0	4 (10.0)
Platelet count decreased	4 (10.0)	0	0	1 (2.5)	3 (7.5)
White blood cell count decreased	4 (10.0)	0	0	0	4 (10.0)
Alanine aminotransferase increased	1 (2.5)	0	0	1 (2.5)	0
Metabolism and nutrition disorders					
-Total	9 (22.5)	0	4 (10.0)	3 (7.5)	2 (5.0)
Decreased appetite	4 (10.0)	0	2 (5.0)	2 (5.0)	0
Hyperglycaemia	4 (10.0)	0	2 (5.0)	1 (2.5)	1 (2.5)
Hypokalaemia	4 (10.0)	1 (2.5)	0	1 (2.5)	2 (5.0)
Musculoskeletal and connective tissue disorders					

Gender: Male

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Pain in extremity	5 (12.5)	1 (2.5)	1 (2.5)	3 (7.5)	0
Nervous system disorders					
-Total	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Headache	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (12.5)	0	2 (5.0)	2 (5.0)	1 (2.5)
Hypoxia	5 (12.5)	0	2 (5.0)	2 (5.0)	1 (2.5)
Vascular disorders					
-Total	6 (15.0)	0	0	3 (7.5)	3 (7.5)
Hypotension	6 (15.0)	0	0	3 (7.5)	3 (7.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185b
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (74.3)	3 (8.6)	3 (8.6)	10 (28.6)	10 (28.6)
Blood and lymphatic system disorders					
-Total	17 (48.6)	0	1 (2.9)	14 (40.0)	2 (5.7)
Anaemia	10 (28.6)	0	2 (5.7)	8 (22.9)	0
Febrile neutropenia	9 (25.7)	0	0	9 (25.7)	0
Thrombocytopenia	4 (11.4)	0	0	2 (5.7)	2 (5.7)
Gastrointestinal disorders					
-Total	8 (22.9)	1 (2.9)	5 (14.3)	2 (5.7)	0
Nausea	5 (14.3)	0	4 (11.4)	1 (2.9)	0
Abdominal pain	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Constipation	4 (11.4)	2 (5.7)	2 (5.7)	0	0

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (2.9)	0	1 (2.9)	0	0
General disorders and administration site conditions					
-Total	7 (20.0)	3 (8.6)	3 (8.6)	1 (2.9)	0
Fatigue	4 (11.4)	1 (2.9)	2 (5.7)	1 (2.9)	0
Pyrexia	3 (8.6)	2 (5.7)	1 (2.9)	0	0
Investigations					
-Total	14 (40.0)	1 (2.9)	2 (5.7)	2 (5.7)	9 (25.7)
White blood cell count decreased	8 (22.9)	1 (2.9)	1 (2.9)	1 (2.9)	5 (14.3)
Platelet count decreased	6 (17.1)	0	0	0	6 (17.1)
Alanine aminotransferase increased	5 (14.3)	0	1 (2.9)	4 (11.4)	0
Neutrophil count decreased	5 (14.3)	0	0	0	5 (14.3)
Metabolism and nutrition disorders					
-Total	7 (20.0)	1 (2.9)	3 (8.6)	3 (8.6)	0
Decreased appetite	4 (11.4)	1 (2.9)	2 (5.7)	1 (2.9)	0
Hyperglycaemia	3 (8.6)	0	1 (2.9)	2 (5.7)	0
Hypokalaemia	1 (2.9)	0	0	1 (2.9)	0
Musculoskeletal and connective tissue disorders					

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (11.4)	1 (2.9)	1 (2.9)	2 (5.7)	0
Pain in extremity	4 (11.4)	1 (2.9)	1 (2.9)	2 (5.7)	0
Nervous system disorders					
-Total	5 (14.3)	1 (2.9)	2 (5.7)	2 (5.7)	0
Headache	5 (14.3)	1 (2.9)	2 (5.7)	2 (5.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (5.7)	0	2 (5.7)	0	0
Hypoxia	2 (5.7)	0	2 (5.7)	0	0
Vascular disorders					
-Total	1 (2.9)	0	0	1 (2.9)	0
Hypotension	1 (2.9)	0	0	1 (2.9)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185c
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (75.0)	1 (1.7)	3 (5.0)	19 (31.7)	22 (36.7)
Blood and lymphatic system disorders					
-Total	32 (53.3)	1 (1.7)	0	23 (38.3)	8 (13.3)
Anaemia	17 (28.3)	0	2 (3.3)	15 (25.0)	0
Febrile neutropenia	15 (25.0)	0	0	15 (25.0)	0
Thrombocytopenia	8 (13.3)	0	0	2 (3.3)	6 (10.0)
Neutropenia	4 (6.7)	0	0	0	4 (6.7)
Coagulopathy	1 (1.7)	1 (1.7)	0	0	0
Disseminated intravascular coagulation	1 (1.7)	0	0	1 (1.7)	0
Cardiac disorders					

Race: White

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (8.3)	1 (1.7)	2 (3.3)	2 (3.3)	0
Tachycardia	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Bradycardia	1 (1.7)	1 (1.7)	0	0	0
Pericardial effusion	1 (1.7)	0	1 (1.7)	0	0
Sinus tachycardia	1 (1.7)	0	0	1 (1.7)	0
Gastrointestinal disorders					
-Total	16 (26.7)	4 (6.7)	8 (13.3)	3 (5.0)	1 (1.7)
Abdominal pain	6 (10.0)	1 (1.7)	4 (6.7)	1 (1.7)	0
Nausea	6 (10.0)	0	4 (6.7)	2 (3.3)	0
Vomiting	5 (8.3)	3 (5.0)	2 (3.3)	0	0
Stomatitis	4 (6.7)	1 (1.7)	0	2 (3.3)	1 (1.7)
Constipation	3 (5.0)	2 (3.3)	1 (1.7)	0	0
General disorders and administration site conditions					
-Total	18 (30.0)	7 (11.7)	7 (11.7)	3 (5.0)	1 (1.7)
Pyrexia	9 (15.0)	4 (6.7)	3 (5.0)	2 (3.3)	0
Fatigue	7 (11.7)	4 (6.7)	2 (3.3)	1 (1.7)	0
Catheter site pain	3 (5.0)	1 (1.7)	2 (3.3)	0	0

Race: White

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Multiple organ dysfunction syndrome	1 (1.7)	0	0	0	1 (1.7)
Non-cardiac chest pain	1 (1.7)	1 (1.7)	0	0	0
Hepatobiliary disorders					
-Total	1 (1.7)	0	0	1 (1.7)	0
Hyperbilirubinaemia	1 (1.7)	0	0	1 (1.7)	0
Immune system disorders					
-Total	1 (1.7)	0	0	1 (1.7)	0
Anaphylactic reaction	1 (1.7)	0	0	1 (1.7)	0
Infections and infestations					
-Total	7 (11.7)	0	3 (5.0)	3 (5.0)	1 (1.7)
Oral herpes	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Conjunctivitis	1 (1.7)	0	1 (1.7)	0	0
Device related infection	1 (1.7)	0	0	1 (1.7)	0
Escherichia urinary tract infection	1 (1.7)	0	1 (1.7)	0	0
Klebsiella sepsis	1 (1.7)	0	0	0	1 (1.7)
Pneumonia fungal	1 (1.7)	0	0	1 (1.7)	0

Race: White

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Procedural pain	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Subdural haematoma	1 (1.7)	0	1 (1.7)	0	0
Investigations					
-Total	21 (35.0)	1 (1.7)	1 (1.7)	4 (6.7)	15 (25.0)
Platelet count decreased	9 (15.0)	0	0	1 (1.7)	8 (13.3)
White blood cell count decreased	9 (15.0)	1 (1.7)	0	1 (1.7)	7 (11.7)
Neutrophil count decreased	7 (11.7)	0	0	0	7 (11.7)
Alanine aminotransferase increased	4 (6.7)	0	1 (1.7)	3 (5.0)	0
Aspartate aminotransferase increased	3 (5.0)	1 (1.7)	0	2 (3.3)	0
Blood lactate dehydrogenase increased	1 (1.7)	0	0	1 (1.7)	0
Electrocardiogram qt prolonged	1 (1.7)	0	0	1 (1.7)	0
Metabolism and nutrition disorders					
-Total	15 (25.0)	1 (1.7)	6 (10.0)	6 (10.0)	2 (3.3)
Decreased appetite	7 (11.7)	0	4 (6.7)	3 (5.0)	0

Race: White

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	5 (8.3)	0	1 (1.7)	3 (5.0)	1 (1.7)
Dehydration	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Hypomagnesaemia	3 (5.0)	3 (5.0)	0	0	0
Hypocalcaemia	2 (3.3)	0	0	0	2 (3.3)
Hyperkalaemia	1 (1.7)	0	1 (1.7)	0	0
Tumour lysis syndrome	1 (1.7)	0	0	1 (1.7)	0
Vitamin d deficiency	1 (1.7)	0	1 (1.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	11 (18.3)	3 (5.0)	3 (5.0)	5 (8.3)	0
Pain in extremity	7 (11.7)	2 (3.3)	1 (1.7)	4 (6.7)	0
Neck pain	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Back pain	1 (1.7)	1 (1.7)	0	0	0
Bone pain	1 (1.7)	0	0	1 (1.7)	0
Pain in jaw	1 (1.7)	0	1 (1.7)	0	0
Nervous system disorders					
-Total	5 (8.3)	1 (1.7)	2 (3.3)	2 (3.3)	0
Headache	5 (8.3)	1 (1.7)	2 (3.3)	2 (3.3)	0

Race: White

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	4 (6.7)	3 (5.0)	1 (1.7)	0	0
Mental status changes	2 (3.3)	2 (3.3)	0	0	0
Anxiety	1 (1.7)	0	1 (1.7)	0	0
Depression	1 (1.7)	1 (1.7)	0	0	0
Renal and urinary disorders					
-Total	1 (1.7)	0	0	0	1 (1.7)
Acute kidney injury	1 (1.7)	0	0	0	1 (1.7)
Respiratory, thoracic and mediastinal disorders					
-Total	8 (13.3)	0	5 (8.3)	1 (1.7)	2 (3.3)
Hypoxia	6 (10.0)	0	4 (6.7)	1 (1.7)	1 (1.7)
Cough	2 (3.3)	2 (3.3)	0	0	0
Epistaxis	2 (3.3)	0	2 (3.3)	0	0
Oropharyngeal pain	1 (1.7)	1 (1.7)	0	0	0
Pulmonary oedema	1 (1.7)	0	0	0	1 (1.7)
Skin and subcutaneous tissue disorders					
-Total	2 (3.3)	0	2 (3.3)	0	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash erythematous	2 (3.3)	0	2 (3.3)	0	0
Vascular disorders					
-Total	8 (13.3)	2 (3.3)	0	4 (6.7)	2 (3.3)
Hypotension	6 (10.0)	0	0	4 (6.7)	2 (3.3)
Hypertension	2 (3.3)	2 (3.3)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185c
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	2 (33.3)	3 (50.0)	1 (16.7)
Blood and lymphatic system disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Anaemia	1 (16.7)	0	0	1 (16.7)	0
Gastrointestinal disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Dry mouth	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	1 (16.7)	1 (16.7)	0	0	0
Oedema peripheral	1 (16.7)	1 (16.7)	0	0	0

Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (16.7)	1 (16.7)	0	0	0
Infections and infestations					
-Total	4 (66.7)	0	0	4 (66.7)	0
Alpha haemolytic streptococcal infection	1 (16.7)	0	0	1 (16.7)	0
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Device related infection	1 (16.7)	0	0	1 (16.7)	0
Escherichia infection	1 (16.7)	0	0	1 (16.7)	0
Gastroenteritis	1 (16.7)	0	0	1 (16.7)	0
Oral herpes	1 (16.7)	0	1 (16.7)	0	0
Staphylococcal infection	1 (16.7)	0	0	1 (16.7)	0
Streptococcal infection	1 (16.7)	0	0	1 (16.7)	0
Investigations					
-Total	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Blood fibrinogen decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin m decreased	1 (16.7)	1 (16.7)	0	0	0
Neutrophil count decreased	1 (16.7)	0	0	0	1 (16.7)
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)

Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (16.7)	0	0	0	1 (16.7)
Metabolism and nutrition disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Dehydration	1 (16.7)	0	0	1 (16.7)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (33.3)	0	2 (33.3)	0	0
Bone pain	1 (16.7)	0	1 (16.7)	0	0
Pain in extremity	1 (16.7)	0	1 (16.7)	0	0
Pain in jaw	1 (16.7)	0	1 (16.7)	0	0
Nervous system disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Headache	1 (16.7)	1 (16.7)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
/vob/CCTL019/haq/haq_eu_5/pgm/saf/t185_gd_b2205.sas@@/main/3 29SEP20:17:54 Final

Table 185c
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (88.9)	0	0	4 (44.4)	4 (44.4)
Blood and lymphatic system disorders					
-Total	8 (88.9)	0	0	5 (55.6)	3 (33.3)
Anaemia	3 (33.3)	0	0	3 (33.3)	0
Febrile neutropenia	3 (33.3)	0	0	3 (33.3)	0
Neutropenia	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Pancytopenia	2 (22.2)	0	0	0	2 (22.2)
Thrombocytopenia	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Coagulopathy	1 (11.1)	0	0	1 (11.1)	0
Disseminated intravascular coagulation	1 (11.1)	0	0	1 (11.1)	0

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukocytosis	1 (11.1)	1 (11.1)	0	0	0
Lymphopenia	1 (11.1)	0	0	0	1 (11.1)
Cardiac disorders					
-Total	3 (33.3)	0	1 (11.1)	0	2 (22.2)
Bradycardia	1 (11.1)	0	0	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	0	0	1 (11.1)
Pericardial effusion	1 (11.1)	0	1 (11.1)	0	0
Right ventricular dysfunction	1 (11.1)	0	0	1 (11.1)	0
Sinus tachycardia	1 (11.1)	0	0	1 (11.1)	0
Tachycardia	1 (11.1)	1 (11.1)	0	0	0
Ventricular tachycardia	1 (11.1)	0	0	1 (11.1)	0
Eye disorders					
-Total	2 (22.2)	0	2 (22.2)	0	0
Photophobia	1 (11.1)	0	1 (11.1)	0	0
Retinopathy	1 (11.1)	0	1 (11.1)	0	0
Gastrointestinal disorders					
-Total	7 (77.8)	1 (11.1)	3 (33.3)	3 (33.3)	0
Nausea	4 (44.4)	0	3 (33.3)	1 (11.1)	0

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	4 (44.4)	1 (11.1)	2 (22.2)	1 (11.1)	0
Abdominal pain	3 (33.3)	0	1 (11.1)	2 (22.2)	0
Constipation	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Haematochezia	1 (11.1)	0	0	1 (11.1)	0
Stomatitis	1 (11.1)	0	0	1 (11.1)	0
General disorders and administration site conditions					
-Total	5 (55.6)	1 (11.1)	1 (11.1)	2 (22.2)	1 (11.1)
Non-cardiac chest pain	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Pyrexia	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Catheter site bruise	1 (11.1)	1 (11.1)	0	0	0
Catheter site pain	1 (11.1)	0	1 (11.1)	0	0
Device related thrombosis	1 (11.1)	0	1 (11.1)	0	0
Multiple organ dysfunction syndrome	1 (11.1)	0	0	0	1 (11.1)
Oedema peripheral	1 (11.1)	0	1 (11.1)	0	0
Pain	1 (11.1)	0	1 (11.1)	0	0
Physical deconditioning	1 (11.1)	0	0	1 (11.1)	0
Hepatobiliary disorders					

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Hyperbilirubinaemia	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Hepatic steatosis	1 (11.1)	0	1 (11.1)	0	0
Immune system disorders					
-Total	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Anaphylactic reaction	1 (11.1)	0	0	1 (11.1)	0
Drug hypersensitivity	1 (11.1)	0	1 (11.1)	0	0
Infections and infestations					
-Total	4 (44.4)	0	0	2 (22.2)	2 (22.2)
Abscess limb	1 (11.1)	0	0	1 (11.1)	0
Device related infection	1 (11.1)	0	0	1 (11.1)	0
Escherichia urinary tract infection	1 (11.1)	0	0	1 (11.1)	0
Klebsiella sepsis	1 (11.1)	0	0	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	1 (11.1)	0	0
Rhinovirus infection	1 (11.1)	0	1 (11.1)	0	0
Staphylococcal scalded skin syndrome	1 (11.1)	0	1 (11.1)	0	0
Staphylococcal sepsis	1 (11.1)	0	0	0	1 (11.1)

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Procedural pain	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Extradural haematoma	1 (11.1)	0	0	1 (11.1)	0
Procedural hypertension	1 (11.1)	0	1 (11.1)	0	0
Subdural haematoma	1 (11.1)	0	0	1 (11.1)	0
Investigations					
-Total	6 (66.7)	0	1 (11.1)	3 (33.3)	2 (22.2)
Alanine aminotransferase increased	2 (22.2)	0	0	2 (22.2)	0
Aspartate aminotransferase increased	2 (22.2)	0	1 (11.1)	1 (11.1)	0
White blood cell count decreased	2 (22.2)	0	1 (11.1)	0	1 (11.1)
Blood lactate dehydrogenase increased	1 (11.1)	0	0	1 (11.1)	0
Computerised tomogram thorax abnormal	1 (11.1)	0	0	1 (11.1)	0
Electrocardiogram qt prolonged	1 (11.1)	0	0	1 (11.1)	0
Neutrophil count decreased	1 (11.1)	0	0	0	1 (11.1)

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Transaminases increased	1 (11.1)	0	0	1 (11.1)	0
Metabolism and nutrition disorders					
-Total	5 (55.6)	1 (11.1)	2 (22.2)	2 (22.2)	0
Fluid overload	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Hyperglycaemia	2 (22.2)	0	2 (22.2)	0	0
Decreased appetite	1 (11.1)	1 (11.1)	0	0	0
Hyperkalaemia	1 (11.1)	0	0	1 (11.1)	0
Hypocalcaemia	1 (11.1)	1 (11.1)	0	0	0
Hypomagnesaemia	1 (11.1)	1 (11.1)	0	0	0
Tumour lysis syndrome	1 (11.1)	0	0	1 (11.1)	0
Vitamin d deficiency	1 (11.1)	0	1 (11.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (55.6)	1 (11.1)	1 (11.1)	3 (33.3)	0
Arthralgia	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Back pain	2 (22.2)	0	0	2 (22.2)	0
Muscle spasms	1 (11.1)	1 (11.1)	0	0	0
Myopathy	1 (11.1)	0	0	1 (11.1)	0

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Myositis	1 (11.1)	0	0	1 (11.1)	0
Neck pain	1 (11.1)	0	1 (11.1)	0	0
Pain in extremity	1 (11.1)	0	0	1 (11.1)	0
Synovitis	1 (11.1)	0	1 (11.1)	0	0
Nervous system disorders					
-Total	4 (44.4)	0	2 (22.2)	1 (11.1)	1 (11.1)
Headache	4 (44.4)	0	2 (22.2)	2 (22.2)	0
Hyporesponsive to stimuli	1 (11.1)	0	0	1 (11.1)	0
Seizure	1 (11.1)	0	0	0	1 (11.1)
Product issues					
-Total	1 (11.1)	0	1 (11.1)	0	0
Device occlusion	1 (11.1)	0	1 (11.1)	0	0
Psychiatric disorders					
-Total	3 (33.3)	0	1 (11.1)	2 (22.2)	0
Agitation	1 (11.1)	0	0	1 (11.1)	0
Anxiety	1 (11.1)	0	1 (11.1)	0	0
Depression	1 (11.1)	0	1 (11.1)	0	0
Mental status changes	1 (11.1)	0	0	1 (11.1)	0

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Acute kidney injury	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Dysuria	1 (11.1)	0	1 (11.1)	0	0
Oliguria	1 (11.1)	0	0	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Cough	1 (11.1)	0	0	1 (11.1)	0
Dyspnoea	1 (11.1)	0	0	1 (11.1)	0
Epistaxis	1 (11.1)	0	0	1 (11.1)	0
Haemoptysis	1 (11.1)	0	0	1 (11.1)	0
Hypoxia	1 (11.1)	0	0	1 (11.1)	0
Oropharyngeal pain	1 (11.1)	0	0	1 (11.1)	0
Pulmonary alveolar haemorrhage	1 (11.1)	0	0	0	1 (11.1)
Pulmonary hypertension	1 (11.1)	0	0	1 (11.1)	0
Pulmonary oedema	1 (11.1)	0	0	0	1 (11.1)
Respiratory distress	1 (11.1)	0	0	0	1 (11.1)

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (11.1)	0	0	1 (11.1)	0
Skin and subcutaneous tissue disorders					
-Total	3 (33.3)	2 (22.2)	1 (11.1)	0	0
Cold sweat	1 (11.1)	1 (11.1)	0	0	0
Night sweats	1 (11.1)	1 (11.1)	0	0	0
Rash	1 (11.1)	1 (11.1)	0	0	0
Rash erythematous	1 (11.1)	1 (11.1)	0	0	0
Urticaria	1 (11.1)	0	1 (11.1)	0	0
Vascular disorders					
-Total	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Hypertension	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Hypotension	1 (11.1)	0	0	0	1 (11.1)
Venous thrombosis limb	1 (11.1)	1 (11.1)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185d
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (70.0)	0	1 (3.3)	11 (36.7)	9 (30.0)
Blood and lymphatic system disorders					
-Total	16 (53.3)	0	0	13 (43.3)	3 (10.0)
Anaemia	9 (30.0)	0	1 (3.3)	8 (26.7)	0
Febrile neutropenia	8 (26.7)	0	0	8 (26.7)	0
Neutropenia	3 (10.0)	0	0	1 (3.3)	2 (6.7)
Thrombocytopenia	3 (10.0)	0	0	1 (3.3)	2 (6.7)
Gastrointestinal disorders					
-Total	8 (26.7)	2 (6.7)	5 (16.7)	1 (3.3)	0
Vomiting	5 (16.7)	2 (6.7)	3 (10.0)	0	0
Nausea	4 (13.3)	0	4 (13.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	3 (10.0)	0	2 (6.7)	1 (3.3)	0
General disorders and administration site conditions					
-Total	6 (20.0)	2 (6.7)	3 (10.0)	1 (3.3)	0
Pyrexia	6 (20.0)	2 (6.7)	3 (10.0)	1 (3.3)	0
Fatigue	1 (3.3)	1 (3.3)	0	0	0
Investigations					
-Total	11 (36.7)	0	2 (6.7)	2 (6.7)	7 (23.3)
Neutrophil count decreased	5 (16.7)	0	0	0	5 (16.7)
White blood cell count decreased	5 (16.7)	0	1 (3.3)	0	4 (13.3)
Alanine aminotransferase increased	4 (13.3)	0	1 (3.3)	3 (10.0)	0
Platelet count decreased	4 (13.3)	0	0	1 (3.3)	3 (10.0)
Metabolism and nutrition disorders					
-Total	10 (33.3)	3 (10.0)	4 (13.3)	3 (10.0)	0
Hyperglycaemia	5 (16.7)	0	2 (6.7)	3 (10.0)	0
Decreased appetite	4 (13.3)	1 (3.3)	2 (6.7)	1 (3.3)	0
Hypomagnesaemia	4 (13.3)	4 (13.3)	0	0	0
Musculoskeletal and connective tissue disorders					

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Pain in extremity	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Nervous system disorders					
-Total	5 (16.7)	1 (3.3)	2 (6.7)	2 (6.7)	0
Headache	5 (16.7)	1 (3.3)	2 (6.7)	2 (6.7)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (6.7)	0	2 (6.7)	0	0
Hypoxia	2 (6.7)	0	2 (6.7)	0	0
Vascular disorders					
-Total	3 (10.0)	0	0	2 (6.7)	1 (3.3)
Hypotension	3 (10.0)	0	0	2 (6.7)	1 (3.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185d
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (73.3)	3 (6.7)	3 (6.7)	12 (26.7)	15 (33.3)
Blood and lymphatic system disorders					
-Total	22 (48.9)	0	0	16 (35.6)	6 (13.3)
Anaemia	12 (26.7)	0	1 (2.2)	11 (24.4)	0
Febrile neutropenia	10 (22.2)	0	0	10 (22.2)	0
Thrombocytopenia	7 (15.6)	0	0	2 (4.4)	5 (11.1)
Neutropenia	3 (6.7)	0	0	0	3 (6.7)
Gastrointestinal disorders					
-Total	11 (24.4)	2 (4.4)	5 (11.1)	4 (8.9)	0
Abdominal pain	6 (13.3)	1 (2.2)	3 (6.7)	2 (4.4)	0
Nausea	6 (13.3)	0	3 (6.7)	3 (6.7)	0

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	4 (8.9)	2 (4.4)	1 (2.2)	1 (2.2)	0
General disorders and administration site conditions					
-Total	11 (24.4)	6 (13.3)	3 (6.7)	2 (4.4)	0
Fatigue	6 (13.3)	3 (6.7)	2 (4.4)	1 (2.2)	0
Pyrexia	6 (13.3)	4 (8.9)	1 (2.2)	1 (2.2)	0
Investigations					
-Total	13 (28.9)	1 (2.2)	0	1 (2.2)	11 (24.4)
White blood cell count decreased	7 (15.6)	1 (2.2)	0	1 (2.2)	5 (11.1)
Platelet count decreased	6 (13.3)	0	0	0	6 (13.3)
Neutrophil count decreased	4 (8.9)	0	0	0	4 (8.9)
Alanine aminotransferase increased	2 (4.4)	0	0	2 (4.4)	0
Metabolism and nutrition disorders					
-Total	6 (13.3)	0	3 (6.7)	2 (4.4)	1 (2.2)
Decreased appetite	4 (8.9)	0	2 (4.4)	2 (4.4)	0
Hyperglycaemia	2 (4.4)	0	1 (2.2)	0	1 (2.2)
Musculoskeletal and connective tissue disorders					
-Total	6 (13.3)	1 (2.2)	1 (2.2)	4 (8.9)	0

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	6 (13.3)	1 (2.2)	1 (2.2)	4 (8.9)	0
Nervous system disorders					
-Total	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Headache	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (11.1)	0	2 (4.4)	2 (4.4)	1 (2.2)
Hypoxia	5 (11.1)	0	2 (4.4)	2 (4.4)	1 (2.2)
Vascular disorders					
-Total	4 (8.9)	0	0	2 (4.4)	2 (4.4)
Hypotension	4 (8.9)	0	0	2 (4.4)	2 (4.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185e
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	1 (12.5)	0	4 (50.0)	3 (37.5)
Blood and lymphatic system disorders					
-Total	5 (62.5)	0	0	5 (62.5)	0
Febrile neutropenia	3 (37.5)	0	0	3 (37.5)	0
Anaemia	2 (25.0)	0	0	2 (25.0)	0
Cardiac disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Tachycardia	1 (12.5)	0	0	1 (12.5)	0
Gastrointestinal disorders					
-Total	4 (50.0)	2 (25.0)	0	1 (12.5)	1 (12.5)
Abdominal pain	2 (25.0)	1 (12.5)	1 (12.5)	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Nausea	2 (25.0)	0	0	2 (25.0)	0
Stomatitis	2 (25.0)	1 (12.5)	0	0	1 (12.5)
Vomiting	2 (25.0)	2 (25.0)	0	0	0
Dyspepsia	1 (12.5)	0	1 (12.5)	0	0
General disorders and administration site conditions					
-Total	4 (50.0)	2 (25.0)	0	2 (25.0)	0
Fatigue	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Pyrexia	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Catheter site pain	1 (12.5)	1 (12.5)	0	0	0
Chills	1 (12.5)	1 (12.5)	0	0	0
Pain	1 (12.5)	0	0	1 (12.5)	0
Immune system disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypogammaglobulinaemia	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	2 (25.0)	0	0	0	2 (25.0)

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (12.5)	0	0	1 (12.5)	0
Clostridium difficile infection	1 (12.5)	0	1 (12.5)	0	0
Human polyomavirus infection	1 (12.5)	0	0	0	1 (12.5)
Oral herpes	1 (12.5)	0	0	1 (12.5)	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Injury, poisoning and procedural complications					
-Total	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Procedural pain	1 (12.5)	0	0	1 (12.5)	0
Wound	1 (12.5)	1 (12.5)	0	0	0
Investigations					
-Total	1 (12.5)	0	0	0	1 (12.5)
Neutrophil count decreased	1 (12.5)	0	0	0	1 (12.5)
White blood cell count decreased	1 (12.5)	0	0	0	1 (12.5)
Metabolism and nutrition disorders					
-Total	2 (25.0)	0	2 (25.0)	0	0
Decreased appetite	1 (12.5)	0	1 (12.5)	0	0
Dehydration	1 (12.5)	0	1 (12.5)	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypomagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Vitamin d deficiency	1 (12.5)	0	1 (12.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Pain in extremity	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Neck pain	1 (12.5)	0	1 (12.5)	0	0
Nervous system disorders					
-Total	2 (25.0)	0	2 (25.0)	0	0
Headache	2 (25.0)	0	2 (25.0)	0	0
Psychiatric disorders					
-Total	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Anxiety	1 (12.5)	0	1 (12.5)	0	0
Confusional state	1 (12.5)	0	1 (12.5)	0	0
Depression	1 (12.5)	1 (12.5)	0	0	0
Renal and urinary disorders					
-Total	1 (12.5)	0	0	0	1 (12.5)
Cystitis haemorrhagic	1 (12.5)	0	0	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	2 (25.0)	0	1 (12.5)	0	1 (12.5)
Hypoxia	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Aspiration	1 (12.5)	0	0	0	1 (12.5)
Cough	1 (12.5)	1 (12.5)	0	0	0
Epistaxis	1 (12.5)	0	1 (12.5)	0	0
Nasal congestion	1 (12.5)	1 (12.5)	0	0	0
Oropharyngeal pain	1 (12.5)	1 (12.5)	0	0	0
Pleural effusion	1 (12.5)	0	1 (12.5)	0	0
Rhinorrhoea	1 (12.5)	1 (12.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (25.0)	2 (25.0)	0	0	0
Dermatitis diaper	1 (12.5)	1 (12.5)	0	0	0
Rash papular	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	3 (37.5)	1 (12.5)	0	1 (12.5)	1 (12.5)
Hypotension	2 (25.0)	0	0	1 (12.5)	1 (12.5)

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (12.5)	1 (12.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185e
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (71.6)	2 (3.0)	5 (7.5)	21 (31.3)	20 (29.9)
Blood and lymphatic system disorders					
-Total	32 (47.8)	0	1 (1.5)	24 (35.8)	7 (10.4)
Anaemia	19 (28.4)	0	2 (3.0)	17 (25.4)	0
Febrile neutropenia	15 (22.4)	0	0	15 (22.4)	0
Thrombocytopenia	10 (14.9)	0	0	3 (4.5)	7 (10.4)
Cardiac disorders					
-Total	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Tachycardia	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Gastrointestinal disorders					
-Total	17 (25.4)	2 (3.0)	10 (14.9)	5 (7.5)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	8 (11.9)	0	7 (10.4)	1 (1.5)	0
Abdominal pain	7 (10.4)	0	4 (6.0)	3 (4.5)	0
Vomiting	7 (10.4)	2 (3.0)	4 (6.0)	1 (1.5)	0
Stomatitis	3 (4.5)	0	0	3 (4.5)	0
Diarrhoea	1 (1.5)	0	0	1 (1.5)	0
General disorders and administration site conditions					
-Total	17 (25.4)	7 (10.4)	9 (13.4)	1 (1.5)	0
Pyrexia	10 (14.9)	5 (7.5)	4 (6.0)	1 (1.5)	0
Fatigue	5 (7.5)	3 (4.5)	2 (3.0)	0	0
Catheter site pain	3 (4.5)	0	3 (4.5)	0	0
Pain	2 (3.0)	0	2 (3.0)	0	0
Chills	1 (1.5)	1 (1.5)	0	0	0
Immune system disorders					
-Total	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Hypogammaglobulinaemia	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Infections and infestations					
-Total	3 (4.5)	0	3 (4.5)	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	2 (3.0)	0	2 (3.0)	0	0
Pneumonia	1 (1.5)	0	1 (1.5)	0	0
Injury, poisoning and procedural complications					
-Total	3 (4.5)	0	2 (3.0)	1 (1.5)	0
Procedural pain	3 (4.5)	0	2 (3.0)	1 (1.5)	0
Investigations					
-Total	19 (28.4)	1 (1.5)	1 (1.5)	0	17 (25.4)
White blood cell count decreased	11 (16.4)	1 (1.5)	1 (1.5)	1 (1.5)	8 (11.9)
Platelet count decreased	10 (14.9)	0	0	1 (1.5)	9 (13.4)
Neutrophil count decreased	8 (11.9)	0	0	0	8 (11.9)
Metabolism and nutrition disorders					
-Total	16 (23.9)	2 (3.0)	7 (10.4)	6 (9.0)	1 (1.5)
Decreased appetite	7 (10.4)	1 (1.5)	3 (4.5)	3 (4.5)	0
Hyperglycaemia	7 (10.4)	0	3 (4.5)	3 (4.5)	1 (1.5)
Dehydration	3 (4.5)	0	1 (1.5)	2 (3.0)	0
Hypomagnesaemia	3 (4.5)	3 (4.5)	0	0	0
Vitamin d deficiency	1 (1.5)	0	1 (1.5)	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	9 (13.4)	2 (3.0)	3 (4.5)	4 (6.0)	0
Pain in extremity	7 (10.4)	1 (1.5)	2 (3.0)	4 (6.0)	0
Neck pain	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Nervous system disorders					
-Total	8 (11.9)	2 (3.0)	2 (3.0)	4 (6.0)	0
Headache	8 (11.9)	2 (3.0)	2 (3.0)	4 (6.0)	0
Psychiatric disorders					
-Total	2 (3.0)	0	2 (3.0)	0	0
Anxiety	1 (1.5)	0	1 (1.5)	0	0
Confusional state	1 (1.5)	0	1 (1.5)	0	0
Depression	1 (1.5)	0	1 (1.5)	0	0
Renal and urinary disorders					
-Total	1 (1.5)	0	0	1 (1.5)	0
Cystitis haemorrhagic	1 (1.5)	0	0	1 (1.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (10.4)	0	4 (6.0)	2 (3.0)	1 (1.5)

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	5 (7.5)	0	3 (4.5)	1 (1.5)	1 (1.5)
Cough	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Epistaxis	2 (3.0)	0	1 (1.5)	1 (1.5)	0
Pleural effusion	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Oropharyngeal pain	1 (1.5)	0	0	1 (1.5)	0
Skin and subcutaneous tissue disorders					
-Total	1 (1.5)	1 (1.5)	0	0	0
Rash papular	1 (1.5)	1 (1.5)	0	0	0
Vascular disorders					
-Total	7 (10.4)	1 (1.5)	0	4 (6.0)	2 (3.0)
Hypotension	5 (7.5)	0	0	3 (4.5)	2 (3.0)
Hypertension	3 (4.5)	1 (1.5)	1 (1.5)	1 (1.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
/vob/CCTL019/haq/haq_eu_5/pgm/saf/t185_gd_b2205.sas@@/main/3 29SEP20:17:55 Final

Table 185f
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	1 (50.0)	1 (50.0)	0
Cardiac disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Sinus tachycardia	1 (50.0)	0	0	1 (50.0)	0
General disorders and administration site conditions					
-Total	1 (50.0)	0	1 (50.0)	0	0
Fatigue	1 (50.0)	1 (50.0)	0	0	0
Non-cardiac chest pain	1 (50.0)	1 (50.0)	0	0	0
Pyrexia	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	0	1 (50.0)	0
Bacteraemia	1 (50.0)	0	0	1 (50.0)	0
Investigations					
-Total	1 (50.0)	0	1 (50.0)	0	0
Blood fibrinogen decreased	1 (50.0)	0	1 (50.0)	0	0
Blood immunoglobulin m decreased	1 (50.0)	1 (50.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Decreased appetite	1 (50.0)	0	1 (50.0)	0	0
Nervous system disorders					
-Total	2 (100)	2 (100)	0	0	0
Headache	2 (100)	2 (100)	0	0	0
Reproductive system and breast disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Scrotal pain	1 (50.0)	0	1 (50.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin irritation	1 (50.0)	1 (50.0)	0	0	0
Vascular disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Hypotension	1 (50.0)	0	0	1 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185f
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (69.9)	2 (2.7)	5 (6.8)	22 (30.1)	22 (30.1)
Blood and lymphatic system disorders					
-Total	37 (50.7)	0	1 (1.4)	29 (39.7)	7 (9.6)
Anaemia	21 (28.8)	0	2 (2.7)	19 (26.0)	0
Febrile neutropenia	18 (24.7)	0	0	18 (24.7)	0
Thrombocytopenia	10 (13.7)	0	0	3 (4.1)	7 (9.6)
Cardiac disorders					
-Total	1 (1.4)	0	0	1 (1.4)	0
Sinus tachycardia	1 (1.4)	0	0	1 (1.4)	0
Gastrointestinal disorders					
-Total	19 (26.0)	4 (5.5)	10 (13.7)	5 (6.8)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	10 (13.7)	0	7 (9.6)	3 (4.1)	0
Abdominal pain	9 (12.3)	1 (1.4)	5 (6.8)	3 (4.1)	0
Vomiting	9 (12.3)	4 (5.5)	4 (5.5)	1 (1.4)	0
General disorders and administration site conditions					
-Total	17 (23.3)	8 (11.0)	5 (6.8)	4 (5.5)	0
Pyrexia	11 (15.1)	6 (8.2)	3 (4.1)	2 (2.7)	0
Fatigue	6 (8.2)	3 (4.1)	2 (2.7)	1 (1.4)	0
Non-cardiac chest pain	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Investigations					
-Total	20 (27.4)	1 (1.4)	1 (1.4)	0	18 (24.7)
White blood cell count decreased	12 (16.4)	1 (1.4)	1 (1.4)	1 (1.4)	9 (12.3)
Platelet count decreased	10 (13.7)	0	0	1 (1.4)	9 (12.3)
Neutrophil count decreased	9 (12.3)	0	0	0	9 (12.3)
Metabolism and nutrition disorders					
-Total	7 (9.6)	1 (1.4)	3 (4.1)	3 (4.1)	0
Decreased appetite	7 (9.6)	1 (1.4)	3 (4.1)	3 (4.1)	0
Musculoskeletal and connective tissue disorders					

Philadelphia chromosome/BCR-ABL: Negative

Group term Preferred term	All patients N=73 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	9 (12.3)	2 (2.7)	2 (2.7)	5 (6.8)	0
Pain in extremity	9 (12.3)	2 (2.7)	2 (2.7)	5 (6.8)	0
Nervous system disorders					
-Total	8 (11.0)	0	4 (5.5)	4 (5.5)	0
Headache	8 (11.0)	0	4 (5.5)	4 (5.5)	0
Vascular disorders					
-Total	6 (8.2)	0	0	3 (4.1)	3 (4.1)
Hypotension	6 (8.2)	0	0	3 (4.1)	3 (4.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185g
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	2 (66.7)	1 (33.3)
Blood and lymphatic system disorders					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Febrile neutropenia	1 (33.3)	0	0	1 (33.3)	0
Leukopenia	1 (33.3)	0	0	0	1 (33.3)
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Cardiac disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Tachycardia	1 (33.3)	0	0	1 (33.3)	0
Gastrointestinal disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (33.3)	1 (33.3)	0	0	0
Colitis	1 (33.3)	1 (33.3)	0	0	0
Diarrhoea	1 (33.3)	0	1 (33.3)	0	0
Dyspepsia	1 (33.3)	0	1 (33.3)	0	0
Nausea	1 (33.3)	0	0	1 (33.3)	0
Perianal erythema	1 (33.3)	0	1 (33.3)	0	0
General disorders and administration site conditions					
-Total	1 (33.3)	1 (33.3)	0	0	0
Chills	1 (33.3)	1 (33.3)	0	0	0
Fatigue	1 (33.3)	1 (33.3)	0	0	0
Pyrexia	1 (33.3)	1 (33.3)	0	0	0
Infections and infestations					
-Total	1 (33.3)	0	0	1 (33.3)	0
Escherichia bacteraemia	1 (33.3)	0	0	1 (33.3)	0
Sinusitis	1 (33.3)	1 (33.3)	0	0	0
Investigations					
-Total	2 (66.7)	0	0	2 (66.7)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Alanine aminotransferase increased	1 (33.3)	0	0	1 (33.3)	0
Metabolism and nutrition disorders					
-Total	2 (66.7)	0	1 (33.3)	0	1 (33.3)
Decreased appetite	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Hyperuricaemia	1 (33.3)	0	0	0	1 (33.3)
Hypokalaemia	1 (33.3)	1 (33.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Bone pain	1 (33.3)	0	0	1 (33.3)	0
Neck pain	1 (33.3)	0	1 (33.3)	0	0
Nervous system disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Headache	1 (33.3)	0	1 (33.3)	0	0
Psychiatric disorders					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Anxiety	1 (33.3)	0	1 (33.3)	0	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Irritability	1 (33.3)	1 (33.3)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Cough	1 (33.3)	1 (33.3)	0	0	0
Hypoxia	1 (33.3)	0	1 (33.3)	0	0
Nasal congestion	1 (33.3)	1 (33.3)	0	0	0
Oropharyngeal pain	1 (33.3)	1 (33.3)	0	0	0
Rhinorrhoea	1 (33.3)	1 (33.3)	0	0	0
Vascular disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Hypertension	1 (33.3)	1 (33.3)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185g
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (72.2)	3 (4.2)	5 (6.9)	22 (30.6)	22 (30.6)
Blood and lymphatic system disorders					
-Total	36 (50.0)	0	0	28 (38.9)	8 (11.1)
Anaemia	21 (29.2)	0	2 (2.8)	19 (26.4)	0
Febrile neutropenia	17 (23.6)	0	0	17 (23.6)	0
Thrombocytopenia	10 (13.9)	0	0	3 (4.2)	7 (9.7)
Neutropenia	5 (6.9)	0	0	1 (1.4)	4 (5.6)
Cardiac disorders					
-Total	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Tachycardia	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Gastrointestinal disorders					

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	20 (27.8)	4 (5.6)	10 (13.9)	6 (8.3)	0
Nausea	9 (12.5)	0	7 (9.7)	2 (2.8)	0
Vomiting	9 (12.5)	4 (5.6)	4 (5.6)	1 (1.4)	0
Abdominal pain	8 (11.1)	0	5 (6.9)	3 (4.2)	0
Colitis	3 (4.2)	0	0	3 (4.2)	0
Diarrhoea	2 (2.8)	1 (1.4)	0	1 (1.4)	0
General disorders and administration site conditions					
-Total	16 (22.2)	7 (9.7)	6 (8.3)	3 (4.2)	0
Pyrexia	11 (15.3)	5 (6.9)	4 (5.6)	2 (2.8)	0
Fatigue	6 (8.3)	3 (4.2)	2 (2.8)	1 (1.4)	0
Chills	1 (1.4)	1 (1.4)	0	0	0
Infections and infestations					
-Total	1 (1.4)	0	0	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Investigations					
-Total	23 (31.9)	1 (1.4)	2 (2.8)	2 (2.8)	18 (25.0)
White blood cell count decreased	12 (16.7)	1 (1.4)	1 (1.4)	1 (1.4)	9 (12.5)

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	10 (13.9)	0	0	1 (1.4)	9 (12.5)
Neutrophil count decreased	9 (12.5)	0	0	0	9 (12.5)
Alanine aminotransferase increased	5 (6.9)	0	1 (1.4)	4 (5.6)	0
Aspartate aminotransferase increased	3 (4.2)	0	1 (1.4)	2 (2.8)	0
Metabolism and nutrition disorders					
-Total	12 (16.7)	2 (2.8)	3 (4.2)	5 (6.9)	2 (2.8)
Decreased appetite	6 (8.3)	1 (1.4)	3 (4.2)	2 (2.8)	0
Hypokalaemia	4 (5.6)	0	0	2 (2.8)	2 (2.8)
Hyperuricaemia	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Musculoskeletal and connective tissue disorders					
-Total	11 (15.3)	3 (4.2)	3 (4.2)	5 (6.9)	0
Pain in extremity	9 (12.5)	2 (2.8)	2 (2.8)	5 (6.9)	0
Neck pain	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Bone pain	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	9 (12.5)	2 (2.8)	3 (4.2)	4 (5.6)	0
Headache	9 (12.5)	2 (2.8)	3 (4.2)	4 (5.6)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Anxiety	1 (1.4)	0	1 (1.4)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (8.3)	0	3 (4.2)	2 (2.8)	1 (1.4)
Hypoxia	6 (8.3)	0	3 (4.2)	2 (2.8)	1 (1.4)
Cough	2 (2.8)	1 (1.4)	0	1 (1.4)	0
Oropharyngeal pain	1 (1.4)	0	0	1 (1.4)	0
Vascular disorders					
-Total	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Hypertension	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185h
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Blood and lymphatic system disorders					
-Total	1 (100)	0	0	1 (100)	0
Febrile neutropenia	1 (100)	0	0	1 (100)	0
Cardiac disorders					
-Total	1 (100)	0	1 (100)	0	0
Tachycardia	1 (100)	0	1 (100)	0	0
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Haematemesis	1 (100)	0	1 (100)	0	0
Vomiting	1 (100)	0	1 (100)	0	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Psychiatric disorders					
-Total	1 (100)	0	1 (100)	0	0
Insomnia	1 (100)	0	1 (100)	0	0
Mental status changes	1 (100)	1 (100)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	0	1 (100)	0	0
Rash erythematous	1 (100)	0	1 (100)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185h
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (70.3)	3 (4.1)	7 (9.5)	21 (28.4)	21 (28.4)
Blood and lymphatic system disorders					
-Total	36 (48.6)	0	1 (1.4)	28 (37.8)	7 (9.5)
Anaemia	21 (28.4)	0	2 (2.7)	19 (25.7)	0
Febrile neutropenia	17 (23.0)	0	0	17 (23.0)	0
Thrombocytopenia	10 (13.5)	0	0	3 (4.1)	7 (9.5)
Cardiac disorders					
-Total	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Tachycardia	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Gastrointestinal disorders					
-Total	18 (24.3)	4 (5.4)	9 (12.2)	5 (6.8)	0

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	10 (13.5)	0	7 (9.5)	3 (4.1)	0
Abdominal pain	9 (12.2)	1 (1.4)	5 (6.8)	3 (4.1)	0
Vomiting	8 (10.8)	4 (5.4)	3 (4.1)	1 (1.4)	0
General disorders and administration site conditions					
-Total	12 (16.2)	6 (8.1)	4 (5.4)	2 (2.7)	0
Pyrexia	12 (16.2)	6 (8.1)	4 (5.4)	2 (2.7)	0
Investigations					
-Total	20 (27.0)	1 (1.4)	1 (1.4)	0	18 (24.3)
White blood cell count decreased	12 (16.2)	1 (1.4)	1 (1.4)	1 (1.4)	9 (12.2)
Platelet count decreased	10 (13.5)	0	0	1 (1.4)	9 (12.2)
Neutrophil count decreased	9 (12.2)	0	0	0	9 (12.2)
Metabolism and nutrition disorders					
-Total	8 (10.8)	1 (1.4)	4 (5.4)	3 (4.1)	0
Decreased appetite	8 (10.8)	1 (1.4)	4 (5.4)	3 (4.1)	0
Musculoskeletal and connective tissue disorders					
-Total	9 (12.2)	2 (2.7)	2 (2.7)	5 (6.8)	0
Pain in extremity	9 (12.2)	2 (2.7)	2 (2.7)	5 (6.8)	0

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	10 (13.5)	2 (2.7)	4 (5.4)	4 (5.4)	0
Headache	10 (13.5)	2 (2.7)	4 (5.4)	4 (5.4)	0
Psychiatric disorders					
-Total	3 (4.1)	1 (1.4)	1 (1.4)	1 (1.4)	0
Mental status changes	2 (2.7)	1 (1.4)	0	1 (1.4)	0
Insomnia	1 (1.4)	0	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (2.7)	1 (1.4)	1 (1.4)	0	0
Rash erythematous	2 (2.7)	1 (1.4)	1 (1.4)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185i
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	1 (25.0)	1 (25.0)	1 (25.0)	1 (25.0)
Blood and lymphatic system disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Anaemia	1 (25.0)	0	0	1 (25.0)	0
Endocrine disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Cushingoid	1 (25.0)	1 (25.0)	0	0	0
Gastrointestinal disorders					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Colitis	1 (25.0)	0	0	1 (25.0)	0
Dry mouth	1 (25.0)	1 (25.0)	0	0	0

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Cholecystitis	1 (25.0)	0	0	1 (25.0)	0
Immune system disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Hypogammaglobulinaemia	1 (25.0)	0	1 (25.0)	0	0
Infections and infestations					
-Total	2 (50.0)	0	0	2 (50.0)	0
Cytomegalovirus viraemia	1 (25.0)	0	1 (25.0)	0	0
Enterococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Gastroenteritis	1 (25.0)	0	0	1 (25.0)	0
Streptococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Investigations					
-Total	3 (75.0)	1 (25.0)	1 (25.0)	0	1 (25.0)
Alanine aminotransferase increased	1 (25.0)	0	0	1 (25.0)	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0	0	0
Blood fibrinogen decreased	1 (25.0)	0	1 (25.0)	0	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0	0	0

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Coronavirus test positive	1 (25.0)	1 (25.0)	0	0	0
Lymphocyte count decreased	1 (25.0)	0	0	1 (25.0)	0
Neutrophil count decreased	1 (25.0)	0	0	0	1 (25.0)
Platelet count decreased	1 (25.0)	0	0	0	1 (25.0)
White blood cell count decreased	1 (25.0)	0	0	0	1 (25.0)
Metabolism and nutrition disorders					
-Total	2 (50.0)	0	0	2 (50.0)	0
Dehydration	1 (25.0)	0	0	1 (25.0)	0
Hyperglycaemia	1 (25.0)	0	0	1 (25.0)	0
Hyperuricaemia	1 (25.0)	1 (25.0)	0	0	0
Nervous system disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Headache	1 (25.0)	1 (25.0)	0	0	0
Neuralgia	1 (25.0)	0	1 (25.0)	0	0
Psychiatric disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Insomnia	1 (25.0)	0	1 (25.0)	0	0

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Idiopathic pneumonia syndrome	1 (25.0)	0	0	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185i
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (74.6)	1 (1.4)	8 (11.3)	23 (32.4)	21 (29.6)
Blood and lymphatic system disorders					
-Total	36 (50.7)	0	1 (1.4)	28 (39.4)	7 (9.9)
Anaemia	20 (28.2)	0	2 (2.8)	18 (25.4)	0
Febrile neutropenia	18 (25.4)	0	0	18 (25.4)	0
Thrombocytopenia	10 (14.1)	0	0	3 (4.2)	7 (9.9)
Gastrointestinal disorders					
-Total	21 (29.6)	5 (7.0)	10 (14.1)	6 (8.5)	0
Nausea	10 (14.1)	0	7 (9.9)	3 (4.2)	0
Abdominal pain	9 (12.7)	1 (1.4)	5 (7.0)	3 (4.2)	0
Vomiting	9 (12.7)	4 (5.6)	4 (5.6)	1 (1.4)	0

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	3 (4.2)	1 (1.4)	0	2 (2.8)	0
General disorders and administration site conditions					
-Total	12 (16.9)	6 (8.5)	4 (5.6)	2 (2.8)	0
Pyrexia	12 (16.9)	6 (8.5)	4 (5.6)	2 (2.8)	0
Immune system disorders					
-Total	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Hypogammaglobulinaemia	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Infections and infestations					
-Total	1 (1.4)	0	0	1 (1.4)	0
Enterococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Investigations					
-Total	23 (32.4)	1 (1.4)	2 (2.8)	3 (4.2)	17 (23.9)
White blood cell count decreased	11 (15.5)	1 (1.4)	1 (1.4)	1 (1.4)	8 (11.3)
Platelet count decreased	9 (12.7)	0	0	1 (1.4)	8 (11.3)
Neutrophil count decreased	8 (11.3)	0	0	0	8 (11.3)
Alanine aminotransferase increased	5 (7.0)	0	1 (1.4)	4 (5.6)	0
Metabolism and nutrition disorders					

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	16 (22.5)	1 (1.4)	9 (12.7)	4 (5.6)	2 (2.8)
Decreased appetite	8 (11.3)	1 (1.4)	4 (5.6)	3 (4.2)	0
Hyperglycaemia	6 (8.5)	0	3 (4.2)	2 (2.8)	1 (1.4)
Dehydration	3 (4.2)	0	2 (2.8)	1 (1.4)	0
Hyperuricaemia	3 (4.2)	1 (1.4)	0	1 (1.4)	1 (1.4)
Musculoskeletal and connective tissue disorders					
-Total	9 (12.7)	2 (2.8)	2 (2.8)	5 (7.0)	0
Pain in extremity	9 (12.7)	2 (2.8)	2 (2.8)	5 (7.0)	0
Nervous system disorders					
-Total	9 (12.7)	1 (1.4)	4 (5.6)	4 (5.6)	0
Headache	9 (12.7)	1 (1.4)	4 (5.6)	4 (5.6)	0
Psychiatric disorders					
-Total	1 (1.4)	0	1 (1.4)	0	0
Insomnia	1 (1.4)	0	1 (1.4)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185j
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes >=5 unrelated abnormalities
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (68.2)	1 (4.5)	2 (9.1)	5 (22.7)	7 (31.8)
Blood and lymphatic system disorders					
-Total	9 (40.9)	0	0	4 (18.2)	5 (22.7)
Febrile neutropenia	5 (22.7)	0	0	5 (22.7)	0
Neutropenia	4 (18.2)	0	0	0	4 (18.2)
Anaemia	3 (13.6)	0	1 (4.5)	2 (9.1)	0
Thrombocytopenia	3 (13.6)	0	0	0	3 (13.6)
Gastrointestinal disorders					
-Total	4 (18.2)	1 (4.5)	3 (13.6)	0	0
Nausea	3 (13.6)	0	3 (13.6)	0	0
Vomiting	2 (9.1)	1 (4.5)	1 (4.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Pyrexia	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Investigations					
-Total	3 (13.6)	0	0	0	3 (13.6)
Platelet count decreased	2 (9.1)	0	0	0	2 (9.1)
White blood cell count decreased	2 (9.1)	0	0	0	2 (9.1)
Metabolism and nutrition disorders					
-Total	4 (18.2)	0	3 (13.6)	1 (4.5)	0
Decreased appetite	3 (13.6)	0	2 (9.1)	1 (4.5)	0
Hyperglycaemia	1 (4.5)	0	1 (4.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Pain in extremity	1 (4.5)	1 (4.5)	0	0	0
Nervous system disorders					
-Total	1 (4.5)	1 (4.5)	0	0	0
Headache	1 (4.5)	1 (4.5)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	1 (4.5)	0	1 (4.5)	0	0
Hypoxia	1 (4.5)	0	1 (4.5)	0	0
Vascular disorders					
-Total	3 (13.6)	0	0	2 (9.1)	1 (4.5)
Hypotension	3 (13.6)	0	0	2 (9.1)	1 (4.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185j
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes >=5 unrelated abnormalities
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (73.6)	2 (3.8)	2 (3.8)	18 (34.0)	17 (32.1)
Blood and lymphatic system disorders					
-Total	29 (54.7)	0	0	25 (47.2)	4 (7.5)
Anaemia	18 (34.0)	0	1 (1.9)	17 (32.1)	0
Febrile neutropenia	13 (24.5)	0	0	13 (24.5)	0
Thrombocytopenia	7 (13.2)	0	0	3 (5.7)	4 (7.5)
Neutropenia	2 (3.8)	0	0	1 (1.9)	1 (1.9)
Gastrointestinal disorders					
-Total	15 (28.3)	3 (5.7)	7 (13.2)	5 (9.4)	0
Abdominal pain	9 (17.0)	1 (1.9)	5 (9.4)	3 (5.7)	0
Nausea	7 (13.2)	0	4 (7.5)	3 (5.7)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	7 (13.2)	3 (5.7)	3 (5.7)	1 (1.9)	0
General disorders and administration site conditions					
-Total	9 (17.0)	5 (9.4)	2 (3.8)	2 (3.8)	0
Pyrexia	9 (17.0)	5 (9.4)	2 (3.8)	2 (3.8)	0
Investigations					
-Total	21 (39.6)	1 (1.9)	2 (3.8)	3 (5.7)	15 (28.3)
White blood cell count decreased	10 (18.9)	1 (1.9)	1 (1.9)	1 (1.9)	7 (13.2)
Neutrophil count decreased	9 (17.0)	0	0	0	9 (17.0)
Platelet count decreased	8 (15.1)	0	0	1 (1.9)	7 (13.2)
Alanine aminotransferase increased	6 (11.3)	0	1 (1.9)	5 (9.4)	0
Metabolism and nutrition disorders					
-Total	10 (18.9)	1 (1.9)	4 (7.5)	4 (7.5)	1 (1.9)
Hyperglycaemia	6 (11.3)	0	2 (3.8)	3 (5.7)	1 (1.9)
Decreased appetite	5 (9.4)	1 (1.9)	2 (3.8)	2 (3.8)	0
Musculoskeletal and connective tissue disorders					
-Total	8 (15.1)	1 (1.9)	2 (3.8)	5 (9.4)	0
Pain in extremity	8 (15.1)	1 (1.9)	2 (3.8)	5 (9.4)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	9 (17.0)	1 (1.9)	4 (7.5)	4 (7.5)	0
Headache	9 (17.0)	1 (1.9)	4 (7.5)	4 (7.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (11.3)	0	3 (5.7)	2 (3.8)	1 (1.9)
Hypoxia	6 (11.3)	0	3 (5.7)	2 (3.8)	1 (1.9)
Vascular disorders					
-Total	4 (7.5)	0	0	2 (3.8)	2 (3.8)
Hypotension	4 (7.5)	0	0	2 (3.8)	2 (3.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185k
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=75				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (70.7)	3 (4.0)	7 (9.3)	22 (29.3)	21 (28.0)
Blood and lymphatic system disorders					
-Total	37 (49.3)	0	1 (1.3)	29 (38.7)	7 (9.3)
Anaemia	21 (28.0)	0	2 (2.7)	19 (25.3)	0
Febrile neutropenia	18 (24.0)	0	0	18 (24.0)	0
Thrombocytopenia	10 (13.3)	0	0	3 (4.0)	7 (9.3)
Gastrointestinal disorders					
-Total	19 (25.3)	4 (5.3)	10 (13.3)	5 (6.7)	0
Nausea	10 (13.3)	0	7 (9.3)	3 (4.0)	0
Abdominal pain	9 (12.0)	1 (1.3)	5 (6.7)	3 (4.0)	0
Vomiting	9 (12.0)	4 (5.3)	4 (5.3)	1 (1.3)	0

Region: US

	All patients N=75				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	12 (16.0)	6 (8.0)	4 (5.3)	2 (2.7)	0
Pyrexia	12 (16.0)	6 (8.0)	4 (5.3)	2 (2.7)	0
Investigations					
-Total	20 (26.7)	1 (1.3)	1 (1.3)	0	18 (24.0)
White blood cell count decreased	12 (16.0)	1 (1.3)	1 (1.3)	1 (1.3)	9 (12.0)
Platelet count decreased	10 (13.3)	0	0	1 (1.3)	9 (12.0)
Neutrophil count decreased	9 (12.0)	0	0	0	9 (12.0)
Metabolism and nutrition disorders					
-Total	8 (10.7)	1 (1.3)	4 (5.3)	3 (4.0)	0
Decreased appetite	8 (10.7)	1 (1.3)	4 (5.3)	3 (4.0)	0
Musculoskeletal and connective tissue disorders					
-Total	9 (12.0)	2 (2.7)	2 (2.7)	5 (6.7)	0
Pain in extremity	9 (12.0)	2 (2.7)	2 (2.7)	5 (6.7)	0
Nervous system disorders					
-Total	10 (13.3)	2 (2.7)	4 (5.3)	4 (5.3)	0
Headache	10 (13.3)	2 (2.7)	4 (5.3)	4 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185l
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (75.0)	2 (6.3)	4 (12.5)	10 (31.3)	8 (25.0)
Blood and lymphatic system disorders					
-Total	16 (50.0)	0	0	13 (40.6)	3 (9.4)
Anaemia	10 (31.3)	0	0	10 (31.3)	0
Febrile neutropenia	6 (18.8)	0	0	6 (18.8)	0
Thrombocytopenia	5 (15.6)	0	0	2 (6.3)	3 (9.4)
Gastrointestinal disorders					
-Total	7 (21.9)	2 (6.3)	4 (12.5)	1 (3.1)	0
Abdominal pain	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Nausea	3 (9.4)	0	3 (9.4)	0	0
Vomiting	3 (9.4)	2 (6.3)	1 (3.1)	0	0

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	7 (21.9)	4 (12.5)	3 (9.4)	0	0
Pyrexia	6 (18.8)	3 (9.4)	3 (9.4)	0	0
Fatigue	2 (6.3)	2 (6.3)	0	0	0
Investigations					
-Total	11 (34.4)	0	2 (6.3)	2 (6.3)	7 (21.9)
Alanine aminotransferase increased	4 (12.5)	0	1 (3.1)	3 (9.4)	0
Neutrophil count decreased	4 (12.5)	0	0	0	4 (12.5)
Platelet count decreased	3 (9.4)	0	0	0	3 (9.4)
White blood cell count decreased	3 (9.4)	0	1 (3.1)	0	2 (6.3)
Metabolism and nutrition disorders					
-Total	7 (21.9)	0	3 (9.4)	3 (9.4)	1 (3.1)
Hyperglycaemia	5 (15.6)	0	2 (6.3)	2 (6.3)	1 (3.1)
Decreased appetite	3 (9.4)	0	1 (3.1)	2 (6.3)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0
Pain in extremity	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0

Prior SCT therapy: Yes

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Nervous system disorders					
-Total	6 (18.8)	2 (6.3)	2 (6.3)	2 (6.3)	0
Headache	6 (18.8)	2 (6.3)	2 (6.3)	2 (6.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185l
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (69.8)	1 (2.3)	2 (4.7)	12 (27.9)	15 (34.9)
Blood and lymphatic system disorders					
-Total	22 (51.2)	0	0	16 (37.2)	6 (14.0)
Febrile neutropenia	12 (27.9)	0	0	12 (27.9)	0
Anaemia	11 (25.6)	0	2 (4.7)	9 (20.9)	0
Neutropenia	6 (14.0)	0	0	1 (2.3)	5 (11.6)
Thrombocytopenia	5 (11.6)	0	0	1 (2.3)	4 (9.3)
Gastrointestinal disorders					
-Total	12 (27.9)	2 (4.7)	6 (14.0)	4 (9.3)	0
Nausea	7 (16.3)	0	4 (9.3)	3 (7.0)	0
Vomiting	6 (14.0)	2 (4.7)	3 (7.0)	1 (2.3)	0

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	5 (11.6)	1 (2.3)	2 (4.7)	2 (4.7)	0
General disorders and administration site conditions					
-Total	10 (23.3)	4 (9.3)	3 (7.0)	3 (7.0)	0
Pyrexia	6 (14.0)	3 (7.0)	1 (2.3)	2 (4.7)	0
Fatigue	5 (11.6)	2 (4.7)	2 (4.7)	1 (2.3)	0
Investigations					
-Total	13 (30.2)	1 (2.3)	0	1 (2.3)	11 (25.6)
White blood cell count decreased	9 (20.9)	1 (2.3)	0	1 (2.3)	7 (16.3)
Platelet count decreased	7 (16.3)	0	0	1 (2.3)	6 (14.0)
Neutrophil count decreased	5 (11.6)	0	0	0	5 (11.6)
Alanine aminotransferase increased	2 (4.7)	0	0	2 (4.7)	0
Metabolism and nutrition disorders					
-Total	7 (16.3)	1 (2.3)	4 (9.3)	2 (4.7)	0
Decreased appetite	5 (11.6)	1 (2.3)	3 (7.0)	1 (2.3)	0
Hyperglycaemia	2 (4.7)	0	1 (2.3)	1 (2.3)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (11.6)	1 (2.3)	1 (2.3)	3 (7.0)	0

Prior SCT therapy: No

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain in extremity	5 (11.6)	1 (2.3)	1 (2.3)	3 (7.0)	0
Nervous system disorders					
-Total	4 (9.3)	0	2 (4.7)	2 (4.7)	0
Headache	4 (9.3)	0	2 (4.7)	2 (4.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185m
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (83.3)	0	4 (22.2)	6 (33.3)	5 (27.8)
Blood and lymphatic system disorders					
-Total	7 (38.9)	0	1 (5.6)	5 (27.8)	1 (5.6)
Anaemia	5 (27.8)	0	1 (5.6)	4 (22.2)	0
Febrile neutropenia	3 (16.7)	0	0	3 (16.7)	0
Thrombocytopenia	1 (5.6)	0	0	0	1 (5.6)
Gastrointestinal disorders					
-Total	3 (16.7)	0	3 (16.7)	0	0
Nausea	2 (11.1)	0	2 (11.1)	0	0
Abdominal pain	1 (5.6)	0	1 (5.6)	0	0
Vomiting	1 (5.6)	0	1 (5.6)	0	0

Eligibility for SCT: Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	5 (27.8)	1 (5.6)	2 (11.1)	2 (11.1)	0
Pyrexia	3 (16.7)	1 (5.6)	0	2 (11.1)	0
Catheter site pain	2 (11.1)	0	2 (11.1)	0	0
Fatigue	1 (5.6)	0	1 (5.6)	0	0
Infections and infestations					
-Total	5 (27.8)	0	2 (11.1)	3 (16.7)	0
Conjunctivitis	2 (11.1)	0	2 (11.1)	0	0
Device related infection	2 (11.1)	0	0	2 (11.1)	0
Escherichia urinary tract infection	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Investigations					
-Total	6 (33.3)	1 (5.6)	1 (5.6)	0	4 (22.2)
White blood cell count decreased	5 (27.8)	1 (5.6)	1 (5.6)	0	3 (16.7)
Platelet count decreased	3 (16.7)	0	0	1 (5.6)	2 (11.1)
Neutrophil count decreased	2 (11.1)	0	0	0	2 (11.1)
Metabolism and nutrition disorders					
-Total	4 (22.2)	0	3 (16.7)	1 (5.6)	0

Eligibility for SCT: Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	2 (11.1)	0	2 (11.1)	0	0
Hyperglycaemia	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Musculoskeletal and connective tissue disorders					
-Total	6 (33.3)	1 (5.6)	4 (22.2)	1 (5.6)	0
Neck pain	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain in extremity	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Pain in jaw	2 (11.1)	0	2 (11.1)	0	0
Nervous system disorders					
-Total	1 (5.6)	0	1 (5.6)	0	0
Headache	1 (5.6)	0	1 (5.6)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Hypoxia	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Pleural effusion	2 (11.1)	0	2 (11.1)	0	0
Vascular disorders					
-Total	1 (5.6)	0	0	0	1 (5.6)
Hypotension	1 (5.6)	0	0	0	1 (5.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185m
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (73.7)	2 (3.5)	3 (5.3)	20 (35.1)	17 (29.8)
Blood and lymphatic system disorders					
-Total	30 (52.6)	0	0	24 (42.1)	6 (10.5)
Anaemia	16 (28.1)	0	1 (1.8)	15 (26.3)	0
Febrile neutropenia	15 (26.3)	0	0	15 (26.3)	0
Thrombocytopenia	9 (15.8)	0	0	3 (5.3)	6 (10.5)
Gastrointestinal disorders					
-Total	16 (28.1)	4 (7.0)	7 (12.3)	5 (8.8)	0
Abdominal pain	8 (14.0)	1 (1.8)	4 (7.0)	3 (5.3)	0
Nausea	8 (14.0)	0	5 (8.8)	3 (5.3)	0
Vomiting	8 (14.0)	4 (7.0)	3 (5.3)	1 (1.8)	0

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	14 (24.6)	8 (14.0)	5 (8.8)	1 (1.8)	0
Pyrexia	9 (15.8)	5 (8.8)	4 (7.0)	0	0
Fatigue	6 (10.5)	4 (7.0)	1 (1.8)	1 (1.8)	0
Catheter site pain	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Infections and infestations					
-Total	1 (1.8)	0	0	1 (1.8)	0
Device related infection	1 (1.8)	0	0	1 (1.8)	0
Investigations					
-Total	18 (31.6)	0	1 (1.8)	3 (5.3)	14 (24.6)
Neutrophil count decreased	7 (12.3)	0	0	0	7 (12.3)
Platelet count decreased	7 (12.3)	0	0	0	7 (12.3)
White blood cell count decreased	7 (12.3)	0	0	1 (1.8)	6 (10.5)
Alanine aminotransferase increased	6 (10.5)	0	1 (1.8)	5 (8.8)	0
Metabolism and nutrition disorders					
-Total	10 (17.5)	1 (1.8)	4 (7.0)	4 (7.0)	1 (1.8)
Decreased appetite	6 (10.5)	1 (1.8)	2 (3.5)	3 (5.3)	0

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	5 (8.8)	0	2 (3.5)	2 (3.5)	1 (1.8)
Musculoskeletal and connective tissue disorders					
-Total	8 (14.0)	2 (3.5)	2 (3.5)	4 (7.0)	0
Pain in extremity	7 (12.3)	2 (3.5)	1 (1.8)	4 (7.0)	0
Neck pain	1 (1.8)	0	1 (1.8)	0	0
Nervous system disorders					
-Total	9 (15.8)	2 (3.5)	3 (5.3)	4 (7.0)	0
Headache	9 (15.8)	2 (3.5)	3 (5.3)	4 (7.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (8.8)	1 (1.8)	2 (3.5)	1 (1.8)	1 (1.8)
Hypoxia	4 (7.0)	0	2 (3.5)	1 (1.8)	1 (1.8)
Pleural effusion	1 (1.8)	1 (1.8)	0	0	0
Vascular disorders					
-Total	6 (10.5)	0	0	4 (7.0)	2 (3.5)
Hypotension	6 (10.5)	0	0	4 (7.0)	2 (3.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185n
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (63.6)	0	1 (4.5)	7 (31.8)	6 (27.3)
Blood and lymphatic system disorders					
-Total	11 (50.0)	0	0	8 (36.4)	3 (13.6)
Anaemia	7 (31.8)	0	0	7 (31.8)	0
Febrile neutropenia	4 (18.2)	0	0	4 (18.2)	0
Thrombocytopenia	4 (18.2)	0	0	1 (4.5)	3 (13.6)
Gastrointestinal disorders					
-Total	8 (36.4)	2 (9.1)	3 (13.6)	3 (13.6)	0
Vomiting	4 (18.2)	2 (9.1)	1 (4.5)	1 (4.5)	0
Abdominal pain	3 (13.6)	0	1 (4.5)	2 (9.1)	0
Stomatitis	3 (13.6)	1 (4.5)	0	2 (9.1)	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (9.1)	0	1 (4.5)	1 (4.5)	0
General disorders and administration site conditions					
-Total	2 (9.1)	2 (9.1)	0	0	0
Pyrexia	2 (9.1)	2 (9.1)	0	0	0
Investigations					
-Total	5 (22.7)	0	0	0	5 (22.7)
Neutrophil count decreased	3 (13.6)	0	0	0	3 (13.6)
White blood cell count decreased	3 (13.6)	0	0	0	3 (13.6)
Platelet count decreased	1 (4.5)	0	0	0	1 (4.5)
Metabolism and nutrition disorders					
-Total	4 (18.2)	0	2 (9.1)	2 (9.1)	0
Dehydration	3 (13.6)	0	1 (4.5)	2 (9.1)	0
Decreased appetite	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (18.2)	1 (4.5)	1 (4.5)	2 (9.1)	0
Pain in extremity	4 (18.2)	1 (4.5)	1 (4.5)	2 (9.1)	0
Nervous system disorders					

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Headache	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Vascular disorders					
-Total	1 (4.5)	0	0	0	1 (4.5)
Hypotension	1 (4.5)	0	0	0	1 (4.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185n
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (79.2)	2 (3.8)	5 (9.4)	18 (34.0)	17 (32.1)
Blood and lymphatic system disorders					
-Total	26 (49.1)	0	1 (1.9)	21 (39.6)	4 (7.5)
Anaemia	14 (26.4)	0	2 (3.8)	12 (22.6)	0
Febrile neutropenia	14 (26.4)	0	0	14 (26.4)	0
Thrombocytopenia	6 (11.3)	0	0	2 (3.8)	4 (7.5)
Gastrointestinal disorders					
-Total	13 (24.5)	2 (3.8)	7 (13.2)	3 (5.7)	1 (1.9)
Nausea	8 (15.1)	0	6 (11.3)	2 (3.8)	0
Abdominal pain	6 (11.3)	1 (1.9)	4 (7.5)	1 (1.9)	0
Vomiting	5 (9.4)	2 (3.8)	3 (5.7)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	2 (3.8)	0	0	1 (1.9)	1 (1.9)
General disorders and administration site conditions					
-Total	10 (18.9)	4 (7.5)	4 (7.5)	2 (3.8)	0
Pyrexia	10 (18.9)	4 (7.5)	4 (7.5)	2 (3.8)	0
Investigations					
-Total	19 (35.8)	1 (1.9)	2 (3.8)	3 (5.7)	13 (24.5)
Platelet count decreased	9 (17.0)	0	0	1 (1.9)	8 (15.1)
White blood cell count decreased	9 (17.0)	1 (1.9)	1 (1.9)	1 (1.9)	6 (11.3)
Alanine aminotransferase increased	6 (11.3)	0	1 (1.9)	5 (9.4)	0
Neutrophil count decreased	6 (11.3)	0	0	0	6 (11.3)
Metabolism and nutrition disorders					
-Total	13 (24.5)	1 (1.9)	7 (13.2)	4 (7.5)	1 (1.9)
Hyperglycaemia	7 (13.2)	0	3 (5.7)	3 (5.7)	1 (1.9)
Decreased appetite	6 (11.3)	1 (1.9)	3 (5.7)	2 (3.8)	0
Dehydration	1 (1.9)	0	1 (1.9)	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (9.4)	1 (1.9)	1 (1.9)	3 (5.7)	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	5 (9.4)	1 (1.9)	1 (1.9)	3 (5.7)	0
Nervous system disorders					
-Total	8 (15.1)	2 (3.8)	3 (5.7)	3 (5.7)	0
Headache	8 (15.1)	2 (3.8)	3 (5.7)	3 (5.7)	0
Vascular disorders					
-Total	6 (11.3)	0	0	4 (7.5)	2 (3.8)
Hypotension	6 (11.3)	0	0	4 (7.5)	2 (3.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185o
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	0	3 (42.9)	3 (42.9)
Blood and lymphatic system disorders					
-Total	5 (71.4)	0	0	3 (42.9)	2 (28.6)
Anaemia	2 (28.6)	0	0	2 (28.6)	0
Febrile neutropenia	2 (28.6)	0	0	2 (28.6)	0
Neutropenia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Leukopenia	1 (14.3)	0	0	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	0	0	1 (14.3)
Gastrointestinal disorders					
-Total	4 (57.1)	1 (14.3)	3 (42.9)	0	0
Vomiting	2 (28.6)	1 (14.3)	1 (14.3)	0	0

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abdominal pain	1 (14.3)	0	1 (14.3)	0	0
Colitis	1 (14.3)	1 (14.3)	0	0	0
Constipation	1 (14.3)	0	1 (14.3)	0	0
Nausea	1 (14.3)	0	1 (14.3)	0	0
Perianal erythema	1 (14.3)	0	1 (14.3)	0	0
Hepatobiliary disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Hyperbilirubinaemia	1 (14.3)	0	1 (14.3)	0	0
Immune system disorders					
-Total	2 (28.6)	0	0	2 (28.6)	0
Anaphylactic reaction	2 (28.6)	0	0	2 (28.6)	0
Hypogammaglobulinaemia	1 (14.3)	1 (14.3)	0	0	0
Infections and infestations					
-Total	3 (42.9)	0	0	3 (42.9)	0
Device related infection	1 (14.3)	0	0	1 (14.3)	0
Escherichia bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Escherichia infection	1 (14.3)	0	0	1 (14.3)	0
Sinusitis	1 (14.3)	1 (14.3)	0	0	0

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal infection	1 (14.3)	0	0	1 (14.3)	0
Injury, poisoning and procedural complications					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Extradural haematoma	1 (14.3)	0	0	1 (14.3)	0
Procedural pain	1 (14.3)	0	0	1 (14.3)	0
Radiation skin injury	1 (14.3)	0	1 (14.3)	0	0
Subdural haematoma	1 (14.3)	0	0	1 (14.3)	0
Investigations					
-Total	4 (57.1)	0	0	3 (42.9)	1 (14.3)
Aspartate aminotransferase increased	3 (42.9)	0	1 (14.3)	2 (28.6)	0
Alanine aminotransferase increased	2 (28.6)	0	0	2 (28.6)	0
Blood bilirubin increased	1 (14.3)	0	0	1 (14.3)	0
Platelet count decreased	1 (14.3)	0	0	0	1 (14.3)
White blood cell count decreased	1 (14.3)	0	0	0	1 (14.3)
Metabolism and nutrition disorders					
-Total	4 (57.1)	0	0	3 (42.9)	1 (14.3)
Hypokalaemia	2 (28.6)	1 (14.3)	0	1 (14.3)	0

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	2 (28.6)	0	0	2 (28.6)	0
Decreased appetite	1 (14.3)	0	0	1 (14.3)	0
Hyperglycaemia	1 (14.3)	0	0	1 (14.3)	0
Hyperkalaemia	1 (14.3)	0	1 (14.3)	0	0
Hyperuricaemia	1 (14.3)	0	0	0	1 (14.3)
Malnutrition	1 (14.3)	0	1 (14.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Back pain	1 (14.3)	1 (14.3)	0	0	0
Bone pain	1 (14.3)	0	0	1 (14.3)	0
Muscle spasms	1 (14.3)	1 (14.3)	0	0	0
Musculoskeletal chest pain	1 (14.3)	1 (14.3)	0	0	0
Pain in extremity	1 (14.3)	0	1 (14.3)	0	0
Pain in jaw	1 (14.3)	0	1 (14.3)	0	0
Nervous system disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Headache	1 (14.3)	0	0	1 (14.3)	0

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Psychiatric disorders					
-Total	2 (28.6)	1 (14.3)	0	1 (14.3)	0
Irritability	1 (14.3)	1 (14.3)	0	0	0
Mental status changes	1 (14.3)	0	0	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Epistaxis	1 (14.3)	0	0	1 (14.3)	0
Skin and subcutaneous tissue disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Urticaria	1 (14.3)	0	1 (14.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185o
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (76.5)	2 (2.9)	4 (5.9)	25 (36.8)	21 (30.9)
Blood and lymphatic system disorders					
-Total	33 (48.5)	0	0	26 (38.2)	7 (10.3)
Anaemia	19 (27.9)	0	2 (2.9)	17 (25.0)	0
Febrile neutropenia	16 (23.5)	0	0	16 (23.5)	0
Thrombocytopenia	9 (13.2)	0	0	3 (4.4)	6 (8.8)
Neutropenia	4 (5.9)	0	0	0	4 (5.9)
Gastrointestinal disorders					
-Total	20 (29.4)	4 (5.9)	9 (13.2)	7 (10.3)	0
Nausea	9 (13.2)	0	6 (8.8)	3 (4.4)	0
Abdominal pain	8 (11.8)	1 (1.5)	4 (5.9)	3 (4.4)	0

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	7 (10.3)	3 (4.4)	3 (4.4)	1 (1.5)	0
Constipation	4 (5.9)	3 (4.4)	1 (1.5)	0	0
Colitis	3 (4.4)	0	0	3 (4.4)	0
General disorders and administration site conditions					
-Total	17 (25.0)	8 (11.8)	6 (8.8)	3 (4.4)	0
Pyrexia	12 (17.6)	6 (8.8)	4 (5.9)	2 (2.9)	0
Fatigue	7 (10.3)	4 (5.9)	2 (2.9)	1 (1.5)	0
Hepatobiliary disorders					
-Total	2 (2.9)	0	0	2 (2.9)	0
Hyperbilirubinaemia	2 (2.9)	0	0	2 (2.9)	0
Immune system disorders					
-Total	2 (2.9)	0	2 (2.9)	0	0
Hypogammaglobulinaemia	2 (2.9)	0	2 (2.9)	0	0
Infections and infestations					
-Total	3 (4.4)	0	0	3 (4.4)	0
Device related infection	2 (2.9)	0	0	2 (2.9)	0
Escherichia bacteraemia	1 (1.5)	0	0	1 (1.5)	0

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	4 (5.9)	0	3 (4.4)	1 (1.5)	0
Procedural pain	3 (4.4)	0	2 (2.9)	1 (1.5)	0
Subdural haematoma	1 (1.5)	0	1 (1.5)	0	0
Investigations					
-Total	21 (30.9)	1 (1.5)	2 (2.9)	1 (1.5)	17 (25.0)
White blood cell count decreased	11 (16.2)	1 (1.5)	1 (1.5)	1 (1.5)	8 (11.8)
Neutrophil count decreased	9 (13.2)	0	0	0	9 (13.2)
Platelet count decreased	9 (13.2)	0	0	1 (1.5)	8 (11.8)
Alanine aminotransferase increased	4 (5.9)	0	1 (1.5)	3 (4.4)	0
Aspartate aminotransferase increased	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Metabolism and nutrition disorders					
-Total	16 (23.5)	1 (1.5)	7 (10.3)	6 (8.8)	2 (2.9)
Decreased appetite	7 (10.3)	1 (1.5)	4 (5.9)	2 (2.9)	0
Hyperglycaemia	6 (8.8)	0	3 (4.4)	2 (2.9)	1 (1.5)
Hyperuricaemia	3 (4.4)	2 (2.9)	0	1 (1.5)	0
Hypokalaemia	3 (4.4)	0	0	1 (1.5)	2 (2.9)

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (1.5)	0	0	1 (1.5)	0
Musculoskeletal and connective tissue disorders					
-Total	10 (14.7)	2 (2.9)	2 (2.9)	6 (8.8)	0
Pain in extremity	8 (11.8)	2 (2.9)	1 (1.5)	5 (7.4)	0
Back pain	2 (2.9)	0	0	2 (2.9)	0
Bone pain	1 (1.5)	0	1 (1.5)	0	0
Pain in jaw	1 (1.5)	0	1 (1.5)	0	0
Nervous system disorders					
-Total	9 (13.2)	2 (2.9)	4 (5.9)	3 (4.4)	0
Headache	9 (13.2)	2 (2.9)	4 (5.9)	3 (4.4)	0
Psychiatric disorders					
-Total	2 (2.9)	2 (2.9)	0	0	0
Mental status changes	2 (2.9)	2 (2.9)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	8 (11.8)	0	5 (7.4)	2 (2.9)	1 (1.5)
Hypoxia	7 (10.3)	0	4 (5.9)	2 (2.9)	1 (1.5)
Epistaxis	2 (2.9)	0	2 (2.9)	0	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	7 (10.3)	0	0	4 (5.9)	3 (4.4)
Hypotension	7 (10.3)	0	0	4 (5.9)	3 (4.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185p
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	0	1 (25.0)	2 (50.0)	0
Blood and lymphatic system disorders					
-Total	2 (50.0)	0	0	2 (50.0)	0
Anaemia	1 (25.0)	0	0	1 (25.0)	0
Febrile neutropenia	1 (25.0)	0	0	1 (25.0)	0
Cardiac disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Bradycardia	1 (25.0)	1 (25.0)	0	0	0
Gastrointestinal disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Gastrointestinal haemorrhage	1 (25.0)	1 (25.0)	0	0	0

Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (25.0)	0	0	1 (25.0)	0
Infections and infestations					
-Total	2 (50.0)	0	2 (50.0)	0	0
Conjunctivitis	1 (25.0)	0	1 (25.0)	0	0
Metapneumovirus infection	1 (25.0)	0	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (50.0)	2 (50.0)	0	0	0
Dermatitis diaper	1 (25.0)	1 (25.0)	0	0	0
Rash papular	1 (25.0)	1 (25.0)	0	0	0
Vascular disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Hypertension	1 (25.0)	1 (25.0)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185p
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (74.6)	3 (4.2)	7 (9.9)	21 (29.6)	22 (31.0)
Blood and lymphatic system disorders					
-Total	35 (49.3)	0	1 (1.4)	27 (38.0)	7 (9.9)
Anaemia	20 (28.2)	0	2 (2.8)	18 (25.4)	0
Febrile neutropenia	17 (23.9)	0	0	17 (23.9)	0
Thrombocytopenia	10 (14.1)	0	0	3 (4.2)	7 (9.9)
Cardiac disorders					
-Total	1 (1.4)	0	0	0	1 (1.4)
Bradycardia	1 (1.4)	0	0	0	1 (1.4)
Gastrointestinal disorders					
-Total	21 (29.6)	4 (5.6)	10 (14.1)	6 (8.5)	1 (1.4)

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	10 (14.1)	0	7 (9.9)	3 (4.2)	0
Abdominal pain	9 (12.7)	1 (1.4)	5 (7.0)	3 (4.2)	0
Vomiting	9 (12.7)	4 (5.6)	4 (5.6)	1 (1.4)	0
Stomatitis	4 (5.6)	1 (1.4)	0	2 (2.8)	1 (1.4)
Gastrointestinal haemorrhage	1 (1.4)	0	0	1 (1.4)	0
General disorders and administration site conditions					
-Total	12 (16.9)	6 (8.5)	4 (5.6)	2 (2.8)	0
Pyrexia	12 (16.9)	6 (8.5)	4 (5.6)	2 (2.8)	0
Infections and infestations					
-Total	1 (1.4)	0	1 (1.4)	0	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Investigations					
-Total	20 (28.2)	1 (1.4)	1 (1.4)	0	18 (25.4)
White blood cell count decreased	12 (16.9)	1 (1.4)	1 (1.4)	1 (1.4)	9 (12.7)
Platelet count decreased	10 (14.1)	0	0	1 (1.4)	9 (12.7)
Neutrophil count decreased	9 (12.7)	0	0	0	9 (12.7)
Metabolism and nutrition disorders					

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (11.3)	1 (1.4)	4 (5.6)	3 (4.2)	0
Decreased appetite	8 (11.3)	1 (1.4)	4 (5.6)	3 (4.2)	0
Musculoskeletal and connective tissue disorders					
-Total	9 (12.7)	2 (2.8)	2 (2.8)	5 (7.0)	0
Pain in extremity	9 (12.7)	2 (2.8)	2 (2.8)	5 (7.0)	0
Nervous system disorders					
-Total	10 (14.1)	2 (2.8)	4 (5.6)	4 (5.6)	0
Headache	10 (14.1)	2 (2.8)	4 (5.6)	4 (5.6)	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (8.5)	0	3 (4.2)	2 (2.8)	1 (1.4)
Hypoxia	6 (8.5)	0	3 (4.2)	2 (2.8)	1 (1.4)
Skin and subcutaneous tissue disorders					
-Total	1 (1.4)	1 (1.4)	0	0	0
Rash papular	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0

Down syndrome: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185q
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (75.0)	1 (3.1)	4 (12.5)	10 (31.3)	9 (28.1)
Blood and lymphatic system disorders					
-Total	16 (50.0)	0	0	15 (46.9)	1 (3.1)
Febrile neutropenia	9 (28.1)	0	0	9 (28.1)	0
Anaemia	7 (21.9)	0	1 (3.1)	6 (18.8)	0
Neutropenia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Thrombocytopenia	1 (3.1)	0	0	1 (3.1)	0
Gastrointestinal disorders					
-Total	10 (31.3)	3 (9.4)	6 (18.8)	1 (3.1)	0
Nausea	5 (15.6)	0	5 (15.6)	0	0
Vomiting	4 (12.5)	3 (9.4)	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	3 (9.4)	0	3 (9.4)	0	0
Colitis	1 (3.1)	0	0	1 (3.1)	0
General disorders and administration site conditions					
-Total	8 (25.0)	2 (6.3)	5 (15.6)	1 (3.1)	0
Catheter site pain	4 (12.5)	1 (3.1)	3 (9.4)	0	0
Pyrexia	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Fatigue	2 (6.3)	0	2 (6.3)	0	0
Pain	1 (3.1)	0	1 (3.1)	0	0
Injury, poisoning and procedural complications					
-Total	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Procedural pain	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Investigations					
-Total	14 (43.8)	1 (3.1)	2 (6.3)	3 (9.4)	8 (25.0)
White blood cell count decreased	7 (21.9)	1 (3.1)	1 (3.1)	1 (3.1)	4 (12.5)
Alanine aminotransferase increased	6 (18.8)	0	1 (3.1)	5 (15.6)	0
Platelet count decreased	6 (18.8)	0	0	0	6 (18.8)

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0
Neutrophil count decreased	4 (12.5)	0	0	0	4 (12.5)
Metabolism and nutrition disorders					
-Total	5 (15.6)	0	2 (6.3)	3 (9.4)	0
Hyperglycaemia	4 (12.5)	0	1 (3.1)	3 (9.4)	0
Decreased appetite	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Hypokalaemia	1 (3.1)	0	0	1 (3.1)	0
Musculoskeletal and connective tissue disorders					
-Total	5 (15.6)	2 (6.3)	2 (6.3)	1 (3.1)	0
Pain in extremity	5 (15.6)	2 (6.3)	2 (6.3)	1 (3.1)	0
Nervous system disorders					
-Total	6 (18.8)	0	3 (9.4)	3 (9.4)	0
Headache	6 (18.8)	0	3 (9.4)	3 (9.4)	0
Renal and urinary disorders					
-Total	1 (3.1)	1 (3.1)	0	0	0
Acute kidney injury	1 (3.1)	1 (3.1)	0	0	0

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	2 (6.3)	0	2 (6.3)	0	0
Hypoxia	2 (6.3)	0	2 (6.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185q
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (68.8)	1 (3.1)	0	12 (37.5)	9 (28.1)
Blood and lymphatic system disorders					
-Total	17 (53.1)	0	0	12 (37.5)	5 (15.6)
Anaemia	10 (31.3)	0	1 (3.1)	9 (28.1)	0
Febrile neutropenia	8 (25.0)	0	0	8 (25.0)	0
Thrombocytopenia	5 (15.6)	0	0	1 (3.1)	4 (12.5)
Neutropenia	2 (6.3)	0	0	0	2 (6.3)
Gastrointestinal disorders					
-Total	7 (21.9)	2 (6.3)	2 (6.3)	3 (9.4)	0
Abdominal pain	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Nausea	2 (6.3)	0	0	2 (6.3)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Colitis	1 (3.1)	1 (3.1)	0	0	0
General disorders and administration site conditions					
-Total	10 (31.3)	7 (21.9)	2 (6.3)	1 (3.1)	0
Pyrexia	7 (21.9)	5 (15.6)	2 (6.3)	0	0
Fatigue	5 (15.6)	4 (12.5)	0	1 (3.1)	0
Investigations					
-Total	7 (21.9)	0	0	1 (3.1)	6 (18.8)
White blood cell count decreased	4 (12.5)	0	0	0	4 (12.5)
Neutrophil count decreased	3 (9.4)	0	0	0	3 (9.4)
Platelet count decreased	3 (9.4)	0	0	1 (3.1)	2 (6.3)
Aspartate aminotransferase increased	1 (3.1)	0	0	1 (3.1)	0
Metabolism and nutrition disorders					
-Total	6 (18.8)	1 (3.1)	3 (9.4)	2 (6.3)	0
Decreased appetite	5 (15.6)	1 (3.1)	3 (9.4)	1 (3.1)	0
Hypokalaemia	2 (6.3)	1 (3.1)	0	1 (3.1)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	2 (6.3)	0	0	2 (6.3)	0
Pain in extremity	2 (6.3)	0	0	2 (6.3)	0
Nervous system disorders					
-Total	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Headache	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (6.3)	0	2 (6.3)	0	0
Hypoxia	2 (6.3)	0	2 (6.3)	0	0
Vascular disorders					
-Total	2 (6.3)	0	0	2 (6.3)	0
Hypotension	2 (6.3)	0	0	2 (6.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185q
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	0	1 (9.1)	1 (9.1)	6 (54.5)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Febrile neutropenia	1 (9.1)	0	0	1 (9.1)	0
Gastrointestinal disorders					
-Total	5 (45.5)	0	2 (18.2)	3 (27.3)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
General disorders and administration site conditions					
-Total	4 (36.4)	0	1 (9.1)	1 (9.1)	2 (18.2)
Multiple organ dysfunction syndrome	2 (18.2)	0	0	0	2 (18.2)
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pyrexia	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Infections and infestations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Investigations					
-Total	4 (36.4)	0	0	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Platelet count decreased	1 (9.1)	0	0	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	5 (45.5)	0	2 (18.2)	1 (9.1)	2 (18.2)
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Hypokalaemia	2 (18.2)	0	0	0	2 (18.2)
Decreased appetite	1 (9.1)	0	0	1 (9.1)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (18.2)	0	0	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Nervous system disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Headache	1 (9.1)	0	0	1 (9.1)	0
Renal and urinary disorders					
-Total	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Respiratory, thoracic and mediastinal disorders					
-Total	4 (36.4)	0	0	1 (9.1)	3 (27.3)

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Vascular disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Hypotension	5 (45.5)	0	0	2 (18.2)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185r
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	1 (12.5)	0	4 (50.0)	3 (37.5)
Blood and lymphatic system disorders					
-Total	5 (62.5)	0	0	5 (62.5)	0
Febrile neutropenia	3 (37.5)	0	0	3 (37.5)	0
Anaemia	2 (25.0)	0	0	2 (25.0)	0
Cardiac disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Tachycardia	1 (12.5)	0	0	1 (12.5)	0
Gastrointestinal disorders					
-Total	4 (50.0)	2 (25.0)	0	1 (12.5)	1 (12.5)
Abdominal pain	2 (25.0)	1 (12.5)	1 (12.5)	0	0

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Nausea	2 (25.0)	0	0	2 (25.0)	0
Stomatitis	2 (25.0)	1 (12.5)	0	0	1 (12.5)
Vomiting	2 (25.0)	2 (25.0)	0	0	0
Dyspepsia	1 (12.5)	0	1 (12.5)	0	0
General disorders and administration site conditions					
-Total	4 (50.0)	2 (25.0)	0	2 (25.0)	0
Fatigue	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Pyrexia	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Catheter site pain	1 (12.5)	1 (12.5)	0	0	0
Chills	1 (12.5)	1 (12.5)	0	0	0
Pain	1 (12.5)	0	0	1 (12.5)	0
Immune system disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hypogammaglobulinaemia	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	2 (25.0)	0	0	0	2 (25.0)

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cellulitis	1 (12.5)	0	0	1 (12.5)	0
Clostridium difficile infection	1 (12.5)	0	1 (12.5)	0	0
Human polyomavirus infection	1 (12.5)	0	0	0	1 (12.5)
Oral herpes	1 (12.5)	0	0	1 (12.5)	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Injury, poisoning and procedural complications					
-Total	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Procedural pain	1 (12.5)	0	0	1 (12.5)	0
Wound	1 (12.5)	1 (12.5)	0	0	0
Investigations					
-Total	1 (12.5)	0	0	0	1 (12.5)
Neutrophil count decreased	1 (12.5)	0	0	0	1 (12.5)
White blood cell count decreased	1 (12.5)	0	0	0	1 (12.5)
Metabolism and nutrition disorders					
-Total	2 (25.0)	0	2 (25.0)	0	0
Decreased appetite	1 (12.5)	0	1 (12.5)	0	0
Dehydration	1 (12.5)	0	1 (12.5)	0	0

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypomagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Vitamin d deficiency	1 (12.5)	0	1 (12.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Pain in extremity	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Neck pain	1 (12.5)	0	1 (12.5)	0	0
Nervous system disorders					
-Total	2 (25.0)	0	2 (25.0)	0	0
Headache	2 (25.0)	0	2 (25.0)	0	0
Psychiatric disorders					
-Total	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Anxiety	1 (12.5)	0	1 (12.5)	0	0
Confusional state	1 (12.5)	0	1 (12.5)	0	0
Depression	1 (12.5)	1 (12.5)	0	0	0
Renal and urinary disorders					
-Total	1 (12.5)	0	0	0	1 (12.5)
Cystitis haemorrhagic	1 (12.5)	0	0	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	2 (25.0)	0	1 (12.5)	0	1 (12.5)
Hypoxia	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Aspiration	1 (12.5)	0	0	0	1 (12.5)
Cough	1 (12.5)	1 (12.5)	0	0	0
Epistaxis	1 (12.5)	0	1 (12.5)	0	0
Nasal congestion	1 (12.5)	1 (12.5)	0	0	0
Oropharyngeal pain	1 (12.5)	1 (12.5)	0	0	0
Pleural effusion	1 (12.5)	0	1 (12.5)	0	0
Rhinorrhoea	1 (12.5)	1 (12.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (25.0)	2 (25.0)	0	0	0
Dermatitis diaper	1 (12.5)	1 (12.5)	0	0	0
Rash papular	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	3 (37.5)	1 (12.5)	0	1 (12.5)	1 (12.5)
Hypotension	2 (25.0)	0	0	1 (12.5)	1 (12.5)

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (12.5)	1 (12.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185r
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (73.9)	0	2 (8.7)	9 (39.1)	6 (26.1)
Blood and lymphatic system disorders					
-Total	12 (52.2)	0	0	9 (39.1)	3 (13.0)
Febrile neutropenia	6 (26.1)	0	0	6 (26.1)	0
Anaemia	5 (21.7)	0	0	5 (21.7)	0
Neutropenia	2 (8.7)	0	0	0	2 (8.7)
Thrombocytopenia	2 (8.7)	0	0	0	2 (8.7)
Cardiac disorders					
-Total	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Tachycardia	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Gastrointestinal disorders					

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (43.5)	1 (4.3)	6 (26.1)	3 (13.0)	0
Abdominal pain	5 (21.7)	0	3 (13.0)	2 (8.7)	0
Nausea	5 (21.7)	0	4 (17.4)	1 (4.3)	0
Vomiting	3 (13.0)	0	2 (8.7)	1 (4.3)	0
Constipation	2 (8.7)	2 (8.7)	0	0	0
Colitis	1 (4.3)	1 (4.3)	0	0	0
Stomatitis	1 (4.3)	0	0	1 (4.3)	0
General disorders and administration site conditions					
-Total	4 (17.4)	1 (4.3)	3 (13.0)	0	0
Pyrexia	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Catheter site pain	1 (4.3)	0	1 (4.3)	0	0
Pain	1 (4.3)	0	1 (4.3)	0	0
Immune system disorders					
-Total	1 (4.3)	1 (4.3)	0	0	0
Hypogammaglobulinaemia	1 (4.3)	1 (4.3)	0	0	0
Infections and infestations					
-Total	1 (4.3)	0	1 (4.3)	0	0

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (4.3)	0	1 (4.3)	0	0
Injury, poisoning and procedural complications					
-Total	1 (4.3)	0	1 (4.3)	0	0
Procedural pain	1 (4.3)	0	1 (4.3)	0	0
Investigations					
-Total	7 (30.4)	0	2 (8.7)	1 (4.3)	4 (17.4)
Platelet count decreased	3 (13.0)	0	0	0	3 (13.0)
White blood cell count decreased	3 (13.0)	0	1 (4.3)	0	2 (8.7)
Alanine aminotransferase increased	1 (4.3)	0	1 (4.3)	0	0
Aspartate aminotransferase increased	1 (4.3)	0	0	1 (4.3)	0
Metabolism and nutrition disorders					
-Total	7 (30.4)	1 (4.3)	2 (8.7)	4 (17.4)	0
Hyperglycaemia	4 (17.4)	0	2 (8.7)	2 (8.7)	0
Decreased appetite	3 (13.0)	1 (4.3)	0	2 (8.7)	0
Hypokalaemia	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Dehydration	1 (4.3)	0	0	1 (4.3)	0
Hypomagnesaemia	1 (4.3)	1 (4.3)	0	0	0

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vitamin d deficiency	1 (4.3)	0	1 (4.3)	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (17.4)	0	2 (8.7)	2 (8.7)	0
Back pain	3 (13.0)	1 (4.3)	0	2 (8.7)	0
Pain in extremity	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Neck pain	1 (4.3)	0	1 (4.3)	0	0
Nervous system disorders					
-Total	4 (17.4)	0	2 (8.7)	2 (8.7)	0
Headache	4 (17.4)	0	2 (8.7)	2 (8.7)	0
Psychiatric disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Anxiety	1 (4.3)	0	1 (4.3)	0	0
Depression	1 (4.3)	0	1 (4.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (13.0)	0	2 (8.7)	1 (4.3)	0
Hypoxia	3 (13.0)	0	2 (8.7)	1 (4.3)	0
Cough	2 (8.7)	1 (4.3)	0	1 (4.3)	0

Number of previous relapses: 1

Group term Preferred term	All patients N=23 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Oropharyngeal pain	1 (4.3)	0	0	1 (4.3)	0
Pleural effusion	1 (4.3)	0	1 (4.3)	0	0
Vascular disorders					
-Total	2 (8.7)	0	0	1 (4.3)	1 (4.3)
Hypertension	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Hypotension	1 (4.3)	0	0	0	1 (4.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185r
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (70.8)	0	1 (4.2)	7 (29.2)	9 (37.5)
Blood and lymphatic system disorders					
-Total	12 (50.0)	0	0	8 (33.3)	4 (16.7)
Anaemia	7 (29.2)	0	2 (8.3)	5 (20.8)	0
Febrile neutropenia	7 (29.2)	0	0	7 (29.2)	0
Neutropenia	4 (16.7)	0	0	1 (4.2)	3 (12.5)
Thrombocytopenia	4 (16.7)	0	0	1 (4.2)	3 (12.5)
Gastrointestinal disorders					
-Total	5 (20.8)	1 (4.2)	4 (16.7)	0	0
Constipation	3 (12.5)	1 (4.2)	2 (8.3)	0	0

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (8.3)	0	2 (8.3)	0	0
Abdominal pain	1 (4.2)	0	1 (4.2)	0	0
Vomiting	1 (4.2)	0	1 (4.2)	0	0
General disorders and administration site conditions					
-Total	8 (33.3)	4 (16.7)	3 (12.5)	1 (4.2)	0
Fatigue	4 (16.7)	2 (8.3)	2 (8.3)	0	0
Pyrexia	3 (12.5)	2 (8.3)	0	1 (4.2)	0
Catheter site pain	2 (8.3)	0	2 (8.3)	0	0
Infections and infestations					
-Total	1 (4.2)	0	1 (4.2)	0	0
Oral herpes	1 (4.2)	0	1 (4.2)	0	0
Injury, poisoning and procedural complications					
-Total	1 (4.2)	0	1 (4.2)	0	0
Procedural pain	1 (4.2)	0	1 (4.2)	0	0
Investigations					
-Total	9 (37.5)	1 (4.2)	0	2 (8.3)	6 (25.0)
White blood cell count decreased	6 (25.0)	1 (4.2)	0	1 (4.2)	4 (16.7)

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	4 (16.7)	0	0	0	4 (16.7)
Platelet count decreased	4 (16.7)	0	0	1 (4.2)	3 (12.5)
Alanine aminotransferase increased	3 (12.5)	0	0	3 (12.5)	0
Aspartate aminotransferase increased	3 (12.5)	1 (4.2)	1 (4.2)	1 (4.2)	0
Metabolism and nutrition disorders					
-Total	4 (16.7)	0	3 (12.5)	0	1 (4.2)
Decreased appetite	2 (8.3)	0	2 (8.3)	0	0
Hypomagnesaemia	2 (8.3)	2 (8.3)	0	0	0
Dehydration	1 (4.2)	0	1 (4.2)	0	0
Hypokalaemia	1 (4.2)	0	0	0	1 (4.2)
Musculoskeletal and connective tissue disorders					
-Total	2 (8.3)	1 (4.2)	0	1 (4.2)	0
Neck pain	1 (4.2)	1 (4.2)	0	0	0
Pain in extremity	1 (4.2)	0	0	1 (4.2)	0
Nervous system disorders					
-Total	1 (4.2)	0	0	1 (4.2)	0
Headache	1 (4.2)	0	0	1 (4.2)	0

Number of previous relapses: 2

Group term Preferred term	All patients N=24 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Psychiatric disorders					
-Total	1 (4.2)	0	1 (4.2)	0	0
Confusional state	1 (4.2)	0	1 (4.2)	0	0
Vascular disorders					
-Total	1 (4.2)	0	0	0	1 (4.2)
Hypotension	1 (4.2)	0	0	0	1 (4.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 185r
Adverse events before study treatment, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (75.0)	2 (10.0)	1 (5.0)	5 (25.0)	7 (35.0)
Blood and lymphatic system disorders					
-Total	9 (45.0)	0	0	7 (35.0)	2 (10.0)
Anaemia	7 (35.0)	0	0	7 (35.0)	0
Thrombocytopenia	4 (20.0)	0	0	2 (10.0)	2 (10.0)
Febrile neutropenia	2 (10.0)	0	0	2 (10.0)	0
Gastrointestinal disorders					
-Total	7 (35.0)	2 (10.0)	1 (5.0)	4 (20.0)	0
Colitis	3 (15.0)	0	0	3 (15.0)	0
Vomiting	3 (15.0)	2 (10.0)	1 (5.0)	0	0

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	2 (10.0)	0	0	2 (10.0)	0
Abdominal pain	1 (5.0)	0	0	1 (5.0)	0
Diarrhoea	1 (5.0)	0	0	1 (5.0)	0
Nausea	1 (5.0)	0	1 (5.0)	0	0
General disorders and administration site conditions					
-Total	6 (30.0)	2 (10.0)	2 (10.0)	0	2 (10.0)
Pyrexia	4 (20.0)	2 (10.0)	2 (10.0)	0	0
Multiple organ dysfunction syndrome	2 (10.0)	0	0	0	2 (10.0)
Chills	1 (5.0)	1 (5.0)	0	0	0
Fatigue	1 (5.0)	1 (5.0)	0	0	0
Pain	1 (5.0)	0	1 (5.0)	0	0
Immune system disorders					
-Total	1 (5.0)	0	1 (5.0)	0	0
Hypogammaglobulinaemia	1 (5.0)	0	1 (5.0)	0	0
Infections and infestations					
-Total	5 (25.0)	0	1 (5.0)	2 (10.0)	2 (10.0)
Enterococcal bacteraemia	2 (10.0)	0	0	2 (10.0)	0

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella sepsis	2 (10.0)	0	0	0	2 (10.0)
Oral herpes	1 (5.0)	0	1 (5.0)	0	0
Injury, poisoning and procedural complications					
-Total	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Subdural haematoma	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Procedural pain	1 (5.0)	0	0	1 (5.0)	0
Investigations					
-Total	8 (40.0)	0	0	1 (5.0)	7 (35.0)
Neutrophil count decreased	4 (20.0)	0	0	0	4 (20.0)
Platelet count decreased	3 (15.0)	0	0	0	3 (15.0)
Alanine aminotransferase increased	2 (10.0)	0	0	2 (10.0)	0
White blood cell count decreased	2 (10.0)	0	0	0	2 (10.0)
Aspartate aminotransferase increased	1 (5.0)	0	0	1 (5.0)	0
Metabolism and nutrition disorders					
-Total	6 (30.0)	0	2 (10.0)	3 (15.0)	1 (5.0)
Hyperglycaemia	3 (15.0)	0	1 (5.0)	1 (5.0)	1 (5.0)
Decreased appetite	2 (10.0)	0	1 (5.0)	1 (5.0)	0

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Dehydration	1 (5.0)	0	0	1 (5.0)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0
Pain in extremity	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0
Nervous system disorders					
-Total	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Headache	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Renal and urinary disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Cystitis haemorrhagic	1 (5.0)	0	0	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (20.0)	0	2 (10.0)	1 (5.0)	1 (5.0)
Epistaxis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Hypoxia	2 (10.0)	0	1 (5.0)	0	1 (5.0)
Pleural effusion	1 (5.0)	1 (5.0)	0	0	0

Number of previous relapses: >=3

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	1 (5.0)	1 (5.0)	0	0	0
Rash papular	1 (5.0)	1 (5.0)	0	0	0
Vascular disorders					
-Total	4 (20.0)	1 (5.0)	0	3 (15.0)	0
Hypotension	3 (15.0)	0	0	3 (15.0)	0
Hypertension	1 (5.0)	1 (5.0)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186a
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (65.0)	2 (10.0)	2 (10.0)	3 (15.0)	6 (30.0)
Blood and lymphatic system disorders					
-Total	6 (30.0)	0	0	5 (25.0)	1 (5.0)
Anaemia	3 (15.0)	0	0	3 (15.0)	0
Febrile neutropenia	3 (15.0)	0	0	3 (15.0)	0
Neutropenia	1 (5.0)	0	0	0	1 (5.0)
Gastrointestinal disorders					
-Total	6 (30.0)	3 (15.0)	3 (15.0)	0	0
Abdominal pain	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Constipation	2 (10.0)	2 (10.0)	0	0	0

Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Nausea	2 (10.0)	1 (5.0)	1 (5.0)	0	0
General disorders and administration site conditions					
-Total	4 (20.0)	1 (5.0)	3 (15.0)	0	0
Pyrexia	3 (15.0)	0	3 (15.0)	0	0
Catheter site pain	1 (5.0)	1 (5.0)	0	0	0
Infections and infestations					
-Total	1 (5.0)	0	0	1 (5.0)	0
Device related infection	1 (5.0)	0	0	1 (5.0)	0
Investigations					
-Total	9 (45.0)	0	2 (10.0)	1 (5.0)	6 (30.0)
White blood cell count decreased	6 (30.0)	0	0	1 (5.0)	5 (25.0)
Neutrophil count decreased	3 (15.0)	0	0	0	3 (15.0)
C-reactive protein increased	2 (10.0)	0	2 (10.0)	0	0
Lymphocyte count decreased	2 (10.0)	0	0	0	2 (10.0)
Platelet count decreased	2 (10.0)	0	1 (5.0)	0	1 (5.0)
Alanine aminotransferase increased	1 (5.0)	0	1 (5.0)	0	0

Age: <10 years

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders					
-Total	5 (25.0)	2 (10.0)	1 (5.0)	2 (10.0)	0
Hypokalaemia	2 (10.0)	0	0	2 (10.0)	0
Hypophosphataemia	2 (10.0)	2 (10.0)	0	0	0
Decreased appetite	1 (5.0)	0	1 (5.0)	0	0
Fluid overload	1 (5.0)	0	1 (5.0)	0	0
Hypomagnesaemia	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Pain in jaw	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Nervous system disorders					
-Total	2 (10.0)	0	2 (10.0)	0	0
Headache	2 (10.0)	0	2 (10.0)	0	0
Psychiatric disorders					
-Total	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Anxiety	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Respiratory, thoracic and mediastinal disorders					

Age: <10 years

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (15.0)	0	0	3 (15.0)	0
Hypoxia	2 (10.0)	0	0	2 (10.0)	0
Tachypnoea	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Dyspnoea	1 (5.0)	1 (5.0)	0	0	0
Epistaxis	1 (5.0)	0	0	1 (5.0)	0
Vascular disorders					
-Total	1 (5.0)	0	0	1 (5.0)	0
Hypertension	1 (5.0)	0	0	1 (5.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186a
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (72.7)	3 (9.1)	2 (6.1)	7 (21.2)	12 (36.4)
Blood and lymphatic system disorders					
-Total	7 (21.2)	0	0	7 (21.2)	0
Febrile neutropenia	5 (15.2)	0	0	5 (15.2)	0
Anaemia	2 (6.1)	0	0	2 (6.1)	0
Neutropenia	1 (3.0)	0	0	1 (3.0)	0
Gastrointestinal disorders					
-Total	4 (12.1)	4 (12.1)	0	0	0
Nausea	3 (9.1)	3 (9.1)	0	0	0
Vomiting	2 (6.1)	2 (6.1)	0	0	0

Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (3.0)	1 (3.0)	0	0	0
General disorders and administration site conditions					
-Total	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Pyrexia	3 (9.1)	1 (3.0)	2 (6.1)	0	0
Investigations					
-Total	16 (48.5)	0	1 (3.0)	4 (12.1)	11 (33.3)
White blood cell count decreased	11 (33.3)	0	0	2 (6.1)	9 (27.3)
Neutrophil count decreased	7 (21.2)	0	0	0	7 (21.2)
Alanine aminotransferase increased	6 (18.2)	1 (3.0)	1 (3.0)	3 (9.1)	1 (3.0)
Lymphocyte count decreased	2 (6.1)	0	0	1 (3.0)	1 (3.0)
Platelet count decreased	2 (6.1)	0	0	2 (6.1)	0
Metabolism and nutrition disorders					
-Total	5 (15.2)	3 (9.1)	0	0	2 (6.1)
Hypokalaemia	3 (9.1)	1 (3.0)	0	0	2 (6.1)
Decreased appetite	1 (3.0)	1 (3.0)	0	0	0
Hyperuricaemia	1 (3.0)	1 (3.0)	0	0	0
Nervous system disorders					

Age: >=10 years to <18 years

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (9.1)	3 (9.1)	0	0	0
Headache	3 (9.1)	3 (9.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (3.0)	0	0	1 (3.0)	0
Hypoxia	1 (3.0)	0	0	1 (3.0)	0
Vascular disorders					
-Total	2 (6.1)	0	0	2 (6.1)	0
Hypotension	2 (6.1)	0	0	2 (6.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186a
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=18

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (87.5)	1 (12.5)	1 (12.5)	2 (25.0)	3 (37.5)
Blood and lymphatic system disorders					
-Total	3 (37.5)	0	1 (12.5)	0	2 (25.0)
Anaemia	2 (25.0)	0	2 (25.0)	0	0
Neutropenia	2 (25.0)	0	0	0	2 (25.0)
Febrile neutropenia	1 (12.5)	0	1 (12.5)	0	0
Gastrointestinal disorders					
-Total	4 (50.0)	1 (12.5)	3 (37.5)	0	0
Nausea	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Diarrhoea	1 (12.5)	0	1 (12.5)	0	0

Age: >=18

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (12.5)	0	1 (12.5)	0	0
General disorders and administration site conditions					
-Total	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Catheter site pain	1 (12.5)	1 (12.5)	0	0	0
Medical device pain	1 (12.5)	0	1 (12.5)	0	0
Pain	1 (12.5)	0	1 (12.5)	0	0
Infections and infestations					
-Total	1 (12.5)	0	0	1 (12.5)	0
Device related infection	1 (12.5)	0	1 (12.5)	0	0
Necrotising fasciitis	1 (12.5)	0	0	1 (12.5)	0
Investigations					
-Total	2 (25.0)	0	0	0	2 (25.0)
White blood cell count decreased	2 (25.0)	0	0	0	2 (25.0)
Metabolism and nutrition disorders					
-Total	2 (25.0)	0	0	2 (25.0)	0
Decreased appetite	1 (12.5)	0	1 (12.5)	0	0
Fluid overload	1 (12.5)	0	1 (12.5)	0	0

Age: >=18

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	1 (12.5)	0	0	1 (12.5)	0
Hypomagnesaemia	1 (12.5)	0	1 (12.5)	0	0
Hypophosphataemia	1 (12.5)	1 (12.5)	0	0	0
Tumour lysis syndrome	1 (12.5)	0	0	1 (12.5)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Pain in extremity	1 (12.5)	0	0	1 (12.5)	0
Psychiatric disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Insomnia	1 (12.5)	0	1 (12.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (25.0)	0	2 (25.0)	0	0
Dyspnoea	1 (12.5)	0	1 (12.5)	0	0
Epistaxis	1 (12.5)	0	1 (12.5)	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0

Age: >=18

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin haemorrhage	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Hypertension	1 (12.5)	1 (12.5)	0	0	0
Hypotension	1 (12.5)	0	0	1 (12.5)	0
Phlebitis	1 (12.5)	0	1 (12.5)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186b
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Male

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (69.0)	3 (10.3)	3 (10.3)	5 (17.2)	9 (31.0)
Blood and lymphatic system disorders					
-Total	8 (27.6)	0	2 (6.9)	6 (20.7)	0
Febrile neutropenia	6 (20.7)	0	1 (3.4)	5 (17.2)	0
Anaemia	4 (13.8)	0	2 (6.9)	2 (6.9)	0
Gastrointestinal disorders					
-Total	6 (20.7)	4 (13.8)	2 (6.9)	0	0
Nausea	5 (17.2)	3 (10.3)	2 (6.9)	0	0
Vomiting	3 (10.3)	2 (6.9)	1 (3.4)	0	0
General disorders and administration site conditions					

Gender: Male

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (10.3)	1 (3.4)	2 (6.9)	0	0
Pyrexia	3 (10.3)	1 (3.4)	2 (6.9)	0	0
Investigations					
-Total	11 (37.9)	0	0	2 (6.9)	9 (31.0)
White blood cell count decreased	9 (31.0)	0	0	2 (6.9)	7 (24.1)
Neutrophil count decreased	4 (13.8)	0	0	0	4 (13.8)
Alanine aminotransferase increased	3 (10.3)	0	1 (3.4)	1 (3.4)	1 (3.4)
Metabolism and nutrition disorders					
-Total	3 (10.3)	1 (3.4)	0	1 (3.4)	1 (3.4)
Hypokalaemia	3 (10.3)	1 (3.4)	0	1 (3.4)	1 (3.4)
Nervous system disorders					
-Total	1 (3.4)	0	1 (3.4)	0	0
Headache	1 (3.4)	0	1 (3.4)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186b
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Female

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (62.5)	1 (3.1)	3 (9.4)	5 (15.6)	11 (34.4)
Blood and lymphatic system disorders					
-Total	6 (18.8)	0	0	6 (18.8)	0
Anaemia	3 (9.4)	0	0	3 (9.4)	0
Febrile neutropenia	3 (9.4)	0	0	3 (9.4)	0
Gastrointestinal disorders					
-Total	6 (18.8)	3 (9.4)	3 (9.4)	0	0
Diarrhoea	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Nausea	3 (9.4)	2 (6.3)	1 (3.1)	0	0
General disorders and administration site conditions					

Gender: Female

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (9.4)	0	3 (9.4)	0	0
Pyrexia	3 (9.4)	0	3 (9.4)	0	0
Investigations					
-Total	14 (43.8)	0	1 (3.1)	3 (9.4)	10 (31.3)
White blood cell count decreased	10 (31.3)	0	0	1 (3.1)	9 (28.1)
Neutrophil count decreased	6 (18.8)	0	0	0	6 (18.8)
Alanine aminotransferase increased	4 (12.5)	1 (3.1)	1 (3.1)	2 (6.3)	0
Lymphocyte count decreased	4 (12.5)	0	0	1 (3.1)	3 (9.4)
Metabolism and nutrition disorders					
-Total	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Hypokalaemia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Nervous system disorders					
-Total	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Headache	4 (12.5)	3 (9.4)	1 (3.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186c
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: White

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (66.0)	3 (6.0)	5 (10.0)	10 (20.0)	15 (30.0)
Blood and lymphatic system disorders					
-Total	13 (26.0)	0	2 (4.0)	11 (22.0)	0
Febrile neutropenia	8 (16.0)	0	1 (2.0)	7 (14.0)	0
Anaemia	7 (14.0)	0	2 (4.0)	5 (10.0)	0
Gastrointestinal disorders					
-Total	9 (18.0)	4 (8.0)	5 (10.0)	0	0
Nausea	6 (12.0)	3 (6.0)	3 (6.0)	0	0
Diarrhoea	3 (6.0)	1 (2.0)	2 (4.0)	0	0
General disorders and administration site conditions					

Race: White

	All patients N=50				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (12.0)	2 (4.0)	4 (8.0)	0	0
Pyrexia	5 (10.0)	1 (2.0)	4 (8.0)	0	0
Catheter site pain	1 (2.0)	1 (2.0)	0	0	0
Investigations					
-Total	20 (40.0)	0	1 (2.0)	4 (8.0)	15 (30.0)
White blood cell count decreased	16 (32.0)	0	0	3 (6.0)	13 (26.0)
Neutrophil count decreased	10 (20.0)	0	0	0	10 (20.0)
Alanine aminotransferase increased	6 (12.0)	1 (2.0)	1 (2.0)	3 (6.0)	1 (2.0)
Platelet count decreased	3 (6.0)	0	1 (2.0)	2 (4.0)	0
Aspartate aminotransferase increased	2 (4.0)	0	1 (2.0)	0	1 (2.0)
Metabolism and nutrition disorders					
-Total	6 (12.0)	1 (2.0)	2 (4.0)	2 (4.0)	1 (2.0)
Hypokalaemia	4 (8.0)	1 (2.0)	0	2 (4.0)	1 (2.0)
Decreased appetite	2 (4.0)	0	2 (4.0)	0	0
Nervous system disorders					
-Total	4 (8.0)	2 (4.0)	2 (4.0)	0	0
Headache	4 (8.0)	2 (4.0)	2 (4.0)	0	0

Race: White

Group term Preferred term	All patients N=50 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	2 (4.0)	0	0	2 (4.0)	0
Hypotension	2 (4.0)	0	0	2 (4.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186c
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Asian

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	1 (20.0)	1 (20.0)	2 (40.0)
General disorders and administration site conditions					
-Total	1 (20.0)	0	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	1 (20.0)	0	0
Investigations					
-Total	3 (60.0)	0	1 (20.0)	0	2 (40.0)
White blood cell count decreased	2 (40.0)	0	0	0	2 (40.0)
Alanine aminotransferase increased	1 (20.0)	0	1 (20.0)	0	0
Aspartate aminotransferase increased	1 (20.0)	1 (20.0)	0	0	0

Race: Asian

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood uric acid increased	1 (20.0)	1 (20.0)	0	0	0
Platelet count decreased	1 (20.0)	0	0	0	1 (20.0)
Metabolism and nutrition disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Hyperglycaemia	1 (20.0)	0	0	1 (20.0)	0
Skin and subcutaneous tissue disorders					
-Total	1 (20.0)	1 (20.0)	0	0	0
Pruritus generalised	1 (20.0)	1 (20.0)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186c
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Other

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (83.3)	2 (33.3)	0	1 (16.7)	2 (33.3)
Blood and lymphatic system disorders					
-Total	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Febrile neutropenia	1 (16.7)	0	0	1 (16.7)	0
Hypofibrinogenaemia	1 (16.7)	0	0	0	1 (16.7)
Cardiac disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Tachycardia	1 (16.7)	1 (16.7)	0	0	0
Gastrointestinal disorders					
-Total	2 (33.3)	2 (33.3)	0	0	0

Race: Other

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (33.3)	2 (33.3)	0	0	0
Abdominal pain lower	1 (16.7)	1 (16.7)	0	0	0
Diarrhoea	1 (16.7)	1 (16.7)	0	0	0
Haematochezia	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	3 (50.0)	1 (16.7)	2 (33.3)	0	0
Catheter site pain	1 (16.7)	1 (16.7)	0	0	0
Chills	1 (16.7)	0	1 (16.7)	0	0
Device related thrombosis	1 (16.7)	0	1 (16.7)	0	0
Investigations					
-Total	2 (33.3)	0	0	0	2 (33.3)
Lipase increased	1 (16.7)	0	0	0	1 (16.7)
Weight decreased	1 (16.7)	1 (16.7)	0	0	0
White blood cell count decreased	1 (16.7)	0	0	0	1 (16.7)
Metabolism and nutrition disorders					
-Total	2 (33.3)	1 (16.7)	0	0	1 (16.7)
Decreased appetite	1 (16.7)	1 (16.7)	0	0	0

Race: Other

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	1 (16.7)	0	0	0	1 (16.7)
Nervous system disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Headache	1 (16.7)	1 (16.7)	0	0	0
Product issues					
-Total	1 (16.7)	1 (16.7)	0	0	0
Device occlusion	1 (16.7)	1 (16.7)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Nasal discomfort	1 (16.7)	1 (16.7)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Rash pruritic	1 (16.7)	1 (16.7)	0	0	0
Vascular disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Hypotension	1 (16.7)	0	0	1 (16.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186d
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Hispanic or Latino

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (65.2)	0	1 (4.3)	5 (21.7)	9 (39.1)
Blood and lymphatic system disorders					
-Total	6 (26.1)	0	1 (4.3)	5 (21.7)	0
Febrile neutropenia	5 (21.7)	0	1 (4.3)	4 (17.4)	0
Anaemia	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Gastrointestinal disorders					
-Total	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Nausea	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Investigations					
-Total	11 (47.8)	0	0	2 (8.7)	9 (39.1)

Ethnicity: Hispanic or Latino

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	10 (43.5)	0	0	2 (8.7)	8 (34.8)
Neutrophil count decreased	6 (26.1)	0	0	0	6 (26.1)
Alanine aminotransferase increased	2 (8.7)	0	0	2 (8.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186d
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Other

	All patients N=38				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (57.9)	4 (10.5)	4 (10.5)	5 (13.2)	9 (23.7)
Blood and lymphatic system disorders					
-Total	8 (21.1)	0	1 (2.6)	7 (18.4)	0
Anaemia	5 (13.2)	0	1 (2.6)	4 (10.5)	0
Febrile neutropenia	4 (10.5)	0	0	4 (10.5)	0
Gastrointestinal disorders					
-Total	5 (13.2)	4 (10.5)	1 (2.6)	0	0
Nausea	5 (13.2)	4 (10.5)	1 (2.6)	0	0
General disorders and administration site conditions					
-Total	6 (15.8)	1 (2.6)	5 (13.2)	0	0

Ethnicity: Other

Group term Preferred term	All patients N=38 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pyrexia	6 (15.8)	1 (2.6)	5 (13.2)	0	0
Investigations					
-Total	12 (31.6)	0	1 (2.6)	2 (5.3)	9 (23.7)
White blood cell count decreased	9 (23.7)	0	0	1 (2.6)	8 (21.1)
Alanine aminotransferase increased	5 (13.2)	1 (2.6)	2 (5.3)	1 (2.6)	1 (2.6)
Neutrophil count decreased	4 (10.5)	0	0	0	4 (10.5)
Platelet count decreased	4 (10.5)	0	1 (2.6)	2 (5.3)	1 (2.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186e
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (57.1)	0	0	1 (14.3)	3 (42.9)
Blood and lymphatic system disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)
Anaemia	1 (14.3)	0	1 (14.3)	0	0
Neutropenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0
Gastrointestinal disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0

Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (14.3)	1 (14.3)	0	0	0
General disorders and administration site conditions					
-Total	1 (14.3)	0	1 (14.3)	0	0
Pyrexia	1 (14.3)	0	1 (14.3)	0	0
Investigations					
-Total	2 (28.6)	0	0	0	2 (28.6)
Neutrophil count decreased	2 (28.6)	0	0	0	2 (28.6)
White blood cell count decreased	2 (28.6)	0	0	0	2 (28.6)
Metabolism and nutrition disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Hypokalaemia	1 (14.3)	1 (14.3)	0	0	0
Nervous system disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Dysgeusia	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	2 (28.6)	0	2 (28.6)	0	0
Depression	1 (14.3)	0	1 (14.3)	0	0

Response status at study entry: Primary refractory

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Insomnia	1 (14.3)	0	1 (14.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186e
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Relapsed disease

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (63.0)	4 (7.4)	3 (5.6)	9 (16.7)	18 (33.3)
Blood and lymphatic system disorders					
-Total	15 (27.8)	0	1 (1.9)	12 (22.2)	2 (3.7)
Febrile neutropenia	9 (16.7)	0	1 (1.9)	8 (14.8)	0
Anaemia	6 (11.1)	0	1 (1.9)	5 (9.3)	0
Neutropenia	3 (5.6)	0	0	1 (1.9)	2 (3.7)
Gastrointestinal disorders					
-Total	8 (14.8)	5 (9.3)	3 (5.6)	0	0
Nausea	8 (14.8)	5 (9.3)	3 (5.6)	0	0
Vomiting	2 (3.7)	1 (1.9)	1 (1.9)	0	0

Response status at study entry: Relapsed disease

	All patients N=54				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	5 (9.3)	1 (1.9)	4 (7.4)	0	0
Pyrexia	5 (9.3)	1 (1.9)	4 (7.4)	0	0
Investigations					
-Total	21 (38.9)	0	1 (1.9)	4 (7.4)	16 (29.6)
White blood cell count decreased	17 (31.5)	0	0	3 (5.6)	14 (25.9)
Neutrophil count decreased	8 (14.8)	0	0	0	8 (14.8)
Alanine aminotransferase increased	7 (13.0)	1 (1.9)	2 (3.7)	3 (5.6)	1 (1.9)
Metabolism and nutrition disorders					
-Total	4 (7.4)	0	0	2 (3.7)	2 (3.7)
Hypokalaemia	4 (7.4)	0	0	2 (3.7)	2 (3.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186f
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	0	1 (50.0)	0
Investigations					
-Total	1 (50.0)	0	1 (50.0)	0	0
Alanine aminotransferase increased	1 (50.0)	0	1 (50.0)	0	0
Aspartate aminotransferase increased	1 (50.0)	1 (50.0)	0	0	0
Blood uric acid increased	1 (50.0)	1 (50.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Hyperglycaemia	1 (50.0)	0	0	1 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186f
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (61.0)	3 (5.1)	5 (8.5)	10 (16.9)	18 (30.5)
Blood and lymphatic system disorders					
-Total	14 (23.7)	0	2 (3.4)	12 (20.3)	0
Febrile neutropenia	9 (15.3)	0	1 (1.7)	8 (13.6)	0
Anaemia	7 (11.9)	0	2 (3.4)	5 (8.5)	0
Gastrointestinal disorders					
-Total	8 (13.6)	5 (8.5)	3 (5.1)	0	0
Nausea	8 (13.6)	5 (8.5)	3 (5.1)	0	0
General disorders and administration site conditions					
-Total	6 (10.2)	1 (1.7)	5 (8.5)	0	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	6 (10.2)	1 (1.7)	5 (8.5)	0	0
Investigations					
-Total	23 (39.0)	0	1 (1.7)	4 (6.8)	18 (30.5)
White blood cell count decreased	19 (32.2)	0	0	3 (5.1)	16 (27.1)
Neutrophil count decreased	10 (16.9)	0	0	0	10 (16.9)
Alanine aminotransferase increased	6 (10.2)	1 (1.7)	1 (1.7)	3 (5.1)	1 (1.7)
Aspartate aminotransferase increased	2 (3.4)	0	1 (1.7)	0	1 (1.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186g
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	0	3 (100)
Blood and lymphatic system disorders					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Anaemia	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Febrile neutropenia	1 (33.3)	0	0	1 (33.3)	0
Lymphopenia	1 (33.3)	0	0	0	1 (33.3)
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Cardiac disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Bradycardia	1 (33.3)	0	1 (33.3)	0	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Nausea	1 (33.3)	1 (33.3)	0	0	0
General disorders and administration site conditions					
-Total	1 (33.3)	0	1 (33.3)	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Infections and infestations					
-Total	1 (33.3)	0	1 (33.3)	0	0
Pneumonia	1 (33.3)	0	1 (33.3)	0	0
Investigations					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0	0	0
Blood lactic acid increased	1 (33.3)	0	1 (33.3)	0	0
C-reactive protein increased	1 (33.3)	0	1 (33.3)	0	0
Neutrophil count decreased	1 (33.3)	0	0	0	1 (33.3)
Platelet count decreased	1 (33.3)	0	0	1 (33.3)	0
Protein total decreased	1 (33.3)	0	0	1 (33.3)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (33.3)	0	0	0	1 (33.3)
Metabolism and nutrition disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Fluid overload	1 (33.3)	0	1 (33.3)	0	0
Hypermagnesaemia	1 (33.3)	1 (33.3)	0	0	0
Hypokalaemia	1 (33.3)	0	0	1 (33.3)	0
Nervous system disorders					
-Total	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Headache	1 (33.3)	1 (33.3)	0	0	0
Hypotonia	1 (33.3)	0	1 (33.3)	0	0
Psychiatric disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Insomnia	1 (33.3)	0	1 (33.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Hypoxia	1 (33.3)	0	0	1 (33.3)	0
Tachypnoea	1 (33.3)	0	0	1 (33.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186g
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: No

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (62.1)	4 (6.9)	5 (8.6)	8 (13.8)	19 (32.8)
Blood and lymphatic system disorders					
-Total	13 (22.4)	0	1 (1.7)	10 (17.2)	2 (3.4)
Febrile neutropenia	8 (13.8)	0	1 (1.7)	7 (12.1)	0
Anaemia	5 (8.6)	0	1 (1.7)	4 (6.9)	0
Neutropenia	3 (5.2)	0	0	1 (1.7)	2 (3.4)
Gastrointestinal disorders					
-Total	7 (12.1)	4 (6.9)	3 (5.2)	0	0
Nausea	7 (12.1)	4 (6.9)	3 (5.2)	0	0
General disorders and administration site conditions					

Mixed-lineage leukemia rearrangement: No

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (8.6)	1 (1.7)	4 (6.9)	0	0
Pyrexia	5 (8.6)	1 (1.7)	4 (6.9)	0	0
Investigations					
-Total	23 (39.7)	0	2 (3.4)	4 (6.9)	17 (29.3)
White blood cell count decreased	18 (31.0)	0	0	3 (5.2)	15 (25.9)
Neutrophil count decreased	9 (15.5)	0	0	0	9 (15.5)
Alanine aminotransferase increased	6 (10.3)	0	2 (3.4)	3 (5.2)	1 (1.7)
Platelet count decreased	3 (5.2)	0	1 (1.7)	1 (1.7)	1 (1.7)
C-reactive protein increased	1 (1.7)	0	1 (1.7)	0	0
Metabolism and nutrition disorders					
-Total	5 (8.6)	1 (1.7)	1 (1.7)	1 (1.7)	2 (3.4)
Hypokalaemia	4 (6.9)	1 (1.7)	0	1 (1.7)	2 (3.4)
Fluid overload	1 (1.7)	0	1 (1.7)	0	0
Nervous system disorders					
-Total	4 (6.9)	2 (3.4)	2 (3.4)	0	0
Headache	4 (6.9)	2 (3.4)	2 (3.4)	0	0
Respiratory, thoracic and mediastinal disorders					

Mixed-lineage leukemia rearrangement: No

	All patients N=58				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (3.4)	0	0	2 (3.4)	0
Hypoxia	2 (3.4)	0	0	2 (3.4)	0
Tachypnoea	1 (1.7)	0	1 (1.7)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186h
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Blood and lymphatic system disorders					
-Total	1 (100)	0	0	1 (100)	0
Febrile neutropenia	1 (100)	0	0	1 (100)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186h
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: No

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (60.0)	4 (6.7)	5 (8.3)	9 (15.0)	18 (30.0)
Blood and lymphatic system disorders					
-Total	13 (21.7)	0	2 (3.3)	11 (18.3)	0
Febrile neutropenia	8 (13.3)	0	1 (1.7)	7 (11.7)	0
Anaemia	7 (11.7)	0	2 (3.3)	5 (8.3)	0
Gastrointestinal disorders					
-Total	8 (13.3)	5 (8.3)	3 (5.0)	0	0
Nausea	8 (13.3)	5 (8.3)	3 (5.0)	0	0
General disorders and administration site conditions					
-Total	6 (10.0)	1 (1.7)	5 (8.3)	0	0

Hypodiploidy: No

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pyrexia	6 (10.0)	1 (1.7)	5 (8.3)	0	0
Investigations					
-Total	23 (38.3)	0	1 (1.7)	4 (6.7)	18 (30.0)
White blood cell count decreased	19 (31.7)	0	0	3 (5.0)	16 (26.7)
Neutrophil count decreased	10 (16.7)	0	0	0	10 (16.7)
Alanine aminotransferase increased	7 (11.7)	1 (1.7)	2 (3.3)	3 (5.0)	1 (1.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186i
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	1 (25.0)	0	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Febrile neutropenia	1 (25.0)	0	0	1 (25.0)	0
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
Eye disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Eye irritation	1 (25.0)	1 (25.0)	0	0	0
Infections and infestations					
-Total	1 (25.0)	0	0	1 (25.0)	0

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Investigations					
-Total	4 (100)	1 (25.0)	1 (25.0)	0	2 (50.0)
Alanine aminotransferase increased	1 (25.0)	0	1 (25.0)	0	0
Aspartate aminotransferase increased	1 (25.0)	1 (25.0)	0	0	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0	0	0
Blood uric acid increased	1 (25.0)	1 (25.0)	0	0	0
Lymphocyte count decreased	1 (25.0)	0	0	0	1 (25.0)
White blood cell count decreased	1 (25.0)	0	0	0	1 (25.0)
Metabolism and nutrition disorders					
-Total	2 (50.0)	0	0	2 (50.0)	0
Hyperglycaemia	1 (25.0)	0	0	1 (25.0)	0
Hypokalaemia	1 (25.0)	0	0	1 (25.0)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Pain in jaw	1 (25.0)	1 (25.0)	0	0	0

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Skin and subcutaneous tissue disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Pruritus generalised	1 (25.0)	1 (25.0)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186i
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (63.2)	3 (5.3)	4 (7.0)	10 (17.5)	19 (33.3)
Blood and lymphatic system disorders					
-Total	15 (26.3)	0	1 (1.8)	12 (21.1)	2 (3.5)
Febrile neutropenia	8 (14.0)	0	1 (1.8)	7 (12.3)	0
Anaemia	7 (12.3)	0	2 (3.5)	5 (8.8)	0
Neutropenia	3 (5.3)	0	0	1 (1.8)	2 (3.5)
Gastrointestinal disorders					
-Total	8 (14.0)	5 (8.8)	3 (5.3)	0	0
Nausea	8 (14.0)	5 (8.8)	3 (5.3)	0	0
General disorders and administration site conditions					

BCR-ABL1-like: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (10.5)	1 (1.8)	5 (8.8)	0	0
Pyrexia	6 (10.5)	1 (1.8)	5 (8.8)	0	0
Investigations					
-Total	23 (40.4)	0	1 (1.8)	5 (8.8)	17 (29.8)
White blood cell count decreased	18 (31.6)	0	0	3 (5.3)	15 (26.3)
Neutrophil count decreased	10 (17.5)	0	0	0	10 (17.5)
Alanine aminotransferase increased	6 (10.5)	1 (1.8)	1 (1.8)	3 (5.3)	1 (1.8)
Lymphocyte count decreased	3 (5.3)	0	0	1 (1.8)	2 (3.5)
Aspartate aminotransferase increased	2 (3.5)	0	1 (1.8)	0	1 (1.8)
Metabolism and nutrition disorders					
-Total	4 (7.0)	1 (1.8)	0	1 (1.8)	2 (3.5)
Hypokalaemia	4 (7.0)	1 (1.8)	0	1 (1.8)	2 (3.5)
Musculoskeletal and connective tissue disorders					
-Total	1 (1.8)	0	1 (1.8)	0	0
Pain in jaw	1 (1.8)	0	1 (1.8)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186j
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (66.7)	1 (5.6)	2 (11.1)	2 (11.1)	7 (38.9)
Blood and lymphatic system disorders					
-Total	4 (22.2)	0	0	3 (16.7)	1 (5.6)
Neutropenia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Anaemia	1 (5.6)	0	0	1 (5.6)	0
Febrile neutropenia	1 (5.6)	0	0	1 (5.6)	0
Gastrointestinal disorders					
-Total	4 (22.2)	3 (16.7)	1 (5.6)	0	0
Diarrhoea	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Nausea	2 (11.1)	2 (11.1)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	3 (16.7)	0	3 (16.7)	0	0
Pyrexia	3 (16.7)	0	3 (16.7)	0	0
Investigations					
-Total	7 (38.9)	0	0	1 (5.6)	6 (33.3)
White blood cell count decreased	6 (33.3)	0	0	0	6 (33.3)
Neutrophil count decreased	3 (16.7)	0	0	0	3 (16.7)
Alanine aminotransferase increased	2 (11.1)	0	0	2 (11.1)	0
Metabolism and nutrition disorders					
-Total	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Hypokalaemia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Nervous system disorders					
-Total	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Headache	2 (11.1)	1 (5.6)	1 (5.6)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186j
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (62.8)	3 (7.0)	3 (7.0)	7 (16.3)	14 (32.6)
Blood and lymphatic system disorders					
-Total	12 (27.9)	0	1 (2.3)	9 (20.9)	2 (4.7)
Febrile neutropenia	8 (18.6)	0	1 (2.3)	7 (16.3)	0
Anaemia	6 (14.0)	0	2 (4.7)	4 (9.3)	0
Neutropenia	2 (4.7)	0	0	0	2 (4.7)
Gastrointestinal disorders					
-Total	7 (16.3)	3 (7.0)	4 (9.3)	0	0
Nausea	6 (14.0)	3 (7.0)	3 (7.0)	0	0
Diarrhoea	2 (4.7)	1 (2.3)	1 (2.3)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Pyrexia	3 (7.0)	1 (2.3)	2 (4.7)	0	0
Investigations					
-Total	16 (37.2)	0	1 (2.3)	3 (7.0)	12 (27.9)
White blood cell count decreased	13 (30.2)	0	0	3 (7.0)	10 (23.3)
Neutrophil count decreased	7 (16.3)	0	0	0	7 (16.3)
Alanine aminotransferase increased	5 (11.6)	1 (2.3)	2 (4.7)	1 (2.3)	1 (2.3)
Metabolism and nutrition disorders					
-Total	3 (7.0)	1 (2.3)	0	1 (2.3)	1 (2.3)
Hypokalaemia	3 (7.0)	1 (2.3)	0	1 (2.3)	1 (2.3)
Nervous system disorders					
-Total	3 (7.0)	2 (4.7)	1 (2.3)	0	0
Headache	3 (7.0)	2 (4.7)	1 (2.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused)

are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
/vob/CCTL019/haq/haq_eu_5/pgm/saf/t186_gd_b2205.sas@@/main/3 03DEC20:14:28 Final

Table 186k
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: US

	All patients N=61				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (55.7)	3 (4.9)	3 (4.9)	10 (16.4)	18 (29.5)
Blood and lymphatic system disorders					
-Total	14 (23.0)	0	2 (3.3)	12 (19.7)	0
Febrile neutropenia	9 (14.8)	0	1 (1.6)	8 (13.1)	0
Anaemia	7 (11.5)	0	2 (3.3)	5 (8.2)	0
Gastrointestinal disorders					
-Total	8 (13.1)	5 (8.2)	3 (4.9)	0	0
Nausea	8 (13.1)	5 (8.2)	3 (4.9)	0	0
Investigations					
-Total	23 (37.7)	0	1 (1.6)	4 (6.6)	18 (29.5)

Region: US

Group term Preferred term	All patients N=61 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	19 (31.1)	0	0	3 (4.9)	16 (26.2)
Neutrophil count decreased	10 (16.4)	0	0	0	10 (16.4)
Alanine aminotransferase increased	7 (11.5)	1 (1.6)	2 (3.3)	3 (4.9)	1 (1.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186l
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (60.7)	2 (7.1)	2 (7.1)	3 (10.7)	10 (35.7)
Blood and lymphatic system disorders					
-Total	6 (21.4)	0	0	6 (21.4)	0
Febrile neutropenia	4 (14.3)	0	0	4 (14.3)	0
Anaemia	3 (10.7)	0	0	3 (10.7)	0
Gastrointestinal disorders					
-Total	2 (7.1)	2 (7.1)	0	0	0
Nausea	2 (7.1)	2 (7.1)	0	0	0
General disorders and administration site conditions					
-Total	3 (10.7)	1 (3.6)	2 (7.1)	0	0

Prior SCT therapy: Yes

	All patients N=28				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	3 (10.7)	1 (3.6)	2 (7.1)	0	0
Investigations					
-Total	12 (42.9)	0	2 (7.1)	1 (3.6)	9 (32.1)
White blood cell count decreased	7 (25.0)	0	0	1 (3.6)	6 (21.4)
Neutrophil count decreased	5 (17.9)	0	0	0	5 (17.9)
Alanine aminotransferase increased	4 (14.3)	1 (3.6)	1 (3.6)	1 (3.6)	1 (3.6)
Aspartate aminotransferase increased	3 (10.7)	1 (3.6)	1 (3.6)	0	1 (3.6)
Lymphocyte count decreased	3 (10.7)	0	0	0	3 (10.7)
Platelet count decreased	3 (10.7)	0	0	2 (7.1)	1 (3.6)
Metabolism and nutrition disorders					
-Total	3 (10.7)	0	0	1 (3.6)	2 (7.1)
Hypokalaemia	3 (10.7)	0	0	1 (3.6)	2 (7.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
/vob/CCTL019/haq/haq_eu_5/pgm/saf/t186_gd_b2205.sas@@/main/3 03DEC20:14:29 Final

Table 186l
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: No

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (66.7)	1 (3.0)	4 (12.1)	7 (21.2)	10 (30.3)
Blood and lymphatic system disorders					
-Total	8 (24.2)	0	2 (6.1)	6 (18.2)	0
Febrile neutropenia	5 (15.2)	0	1 (3.0)	4 (12.1)	0
Anaemia	4 (12.1)	0	2 (6.1)	2 (6.1)	0
Gastrointestinal disorders					
-Total	6 (18.2)	3 (9.1)	3 (9.1)	0	0
Nausea	6 (18.2)	3 (9.1)	3 (9.1)	0	0
General disorders and administration site conditions					
-Total	3 (9.1)	0	3 (9.1)	0	0

Prior SCT therapy: No

	All patients N=33				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	3 (9.1)	0	3 (9.1)	0	0
Investigations					
-Total	14 (42.4)	0	0	4 (12.1)	10 (30.3)
White blood cell count decreased	12 (36.4)	0	0	2 (6.1)	10 (30.3)
Neutrophil count decreased	5 (15.2)	0	0	0	5 (15.2)
Alanine aminotransferase increased	3 (9.1)	0	1 (3.0)	2 (6.1)	0
Lymphocyte count decreased	1 (3.0)	0	0	1 (3.0)	0
Platelet count decreased	1 (3.0)	0	1 (3.0)	0	0
Metabolism and nutrition disorders					
-Total	2 (6.1)	1 (3.0)	0	1 (3.0)	0
Hypokalaemia	2 (6.1)	1 (3.0)	0	1 (3.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186m
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (85.7)	2 (14.3)	2 (14.3)	2 (14.3)	6 (42.9)
Blood and lymphatic system disorders					
-Total	3 (21.4)	0	1 (7.1)	2 (14.3)	0
Anaemia	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Febrile neutropenia	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Gastrointestinal disorders					
-Total	5 (35.7)	0	5 (35.7)	0	0
Nausea	3 (21.4)	0	3 (21.4)	0	0
Diarrhoea	2 (14.3)	0	2 (14.3)	0	0
General disorders and administration site conditions					

Eligibility for SCT: Yes

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (7.1)	0	1 (7.1)	0	0
Pyrexia	1 (7.1)	0	1 (7.1)	0	0
Investigations					
-Total	8 (57.1)	0	0	2 (14.3)	6 (42.9)
White blood cell count decreased	8 (57.1)	0	0	2 (14.3)	6 (42.9)
Neutrophil count decreased	2 (14.3)	0	0	0	2 (14.3)
Metabolism and nutrition disorders					
-Total	4 (28.6)	3 (21.4)	1 (7.1)	0	0
Decreased appetite	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Hyperphosphataemia	2 (14.3)	2 (14.3)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186m
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: No

	All patients N=47				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (61.7)	4 (8.5)	4 (8.5)	8 (17.0)	13 (27.7)
Blood and lymphatic system disorders					
-Total	11 (23.4)	0	1 (2.1)	10 (21.3)	0
Febrile neutropenia	7 (14.9)	0	0	7 (14.9)	0
Anaemia	5 (10.6)	0	1 (2.1)	4 (8.5)	0
Gastrointestinal disorders					
-Total	6 (12.8)	6 (12.8)	0	0	0
Nausea	5 (10.6)	5 (10.6)	0	0	0
Diarrhoea	2 (4.3)	2 (4.3)	0	0	0
General disorders and administration site conditions					

Eligibility for SCT: No

	All patients N=47				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (10.6)	1 (2.1)	4 (8.5)	0	0
Pyrexia	5 (10.6)	1 (2.1)	4 (8.5)	0	0
Investigations					
-Total	15 (31.9)	0	1 (2.1)	2 (4.3)	12 (25.5)
White blood cell count decreased	11 (23.4)	0	0	1 (2.1)	10 (21.3)
Neutrophil count decreased	8 (17.0)	0	0	0	8 (17.0)
Alanine aminotransferase increased	7 (14.9)	1 (2.1)	2 (4.3)	3 (6.4)	1 (2.1)
Metabolism and nutrition disorders					
-Total	7 (14.9)	1 (2.1)	2 (4.3)	2 (4.3)	2 (4.3)
Hypokalaemia	5 (10.6)	1 (2.1)	0	2 (4.3)	2 (4.3)
Decreased appetite	1 (2.1)	0	1 (2.1)	0	0
Hyperphosphataemia	1 (2.1)	0	1 (2.1)	0	0
Nervous system disorders					
-Total	5 (10.6)	3 (6.4)	2 (4.3)	0	0
Headache	5 (10.6)	3 (6.4)	2 (4.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186n
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: Low

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (66.7)	3 (14.3)	1 (4.8)	4 (19.0)	6 (28.6)
Blood and lymphatic system disorders					
-Total	3 (14.3)	0	0	3 (14.3)	0
Febrile neutropenia	3 (14.3)	0	0	3 (14.3)	0
Anaemia	1 (4.8)	0	0	1 (4.8)	0
Gastrointestinal disorders					
-Total	4 (19.0)	3 (14.3)	1 (4.8)	0	0
Nausea	3 (14.3)	2 (9.5)	1 (4.8)	0	0
Vomiting	3 (14.3)	2 (9.5)	1 (4.8)	0	0
General disorders and administration site conditions					

Baseline bone marrow tumor burden: Low

	All patients N=21				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Pyrexia	2 (9.5)	1 (4.8)	1 (4.8)	0	0
Investigations					
-Total	8 (38.1)	0	0	2 (9.5)	6 (28.6)
White blood cell count decreased	6 (28.6)	0	0	1 (4.8)	5 (23.8)
Neutrophil count decreased	3 (14.3)	0	0	0	3 (14.3)
Alanine aminotransferase increased	2 (9.5)	0	0	1 (4.8)	1 (4.8)
Nervous system disorders					
-Total	1 (4.8)	0	1 (4.8)	0	0
Headache	1 (4.8)	0	1 (4.8)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186n
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: High

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (62.5)	1 (2.5)	5 (12.5)	6 (15.0)	13 (32.5)
Blood and lymphatic system disorders					
-Total	11 (27.5)	0	2 (5.0)	9 (22.5)	0
Anaemia	6 (15.0)	0	2 (5.0)	4 (10.0)	0
Febrile neutropenia	6 (15.0)	0	1 (2.5)	5 (12.5)	0
Gastrointestinal disorders					
-Total	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Nausea	5 (12.5)	3 (7.5)	2 (5.0)	0	0
General disorders and administration site conditions					
-Total	4 (10.0)	0	4 (10.0)	0	0

Baseline bone marrow tumor burden: High

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	4 (10.0)	0	4 (10.0)	0	0
Investigations					
-Total	17 (42.5)	0	1 (2.5)	3 (7.5)	13 (32.5)
White blood cell count decreased	13 (32.5)	0	0	2 (5.0)	11 (27.5)
Neutrophil count decreased	7 (17.5)	0	0	0	7 (17.5)
Alanine aminotransferase increased	5 (12.5)	1 (2.5)	2 (5.0)	2 (5.0)	0
Lymphocyte count decreased	4 (10.0)	0	0	1 (2.5)	3 (7.5)
Nervous system disorders					
-Total	4 (10.0)	3 (7.5)	1 (2.5)	0	0
Headache	4 (10.0)	3 (7.5)	1 (2.5)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186o
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	1 (25.0)	0	0	2 (50.0)
Blood and lymphatic system disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Febrile neutropenia	1 (25.0)	0	0	1 (25.0)	0
Lymphopenia	1 (25.0)	0	0	0	1 (25.0)
Cardiac disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Bradycardia	1 (25.0)	0	1 (25.0)	0	0
Gastrointestinal disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0

Baseline extramedullary disease presence: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (25.0)	1 (25.0)	0	0	0
Pancreatic failure	1 (25.0)	0	1 (25.0)	0	0
General disorders and administration site conditions					
-Total	1 (25.0)	0	1 (25.0)	0	0
Pyrexia	1 (25.0)	0	1 (25.0)	0	0
Infections and infestations					
-Total	1 (25.0)	0	1 (25.0)	0	0
Pneumonia	1 (25.0)	0	1 (25.0)	0	0
Investigations					
-Total	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Blood lactic acid increased	1 (25.0)	0	1 (25.0)	0	0
C-reactive protein increased	1 (25.0)	0	1 (25.0)	0	0
Protein total decreased	1 (25.0)	0	0	1 (25.0)	0
White blood cell count decreased	1 (25.0)	0	0	0	1 (25.0)
Metabolism and nutrition disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Fluid overload	1 (25.0)	0	1 (25.0)	0	0

Baseline extramedullary disease presence: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypermagnesaemia	1 (25.0)	1 (25.0)	0	0	0
Hypokalaemia	1 (25.0)	0	0	1 (25.0)	0
Nervous system disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Hypotonia	1 (25.0)	0	1 (25.0)	0	0
Product issues					
-Total	1 (25.0)	1 (25.0)	0	0	0
Device occlusion	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Hypoxia	1 (25.0)	0	0	1 (25.0)	0
Tachypnoea	1 (25.0)	0	0	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186o
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (63.2)	4 (7.0)	5 (8.8)	9 (15.8)	18 (31.6)
Blood and lymphatic system disorders					
-Total	13 (22.8)	0	2 (3.5)	11 (19.3)	0
Febrile neutropenia	8 (14.0)	0	1 (1.8)	7 (12.3)	0
Anaemia	7 (12.3)	0	2 (3.5)	5 (8.8)	0
Gastrointestinal disorders					
-Total	7 (12.3)	4 (7.0)	3 (5.3)	0	0
Nausea	7 (12.3)	4 (7.0)	3 (5.3)	0	0
General disorders and administration site conditions					
-Total	5 (8.8)	1 (1.8)	4 (7.0)	0	0

Baseline extramedullary disease presence: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	5 (8.8)	1 (1.8)	4 (7.0)	0	0
Investigations					
-Total	23 (40.4)	0	2 (3.5)	4 (7.0)	17 (29.8)
White blood cell count decreased	18 (31.6)	0	0	3 (5.3)	15 (26.3)
Neutrophil count decreased	10 (17.5)	0	0	0	10 (17.5)
Alanine aminotransferase increased	7 (12.3)	1 (1.8)	2 (3.5)	3 (5.3)	1 (1.8)
C-reactive protein increased	1 (1.8)	0	1 (1.8)	0	0
Metabolism and nutrition disorders					
-Total	5 (8.8)	1 (1.8)	1 (1.8)	1 (1.8)	2 (3.5)
Hypokalaemia	4 (7.0)	1 (1.8)	0	1 (1.8)	2 (3.5)
Fluid overload	1 (1.8)	0	1 (1.8)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (3.5)	0	0	2 (3.5)	0
Hypoxia	2 (3.5)	0	0	2 (3.5)	0
Tachypnoea	1 (1.8)	0	1 (1.8)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186p
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Blood and lymphatic system disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Thrombocytopenia	1 (25.0)	0	0	1 (25.0)	0
Immune system disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Hypogammaglobulinaemia	1 (25.0)	1 (25.0)	0	0	0
Infections and infestations					
-Total	1 (25.0)	1 (25.0)	0	0	0
Viral upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0

Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	1 (25.0)	0	1 (25.0)	0	0
Radiation skin injury	1 (25.0)	0	1 (25.0)	0	0
Metabolism and nutrition disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Hyperphosphataemia	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Arthralgia	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Cough	1 (25.0)	1 (25.0)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186p
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (66.7)	5 (8.8)	5 (8.8)	10 (17.5)	18 (31.6)
Blood and lymphatic system disorders					
-Total	14 (24.6)	0	2 (3.5)	10 (17.5)	2 (3.5)
Febrile neutropenia	9 (15.8)	0	1 (1.8)	8 (14.0)	0
Anaemia	7 (12.3)	0	2 (3.5)	5 (8.8)	0
Thrombocytopenia	2 (3.5)	0	0	0	2 (3.5)
Gastrointestinal disorders					
-Total	8 (14.0)	5 (8.8)	3 (5.3)	0	0
Nausea	8 (14.0)	5 (8.8)	3 (5.3)	0	0
General disorders and administration site conditions					

Down syndrome: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (10.5)	1 (1.8)	5 (8.8)	0	0
Pyrexia	6 (10.5)	1 (1.8)	5 (8.8)	0	0
Investigations					
-Total	23 (40.4)	0	1 (1.8)	4 (7.0)	18 (31.6)
White blood cell count decreased	19 (33.3)	0	0	3 (5.3)	16 (28.1)
Neutrophil count decreased	10 (17.5)	0	0	0	10 (17.5)
Alanine aminotransferase increased	7 (12.3)	1 (1.8)	2 (3.5)	3 (5.3)	1 (1.8)
Metabolism and nutrition disorders					
-Total	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Hyperphosphataemia	2 (3.5)	1 (1.8)	1 (1.8)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186q
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: > Median

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (80.6)	3 (9.7)	3 (9.7)	6 (19.4)	13 (41.9)
Blood and lymphatic system disorders					
-Total	7 (22.6)	0	1 (3.2)	6 (19.4)	0
Anaemia	4 (12.9)	0	1 (3.2)	3 (9.7)	0
Febrile neutropenia	3 (9.7)	0	1 (3.2)	2 (6.5)	0
Thrombocytopenia	1 (3.2)	0	0	1 (3.2)	0
Gastrointestinal disorders					
-Total	5 (16.1)	2 (6.5)	3 (9.7)	0	0
Nausea	5 (16.1)	2 (6.5)	3 (9.7)	0	0
General disorders and administration site conditions					

Time since enrollment to CTL019 infusion: > Median

	All patients N=31				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (6.5)	0	2 (6.5)	0	0
Pyrexia	2 (6.5)	0	2 (6.5)	0	0
Investigations					
-Total	17 (54.8)	2 (6.5)	0	3 (9.7)	12 (38.7)
White blood cell count decreased	14 (45.2)	0	0	3 (9.7)	11 (35.5)
Neutrophil count decreased	6 (19.4)	0	0	0	6 (19.4)
Alanine aminotransferase increased	4 (12.9)	1 (3.2)	1 (3.2)	2 (6.5)	0
International normalised ratio increased	1 (3.2)	1 (3.2)	0	0	0
Weight increased	1 (3.2)	1 (3.2)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (12.9)	1 (3.2)	0	2 (6.5)	1 (3.2)
Hypokalaemia	3 (9.7)	1 (3.2)	0	1 (3.2)	1 (3.2)
Hypoglycaemia	1 (3.2)	0	0	1 (3.2)	0
Nervous system disorders					
-Total	4 (12.9)	2 (6.5)	2 (6.5)	0	0
Headache	4 (12.9)	2 (6.5)	2 (6.5)	0	0
Respiratory, thoracic and mediastinal disorders					

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=31 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (3.2)	0	0	1 (3.2)	0
Hypoxia	1 (3.2)	0	0	1 (3.2)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186q
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: <=Median

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (55.2)	1 (3.4)	4 (13.8)	6 (20.7)	5 (17.2)
Blood and lymphatic system disorders					
-Total	7 (24.1)	0	1 (3.4)	5 (17.2)	1 (3.4)
Febrile neutropenia	5 (17.2)	0	0	5 (17.2)	0
Anaemia	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Thrombocytopenia	1 (3.4)	0	0	0	1 (3.4)
Gastrointestinal disorders					
-Total	3 (10.3)	3 (10.3)	0	0	0
Nausea	3 (10.3)	3 (10.3)	0	0	0
General disorders and administration site conditions					

Time since enrollment to CTL019 infusion: <=Median

	All patients N=29				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (10.3)	1 (3.4)	2 (6.9)	0	0
Pyrexia	3 (10.3)	1 (3.4)	2 (6.9)	0	0
Investigations					
-Total	8 (27.6)	0	2 (6.9)	1 (3.4)	5 (17.2)
White blood cell count decreased	5 (17.2)	0	0	0	5 (17.2)
Neutrophil count decreased	3 (10.3)	0	0	0	3 (10.3)
Alanine aminotransferase increased	2 (6.9)	0	1 (3.4)	1 (3.4)	0
Aspartate aminotransferase increased	2 (6.9)	1 (3.4)	1 (3.4)	0	0
Metabolism and nutrition disorders					
-Total	1 (3.4)	0	0	1 (3.4)	0
Hypokalaemia	1 (3.4)	0	0	1 (3.4)	0
Nervous system disorders					
-Total	1 (3.4)	1 (3.4)	0	0	0
Headache	1 (3.4)	1 (3.4)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (3.4)	0	0	1 (3.4)	0
Hypoxia	1 (3.4)	0	0	1 (3.4)	0

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=29 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	2 (6.9)	0	0	2 (6.9)	0
Hypotension	2 (6.9)	0	0	2 (6.9)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186q
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: Missing

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
Blood and lymphatic system disorders					
-Total	1 (100)	0	0	0	1 (100)
Anaemia	1 (100)	0	0	1 (100)	0
Disseminated intravascular coagulation	1 (100)	0	0	0	1 (100)
Febrile neutropenia	1 (100)	0	0	1 (100)	0
Thrombocytopenia	1 (100)	0	0	0	1 (100)
Gastrointestinal disorders					
-Total	1 (100)	0	0	1 (100)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	1 (100)	0	0	1 (100)	0
General disorders and administration site conditions					
-Total	1 (100)	0	0	0	1 (100)
Multiple organ dysfunction syndrome	1 (100)	0	0	0	1 (100)
Pyrexia	1 (100)	0	1 (100)	0	0
Hepatobiliary disorders					
-Total	1 (100)	0	0	0	1 (100)
Hepatic failure	1 (100)	0	0	0	1 (100)
Infections and infestations					
-Total	1 (100)	0	0	0	1 (100)
Bronchitis	1 (100)	0	1 (100)	0	0
Staphylococcal infection	1 (100)	0	0	0	1 (100)
Investigations					
-Total	1 (100)	0	0	0	1 (100)
Activated partial thromboplastin time prolonged	1 (100)	0	1 (100)	0	0
Alanine aminotransferase increased	1 (100)	0	0	0	1 (100)

Time since enrollment to CTL019 infusion: Missing

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (100)	0	0	0	1 (100)
Blood bilirubin increased	1 (100)	0	0	0	1 (100)
International normalised ratio increased	1 (100)	0	1 (100)	0	0
Neutrophil count decreased	1 (100)	0	0	0	1 (100)
Weight increased	1 (100)	1 (100)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (100)	0	0	0	1 (100)
Hypernatraemia	1 (100)	0	0	0	1 (100)
Hypoalbuminaemia	1 (100)	0	1 (100)	0	0
Hypoglycaemia	1 (100)	0	1 (100)	0	0
Hypokalaemia	1 (100)	0	0	0	1 (100)
Nervous system disorders					
-Total	1 (100)	0	1 (100)	0	0
Somnolence	1 (100)	0	1 (100)	0	0
Psychiatric disorders					
-Total	1 (100)	0	0	1 (100)	0
Delirium	1 (100)	0	0	1 (100)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	1 (100)	0	1 (100)	0	0
Urinary retention	1 (100)	0	1 (100)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	0	0	1 (100)	0
Hypoxia	1 (100)	0	0	1 (100)	0
Pleural effusion	1 (100)	0	0	1 (100)	0
Vascular disorders					
-Total	1 (100)	0	0	1 (100)	0
Hypotension	1 (100)	0	0	1 (100)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186r
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (57.1)	0	0	1 (14.3)	3 (42.9)
Blood and lymphatic system disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)
Anaemia	1 (14.3)	0	1 (14.3)	0	0
Neutropenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0
Gastrointestinal disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0

Number of previous relapses: 0

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (14.3)	1 (14.3)	0	0	0
General disorders and administration site conditions					
-Total	1 (14.3)	0	1 (14.3)	0	0
Pyrexia	1 (14.3)	0	1 (14.3)	0	0
Investigations					
-Total	2 (28.6)	0	0	0	2 (28.6)
Neutrophil count decreased	2 (28.6)	0	0	0	2 (28.6)
White blood cell count decreased	2 (28.6)	0	0	0	2 (28.6)
Metabolism and nutrition disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Hypokalaemia	1 (14.3)	1 (14.3)	0	0	0
Nervous system disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Dysgeusia	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	2 (28.6)	0	2 (28.6)	0	0
Depression	1 (14.3)	0	1 (14.3)	0	0

Number of previous relapses: 0

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Insomnia	1 (14.3)	0	1 (14.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186r
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 1

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (73.7)	2 (10.5)	2 (10.5)	4 (21.1)	6 (31.6)
Blood and lymphatic system disorders					
-Total	4 (21.1)	0	0	4 (21.1)	0
Febrile neutropenia	3 (15.8)	0	0	3 (15.8)	0
Anaemia	1 (5.3)	0	0	1 (5.3)	0
Gastrointestinal disorders					
-Total	4 (21.1)	3 (15.8)	1 (5.3)	0	0
Nausea	4 (21.1)	3 (15.8)	1 (5.3)	0	0
Diarrhoea	1 (5.3)	1 (5.3)	0	0	0
Vomiting	1 (5.3)	0	1 (5.3)	0	0

Number of previous relapses: 1

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	1 (5.3)	0	1 (5.3)	0	0
Pyrexia	1 (5.3)	0	1 (5.3)	0	0
Investigations					
-Total	6 (31.6)	0	0	1 (5.3)	5 (26.3)
White blood cell count decreased	6 (31.6)	0	0	1 (5.3)	5 (26.3)
Alanine aminotransferase increased	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Neutrophil count decreased	1 (5.3)	0	0	0	1 (5.3)
Platelet count decreased	1 (5.3)	0	1 (5.3)	0	0
Metabolism and nutrition disorders					
-Total	6 (31.6)	2 (10.5)	2 (10.5)	1 (5.3)	1 (5.3)
Decreased appetite	3 (15.8)	1 (5.3)	2 (10.5)	0	0
Hypokalaemia	2 (10.5)	0	0	1 (5.3)	1 (5.3)
Hyperphosphataemia	1 (5.3)	1 (5.3)	0	0	0
Nervous system disorders					
-Total	3 (15.8)	2 (10.5)	1 (5.3)	0	0
Headache	3 (15.8)	2 (10.5)	1 (5.3)	0	0

Number of previous relapses: 1

Group term Preferred term	All patients N=19 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	1 (5.3)	0	0	1 (5.3)	0
Hypoxia	1 (5.3)	0	0	1 (5.3)	0
Vascular disorders					
-Total	1 (5.3)	0	0	1 (5.3)	0
Hypotension	1 (5.3)	0	0	1 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186r
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 2

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (68.4)	2 (10.5)	2 (10.5)	4 (21.1)	5 (26.3)
Blood and lymphatic system disorders					
-Total	5 (26.3)	0	1 (5.3)	3 (15.8)	1 (5.3)
Anaemia	3 (15.8)	0	1 (5.3)	2 (10.5)	0
Febrile neutropenia	2 (10.5)	0	1 (5.3)	1 (5.3)	0
Neutropenia	1 (5.3)	0	0	0	1 (5.3)
Gastrointestinal disorders					
-Total	6 (31.6)	2 (10.5)	4 (21.1)	0	0
Nausea	4 (21.1)	2 (10.5)	2 (10.5)	0	0
Diarrhoea	2 (10.5)	0	2 (10.5)	0	0

Number of previous relapses: 2

	All patients N=19				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (5.3)	1 (5.3)	0	0	0
General disorders and administration site conditions					
-Total	1 (5.3)	0	1 (5.3)	0	0
Pyrexia	1 (5.3)	0	1 (5.3)	0	0
Investigations					
-Total	10 (52.6)	0	1 (5.3)	4 (21.1)	5 (26.3)
White blood cell count decreased	6 (31.6)	0	0	1 (5.3)	5 (26.3)
Alanine aminotransferase increased	3 (15.8)	1 (5.3)	0	2 (10.5)	0
Neutrophil count decreased	3 (15.8)	0	0	0	3 (15.8)
Aspartate aminotransferase increased	1 (5.3)	0	1 (5.3)	0	0
Lymphocyte count decreased	1 (5.3)	0	0	1 (5.3)	0
Platelet count decreased	1 (5.3)	0	0	1 (5.3)	0
Metabolism and nutrition disorders					
-Total	1 (5.3)	1 (5.3)	0	0	0
Hypophosphataemia	1 (5.3)	1 (5.3)	0	0	0
Nervous system disorders					
-Total	1 (5.3)	1 (5.3)	0	0	0

Number of previous relapses: 2

Group term Preferred term	All patients N=19 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Headache	1 (5.3)	1 (5.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	2 (10.5)	2 (10.5)	0	0	0
Alopecia	2 (10.5)	2 (10.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 186r
Adverse events during the lymphodepleting period, in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (81.3)	2 (12.5)	1 (6.3)	3 (18.8)	7 (43.8)
Blood and lymphatic system disorders					
-Total	6 (37.5)	0	0	5 (31.3)	1 (6.3)
Febrile neutropenia	4 (25.0)	0	0	4 (25.0)	0
Anaemia	2 (12.5)	0	0	2 (12.5)	0
Neutropenia	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Gastrointestinal disorders					
-Total	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Abdominal pain	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Diarrhoea	1 (6.3)	1 (6.3)	0	0	0

Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	3 (18.8)	1 (6.3)	2 (12.5)	0	0
Pyrexia	3 (18.8)	1 (6.3)	2 (12.5)	0	0
Infections and infestations					
-Total	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Device related infection	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Investigations					
-Total	9 (56.3)	1 (6.3)	1 (6.3)	0	7 (43.8)
White blood cell count decreased	5 (31.3)	0	0	1 (6.3)	4 (25.0)
Neutrophil count decreased	4 (25.0)	0	0	0	4 (25.0)
Lymphocyte count decreased	3 (18.8)	0	0	0	3 (18.8)
Alanine aminotransferase increased	2 (12.5)	0	1 (6.3)	0	1 (6.3)
Aspartate aminotransferase increased	2 (12.5)	1 (6.3)	0	0	1 (6.3)
International normalised ratio increased	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Platelet count decreased	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Metabolism and nutrition disorders					

Number of previous relapses: >=3

	All patients N=16				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (37.5)	2 (12.5)	1 (6.3)	2 (12.5)	1 (6.3)
Hyperphosphataemia	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Hypoglycaemia	2 (12.5)	0	1 (6.3)	1 (6.3)	0
Hypokalaemia	2 (12.5)	0	0	1 (6.3)	1 (6.3)
Hypophosphataemia	2 (12.5)	2 (12.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Pain in jaw	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Nervous system disorders					
-Total	1 (6.3)	0	1 (6.3)	0	0
Headache	1 (6.3)	0	1 (6.3)	0	0
Psychiatric disorders					
-Total	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Anxiety	2 (12.5)	1 (6.3)	1 (6.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (18.8)	0	1 (6.3)	2 (12.5)	0
Dyspnoea	2 (12.5)	1 (6.3)	1 (6.3)	0	0

Number of previous relapses: >=3

Group term Preferred term	All patients N=16 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (12.5)	0	0	2 (12.5)	0
Vascular disorders					
-Total	2 (12.5)	0	0	2 (12.5)	0
Hypotension	2 (12.5)	0	0	2 (12.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187a
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: <10 years

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	0	1 (50.0)	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0
Escherichia infection	1 (50.0)	0	0	1 (50.0)	0
Streptococcal infection	1 (50.0)	0	0	1 (50.0)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Pain in jaw	1 (50.0)	0	1 (50.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187a
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=10 years to <18 years

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	0	0	4 (80.0)
Blood and lymphatic system disorders					
-Total	3 (60.0)	0	0	1 (20.0)	2 (40.0)
Anaemia	2 (40.0)	0	0	2 (40.0)	0
Disseminated intravascular coagulation	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Febrile neutropenia	2 (40.0)	0	0	2 (40.0)	0
Thrombocytopenia	2 (40.0)	0	0	0	2 (40.0)
Neutropenia	1 (20.0)	0	0	0	1 (20.0)
Endocrine disorders					
-Total	1 (20.0)	0	1 (20.0)	0	0

Age: >=10 years to <18 years

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Adrenal insufficiency	1 (20.0)	0	1 (20.0)	0	0
Gastrointestinal disorders					
-Total	3 (60.0)	0	0	3 (60.0)	0
Colitis	2 (40.0)	0	0	2 (40.0)	0
Abdominal pain	1 (20.0)	0	0	1 (20.0)	0
Ascites	1 (20.0)	0	0	1 (20.0)	0
Diarrhoea	1 (20.0)	0	0	1 (20.0)	0
Gastrointestinal haemorrhage	1 (20.0)	0	0	1 (20.0)	0
Stomatitis	1 (20.0)	0	0	1 (20.0)	0
General disorders and administration site conditions					
-Total	3 (60.0)	0	1 (20.0)	0	2 (40.0)
Multiple organ dysfunction syndrome	2 (40.0)	0	0	0	2 (40.0)
Pyrexia	2 (40.0)	0	2 (40.0)	0	0
Chills	1 (20.0)	1 (20.0)	0	0	0
Hepatobiliary disorders					
-Total	1 (20.0)	0	0	0	1 (20.0)
Hepatic failure	1 (20.0)	0	0	0	1 (20.0)

Age: >=10 years to <18 years

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	4 (80.0)	0	0	0	4 (80.0)
Bronchitis	1 (20.0)	0	1 (20.0)	0	0
Candida sepsis	1 (20.0)	0	0	0	1 (20.0)
Clostridium difficile colitis	1 (20.0)	0	0	1 (20.0)	0
Klebsiella infection	1 (20.0)	0	0	1 (20.0)	0
Klebsiella sepsis	1 (20.0)	0	0	0	1 (20.0)
Oral herpes	1 (20.0)	0	1 (20.0)	0	0
Pneumonia fungal	1 (20.0)	0	0	1 (20.0)	0
Sepsis	1 (20.0)	0	0	0	1 (20.0)
Staphylococcal bacteraemia	1 (20.0)	0	0	1 (20.0)	0
Staphylococcal infection	1 (20.0)	0	0	0	1 (20.0)
Investigations					
-Total	2 (40.0)	0	0	0	2 (40.0)
Activated partial thromboplastin time prolonged	1 (20.0)	0	1 (20.0)	0	0
Alanine aminotransferase increased	1 (20.0)	0	0	0	1 (20.0)
Aspartate aminotransferase increased	1 (20.0)	0	0	0	1 (20.0)

Age: >=10 years to <18 years

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (20.0)	0	0	0	1 (20.0)
International normalised ratio increased	1 (20.0)	0	1 (20.0)	0	0
Neutrophil count decreased	1 (20.0)	0	0	0	1 (20.0)
Platelet count decreased	1 (20.0)	0	0	0	1 (20.0)
Weight increased	1 (20.0)	1 (20.0)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (60.0)	0	0	0	3 (60.0)
Hypernatraemia	3 (60.0)	0	0	1 (20.0)	2 (40.0)
Hypokalaemia	3 (60.0)	0	0	0	3 (60.0)
Hypoalbuminaemia	2 (40.0)	0	1 (20.0)	0	1 (20.0)
Decreased appetite	1 (20.0)	0	0	1 (20.0)	0
Dehydration	1 (20.0)	0	0	1 (20.0)	0
Hyperglycaemia	1 (20.0)	0	0	0	1 (20.0)
Hypocalcaemia	1 (20.0)	0	0	0	1 (20.0)
Hypoglycaemia	1 (20.0)	0	1 (20.0)	0	0
Hypomagnesaemia	1 (20.0)	1 (20.0)	0	0	0
Hypophosphataemia	1 (20.0)	0	0	1 (20.0)	0

Age: >=10 years to <18 years

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Pain in extremity	1 (20.0)	0	0	1 (20.0)	0
Nervous system disorders					
-Total	2 (40.0)	0	1 (20.0)	1 (20.0)	0
Leukoencephalopathy	1 (20.0)	0	0	1 (20.0)	0
Somnolence	1 (20.0)	0	1 (20.0)	0	0
Psychiatric disorders					
-Total	1 (20.0)	0	0	1 (20.0)	0
Delirium	1 (20.0)	0	0	1 (20.0)	0
Renal and urinary disorders					
-Total	3 (60.0)	1 (20.0)	0	1 (20.0)	1 (20.0)
Acute kidney injury	1 (20.0)	0	0	0	1 (20.0)
Cystitis haemorrhagic	1 (20.0)	0	0	1 (20.0)	0
Haematuria	1 (20.0)	1 (20.0)	0	0	0
Urinary retention	1 (20.0)	0	1 (20.0)	0	0
Respiratory, thoracic and mediastinal disorders					

Age: >=10 years to <18 years

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (60.0)	0	0	1 (20.0)	2 (40.0)
Hypoxia	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Pleural effusion	1 (20.0)	0	0	1 (20.0)	0
Pulmonary oedema	1 (20.0)	0	0	0	1 (20.0)
Respiratory failure	1 (20.0)	0	0	0	1 (20.0)
Vascular disorders					
-Total	4 (80.0)	0	0	3 (60.0)	1 (20.0)
Hypotension	4 (80.0)	0	0	3 (60.0)	1 (20.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187a
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=18

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	1 (25.0)	0	3 (75.0)
Blood and lymphatic system disorders					
-Total	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Anaemia	2 (50.0)	0	0	2 (50.0)	0
Thrombocytopenia	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Disseminated intravascular coagulation	1 (25.0)	0	0	1 (25.0)	0
Lymphopenia	1 (25.0)	0	0	0	1 (25.0)
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
Cardiac disorders					
-Total	2 (50.0)	0	0	0	2 (50.0)

Age: >=18

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (25.0)	0	0	0	1 (25.0)
Cardiovascular insufficiency	1 (25.0)	0	0	0	1 (25.0)
Right ventricular dysfunction	1 (25.0)	0	0	1 (25.0)	0
Sinus tachycardia	1 (25.0)	0	0	1 (25.0)	0
Ventricular tachycardia	1 (25.0)	0	0	1 (25.0)	0
Eye disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Photophobia	1 (25.0)	0	1 (25.0)	0	0
Gastrointestinal disorders					
-Total	3 (75.0)	0	2 (50.0)	1 (25.0)	0
Nausea	3 (75.0)	0	2 (50.0)	1 (25.0)	0
Vomiting	3 (75.0)	0	2 (50.0)	1 (25.0)	0
Abdominal pain	1 (25.0)	0	0	1 (25.0)	0
Constipation	1 (25.0)	1 (25.0)	0	0	0
Haematochezia	1 (25.0)	0	0	1 (25.0)	0
General disorders and administration site conditions					
-Total	3 (75.0)	0	0	2 (50.0)	1 (25.0)

Age: >=18

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Multiple organ dysfunction syndrome	1 (25.0)	0	0	0	1 (25.0)
Non-cardiac chest pain	1 (25.0)	0	0	1 (25.0)	0
Pyrexia	1 (25.0)	0	0	1 (25.0)	0
Infections and infestations					
-Total	2 (50.0)	0	0	0	2 (50.0)
Klebsiella sepsis	1 (25.0)	0	0	0	1 (25.0)
Pneumonia	1 (25.0)	0	0	0	1 (25.0)
Investigations					
-Total	2 (50.0)	0	0	0	2 (50.0)
Blood lactate dehydrogenase increased	1 (25.0)	0	0	1 (25.0)	0
Computerised tomogram thorax abnormal	1 (25.0)	0	0	1 (25.0)	0
Electrocardiogram qt prolonged	1 (25.0)	0	0	1 (25.0)	0
Neutrophil count decreased	1 (25.0)	0	0	0	1 (25.0)
White blood cell count decreased	1 (25.0)	0	0	0	1 (25.0)
Metabolism and nutrition disorders					
-Total	3 (75.0)	0	2 (50.0)	1 (25.0)	0

Age: >=18

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	2 (50.0)	0	2 (50.0)	0	0
Fluid overload	1 (25.0)	0	0	1 (25.0)	0
Hyperkalaemia	1 (25.0)	0	0	1 (25.0)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Arthralgia	1 (25.0)	0	0	1 (25.0)	0
Back pain	1 (25.0)	0	0	1 (25.0)	0
Pain in extremity	1 (25.0)	0	0	1 (25.0)	0
Nervous system disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Headache	1 (25.0)	0	0	1 (25.0)	0
Hyporesponsive to stimuli	1 (25.0)	0	0	1 (25.0)	0
Seizure	1 (25.0)	0	0	0	1 (25.0)
Product issues					
-Total	1 (25.0)	0	1 (25.0)	0	0
Device occlusion	1 (25.0)	0	1 (25.0)	0	0
Psychiatric disorders					

Age: >=18

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Agitation	1 (25.0)	0	0	1 (25.0)	0
Confusional state	1 (25.0)	0	1 (25.0)	0	0
Renal and urinary disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Acute kidney injury	1 (25.0)	0	0	1 (25.0)	0
Oliguria	1 (25.0)	0	0	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (50.0)	0	0	0	2 (50.0)
Hypoxia	2 (50.0)	0	0	2 (50.0)	0
Aspiration	1 (25.0)	0	0	0	1 (25.0)
Cough	1 (25.0)	0	0	1 (25.0)	0
Dyspnoea	1 (25.0)	0	0	1 (25.0)	0
Epistaxis	1 (25.0)	0	1 (25.0)	0	0
Haemoptysis	1 (25.0)	0	0	1 (25.0)	0
Oropharyngeal pain	1 (25.0)	0	0	1 (25.0)	0
Pleural effusion	1 (25.0)	0	1 (25.0)	0	0

Age: >=18

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary alveolar haemorrhage	1 (25.0)	0	0	0	1 (25.0)
Pulmonary hypertension	1 (25.0)	0	0	1 (25.0)	0
Pulmonary oedema	1 (25.0)	0	0	0	1 (25.0)
Respiratory distress	1 (25.0)	0	0	0	1 (25.0)
Tachypnoea	1 (25.0)	0	0	1 (25.0)	0
Vascular disorders					
-Total	2 (50.0)	0	0	0	2 (50.0)
Hypotension	2 (50.0)	0	0	0	2 (50.0)
Hypertension	1 (25.0)	0	1 (25.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187b
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Male

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (90.0)	0	1 (10.0)	1 (10.0)	7 (70.0)
Blood and lymphatic system disorders					
-Total	5 (50.0)	0	0	2 (20.0)	3 (30.0)
Anaemia	4 (40.0)	0	0	4 (40.0)	0
Thrombocytopenia	4 (40.0)	0	0	1 (10.0)	3 (30.0)
Disseminated intravascular coagulation	3 (30.0)	0	0	2 (20.0)	1 (10.0)
Febrile neutropenia	2 (20.0)	0	0	2 (20.0)	0
Neutropenia	2 (20.0)	0	0	0	2 (20.0)
Lymphopenia	1 (10.0)	0	0	0	1 (10.0)
Cardiac disorders					

Gender: Male

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (20.0)	0	0	0	2 (20.0)
Bradycardia	1 (10.0)	0	0	0	1 (10.0)
Cardiovascular insufficiency	1 (10.0)	0	0	0	1 (10.0)
Right ventricular dysfunction	1 (10.0)	0	0	1 (10.0)	0
Sinus tachycardia	1 (10.0)	0	0	1 (10.0)	0
Ventricular tachycardia	1 (10.0)	0	0	1 (10.0)	0
Endocrine disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Adrenal insufficiency	1 (10.0)	0	1 (10.0)	0	0
Eye disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Photophobia	1 (10.0)	0	1 (10.0)	0	0
Gastrointestinal disorders					
-Total	6 (60.0)	0	2 (20.0)	4 (40.0)	0
Nausea	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Vomiting	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Abdominal pain	2 (20.0)	0	0	2 (20.0)	0
Colitis	2 (20.0)	0	0	2 (20.0)	0

Gender: Male

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	1 (10.0)	0	0	1 (10.0)	0
Constipation	1 (10.0)	1 (10.0)	0	0	0
Diarrhoea	1 (10.0)	0	0	1 (10.0)	0
Gastrointestinal haemorrhage	1 (10.0)	0	0	1 (10.0)	0
Haematochezia	1 (10.0)	0	0	1 (10.0)	0
Stomatitis	1 (10.0)	0	0	1 (10.0)	0
General disorders and administration site conditions					
-Total	6 (60.0)	0	1 (10.0)	2 (20.0)	3 (30.0)
Multiple organ dysfunction syndrome	3 (30.0)	0	0	0	3 (30.0)
Pyrexia	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Pain	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Chills	1 (10.0)	1 (10.0)	0	0	0
Non-cardiac chest pain	1 (10.0)	0	0	1 (10.0)	0
Hepatobiliary disorders					
-Total	1 (10.0)	0	0	0	1 (10.0)
Hepatic failure	1 (10.0)	0	0	0	1 (10.0)
Infections and infestations					

Gender: Male

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	7 (70.0)	0	0	1 (10.0)	6 (60.0)
Klebsiella sepsis	2 (20.0)	0	0	0	2 (20.0)
Bronchitis	1 (10.0)	0	1 (10.0)	0	0
Candida sepsis	1 (10.0)	0	0	0	1 (10.0)
Clostridium difficile colitis	1 (10.0)	0	0	1 (10.0)	0
Escherichia infection	1 (10.0)	0	0	1 (10.0)	0
Klebsiella infection	1 (10.0)	0	0	1 (10.0)	0
Oral herpes	1 (10.0)	0	1 (10.0)	0	0
Pneumonia	1 (10.0)	0	0	0	1 (10.0)
Pneumonia fungal	1 (10.0)	0	0	1 (10.0)	0
Sepsis	1 (10.0)	0	0	0	1 (10.0)
Staphylococcal bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Staphylococcal infection	1 (10.0)	0	0	0	1 (10.0)
Streptococcal infection	1 (10.0)	0	0	1 (10.0)	0
Investigations					
-Total	4 (40.0)	0	0	0	4 (40.0)
Neutrophil count decreased	2 (20.0)	0	0	0	2 (20.0)

Gender: Male

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	1 (10.0)	0	1 (10.0)	0	0
Alanine aminotransferase increased	1 (10.0)	0	0	0	1 (10.0)
Aspartate aminotransferase increased	1 (10.0)	0	0	0	1 (10.0)
Blood bilirubin increased	1 (10.0)	0	0	0	1 (10.0)
Blood lactate dehydrogenase increased	1 (10.0)	0	0	1 (10.0)	0
Computerised tomogram thorax abnormal	1 (10.0)	0	0	1 (10.0)	0
Electrocardiogram qt prolonged	1 (10.0)	0	0	1 (10.0)	0
International normalised ratio increased	1 (10.0)	0	1 (10.0)	0	0
Platelet count decreased	1 (10.0)	0	0	0	1 (10.0)
Weight increased	1 (10.0)	1 (10.0)	0	0	0
White blood cell count decreased	1 (10.0)	0	0	0	1 (10.0)
Metabolism and nutrition disorders					
-Total	6 (60.0)	0	2 (20.0)	1 (10.0)	3 (30.0)
Hyperglycaemia	3 (30.0)	0	2 (20.0)	0	1 (10.0)
Hypernatraemia	3 (30.0)	0	0	1 (10.0)	2 (20.0)

Gender: Male

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	3 (30.0)	0	0	0	3 (30.0)
Hypoalbuminaemia	2 (20.0)	0	1 (10.0)	0	1 (10.0)
Decreased appetite	1 (10.0)	0	0	1 (10.0)	0
Dehydration	1 (10.0)	0	0	1 (10.0)	0
Fluid overload	1 (10.0)	0	0	1 (10.0)	0
Hyperkalaemia	1 (10.0)	0	0	1 (10.0)	0
Hypocalcaemia	1 (10.0)	0	0	0	1 (10.0)
Hypoglycaemia	1 (10.0)	0	1 (10.0)	0	0
Hypomagnesaemia	1 (10.0)	1 (10.0)	0	0	0
Hypophosphataemia	1 (10.0)	0	0	1 (10.0)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (30.0)	0	1 (10.0)	2 (20.0)	0
Pain in extremity	2 (20.0)	0	0	2 (20.0)	0
Arthralgia	1 (10.0)	0	0	1 (10.0)	0
Back pain	1 (10.0)	0	0	1 (10.0)	0
Pain in jaw	1 (10.0)	0	1 (10.0)	0	0
Nervous system disorders					

Gender: Male

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (30.0)	0	1 (10.0)	1 (10.0)	1 (10.0)
Headache	1 (10.0)	0	0	1 (10.0)	0
Hyporesponsive to stimuli	1 (10.0)	0	0	1 (10.0)	0
Leukoencephalopathy	1 (10.0)	0	0	1 (10.0)	0
Seizure	1 (10.0)	0	0	0	1 (10.0)
Somnolence	1 (10.0)	0	1 (10.0)	0	0
Product issues					
-Total	1 (10.0)	0	1 (10.0)	0	0
Device occlusion	1 (10.0)	0	1 (10.0)	0	0
Psychiatric disorders					
-Total	3 (30.0)	0	1 (10.0)	2 (20.0)	0
Agitation	1 (10.0)	0	0	1 (10.0)	0
Confusional state	1 (10.0)	0	1 (10.0)	0	0
Delirium	1 (10.0)	0	0	1 (10.0)	0
Renal and urinary disorders					
-Total	4 (40.0)	1 (10.0)	0	2 (20.0)	1 (10.0)
Acute kidney injury	2 (20.0)	0	0	1 (10.0)	1 (10.0)
Cystitis haemorrhagic	1 (10.0)	0	0	1 (10.0)	0

Gender: Male

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	1 (10.0)	1 (10.0)	0	0	0
Oliguria	1 (10.0)	0	0	1 (10.0)	0
Urinary retention	1 (10.0)	0	1 (10.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (50.0)	0	0	1 (10.0)	4 (40.0)
Hypoxia	4 (40.0)	0	0	3 (30.0)	1 (10.0)
Pleural effusion	2 (20.0)	0	1 (10.0)	1 (10.0)	0
Pulmonary oedema	2 (20.0)	0	0	0	2 (20.0)
Aspiration	1 (10.0)	0	0	0	1 (10.0)
Cough	1 (10.0)	0	0	1 (10.0)	0
Dyspnoea	1 (10.0)	0	0	1 (10.0)	0
Epistaxis	1 (10.0)	0	1 (10.0)	0	0
Haemoptysis	1 (10.0)	0	0	1 (10.0)	0
Oropharyngeal pain	1 (10.0)	0	0	1 (10.0)	0
Pulmonary alveolar haemorrhage	1 (10.0)	0	0	0	1 (10.0)
Pulmonary hypertension	1 (10.0)	0	0	1 (10.0)	0
Respiratory distress	1 (10.0)	0	0	0	1 (10.0)

Gender: Male

Group term Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	1 (10.0)	0	0	0	1 (10.0)
Tachypnoea	1 (10.0)	0	0	1 (10.0)	0
Vascular disorders					
-Total	6 (60.0)	0	0	3 (30.0)	3 (30.0)
Hypotension	6 (60.0)	0	0	3 (30.0)	3 (30.0)
Hypertension	1 (10.0)	0	1 (10.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187c
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: White

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (75.0)	0	1 (12.5)	0	5 (62.5)
Blood and lymphatic system disorders					
-Total	3 (37.5)	0	0	1 (12.5)	2 (25.0)
Anaemia	2 (25.0)	0	0	2 (25.0)	0
Disseminated intravascular coagulation	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Febrile neutropenia	2 (25.0)	0	0	2 (25.0)	0
Thrombocytopenia	2 (25.0)	0	0	0	2 (25.0)
Neutropenia	1 (12.5)	0	0	0	1 (12.5)
Endocrine disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0

Race: White

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Adrenal insufficiency	1 (12.5)	0	1 (12.5)	0	0
Gastrointestinal disorders					
-Total	4 (50.0)	0	1 (12.5)	3 (37.5)	0
Colitis	2 (25.0)	0	0	2 (25.0)	0
Abdominal pain	1 (12.5)	0	0	1 (12.5)	0
Ascites	1 (12.5)	0	0	1 (12.5)	0
Constipation	1 (12.5)	1 (12.5)	0	0	0
Diarrhoea	1 (12.5)	0	0	1 (12.5)	0
Gastrointestinal haemorrhage	1 (12.5)	0	0	1 (12.5)	0
Nausea	1 (12.5)	0	1 (12.5)	0	0
Stomatitis	1 (12.5)	0	0	1 (12.5)	0
Vomiting	1 (12.5)	0	1 (12.5)	0	0
General disorders and administration site conditions					
-Total	4 (50.0)	0	1 (12.5)	1 (12.5)	2 (25.0)
Pyrexia	3 (37.5)	0	2 (25.0)	1 (12.5)	0
Multiple organ dysfunction syndrome	2 (25.0)	0	0	0	2 (25.0)
Chills	1 (12.5)	1 (12.5)	0	0	0

Race: White

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	1 (12.5)	0	0	1 (12.5)	0
Hepatobiliary disorders					
-Total	1 (12.5)	0	0	0	1 (12.5)
Hepatic failure	1 (12.5)	0	0	0	1 (12.5)
Infections and infestations					
-Total	5 (62.5)	0	0	0	5 (62.5)
Bronchitis	1 (12.5)	0	1 (12.5)	0	0
Candida sepsis	1 (12.5)	0	0	0	1 (12.5)
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0
Klebsiella infection	1 (12.5)	0	0	1 (12.5)	0
Klebsiella sepsis	1 (12.5)	0	0	0	1 (12.5)
Oral herpes	1 (12.5)	0	1 (12.5)	0	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Pneumonia fungal	1 (12.5)	0	0	1 (12.5)	0
Sepsis	1 (12.5)	0	0	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Investigations					

Race: White

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (25.0)	0	0	0	2 (25.0)
Activated partial thromboplastin time prolonged	1 (12.5)	0	1 (12.5)	0	0
Alanine aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)
Aspartate aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)
Blood bilirubin increased	1 (12.5)	0	0	0	1 (12.5)
International normalised ratio increased	1 (12.5)	0	1 (12.5)	0	0
Neutrophil count decreased	1 (12.5)	0	0	0	1 (12.5)
Platelet count decreased	1 (12.5)	0	0	0	1 (12.5)
Weight increased	1 (12.5)	1 (12.5)	0	0	0
Metabolism and nutrition disorders					
-Total	4 (50.0)	0	1 (12.5)	0	3 (37.5)
Hypernatraemia	3 (37.5)	0	0	1 (12.5)	2 (25.0)
Hypokalaemia	3 (37.5)	0	0	0	3 (37.5)
Hyperglycaemia	2 (25.0)	0	1 (12.5)	0	1 (12.5)
Hypoalbuminaemia	2 (25.0)	0	1 (12.5)	0	1 (12.5)
Decreased appetite	1 (12.5)	0	0	1 (12.5)	0

Race: White

Group term Preferred term	All patients N=8 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Dehydration	1 (12.5)	0	0	1 (12.5)	0
Hypocalcaemia	1 (12.5)	0	0	0	1 (12.5)
Hypoglycaemia	1 (12.5)	0	1 (12.5)	0	0
Hypomagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Hypophosphataemia	1 (12.5)	0	0	1 (12.5)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (12.5)	0	0	1 (12.5)	0
Pain in extremity	1 (12.5)	0	0	1 (12.5)	0
Nervous system disorders					
-Total	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Leukoencephalopathy	1 (12.5)	0	0	1 (12.5)	0
Somnolence	1 (12.5)	0	1 (12.5)	0	0
Psychiatric disorders					
-Total	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Confusional state	1 (12.5)	0	1 (12.5)	0	0
Delirium	1 (12.5)	0	0	1 (12.5)	0
Renal and urinary disorders					

Race: White

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (37.5)	1 (12.5)	0	1 (12.5)	1 (12.5)
Acute kidney injury	1 (12.5)	0	0	0	1 (12.5)
Cystitis haemorrhagic	1 (12.5)	0	0	1 (12.5)	0
Haematuria	1 (12.5)	1 (12.5)	0	0	0
Urinary retention	1 (12.5)	0	1 (12.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (50.0)	0	0	1 (12.5)	3 (37.5)
Hypoxia	3 (37.5)	0	0	2 (25.0)	1 (12.5)
Pleural effusion	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Aspiration	1 (12.5)	0	0	0	1 (12.5)
Epistaxis	1 (12.5)	0	1 (12.5)	0	0
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)
Respiratory failure	1 (12.5)	0	0	0	1 (12.5)
Vascular disorders					
-Total	5 (62.5)	0	0	3 (37.5)	2 (25.0)
Hypotension	5 (62.5)	0	0	3 (37.5)	2 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187c
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Asian

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Infections and infestations					
-Total	1 (100)	0	0	1 (100)	0
Escherichia infection	1 (100)	0	0	1 (100)	0
Streptococcal infection	1 (100)	0	0	1 (100)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (100)	0	1 (100)	0	0
Pain in jaw	1 (100)	0	1 (100)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187c
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Other

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Anaemia	2 (100)	0	0	2 (100)	0
Thrombocytopenia	2 (100)	0	0	1 (50.0)	1 (50.0)
Disseminated intravascular coagulation	1 (50.0)	0	0	1 (50.0)	0
Lymphopenia	1 (50.0)	0	0	0	1 (50.0)
Neutropenia	1 (50.0)	0	0	0	1 (50.0)
Cardiac disorders					
-Total	2 (100)	0	0	0	2 (100)

Race: Other

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (50.0)	0	0	0	1 (50.0)
Cardiovascular insufficiency	1 (50.0)	0	0	0	1 (50.0)
Right ventricular dysfunction	1 (50.0)	0	0	1 (50.0)	0
Sinus tachycardia	1 (50.0)	0	0	1 (50.0)	0
Ventricular tachycardia	1 (50.0)	0	0	1 (50.0)	0
Eye disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Photophobia	1 (50.0)	0	1 (50.0)	0	0
Gastrointestinal disorders					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Nausea	2 (100)	0	1 (50.0)	1 (50.0)	0
Vomiting	2 (100)	0	1 (50.0)	1 (50.0)	0
Abdominal pain	1 (50.0)	0	0	1 (50.0)	0
Haematochezia	1 (50.0)	0	0	1 (50.0)	0
General disorders and administration site conditions					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Multiple organ dysfunction syndrome	1 (50.0)	0	0	0	1 (50.0)

Race: Other

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Non-cardiac chest pain	1 (50.0)	0	0	1 (50.0)	0
Pain	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Klebsiella sepsis	1 (50.0)	0	0	0	1 (50.0)
Investigations					
-Total	2 (100)	0	0	0	2 (100)
Blood lactate dehydrogenase increased	1 (50.0)	0	0	1 (50.0)	0
Computerised tomogram thorax abnormal	1 (50.0)	0	0	1 (50.0)	0
Electrocardiogram qt prolonged	1 (50.0)	0	0	1 (50.0)	0
Neutrophil count decreased	1 (50.0)	0	0	0	1 (50.0)
White blood cell count decreased	1 (50.0)	0	0	0	1 (50.0)
Metabolism and nutrition disorders					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Fluid overload	1 (50.0)	0	0	1 (50.0)	0
Hyperglycaemia	1 (50.0)	0	1 (50.0)	0	0
Hyperkalaemia	1 (50.0)	0	0	1 (50.0)	0

Race: Other

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Arthralgia	1 (50.0)	0	0	1 (50.0)	0
Back pain	1 (50.0)	0	0	1 (50.0)	0
Pain in extremity	1 (50.0)	0	0	1 (50.0)	0
Nervous system disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Headache	1 (50.0)	0	0	1 (50.0)	0
Hyporesponsive to stimuli	1 (50.0)	0	0	1 (50.0)	0
Seizure	1 (50.0)	0	0	0	1 (50.0)
Product issues					
-Total	1 (50.0)	0	1 (50.0)	0	0
Device occlusion	1 (50.0)	0	1 (50.0)	0	0
Psychiatric disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Agitation	1 (50.0)	0	0	1 (50.0)	0
Renal and urinary disorders					

Race: Other

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	0	1 (50.0)	0
Acute kidney injury	1 (50.0)	0	0	1 (50.0)	0
Oliguria	1 (50.0)	0	0	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Cough	1 (50.0)	0	0	1 (50.0)	0
Dyspnoea	1 (50.0)	0	0	1 (50.0)	0
Haemoptysis	1 (50.0)	0	0	1 (50.0)	0
Hypoxia	1 (50.0)	0	0	1 (50.0)	0
Oropharyngeal pain	1 (50.0)	0	0	1 (50.0)	0
Pulmonary alveolar haemorrhage	1 (50.0)	0	0	0	1 (50.0)
Pulmonary hypertension	1 (50.0)	0	0	1 (50.0)	0
Pulmonary oedema	1 (50.0)	0	0	0	1 (50.0)
Respiratory distress	1 (50.0)	0	0	0	1 (50.0)
Tachypnoea	1 (50.0)	0	0	1 (50.0)	0
Vascular disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)

Race: Other

Group term Preferred term	All patients N=2 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	1 (50.0)	0	1 (50.0)	0	0
Hypotension	1 (50.0)	0	0	0	1 (50.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187d
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Hispanic or Latino

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	1 (20.0)	0	3 (60.0)
Blood and lymphatic system disorders					
-Total	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Thrombocytopenia	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Anaemia	1 (20.0)	0	0	1 (20.0)	0
Febrile neutropenia	1 (20.0)	0	0	1 (20.0)	0
Neutropenia	1 (20.0)	0	0	0	1 (20.0)
Cardiac disorders					
-Total	1 (20.0)	0	0	0	1 (20.0)
Cardiovascular insufficiency	1 (20.0)	0	0	0	1 (20.0)
Endocrine disorders					

Ethnicity: Hispanic or Latino

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (20.0)	0	1 (20.0)	0	0
Adrenal insufficiency	1 (20.0)	0	1 (20.0)	0	0
Gastrointestinal disorders					
-Total	3 (60.0)	0	2 (40.0)	1 (20.0)	0
Nausea	2 (40.0)	0	2 (40.0)	0	0
Vomiting	2 (40.0)	0	2 (40.0)	0	0
Constipation	1 (20.0)	1 (20.0)	0	0	0
Gastrointestinal haemorrhage	1 (20.0)	0	0	1 (20.0)	0
General disorders and administration site conditions					
-Total	2 (40.0)	0	1 (20.0)	0	1 (20.0)
Chills	1 (20.0)	1 (20.0)	0	0	0
Multiple organ dysfunction syndrome	1 (20.0)	0	0	0	1 (20.0)
Pain	1 (20.0)	0	1 (20.0)	0	0
Pyrexia	1 (20.0)	0	1 (20.0)	0	0
Infections and infestations					
-Total	3 (60.0)	0	0	0	3 (60.0)
Candida sepsis	1 (20.0)	0	0	0	1 (20.0)

Ethnicity: Hispanic or Latino

	All patients N=5				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella sepsis	1 (20.0)	0	0	0	1 (20.0)
Pneumonia fungal	1 (20.0)	0	0	1 (20.0)	0
Sepsis	1 (20.0)	0	0	0	1 (20.0)
Investigations					
-Total	1 (20.0)	0	0	0	1 (20.0)
Neutrophil count decreased	1 (20.0)	0	0	0	1 (20.0)
Metabolism and nutrition disorders					
-Total	3 (60.0)	0	2 (40.0)	0	1 (20.0)
Hyperglycaemia	2 (40.0)	0	2 (40.0)	0	0
Hypernatraemia	1 (20.0)	0	0	0	1 (20.0)
Hypokalaemia	1 (20.0)	0	0	0	1 (20.0)
Hypomagnesaemia	1 (20.0)	1 (20.0)	0	0	0
Hypophosphataemia	1 (20.0)	0	0	1 (20.0)	0
Product issues					
-Total	1 (20.0)	0	1 (20.0)	0	0
Device occlusion	1 (20.0)	0	1 (20.0)	0	0
Renal and urinary disorders					
-Total	1 (20.0)	0	0	0	1 (20.0)

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=5 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	1 (20.0)	0	0	0	1 (20.0)
Respiratory, thoracic and mediastinal disorders					
-Total	1 (20.0)	0	0	0	1 (20.0)
Pulmonary oedema	1 (20.0)	0	0	0	1 (20.0)
Respiratory failure	1 (20.0)	0	0	0	1 (20.0)
Vascular disorders					
-Total	2 (40.0)	0	0	1 (20.0)	1 (20.0)
Hypotension	2 (40.0)	0	0	1 (20.0)	1 (20.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187d
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Other

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (83.3)	0	0	1 (16.7)	4 (66.7)
Blood and lymphatic system disorders					
-Total	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Anaemia	3 (50.0)	0	0	3 (50.0)	0
Disseminated intravascular coagulation	3 (50.0)	0	0	2 (33.3)	1 (16.7)
Thrombocytopenia	2 (33.3)	0	0	0	2 (33.3)
Febrile neutropenia	1 (16.7)	0	0	1 (16.7)	0
Lymphopenia	1 (16.7)	0	0	0	1 (16.7)
Neutropenia	1 (16.7)	0	0	0	1 (16.7)
Cardiac disorders					

Ethnicity: Other

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (16.7)	0	0	0	1 (16.7)
Bradycardia	1 (16.7)	0	0	0	1 (16.7)
Right ventricular dysfunction	1 (16.7)	0	0	1 (16.7)	0
Sinus tachycardia	1 (16.7)	0	0	1 (16.7)	0
Ventricular tachycardia	1 (16.7)	0	0	1 (16.7)	0
Eye disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Photophobia	1 (16.7)	0	1 (16.7)	0	0
Gastrointestinal disorders					
-Total	3 (50.0)	0	0	3 (50.0)	0
Abdominal pain	2 (33.3)	0	0	2 (33.3)	0
Colitis	2 (33.3)	0	0	2 (33.3)	0
Ascites	1 (16.7)	0	0	1 (16.7)	0
Diarrhoea	1 (16.7)	0	0	1 (16.7)	0
Haematochezia	1 (16.7)	0	0	1 (16.7)	0
Nausea	1 (16.7)	0	0	1 (16.7)	0
Stomatitis	1 (16.7)	0	0	1 (16.7)	0
Vomiting	1 (16.7)	0	0	1 (16.7)	0

Ethnicity: Other

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	4 (66.7)	0	0	2 (33.3)	2 (33.3)
Multiple organ dysfunction syndrome	2 (33.3)	0	0	0	2 (33.3)
Pyrexia	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Non-cardiac chest pain	1 (16.7)	0	0	1 (16.7)	0
Pain	1 (16.7)	0	0	1 (16.7)	0
Hepatobiliary disorders					
-Total	1 (16.7)	0	0	0	1 (16.7)
Hepatic failure	1 (16.7)	0	0	0	1 (16.7)
Infections and infestations					
-Total	4 (66.7)	0	0	1 (16.7)	3 (50.0)
Bronchitis	1 (16.7)	0	1 (16.7)	0	0
Clostridium difficile colitis	1 (16.7)	0	0	1 (16.7)	0
Escherichia infection	1 (16.7)	0	0	1 (16.7)	0
Klebsiella infection	1 (16.7)	0	0	1 (16.7)	0
Klebsiella sepsis	1 (16.7)	0	0	0	1 (16.7)
Oral herpes	1 (16.7)	0	1 (16.7)	0	0

Ethnicity: Other

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	1 (16.7)	0	0	0	1 (16.7)
Staphylococcal bacteraemia	1 (16.7)	0	0	1 (16.7)	0
Staphylococcal infection	1 (16.7)	0	0	0	1 (16.7)
Streptococcal infection	1 (16.7)	0	0	1 (16.7)	0
Investigations					
-Total	3 (50.0)	0	0	0	3 (50.0)
Activated partial thromboplastin time prolonged	1 (16.7)	0	1 (16.7)	0	0
Alanine aminotransferase increased	1 (16.7)	0	0	0	1 (16.7)
Aspartate aminotransferase increased	1 (16.7)	0	0	0	1 (16.7)
Blood bilirubin increased	1 (16.7)	0	0	0	1 (16.7)
Blood lactate dehydrogenase increased	1 (16.7)	0	0	1 (16.7)	0
Computerised tomogram thorax abnormal	1 (16.7)	0	0	1 (16.7)	0
Electrocardiogram qt prolonged	1 (16.7)	0	0	1 (16.7)	0
International normalised ratio increased	1 (16.7)	0	1 (16.7)	0	0
Neutrophil count decreased	1 (16.7)	0	0	0	1 (16.7)

Ethnicity: Other

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	1 (16.7)	0	0	0	1 (16.7)
Weight increased	1 (16.7)	1 (16.7)	0	0	0
White blood cell count decreased	1 (16.7)	0	0	0	1 (16.7)
Metabolism and nutrition disorders					
-Total	3 (50.0)	0	0	1 (16.7)	2 (33.3)
Hypernatraemia	2 (33.3)	0	0	1 (16.7)	1 (16.7)
Hypoalbuminaemia	2 (33.3)	0	1 (16.7)	0	1 (16.7)
Hypokalaemia	2 (33.3)	0	0	0	2 (33.3)
Decreased appetite	1 (16.7)	0	0	1 (16.7)	0
Dehydration	1 (16.7)	0	0	1 (16.7)	0
Fluid overload	1 (16.7)	0	0	1 (16.7)	0
Hyperglycaemia	1 (16.7)	0	0	0	1 (16.7)
Hyperkalaemia	1 (16.7)	0	0	1 (16.7)	0
Hypocalcaemia	1 (16.7)	0	0	0	1 (16.7)
Hypoglycaemia	1 (16.7)	0	1 (16.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	3 (50.0)	0	1 (16.7)	2 (33.3)	0

Ethnicity: Other

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	2 (33.3)	0	0	2 (33.3)	0
Arthralgia	1 (16.7)	0	0	1 (16.7)	0
Back pain	1 (16.7)	0	0	1 (16.7)	0
Pain in jaw	1 (16.7)	0	1 (16.7)	0	0
Nervous system disorders					
-Total	3 (50.0)	0	1 (16.7)	1 (16.7)	1 (16.7)
Headache	1 (16.7)	0	0	1 (16.7)	0
Hyporesponsive to stimuli	1 (16.7)	0	0	1 (16.7)	0
Leukoencephalopathy	1 (16.7)	0	0	1 (16.7)	0
Seizure	1 (16.7)	0	0	0	1 (16.7)
Somnolence	1 (16.7)	0	1 (16.7)	0	0
Psychiatric disorders					
-Total	3 (50.0)	0	1 (16.7)	2 (33.3)	0
Agitation	1 (16.7)	0	0	1 (16.7)	0
Confusional state	1 (16.7)	0	1 (16.7)	0	0
Delirium	1 (16.7)	0	0	1 (16.7)	0
Renal and urinary disorders					
-Total	3 (50.0)	1 (16.7)	0	2 (33.3)	0

Ethnicity: Other

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (16.7)	0	0	1 (16.7)	0
Cystitis haemorrhagic	1 (16.7)	0	0	1 (16.7)	0
Haematuria	1 (16.7)	1 (16.7)	0	0	0
Oliguria	1 (16.7)	0	0	1 (16.7)	0
Urinary retention	1 (16.7)	0	1 (16.7)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (66.7)	0	0	1 (16.7)	3 (50.0)
Hypoxia	4 (66.7)	0	0	3 (50.0)	1 (16.7)
Pleural effusion	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Aspiration	1 (16.7)	0	0	0	1 (16.7)
Cough	1 (16.7)	0	0	1 (16.7)	0
Dyspnoea	1 (16.7)	0	0	1 (16.7)	0
Epistaxis	1 (16.7)	0	1 (16.7)	0	0
Haemoptysis	1 (16.7)	0	0	1 (16.7)	0
Oropharyngeal pain	1 (16.7)	0	0	1 (16.7)	0
Pulmonary alveolar haemorrhage	1 (16.7)	0	0	0	1 (16.7)
Pulmonary hypertension	1 (16.7)	0	0	1 (16.7)	0

Ethnicity: Other

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary oedema	1 (16.7)	0	0	0	1 (16.7)
Respiratory distress	1 (16.7)	0	0	0	1 (16.7)
Tachypnoea	1 (16.7)	0	0	1 (16.7)	0
Vascular disorders					
-Total	4 (66.7)	0	0	2 (33.3)	2 (33.3)
Hypotension	4 (66.7)	0	0	2 (33.3)	2 (33.3)
Hypertension	1 (16.7)	0	1 (16.7)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187e
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Primary refractory

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
General disorders and administration site conditions					
-Total	1 (100)	0	0	1 (100)	0
Pain	1 (100)	0	0	1 (100)	0
Pyrexia	1 (100)	0	0	1 (100)	0
Infections and infestations					
-Total	1 (100)	0	0	0	1 (100)
Pneumonia	1 (100)	0	0	0	1 (100)
Psychiatric disorders					
-Total	1 (100)	0	1 (100)	0	0

Response status at study entry: Primary refractory

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	1 (100)	0	1 (100)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	0	0	0	1 (100)
Aspiration	1 (100)	0	0	0	1 (100)
Epistaxis	1 (100)	0	1 (100)	0	0
Hypoxia	1 (100)	0	0	1 (100)	0
Pleural effusion	1 (100)	0	1 (100)	0	0
Vascular disorders					
-Total	1 (100)	0	0	0	1 (100)
Hypotension	1 (100)	0	0	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187e
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Relapsed disease

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (80.0)	0	1 (10.0)	1 (10.0)	6 (60.0)
Blood and lymphatic system disorders					
-Total	5 (50.0)	0	0	2 (20.0)	3 (30.0)
Anaemia	4 (40.0)	0	0	4 (40.0)	0
Thrombocytopenia	4 (40.0)	0	0	1 (10.0)	3 (30.0)
Disseminated intravascular coagulation	3 (30.0)	0	0	2 (20.0)	1 (10.0)
Febrile neutropenia	2 (20.0)	0	0	2 (20.0)	0
Neutropenia	2 (20.0)	0	0	0	2 (20.0)
Lymphopenia	1 (10.0)	0	0	0	1 (10.0)
Cardiac disorders					

Response status at study entry: Relapsed disease

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (20.0)	0	0	0	2 (20.0)
Bradycardia	1 (10.0)	0	0	0	1 (10.0)
Cardiovascular insufficiency	1 (10.0)	0	0	0	1 (10.0)
Right ventricular dysfunction	1 (10.0)	0	0	1 (10.0)	0
Sinus tachycardia	1 (10.0)	0	0	1 (10.0)	0
Ventricular tachycardia	1 (10.0)	0	0	1 (10.0)	0
Endocrine disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Adrenal insufficiency	1 (10.0)	0	1 (10.0)	0	0
Eye disorders					
-Total	1 (10.0)	0	1 (10.0)	0	0
Photophobia	1 (10.0)	0	1 (10.0)	0	0
Gastrointestinal disorders					
-Total	6 (60.0)	0	2 (20.0)	4 (40.0)	0
Nausea	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Vomiting	3 (30.0)	0	2 (20.0)	1 (10.0)	0
Abdominal pain	2 (20.0)	0	0	2 (20.0)	0
Colitis	2 (20.0)	0	0	2 (20.0)	0

Response status at study entry: Relapsed disease

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	1 (10.0)	0	0	1 (10.0)	0
Constipation	1 (10.0)	1 (10.0)	0	0	0
Diarrhoea	1 (10.0)	0	0	1 (10.0)	0
Gastrointestinal haemorrhage	1 (10.0)	0	0	1 (10.0)	0
Haematochezia	1 (10.0)	0	0	1 (10.0)	0
Stomatitis	1 (10.0)	0	0	1 (10.0)	0
General disorders and administration site conditions					
-Total	5 (50.0)	0	1 (10.0)	1 (10.0)	3 (30.0)
Multiple organ dysfunction syndrome	3 (30.0)	0	0	0	3 (30.0)
Pyrexia	2 (20.0)	0	2 (20.0)	0	0
Chills	1 (10.0)	1 (10.0)	0	0	0
Non-cardiac chest pain	1 (10.0)	0	0	1 (10.0)	0
Pain	1 (10.0)	0	1 (10.0)	0	0
Hepatobiliary disorders					
-Total	1 (10.0)	0	0	0	1 (10.0)
Hepatic failure	1 (10.0)	0	0	0	1 (10.0)
Infections and infestations					

Response status at study entry: Relapsed disease

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (60.0)	0	0	1 (10.0)	5 (50.0)
Klebsiella sepsis	2 (20.0)	0	0	0	2 (20.0)
Bronchitis	1 (10.0)	0	1 (10.0)	0	0
Candida sepsis	1 (10.0)	0	0	0	1 (10.0)
Clostridium difficile colitis	1 (10.0)	0	0	1 (10.0)	0
Escherichia infection	1 (10.0)	0	0	1 (10.0)	0
Klebsiella infection	1 (10.0)	0	0	1 (10.0)	0
Oral herpes	1 (10.0)	0	1 (10.0)	0	0
Pneumonia fungal	1 (10.0)	0	0	1 (10.0)	0
Sepsis	1 (10.0)	0	0	0	1 (10.0)
Staphylococcal bacteraemia	1 (10.0)	0	0	1 (10.0)	0
Staphylococcal infection	1 (10.0)	0	0	0	1 (10.0)
Streptococcal infection	1 (10.0)	0	0	1 (10.0)	0
Investigations					
-Total	4 (40.0)	0	0	0	4 (40.0)
Neutrophil count decreased	2 (20.0)	0	0	0	2 (20.0)
Activated partial thromboplastin time prolonged	1 (10.0)	0	1 (10.0)	0	0

Response status at study entry: Relapsed disease

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (10.0)	0	0	0	1 (10.0)
Aspartate aminotransferase increased	1 (10.0)	0	0	0	1 (10.0)
Blood bilirubin increased	1 (10.0)	0	0	0	1 (10.0)
Blood lactate dehydrogenase increased	1 (10.0)	0	0	1 (10.0)	0
Computerised tomogram thorax abnormal	1 (10.0)	0	0	1 (10.0)	0
Electrocardiogram qt prolonged	1 (10.0)	0	0	1 (10.0)	0
International normalised ratio increased	1 (10.0)	0	1 (10.0)	0	0
Platelet count decreased	1 (10.0)	0	0	0	1 (10.0)
Weight increased	1 (10.0)	1 (10.0)	0	0	0
White blood cell count decreased	1 (10.0)	0	0	0	1 (10.0)
Metabolism and nutrition disorders					
-Total	6 (60.0)	0	2 (20.0)	1 (10.0)	3 (30.0)
Hyperglycaemia	3 (30.0)	0	2 (20.0)	0	1 (10.0)
Hypernatraemia	3 (30.0)	0	0	1 (10.0)	2 (20.0)
Hypokalaemia	3 (30.0)	0	0	0	3 (30.0)

Response status at study entry: Relapsed disease

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	2 (20.0)	0	1 (10.0)	0	1 (10.0)
Decreased appetite	1 (10.0)	0	0	1 (10.0)	0
Dehydration	1 (10.0)	0	0	1 (10.0)	0
Fluid overload	1 (10.0)	0	0	1 (10.0)	0
Hyperkalaemia	1 (10.0)	0	0	1 (10.0)	0
Hypocalcaemia	1 (10.0)	0	0	0	1 (10.0)
Hypoglycaemia	1 (10.0)	0	1 (10.0)	0	0
Hypomagnesaemia	1 (10.0)	1 (10.0)	0	0	0
Hypophosphataemia	1 (10.0)	0	0	1 (10.0)	0
Musculoskeletal and connective tissue disorders					
-Total	3 (30.0)	0	1 (10.0)	2 (20.0)	0
Pain in extremity	2 (20.0)	0	0	2 (20.0)	0
Arthralgia	1 (10.0)	0	0	1 (10.0)	0
Back pain	1 (10.0)	0	0	1 (10.0)	0
Pain in jaw	1 (10.0)	0	1 (10.0)	0	0
Nervous system disorders					
-Total	3 (30.0)	0	1 (10.0)	1 (10.0)	1 (10.0)

Response status at study entry: Relapsed disease

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (10.0)	0	0	1 (10.0)	0
Hyporesponsive to stimuli	1 (10.0)	0	0	1 (10.0)	0
Leukoencephalopathy	1 (10.0)	0	0	1 (10.0)	0
Seizure	1 (10.0)	0	0	0	1 (10.0)
Somnolence	1 (10.0)	0	1 (10.0)	0	0
Product issues					
-Total	1 (10.0)	0	1 (10.0)	0	0
Device occlusion	1 (10.0)	0	1 (10.0)	0	0
Psychiatric disorders					
-Total	2 (20.0)	0	0	2 (20.0)	0
Agitation	1 (10.0)	0	0	1 (10.0)	0
Delirium	1 (10.0)	0	0	1 (10.0)	0
Renal and urinary disorders					
-Total	4 (40.0)	1 (10.0)	0	2 (20.0)	1 (10.0)
Acute kidney injury	2 (20.0)	0	0	1 (10.0)	1 (10.0)
Cystitis haemorrhagic	1 (10.0)	0	0	1 (10.0)	0
Haematuria	1 (10.0)	1 (10.0)	0	0	0
Oliguria	1 (10.0)	0	0	1 (10.0)	0

Response status at study entry: Relapsed disease

	All patients N=10				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary retention	1 (10.0)	0	1 (10.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (40.0)	0	0	1 (10.0)	3 (30.0)
Hypoxia	3 (30.0)	0	0	2 (20.0)	1 (10.0)
Pulmonary oedema	2 (20.0)	0	0	0	2 (20.0)
Cough	1 (10.0)	0	0	1 (10.0)	0
Dyspnoea	1 (10.0)	0	0	1 (10.0)	0
Haemoptysis	1 (10.0)	0	0	1 (10.0)	0
Oropharyngeal pain	1 (10.0)	0	0	1 (10.0)	0
Pleural effusion	1 (10.0)	0	0	1 (10.0)	0
Pulmonary alveolar haemorrhage	1 (10.0)	0	0	0	1 (10.0)
Pulmonary hypertension	1 (10.0)	0	0	1 (10.0)	0
Respiratory distress	1 (10.0)	0	0	0	1 (10.0)
Respiratory failure	1 (10.0)	0	0	0	1 (10.0)
Tachypnoea	1 (10.0)	0	0	1 (10.0)	0
Vascular disorders					
-Total	5 (50.0)	0	0	3 (30.0)	2 (20.0)

Response status at study entry: Relapsed disease

Group term Preferred term	All patients N=10 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	5 (50.0)	0	0	3 (30.0)	2 (20.0)
Hypertension	1 (10.0)	0	1 (10.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187f
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set – non – infused patients

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	0	1 (9.1)	1 (9.1)	6 (54.5)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Gastrointestinal disorders					
-Total	5 (45.5)	0	2 (18.2)	3 (27.3)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
General disorders and administration site conditions					
-Total	5 (45.5)	0	1 (9.1)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	0	0	3 (27.3)
Pyrexia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Infections and infestations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Investigations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Metabolism and nutrition disorders					
-Total	5 (45.5)	0	2 (18.2)	0	3 (27.3)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	0	0	3 (27.3)
Hypoalbuminaemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Musculoskeletal and connective tissue disorders					
-Total	2 (18.2)	0	0	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Renal and urinary disorders					
-Total	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Hypoxia	4 (36.4)	0	0	3 (27.3)	1 (9.1)
Pleural effusion	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Vascular disorders					
-Total	6 (54.5)	0	0	3 (27.3)	3 (27.3)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	6 (54.5)	0	0	3 (27.3)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187g
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set – non – infused patients

Mixed-lineage leukemia rearrangement: No

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	0	1 (9.1)	1 (9.1)	6 (54.5)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Gastrointestinal disorders					
-Total	5 (45.5)	0	2 (18.2)	3 (27.3)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
General disorders and administration site conditions					
-Total	5 (45.5)	0	1 (9.1)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	0	0	3 (27.3)
Pyrexia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Infections and infestations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Investigations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Metabolism and nutrition disorders					
-Total	5 (45.5)	0	2 (18.2)	0	3 (27.3)

Mixed-lineage leukemia rearrangement: No

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	0	0	3 (27.3)
Hypoalbuminaemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Musculoskeletal and connective tissue disorders					
-Total	2 (18.2)	0	0	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Renal and urinary disorders					
-Total	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Hypoxia	4 (36.4)	0	0	3 (27.3)	1 (9.1)
Pleural effusion	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Vascular disorders					
-Total	6 (54.5)	0	0	3 (27.3)	3 (27.3)

Mixed-lineage leukemia rearrangement: No

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	6 (54.5)	0	0	3 (27.3)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187h
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: No

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	0	1 (9.1)	1 (9.1)	6 (54.5)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Gastrointestinal disorders					
-Total	5 (45.5)	0	2 (18.2)	3 (27.3)	0

Hypodiploidy: No

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
General disorders and administration site conditions					
-Total	5 (45.5)	0	1 (9.1)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	0	0	3 (27.3)
Pyrexia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Infections and infestations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Investigations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Metabolism and nutrition disorders					
-Total	5 (45.5)	0	2 (18.2)	0	3 (27.3)

Hypodiploidy: No

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	0	0	3 (27.3)
Hypoalbuminaemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Musculoskeletal and connective tissue disorders					
-Total	2 (18.2)	0	0	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Renal and urinary disorders					
-Total	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Hypoxia	4 (36.4)	0	0	3 (27.3)	1 (9.1)
Pleural effusion	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Vascular disorders					
-Total	6 (54.5)	0	0	3 (27.3)	3 (27.3)

Hypodiploidy: No

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	6 (54.5)	0	0	3 (27.3)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187i
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: No

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	0	1 (9.1)	1 (9.1)	6 (54.5)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Gastrointestinal disorders					
-Total	5 (45.5)	0	2 (18.2)	3 (27.3)	0

BCR-ABL1-like: No

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
General disorders and administration site conditions					
-Total	5 (45.5)	0	1 (9.1)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	0	0	3 (27.3)
Pyrexia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Infections and infestations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Investigations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Metabolism and nutrition disorders					
-Total	5 (45.5)	0	2 (18.2)	0	3 (27.3)

BCR-ABL1-like: No

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	0	0	3 (27.3)
Hypoalbuminaemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Musculoskeletal and connective tissue disorders					
-Total	2 (18.2)	0	0	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Renal and urinary disorders					
-Total	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Hypoxia	4 (36.4)	0	0	3 (27.3)	1 (9.1)
Pleural effusion	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Vascular disorders					
-Total	6 (54.5)	0	0	3 (27.3)	3 (27.3)

BCR-ABL1-like: No

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	6 (54.5)	0	0	3 (27.3)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187j
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	1 (33.3)	0	2 (66.7)
Blood and lymphatic system disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Febrile neutropenia	1 (33.3)	0	0	1 (33.3)	0
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	0	0	1 (33.3)
Endocrine disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Adrenal insufficiency	1 (33.3)	0	1 (33.3)	0	0
Gastrointestinal disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Constipation	1 (33.3)	1 (33.3)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal haemorrhage	1 (33.3)	0	0	1 (33.3)	0
Nausea	1 (33.3)	0	1 (33.3)	0	0
Vomiting	1 (33.3)	0	1 (33.3)	0	0
General disorders and administration site conditions					
-Total	1 (33.3)	0	1 (33.3)	0	0
Chills	1 (33.3)	1 (33.3)	0	0	0
Pyrexia	1 (33.3)	0	1 (33.3)	0	0
Infections and infestations					
-Total	2 (66.7)	0	0	0	2 (66.7)
Candida sepsis	1 (33.3)	0	0	0	1 (33.3)
Pneumonia fungal	1 (33.3)	0	0	1 (33.3)	0
Sepsis	1 (33.3)	0	0	0	1 (33.3)
Metabolism and nutrition disorders					
-Total	2 (66.7)	0	1 (33.3)	0	1 (33.3)
Hyperglycaemia	1 (33.3)	0	1 (33.3)	0	0
Hypernatraemia	1 (33.3)	0	0	0	1 (33.3)
Hypokalaemia	1 (33.3)	0	0	0	1 (33.3)
Hypomagnesaemia	1 (33.3)	1 (33.3)	0	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	1 (33.3)	0	0	1 (33.3)	0
Renal and urinary disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Acute kidney injury	1 (33.3)	0	0	0	1 (33.3)
Respiratory, thoracic and mediastinal disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	0	0	1 (33.3)
Respiratory failure	1 (33.3)	0	0	0	1 (33.3)
Vascular disorders					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Hypotension	2 (66.7)	0	0	1 (33.3)	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187j
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (75.0)	0	0	1 (12.5)	5 (62.5)
Blood and lymphatic system disorders					
-Total	4 (50.0)	0	0	2 (25.0)	2 (25.0)
Anaemia	4 (50.0)	0	0	4 (50.0)	0
Disseminated intravascular coagulation	3 (37.5)	0	0	2 (25.0)	1 (12.5)
Thrombocytopenia	3 (37.5)	0	0	1 (12.5)	2 (25.0)
Febrile neutropenia	1 (12.5)	0	0	1 (12.5)	0
Lymphopenia	1 (12.5)	0	0	0	1 (12.5)
Neutropenia	1 (12.5)	0	0	0	1 (12.5)
Cardiac disorders					

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (25.0)	0	0	0	2 (25.0)
Bradycardia	1 (12.5)	0	0	0	1 (12.5)
Cardiovascular insufficiency	1 (12.5)	0	0	0	1 (12.5)
Right ventricular dysfunction	1 (12.5)	0	0	1 (12.5)	0
Sinus tachycardia	1 (12.5)	0	0	1 (12.5)	0
Ventricular tachycardia	1 (12.5)	0	0	1 (12.5)	0
Eye disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Photophobia	1 (12.5)	0	1 (12.5)	0	0
Gastrointestinal disorders					
-Total	4 (50.0)	0	1 (12.5)	3 (37.5)	0
Abdominal pain	2 (25.0)	0	0	2 (25.0)	0
Colitis	2 (25.0)	0	0	2 (25.0)	0
Nausea	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Vomiting	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Ascites	1 (12.5)	0	0	1 (12.5)	0
Diarrhoea	1 (12.5)	0	0	1 (12.5)	0
Haematochezia	1 (12.5)	0	0	1 (12.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (12.5)	0	0	1 (12.5)	0
General disorders and administration site conditions					
-Total	5 (62.5)	0	0	2 (25.0)	3 (37.5)
Multiple organ dysfunction syndrome	3 (37.5)	0	0	0	3 (37.5)
Pain	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Pyrexia	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Non-cardiac chest pain	1 (12.5)	0	0	1 (12.5)	0
Hepatobiliary disorders					
-Total	1 (12.5)	0	0	0	1 (12.5)
Hepatic failure	1 (12.5)	0	0	0	1 (12.5)
Infections and infestations					
-Total	5 (62.5)	0	0	1 (12.5)	4 (50.0)
Klebsiella sepsis	2 (25.0)	0	0	0	2 (25.0)
Bronchitis	1 (12.5)	0	1 (12.5)	0	0
Clostridium difficile colitis	1 (12.5)	0	0	1 (12.5)	0
Escherichia infection	1 (12.5)	0	0	1 (12.5)	0
Klebsiella infection	1 (12.5)	0	0	1 (12.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (12.5)	0	1 (12.5)	0	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	0	0	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	0	0	1 (12.5)
Streptococcal infection	1 (12.5)	0	0	1 (12.5)	0
Investigations					
-Total	4 (50.0)	0	0	0	4 (50.0)
Neutrophil count decreased	2 (25.0)	0	0	0	2 (25.0)
Activated partial thromboplastin time prolonged	1 (12.5)	0	1 (12.5)	0	0
Alanine aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)
Aspartate aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)
Blood bilirubin increased	1 (12.5)	0	0	0	1 (12.5)
Blood lactate dehydrogenase increased	1 (12.5)	0	0	1 (12.5)	0
Computerised tomogram thorax abnormal	1 (12.5)	0	0	1 (12.5)	0
Electrocardiogram qt prolonged	1 (12.5)	0	0	1 (12.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	1 (12.5)	0	1 (12.5)	0	0
Platelet count decreased	1 (12.5)	0	0	0	1 (12.5)
Weight increased	1 (12.5)	1 (12.5)	0	0	0
White blood cell count decreased	1 (12.5)	0	0	0	1 (12.5)
Metabolism and nutrition disorders					
-Total	4 (50.0)	0	1 (12.5)	1 (12.5)	2 (25.0)
Hyperglycaemia	2 (25.0)	0	1 (12.5)	0	1 (12.5)
Hypernatraemia	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Hypoalbuminaemia	2 (25.0)	0	1 (12.5)	0	1 (12.5)
Hypokalaemia	2 (25.0)	0	0	0	2 (25.0)
Decreased appetite	1 (12.5)	0	0	1 (12.5)	0
Dehydration	1 (12.5)	0	0	1 (12.5)	0
Fluid overload	1 (12.5)	0	0	1 (12.5)	0
Hyperkalaemia	1 (12.5)	0	0	1 (12.5)	0
Hypocalcaemia	1 (12.5)	0	0	0	1 (12.5)
Hypoglycaemia	1 (12.5)	0	1 (12.5)	0	0
Musculoskeletal and connective tissue disorders					

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (37.5)	0	1 (12.5)	2 (25.0)	0
Pain in extremity	2 (25.0)	0	0	2 (25.0)	0
Arthralgia	1 (12.5)	0	0	1 (12.5)	0
Back pain	1 (12.5)	0	0	1 (12.5)	0
Pain in jaw	1 (12.5)	0	1 (12.5)	0	0
Nervous system disorders					
-Total	3 (37.5)	0	1 (12.5)	1 (12.5)	1 (12.5)
Headache	1 (12.5)	0	0	1 (12.5)	0
Hyporesponsive to stimuli	1 (12.5)	0	0	1 (12.5)	0
Leukoencephalopathy	1 (12.5)	0	0	1 (12.5)	0
Seizure	1 (12.5)	0	0	0	1 (12.5)
Somnolence	1 (12.5)	0	1 (12.5)	0	0
Product issues					
-Total	1 (12.5)	0	1 (12.5)	0	0
Device occlusion	1 (12.5)	0	1 (12.5)	0	0
Psychiatric disorders					
-Total	3 (37.5)	0	1 (12.5)	2 (25.0)	0
Agitation	1 (12.5)	0	0	1 (12.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	1 (12.5)	0	1 (12.5)	0	0
Delirium	1 (12.5)	0	0	1 (12.5)	0
Renal and urinary disorders					
-Total	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Acute kidney injury	1 (12.5)	0	0	1 (12.5)	0
Cystitis haemorrhagic	1 (12.5)	0	0	1 (12.5)	0
Haematuria	1 (12.5)	1 (12.5)	0	0	0
Oliguria	1 (12.5)	0	0	1 (12.5)	0
Urinary retention	1 (12.5)	0	1 (12.5)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (50.0)	0	0	1 (12.5)	3 (37.5)
Hypoxia	4 (50.0)	0	0	3 (37.5)	1 (12.5)
Pleural effusion	2 (25.0)	0	1 (12.5)	1 (12.5)	0
Aspiration	1 (12.5)	0	0	0	1 (12.5)
Cough	1 (12.5)	0	0	1 (12.5)	0
Dyspnoea	1 (12.5)	0	0	1 (12.5)	0
Epistaxis	1 (12.5)	0	1 (12.5)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haemoptysis	1 (12.5)	0	0	1 (12.5)	0
Oropharyngeal pain	1 (12.5)	0	0	1 (12.5)	0
Pulmonary alveolar haemorrhage	1 (12.5)	0	0	0	1 (12.5)
Pulmonary hypertension	1 (12.5)	0	0	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)
Respiratory distress	1 (12.5)	0	0	0	1 (12.5)
Tachypnoea	1 (12.5)	0	0	1 (12.5)	0
Vascular disorders					
-Total	4 (50.0)	0	0	2 (25.0)	2 (25.0)
Hypotension	4 (50.0)	0	0	2 (25.0)	2 (25.0)
Hypertension	1 (12.5)	0	1 (12.5)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187k
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: US

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	0	1 (9.1)	1 (9.1)	6 (54.5)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Gastrointestinal disorders					
-Total	5 (45.5)	0	2 (18.2)	3 (27.3)	0

Region: US

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
General disorders and administration site conditions					
-Total	5 (45.5)	0	1 (9.1)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	0	0	3 (27.3)
Pyrexia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Infections and infestations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Investigations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Metabolism and nutrition disorders					
-Total	5 (45.5)	0	2 (18.2)	0	3 (27.3)

Region: US

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	0	0	3 (27.3)
Hypoalbuminaemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Musculoskeletal and connective tissue disorders					
-Total	2 (18.2)	0	0	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Renal and urinary disorders					
-Total	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Hypoxia	4 (36.4)	0	0	3 (27.3)	1 (9.1)
Pleural effusion	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Vascular disorders					
-Total	6 (54.5)	0	0	3 (27.3)	3 (27.3)

Region: US

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	6 (54.5)	0	0	3 (27.3)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187l
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	0	0	4 (100)
Blood and lymphatic system disorders					
-Total	3 (75.0)	0	0	2 (50.0)	1 (25.0)
Anaemia	3 (75.0)	0	0	3 (75.0)	0
Disseminated intravascular coagulation	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Thrombocytopenia	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Febrile neutropenia	1 (25.0)	0	0	1 (25.0)	0
Cardiac disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Cardiovascular insufficiency	1 (25.0)	0	0	0	1 (25.0)

Prior SCT therapy: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	3 (75.0)	0	1 (25.0)	2 (50.0)	0
Colitis	2 (50.0)	0	0	2 (50.0)	0
Abdominal pain	1 (25.0)	0	0	1 (25.0)	0
Ascites	1 (25.0)	0	0	1 (25.0)	0
Diarrhoea	1 (25.0)	0	0	1 (25.0)	0
Nausea	1 (25.0)	0	1 (25.0)	0	0
Stomatitis	1 (25.0)	0	0	1 (25.0)	0
Vomiting	1 (25.0)	0	1 (25.0)	0	0
General disorders and administration site conditions					
-Total	4 (100)	0	1 (25.0)	0	3 (75.0)
Multiple organ dysfunction syndrome	3 (75.0)	0	0	0	3 (75.0)
Pyrexia	2 (50.0)	0	2 (50.0)	0	0
Chills	1 (25.0)	1 (25.0)	0	0	0
Pain	1 (25.0)	0	1 (25.0)	0	0
Hepatobiliary disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)

Prior SCT therapy: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic failure	1 (25.0)	0	0	0	1 (25.0)
Infections and infestations					
-Total	4 (100)	0	0	0	4 (100)
Klebsiella sepsis	2 (50.0)	0	0	0	2 (50.0)
Bronchitis	1 (25.0)	0	1 (25.0)	0	0
Clostridium difficile colitis	1 (25.0)	0	0	1 (25.0)	0
Klebsiella infection	1 (25.0)	0	0	1 (25.0)	0
Oral herpes	1 (25.0)	0	1 (25.0)	0	0
Sepsis	1 (25.0)	0	0	0	1 (25.0)
Staphylococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Staphylococcal infection	1 (25.0)	0	0	0	1 (25.0)
Investigations					
-Total	3 (75.0)	0	0	0	3 (75.0)
Neutrophil count decreased	2 (50.0)	0	0	0	2 (50.0)
Activated partial thromboplastin time prolonged	1 (25.0)	0	1 (25.0)	0	0
Alanine aminotransferase increased	1 (25.0)	0	0	0	1 (25.0)
Aspartate aminotransferase increased	1 (25.0)	0	0	0	1 (25.0)

Prior SCT therapy: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (25.0)	0	0	0	1 (25.0)
International normalised ratio increased	1 (25.0)	0	1 (25.0)	0	0
Platelet count decreased	1 (25.0)	0	0	0	1 (25.0)
Weight increased	1 (25.0)	1 (25.0)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (75.0)	0	1 (25.0)	0	2 (50.0)
Hyperglycaemia	2 (50.0)	0	1 (25.0)	0	1 (25.0)
Hypernatraemia	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Hypoalbuminaemia	2 (50.0)	0	1 (25.0)	0	1 (25.0)
Hypokalaemia	2 (50.0)	0	0	0	2 (50.0)
Decreased appetite	1 (25.0)	0	0	1 (25.0)	0
Dehydration	1 (25.0)	0	0	1 (25.0)	0
Hypocalcaemia	1 (25.0)	0	0	0	1 (25.0)
Hypoglycaemia	1 (25.0)	0	1 (25.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Pain in extremity	1 (25.0)	0	0	1 (25.0)	0

Prior SCT therapy: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Leukoencephalopathy	1 (25.0)	0	0	1 (25.0)	0
Somnolence	1 (25.0)	0	1 (25.0)	0	0
Product issues					
-Total	1 (25.0)	0	1 (25.0)	0	0
Device occlusion	1 (25.0)	0	1 (25.0)	0	0
Psychiatric disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Delirium	1 (25.0)	0	0	1 (25.0)	0
Renal and urinary disorders					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Cystitis haemorrhagic	1 (25.0)	0	0	1 (25.0)	0
Haematuria	1 (25.0)	1 (25.0)	0	0	0
Urinary retention	1 (25.0)	0	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (50.0)	0	0	1 (25.0)	1 (25.0)

Prior SCT therapy: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Pleural effusion	1 (25.0)	0	0	1 (25.0)	0
Vascular disorders					
-Total	3 (75.0)	0	0	3 (75.0)	0
Hypotension	3 (75.0)	0	0	3 (75.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187l
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: No

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	0	1 (14.3)	1 (14.3)	3 (42.9)
Blood and lymphatic system disorders					
-Total	2 (28.6)	0	0	0	2 (28.6)
Neutropenia	2 (28.6)	0	0	0	2 (28.6)
Thrombocytopenia	2 (28.6)	0	0	0	2 (28.6)
Anaemia	1 (14.3)	0	0	1 (14.3)	0
Disseminated intravascular coagulation	1 (14.3)	0	0	1 (14.3)	0
Febrile neutropenia	1 (14.3)	0	0	1 (14.3)	0
Lymphopenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					

Prior SCT therapy: No

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (14.3)	0	0	0	1 (14.3)
Bradycardia	1 (14.3)	0	0	0	1 (14.3)
Right ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0
Sinus tachycardia	1 (14.3)	0	0	1 (14.3)	0
Ventricular tachycardia	1 (14.3)	0	0	1 (14.3)	0
Endocrine disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Adrenal insufficiency	1 (14.3)	0	1 (14.3)	0	0
Eye disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Photophobia	1 (14.3)	0	1 (14.3)	0	0
Gastrointestinal disorders					
-Total	3 (42.9)	0	1 (14.3)	2 (28.6)	0
Nausea	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Vomiting	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Abdominal pain	1 (14.3)	0	0	1 (14.3)	0
Constipation	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal haemorrhage	1 (14.3)	0	0	1 (14.3)	0

Prior SCT therapy: No

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematochezia	1 (14.3)	0	0	1 (14.3)	0
General disorders and administration site conditions					
-Total	2 (28.6)	0	0	2 (28.6)	0
Non-cardiac chest pain	1 (14.3)	0	0	1 (14.3)	0
Pain	1 (14.3)	0	0	1 (14.3)	0
Pyrexia	1 (14.3)	0	0	1 (14.3)	0
Infections and infestations					
-Total	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Candida sepsis	1 (14.3)	0	0	0	1 (14.3)
Escherichia infection	1 (14.3)	0	0	1 (14.3)	0
Pneumonia	1 (14.3)	0	0	0	1 (14.3)
Pneumonia fungal	1 (14.3)	0	0	1 (14.3)	0
Streptococcal infection	1 (14.3)	0	0	1 (14.3)	0
Investigations					
-Total	1 (14.3)	0	0	0	1 (14.3)
Blood lactate dehydrogenase increased	1 (14.3)	0	0	1 (14.3)	0

Prior SCT therapy: No

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Computerised tomogram thorax abnormal	1 (14.3)	0	0	1 (14.3)	0
Electrocardiogram qt prolonged	1 (14.3)	0	0	1 (14.3)	0
White blood cell count decreased	1 (14.3)	0	0	0	1 (14.3)
Metabolism and nutrition disorders					
-Total	3 (42.9)	0	1 (14.3)	1 (14.3)	1 (14.3)
Fluid overload	1 (14.3)	0	0	1 (14.3)	0
Hyperglycaemia	1 (14.3)	0	1 (14.3)	0	0
Hyperkalaemia	1 (14.3)	0	0	1 (14.3)	0
Hypernatraemia	1 (14.3)	0	0	0	1 (14.3)
Hypokalaemia	1 (14.3)	0	0	0	1 (14.3)
Hypomagnesaemia	1 (14.3)	1 (14.3)	0	0	0
Hypophosphataemia	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Arthralgia	1 (14.3)	0	0	1 (14.3)	0
Back pain	1 (14.3)	0	0	1 (14.3)	0
Pain in extremity	1 (14.3)	0	0	1 (14.3)	0

Prior SCT therapy: No

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in jaw	1 (14.3)	0	1 (14.3)	0	0
Nervous system disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)
Headache	1 (14.3)	0	0	1 (14.3)	0
Hyporesponsive to stimuli	1 (14.3)	0	0	1 (14.3)	0
Seizure	1 (14.3)	0	0	0	1 (14.3)
Psychiatric disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Agitation	1 (14.3)	0	0	1 (14.3)	0
Confusional state	1 (14.3)	0	1 (14.3)	0	0
Renal and urinary disorders					
-Total	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Acute kidney injury	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Oliguria	1 (14.3)	0	0	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (42.9)	0	0	0	3 (42.9)
Hypoxia	2 (28.6)	0	0	2 (28.6)	0

Prior SCT therapy: No

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	2 (28.6)	0	0	0	2 (28.6)
Aspiration	1 (14.3)	0	0	0	1 (14.3)
Cough	1 (14.3)	0	0	1 (14.3)	0
Dyspnoea	1 (14.3)	0	0	1 (14.3)	0
Epistaxis	1 (14.3)	0	1 (14.3)	0	0
Haemoptysis	1 (14.3)	0	0	1 (14.3)	0
Oropharyngeal pain	1 (14.3)	0	0	1 (14.3)	0
Pleural effusion	1 (14.3)	0	1 (14.3)	0	0
Pulmonary alveolar haemorrhage	1 (14.3)	0	0	0	1 (14.3)
Pulmonary hypertension	1 (14.3)	0	0	1 (14.3)	0
Respiratory distress	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Tachypnoea	1 (14.3)	0	0	1 (14.3)	0
Vascular disorders					
-Total	3 (42.9)	0	0	0	3 (42.9)
Hypotension	3 (42.9)	0	0	0	3 (42.9)
Hypertension	1 (14.3)	0	1 (14.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187m
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	0	1 (25.0)	1 (25.0)	1 (25.0)
Gastrointestinal disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Constipation	1 (25.0)	1 (25.0)	0	0	0
Nausea	1 (25.0)	0	1 (25.0)	0	0
Vomiting	1 (25.0)	0	1 (25.0)	0	0
General disorders and administration site conditions					
-Total	1 (25.0)	0	0	1 (25.0)	0
Pain	1 (25.0)	0	0	1 (25.0)	0
Pyrexia	1 (25.0)	0	0	1 (25.0)	0

Eligibility for SCT: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Escherichia infection	1 (25.0)	0	0	1 (25.0)	0
Pneumonia	1 (25.0)	0	0	0	1 (25.0)
Streptococcal infection	1 (25.0)	0	0	1 (25.0)	0
Metabolism and nutrition disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Hyperglycaemia	1 (25.0)	0	1 (25.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Pain in jaw	1 (25.0)	0	1 (25.0)	0	0
Psychiatric disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Confusional state	1 (25.0)	0	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Aspiration	1 (25.0)	0	0	0	1 (25.0)

Eligibility for SCT: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	1 (25.0)	0	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	0	1 (25.0)	0
Pleural effusion	1 (25.0)	0	1 (25.0)	0	0
Vascular disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Hypotension	1 (25.0)	0	0	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187m
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: No

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	0	0	6 (85.7)
Blood and lymphatic system disorders					
-Total	5 (71.4)	0	0	2 (28.6)	3 (42.9)
Anaemia	4 (57.1)	0	0	4 (57.1)	0
Thrombocytopenia	4 (57.1)	0	0	1 (14.3)	3 (42.9)
Disseminated intravascular coagulation	3 (42.9)	0	0	2 (28.6)	1 (14.3)
Febrile neutropenia	2 (28.6)	0	0	2 (28.6)	0
Neutropenia	2 (28.6)	0	0	0	2 (28.6)
Lymphopenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					

Eligibility for SCT: No

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (28.6)	0	0	0	2 (28.6)
Bradycardia	1 (14.3)	0	0	0	1 (14.3)
Cardiovascular insufficiency	1 (14.3)	0	0	0	1 (14.3)
Right ventricular dysfunction	1 (14.3)	0	0	1 (14.3)	0
Sinus tachycardia	1 (14.3)	0	0	1 (14.3)	0
Ventricular tachycardia	1 (14.3)	0	0	1 (14.3)	0
Endocrine disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Adrenal insufficiency	1 (14.3)	0	1 (14.3)	0	0
Eye disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Photophobia	1 (14.3)	0	1 (14.3)	0	0
Gastrointestinal disorders					
-Total	5 (71.4)	0	1 (14.3)	4 (57.1)	0
Abdominal pain	2 (28.6)	0	0	2 (28.6)	0
Colitis	2 (28.6)	0	0	2 (28.6)	0
Nausea	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Vomiting	2 (28.6)	0	1 (14.3)	1 (14.3)	0

Eligibility for SCT: No

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	1 (14.3)	0	0	1 (14.3)	0
Diarrhoea	1 (14.3)	0	0	1 (14.3)	0
Gastrointestinal haemorrhage	1 (14.3)	0	0	1 (14.3)	0
Haematochezia	1 (14.3)	0	0	1 (14.3)	0
Stomatitis	1 (14.3)	0	0	1 (14.3)	0
General disorders and administration site conditions					
-Total	5 (71.4)	0	1 (14.3)	1 (14.3)	3 (42.9)
Multiple organ dysfunction syndrome	3 (42.9)	0	0	0	3 (42.9)
Pyrexia	2 (28.6)	0	2 (28.6)	0	0
Chills	1 (14.3)	1 (14.3)	0	0	0
Non-cardiac chest pain	1 (14.3)	0	0	1 (14.3)	0
Pain	1 (14.3)	0	1 (14.3)	0	0
Hepatobiliary disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)
Hepatic failure	1 (14.3)	0	0	0	1 (14.3)
Infections and infestations					
-Total	5 (71.4)	0	0	0	5 (71.4)

Eligibility for SCT: No

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella sepsis	2 (28.6)	0	0	0	2 (28.6)
Bronchitis	1 (14.3)	0	1 (14.3)	0	0
Candida sepsis	1 (14.3)	0	0	0	1 (14.3)
Clostridium difficile colitis	1 (14.3)	0	0	1 (14.3)	0
Klebsiella infection	1 (14.3)	0	0	1 (14.3)	0
Oral herpes	1 (14.3)	0	1 (14.3)	0	0
Pneumonia fungal	1 (14.3)	0	0	1 (14.3)	0
Sepsis	1 (14.3)	0	0	0	1 (14.3)
Staphylococcal bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Staphylococcal infection	1 (14.3)	0	0	0	1 (14.3)
Investigations					
-Total	4 (57.1)	0	0	0	4 (57.1)
Neutrophil count decreased	2 (28.6)	0	0	0	2 (28.6)
Activated partial thromboplastin time prolonged	1 (14.3)	0	1 (14.3)	0	0
Alanine aminotransferase increased	1 (14.3)	0	0	0	1 (14.3)
Aspartate aminotransferase increased	1 (14.3)	0	0	0	1 (14.3)
Blood bilirubin increased	1 (14.3)	0	0	0	1 (14.3)

Eligibility for SCT: No

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	1 (14.3)	0	0	1 (14.3)	0
Computerised tomogram thorax abnormal	1 (14.3)	0	0	1 (14.3)	0
Electrocardiogram qt prolonged	1 (14.3)	0	0	1 (14.3)	0
International normalised ratio increased	1 (14.3)	0	1 (14.3)	0	0
Platelet count decreased	1 (14.3)	0	0	0	1 (14.3)
Weight increased	1 (14.3)	1 (14.3)	0	0	0
White blood cell count decreased	1 (14.3)	0	0	0	1 (14.3)
Metabolism and nutrition disorders					
-Total	5 (71.4)	0	1 (14.3)	1 (14.3)	3 (42.9)
Hypernatraemia	3 (42.9)	0	0	1 (14.3)	2 (28.6)
Hypokalaemia	3 (42.9)	0	0	0	3 (42.9)
Hyperglycaemia	2 (28.6)	0	1 (14.3)	0	1 (14.3)
Hypoalbuminaemia	2 (28.6)	0	1 (14.3)	0	1 (14.3)
Decreased appetite	1 (14.3)	0	0	1 (14.3)	0
Dehydration	1 (14.3)	0	0	1 (14.3)	0
Fluid overload	1 (14.3)	0	0	1 (14.3)	0

Eligibility for SCT: No

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (14.3)	0	0	1 (14.3)	0
Hypocalcaemia	1 (14.3)	0	0	0	1 (14.3)
Hypoglycaemia	1 (14.3)	0	1 (14.3)	0	0
Hypomagnesaemia	1 (14.3)	1 (14.3)	0	0	0
Hypophosphataemia	1 (14.3)	0	0	1 (14.3)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (28.6)	0	0	2 (28.6)	0
Pain in extremity	2 (28.6)	0	0	2 (28.6)	0
Arthralgia	1 (14.3)	0	0	1 (14.3)	0
Back pain	1 (14.3)	0	0	1 (14.3)	0
Nervous system disorders					
-Total	3 (42.9)	0	1 (14.3)	1 (14.3)	1 (14.3)
Headache	1 (14.3)	0	0	1 (14.3)	0
Hyporesponsive to stimuli	1 (14.3)	0	0	1 (14.3)	0
Leukoencephalopathy	1 (14.3)	0	0	1 (14.3)	0
Seizure	1 (14.3)	0	0	0	1 (14.3)
Somnolence	1 (14.3)	0	1 (14.3)	0	0

Eligibility for SCT: No

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Product issues					
-Total	1 (14.3)	0	1 (14.3)	0	0
Device occlusion	1 (14.3)	0	1 (14.3)	0	0
Psychiatric disorders					
-Total	2 (28.6)	0	0	2 (28.6)	0
Agitation	1 (14.3)	0	0	1 (14.3)	0
Delirium	1 (14.3)	0	0	1 (14.3)	0
Renal and urinary disorders					
-Total	4 (57.1)	1 (14.3)	0	2 (28.6)	1 (14.3)
Acute kidney injury	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Cystitis haemorrhagic	1 (14.3)	0	0	1 (14.3)	0
Haematuria	1 (14.3)	1 (14.3)	0	0	0
Oliguria	1 (14.3)	0	0	1 (14.3)	0
Urinary retention	1 (14.3)	0	1 (14.3)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	4 (57.1)	0	0	1 (14.3)	3 (42.9)
Hypoxia	3 (42.9)	0	0	2 (28.6)	1 (14.3)

Eligibility for SCT: No

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	2 (28.6)	0	0	0	2 (28.6)
Cough	1 (14.3)	0	0	1 (14.3)	0
Dyspnoea	1 (14.3)	0	0	1 (14.3)	0
Haemoptysis	1 (14.3)	0	0	1 (14.3)	0
Oropharyngeal pain	1 (14.3)	0	0	1 (14.3)	0
Pleural effusion	1 (14.3)	0	0	1 (14.3)	0
Pulmonary alveolar haemorrhage	1 (14.3)	0	0	0	1 (14.3)
Pulmonary hypertension	1 (14.3)	0	0	1 (14.3)	0
Respiratory distress	1 (14.3)	0	0	0	1 (14.3)
Respiratory failure	1 (14.3)	0	0	0	1 (14.3)
Tachypnoea	1 (14.3)	0	0	1 (14.3)	0
Vascular disorders					
-Total	5 (71.4)	0	0	3 (42.9)	2 (28.6)
Hypotension	5 (71.4)	0	0	3 (42.9)	2 (28.6)
Hypertension	1 (14.3)	0	1 (14.3)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187n
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: Low

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	0	2 (100)
Blood and lymphatic system disorders					
-Total	2 (100)	0	0	0	2 (100)
Anaemia	2 (100)	0	0	2 (100)	0
Disseminated intravascular coagulation	2 (100)	0	0	1 (50.0)	1 (50.0)
Thrombocytopenia	2 (100)	0	0	0	2 (100)
Febrile neutropenia	1 (50.0)	0	0	1 (50.0)	0
Lymphopenia	1 (50.0)	0	0	0	1 (50.0)
Neutropenia	1 (50.0)	0	0	0	1 (50.0)
Cardiac disorders					

Baseline bone marrow tumor burden: Low

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	0	0	1 (50.0)
Bradycardia	1 (50.0)	0	0	0	1 (50.0)
Right ventricular dysfunction	1 (50.0)	0	0	1 (50.0)	0
Sinus tachycardia	1 (50.0)	0	0	1 (50.0)	0
Ventricular tachycardia	1 (50.0)	0	0	1 (50.0)	0
Eye disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Photophobia	1 (50.0)	0	1 (50.0)	0	0
Gastrointestinal disorders					
-Total	2 (100)	0	0	2 (100)	0
Abdominal pain	2 (100)	0	0	2 (100)	0
Ascites	1 (50.0)	0	0	1 (50.0)	0
Colitis	1 (50.0)	0	0	1 (50.0)	0
Diarrhoea	1 (50.0)	0	0	1 (50.0)	0
Haematochezia	1 (50.0)	0	0	1 (50.0)	0
Nausea	1 (50.0)	0	0	1 (50.0)	0
Stomatitis	1 (50.0)	0	0	1 (50.0)	0
Vomiting	1 (50.0)	0	0	1 (50.0)	0

Baseline bone marrow tumor burden: Low

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Multiple organ dysfunction syndrome	1 (50.0)	0	0	0	1 (50.0)
Non-cardiac chest pain	1 (50.0)	0	0	1 (50.0)	0
Pyrexia	1 (50.0)	0	1 (50.0)	0	0
Hepatobiliary disorders					
-Total	1 (50.0)	0	0	0	1 (50.0)
Hepatic failure	1 (50.0)	0	0	0	1 (50.0)
Infections and infestations					
-Total	1 (50.0)	0	0	0	1 (50.0)
Bronchitis	1 (50.0)	0	1 (50.0)	0	0
Oral herpes	1 (50.0)	0	1 (50.0)	0	0
Staphylococcal bacteraemia	1 (50.0)	0	0	1 (50.0)	0
Staphylococcal infection	1 (50.0)	0	0	0	1 (50.0)
Investigations					
-Total	2 (100)	0	0	0	2 (100)
Activated partial thromboplastin time prolonged	1 (50.0)	0	1 (50.0)	0	0

Baseline bone marrow tumor burden: Low

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (50.0)	0	0	0	1 (50.0)
Aspartate aminotransferase increased	1 (50.0)	0	0	0	1 (50.0)
Blood bilirubin increased	1 (50.0)	0	0	0	1 (50.0)
Blood lactate dehydrogenase increased	1 (50.0)	0	0	1 (50.0)	0
Computerised tomogram thorax abnormal	1 (50.0)	0	0	1 (50.0)	0
Electrocardiogram qt prolonged	1 (50.0)	0	0	1 (50.0)	0
International normalised ratio increased	1 (50.0)	0	1 (50.0)	0	0
Neutrophil count decreased	1 (50.0)	0	0	0	1 (50.0)
Weight increased	1 (50.0)	1 (50.0)	0	0	0
White blood cell count decreased	1 (50.0)	0	0	0	1 (50.0)
Metabolism and nutrition disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Decreased appetite	1 (50.0)	0	0	1 (50.0)	0
Dehydration	1 (50.0)	0	0	1 (50.0)	0
Fluid overload	1 (50.0)	0	0	1 (50.0)	0

Baseline bone marrow tumor burden: Low

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (50.0)	0	0	1 (50.0)	0
Hypernatraemia	1 (50.0)	0	0	0	1 (50.0)
Hypoalbuminaemia	1 (50.0)	0	1 (50.0)	0	0
Hypoglycaemia	1 (50.0)	0	1 (50.0)	0	0
Hypokalaemia	1 (50.0)	0	0	0	1 (50.0)
Musculoskeletal and connective tissue disorders					
-Total	2 (100)	0	0	2 (100)	0
Pain in extremity	2 (100)	0	0	2 (100)	0
Arthralgia	1 (50.0)	0	0	1 (50.0)	0
Back pain	1 (50.0)	0	0	1 (50.0)	0
Nervous system disorders					
-Total	2 (100)	0	1 (50.0)	0	1 (50.0)
Headache	1 (50.0)	0	0	1 (50.0)	0
Hyporesponsive to stimuli	1 (50.0)	0	0	1 (50.0)	0
Seizure	1 (50.0)	0	0	0	1 (50.0)
Somnolence	1 (50.0)	0	1 (50.0)	0	0
Psychiatric disorders					

Baseline bone marrow tumor burden: Low

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (100)	0	0	2 (100)	0
Agitation	1 (50.0)	0	0	1 (50.0)	0
Delirium	1 (50.0)	0	0	1 (50.0)	0
Renal and urinary disorders					
-Total	2 (100)	0	0	2 (100)	0
Acute kidney injury	1 (50.0)	0	0	1 (50.0)	0
Cystitis haemorrhagic	1 (50.0)	0	0	1 (50.0)	0
Oliguria	1 (50.0)	0	0	1 (50.0)	0
Urinary retention	1 (50.0)	0	1 (50.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Hypoxia	2 (100)	0	0	2 (100)	0
Cough	1 (50.0)	0	0	1 (50.0)	0
Dyspnoea	1 (50.0)	0	0	1 (50.0)	0
Haemoptysis	1 (50.0)	0	0	1 (50.0)	0
Oropharyngeal pain	1 (50.0)	0	0	1 (50.0)	0
Pleural effusion	1 (50.0)	0	0	1 (50.0)	0

Baseline bone marrow tumor burden: Low

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary alveolar haemorrhage	1 (50.0)	0	0	0	1 (50.0)
Pulmonary hypertension	1 (50.0)	0	0	1 (50.0)	0
Pulmonary oedema	1 (50.0)	0	0	0	1 (50.0)
Respiratory distress	1 (50.0)	0	0	0	1 (50.0)
Tachypnoea	1 (50.0)	0	0	1 (50.0)	0
Vascular disorders					
-Total	2 (100)	0	0	1 (50.0)	1 (50.0)
Hypotension	2 (100)	0	0	1 (50.0)	1 (50.0)
Hypertension	1 (50.0)	0	1 (50.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187n
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: High

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (77.8)	0	1 (11.1)	1 (11.1)	5 (55.6)
Blood and lymphatic system disorders					
-Total	3 (33.3)	0	0	2 (22.2)	1 (11.1)
Anaemia	2 (22.2)	0	0	2 (22.2)	0
Thrombocytopenia	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Disseminated intravascular coagulation	1 (11.1)	0	0	1 (11.1)	0
Febrile neutropenia	1 (11.1)	0	0	1 (11.1)	0
Neutropenia	1 (11.1)	0	0	0	1 (11.1)
Cardiac disorders					
-Total	1 (11.1)	0	0	0	1 (11.1)

Baseline bone marrow tumor burden: High

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiovascular insufficiency	1 (11.1)	0	0	0	1 (11.1)
Endocrine disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Adrenal insufficiency	1 (11.1)	0	1 (11.1)	0	0
Gastrointestinal disorders					
-Total	4 (44.4)	0	2 (22.2)	2 (22.2)	0
Nausea	2 (22.2)	0	2 (22.2)	0	0
Vomiting	2 (22.2)	0	2 (22.2)	0	0
Colitis	1 (11.1)	0	0	1 (11.1)	0
Constipation	1 (11.1)	1 (11.1)	0	0	0
Gastrointestinal haemorrhage	1 (11.1)	0	0	1 (11.1)	0
General disorders and administration site conditions					
-Total	4 (44.4)	0	1 (11.1)	1 (11.1)	2 (22.2)
Multiple organ dysfunction syndrome	2 (22.2)	0	0	0	2 (22.2)
Pain	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Pyrexia	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Chills	1 (11.1)	1 (11.1)	0	0	0

Baseline bone marrow tumor burden: High

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	6 (66.7)	0	0	1 (11.1)	5 (55.6)
Klebsiella sepsis	2 (22.2)	0	0	0	2 (22.2)
Candida sepsis	1 (11.1)	0	0	0	1 (11.1)
Clostridium difficile colitis	1 (11.1)	0	0	1 (11.1)	0
Escherichia infection	1 (11.1)	0	0	1 (11.1)	0
Klebsiella infection	1 (11.1)	0	0	1 (11.1)	0
Pneumonia	1 (11.1)	0	0	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	0	1 (11.1)	0
Sepsis	1 (11.1)	0	0	0	1 (11.1)
Streptococcal infection	1 (11.1)	0	0	1 (11.1)	0
Investigations					
-Total	2 (22.2)	0	0	0	2 (22.2)
Neutrophil count decreased	1 (11.1)	0	0	0	1 (11.1)
Platelet count decreased	1 (11.1)	0	0	0	1 (11.1)
Metabolism and nutrition disorders					
-Total	4 (44.4)	0	2 (22.2)	0	2 (22.2)
Hyperglycaemia	3 (33.3)	0	2 (22.2)	0	1 (11.1)

Baseline bone marrow tumor burden: High

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Hypokalaemia	2 (22.2)	0	0	0	2 (22.2)
Hypoalbuminaemia	1 (11.1)	0	0	0	1 (11.1)
Hypocalcaemia	1 (11.1)	0	0	0	1 (11.1)
Hypomagnesaemia	1 (11.1)	1 (11.1)	0	0	0
Hypophosphataemia	1 (11.1)	0	0	1 (11.1)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Pain in jaw	1 (11.1)	0	1 (11.1)	0	0
Nervous system disorders					
-Total	1 (11.1)	0	0	1 (11.1)	0
Leukoencephalopathy	1 (11.1)	0	0	1 (11.1)	0
Product issues					
-Total	1 (11.1)	0	1 (11.1)	0	0
Device occlusion	1 (11.1)	0	1 (11.1)	0	0
Psychiatric disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0

Baseline bone marrow tumor burden: High

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	1 (11.1)	0	1 (11.1)	0	0
Renal and urinary disorders					
-Total	2 (22.2)	1 (11.1)	0	0	1 (11.1)
Acute kidney injury	1 (11.1)	0	0	0	1 (11.1)
Haematuria	1 (11.1)	1 (11.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (33.3)	0	0	0	3 (33.3)
Hypoxia	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Aspiration	1 (11.1)	0	0	0	1 (11.1)
Epistaxis	1 (11.1)	0	1 (11.1)	0	0
Pleural effusion	1 (11.1)	0	1 (11.1)	0	0
Pulmonary oedema	1 (11.1)	0	0	0	1 (11.1)
Respiratory failure	1 (11.1)	0	0	0	1 (11.1)
Vascular disorders					
-Total	4 (44.4)	0	0	2 (22.2)	2 (22.2)
Hypotension	4 (44.4)	0	0	2 (22.2)	2 (22.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187o
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set – non – infused patients

Baseline extramedullary disease presence: Yes

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	0	1 (50.0)	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0
Escherichia infection	1 (50.0)	0	0	1 (50.0)	0
Streptococcal infection	1 (50.0)	0	0	1 (50.0)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Pain in jaw	1 (50.0)	0	1 (50.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187o
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set – non – infused patients

Baseline extramedullary disease presence: No

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (88.9)	0	1 (11.1)	0	7 (77.8)
Blood and lymphatic system disorders					
-Total	5 (55.6)	0	0	2 (22.2)	3 (33.3)
Anaemia	4 (44.4)	0	0	4 (44.4)	0
Thrombocytopenia	4 (44.4)	0	0	1 (11.1)	3 (33.3)
Disseminated intravascular coagulation	3 (33.3)	0	0	2 (22.2)	1 (11.1)
Febrile neutropenia	2 (22.2)	0	0	2 (22.2)	0
Neutropenia	2 (22.2)	0	0	0	2 (22.2)
Lymphopenia	1 (11.1)	0	0	0	1 (11.1)
Cardiac disorders					

Baseline extramedullary disease presence: No

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (22.2)	0	0	0	2 (22.2)
Bradycardia	1 (11.1)	0	0	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	0	0	1 (11.1)
Right ventricular dysfunction	1 (11.1)	0	0	1 (11.1)	0
Sinus tachycardia	1 (11.1)	0	0	1 (11.1)	0
Ventricular tachycardia	1 (11.1)	0	0	1 (11.1)	0
Endocrine disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Adrenal insufficiency	1 (11.1)	0	1 (11.1)	0	0
Eye disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Photophobia	1 (11.1)	0	1 (11.1)	0	0
Gastrointestinal disorders					
-Total	6 (66.7)	0	2 (22.2)	4 (44.4)	0
Nausea	3 (33.3)	0	2 (22.2)	1 (11.1)	0
Vomiting	3 (33.3)	0	2 (22.2)	1 (11.1)	0
Abdominal pain	2 (22.2)	0	0	2 (22.2)	0
Colitis	2 (22.2)	0	0	2 (22.2)	0

Baseline extramedullary disease presence: No

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	1 (11.1)	0	0	1 (11.1)	0
Constipation	1 (11.1)	1 (11.1)	0	0	0
Diarrhoea	1 (11.1)	0	0	1 (11.1)	0
Gastrointestinal haemorrhage	1 (11.1)	0	0	1 (11.1)	0
Haematochezia	1 (11.1)	0	0	1 (11.1)	0
Stomatitis	1 (11.1)	0	0	1 (11.1)	0
General disorders and administration site conditions					
-Total	6 (66.7)	0	1 (11.1)	2 (22.2)	3 (33.3)
Multiple organ dysfunction syndrome	3 (33.3)	0	0	0	3 (33.3)
Pyrexia	3 (33.3)	0	2 (22.2)	1 (11.1)	0
Pain	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Chills	1 (11.1)	1 (11.1)	0	0	0
Non-cardiac chest pain	1 (11.1)	0	0	1 (11.1)	0
Hepatobiliary disorders					
-Total	1 (11.1)	0	0	0	1 (11.1)
Hepatic failure	1 (11.1)	0	0	0	1 (11.1)
Infections and infestations					

Baseline extramedullary disease presence: No

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (66.7)	0	0	0	6 (66.7)
Klebsiella sepsis	2 (22.2)	0	0	0	2 (22.2)
Bronchitis	1 (11.1)	0	1 (11.1)	0	0
Candida sepsis	1 (11.1)	0	0	0	1 (11.1)
Clostridium difficile colitis	1 (11.1)	0	0	1 (11.1)	0
Klebsiella infection	1 (11.1)	0	0	1 (11.1)	0
Oral herpes	1 (11.1)	0	1 (11.1)	0	0
Pneumonia	1 (11.1)	0	0	0	1 (11.1)
Pneumonia fungal	1 (11.1)	0	0	1 (11.1)	0
Sepsis	1 (11.1)	0	0	0	1 (11.1)
Staphylococcal bacteraemia	1 (11.1)	0	0	1 (11.1)	0
Staphylococcal infection	1 (11.1)	0	0	0	1 (11.1)
Investigations					
-Total	4 (44.4)	0	0	0	4 (44.4)
Neutrophil count decreased	2 (22.2)	0	0	0	2 (22.2)
Activated partial thromboplastin time prolonged	1 (11.1)	0	1 (11.1)	0	0
Alanine aminotransferase increased	1 (11.1)	0	0	0	1 (11.1)

Baseline extramedullary disease presence: No

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (11.1)	0	0	0	1 (11.1)
Blood bilirubin increased	1 (11.1)	0	0	0	1 (11.1)
Blood lactate dehydrogenase increased	1 (11.1)	0	0	1 (11.1)	0
Computerised tomogram thorax abnormal	1 (11.1)	0	0	1 (11.1)	0
Electrocardiogram qt prolonged	1 (11.1)	0	0	1 (11.1)	0
International normalised ratio increased	1 (11.1)	0	1 (11.1)	0	0
Platelet count decreased	1 (11.1)	0	0	0	1 (11.1)
Weight increased	1 (11.1)	1 (11.1)	0	0	0
White blood cell count decreased	1 (11.1)	0	0	0	1 (11.1)
Metabolism and nutrition disorders					
-Total	6 (66.7)	0	2 (22.2)	1 (11.1)	3 (33.3)
Hyperglycaemia	3 (33.3)	0	2 (22.2)	0	1 (11.1)
Hypernatraemia	3 (33.3)	0	0	1 (11.1)	2 (22.2)
Hypokalaemia	3 (33.3)	0	0	0	3 (33.3)
Hypoalbuminaemia	2 (22.2)	0	1 (11.1)	0	1 (11.1)

Baseline extramedullary disease presence: No

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	1 (11.1)	0	0	1 (11.1)	0
Dehydration	1 (11.1)	0	0	1 (11.1)	0
Fluid overload	1 (11.1)	0	0	1 (11.1)	0
Hyperkalaemia	1 (11.1)	0	0	1 (11.1)	0
Hypocalcaemia	1 (11.1)	0	0	0	1 (11.1)
Hypoglycaemia	1 (11.1)	0	1 (11.1)	0	0
Hypomagnesaemia	1 (11.1)	1 (11.1)	0	0	0
Hypophosphataemia	1 (11.1)	0	0	1 (11.1)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (22.2)	0	0	2 (22.2)	0
Pain in extremity	2 (22.2)	0	0	2 (22.2)	0
Arthralgia	1 (11.1)	0	0	1 (11.1)	0
Back pain	1 (11.1)	0	0	1 (11.1)	0
Nervous system disorders					
-Total	3 (33.3)	0	1 (11.1)	1 (11.1)	1 (11.1)
Headache	1 (11.1)	0	0	1 (11.1)	0
Hyporesponsive to stimuli	1 (11.1)	0	0	1 (11.1)	0

Baseline extramedullary disease presence: No

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Leukoencephalopathy	1 (11.1)	0	0	1 (11.1)	0
Seizure	1 (11.1)	0	0	0	1 (11.1)
Somnolence	1 (11.1)	0	1 (11.1)	0	0
Product issues					
-Total	1 (11.1)	0	1 (11.1)	0	0
Device occlusion	1 (11.1)	0	1 (11.1)	0	0
Psychiatric disorders					
-Total	3 (33.3)	0	1 (11.1)	2 (22.2)	0
Agitation	1 (11.1)	0	0	1 (11.1)	0
Confusional state	1 (11.1)	0	1 (11.1)	0	0
Delirium	1 (11.1)	0	0	1 (11.1)	0
Renal and urinary disorders					
-Total	4 (44.4)	1 (11.1)	0	2 (22.2)	1 (11.1)
Acute kidney injury	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Cystitis haemorrhagic	1 (11.1)	0	0	1 (11.1)	0
Haematuria	1 (11.1)	1 (11.1)	0	0	0
Oliguria	1 (11.1)	0	0	1 (11.1)	0
Urinary retention	1 (11.1)	0	1 (11.1)	0	0

Baseline extramedullary disease presence: No

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	5 (55.6)	0	0	1 (11.1)	4 (44.4)
Hypoxia	4 (44.4)	0	0	3 (33.3)	1 (11.1)
Pleural effusion	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Pulmonary oedema	2 (22.2)	0	0	0	2 (22.2)
Aspiration	1 (11.1)	0	0	0	1 (11.1)
Cough	1 (11.1)	0	0	1 (11.1)	0
Dyspnoea	1 (11.1)	0	0	1 (11.1)	0
Epistaxis	1 (11.1)	0	1 (11.1)	0	0
Haemoptysis	1 (11.1)	0	0	1 (11.1)	0
Oropharyngeal pain	1 (11.1)	0	0	1 (11.1)	0
Pulmonary alveolar haemorrhage	1 (11.1)	0	0	0	1 (11.1)
Pulmonary hypertension	1 (11.1)	0	0	1 (11.1)	0
Respiratory distress	1 (11.1)	0	0	0	1 (11.1)
Respiratory failure	1 (11.1)	0	0	0	1 (11.1)
Tachypnoea	1 (11.1)	0	0	1 (11.1)	0
Vascular disorders					

Baseline extramedullary disease presence: No

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (66.7)	0	0	3 (33.3)	3 (33.3)
Hypotension	6 (66.7)	0	0	3 (33.3)	3 (33.3)
Hypertension	1 (11.1)	0	1 (11.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187p
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: No

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	0	1 (9.1)	1 (9.1)	6 (54.5)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Gastrointestinal disorders					
-Total	5 (45.5)	0	2 (18.2)	3 (27.3)	0

Down syndrome: No

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
General disorders and administration site conditions					
-Total	5 (45.5)	0	1 (9.1)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	0	0	3 (27.3)
Pyrexia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Infections and infestations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Investigations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Metabolism and nutrition disorders					
-Total	5 (45.5)	0	2 (18.2)	0	3 (27.3)

Down syndrome: No

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	0	0	3 (27.3)
Hypoalbuminaemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Musculoskeletal and connective tissue disorders					
-Total	2 (18.2)	0	0	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Renal and urinary disorders					
-Total	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Hypoxia	4 (36.4)	0	0	3 (27.3)	1 (9.1)
Pleural effusion	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Vascular disorders					
-Total	6 (54.5)	0	0	3 (27.3)	3 (27.3)

Down syndrome: No

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	6 (54.5)	0	0	3 (27.3)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187q
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set – non – infused patients

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	0	1 (9.1)	1 (9.1)	6 (54.5)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Gastrointestinal disorders					
-Total	5 (45.5)	0	2 (18.2)	3 (27.3)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
General disorders and administration site conditions					
-Total	5 (45.5)	0	1 (9.1)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	0	0	3 (27.3)
Pyrexia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Infections and infestations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Investigations					
-Total	2 (18.2)	0	0	0	2 (18.2)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Metabolism and nutrition disorders					
-Total	5 (45.5)	0	2 (18.2)	0	3 (27.3)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	3 (27.3)	0	0	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	0	0	3 (27.3)
Hypoalbuminaemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Musculoskeletal and connective tissue disorders					
-Total	2 (18.2)	0	0	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Renal and urinary disorders					
-Total	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Hypoxia	4 (36.4)	0	0	3 (27.3)	1 (9.1)
Pleural effusion	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Vascular disorders					
-Total	6 (54.5)	0	0	3 (27.3)	3 (27.3)

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=11 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	6 (54.5)	0	0	3 (27.3)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187r
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 0

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	0	1 (100)
General disorders and administration site conditions					
-Total	1 (100)	0	0	1 (100)	0
Pain	1 (100)	0	0	1 (100)	0
Pyrexia	1 (100)	0	0	1 (100)	0
Infections and infestations					
-Total	1 (100)	0	0	0	1 (100)
Pneumonia	1 (100)	0	0	0	1 (100)
Psychiatric disorders					
-Total	1 (100)	0	1 (100)	0	0

Number of previous relapses: 0

Group term Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Confusional state	1 (100)	0	1 (100)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (100)	0	0	0	1 (100)
Aspiration	1 (100)	0	0	0	1 (100)
Epistaxis	1 (100)	0	1 (100)	0	0
Hypoxia	1 (100)	0	0	1 (100)	0
Pleural effusion	1 (100)	0	1 (100)	0	0
Vascular disorders					
-Total	1 (100)	0	0	0	1 (100)
Hypotension	1 (100)	0	0	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187r
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 1

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	1 (33.3)	0	1 (33.3)
Blood and lymphatic system disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Anaemia	1 (33.3)	0	0	1 (33.3)	0
Disseminated intravascular coagulation	1 (33.3)	0	0	1 (33.3)	0
Lymphopenia	1 (33.3)	0	0	0	1 (33.3)
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	0	0	1 (33.3)
Cardiac disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)

Number of previous relapses: 1

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (33.3)	0	0	0	1 (33.3)
Right ventricular dysfunction	1 (33.3)	0	0	1 (33.3)	0
Sinus tachycardia	1 (33.3)	0	0	1 (33.3)	0
Ventricular tachycardia	1 (33.3)	0	0	1 (33.3)	0
Eye disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Photophobia	1 (33.3)	0	1 (33.3)	0	0
Gastrointestinal disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Nausea	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Vomiting	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Abdominal pain	1 (33.3)	0	0	1 (33.3)	0
Constipation	1 (33.3)	1 (33.3)	0	0	0
Haematochezia	1 (33.3)	0	0	1 (33.3)	0
General disorders and administration site conditions					
-Total	1 (33.3)	0	0	1 (33.3)	0
Non-cardiac chest pain	1 (33.3)	0	0	1 (33.3)	0

Number of previous relapses: 1

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	1 (33.3)	0	0	0	1 (33.3)
Blood lactate dehydrogenase increased	1 (33.3)	0	0	1 (33.3)	0
Computerised tomogram thorax abnormal	1 (33.3)	0	0	1 (33.3)	0
Electrocardiogram qt prolonged	1 (33.3)	0	0	1 (33.3)	0
White blood cell count decreased	1 (33.3)	0	0	0	1 (33.3)
Metabolism and nutrition disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Fluid overload	1 (33.3)	0	0	1 (33.3)	0
Hyperglycaemia	1 (33.3)	0	1 (33.3)	0	0
Hyperkalaemia	1 (33.3)	0	0	1 (33.3)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Arthralgia	1 (33.3)	0	0	1 (33.3)	0
Back pain	1 (33.3)	0	0	1 (33.3)	0
Pain in extremity	1 (33.3)	0	0	1 (33.3)	0

Number of previous relapses: 1

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Headache	1 (33.3)	0	0	1 (33.3)	0
Hyporesponsive to stimuli	1 (33.3)	0	0	1 (33.3)	0
Seizure	1 (33.3)	0	0	0	1 (33.3)
Psychiatric disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Agitation	1 (33.3)	0	0	1 (33.3)	0
Renal and urinary disorders					
-Total	1 (33.3)	0	0	1 (33.3)	0
Acute kidney injury	1 (33.3)	0	0	1 (33.3)	0
Oliguria	1 (33.3)	0	0	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Cough	1 (33.3)	0	0	1 (33.3)	0
Dyspnoea	1 (33.3)	0	0	1 (33.3)	0
Haemoptysis	1 (33.3)	0	0	1 (33.3)	0

Number of previous relapses: 1

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	1 (33.3)	0	0	1 (33.3)	0
Oropharyngeal pain	1 (33.3)	0	0	1 (33.3)	0
Pulmonary alveolar haemorrhage	1 (33.3)	0	0	0	1 (33.3)
Pulmonary hypertension	1 (33.3)	0	0	1 (33.3)	0
Pulmonary oedema	1 (33.3)	0	0	0	1 (33.3)
Respiratory distress	1 (33.3)	0	0	0	1 (33.3)
Tachypnoea	1 (33.3)	0	0	1 (33.3)	0
Vascular disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Hypertension	1 (33.3)	0	1 (33.3)	0	0
Hypotension	1 (33.3)	0	0	0	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187r
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 2

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Blood and lymphatic system disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Febrile neutropenia	1 (33.3)	0	0	1 (33.3)	0
Neutropenia	1 (33.3)	0	0	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	0	0	1 (33.3)
Endocrine disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Adrenal insufficiency	1 (33.3)	0	1 (33.3)	0	0
Gastrointestinal disorders					

Number of previous relapses: 2

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (33.3)	0	0	1 (33.3)	0
Gastrointestinal haemorrhage	1 (33.3)	0	0	1 (33.3)	0
Infections and infestations					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Candida sepsis	1 (33.3)	0	0	0	1 (33.3)
Escherichia infection	1 (33.3)	0	0	1 (33.3)	0
Pneumonia fungal	1 (33.3)	0	0	1 (33.3)	0
Streptococcal infection	1 (33.3)	0	0	1 (33.3)	0
Metabolism and nutrition disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Hypernatraemia	1 (33.3)	0	0	0	1 (33.3)
Hypokalaemia	1 (33.3)	0	0	0	1 (33.3)
Hypomagnesaemia	1 (33.3)	1 (33.3)	0	0	0
Hypophosphataemia	1 (33.3)	0	0	1 (33.3)	0
Musculoskeletal and connective tissue disorders					
-Total	1 (33.3)	0	1 (33.3)	0	0
Pain in jaw	1 (33.3)	0	1 (33.3)	0	0

Number of previous relapses: 2

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Acute kidney injury	1 (33.3)	0	0	0	1 (33.3)
Respiratory, thoracic and mediastinal disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	0	0	1 (33.3)
Respiratory failure	1 (33.3)	0	0	0	1 (33.3)
Vascular disorders					
-Total	1 (33.3)	0	0	0	1 (33.3)
Hypotension	1 (33.3)	0	0	0	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 187r
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: >=3

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	0	0	4 (100)
Blood and lymphatic system disorders					
-Total	3 (75.0)	0	0	2 (50.0)	1 (25.0)
Anaemia	3 (75.0)	0	0	3 (75.0)	0
Disseminated intravascular coagulation	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Thrombocytopenia	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Febrile neutropenia	1 (25.0)	0	0	1 (25.0)	0
Cardiac disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)
Cardiovascular insufficiency	1 (25.0)	0	0	0	1 (25.0)

Number of previous relapses: >=3

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	3 (75.0)	0	1 (25.0)	2 (50.0)	0
Colitis	2 (50.0)	0	0	2 (50.0)	0
Abdominal pain	1 (25.0)	0	0	1 (25.0)	0
Ascites	1 (25.0)	0	0	1 (25.0)	0
Diarrhoea	1 (25.0)	0	0	1 (25.0)	0
Nausea	1 (25.0)	0	1 (25.0)	0	0
Stomatitis	1 (25.0)	0	0	1 (25.0)	0
Vomiting	1 (25.0)	0	1 (25.0)	0	0
General disorders and administration site conditions					
-Total	4 (100)	0	1 (25.0)	0	3 (75.0)
Multiple organ dysfunction syndrome	3 (75.0)	0	0	0	3 (75.0)
Pyrexia	2 (50.0)	0	2 (50.0)	0	0
Chills	1 (25.0)	1 (25.0)	0	0	0
Pain	1 (25.0)	0	1 (25.0)	0	0
Hepatobiliary disorders					
-Total	1 (25.0)	0	0	0	1 (25.0)

Number of previous relapses: >=3

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatic failure	1 (25.0)	0	0	0	1 (25.0)
Infections and infestations					
-Total	4 (100)	0	0	0	4 (100)
Klebsiella sepsis	2 (50.0)	0	0	0	2 (50.0)
Bronchitis	1 (25.0)	0	1 (25.0)	0	0
Clostridium difficile colitis	1 (25.0)	0	0	1 (25.0)	0
Klebsiella infection	1 (25.0)	0	0	1 (25.0)	0
Oral herpes	1 (25.0)	0	1 (25.0)	0	0
Sepsis	1 (25.0)	0	0	0	1 (25.0)
Staphylococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Staphylococcal infection	1 (25.0)	0	0	0	1 (25.0)
Investigations					
-Total	3 (75.0)	0	0	0	3 (75.0)
Neutrophil count decreased	2 (50.0)	0	0	0	2 (50.0)
Activated partial thromboplastin time prolonged	1 (25.0)	0	1 (25.0)	0	0
Alanine aminotransferase increased	1 (25.0)	0	0	0	1 (25.0)
Aspartate aminotransferase increased	1 (25.0)	0	0	0	1 (25.0)

Number of previous relapses: >=3

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (25.0)	0	0	0	1 (25.0)
International normalised ratio increased	1 (25.0)	0	1 (25.0)	0	0
Platelet count decreased	1 (25.0)	0	0	0	1 (25.0)
Weight increased	1 (25.0)	1 (25.0)	0	0	0
Metabolism and nutrition disorders					
-Total	3 (75.0)	0	1 (25.0)	0	2 (50.0)
Hyperglycaemia	2 (50.0)	0	1 (25.0)	0	1 (25.0)
Hypernatraemia	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Hypoalbuminaemia	2 (50.0)	0	1 (25.0)	0	1 (25.0)
Hypokalaemia	2 (50.0)	0	0	0	2 (50.0)
Decreased appetite	1 (25.0)	0	0	1 (25.0)	0
Dehydration	1 (25.0)	0	0	1 (25.0)	0
Hypocalcaemia	1 (25.0)	0	0	0	1 (25.0)
Hypoglycaemia	1 (25.0)	0	1 (25.0)	0	0
Musculoskeletal and connective tissue disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Pain in extremity	1 (25.0)	0	0	1 (25.0)	0

Number of previous relapses: >=3

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Leukoencephalopathy	1 (25.0)	0	0	1 (25.0)	0
Somnolence	1 (25.0)	0	1 (25.0)	0	0
Product issues					
-Total	1 (25.0)	0	1 (25.0)	0	0
Device occlusion	1 (25.0)	0	1 (25.0)	0	0
Psychiatric disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Delirium	1 (25.0)	0	0	1 (25.0)	0
Renal and urinary disorders					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Cystitis haemorrhagic	1 (25.0)	0	0	1 (25.0)	0
Haematuria	1 (25.0)	1 (25.0)	0	0	0
Urinary retention	1 (25.0)	0	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (50.0)	0	0	1 (25.0)	1 (25.0)

Number of previous relapses: >=3

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (50.0)	0	0	1 (25.0)	1 (25.0)
Pleural effusion	1 (25.0)	0	0	1 (25.0)	0
Vascular disorders					
-Total	3 (75.0)	0	0	3 (75.0)	0
Hypotension	3 (75.0)	0	0	3 (75.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188a
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (95.5)	1 (4.5)	3 (13.6)	3 (13.6)	14 (63.6)
Blood and lymphatic system disorders					
-Total	16 (72.7)	0	1 (4.5)	10 (45.5)	5 (22.7)
Anaemia	11 (50.0)	1 (4.5)	1 (4.5)	9 (40.9)	0
Febrile neutropenia	11 (50.0)	0	0	11 (50.0)	0
Thrombocytopenia	4 (18.2)	0	1 (4.5)	1 (4.5)	2 (9.1)
Neutropenia	3 (13.6)	0	0	0	3 (13.6)
Disseminated intravascular coagulation	1 (4.5)	0	0	1 (4.5)	0
Lymphopenia	1 (4.5)	0	0	0	1 (4.5)
Cardiac disorders					

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (27.3)	3 (13.6)	3 (13.6)	0	0
Sinus tachycardia	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Tachycardia	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Pericardial effusion	1 (4.5)	0	1 (4.5)	0	0
Gastrointestinal disorders					
-Total	16 (72.7)	5 (22.7)	9 (40.9)	2 (9.1)	0
Nausea	12 (54.5)	3 (13.6)	7 (31.8)	2 (9.1)	0
Diarrhoea	9 (40.9)	5 (22.7)	4 (18.2)	0	0
Vomiting	9 (40.9)	5 (22.7)	4 (18.2)	0	0
Constipation	5 (22.7)	5 (22.7)	0	0	0
Abdominal pain	4 (18.2)	2 (9.1)	2 (9.1)	0	0
General disorders and administration site conditions					
-Total	12 (54.5)	6 (27.3)	3 (13.6)	3 (13.6)	0
Pyrexia	8 (36.4)	3 (13.6)	3 (13.6)	2 (9.1)	0
Fatigue	4 (18.2)	4 (18.2)	0	0	0
Catheter site pain	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Oedema peripheral	3 (13.6)	2 (9.1)	0	1 (4.5)	0

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	1 (4.5)	1 (4.5)	0	0	0
Pain	1 (4.5)	0	1 (4.5)	0	0
Hepatobiliary disorders					
-Total	1 (4.5)	0	0	1 (4.5)	0
Hyperbilirubinaemia	1 (4.5)	0	0	1 (4.5)	0
Immune system disorders					
-Total	20 (90.9)	2 (9.1)	12 (54.5)	3 (13.6)	3 (13.6)
Cytokine release syndrome	16 (72.7)	2 (9.1)	8 (36.4)	3 (13.6)	3 (13.6)
Hypogammaglobulinaemia	11 (50.0)	2 (9.1)	7 (31.8)	2 (9.1)	0
Infections and infestations					
-Total	12 (54.5)	2 (9.1)	6 (27.3)	4 (18.2)	0
Upper respiratory tract infection	5 (22.7)	3 (13.6)	2 (9.1)	0	0
Clostridium difficile infection	4 (18.2)	0	3 (13.6)	1 (4.5)	0
Clostridium difficile colitis	3 (13.6)	1 (4.5)	0	2 (9.1)	0
Gastroenteritis	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Pneumonia	3 (13.6)	0	2 (9.1)	1 (4.5)	0
Rhinovirus infection	3 (13.6)	3 (13.6)	0	0	0
Sinusitis	3 (13.6)	1 (4.5)	2 (9.1)	0	0

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Procedural pain	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Investigations					
-Total	16 (72.7)	0	1 (4.5)	3 (13.6)	12 (54.5)
White blood cell count decreased	12 (54.5)	2 (9.1)	0	1 (4.5)	9 (40.9)
Neutrophil count decreased	11 (50.0)	0	1 (4.5)	1 (4.5)	9 (40.9)
Alanine aminotransferase increased	7 (31.8)	0	2 (9.1)	5 (22.7)	0
Aspartate aminotransferase increased	7 (31.8)	1 (4.5)	1 (4.5)	3 (13.6)	2 (9.1)
Lymphocyte count decreased	6 (27.3)	1 (4.5)	1 (4.5)	1 (4.5)	3 (13.6)
Platelet count decreased	6 (27.3)	0	0	0	6 (27.3)
Blood bilirubin increased	3 (13.6)	0	2 (9.1)	1 (4.5)	0
International normalised ratio increased	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Blood fibrinogen decreased	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Prothrombin time prolonged	2 (9.1)	2 (9.1)	0	0	0

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	1 (4.5)	1 (4.5)	0	0	0
Blood creatinine increased	1 (4.5)	0	0	1 (4.5)	0
Transaminases increased	1 (4.5)	1 (4.5)	0	0	0
Weight decreased	1 (4.5)	0	1 (4.5)	0	0
Metabolism and nutrition disorders					
-Total	15 (68.2)	2 (9.1)	4 (18.2)	7 (31.8)	2 (9.1)
Decreased appetite	10 (45.5)	2 (9.1)	4 (18.2)	4 (18.2)	0
Hypokalaemia	7 (31.8)	0	1 (4.5)	6 (27.3)	0
Hypophosphataemia	6 (27.3)	3 (13.6)	0	2 (9.1)	1 (4.5)
Hyperuricaemia	4 (18.2)	2 (9.1)	0	1 (4.5)	1 (4.5)
Hypocalcaemia	4 (18.2)	2 (9.1)	1 (4.5)	0	1 (4.5)
Dehydration	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Fluid overload	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Hyperglycaemia	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Hypoalbuminaemia	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Hypernatraemia	1 (4.5)	0	1 (4.5)	0	0
Hyperphosphataemia	1 (4.5)	1 (4.5)	0	0	0

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	10 (45.5)	4 (18.2)	5 (22.7)	1 (4.5)	0
Pain in extremity	7 (31.8)	4 (18.2)	3 (13.6)	0	0
Pain in jaw	4 (18.2)	1 (4.5)	3 (13.6)	0	0
Myalgia	1 (4.5)	0	0	1 (4.5)	0
Nervous system disorders					
-Total	9 (40.9)	6 (27.3)	3 (13.6)	0	0
Headache	8 (36.4)	5 (22.7)	3 (13.6)	0	0
Dizziness	2 (9.1)	2 (9.1)	0	0	0
Psychiatric disorders					
-Total	4 (18.2)	2 (9.1)	2 (9.1)	0	0
Anxiety	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Confusional state	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Renal and urinary disorders					
-Total	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Acute kidney injury	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders					

Age: <10 years

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (45.5)	3 (13.6)	1 (4.5)	6 (27.3)	0
Cough	5 (22.7)	5 (22.7)	0	0	0
Hypoxia	5 (22.7)	0	0	5 (22.7)	0
Pleural effusion	4 (18.2)	0	2 (9.1)	2 (9.1)	0
Rhinorrhoea	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Tachypnoea	3 (13.6)	0	2 (9.1)	1 (4.5)	0
Epistaxis	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Oropharyngeal pain	2 (9.1)	2 (9.1)	0	0	0
Pulmonary oedema	2 (9.1)	0	0	2 (9.1)	0
Dyspnoea	1 (4.5)	1 (4.5)	0	0	0
Nasal congestion	1 (4.5)	1 (4.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	4 (18.2)	3 (13.6)	1 (4.5)	0	0
Rash	4 (18.2)	3 (13.6)	1 (4.5)	0	0
Vascular disorders					
-Total	9 (40.9)	2 (9.1)	2 (9.1)	2 (9.1)	3 (13.6)
Hypertension	6 (27.3)	2 (9.1)	3 (13.6)	1 (4.5)	0

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	5 (22.7)	1 (4.5)	0	1 (4.5)	3 (13.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188a
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (97.4)	0	0	8 (20.5)	30 (76.9)
Blood and lymphatic system disorders					
-Total	37 (94.9)	0	1 (2.6)	23 (59.0)	13 (33.3)
Febrile neutropenia	24 (61.5)	0	0	23 (59.0)	1 (2.6)
Anaemia	23 (59.0)	1 (2.6)	5 (12.8)	16 (41.0)	1 (2.6)
Neutropenia	11 (28.2)	0	0	3 (7.7)	8 (20.5)
Thrombocytopenia	8 (20.5)	0	0	4 (10.3)	4 (10.3)
Disseminated intravascular coagulation	5 (12.8)	0	2 (5.1)	2 (5.1)	1 (2.6)
Lymphopenia	3 (7.7)	0	1 (2.6)	1 (2.6)	1 (2.6)
Pancytopenia	2 (5.1)	0	0	1 (2.6)	1 (2.6)

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders					
-Total	12 (30.8)	5 (12.8)	4 (10.3)	3 (7.7)	0
Tachycardia	10 (25.6)	6 (15.4)	3 (7.7)	1 (2.6)	0
Sinus tachycardia	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Left ventricular dysfunction	1 (2.6)	0	0	1 (2.6)	0
Pericardial effusion	1 (2.6)	1 (2.6)	0	0	0
Gastrointestinal disorders					
-Total	27 (69.2)	8 (20.5)	11 (28.2)	7 (17.9)	1 (2.6)
Vomiting	16 (41.0)	11 (28.2)	3 (7.7)	2 (5.1)	0
Nausea	14 (35.9)	5 (12.8)	7 (17.9)	2 (5.1)	0
Diarrhoea	13 (33.3)	7 (17.9)	4 (10.3)	2 (5.1)	0
Abdominal pain	10 (25.6)	3 (7.7)	5 (12.8)	2 (5.1)	0
Stomatitis	7 (17.9)	2 (5.1)	1 (2.6)	3 (7.7)	1 (2.6)
Constipation	6 (15.4)	4 (10.3)	2 (5.1)	0	0
General disorders and administration site conditions					
-Total	26 (66.7)	10 (25.6)	11 (28.2)	4 (10.3)	1 (2.6)
Pyrexia	18 (46.2)	7 (17.9)	8 (20.5)	2 (5.1)	1 (2.6)

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	13 (33.3)	10 (25.6)	1 (2.6)	2 (5.1)	0
Chills	8 (20.5)	6 (15.4)	2 (5.1)	0	0
Pain	4 (10.3)	1 (2.6)	1 (2.6)	2 (5.1)	0
Catheter site pain	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Oedema peripheral	1 (2.6)	1 (2.6)	0	0	0
Hepatobiliary disorders					
-Total	3 (7.7)	0	2 (5.1)	1 (2.6)	0
Hyperbilirubinaemia	3 (7.7)	0	2 (5.1)	1 (2.6)	0
Immune system disorders					
-Total	30 (76.9)	3 (7.7)	14 (35.9)	8 (20.5)	5 (12.8)
Cytokine release syndrome	26 (66.7)	4 (10.3)	12 (30.8)	5 (12.8)	5 (12.8)
Hypogammaglobulinaemia	19 (48.7)	2 (5.1)	14 (35.9)	3 (7.7)	0
Infections and infestations					
-Total	16 (41.0)	3 (7.7)	10 (25.6)	3 (7.7)	0
Upper respiratory tract infection	5 (12.8)	2 (5.1)	2 (5.1)	1 (2.6)	0
Clostridium difficile colitis	3 (7.7)	0	2 (5.1)	1 (2.6)	0
Clostridium difficile infection	2 (5.1)	0	2 (5.1)	0	0
Gastroenteritis	2 (5.1)	0	1 (2.6)	1 (2.6)	0

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Influenza	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Pneumonia	2 (5.1)	0	2 (5.1)	0	0
Rhinovirus infection	2 (5.1)	2 (5.1)	0	0	0
Sinusitis	1 (2.6)	0	1 (2.6)	0	0
Injury, poisoning and procedural complications					
-Total	4 (10.3)	0	1 (2.6)	3 (7.7)	0
Procedural pain	4 (10.3)	0	1 (2.6)	3 (7.7)	0
Investigations					
-Total	32 (82.1)	0	4 (10.3)	4 (10.3)	24 (61.5)
White blood cell count decreased	26 (66.7)	2 (5.1)	1 (2.6)	5 (12.8)	18 (46.2)
Neutrophil count decreased	21 (53.8)	1 (2.6)	1 (2.6)	2 (5.1)	17 (43.6)
Alanine aminotransferase increased	17 (43.6)	2 (5.1)	2 (5.1)	12 (30.8)	1 (2.6)
Platelet count decreased	17 (43.6)	2 (5.1)	1 (2.6)	4 (10.3)	10 (25.6)
Aspartate aminotransferase increased	14 (35.9)	3 (7.7)	4 (10.3)	5 (12.8)	2 (5.1)
Lymphocyte count decreased	12 (30.8)	0	2 (5.1)	6 (15.4)	4 (10.3)
Blood creatinine increased	8 (20.5)	5 (12.8)	2 (5.1)	1 (2.6)	0
Blood bilirubin increased	7 (17.9)	2 (5.1)	1 (2.6)	3 (7.7)	1 (2.6)

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	7 (17.9)	6 (15.4)	1 (2.6)	0	0
Activated partial thromboplastin time prolonged	5 (12.8)	2 (5.1)	3 (7.7)	0	0
Prothrombin time prolonged	4 (10.3)	3 (7.7)	1 (2.6)	0	0
Weight decreased	2 (5.1)	2 (5.1)	0	0	0
Blood fibrinogen decreased	1 (2.6)	0	1 (2.6)	0	0
Blood lactate dehydrogenase increased	1 (2.6)	1 (2.6)	0	0	0
Transaminases increased	1 (2.6)	1 (2.6)	0	0	0
Metabolism and nutrition disorders					
-Total	26 (66.7)	3 (7.7)	5 (12.8)	12 (30.8)	6 (15.4)
Decreased appetite	16 (41.0)	5 (12.8)	3 (7.7)	8 (20.5)	0
Hypokalaemia	14 (35.9)	3 (7.7)	3 (7.7)	3 (7.7)	5 (12.8)
Hyperphosphataemia	7 (17.9)	6 (15.4)	1 (2.6)	0	0
Hypernatraemia	6 (15.4)	1 (2.6)	1 (2.6)	1 (2.6)	3 (7.7)
Hypoalbuminaemia	5 (12.8)	1 (2.6)	3 (7.7)	0	1 (2.6)
Hypophosphataemia	5 (12.8)	0	0	5 (12.8)	0
Dehydration	4 (10.3)	1 (2.6)	1 (2.6)	2 (5.1)	0

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	4 (10.3)	0	0	3 (7.7)	1 (2.6)
Hyperuricaemia	3 (7.7)	3 (7.7)	0	0	0
Hypocalcaemia	2 (5.1)	0	0	1 (2.6)	1 (2.6)
Fluid overload	1 (2.6)	0	1 (2.6)	0	0
Musculoskeletal and connective tissue disorders					
-Total	15 (38.5)	8 (20.5)	4 (10.3)	3 (7.7)	0
Pain in extremity	7 (17.9)	4 (10.3)	1 (2.6)	2 (5.1)	0
Arthralgia	6 (15.4)	4 (10.3)	1 (2.6)	1 (2.6)	0
Myalgia	5 (12.8)	4 (10.3)	1 (2.6)	0	0
Musculoskeletal pain	2 (5.1)	1 (2.6)	1 (2.6)	0	0
Pain in jaw	1 (2.6)	1 (2.6)	0	0	0
Nervous system disorders					
-Total	20 (51.3)	8 (20.5)	6 (15.4)	6 (15.4)	0
Headache	18 (46.2)	8 (20.5)	5 (12.8)	5 (12.8)	0
Encephalopathy	4 (10.3)	1 (2.6)	1 (2.6)	2 (5.1)	0
Dizziness	1 (2.6)	1 (2.6)	0	0	0
Peroneal nerve palsy	1 (2.6)	1 (2.6)	0	0	0

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders					
-Total	13 (33.3)	7 (17.9)	5 (12.8)	1 (2.6)	0
Anxiety	5 (12.8)	2 (5.1)	3 (7.7)	0	0
Confusional state	4 (10.3)	1 (2.6)	3 (7.7)	0	0
Depression	4 (10.3)	3 (7.7)	1 (2.6)	0	0
Mental status changes	4 (10.3)	3 (7.7)	0	1 (2.6)	0
Renal and urinary disorders					
-Total	9 (23.1)	2 (5.1)	0	4 (10.3)	3 (7.7)
Acute kidney injury	6 (15.4)	1 (2.6)	0	3 (7.7)	2 (5.1)
Haematuria	4 (10.3)	1 (2.6)	1 (2.6)	1 (2.6)	1 (2.6)
Respiratory, thoracic and mediastinal disorders					
-Total	24 (61.5)	9 (23.1)	4 (10.3)	6 (15.4)	5 (12.8)
Cough	9 (23.1)	7 (17.9)	2 (5.1)	0	0
Epistaxis	8 (20.5)	3 (7.7)	0	4 (10.3)	1 (2.6)
Hypoxia	7 (17.9)	0	3 (7.7)	2 (5.1)	2 (5.1)
Nasal congestion	5 (12.8)	5 (12.8)	0	0	0
Pulmonary oedema	5 (12.8)	1 (2.6)	0	2 (5.1)	2 (5.1)

Age: >=10 years to <18 years

	All patients N=39				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	4 (10.3)	2 (5.1)	2 (5.1)	0	0
Tachypnoea	4 (10.3)	3 (7.7)	0	1 (2.6)	0
Pleural effusion	3 (7.7)	1 (2.6)	1 (2.6)	1 (2.6)	0
Rhinorrhoea	3 (7.7)	3 (7.7)	0	0	0
Dyspnoea	1 (2.6)	0	0	1 (2.6)	0
Skin and subcutaneous tissue disorders					
-Total	8 (20.5)	6 (15.4)	2 (5.1)	0	0
Dry skin	5 (12.8)	5 (12.8)	0	0	0
Rash	5 (12.8)	3 (7.7)	2 (5.1)	0	0
Vascular disorders					
-Total	17 (43.6)	1 (2.6)	1 (2.6)	10 (25.6)	5 (12.8)
Hypotension	15 (38.5)	0	0	10 (25.6)	5 (12.8)
Hypertension	5 (12.8)	2 (5.1)	2 (5.1)	1 (2.6)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188a
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (100)	0	1 (7.1)	2 (14.3)	11 (78.6)
Blood and lymphatic system disorders					
-Total	11 (78.6)	0	0	5 (35.7)	6 (42.9)
Anaemia	7 (50.0)	0	1 (7.1)	6 (42.9)	0
Neutropenia	5 (35.7)	0	0	1 (7.1)	4 (28.6)
Thrombocytopenia	5 (35.7)	0	0	1 (7.1)	4 (28.6)
Febrile neutropenia	3 (21.4)	0	0	3 (21.4)	0
Lymphopenia	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Pancytopenia	2 (14.3)	0	0	0	2 (14.3)
Disseminated intravascular coagulation	1 (7.1)	0	0	1 (7.1)	0

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac disorders					
-Total	7 (50.0)	1 (7.1)	3 (21.4)	3 (21.4)	0
Tachycardia	5 (35.7)	2 (14.3)	2 (14.3)	1 (7.1)	0
Left ventricular dysfunction	2 (14.3)	0	0	2 (14.3)	0
Pericardial effusion	2 (14.3)	0	2 (14.3)	0	0
Sinus tachycardia	1 (7.1)	0	0	1 (7.1)	0
Gastrointestinal disorders					
-Total	11 (78.6)	1 (7.1)	7 (50.0)	3 (21.4)	0
Nausea	10 (71.4)	0	7 (50.0)	3 (21.4)	0
Vomiting	8 (57.1)	1 (7.1)	5 (35.7)	2 (14.3)	0
Diarrhoea	5 (35.7)	2 (14.3)	2 (14.3)	1 (7.1)	0
Abdominal pain	4 (28.6)	1 (7.1)	1 (7.1)	2 (14.3)	0
Constipation	3 (21.4)	2 (14.3)	1 (7.1)	0	0
Dyspepsia	2 (14.3)	0	2 (14.3)	0	0
General disorders and administration site conditions					
-Total	12 (85.7)	1 (7.1)	7 (50.0)	4 (28.6)	0
Pyrexia	10 (71.4)	2 (14.3)	4 (28.6)	4 (28.6)	0

Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	4 (28.6)	1 (7.1)	3 (21.4)	0	0
Chills	3 (21.4)	3 (21.4)	0	0	0
Pain	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Catheter site pain	2 (14.3)	0	2 (14.3)	0	0
Oedema peripheral	1 (7.1)	0	1 (7.1)	0	0
Hepatobiliary disorders					
-Total	2 (14.3)	0	0	2 (14.3)	0
Hyperbilirubinaemia	2 (14.3)	0	0	2 (14.3)	0
Immune system disorders					
-Total	8 (57.1)	0	5 (35.7)	0	3 (21.4)
Cytokine release syndrome	8 (57.1)	0	5 (35.7)	0	3 (21.4)
Hypogammaglobulinaemia	3 (21.4)	0	3 (21.4)	0	0
Infections and infestations					
-Total	6 (42.9)	0	5 (35.7)	0	1 (7.1)
Influenza	2 (14.3)	0	2 (14.3)	0	0
Pneumonia	2 (14.3)	0	1 (7.1)	0	1 (7.1)
Rhinovirus infection	1 (7.1)	0	1 (7.1)	0	0
Sinusitis	1 (7.1)	0	1 (7.1)	0	0

Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Upper respiratory tract infection	1 (7.1)	0	1 (7.1)	0	0
Injury, poisoning and procedural complications					
-Total	1 (7.1)	0	1 (7.1)	0	0
Procedural pain	1 (7.1)	0	1 (7.1)	0	0
Investigations					
-Total	11 (78.6)	0	0	3 (21.4)	8 (57.1)
White blood cell count decreased	6 (42.9)	0	0	2 (14.3)	4 (28.6)
Aspartate aminotransferase increased	3 (21.4)	1 (7.1)	0	1 (7.1)	1 (7.1)
Neutrophil count decreased	3 (21.4)	0	0	0	3 (21.4)
Platelet count decreased	3 (21.4)	1 (7.1)	1 (7.1)	0	1 (7.1)
Prothrombin time prolonged	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Alanine aminotransferase increased	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Blood fibrinogen decreased	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Blood lactate dehydrogenase increased	2 (14.3)	0	0	2 (14.3)	0
Transaminases increased	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Weight decreased	2 (14.3)	0	2 (14.3)	0	0

Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	1 (7.1)	1 (7.1)	0	0	0
Lymphocyte count decreased	1 (7.1)	0	0	0	1 (7.1)
Metabolism and nutrition disorders					
-Total	11 (78.6)	0	4 (28.6)	6 (42.9)	1 (7.1)
Decreased appetite	6 (42.9)	0	3 (21.4)	3 (21.4)	0
Fluid overload	4 (28.6)	0	3 (21.4)	1 (7.1)	0
Hyperglycaemia	4 (28.6)	0	3 (21.4)	1 (7.1)	0
Hypokalaemia	3 (21.4)	2 (14.3)	0	1 (7.1)	0
Hypophosphataemia	3 (21.4)	1 (7.1)	1 (7.1)	1 (7.1)	0
Dehydration	1 (7.1)	0	0	1 (7.1)	0
Hyperphosphataemia	1 (7.1)	1 (7.1)	0	0	0
Hyperuricaemia	1 (7.1)	0	0	0	1 (7.1)
Hypocalcaemia	1 (7.1)	1 (7.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (35.7)	1 (7.1)	1 (7.1)	3 (21.4)	0
Pain in extremity	4 (28.6)	0	1 (7.1)	3 (21.4)	0
Arthralgia	2 (14.3)	0	1 (7.1)	1 (7.1)	0

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Musculoskeletal pain	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Nervous system disorders					
-Total	8 (57.1)	3 (21.4)	4 (28.6)	1 (7.1)	0
Headache	5 (35.7)	1 (7.1)	3 (21.4)	1 (7.1)	0
Dizziness	3 (21.4)	3 (21.4)	0	0	0
Peroneal nerve palsy	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Psychiatric disorders					
-Total	4 (28.6)	0	3 (21.4)	1 (7.1)	0
Anxiety	3 (21.4)	0	2 (14.3)	1 (7.1)	0
Confusional state	2 (14.3)	1 (7.1)	1 (7.1)	0	0
Depression	1 (7.1)	0	1 (7.1)	0	0
Renal and urinary disorders					
-Total	4 (28.6)	1 (7.1)	0	1 (7.1)	2 (14.3)
Acute kidney injury	4 (28.6)	1 (7.1)	0	1 (7.1)	2 (14.3)
Haematuria	2 (14.3)	0	1 (7.1)	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	6 (42.9)	0	2 (14.3)	1 (7.1)	3 (21.4)

Age: >=18

	All patients N=14				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	4 (28.6)	1 (7.1)	3 (21.4)	0	0
Hypoxia	4 (28.6)	0	0	2 (14.3)	2 (14.3)
Dyspnoea	3 (21.4)	0	1 (7.1)	1 (7.1)	1 (7.1)
Pleural effusion	3 (21.4)	0	3 (21.4)	0	0
Cough	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Oropharyngeal pain	2 (14.3)	1 (7.1)	0	1 (7.1)	0
Pulmonary oedema	2 (14.3)	0	0	0	2 (14.3)
Nasal congestion	1 (7.1)	1 (7.1)	0	0	0
Rhinorrhoea	1 (7.1)	1 (7.1)	0	0	0
Tachypnoea	1 (7.1)	0	0	1 (7.1)	0
Skin and subcutaneous tissue disorders					
-Total	1 (7.1)	1 (7.1)	0	0	0
Rash	1 (7.1)	1 (7.1)	0	0	0
Vascular disorders					
-Total	7 (50.0)	0	1 (7.1)	3 (21.4)	3 (21.4)
Hypertension	5 (35.7)	0	4 (28.6)	1 (7.1)	0
Hypotension	5 (35.7)	0	0	2 (14.3)	3 (21.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188b
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (95.0)	1 (2.5)	2 (5.0)	9 (22.5)	26 (65.0)
Blood and lymphatic system disorders					
-Total	33 (82.5)	0	0	21 (52.5)	12 (30.0)
Anaemia	21 (52.5)	2 (5.0)	3 (7.5)	16 (40.0)	0
Febrile neutropenia	19 (47.5)	0	0	19 (47.5)	0
Neutropenia	11 (27.5)	0	0	3 (7.5)	8 (20.0)
Thrombocytopenia	10 (25.0)	0	0	3 (7.5)	7 (17.5)
Disseminated intravascular coagulation	5 (12.5)	0	1 (2.5)	3 (7.5)	1 (2.5)
Cardiac disorders					
-Total	10 (25.0)	3 (7.5)	3 (7.5)	4 (10.0)	0

Gender: Male

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	8 (20.0)	3 (7.5)	3 (7.5)	2 (5.0)	0
Sinus tachycardia	2 (5.0)	0	0	2 (5.0)	0
Gastrointestinal disorders					
-Total	24 (60.0)	6 (15.0)	14 (35.0)	4 (10.0)	0
Vomiting	15 (37.5)	9 (22.5)	5 (12.5)	1 (2.5)	0
Nausea	14 (35.0)	4 (10.0)	8 (20.0)	2 (5.0)	0
Diarrhoea	8 (20.0)	3 (7.5)	4 (10.0)	1 (2.5)	0
Abdominal pain	7 (17.5)	2 (5.0)	3 (7.5)	2 (5.0)	0
Stomatitis	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Constipation	2 (5.0)	2 (5.0)	0	0	0
General disorders and administration site conditions					
-Total	23 (57.5)	5 (12.5)	7 (17.5)	8 (20.0)	3 (7.5)
Pyrexia	17 (42.5)	4 (10.0)	8 (20.0)	5 (12.5)	0
Pain	7 (17.5)	1 (2.5)	3 (7.5)	3 (7.5)	0
Chills	6 (15.0)	6 (15.0)	0	0	0
Fatigue	6 (15.0)	5 (12.5)	0	1 (2.5)	0
Multiple organ dysfunction syndrome	4 (10.0)	0	0	1 (2.5)	3 (7.5)

Gender: Male

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site pain	2 (5.0)	0	2 (5.0)	0	0
Oedema peripheral	1 (2.5)	0	0	1 (2.5)	0
Immune system disorders					
-Total	27 (67.5)	4 (10.0)	13 (32.5)	4 (10.0)	6 (15.0)
Cytokine release syndrome	23 (57.5)	4 (10.0)	10 (25.0)	3 (7.5)	6 (15.0)
Hypogammaglobulinaemia	17 (42.5)	2 (5.0)	13 (32.5)	2 (5.0)	0
Infections and infestations					
-Total	13 (32.5)	2 (5.0)	6 (15.0)	4 (10.0)	1 (2.5)
Upper respiratory tract infection	6 (15.0)	2 (5.0)	4 (10.0)	0	0
Pneumonia	3 (7.5)	0	2 (5.0)	0	1 (2.5)
Clostridium difficile colitis	2 (5.0)	0	0	2 (5.0)	0
Clostridium difficile infection	1 (2.5)	0	1 (2.5)	0	0
Device related infection	1 (2.5)	0	0	1 (2.5)	0
Rhinovirus infection	1 (2.5)	1 (2.5)	0	0	0
Urinary tract infection	1 (2.5)	0	0	1 (2.5)	0
Injury, poisoning and procedural complications					
-Total	2 (5.0)	0	0	2 (5.0)	0

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Procedural pain	2 (5.0)	0	0	2 (5.0)	0
Investigations					
-Total	28 (70.0)	0	3 (7.5)	5 (12.5)	20 (50.0)
White blood cell count decreased	19 (47.5)	3 (7.5)	0	3 (7.5)	13 (32.5)
Neutrophil count decreased	15 (37.5)	1 (2.5)	1 (2.5)	2 (5.0)	11 (27.5)
Aspartate aminotransferase increased	10 (25.0)	0	2 (5.0)	4 (10.0)	4 (10.0)
Platelet count decreased	10 (25.0)	2 (5.0)	1 (2.5)	2 (5.0)	5 (12.5)
Alanine aminotransferase increased	9 (22.5)	1 (2.5)	1 (2.5)	6 (15.0)	1 (2.5)
Lymphocyte count decreased	7 (17.5)	1 (2.5)	2 (5.0)	2 (5.0)	2 (5.0)
Blood bilirubin increased	6 (15.0)	2 (5.0)	0	3 (7.5)	1 (2.5)
International normalised ratio increased	5 (12.5)	4 (10.0)	1 (2.5)	0	0
Activated partial thromboplastin time prolonged	4 (10.0)	2 (5.0)	2 (5.0)	0	0
Blood creatinine increased	4 (10.0)	2 (5.0)	0	2 (5.0)	0
Prothrombin time prolonged	2 (5.0)	1 (2.5)	1 (2.5)	0	0
Weight decreased	1 (2.5)	1 (2.5)	0	0	0
Metabolism and nutrition disorders					

Gender: Male

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	23 (57.5)	2 (5.0)	6 (15.0)	10 (25.0)	5 (12.5)
Decreased appetite	14 (35.0)	2 (5.0)	4 (10.0)	8 (20.0)	0
Hypokalaemia	11 (27.5)	4 (10.0)	1 (2.5)	3 (7.5)	3 (7.5)
Hypophosphataemia	7 (17.5)	2 (5.0)	0	5 (12.5)	0
Hyperglycaemia	5 (12.5)	0	3 (7.5)	1 (2.5)	1 (2.5)
Fluid overload	4 (10.0)	0	3 (7.5)	1 (2.5)	0
Hypernatraemia	4 (10.0)	0	1 (2.5)	1 (2.5)	2 (5.0)
Hypoalbuminaemia	4 (10.0)	0	3 (7.5)	0	1 (2.5)
Dehydration	3 (7.5)	0	1 (2.5)	2 (5.0)	0
Hyperphosphataemia	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Hyperuricaemia	3 (7.5)	1 (2.5)	0	0	2 (5.0)
Hypocalcaemia	3 (7.5)	1 (2.5)	0	1 (2.5)	1 (2.5)
Musculoskeletal and connective tissue disorders					
-Total	11 (27.5)	4 (10.0)	3 (7.5)	4 (10.0)	0
Pain in extremity	7 (17.5)	2 (5.0)	2 (5.0)	3 (7.5)	0
Arthralgia	4 (10.0)	2 (5.0)	0	2 (5.0)	0
Myalgia	2 (5.0)	1 (2.5)	1 (2.5)	0	0

Gender: Male

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	13 (32.5)	6 (15.0)	4 (10.0)	3 (7.5)	0
Headache	13 (32.5)	6 (15.0)	4 (10.0)	3 (7.5)	0
Dizziness	1 (2.5)	1 (2.5)	0	0	0
Psychiatric disorders					
-Total	7 (17.5)	3 (7.5)	4 (10.0)	0	0
Confusional state	5 (12.5)	3 (7.5)	2 (5.0)	0	0
Anxiety	4 (10.0)	1 (2.5)	3 (7.5)	0	0
Renal and urinary disorders					
-Total	5 (12.5)	0	1 (2.5)	1 (2.5)	3 (7.5)
Acute kidney injury	5 (12.5)	0	1 (2.5)	1 (2.5)	3 (7.5)
Respiratory, thoracic and mediastinal disorders					
-Total	21 (52.5)	4 (10.0)	5 (12.5)	7 (17.5)	5 (12.5)
Hypoxia	10 (25.0)	0	2 (5.0)	5 (12.5)	3 (7.5)
Epistaxis	8 (20.0)	1 (2.5)	3 (7.5)	4 (10.0)	0
Cough	7 (17.5)	4 (10.0)	2 (5.0)	1 (2.5)	0
Pleural effusion	7 (17.5)	1 (2.5)	4 (10.0)	2 (5.0)	0

Gender: Male

	All patients N=40				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	6 (15.0)	0	0	3 (7.5)	3 (7.5)
Nasal congestion	4 (10.0)	4 (10.0)	0	0	0
Tachypnoea	4 (10.0)	1 (2.5)	1 (2.5)	2 (5.0)	0
Oropharyngeal pain	3 (7.5)	1 (2.5)	1 (2.5)	1 (2.5)	0
Rhinorrhoea	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Rhinitis allergic	1 (2.5)	1 (2.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	12 (30.0)	10 (25.0)	1 (2.5)	1 (2.5)	0
Erythema	4 (10.0)	4 (10.0)	0	0	0
Rash maculo-papular	4 (10.0)	3 (7.5)	0	1 (2.5)	0
Rash	3 (7.5)	2 (5.0)	1 (2.5)	0	0
Dry skin	1 (2.5)	1 (2.5)	0	0	0
Pruritus	1 (2.5)	1 (2.5)	0	0	0
Vascular disorders					
-Total	19 (47.5)	1 (2.5)	2 (5.0)	9 (22.5)	7 (17.5)
Hypotension	16 (40.0)	0	0	9 (22.5)	7 (17.5)
Hypertension	10 (25.0)	3 (7.5)	6 (15.0)	1 (2.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188b
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (97.1)	0	0	6 (17.1)	28 (80.0)
Blood and lymphatic system disorders					
-Total	30 (85.7)	0	2 (5.7)	19 (54.3)	9 (25.7)
Anaemia	20 (57.1)	0	4 (11.4)	15 (42.9)	1 (2.9)
Febrile neutropenia	19 (54.3)	0	0	18 (51.4)	1 (2.9)
Neutropenia	8 (22.9)	0	0	1 (2.9)	7 (20.0)
Thrombocytopenia	7 (20.0)	0	1 (2.9)	3 (8.6)	3 (8.6)
Disseminated intravascular coagulation	2 (5.7)	0	1 (2.9)	1 (2.9)	0
Cardiac disorders					
-Total	13 (37.1)	8 (22.9)	5 (14.3)	0	0

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	9 (25.7)	6 (17.1)	3 (8.6)	0	0
Sinus tachycardia	5 (14.3)	3 (8.6)	2 (5.7)	0	0
Gastrointestinal disorders					
-Total	30 (85.7)	8 (22.9)	13 (37.1)	8 (22.9)	1 (2.9)
Nausea	22 (62.9)	4 (11.4)	13 (37.1)	5 (14.3)	0
Diarrhoea	19 (54.3)	11 (31.4)	6 (17.1)	2 (5.7)	0
Vomiting	18 (51.4)	8 (22.9)	7 (20.0)	3 (8.6)	0
Constipation	12 (34.3)	9 (25.7)	3 (8.6)	0	0
Abdominal pain	11 (31.4)	4 (11.4)	5 (14.3)	2 (5.7)	0
Stomatitis	3 (8.6)	1 (2.9)	0	1 (2.9)	1 (2.9)
General disorders and administration site conditions					
-Total	28 (80.0)	12 (34.3)	12 (34.3)	3 (8.6)	1 (2.9)
Pyrexia	19 (54.3)	8 (22.9)	7 (20.0)	3 (8.6)	1 (2.9)
Fatigue	15 (42.9)	10 (28.6)	4 (11.4)	1 (2.9)	0
Chills	6 (17.1)	4 (11.4)	2 (5.7)	0	0
Catheter site pain	5 (14.3)	2 (5.7)	3 (8.6)	0	0
Oedema peripheral	4 (11.4)	3 (8.6)	1 (2.9)	0	0

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pain	1 (2.9)	0	1 (2.9)	0	0
Immune system disorders					
-Total	31 (88.6)	1 (2.9)	18 (51.4)	7 (20.0)	5 (14.3)
Cytokine release syndrome	27 (77.1)	2 (5.7)	15 (42.9)	5 (14.3)	5 (14.3)
Hypogammaglobulinaemia	16 (45.7)	2 (5.7)	11 (31.4)	3 (8.6)	0
Infections and infestations					
-Total	22 (62.9)	3 (8.6)	11 (31.4)	8 (22.9)	0
Clostridium difficile infection	5 (14.3)	0	4 (11.4)	1 (2.9)	0
Rhinovirus infection	5 (14.3)	4 (11.4)	1 (2.9)	0	0
Upper respiratory tract infection	5 (14.3)	3 (8.6)	1 (2.9)	1 (2.9)	0
Clostridium difficile colitis	4 (11.4)	1 (2.9)	2 (5.7)	1 (2.9)	0
Device related infection	4 (11.4)	0	1 (2.9)	3 (8.6)	0
Pneumonia	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Urinary tract infection	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Injury, poisoning and procedural complications					
-Total	9 (25.7)	2 (5.7)	6 (17.1)	1 (2.9)	0
Procedural pain	6 (17.1)	1 (2.9)	4 (11.4)	1 (2.9)	0

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Transfusion reaction	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Investigations					
-Total	31 (88.6)	0	2 (5.7)	5 (14.3)	24 (68.6)
White blood cell count decreased	25 (71.4)	1 (2.9)	1 (2.9)	5 (14.3)	18 (51.4)
Neutrophil count decreased	20 (57.1)	0	1 (2.9)	1 (2.9)	18 (51.4)
Alanine aminotransferase increased	17 (48.6)	2 (5.7)	3 (8.6)	12 (34.3)	0
Platelet count decreased	16 (45.7)	1 (2.9)	1 (2.9)	2 (5.7)	12 (34.3)
Aspartate aminotransferase increased	14 (40.0)	5 (14.3)	3 (8.6)	5 (14.3)	1 (2.9)
Lymphocyte count decreased	12 (34.3)	0	1 (2.9)	5 (14.3)	6 (17.1)
Prothrombin time prolonged	7 (20.0)	4 (11.4)	2 (5.7)	1 (2.9)	0
International normalised ratio increased	6 (17.1)	5 (14.3)	0	1 (2.9)	0
Blood creatinine increased	5 (14.3)	3 (8.6)	2 (5.7)	0	0
Blood bilirubin increased	4 (11.4)	0	3 (8.6)	1 (2.9)	0
Weight decreased	4 (11.4)	1 (2.9)	3 (8.6)	0	0
Activated partial thromboplastin time prolonged	2 (5.7)	1 (2.9)	1 (2.9)	0	0
Metabolism and nutrition disorders					

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	29 (82.9)	3 (8.6)	7 (20.0)	15 (42.9)	4 (11.4)
Decreased appetite	18 (51.4)	5 (14.3)	6 (17.1)	7 (20.0)	0
Hypokalaemia	13 (37.1)	1 (2.9)	3 (8.6)	7 (20.0)	2 (5.7)
Hypophosphataemia	7 (20.0)	2 (5.7)	1 (2.9)	3 (8.6)	1 (2.9)
Hyperphosphataemia	6 (17.1)	6 (17.1)	0	0	0
Hyperglycaemia	5 (14.3)	0	1 (2.9)	4 (11.4)	0
Hyperuricaemia	5 (14.3)	4 (11.4)	0	1 (2.9)	0
Dehydration	4 (11.4)	1 (2.9)	1 (2.9)	2 (5.7)	0
Hypocalcaemia	4 (11.4)	2 (5.7)	1 (2.9)	0	1 (2.9)
Fluid overload	3 (8.6)	1 (2.9)	2 (5.7)	0	0
Hypernatraemia	3 (8.6)	1 (2.9)	1 (2.9)	0	1 (2.9)
Hypoalbuminaemia	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)	0
Musculoskeletal and connective tissue disorders					
-Total	15 (42.9)	8 (22.9)	4 (11.4)	3 (8.6)	0
Pain in extremity	11 (31.4)	6 (17.1)	3 (8.6)	2 (5.7)	0
Arthralgia	4 (11.4)	2 (5.7)	2 (5.7)	0	0
Myalgia	4 (11.4)	3 (8.6)	0	1 (2.9)	0

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders					
-Total	20 (57.1)	10 (28.6)	7 (20.0)	3 (8.6)	0
Headache	18 (51.4)	8 (22.9)	7 (20.0)	3 (8.6)	0
Dizziness	5 (14.3)	5 (14.3)	0	0	0
Psychiatric disorders					
-Total	9 (25.7)	2 (5.7)	6 (17.1)	1 (2.9)	0
Anxiety	6 (17.1)	2 (5.7)	3 (8.6)	1 (2.9)	0
Confusional state	3 (8.6)	0	3 (8.6)	0	0
Renal and urinary disorders					
-Total	7 (20.0)	2 (5.7)	0	4 (11.4)	1 (2.9)
Acute kidney injury	7 (20.0)	2 (5.7)	0	4 (11.4)	1 (2.9)
Respiratory, thoracic and mediastinal disorders					
-Total	21 (60.0)	9 (25.7)	3 (8.6)	6 (17.1)	3 (8.6)
Cough	9 (25.7)	9 (25.7)	0	0	0
Epistaxis	6 (17.1)	3 (8.6)	1 (2.9)	1 (2.9)	1 (2.9)
Hypoxia	6 (17.1)	0	1 (2.9)	4 (11.4)	1 (2.9)
Oropharyngeal pain	5 (14.3)	4 (11.4)	1 (2.9)	0	0

Gender: Female

	All patients N=35				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinitis allergic	4 (11.4)	3 (8.6)	1 (2.9)	0	0
Rhinorrhoea	4 (11.4)	4 (11.4)	0	0	0
Tachypnoea	4 (11.4)	2 (5.7)	1 (2.9)	1 (2.9)	0
Nasal congestion	3 (8.6)	3 (8.6)	0	0	0
Pleural effusion	3 (8.6)	0	2 (5.7)	1 (2.9)	0
Pulmonary oedema	3 (8.6)	1 (2.9)	0	1 (2.9)	1 (2.9)
Skin and subcutaneous tissue disorders					
-Total	13 (37.1)	9 (25.7)	4 (11.4)	0	0
Rash	7 (20.0)	5 (14.3)	2 (5.7)	0	0
Dry skin	4 (11.4)	4 (11.4)	0	0	0
Petechiae	4 (11.4)	3 (8.6)	1 (2.9)	0	0
Pruritus	4 (11.4)	4 (11.4)	0	0	0
Erythema	1 (2.9)	1 (2.9)	0	0	0
Rash maculo-papular	1 (2.9)	0	1 (2.9)	0	0
Vascular disorders					
-Total	14 (40.0)	2 (5.7)	2 (5.7)	6 (17.1)	4 (11.4)
Hypotension	9 (25.7)	1 (2.9)	0	4 (11.4)	4 (11.4)

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypertension	6 (17.1)	1 (2.9)	3 (8.6)	2 (5.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188c
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	58 (96.7)	1 (1.7)	2 (3.3)	11 (18.3)	44 (73.3)
Blood and lymphatic system disorders					
-Total	53 (88.3)	2 (3.3)	1 (1.7)	32 (53.3)	18 (30.0)
Anaemia	32 (53.3)	2 (3.3)	6 (10.0)	23 (38.3)	1 (1.7)
Febrile neutropenia	31 (51.7)	0	0	31 (51.7)	0
Neutropenia	16 (26.7)	0	0	3 (5.0)	13 (21.7)
Thrombocytopenia	15 (25.0)	0	1 (1.7)	5 (8.3)	9 (15.0)
Disseminated intravascular coagulation	5 (8.3)	0	1 (1.7)	3 (5.0)	1 (1.7)
Lymphopenia	3 (5.0)	0	1 (1.7)	1 (1.7)	1 (1.7)
Coagulopathy	2 (3.3)	2 (3.3)	0	0	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pancytopenia	2 (3.3)	0	0	1 (1.7)	1 (1.7)
Cardiac disorders					
-Total	21 (35.0)	8 (13.3)	10 (16.7)	3 (5.0)	0
Tachycardia	13 (21.7)	5 (8.3)	6 (10.0)	2 (3.3)	0
Sinus tachycardia	6 (10.0)	3 (5.0)	2 (3.3)	1 (1.7)	0
Pericardial effusion	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Bradycardia	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Endocrine disorders					
-Total	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Adrenal insufficiency	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Eye disorders					
-Total	9 (15.0)	5 (8.3)	4 (6.7)	0	0
Periorbital oedema	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Vision blurred	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Conjunctival haemorrhage	2 (3.3)	2 (3.3)	0	0	0
Photophobia	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Dry eye	1 (1.7)	0	1 (1.7)	0	0
Uveitis	1 (1.7)	0	1 (1.7)	0	0

Race: White

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	44 (73.3)	12 (20.0)	21 (35.0)	10 (16.7)	1 (1.7)
Nausea	26 (43.3)	5 (8.3)	15 (25.0)	6 (10.0)	0
Vomiting	25 (41.7)	12 (20.0)	10 (16.7)	3 (5.0)	0
Diarrhoea	23 (38.3)	12 (20.0)	8 (13.3)	3 (5.0)	0
Abdominal pain	14 (23.3)	5 (8.3)	7 (11.7)	2 (3.3)	0
Constipation	11 (18.3)	9 (15.0)	2 (3.3)	0	0
Stomatitis	6 (10.0)	2 (3.3)	1 (1.7)	2 (3.3)	1 (1.7)
Abdominal pain upper	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Abdominal pain lower	1 (1.7)	0	1 (1.7)	0	0
Dysphagia	1 (1.7)	0	0	1 (1.7)	0
General disorders and administration site conditions					
-Total	40 (66.7)	12 (20.0)	14 (23.3)	11 (18.3)	3 (5.0)
Pyrexia	29 (48.3)	8 (13.3)	12 (20.0)	8 (13.3)	1 (1.7)
Fatigue	17 (28.3)	11 (18.3)	4 (6.7)	2 (3.3)	0
Chills	10 (16.7)	10 (16.7)	0	0	0
Pain	6 (10.0)	1 (1.7)	2 (3.3)	3 (5.0)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Catheter site pain	5 (8.3)	1 (1.7)	4 (6.7)	0	0
Malaise	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Multiple organ dysfunction syndrome	3 (5.0)	0	0	1 (1.7)	2 (3.3)
Oedema peripheral	3 (5.0)	2 (3.3)	0	1 (1.7)	0
Non-cardiac chest pain	2 (3.3)	2 (3.3)	0	0	0
Hepatobiliary disorders					
-Total	4 (6.7)	0	1 (1.7)	3 (5.0)	0
Hyperbilirubinaemia	4 (6.7)	0	1 (1.7)	3 (5.0)	0
Immune system disorders					
-Total	47 (78.3)	3 (5.0)	23 (38.3)	11 (18.3)	10 (16.7)
Cytokine release syndrome	40 (66.7)	4 (6.7)	19 (31.7)	7 (11.7)	10 (16.7)
Hypogammaglobulinaemia	27 (45.0)	2 (3.3)	20 (33.3)	5 (8.3)	0
Anaphylactic reaction	1 (1.7)	0	0	1 (1.7)	0
Drug hypersensitivity	1 (1.7)	0	1 (1.7)	0	0
Seasonal allergy	1 (1.7)	1 (1.7)	0	0	0
Infections and infestations					
-Total	36 (60.0)	3 (5.0)	16 (26.7)	13 (21.7)	4 (6.7)
Upper respiratory tract infection	10 (16.7)	4 (6.7)	5 (8.3)	1 (1.7)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia	7 (11.7)	0	5 (8.3)	1 (1.7)	1 (1.7)
Clostridium difficile colitis	5 (8.3)	1 (1.7)	1 (1.7)	3 (5.0)	0
Clostridium difficile infection	5 (8.3)	0	4 (6.7)	1 (1.7)	0
Rhinovirus infection	5 (8.3)	5 (8.3)	0	0	0
Gastroenteritis	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Urinary tract infection	4 (6.7)	0	2 (3.3)	2 (3.3)	0
Device related infection	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Otitis media	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Staphylococcal infection	3 (5.0)	1 (1.7)	0	1 (1.7)	1 (1.7)
Viral upper respiratory tract infection	3 (5.0)	2 (3.3)	0	1 (1.7)	0
Escherichia urinary tract infection	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Oral herpes	2 (3.3)	0	1 (1.7)	1 (1.7)	0
Viral infection	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Conjunctivitis	1 (1.7)	0	1 (1.7)	0	0
Cytomegalovirus infection	1 (1.7)	1 (1.7)	0	0	0
Klebsiella sepsis	1 (1.7)	0	0	0	1 (1.7)
Pneumonia fungal	1 (1.7)	0	0	1 (1.7)	0
Sepsis	1 (1.7)	0	0	0	1 (1.7)

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Injury, poisoning and procedural complications					
-Total	6 (10.0)	1 (1.7)	4 (6.7)	1 (1.7)	0
Procedural pain	4 (6.7)	1 (1.7)	2 (3.3)	1 (1.7)	0
Transfusion reaction	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Subdural haematoma	1 (1.7)	0	1 (1.7)	0	0
Investigations					
-Total	47 (78.3)	0	4 (6.7)	9 (15.0)	34 (56.7)
White blood cell count decreased	33 (55.0)	4 (6.7)	0	6 (10.0)	23 (38.3)
Neutrophil count decreased	27 (45.0)	1 (1.7)	1 (1.7)	3 (5.0)	22 (36.7)
Alanine aminotransferase increased	21 (35.0)	2 (3.3)	2 (3.3)	16 (26.7)	1 (1.7)
Platelet count decreased	21 (35.0)	3 (5.0)	2 (3.3)	3 (5.0)	13 (21.7)
Aspartate aminotransferase increased	18 (30.0)	3 (5.0)	3 (5.0)	7 (11.7)	5 (8.3)
Lymphocyte count decreased	16 (26.7)	1 (1.7)	2 (3.3)	6 (10.0)	7 (11.7)
Blood bilirubin increased	10 (16.7)	2 (3.3)	3 (5.0)	4 (6.7)	1 (1.7)
International normalised ratio increased	9 (15.0)	7 (11.7)	1 (1.7)	1 (1.7)	0
Blood creatinine increased	7 (11.7)	4 (6.7)	1 (1.7)	2 (3.3)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prothrombin time prolonged	7 (11.7)	4 (6.7)	2 (3.3)	1 (1.7)	0
Activated partial thromboplastin time prolonged	5 (8.3)	2 (3.3)	3 (5.0)	0	0
Blood fibrinogen decreased	4 (6.7)	0	1 (1.7)	2 (3.3)	1 (1.7)
Weight decreased	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Blood immunoglobulin m decreased	3 (5.0)	3 (5.0)	0	0	0
C-reactive protein increased	3 (5.0)	0	2 (3.3)	1 (1.7)	0
Transaminases increased	3 (5.0)	3 (5.0)	0	0	0
Blood uric acid increased	2 (3.3)	2 (3.3)	0	0	0
Lipase increased	2 (3.3)	0	0	0	2 (3.3)
Blood immunoglobulin a decreased	1 (1.7)	1 (1.7)	0	0	0
Blood lactate dehydrogenase increased	1 (1.7)	0	0	1 (1.7)	0
Electrocardiogram qt prolonged	1 (1.7)	0	0	1 (1.7)	0
Haemoglobin decreased	1 (1.7)	1 (1.7)	0	0	0
Metabolism and nutrition disorders					
-Total	43 (71.7)	2 (3.3)	11 (18.3)	22 (36.7)	8 (13.3)
Decreased appetite	27 (45.0)	3 (5.0)	10 (16.7)	14 (23.3)	0
Hypokalaemia	22 (36.7)	4 (6.7)	4 (6.7)	10 (16.7)	4 (6.7)

Race: White

	All patients N=60				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	14 (23.3)	4 (6.7)	1 (1.7)	8 (13.3)	1 (1.7)
Hyperglycaemia	7 (11.7)	0	2 (3.3)	4 (6.7)	1 (1.7)
Hyperphosphataemia	7 (11.7)	6 (10.0)	1 (1.7)	0	0
Hyperuricaemia	7 (11.7)	4 (6.7)	0	1 (1.7)	2 (3.3)
Hypoalbuminaemia	7 (11.7)	1 (1.7)	4 (6.7)	1 (1.7)	1 (1.7)
Dehydration	6 (10.0)	1 (1.7)	2 (3.3)	3 (5.0)	0
Hypernatraemia	6 (10.0)	0	2 (3.3)	1 (1.7)	3 (5.0)
Hypocalcaemia	6 (10.0)	2 (3.3)	1 (1.7)	1 (1.7)	2 (3.3)
Fluid overload	5 (8.3)	1 (1.7)	4 (6.7)	0	0
Hypomagnesaemia	5 (8.3)	4 (6.7)	1 (1.7)	0	0
Tumour lysis syndrome	3 (5.0)	0	0	3 (5.0)	0
Vitamin d deficiency	3 (5.0)	2 (3.3)	1 (1.7)	0	0
Hyperkalaemia	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Acidosis	1 (1.7)	0	0	1 (1.7)	0
Musculoskeletal and connective tissue disorders					
-Total	24 (40.0)	10 (16.7)	7 (11.7)	7 (11.7)	0
Pain in extremity	12 (20.0)	4 (6.7)	4 (6.7)	4 (6.7)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Arthralgia	5 (8.3)	3 (5.0)	1 (1.7)	1 (1.7)	0
Myalgia	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Pain in jaw	4 (6.7)	2 (3.3)	2 (3.3)	0	0
Neck pain	3 (5.0)	1 (1.7)	2 (3.3)	0	0
Back pain	2 (3.3)	2 (3.3)	0	0	0
Muscle spasms	2 (3.3)	2 (3.3)	0	0	0
Muscular weakness	2 (3.3)	1 (1.7)	1 (1.7)	0	0
Musculoskeletal chest pain	2 (3.3)	2 (3.3)	0	0	0
Bone pain	1 (1.7)	0	0	1 (1.7)	0
Joint range of motion decreased	1 (1.7)	1 (1.7)	0	0	0
Nervous system disorders					
-Total	31 (51.7)	14 (23.3)	10 (16.7)	7 (11.7)	0
Headache	24 (40.0)	12 (20.0)	8 (13.3)	4 (6.7)	0
Dizziness	6 (10.0)	6 (10.0)	0	0	0
Encephalopathy	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Seizure	3 (5.0)	0	1 (1.7)	2 (3.3)	0
Dysarthria	1 (1.7)	0	1 (1.7)	0	0
Neuropathy peripheral	1 (1.7)	1 (1.7)	0	0	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Tremor	1 (1.7)	1 (1.7)	0	0	0
Product issues					
-Total	1 (1.7)	1 (1.7)	0	0	0
Device occlusion	1 (1.7)	1 (1.7)	0	0	0
Psychiatric disorders					
-Total	21 (35.0)	10 (16.7)	9 (15.0)	2 (3.3)	0
Anxiety	8 (13.3)	3 (5.0)	4 (6.7)	1 (1.7)	0
Confusional state	8 (13.3)	3 (5.0)	5 (8.3)	0	0
Delirium	4 (6.7)	2 (3.3)	1 (1.7)	1 (1.7)	0
Depression	4 (6.7)	3 (5.0)	1 (1.7)	0	0
Mental status changes	3 (5.0)	3 (5.0)	0	0	0
Agitation	1 (1.7)	0	1 (1.7)	0	0
Renal and urinary disorders					
-Total	12 (20.0)	2 (3.3)	1 (1.7)	4 (6.7)	5 (8.3)
Acute kidney injury	8 (13.3)	0	1 (1.7)	3 (5.0)	4 (6.7)
Haematuria	6 (10.0)	1 (1.7)	2 (3.3)	2 (3.3)	1 (1.7)
Oliguria	2 (3.3)	0	0	2 (3.3)	0
Dysuria	1 (1.7)	1 (1.7)	0	0	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	34 (56.7)	10 (16.7)	8 (13.3)	8 (13.3)	8 (13.3)
Hypoxia	15 (25.0)	0	3 (5.0)	8 (13.3)	4 (6.7)
Cough	12 (20.0)	10 (16.7)	2 (3.3)	0	0
Epistaxis	11 (18.3)	3 (5.0)	4 (6.7)	3 (5.0)	1 (1.7)
Pleural effusion	10 (16.7)	1 (1.7)	6 (10.0)	3 (5.0)	0
Tachypnoea	7 (11.7)	3 (5.0)	2 (3.3)	2 (3.3)	0
Nasal congestion	6 (10.0)	6 (10.0)	0	0	0
Oropharyngeal pain	6 (10.0)	5 (8.3)	1 (1.7)	0	0
Pulmonary oedema	6 (10.0)	1 (1.7)	0	3 (5.0)	2 (3.3)
Rhinorrhoea	6 (10.0)	5 (8.3)	1 (1.7)	0	0
Dyspnoea	4 (6.7)	1 (1.7)	1 (1.7)	1 (1.7)	1 (1.7)
Rhinitis allergic	4 (6.7)	3 (5.0)	1 (1.7)	0	0
Respiratory failure	3 (5.0)	0	0	0	3 (5.0)
Haemoptysis	1 (1.7)	0	0	0	1 (1.7)
Respiratory distress	1 (1.7)	0	0	0	1 (1.7)
Skin and subcutaneous tissue disorders					

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	17 (28.3)	12 (20.0)	5 (8.3)	0	0
Rash	6 (10.0)	5 (8.3)	1 (1.7)	0	0
Erythema	4 (6.7)	4 (6.7)	0	0	0
Rash erythematous	4 (6.7)	1 (1.7)	3 (5.0)	0	0
Hyperhidrosis	3 (5.0)	3 (5.0)	0	0	0
Pruritus	3 (5.0)	3 (5.0)	0	0	0
Dry skin	2 (3.3)	2 (3.3)	0	0	0
Night sweats	1 (1.7)	0	1 (1.7)	0	0
Rash pruritic	1 (1.7)	1 (1.7)	0	0	0
Vascular disorders					
-Total	29 (48.3)	4 (6.7)	3 (5.0)	13 (21.7)	9 (15.0)
Hypotension	22 (36.7)	1 (1.7)	0	12 (20.0)	9 (15.0)
Hypertension	13 (21.7)	4 (6.7)	7 (11.7)	2 (3.3)	0
Orthostatic hypotension	1 (1.7)	1 (1.7)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188c
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (100)	0	0	2 (33.3)	4 (66.7)
Blood and lymphatic system disorders					
-Total	4 (66.7)	0	1 (16.7)	2 (33.3)	1 (16.7)
Anaemia	4 (66.7)	0	1 (16.7)	3 (50.0)	0
Febrile neutropenia	1 (16.7)	0	0	1 (16.7)	0
Lymphopenia	1 (16.7)	0	1 (16.7)	0	0
Neutropenia	1 (16.7)	0	0	0	1 (16.7)
Cardiac disorders					
-Total	1 (16.7)	1 (16.7)	0	0	0
Atrioventricular block second degree	1 (16.7)	1 (16.7)	0	0	0
Gastrointestinal disorders					

Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Diarrhoea	1 (16.7)	0	1 (16.7)	0	0
Dry mouth	1 (16.7)	1 (16.7)	0	0	0
Nausea	1 (16.7)	1 (16.7)	0	0	0
Vomiting	1 (16.7)	1 (16.7)	0	0	0
General disorders and administration site conditions					
-Total	5 (83.3)	3 (50.0)	2 (33.3)	0	0
Fatigue	3 (50.0)	3 (50.0)	0	0	0
Pyrexia	2 (33.3)	1 (16.7)	1 (16.7)	0	0
Oedema peripheral	1 (16.7)	1 (16.7)	0	0	0
Pain	1 (16.7)	0	1 (16.7)	0	0
Immune system disorders					
-Total	5 (83.3)	0	5 (83.3)	0	0
Cytokine release syndrome	4 (66.7)	0	4 (66.7)	0	0
Hypogammaglobulinaemia	3 (50.0)	1 (16.7)	2 (33.3)	0	0
Infections and infestations					
-Total	4 (66.7)	0	0	3 (50.0)	1 (16.7)

Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal infection	2 (33.3)	0	1 (16.7)	1 (16.7)	0
Alpha haemolytic streptococcal infection	1 (16.7)	0	0	1 (16.7)	0
Conjunctivitis	1 (16.7)	0	1 (16.7)	0	0
Device related infection	1 (16.7)	0	0	1 (16.7)	0
Escherichia infection	1 (16.7)	0	0	1 (16.7)	0
Gastroenteritis	1 (16.7)	0	0	1 (16.7)	0
Gingivitis	1 (16.7)	1 (16.7)	0	0	0
Herpes zoster	1 (16.7)	0	0	1 (16.7)	0
Molluscum contagiosum	1 (16.7)	1 (16.7)	0	0	0
Oral herpes	1 (16.7)	0	1 (16.7)	0	0
Pharyngitis	1 (16.7)	0	1 (16.7)	0	0
Respiratory tract infection	1 (16.7)	0	0	0	1 (16.7)
Staphylococcal infection	1 (16.7)	0	0	1 (16.7)	0
Viral infection	1 (16.7)	1 (16.7)	0	0	0
Viral upper respiratory tract infection	1 (16.7)	0	1 (16.7)	0	0
Investigations					
-Total	4 (66.7)	0	1 (16.7)	0	3 (50.0)

Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	4 (66.7)	0	1 (16.7)	0	3 (50.0)
White blood cell count decreased	4 (66.7)	0	1 (16.7)	0	3 (50.0)
Aspartate aminotransferase increased	2 (33.3)	1 (16.7)	0	1 (16.7)	0
Platelet count decreased	2 (33.3)	0	0	0	2 (33.3)
Alanine aminotransferase increased	1 (16.7)	0	1 (16.7)	0	0
Blood fibrinogen decreased	1 (16.7)	0	1 (16.7)	0	0
Blood immunoglobulin a decreased	1 (16.7)	1 (16.7)	0	0	0
Blood immunoglobulin m decreased	1 (16.7)	1 (16.7)	0	0	0
Blood uric acid increased	1 (16.7)	1 (16.7)	0	0	0
International normalised ratio increased	1 (16.7)	1 (16.7)	0	0	0
Lymphocyte count decreased	1 (16.7)	0	1 (16.7)	0	0
Metabolism and nutrition disorders					
-Total	3 (50.0)	1 (16.7)	0	2 (33.3)	0
Decreased appetite	1 (16.7)	1 (16.7)	0	0	0
Dehydration	1 (16.7)	0	0	1 (16.7)	0
Hyperglycaemia	1 (16.7)	0	0	1 (16.7)	0
Hyperphosphataemia	1 (16.7)	1 (16.7)	0	0	0

Race: Asian

	All patients N=6				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	1 (16.7)	1 (16.7)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	5 (83.3)	2 (33.3)	3 (50.0)	0	0
Pain in extremity	3 (50.0)	2 (33.3)	1 (16.7)	0	0
Arthralgia	1 (16.7)	1 (16.7)	0	0	0
Bone pain	1 (16.7)	0	1 (16.7)	0	0
Joint range of motion decreased	1 (16.7)	1 (16.7)	0	0	0
Myalgia	1 (16.7)	1 (16.7)	0	0	0
Osteonecrosis	1 (16.7)	0	1 (16.7)	0	0
Pain in jaw	1 (16.7)	0	1 (16.7)	0	0
Nervous system disorders					
-Total	2 (33.3)	2 (33.3)	0	0	0
Headache	2 (33.3)	2 (33.3)	0	0	0
Renal and urinary disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Dysuria	1 (16.7)	0	1 (16.7)	0	0
Pollakiuria	1 (16.7)	1 (16.7)	0	0	0

Race: Asian

Group term Preferred term	All patients N=6 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Pulmonary oedema	1 (16.7)	0	0	1 (16.7)	0
Skin and subcutaneous tissue disorders					
-Total	1 (16.7)	0	1 (16.7)	0	0
Pruritus generalised	1 (16.7)	1 (16.7)	0	0	0
Rash	1 (16.7)	0	1 (16.7)	0	0
Vascular disorders					
-Total	1 (16.7)	0	0	1 (16.7)	0
Embolism	1 (16.7)	0	0	1 (16.7)	0
Hypertension	1 (16.7)	0	1 (16.7)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188c
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (100)	0	0	0	9 (100)
Blood and lymphatic system disorders					
-Total	9 (100)	0	0	4 (44.4)	5 (55.6)
Febrile neutropenia	6 (66.7)	0	0	5 (55.6)	1 (11.1)
Anaemia	5 (55.6)	0	0	5 (55.6)	0
Disseminated intravascular coagulation	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Lymphopenia	2 (22.2)	0	0	0	2 (22.2)
Neutropenia	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Pancytopenia	2 (22.2)	0	0	0	2 (22.2)
Thrombocytopenia	2 (22.2)	0	0	1 (11.1)	1 (11.1)

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Coagulopathy	1 (11.1)	0	0	1 (11.1)	0
Hypofibrinogenaemia	1 (11.1)	0	0	0	1 (11.1)
Leukocytosis	1 (11.1)	1 (11.1)	0	0	0
Lymphadenopathy	1 (11.1)	0	1 (11.1)	0	0
Cardiac disorders					
-Total	6 (66.7)	2 (22.2)	2 (22.2)	0	2 (22.2)
Tachycardia	4 (44.4)	4 (44.4)	0	0	0
Ventricular tachycardia	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Bradycardia	1 (11.1)	0	0	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	0	0	1 (11.1)
Pericardial effusion	1 (11.1)	0	1 (11.1)	0	0
Right ventricular dysfunction	1 (11.1)	0	0	1 (11.1)	0
Sinus tachycardia	1 (11.1)	0	0	1 (11.1)	0
Endocrine disorders					
-Total	1 (11.1)	0	1 (11.1)	0	0
Adrenal insufficiency	1 (11.1)	0	1 (11.1)	0	0
Eye disorders					
-Total	4 (44.4)	1 (11.1)	3 (33.3)	0	0

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Conjunctival haemorrhage	1 (11.1)	1 (11.1)	0	0	0
Dry eye	1 (11.1)	1 (11.1)	0	0	0
Periorbital oedema	1 (11.1)	1 (11.1)	0	0	0
Photophobia	1 (11.1)	0	1 (11.1)	0	0
Retinopathy	1 (11.1)	0	1 (11.1)	0	0
Uveitis	1 (11.1)	0	1 (11.1)	0	0
Vision blurred	1 (11.1)	0	1 (11.1)	0	0
Gastrointestinal disorders					
-Total	9 (100)	0	6 (66.7)	3 (33.3)	0
Nausea	9 (100)	2 (22.2)	6 (66.7)	1 (11.1)	0
Vomiting	7 (77.8)	4 (44.4)	2 (22.2)	1 (11.1)	0
Abdominal pain	4 (44.4)	1 (11.1)	1 (11.1)	2 (22.2)	0
Constipation	3 (33.3)	2 (22.2)	1 (11.1)	0	0
Diarrhoea	3 (33.3)	2 (22.2)	1 (11.1)	0	0
Haematochezia	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Abdominal pain lower	1 (11.1)	1 (11.1)	0	0	0
Abdominal pain upper	1 (11.1)	0	1 (11.1)	0	0
Dysphagia	1 (11.1)	0	1 (11.1)	0	0

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Flatulence	1 (11.1)	1 (11.1)	0	0	0
Lip pain	1 (11.1)	0	1 (11.1)	0	0
Stomatitis	1 (11.1)	0	0	1 (11.1)	0
General disorders and administration site conditions					
-Total	8 (88.9)	1 (11.1)	3 (33.3)	3 (33.3)	1 (11.1)
Pyrexia	5 (55.6)	3 (33.3)	2 (22.2)	0	0
Catheter site pain	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Chills	2 (22.2)	0	2 (22.2)	0	0
Non-cardiac chest pain	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Physical deconditioning	2 (22.2)	0	0	2 (22.2)	0
Catheter site bruise	1 (11.1)	1 (11.1)	0	0	0
Catheter site haemorrhage	1 (11.1)	1 (11.1)	0	0	0
Device related thrombosis	1 (11.1)	0	1 (11.1)	0	0
Fatigue	1 (11.1)	1 (11.1)	0	0	0
Injection site haematoma	1 (11.1)	1 (11.1)	0	0	0
Malaise	1 (11.1)	0	1 (11.1)	0	0
Multiple organ dysfunction syndrome	1 (11.1)	0	0	0	1 (11.1)

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oedema peripheral	1 (11.1)	0	1 (11.1)	0	0
Pain	1 (11.1)	0	1 (11.1)	0	0
Hepatobiliary disorders					
-Total	3 (33.3)	1 (11.1)	1 (11.1)	1 (11.1)	0
Hyperbilirubinaemia	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Gallbladder enlargement	1 (11.1)	1 (11.1)	0	0	0
Hepatic steatosis	1 (11.1)	0	1 (11.1)	0	0
Immune system disorders					
-Total	6 (66.7)	1 (11.1)	2 (22.2)	2 (22.2)	1 (11.1)
Cytokine release syndrome	6 (66.7)	2 (22.2)	2 (22.2)	1 (11.1)	1 (11.1)
Hypogammaglobulinaemia	3 (33.3)	1 (11.1)	2 (22.2)	0	0
Immunodeficiency common variable	2 (22.2)	0	2 (22.2)	0	0
Anaphylactic reaction	1 (11.1)	0	0	1 (11.1)	0
Drug hypersensitivity	1 (11.1)	0	1 (11.1)	0	0
Immunodeficiency	1 (11.1)	0	1 (11.1)	0	0
Seasonal allergy	1 (11.1)	1 (11.1)	0	0	0
Infections and infestations					
-Total	6 (66.7)	0	1 (11.1)	3 (33.3)	2 (22.2)

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Abscess limb	1 (11.1)	0	0	1 (11.1)	0
Catheter site cellulitis	1 (11.1)	1 (11.1)	0	0	0
Clostridium difficile colitis	1 (11.1)	0	1 (11.1)	0	0
Clostridium difficile infection	1 (11.1)	0	1 (11.1)	0	0
Cytomegalovirus infection	1 (11.1)	1 (11.1)	0	0	0
Device related infection	1 (11.1)	0	0	1 (11.1)	0
Escherichia urinary tract infection	1 (11.1)	0	0	1 (11.1)	0
Herpes simplex	1 (11.1)	1 (11.1)	0	0	0
Klebsiella sepsis	1 (11.1)	0	0	0	1 (11.1)
Meningitis aseptic	1 (11.1)	0	1 (11.1)	0	0
Oral herpes	1 (11.1)	0	1 (11.1)	0	0
Otitis media	1 (11.1)	0	1 (11.1)	0	0
Pneumonia fungal	1 (11.1)	0	1 (11.1)	0	0
Rhinitis	1 (11.1)	1 (11.1)	0	0	0
Rhinovirus infection	1 (11.1)	0	1 (11.1)	0	0
Sepsis	1 (11.1)	0	0	0	1 (11.1)
Staphylococcal scalded skin syndrome	1 (11.1)	0	1 (11.1)	0	0

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal sepsis	1 (11.1)	0	0	0	1 (11.1)
Upper respiratory tract infection	1 (11.1)	1 (11.1)	0	0	0
Urinary tract infection	1 (11.1)	0	1 (11.1)	0	0
Vascular device infection	1 (11.1)	0	0	1 (11.1)	0
Vulvovaginal mycotic infection	1 (11.1)	0	1 (11.1)	0	0
Injury, poisoning and procedural complications					
-Total	6 (66.7)	1 (11.1)	2 (22.2)	2 (22.2)	1 (11.1)
Procedural pain	4 (44.4)	0	2 (22.2)	2 (22.2)	0
Arthropod bite	1 (11.1)	1 (11.1)	0	0	0
Extradural haematoma	1 (11.1)	0	0	1 (11.1)	0
Post procedural haemorrhage	1 (11.1)	1 (11.1)	0	0	0
Procedural hypertension	1 (11.1)	0	1 (11.1)	0	0
Subdural haematoma	1 (11.1)	0	0	1 (11.1)	0
Transfusion reaction	1 (11.1)	1 (11.1)	0	0	0
Transfusion related complication	1 (11.1)	0	0	0	1 (11.1)
Investigations					
-Total	8 (88.9)	0	0	1 (11.1)	7 (77.8)

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	7 (77.8)	0	0	2 (22.2)	5 (55.6)
Alanine aminotransferase increased	4 (44.4)	1 (11.1)	1 (11.1)	2 (22.2)	0
Aspartate aminotransferase increased	4 (44.4)	1 (11.1)	2 (22.2)	1 (11.1)	0
Neutrophil count decreased	4 (44.4)	0	0	0	4 (44.4)
Platelet count decreased	3 (33.3)	0	0	1 (11.1)	2 (22.2)
Blood creatinine increased	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Blood lactate dehydrogenase increased	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Haemoglobin decreased	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Lymphocyte count decreased	2 (22.2)	0	0	1 (11.1)	1 (11.1)
Prothrombin time prolonged	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Activated partial thromboplastin time prolonged	1 (11.1)	1 (11.1)	0	0	0
Blood alkaline phosphatase increased	1 (11.1)	1 (11.1)	0	0	0
Blood immunoglobulin a decreased	1 (11.1)	1 (11.1)	0	0	0
Blood immunoglobulin m decreased	1 (11.1)	1 (11.1)	0	0	0
C-reactive protein increased	1 (11.1)	1 (11.1)	0	0	0

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Computerised tomogram thorax abnormal	1 (11.1)	0	0	1 (11.1)	0
Culture stool positive	1 (11.1)	1 (11.1)	0	0	0
Electrocardiogram qt prolonged	1 (11.1)	0	0	1 (11.1)	0
Hepatic enzyme increased	1 (11.1)	0	1 (11.1)	0	0
International normalised ratio increased	1 (11.1)	1 (11.1)	0	0	0
Lipase increased	1 (11.1)	0	0	0	1 (11.1)
Transaminases increased	1 (11.1)	0	0	1 (11.1)	0
Weight decreased	1 (11.1)	1 (11.1)	0	0	0
Metabolism and nutrition disorders					
-Total	8 (88.9)	1 (11.1)	2 (22.2)	4 (44.4)	1 (11.1)
Decreased appetite	4 (44.4)	3 (33.3)	0	1 (11.1)	0
Fluid overload	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Hyperglycaemia	2 (22.2)	0	2 (22.2)	0	0
Hypokalaemia	2 (22.2)	1 (11.1)	0	0	1 (11.1)
Tumour lysis syndrome	2 (22.2)	0	0	2 (22.2)	0
Acidosis	1 (11.1)	1 (11.1)	0	0	0
Hyperkalaemia	1 (11.1)	0	0	1 (11.1)	0

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	1 (11.1)	1 (11.1)	0	0	0
Hyperphosphataemia	1 (11.1)	1 (11.1)	0	0	0
Hypocalcaemia	1 (11.1)	1 (11.1)	0	0	0
Hypomagnesaemia	1 (11.1)	1 (11.1)	0	0	0
Vitamin d deficiency	1 (11.1)	0	1 (11.1)	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (77.8)	3 (33.3)	1 (11.1)	3 (33.3)	0
Pain in extremity	3 (33.3)	2 (22.2)	0	1 (11.1)	0
Arthralgia	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Back pain	2 (22.2)	0	0	2 (22.2)	0
Coccydynia	1 (11.1)	1 (11.1)	0	0	0
Muscle spasms	1 (11.1)	1 (11.1)	0	0	0
Muscular weakness	1 (11.1)	1 (11.1)	0	0	0
Musculoskeletal chest pain	1 (11.1)	1 (11.1)	0	0	0
Myalgia	1 (11.1)	1 (11.1)	0	0	0
Myopathy	1 (11.1)	0	0	1 (11.1)	0
Myositis	1 (11.1)	0	0	1 (11.1)	0

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neck pain	1 (11.1)	0	1 (11.1)	0	0
Synovitis	1 (11.1)	0	1 (11.1)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (11.1)	0	1 (11.1)	0	0
Myelodysplastic syndrome	1 (11.1)	0	1 (11.1)	0	0
Nervous system disorders					
-Total	6 (66.7)	1 (11.1)	3 (33.3)	1 (11.1)	1 (11.1)
Headache	5 (55.6)	0	3 (33.3)	2 (22.2)	0
Seizure	2 (22.2)	0	1 (11.1)	0	1 (11.1)
Asterixis	1 (11.1)	1 (11.1)	0	0	0
Ataxia	1 (11.1)	0	1 (11.1)	0	0
Dysarthria	1 (11.1)	1 (11.1)	0	0	0
Encephalopathy	1 (11.1)	1 (11.1)	0	0	0
Hyporesponsive to stimuli	1 (11.1)	0	0	1 (11.1)	0
Myoclonus	1 (11.1)	1 (11.1)	0	0	0
Neuropathy peripheral	1 (11.1)	0	1 (11.1)	0	0
Pleocytosis	1 (11.1)	1 (11.1)	0	0	0

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tremor	1 (11.1)	1 (11.1)	0	0	0
Product issues					
-Total	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Device occlusion	2 (22.2)	1 (11.1)	1 (11.1)	0	0
Psychiatric disorders					
-Total	4 (44.4)	0	2 (22.2)	2 (22.2)	0
Agitation	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Anxiety	2 (22.2)	0	2 (22.2)	0	0
Adjustment disorder	1 (11.1)	0	1 (11.1)	0	0
Delirium	1 (11.1)	0	1 (11.1)	0	0
Depression	1 (11.1)	0	1 (11.1)	0	0
Mental status changes	1 (11.1)	0	0	1 (11.1)	0
Suicidal ideation	1 (11.1)	1 (11.1)	0	0	0
Renal and urinary disorders					
-Total	4 (44.4)	1 (11.1)	1 (11.1)	2 (22.2)	0
Acute kidney injury	4 (44.4)	2 (22.2)	0	2 (22.2)	0
Dysuria	1 (11.1)	0	1 (11.1)	0	0
Oliguria	1 (11.1)	0	0	1 (11.1)	0

Race: Other

	All patients N=9				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Reproductive system and breast disorders					
-Total	1 (11.1)	0	0	1 (11.1)	0
Ovarian failure	1 (11.1)	0	0	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	7 (77.8)	3 (33.3)	0	2 (22.2)	2 (22.2)
Cough	4 (44.4)	3 (33.3)	0	1 (11.1)	0
Epistaxis	3 (33.3)	1 (11.1)	0	2 (22.2)	0
Haemoptysis	2 (22.2)	1 (11.1)	0	1 (11.1)	0
Oropharyngeal pain	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Pulmonary oedema	2 (22.2)	0	0	0	2 (22.2)
Dyspnoea	1 (11.1)	0	0	1 (11.1)	0
Hypoxia	1 (11.1)	0	0	1 (11.1)	0
Nasal congestion	1 (11.1)	1 (11.1)	0	0	0
Nasal discomfort	1 (11.1)	1 (11.1)	0	0	0
Pulmonary alveolar haemorrhage	1 (11.1)	0	0	0	1 (11.1)
Pulmonary hypertension	1 (11.1)	0	0	1 (11.1)	0
Respiratory distress	1 (11.1)	0	0	0	1 (11.1)

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	1 (11.1)	0	0	0	1 (11.1)
Rhinitis allergic	1 (11.1)	1 (11.1)	0	0	0
Rhinorrhoea	1 (11.1)	1 (11.1)	0	0	0
Tachypnoea	1 (11.1)	0	0	1 (11.1)	0
Skin and subcutaneous tissue disorders					
-Total	5 (55.6)	3 (33.3)	1 (11.1)	1 (11.1)	0
Dry skin	3 (33.3)	3 (33.3)	0	0	0
Rash	3 (33.3)	2 (22.2)	1 (11.1)	0	0
Pruritus	2 (22.2)	2 (22.2)	0	0	0
Cold sweat	1 (11.1)	1 (11.1)	0	0	0
Dermatitis	1 (11.1)	1 (11.1)	0	0	0
Dermatitis atopic	1 (11.1)	1 (11.1)	0	0	0
Ecchymosis	1 (11.1)	0	0	1 (11.1)	0
Eczema	1 (11.1)	1 (11.1)	0	0	0
Erythema	1 (11.1)	1 (11.1)	0	0	0
Hyperhidrosis	1 (11.1)	1 (11.1)	0	0	0
Night sweats	1 (11.1)	1 (11.1)	0	0	0

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash erythematous	1 (11.1)	1 (11.1)	0	0	0
Rash pruritic	1 (11.1)	1 (11.1)	0	0	0
Rash vesicular	1 (11.1)	1 (11.1)	0	0	0
Skin exfoliation	1 (11.1)	1 (11.1)	0	0	0
Skin fissures	1 (11.1)	1 (11.1)	0	0	0
Urticaria	1 (11.1)	0	1 (11.1)	0	0
Vascular disorders					
-Total	5 (55.6)	0	1 (11.1)	2 (22.2)	2 (22.2)
Hypotension	3 (33.3)	0	0	1 (11.1)	2 (22.2)
Hypertension	2 (22.2)	0	1 (11.1)	1 (11.1)	0
Orthostatic hypotension	1 (11.1)	0	1 (11.1)	0	0
Secondary hypertension	1 (11.1)	0	1 (11.1)	0	0
Venous thrombosis limb	1 (11.1)	1 (11.1)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188d
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (96.7)	0	1 (3.3)	5 (16.7)	23 (76.7)
Blood and lymphatic system disorders					
-Total	27 (90.0)	0	0	20 (66.7)	7 (23.3)
Febrile neutropenia	21 (70.0)	0	0	20 (66.7)	1 (3.3)
Anaemia	17 (56.7)	1 (3.3)	4 (13.3)	12 (40.0)	0
Neutropenia	7 (23.3)	0	0	3 (10.0)	4 (13.3)
Thrombocytopenia	4 (13.3)	0	0	1 (3.3)	3 (10.0)
Disseminated intravascular coagulation	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Cardiac disorders					
-Total	9 (30.0)	6 (20.0)	2 (6.7)	1 (3.3)	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	7 (23.3)	6 (20.0)	1 (3.3)	0	0
Sinus tachycardia	2 (6.7)	0	1 (3.3)	1 (3.3)	0
Gastrointestinal disorders					
-Total	22 (73.3)	4 (13.3)	14 (46.7)	4 (13.3)	0
Vomiting	15 (50.0)	8 (26.7)	6 (20.0)	1 (3.3)	0
Nausea	14 (46.7)	1 (3.3)	12 (40.0)	1 (3.3)	0
Diarrhoea	10 (33.3)	5 (16.7)	4 (13.3)	1 (3.3)	0
Abdominal pain	5 (16.7)	2 (6.7)	2 (6.7)	1 (3.3)	0
Constipation	5 (16.7)	4 (13.3)	1 (3.3)	0	0
Stomatitis	1 (3.3)	0	0	1 (3.3)	0
General disorders and administration site conditions					
-Total	17 (56.7)	6 (20.0)	8 (26.7)	3 (10.0)	0
Pyrexia	12 (40.0)	5 (16.7)	4 (13.3)	3 (10.0)	0
Chills	6 (20.0)	4 (13.3)	2 (6.7)	0	0
Fatigue	4 (13.3)	4 (13.3)	0	0	0
Pain	3 (10.0)	1 (3.3)	2 (6.7)	0	0
Catheter site pain	1 (3.3)	0	1 (3.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	1 (3.3)	0	1 (3.3)	0	0
Hyperbilirubinaemia	1 (3.3)	0	1 (3.3)	0	0
Immune system disorders					
-Total	23 (76.7)	1 (3.3)	15 (50.0)	4 (13.3)	3 (10.0)
Cytokine release syndrome	20 (66.7)	2 (6.7)	12 (40.0)	3 (10.0)	3 (10.0)
Hypogammaglobulinaemia	15 (50.0)	0	14 (46.7)	1 (3.3)	0
Infections and infestations					
-Total	14 (46.7)	2 (6.7)	9 (30.0)	3 (10.0)	0
Influenza	4 (13.3)	1 (3.3)	3 (10.0)	0	0
Upper respiratory tract infection	4 (13.3)	2 (6.7)	2 (6.7)	0	0
Urinary tract infection	4 (13.3)	0	2 (6.7)	2 (6.7)	0
Otitis media	3 (10.0)	0	3 (10.0)	0	0
Parainfluenzae virus infection	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Clostridium difficile colitis	1 (3.3)	0	0	1 (3.3)	0
Pneumonia	1 (3.3)	0	1 (3.3)	0	0
Rhinovirus infection	1 (3.3)	1 (3.3)	0	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Procedural pain	4 (13.3)	1 (3.3)	1 (3.3)	2 (6.7)	0
Investigations					
-Total	23 (76.7)	0	1 (3.3)	2 (6.7)	20 (66.7)
White blood cell count decreased	21 (70.0)	1 (3.3)	0	6 (20.0)	14 (46.7)
Neutrophil count decreased	18 (60.0)	1 (3.3)	0	2 (6.7)	15 (50.0)
Platelet count decreased	12 (40.0)	3 (10.0)	2 (6.7)	2 (6.7)	5 (16.7)
Alanine aminotransferase increased	9 (30.0)	1 (3.3)	0	8 (26.7)	0
Lymphocyte count decreased	9 (30.0)	1 (3.3)	1 (3.3)	4 (13.3)	3 (10.0)
Aspartate aminotransferase increased	5 (16.7)	1 (3.3)	1 (3.3)	3 (10.0)	0
Blood creatinine increased	4 (13.3)	4 (13.3)	0	0	0
Activated partial thromboplastin time prolonged	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Blood bilirubin increased	3 (10.0)	1 (3.3)	1 (3.3)	1 (3.3)	0
Prothrombin time prolonged	2 (6.7)	1 (3.3)	1 (3.3)	0	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	1 (3.3)	1 (3.3)	0	0	0
Metabolism and nutrition disorders					
-Total	22 (73.3)	2 (6.7)	8 (26.7)	7 (23.3)	5 (16.7)
Decreased appetite	14 (46.7)	3 (10.0)	7 (23.3)	4 (13.3)	0
Hypokalaemia	10 (33.3)	3 (10.0)	2 (6.7)	3 (10.0)	2 (6.7)
Hyperglycaemia	5 (16.7)	0	2 (6.7)	3 (10.0)	0
Hyperphosphataemia	5 (16.7)	4 (13.3)	1 (3.3)	0	0
Hyperuricaemia	5 (16.7)	4 (13.3)	0	0	1 (3.3)
Hypomagnesaemia	5 (16.7)	4 (13.3)	1 (3.3)	0	0
Hypophosphataemia	4 (13.3)	1 (3.3)	0	2 (6.7)	1 (3.3)
Tumour lysis syndrome	4 (13.3)	0	0	4 (13.3)	0
Hypernatraemia	3 (10.0)	1 (3.3)	0	0	2 (6.7)
Dehydration	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Fluid overload	1 (3.3)	0	1 (3.3)	0	0
Hypoalbuminaemia	1 (3.3)	0	0	1 (3.3)	0
Hypocalcaemia	1 (3.3)	0	0	0	1 (3.3)
Musculoskeletal and connective tissue disorders					

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (36.7)	7 (23.3)	2 (6.7)	2 (6.7)	0
Pain in extremity	6 (20.0)	4 (13.3)	1 (3.3)	1 (3.3)	0
Arthralgia	4 (13.3)	3 (10.0)	1 (3.3)	0	0
Back pain	3 (10.0)	2 (6.7)	0	1 (3.3)	0
Nervous system disorders					
-Total	11 (36.7)	5 (16.7)	4 (13.3)	2 (6.7)	0
Headache	11 (36.7)	5 (16.7)	4 (13.3)	2 (6.7)	0
Product issues					
-Total	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Device occlusion	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Psychiatric disorders					
-Total	2 (6.7)	1 (3.3)	1 (3.3)	0	0
Anxiety	1 (3.3)	0	1 (3.3)	0	0
Confusional state	1 (3.3)	1 (3.3)	0	0	0
Renal and urinary disorders					
-Total	5 (16.7)	0	0	4 (13.3)	1 (3.3)
Acute kidney injury	4 (13.3)	0	0	3 (10.0)	1 (3.3)
Haematuria	1 (3.3)	0	0	1 (3.3)	0

Ethnicity: Hispanic or Latino

	All patients N=30				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders					
-Total	18 (60.0)	9 (30.0)	5 (16.7)	1 (3.3)	3 (10.0)
Cough	6 (20.0)	4 (13.3)	2 (6.7)	0	0
Epistaxis	5 (16.7)	3 (10.0)	1 (3.3)	1 (3.3)	0
Nasal congestion	5 (16.7)	5 (16.7)	0	0	0
Rhinorrhoea	5 (16.7)	4 (13.3)	1 (3.3)	0	0
Pulmonary oedema	4 (13.3)	1 (3.3)	0	1 (3.3)	2 (6.7)
Oropharyngeal pain	3 (10.0)	2 (6.7)	1 (3.3)	0	0
Respiratory failure	3 (10.0)	0	0	0	3 (10.0)
Tachypnoea	3 (10.0)	3 (10.0)	0	0	0
Hypoxia	2 (6.7)	0	2 (6.7)	0	0
Pleural effusion	1 (3.3)	0	0	1 (3.3)	0
Skin and subcutaneous tissue disorders					
-Total	7 (23.3)	6 (20.0)	1 (3.3)	0	0
Dry skin	3 (10.0)	3 (10.0)	0	0	0
Pruritus	3 (10.0)	3 (10.0)	0	0	0
Rash	3 (10.0)	2 (6.7)	1 (3.3)	0	0

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=30 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	13 (43.3)	1 (3.3)	3 (10.0)	7 (23.3)	2 (6.7)
Hypotension	9 (30.0)	0	0	7 (23.3)	2 (6.7)
Hypertension	4 (13.3)	1 (3.3)	3 (10.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188d
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	43 (95.6)	1 (2.2)	2 (4.4)	9 (20.0)	31 (68.9)
Blood and lymphatic system disorders					
-Total	36 (80.0)	0	2 (4.4)	20 (44.4)	14 (31.1)
Anaemia	24 (53.3)	1 (2.2)	3 (6.7)	19 (42.2)	1 (2.2)
Febrile neutropenia	17 (37.8)	0	0	17 (37.8)	0
Thrombocytopenia	13 (28.9)	0	1 (2.2)	5 (11.1)	7 (15.6)
Neutropenia	12 (26.7)	0	0	1 (2.2)	11 (24.4)
Disseminated intravascular coagulation	5 (11.1)	0	1 (2.2)	3 (6.7)	1 (2.2)
Cardiac disorders					
-Total	14 (31.1)	5 (11.1)	6 (13.3)	3 (6.7)	0

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	10 (22.2)	3 (6.7)	5 (11.1)	2 (4.4)	0
Sinus tachycardia	5 (11.1)	3 (6.7)	1 (2.2)	1 (2.2)	0
Gastrointestinal disorders					
-Total	32 (71.1)	10 (22.2)	13 (28.9)	8 (17.8)	1 (2.2)
Nausea	22 (48.9)	7 (15.6)	9 (20.0)	6 (13.3)	0
Vomiting	18 (40.0)	9 (20.0)	6 (13.3)	3 (6.7)	0
Diarrhoea	17 (37.8)	9 (20.0)	6 (13.3)	2 (4.4)	0
Abdominal pain	13 (28.9)	4 (8.9)	6 (13.3)	3 (6.7)	0
Constipation	9 (20.0)	7 (15.6)	2 (4.4)	0	0
Stomatitis	6 (13.3)	2 (4.4)	1 (2.2)	2 (4.4)	1 (2.2)
General disorders and administration site conditions					
-Total	33 (73.3)	11 (24.4)	14 (31.1)	7 (15.6)	1 (2.2)
Pyrexia	24 (53.3)	7 (15.6)	11 (24.4)	5 (11.1)	1 (2.2)
Fatigue	17 (37.8)	11 (24.4)	4 (8.9)	2 (4.4)	0
Catheter site pain	6 (13.3)	2 (4.4)	4 (8.9)	0	0
Chills	6 (13.3)	6 (13.3)	0	0	0
Pain	5 (11.1)	0	2 (4.4)	3 (6.7)	0

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders					
-Total	5 (11.1)	0	1 (2.2)	4 (8.9)	0
Hyperbilirubinaemia	5 (11.1)	0	1 (2.2)	4 (8.9)	0
Immune system disorders					
-Total	35 (77.8)	4 (8.9)	16 (35.6)	7 (15.6)	8 (17.8)
Cytokine release syndrome	30 (66.7)	4 (8.9)	13 (28.9)	5 (11.1)	8 (17.8)
Hypogammaglobulinaemia	18 (40.0)	4 (8.9)	10 (22.2)	4 (8.9)	0
Infections and infestations					
-Total	20 (44.4)	3 (6.7)	10 (22.2)	6 (13.3)	1 (2.2)
Upper respiratory tract infection	7 (15.6)	3 (6.7)	3 (6.7)	1 (2.2)	0
Pneumonia	6 (13.3)	0	4 (8.9)	1 (2.2)	1 (2.2)
Clostridium difficile colitis	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Rhinovirus infection	5 (11.1)	4 (8.9)	1 (2.2)	0	0
Otitis media	1 (2.2)	0	0	1 (2.2)	0
Parainfluenzae virus infection	1 (2.2)	0	0	1 (2.2)	0
Urinary tract infection	1 (2.2)	0	1 (2.2)	0	0
Injury, poisoning and procedural complications					

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (8.9)	0	3 (6.7)	1 (2.2)	0
Procedural pain	4 (8.9)	0	3 (6.7)	1 (2.2)	0
Investigations					
-Total	36 (80.0)	0	4 (8.9)	8 (17.8)	24 (53.3)
White blood cell count decreased	23 (51.1)	3 (6.7)	1 (2.2)	2 (4.4)	17 (37.8)
Aspartate aminotransferase increased	19 (42.2)	4 (8.9)	4 (8.9)	6 (13.3)	5 (11.1)
Alanine aminotransferase increased	17 (37.8)	2 (4.4)	4 (8.9)	10 (22.2)	1 (2.2)
Neutrophil count decreased	17 (37.8)	0	2 (4.4)	1 (2.2)	14 (31.1)
Platelet count decreased	14 (31.1)	0	0	2 (4.4)	12 (26.7)
International normalised ratio increased	10 (22.2)	8 (17.8)	1 (2.2)	1 (2.2)	0
Lymphocyte count decreased	10 (22.2)	0	2 (4.4)	3 (6.7)	5 (11.1)
Blood bilirubin increased	7 (15.6)	1 (2.2)	2 (4.4)	3 (6.7)	1 (2.2)
Prothrombin time prolonged	7 (15.6)	4 (8.9)	2 (4.4)	1 (2.2)	0
Blood creatinine increased	5 (11.1)	1 (2.2)	2 (4.4)	2 (4.4)	0
Activated partial thromboplastin time prolonged	3 (6.7)	1 (2.2)	2 (4.4)	0	0
Metabolism and nutrition disorders					

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	32 (71.1)	2 (4.4)	5 (11.1)	21 (46.7)	4 (8.9)
Decreased appetite	18 (40.0)	4 (8.9)	3 (6.7)	11 (24.4)	0
Hypokalaemia	14 (31.1)	2 (4.4)	2 (4.4)	7 (15.6)	3 (6.7)
Hypophosphataemia	10 (22.2)	3 (6.7)	1 (2.2)	6 (13.3)	0
Fluid overload	6 (13.3)	1 (2.2)	4 (8.9)	1 (2.2)	0
Hypoalbuminaemia	6 (13.3)	1 (2.2)	4 (8.9)	0	1 (2.2)
Hypocalcaemia	6 (13.3)	3 (6.7)	1 (2.2)	1 (2.2)	1 (2.2)
Dehydration	5 (11.1)	0	1 (2.2)	4 (8.9)	0
Hyperglycaemia	5 (11.1)	0	2 (4.4)	2 (4.4)	1 (2.2)
Hypernatraemia	4 (8.9)	0	2 (4.4)	1 (2.2)	1 (2.2)
Hyperphosphataemia	4 (8.9)	4 (8.9)	0	0	0
Hyperuricaemia	3 (6.7)	1 (2.2)	0	1 (2.2)	1 (2.2)
Hypomagnesaemia	1 (2.2)	1 (2.2)	0	0	0
Tumour lysis syndrome	1 (2.2)	0	0	1 (2.2)	0
Musculoskeletal and connective tissue disorders					
-Total	17 (37.8)	6 (13.3)	5 (11.1)	6 (13.3)	0
Pain in extremity	12 (26.7)	4 (8.9)	4 (8.9)	4 (8.9)	0

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Myalgia	6 (13.3)	4 (8.9)	1 (2.2)	1 (2.2)	0
Arthralgia	4 (8.9)	1 (2.2)	1 (2.2)	2 (4.4)	0
Back pain	1 (2.2)	0	0	1 (2.2)	0
Nervous system disorders					
-Total	20 (44.4)	9 (20.0)	7 (15.6)	4 (8.9)	0
Headache	20 (44.4)	9 (20.0)	7 (15.6)	4 (8.9)	0
Psychiatric disorders					
-Total	14 (31.1)	4 (8.9)	9 (20.0)	1 (2.2)	0
Anxiety	9 (20.0)	3 (6.7)	5 (11.1)	1 (2.2)	0
Confusional state	7 (15.6)	2 (4.4)	5 (11.1)	0	0
Renal and urinary disorders					
-Total	10 (22.2)	3 (6.7)	1 (2.2)	2 (4.4)	4 (8.9)
Acute kidney injury	8 (17.8)	2 (4.4)	1 (2.2)	2 (4.4)	3 (6.7)
Haematuria	5 (11.1)	1 (2.2)	2 (4.4)	1 (2.2)	1 (2.2)
Respiratory, thoracic and mediastinal disorders					
-Total	22 (48.9)	3 (6.7)	2 (4.4)	11 (24.4)	6 (13.3)
Hypoxia	14 (31.1)	0	1 (2.2)	9 (20.0)	4 (8.9)

Ethnicity: Other

	All patients N=45				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	10 (22.2)	9 (20.0)	0	1 (2.2)	0
Epistaxis	9 (20.0)	1 (2.2)	3 (6.7)	4 (8.9)	1 (2.2)
Pleural effusion	9 (20.0)	1 (2.2)	6 (13.3)	2 (4.4)	0
Dyspnoea	5 (11.1)	1 (2.2)	1 (2.2)	2 (4.4)	1 (2.2)
Oropharyngeal pain	5 (11.1)	3 (6.7)	1 (2.2)	1 (2.2)	0
Pulmonary oedema	5 (11.1)	0	0	3 (6.7)	2 (4.4)
Tachypnoea	5 (11.1)	0	2 (4.4)	3 (6.7)	0
Nasal congestion	2 (4.4)	2 (4.4)	0	0	0
Rhinorrhoea	2 (4.4)	2 (4.4)	0	0	0
Respiratory failure	1 (2.2)	0	0	0	1 (2.2)
Skin and subcutaneous tissue disorders					
-Total	8 (17.8)	6 (13.3)	2 (4.4)	0	0
Rash	7 (15.6)	5 (11.1)	2 (4.4)	0	0
Dry skin	2 (4.4)	2 (4.4)	0	0	0
Pruritus	2 (4.4)	2 (4.4)	0	0	0
Vascular disorders					
-Total	20 (44.4)	2 (4.4)	1 (2.2)	8 (17.8)	9 (20.0)

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	16 (35.6)	1 (2.2)	0	6 (13.3)	9 (20.0)
Hypertension	12 (26.7)	3 (6.7)	6 (13.3)	3 (6.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188e
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	0	1 (12.5)	7 (87.5)
Blood and lymphatic system disorders					
-Total	7 (87.5)	0	0	5 (62.5)	2 (25.0)
Anaemia	5 (62.5)	1 (12.5)	0	3 (37.5)	1 (12.5)
Febrile neutropenia	5 (62.5)	0	0	5 (62.5)	0
Neutropenia	2 (25.0)	0	0	0	2 (25.0)
Thrombocytopenia	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Cardiac disorders					
-Total	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Left ventricular dysfunction	2 (25.0)	0	0	2 (25.0)	0
Tachycardia	2 (25.0)	1 (12.5)	0	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Palpitations	1 (12.5)	1 (12.5)	0	0	0
Pericardial effusion	1 (12.5)	1 (12.5)	0	0	0
Endocrine disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Adrenal insufficiency	1 (12.5)	1 (12.5)	0	0	0
Eye disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Eye pain	1 (12.5)	1 (12.5)	0	0	0
Gastrointestinal disorders					
-Total	7 (87.5)	2 (25.0)	1 (12.5)	3 (37.5)	1 (12.5)
Nausea	5 (62.5)	1 (12.5)	2 (25.0)	2 (25.0)	0
Vomiting	5 (62.5)	3 (37.5)	2 (25.0)	0	0
Diarrhoea	4 (50.0)	3 (37.5)	1 (12.5)	0	0
Abdominal pain	3 (37.5)	2 (25.0)	1 (12.5)	0	0
Oral pain	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Stomatitis	2 (25.0)	1 (12.5)	0	0	1 (12.5)
Constipation	1 (12.5)	1 (12.5)	0	0	0
Dyspepsia	1 (12.5)	0	1 (12.5)	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterocolitis	1 (12.5)	0	0	1 (12.5)	0
General disorders and administration site conditions					
-Total	6 (75.0)	1 (12.5)	1 (12.5)	3 (37.5)	1 (12.5)
Pyrexia	5 (62.5)	1 (12.5)	1 (12.5)	2 (25.0)	1 (12.5)
Fatigue	3 (37.5)	2 (25.0)	0	1 (12.5)	0
Pain	2 (25.0)	0	0	2 (25.0)	0
Asthenia	1 (12.5)	1 (12.5)	0	0	0
Catheter site pain	1 (12.5)	0	1 (12.5)	0	0
Chills	1 (12.5)	1 (12.5)	0	0	0
Hepatobiliary disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hepatomegaly	1 (12.5)	0	1 (12.5)	0	0
Immune system disorders					
-Total	7 (87.5)	0	4 (50.0)	0	3 (37.5)
Cytokine release syndrome	5 (62.5)	0	2 (25.0)	0	3 (37.5)
Hypogammaglobulinaemia	4 (50.0)	0	4 (50.0)	0	0
Graft versus host disease	1 (12.5)	0	1 (12.5)	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	6 (75.0)	1 (12.5)	2 (25.0)	1 (12.5)	2 (25.0)
Upper respiratory tract infection	2 (25.0)	0	2 (25.0)	0	0
Viral infection	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Cellulitis	1 (12.5)	0	0	1 (12.5)	0
Clostridium difficile infection	1 (12.5)	0	1 (12.5)	0	0
Corona virus infection	1 (12.5)	0	0	1 (12.5)	0
Ear infection	1 (12.5)	1 (12.5)	0	0	0
Gastroenteritis	1 (12.5)	0	1 (12.5)	0	0
Human polyomavirus infection	1 (12.5)	0	0	0	1 (12.5)
Oral herpes	1 (12.5)	0	0	1 (12.5)	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Respiratory syncytial virus infection	1 (12.5)	0	0	1 (12.5)	0
Rhinovirus infection	1 (12.5)	1 (12.5)	0	0	0
Skin infection	1 (12.5)	0	1 (12.5)	0	0
Tinea capitis	1 (12.5)	1 (12.5)	0	0	0
Injury, poisoning and procedural complications					

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Contusion	1 (12.5)	1 (12.5)	0	0	0
Infusion related reaction	1 (12.5)	0	1 (12.5)	0	0
Procedural nausea	1 (12.5)	0	1 (12.5)	0	0
Procedural pain	1 (12.5)	0	0	1 (12.5)	0
Sunburn	1 (12.5)	1 (12.5)	0	0	0
Tracheal haemorrhage	1 (12.5)	0	0	1 (12.5)	0
Wound	1 (12.5)	1 (12.5)	0	0	0
Investigations					
-Total	7 (87.5)	0	1 (12.5)	2 (25.0)	4 (50.0)
Neutrophil count decreased	4 (50.0)	0	1 (12.5)	0	3 (37.5)
White blood cell count decreased	4 (50.0)	1 (12.5)	0	0	3 (37.5)
Blood magnesium decreased	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Lymphocyte count decreased	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Activated partial thromboplastin time prolonged	1 (12.5)	1 (12.5)	0	0	0
Aspartate aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)
Blood bilirubin increased	1 (12.5)	0	0	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	1 (12.5)	0	1 (12.5)	0	0
Blood fibrinogen decreased	1 (12.5)	0	1 (12.5)	0	0
Blood immunoglobulin m decreased	1 (12.5)	1 (12.5)	0	0	0
Blood phosphorus increased	1 (12.5)	1 (12.5)	0	0	0
Blood uric acid increased	1 (12.5)	1 (12.5)	0	0	0
Cardiac murmur	1 (12.5)	1 (12.5)	0	0	0
Fibrin d dimer increased	1 (12.5)	1 (12.5)	0	0	0
International normalised ratio increased	1 (12.5)	1 (12.5)	0	0	0
Prothrombin time prolonged	1 (12.5)	0	1 (12.5)	0	0
Weight decreased	1 (12.5)	1 (12.5)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (62.5)	1 (12.5)	3 (37.5)	1 (12.5)	0
Decreased appetite	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Hypokalaemia	3 (37.5)	2 (25.0)	1 (12.5)	0	0
Dehydration	1 (12.5)	0	1 (12.5)	0	0
Hypernatraemia	1 (12.5)	0	1 (12.5)	0	0
Hypoalbuminaemia	1 (12.5)	1 (12.5)	0	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypomagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Hypophosphataemia	1 (12.5)	0	0	1 (12.5)	0
Vitamin d deficiency	1 (12.5)	0	1 (12.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	6 (75.0)	3 (37.5)	1 (12.5)	2 (25.0)	0
Pain in extremity	4 (50.0)	3 (37.5)	0	1 (12.5)	0
Arthralgia	1 (12.5)	0	0	1 (12.5)	0
Muscular weakness	1 (12.5)	1 (12.5)	0	0	0
Neck pain	1 (12.5)	0	1 (12.5)	0	0
Pain in jaw	1 (12.5)	1 (12.5)	0	0	0
Nervous system disorders					
-Total	5 (62.5)	3 (37.5)	2 (25.0)	0	0
Headache	4 (50.0)	2 (25.0)	2 (25.0)	0	0
Dizziness	1 (12.5)	1 (12.5)	0	0	0
Dysgeusia	1 (12.5)	1 (12.5)	0	0	0
Peroneal nerve palsy	1 (12.5)	1 (12.5)	0	0	0
Psychiatric disorders					

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (62.5)	1 (12.5)	4 (50.0)	0	0
Confusional state	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Depression	3 (37.5)	2 (25.0)	1 (12.5)	0	0
Anxiety	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Delirium	1 (12.5)	1 (12.5)	0	0	0
Insomnia	1 (12.5)	0	1 (12.5)	0	0
Sleep disorder	1 (12.5)	0	1 (12.5)	0	0
Renal and urinary disorders					
-Total	2 (25.0)	0	0	0	2 (25.0)
Haematuria	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Acute kidney injury	1 (12.5)	0	0	0	1 (12.5)
Cystitis haemorrhagic	1 (12.5)	0	0	0	1 (12.5)
Oliguria	1 (12.5)	0	0	1 (12.5)	0
Renal failure	1 (12.5)	0	0	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders					
-Total	7 (87.5)	2 (25.0)	1 (12.5)	1 (12.5)	3 (37.5)
Cough	3 (37.5)	3 (37.5)	0	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	3 (37.5)	0	1 (12.5)	1 (12.5)	1 (12.5)
Hypoxia	3 (37.5)	0	0	2 (25.0)	1 (12.5)
Rhinorrhoea	3 (37.5)	2 (25.0)	1 (12.5)	0	0
Nasal congestion	2 (25.0)	2 (25.0)	0	0	0
Oropharyngeal pain	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Pleural effusion	2 (25.0)	0	2 (25.0)	0	0
Aspiration	1 (12.5)	0	0	0	1 (12.5)
Dyspnoea	1 (12.5)	0	0	0	1 (12.5)
Haemoptysis	1 (12.5)	0	0	0	1 (12.5)
Interstitial lung disease	1 (12.5)	0	0	0	1 (12.5)
Pharyngeal erythema	1 (12.5)	1 (12.5)	0	0	0
Pharyngeal lesion	1 (12.5)	0	0	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)
Respiratory failure	1 (12.5)	0	0	0	1 (12.5)
Skin and subcutaneous tissue disorders					
-Total	4 (50.0)	3 (37.5)	1 (12.5)	0	0
Erythema	2 (25.0)	2 (25.0)	0	0	0

Response status at study entry: Primary refractory

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alopecia	1 (12.5)	0	1 (12.5)	0	0
Dermatitis diaper	1 (12.5)	1 (12.5)	0	0	0
Dry skin	1 (12.5)	1 (12.5)	0	0	0
Livedo reticularis	1 (12.5)	1 (12.5)	0	0	0
Rash erythematous	1 (12.5)	0	1 (12.5)	0	0
Rash maculo-papular	1 (12.5)	1 (12.5)	0	0	0
Rash papular	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	6 (75.0)	0	1 (12.5)	2 (25.0)	3 (37.5)
Hypotension	5 (62.5)	0	0	2 (25.0)	3 (37.5)
Hypertension	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Haematoma	1 (12.5)	0	1 (12.5)	0	0
Hot flush	1 (12.5)	1 (12.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188e
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	65 (97.0)	1 (1.5)	4 (6.0)	13 (19.4)	47 (70.1)
Blood and lymphatic system disorders					
-Total	56 (83.6)	0	2 (3.0)	35 (52.2)	19 (28.4)
Anaemia	36 (53.7)	1 (1.5)	7 (10.4)	28 (41.8)	0
Febrile neutropenia	33 (49.3)	0	0	32 (47.8)	1 (1.5)
Neutropenia	17 (25.4)	0	0	4 (6.0)	13 (19.4)
Thrombocytopenia	15 (22.4)	0	1 (1.5)	5 (7.5)	9 (13.4)
Disseminated intravascular coagulation	7 (10.4)	0	2 (3.0)	4 (6.0)	1 (1.5)
Cardiac disorders					
-Total	23 (34.3)	9 (13.4)	10 (14.9)	4 (6.0)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	15 (22.4)	8 (11.9)	6 (9.0)	1 (1.5)	0
Sinus tachycardia	7 (10.4)	3 (4.5)	2 (3.0)	2 (3.0)	0
Pericardial effusion	3 (4.5)	0	3 (4.5)	0	0
Left ventricular dysfunction	1 (1.5)	0	0	1 (1.5)	0
Palpitations	1 (1.5)	1 (1.5)	0	0	0
Endocrine disorders					
-Total	2 (3.0)	0	2 (3.0)	0	0
Adrenal insufficiency	2 (3.0)	0	2 (3.0)	0	0
Eye disorders					
-Total	2 (3.0)	0	2 (3.0)	0	0
Eye pain	2 (3.0)	0	2 (3.0)	0	0
Gastrointestinal disorders					
-Total	47 (70.1)	11 (16.4)	25 (37.3)	11 (16.4)	0
Nausea	31 (46.3)	7 (10.4)	19 (28.4)	5 (7.5)	0
Vomiting	28 (41.8)	14 (20.9)	10 (14.9)	4 (6.0)	0
Diarrhoea	23 (34.3)	11 (16.4)	9 (13.4)	3 (4.5)	0
Abdominal pain	15 (22.4)	4 (6.0)	7 (10.4)	4 (6.0)	0
Constipation	13 (19.4)	10 (14.9)	3 (4.5)	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	5 (7.5)	1 (1.5)	1 (1.5)	3 (4.5)	0
Dyspepsia	1 (1.5)	0	1 (1.5)	0	0
Oral pain	1 (1.5)	0	1 (1.5)	0	0
General disorders and administration site conditions					
-Total	44 (65.7)	16 (23.9)	21 (31.3)	7 (10.4)	0
Pyrexia	31 (46.3)	11 (16.4)	14 (20.9)	6 (9.0)	0
Fatigue	18 (26.9)	13 (19.4)	4 (6.0)	1 (1.5)	0
Chills	11 (16.4)	9 (13.4)	2 (3.0)	0	0
Catheter site pain	6 (9.0)	2 (3.0)	4 (6.0)	0	0
Pain	6 (9.0)	1 (1.5)	4 (6.0)	1 (1.5)	0
Asthenia	1 (1.5)	0	1 (1.5)	0	0
Hepatobiliary disorders					
-Total	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Hepatomegaly	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Immune system disorders					
-Total	52 (77.6)	6 (9.0)	27 (40.3)	11 (16.4)	8 (11.9)
Cytokine release syndrome	45 (67.2)	6 (9.0)	23 (34.3)	8 (11.9)	8 (11.9)

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	29 (43.3)	4 (6.0)	20 (29.9)	5 (7.5)	0
Graft versus host disease	1 (1.5)	1 (1.5)	0	0	0
Infections and infestations					
-Total	27 (40.3)	5 (7.5)	18 (26.9)	4 (6.0)	0
Upper respiratory tract infection	9 (13.4)	5 (7.5)	3 (4.5)	1 (1.5)	0
Pneumonia	6 (9.0)	0	5 (7.5)	1 (1.5)	0
Clostridium difficile infection	5 (7.5)	0	4 (6.0)	1 (1.5)	0
Rhinovirus infection	5 (7.5)	4 (6.0)	1 (1.5)	0	0
Gastroenteritis	4 (6.0)	1 (1.5)	2 (3.0)	1 (1.5)	0
Oral herpes	3 (4.5)	0	3 (4.5)	0	0
Ear infection	1 (1.5)	0	1 (1.5)	0	0
Respiratory syncytial virus infection	1 (1.5)	0	1 (1.5)	0	0
Skin infection	1 (1.5)	0	1 (1.5)	0	0
Viral infection	1 (1.5)	1 (1.5)	0	0	0
Injury, poisoning and procedural complications					
-Total	11 (16.4)	4 (6.0)	5 (7.5)	2 (3.0)	0
Procedural pain	7 (10.4)	1 (1.5)	4 (6.0)	2 (3.0)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infusion related reaction	4 (6.0)	2 (3.0)	2 (3.0)	0	0
Contusion	2 (3.0)	2 (3.0)	0	0	0
Investigations					
-Total	52 (77.6)	0	3 (4.5)	9 (13.4)	40 (59.7)
White blood cell count decreased	40 (59.7)	3 (4.5)	1 (1.5)	8 (11.9)	28 (41.8)
Neutrophil count decreased	31 (46.3)	1 (1.5)	1 (1.5)	3 (4.5)	26 (38.8)
Alanine aminotransferase increased	26 (38.8)	3 (4.5)	4 (6.0)	18 (26.9)	1 (1.5)
Platelet count decreased	26 (38.8)	3 (4.5)	2 (3.0)	4 (6.0)	17 (25.4)
Aspartate aminotransferase increased	23 (34.3)	5 (7.5)	5 (7.5)	9 (13.4)	4 (6.0)
Lymphocyte count decreased	17 (25.4)	0	2 (3.0)	7 (10.4)	8 (11.9)
International normalised ratio increased	10 (14.9)	8 (11.9)	1 (1.5)	1 (1.5)	0
Blood bilirubin increased	9 (13.4)	2 (3.0)	3 (4.5)	3 (4.5)	1 (1.5)
Blood creatinine increased	8 (11.9)	5 (7.5)	1 (1.5)	2 (3.0)	0
Prothrombin time prolonged	8 (11.9)	5 (7.5)	2 (3.0)	1 (1.5)	0
Activated partial thromboplastin time prolonged	5 (7.5)	2 (3.0)	3 (4.5)	0	0
Blood fibrinogen decreased	4 (6.0)	0	1 (1.5)	2 (3.0)	1 (1.5)

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	4 (6.0)	4 (6.0)	0	0	0
Weight decreased	4 (6.0)	1 (1.5)	3 (4.5)	0	0
Blood uric acid increased	2 (3.0)	2 (3.0)	0	0	0
Blood phosphorus increased	1 (1.5)	1 (1.5)	0	0	0
Metabolism and nutrition disorders					
-Total	47 (70.1)	4 (6.0)	10 (14.9)	24 (35.8)	9 (13.4)
Decreased appetite	29 (43.3)	6 (9.0)	9 (13.4)	14 (20.9)	0
Hypokalaemia	21 (31.3)	3 (4.5)	3 (4.5)	10 (14.9)	5 (7.5)
Hypophosphataemia	13 (19.4)	4 (6.0)	1 (1.5)	7 (10.4)	1 (1.5)
Hyperglycaemia	10 (14.9)	0	4 (6.0)	5 (7.5)	1 (1.5)
Hyperphosphataemia	9 (13.4)	8 (11.9)	1 (1.5)	0	0
Hyperuricaemia	8 (11.9)	5 (7.5)	0	1 (1.5)	2 (3.0)
Fluid overload	7 (10.4)	1 (1.5)	5 (7.5)	1 (1.5)	0
Hypocalcaemia	7 (10.4)	3 (4.5)	1 (1.5)	1 (1.5)	2 (3.0)
Dehydration	6 (9.0)	1 (1.5)	1 (1.5)	4 (6.0)	0
Hypernatraemia	6 (9.0)	1 (1.5)	1 (1.5)	1 (1.5)	3 (4.5)
Hypoalbuminaemia	6 (9.0)	0	4 (6.0)	1 (1.5)	1 (1.5)
Hypomagnesaemia	5 (7.5)	4 (6.0)	1 (1.5)	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vitamin d deficiency	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	21 (31.3)	8 (11.9)	9 (13.4)	4 (6.0)	0
Pain in extremity	14 (20.9)	5 (7.5)	5 (7.5)	4 (6.0)	0
Arthralgia	7 (10.4)	4 (6.0)	2 (3.0)	1 (1.5)	0
Pain in jaw	4 (6.0)	1 (1.5)	3 (4.5)	0	0
Neck pain	3 (4.5)	1 (1.5)	2 (3.0)	0	0
Muscular weakness	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Nervous system disorders					
-Total	31 (46.3)	15 (22.4)	10 (14.9)	6 (9.0)	0
Headache	27 (40.3)	12 (17.9)	9 (13.4)	6 (9.0)	0
Dizziness	5 (7.5)	5 (7.5)	0	0	0
Peroneal nerve palsy	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Psychiatric disorders					
-Total	18 (26.9)	6 (9.0)	10 (14.9)	2 (3.0)	0
Anxiety	8 (11.9)	2 (3.0)	5 (7.5)	1 (1.5)	0
Confusional state	5 (7.5)	2 (3.0)	3 (4.5)	0	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	4 (6.0)	1 (1.5)	2 (3.0)	1 (1.5)	0
Insomnia	3 (4.5)	0	3 (4.5)	0	0
Depression	2 (3.0)	1 (1.5)	1 (1.5)	0	0
Renal and urinary disorders					
-Total	14 (20.9)	3 (4.5)	1 (1.5)	7 (10.4)	3 (4.5)
Acute kidney injury	11 (16.4)	2 (3.0)	1 (1.5)	5 (7.5)	3 (4.5)
Haematuria	4 (6.0)	1 (1.5)	2 (3.0)	1 (1.5)	0
Oliguria	2 (3.0)	0	0	2 (3.0)	0
Cystitis haemorrhagic	1 (1.5)	0	0	1 (1.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	33 (49.3)	10 (14.9)	6 (9.0)	10 (14.9)	7 (10.4)
Cough	13 (19.4)	10 (14.9)	2 (3.0)	1 (1.5)	0
Hypoxia	13 (19.4)	0	3 (4.5)	7 (10.4)	3 (4.5)
Epistaxis	11 (16.4)	4 (6.0)	3 (4.5)	4 (6.0)	0
Pleural effusion	8 (11.9)	1 (1.5)	4 (6.0)	3 (4.5)	0
Pulmonary oedema	8 (11.9)	1 (1.5)	0	4 (6.0)	3 (4.5)
Tachypnoea	8 (11.9)	3 (4.5)	2 (3.0)	3 (4.5)	0

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oropharyngeal pain	6 (9.0)	4 (6.0)	1 (1.5)	1 (1.5)	0
Nasal congestion	5 (7.5)	5 (7.5)	0	0	0
Dyspnoea	4 (6.0)	1 (1.5)	1 (1.5)	2 (3.0)	0
Rhinorrhoea	4 (6.0)	4 (6.0)	0	0	0
Respiratory failure	3 (4.5)	0	0	0	3 (4.5)
Haemoptysis	2 (3.0)	1 (1.5)	0	1 (1.5)	0
Skin and subcutaneous tissue disorders					
-Total	23 (34.3)	15 (22.4)	7 (10.4)	1 (1.5)	0
Rash	10 (14.9)	7 (10.4)	3 (4.5)	0	0
Dry skin	4 (6.0)	4 (6.0)	0	0	0
Rash erythematous	4 (6.0)	2 (3.0)	2 (3.0)	0	0
Rash maculo-papular	4 (6.0)	2 (3.0)	1 (1.5)	1 (1.5)	0
Alopecia	3 (4.5)	2 (3.0)	1 (1.5)	0	0
Erythema	3 (4.5)	3 (4.5)	0	0	0
Rash papular	3 (4.5)	3 (4.5)	0	0	0
Vascular disorders					
-Total	27 (40.3)	3 (4.5)	3 (4.5)	13 (19.4)	8 (11.9)

Response status at study entry: Relapsed disease

	All patients N=67				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	20 (29.9)	1 (1.5)	0	11 (16.4)	8 (11.9)
Hypertension	13 (19.4)	3 (4.5)	7 (10.4)	3 (4.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188f
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	0	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders					
-Total	2 (100)	0	1 (50.0)	0	1 (50.0)
Anaemia	1 (50.0)	0	1 (50.0)	0	0
Eosinophilia	1 (50.0)	0	0	1 (50.0)	0
Lymphopenia	1 (50.0)	0	1 (50.0)	0	0
Neutropenia	1 (50.0)	0	0	0	1 (50.0)
Cardiac disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Sinus tachycardia	1 (50.0)	0	0	1 (50.0)	0
Gastrointestinal disorders					

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (50.0)	0	1 (50.0)	0	0
Diarrhoea	1 (50.0)	0	1 (50.0)	0	0
Pigmentation lip	1 (50.0)	1 (50.0)	0	0	0
General disorders and administration site conditions					
-Total	2 (100)	1 (50.0)	1 (50.0)	0	0
Fatigue	2 (100)	2 (100)	0	0	0
Chills	1 (50.0)	1 (50.0)	0	0	0
Non-cardiac chest pain	1 (50.0)	1 (50.0)	0	0	0
Pain	1 (50.0)	1 (50.0)	0	0	0
Pyrexia	1 (50.0)	0	1 (50.0)	0	0
Immune system disorders					
-Total	2 (100)	1 (50.0)	1 (50.0)	0	0
Graft versus host disease	1 (50.0)	1 (50.0)	0	0	0
Graft versus host disease in skin	1 (50.0)	1 (50.0)	0	0	0
Hypogammaglobulinaemia	1 (50.0)	0	1 (50.0)	0	0
Infections and infestations					
-Total	1 (50.0)	0	0	1 (50.0)	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (50.0)	0	0	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	0	0	1 (50.0)	0
Otitis media	1 (50.0)	0	1 (50.0)	0	0
Urinary tract infection	1 (50.0)	0	0	1 (50.0)	0
Injury, poisoning and procedural complications					
-Total	1 (50.0)	1 (50.0)	0	0	0
Skin abrasion	1 (50.0)	1 (50.0)	0	0	0
Investigations					
-Total	1 (50.0)	0	1 (50.0)	0	0
Alanine aminotransferase increased	1 (50.0)	0	1 (50.0)	0	0
Aspartate aminotransferase increased	1 (50.0)	1 (50.0)	0	0	0
Blood fibrinogen decreased	1 (50.0)	0	1 (50.0)	0	0
Blood immunoglobulin a decreased	1 (50.0)	1 (50.0)	0	0	0
Blood immunoglobulin m decreased	1 (50.0)	1 (50.0)	0	0	0
Blood uric acid increased	1 (50.0)	1 (50.0)	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	1 (50.0)	1 (50.0)	0	0	0
Lymphocyte count decreased	1 (50.0)	0	1 (50.0)	0	0
Neutrophil count decreased	1 (50.0)	0	1 (50.0)	0	0
White blood cell count decreased	1 (50.0)	0	1 (50.0)	0	0
Metabolism and nutrition disorders					
-Total	2 (100)	0	1 (50.0)	1 (50.0)	0
Decreased appetite	1 (50.0)	0	1 (50.0)	0	0
Hyperglycaemia	1 (50.0)	0	0	1 (50.0)	0
Hyperphosphataemia	1 (50.0)	1 (50.0)	0	0	0
Hyperuricaemia	1 (50.0)	1 (50.0)	0	0	0
Vitamin d deficiency	1 (50.0)	1 (50.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (100)	2 (100)	0	0	0
Joint range of motion decreased	2 (100)	2 (100)	0	0	0
Arthralgia	1 (50.0)	1 (50.0)	0	0	0
Back pain	1 (50.0)	1 (50.0)	0	0	0
Muscle spasms	1 (50.0)	1 (50.0)	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Myalgia	1 (50.0)	1 (50.0)	0	0	0
Pain in extremity	1 (50.0)	1 (50.0)	0	0	0
Nervous system disorders					
-Total	2 (100)	2 (100)	0	0	0
Headache	2 (100)	2 (100)	0	0	0
Reproductive system and breast disorders					
-Total	1 (50.0)	0	1 (50.0)	0	0
Scrotal pain	1 (50.0)	0	1 (50.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Cough	1 (50.0)	1 (50.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (50.0)	1 (50.0)	0	0	0
Macule	1 (50.0)	1 (50.0)	0	0	0
Rash maculo-papular	1 (50.0)	1 (50.0)	0	0	0
Skin irritation	1 (50.0)	1 (50.0)	0	0	0

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders					
-Total	1 (50.0)	0	0	1 (50.0)	0
Hypotension	1 (50.0)	0	0	1 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188f
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	70 (95.9)	1 (1.4)	3 (4.1)	13 (17.8)	53 (72.6)
Blood and lymphatic system disorders					
-Total	61 (83.6)	0	1 (1.4)	39 (53.4)	21 (28.8)
Anaemia	40 (54.8)	2 (2.7)	6 (8.2)	31 (42.5)	1 (1.4)
Febrile neutropenia	38 (52.1)	0	0	37 (50.7)	1 (1.4)
Neutropenia	18 (24.7)	0	0	4 (5.5)	14 (19.2)
Thrombocytopenia	17 (23.3)	0	1 (1.4)	6 (8.2)	10 (13.7)
Lymphopenia	5 (6.8)	0	1 (1.4)	1 (1.4)	3 (4.1)
Cardiac disorders					
-Total	22 (30.1)	11 (15.1)	8 (11.0)	3 (4.1)	0
Tachycardia	17 (23.3)	9 (12.3)	6 (8.2)	2 (2.7)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	6 (8.2)	3 (4.1)	2 (2.7)	1 (1.4)	0
Gastrointestinal disorders					
-Total	52 (71.2)	15 (20.5)	26 (35.6)	11 (15.1)	0
Nausea	36 (49.3)	8 (11.0)	21 (28.8)	7 (9.6)	0
Vomiting	33 (45.2)	17 (23.3)	12 (16.4)	4 (5.5)	0
Diarrhoea	26 (35.6)	14 (19.2)	9 (12.3)	3 (4.1)	0
Abdominal pain	18 (24.7)	6 (8.2)	8 (11.0)	4 (5.5)	0
Constipation	14 (19.2)	11 (15.1)	3 (4.1)	0	0
General disorders and administration site conditions					
-Total	46 (63.0)	15 (20.5)	19 (26.0)	11 (15.1)	1 (1.4)
Pyrexia	35 (47.9)	12 (16.4)	14 (19.2)	8 (11.0)	1 (1.4)
Fatigue	19 (26.0)	13 (17.8)	4 (5.5)	2 (2.7)	0
Chills	11 (15.1)	9 (12.3)	2 (2.7)	0	0
Pain	7 (9.6)	0	4 (5.5)	3 (4.1)	0
Non-cardiac chest pain	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Immune system disorders					
-Total	57 (78.1)	5 (6.8)	30 (41.1)	11 (15.1)	11 (15.1)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	50 (68.5)	6 (8.2)	25 (34.2)	8 (11.0)	11 (15.1)
Hypogammaglobulinaemia	32 (43.8)	4 (5.5)	23 (31.5)	5 (6.8)	0
Graft versus host disease	1 (1.4)	0	1 (1.4)	0	0
Infections and infestations					
-Total	16 (21.9)	2 (2.7)	10 (13.7)	4 (5.5)	0
Upper respiratory tract infection	11 (15.1)	5 (6.8)	5 (6.8)	1 (1.4)	0
Urinary tract infection	4 (5.5)	0	3 (4.1)	1 (1.4)	0
Otitis media	3 (4.1)	0	2 (2.7)	1 (1.4)	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	9 (12.3)	2 (2.7)	4 (5.5)	3 (4.1)	0
Procedural pain	8 (11.0)	1 (1.4)	4 (5.5)	3 (4.1)	0
Skin abrasion	1 (1.4)	1 (1.4)	0	0	0
Investigations					
-Total	58 (79.5)	0	4 (5.5)	10 (13.7)	44 (60.3)
White blood cell count decreased	43 (58.9)	4 (5.5)	0	8 (11.0)	31 (42.5)
Neutrophil count decreased	34 (46.6)	1 (1.4)	1 (1.4)	3 (4.1)	29 (39.7)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	26 (35.6)	3 (4.1)	2 (2.7)	4 (5.5)	17 (23.3)
Alanine aminotransferase increased	25 (34.2)	3 (4.1)	3 (4.1)	18 (24.7)	1 (1.4)
Aspartate aminotransferase increased	23 (31.5)	4 (5.5)	5 (6.8)	9 (12.3)	5 (6.8)
Lymphocyte count decreased	18 (24.7)	1 (1.4)	2 (2.7)	7 (9.6)	8 (11.0)
Blood bilirubin increased	10 (13.7)	2 (2.7)	3 (4.1)	4 (5.5)	1 (1.4)
International normalised ratio increased	10 (13.7)	8 (11.0)	1 (1.4)	1 (1.4)	0
Blood creatinine increased	9 (12.3)	5 (6.8)	2 (2.7)	2 (2.7)	0
Prothrombin time prolonged	9 (12.3)	5 (6.8)	3 (4.1)	1 (1.4)	0
Blood fibrinogen decreased	4 (5.5)	0	1 (1.4)	2 (2.7)	1 (1.4)
Blood immunoglobulin m decreased	4 (5.5)	4 (5.5)	0	0	0
Blood immunoglobulin a decreased	2 (2.7)	2 (2.7)	0	0	0
Blood uric acid increased	2 (2.7)	2 (2.7)	0	0	0
Metabolism and nutrition disorders					
-Total	46 (63.0)	6 (8.2)	12 (16.4)	20 (27.4)	8 (11.0)
Decreased appetite	31 (42.5)	7 (9.6)	9 (12.3)	15 (20.5)	0
Hypokalaemia	24 (32.9)	5 (6.8)	4 (5.5)	10 (13.7)	5 (6.8)
Hypophosphataemia	14 (19.2)	4 (5.5)	1 (1.4)	8 (11.0)	1 (1.4)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	9 (12.3)	0	4 (5.5)	4 (5.5)	1 (1.4)
Hyperphosphataemia	8 (11.0)	7 (9.6)	1 (1.4)	0	0
Hyperuricaemia	7 (9.6)	4 (5.5)	0	1 (1.4)	2 (2.7)
Vitamin d deficiency	3 (4.1)	1 (1.4)	2 (2.7)	0	0
Musculoskeletal and connective tissue disorders					
-Total	27 (37.0)	12 (16.4)	7 (9.6)	8 (11.0)	0
Pain in extremity	17 (23.3)	7 (9.6)	5 (6.8)	5 (6.8)	0
Arthralgia	7 (9.6)	3 (4.1)	2 (2.7)	2 (2.7)	0
Myalgia	5 (6.8)	3 (4.1)	1 (1.4)	1 (1.4)	0
Back pain	3 (4.1)	1 (1.4)	0	2 (2.7)	0
Muscle spasms	2 (2.7)	2 (2.7)	0	0	0
Nervous system disorders					
-Total	29 (39.7)	12 (16.4)	11 (15.1)	6 (8.2)	0
Headache	29 (39.7)	12 (16.4)	11 (15.1)	6 (8.2)	0
Psychiatric disorders					
-Total	16 (21.9)	5 (6.8)	10 (13.7)	1 (1.4)	0
Anxiety	10 (13.7)	3 (4.1)	6 (8.2)	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	8 (11.0)	3 (4.1)	5 (6.8)	0	0
Renal and urinary disorders					
-Total	12 (16.4)	2 (2.7)	1 (1.4)	5 (6.8)	4 (5.5)
Acute kidney injury	12 (16.4)	2 (2.7)	1 (1.4)	5 (6.8)	4 (5.5)
Respiratory, thoracic and mediastinal disorders					
-Total	36 (49.3)	9 (12.3)	6 (8.2)	13 (17.8)	8 (11.0)
Hypoxia	16 (21.9)	0	3 (4.1)	9 (12.3)	4 (5.5)
Cough	15 (20.5)	12 (16.4)	2 (2.7)	1 (1.4)	0
Epistaxis	14 (19.2)	4 (5.5)	4 (5.5)	5 (6.8)	1 (1.4)
Pleural effusion	10 (13.7)	1 (1.4)	6 (8.2)	3 (4.1)	0
Pulmonary oedema	9 (12.3)	1 (1.4)	0	4 (5.5)	4 (5.5)
Oropharyngeal pain	8 (11.0)	5 (6.8)	2 (2.7)	1 (1.4)	0
Tachypnoea	8 (11.0)	3 (4.1)	2 (2.7)	3 (4.1)	0
Skin and subcutaneous tissue disorders					
-Total	15 (20.5)	10 (13.7)	4 (5.5)	1 (1.4)	0
Rash	10 (13.7)	7 (9.6)	3 (4.1)	0	0
Rash maculo-papular	4 (5.5)	2 (2.7)	1 (1.4)	1 (1.4)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Macule	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	32 (43.8)	3 (4.1)	4 (5.5)	14 (19.2)	11 (15.1)
Hypotension	24 (32.9)	1 (1.4)	0	12 (16.4)	11 (15.1)
Hypertension	16 (21.9)	4 (5.5)	9 (12.3)	3 (4.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188g
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	0	0	3 (100)
Blood and lymphatic system disorders					
-Total	3 (100)	0	0	1 (33.3)	2 (66.7)
Anaemia	2 (66.7)	0	0	2 (66.7)	0
Febrile neutropenia	2 (66.7)	0	0	2 (66.7)	0
Neutropenia	2 (66.7)	0	0	0	2 (66.7)
Leukopenia	1 (33.3)	0	0	0	1 (33.3)
Lymphopenia	1 (33.3)	0	0	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	0	0	1 (33.3)
Cardiac disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (33.3)	0	1 (33.3)	0	0
Left ventricular dysfunction	1 (33.3)	0	0	1 (33.3)	0
Pericardial effusion	1 (33.3)	0	1 (33.3)	0	0
Tachycardia	1 (33.3)	0	0	1 (33.3)	0
Eye disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Conjunctival haemorrhage	1 (33.3)	1 (33.3)	0	0	0
Periorbital oedema	1 (33.3)	1 (33.3)	0	0	0
Gastrointestinal disorders					
-Total	2 (66.7)	0	0	2 (66.7)	0
Nausea	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Abdominal pain	1 (33.3)	1 (33.3)	0	0	0
Colitis	1 (33.3)	1 (33.3)	0	0	0
Diarrhoea	1 (33.3)	0	1 (33.3)	0	0
Dyspepsia	1 (33.3)	0	1 (33.3)	0	0
Dysphagia	1 (33.3)	0	0	1 (33.3)	0
Perianal erythema	1 (33.3)	0	1 (33.3)	0	0
Vomiting	1 (33.3)	0	1 (33.3)	0	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	2 (66.7)	0	0	2 (66.7)	0
Pyrexia	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Asthenia	1 (33.3)	1 (33.3)	0	0	0
Chills	1 (33.3)	1 (33.3)	0	0	0
Face oedema	1 (33.3)	0	0	1 (33.3)	0
Fatigue	1 (33.3)	1 (33.3)	0	0	0
Localised oedema	1 (33.3)	0	0	1 (33.3)	0
Mucosal haemorrhage	1 (33.3)	0	1 (33.3)	0	0
Multiple organ dysfunction syndrome	1 (33.3)	0	0	1 (33.3)	0
Oedema peripheral	1 (33.3)	0	0	1 (33.3)	0
Hepatobiliary disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Hepatomegaly	1 (33.3)	0	1 (33.3)	0	0
Hyperbilirubinaemia	1 (33.3)	0	0	1 (33.3)	0
Immune system disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	2 (66.7)	0	0	0	2 (66.7)
Hypogammaglobulinaemia	1 (33.3)	0	0	1 (33.3)	0
Infections and infestations					
-Total	1 (33.3)	0	0	1 (33.3)	0
Escherichia bacteraemia	1 (33.3)	0	0	1 (33.3)	0
Pneumonia	1 (33.3)	0	1 (33.3)	0	0
Sinusitis	1 (33.3)	1 (33.3)	0	0	0
Upper respiratory tract infection	1 (33.3)	1 (33.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Procedural complication	1 (33.3)	1 (33.3)	0	0	0
Tracheal haemorrhage	1 (33.3)	0	0	1 (33.3)	0
Investigations					
-Total	3 (100)	0	0	0	3 (100)
Aspartate aminotransferase increased	3 (100)	1 (33.3)	0	0	2 (66.7)
Alanine aminotransferase increased	2 (66.7)	0	0	2 (66.7)	0
Blood fibrinogen decreased	2 (66.7)	0	1 (33.3)	0	1 (33.3)

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	1 (33.3)	0	0	1 (33.3)	0
Blood lactic acid increased	1 (33.3)	0	1 (33.3)	0	0
Blood phosphorus decreased	1 (33.3)	1 (33.3)	0	0	0
Blood urea increased	1 (33.3)	0	0	1 (33.3)	0
C-reactive protein increased	1 (33.3)	0	1 (33.3)	0	0
International normalised ratio increased	1 (33.3)	1 (33.3)	0	0	0
Neutrophil count decreased	1 (33.3)	0	0	0	1 (33.3)
Platelet count decreased	1 (33.3)	0	0	1 (33.3)	0
Protein total decreased	1 (33.3)	0	0	1 (33.3)	0
Prothrombin time prolonged	1 (33.3)	0	1 (33.3)	0	0
White blood cell count decreased	1 (33.3)	0	0	0	1 (33.3)
Metabolism and nutrition disorders					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Decreased appetite	2 (66.7)	0	0	2 (66.7)	0
Hypokalaemia	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Hypophosphataemia	2 (66.7)	1 (33.3)	0	1 (33.3)	0
Acidosis	1 (33.3)	0	0	1 (33.3)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fluid overload	1 (33.3)	0	1 (33.3)	0	0
Hyperalbuminaemia	1 (33.3)	1 (33.3)	0	0	0
Hypercalcaemia	1 (33.3)	1 (33.3)	0	0	0
Hyperchloraemia	1 (33.3)	1 (33.3)	0	0	0
Hypermagnesaemia	1 (33.3)	1 (33.3)	0	0	0
Hypernatraemia	1 (33.3)	0	1 (33.3)	0	0
Hyperuricaemia	1 (33.3)	0	0	0	1 (33.3)
Hypoalbuminaemia	1 (33.3)	0	1 (33.3)	0	0
Metabolic alkalosis	1 (33.3)	1 (33.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (66.7)	0	1 (33.3)	1 (33.3)	0
Bone pain	1 (33.3)	0	0	1 (33.3)	0
Neck pain	1 (33.3)	0	1 (33.3)	0	0
Nervous system disorders					
-Total	3 (100)	1 (33.3)	2 (66.7)	0	0
Headache	2 (66.7)	1 (33.3)	1 (33.3)	0	0
Dizziness	1 (33.3)	1 (33.3)	0	0	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotonia	1 (33.3)	0	1 (33.3)	0	0
Psychiatric disorders					
-Total	2 (66.7)	0	2 (66.7)	0	0
Insomnia	2 (66.7)	0	2 (66.7)	0	0
Anxiety	1 (33.3)	0	1 (33.3)	0	0
Confusional state	1 (33.3)	1 (33.3)	0	0	0
Delirium	1 (33.3)	0	1 (33.3)	0	0
Irritability	1 (33.3)	1 (33.3)	0	0	0
Renal and urinary disorders					
-Total	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Acute kidney injury	1 (33.3)	0	0	0	1 (33.3)
Haematuria	1 (33.3)	0	0	1 (33.3)	0
Renal impairment	1 (33.3)	0	0	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)
Hypoxia	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Pleural effusion	2 (66.7)	0	1 (33.3)	1 (33.3)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	2 (66.7)	0	0	1 (33.3)	1 (33.3)
Cough	1 (33.3)	1 (33.3)	0	0	0
Dyspnoea	1 (33.3)	0	0	0	1 (33.3)
Epistaxis	1 (33.3)	0	1 (33.3)	0	0
Interstitial lung disease	1 (33.3)	0	0	0	1 (33.3)
Nasal congestion	1 (33.3)	1 (33.3)	0	0	0
Oropharyngeal pain	1 (33.3)	1 (33.3)	0	0	0
Respiratory distress	1 (33.3)	0	0	0	1 (33.3)
Rhinorrhoea	1 (33.3)	1 (33.3)	0	0	0
Tachypnoea	1 (33.3)	0	0	1 (33.3)	0
Skin and subcutaneous tissue disorders					
-Total	1 (33.3)	1 (33.3)	0	0	0
Hyperhidrosis	1 (33.3)	1 (33.3)	0	0	0
Papule	1 (33.3)	1 (33.3)	0	0	0
Rash papular	1 (33.3)	1 (33.3)	0	0	0
Vascular disorders					
-Total	2 (66.7)	0	0	0	2 (66.7)

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypertension	2 (66.7)	0	2 (66.7)	0	0
Hypotension	2 (66.7)	0	0	0	2 (66.7)
Capillary leak syndrome	1 (33.3)	0	0	0	1 (33.3)
Flushing	1 (33.3)	1 (33.3)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188g
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	69 (95.8)	1 (1.4)	3 (4.2)	14 (19.4)	51 (70.8)
Blood and lymphatic system disorders					
-Total	60 (83.3)	0	2 (2.8)	38 (52.8)	20 (27.8)
Anaemia	39 (54.2)	2 (2.8)	7 (9.7)	29 (40.3)	1 (1.4)
Febrile neutropenia	36 (50.0)	0	0	35 (48.6)	1 (1.4)
Neutropenia	17 (23.6)	0	0	4 (5.6)	13 (18.1)
Thrombocytopenia	16 (22.2)	0	1 (1.4)	6 (8.3)	9 (12.5)
Lymphopenia	5 (6.9)	0	2 (2.8)	1 (1.4)	2 (2.8)
Cardiac disorders					
-Total	19 (26.4)	8 (11.1)	7 (9.7)	3 (4.2)	1 (1.4)
Tachycardia	16 (22.2)	9 (12.5)	6 (8.3)	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pericardial effusion	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Bradycardia	2 (2.8)	1 (1.4)	0	0	1 (1.4)
Left ventricular dysfunction	2 (2.8)	0	0	2 (2.8)	0
Eye disorders					
-Total	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Periorbital oedema	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Conjunctival haemorrhage	2 (2.8)	2 (2.8)	0	0	0
Gastrointestinal disorders					
-Total	52 (72.2)	14 (19.4)	26 (36.1)	12 (16.7)	0
Nausea	34 (47.2)	7 (9.7)	21 (29.2)	6 (8.3)	0
Vomiting	32 (44.4)	17 (23.6)	11 (15.3)	4 (5.6)	0
Diarrhoea	26 (36.1)	14 (19.4)	9 (12.5)	3 (4.2)	0
Abdominal pain	17 (23.6)	5 (6.9)	8 (11.1)	4 (5.6)	0
Constipation	14 (19.4)	11 (15.3)	3 (4.2)	0	0
Colitis	3 (4.2)	0	0	3 (4.2)	0
Dyspepsia	1 (1.4)	0	1 (1.4)	0	0
Dysphagia	1 (1.4)	0	1 (1.4)	0	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	46 (63.9)	16 (22.2)	17 (23.6)	9 (12.5)	4 (5.6)
Pyrexia	34 (47.2)	12 (16.7)	14 (19.4)	7 (9.7)	1 (1.4)
Fatigue	20 (27.8)	14 (19.4)	4 (5.6)	2 (2.8)	0
Chills	11 (15.3)	9 (12.5)	2 (2.8)	0	0
Pain	8 (11.1)	1 (1.4)	4 (5.6)	3 (4.2)	0
Oedema peripheral	4 (5.6)	3 (4.2)	1 (1.4)	0	0
Multiple organ dysfunction syndrome	3 (4.2)	0	0	0	3 (4.2)
Asthenia	1 (1.4)	0	1 (1.4)	0	0
Face oedema	1 (1.4)	0	1 (1.4)	0	0
Hepatobiliary disorders					
-Total	6 (8.3)	1 (1.4)	2 (2.8)	3 (4.2)	0
Hyperbilirubinaemia	5 (6.9)	0	2 (2.8)	3 (4.2)	0
Hepatomegaly	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Immune system disorders					
-Total	56 (77.8)	5 (6.9)	31 (43.1)	11 (15.3)	9 (12.5)
Cytokine release syndrome	48 (66.7)	6 (8.3)	25 (34.7)	8 (11.1)	9 (12.5)

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	32 (44.4)	4 (5.6)	24 (33.3)	4 (5.6)	0
Infections and infestations					
-Total	16 (22.2)	3 (4.2)	9 (12.5)	3 (4.2)	1 (1.4)
Upper respiratory tract infection	10 (13.9)	4 (5.6)	5 (6.9)	1 (1.4)	0
Pneumonia	6 (8.3)	0	4 (5.6)	1 (1.4)	1 (1.4)
Sinusitis	4 (5.6)	0	4 (5.6)	0	0
Escherichia bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	8 (11.1)	1 (1.4)	4 (5.6)	3 (4.2)	0
Procedural pain	8 (11.1)	1 (1.4)	4 (5.6)	3 (4.2)	0
Investigations					
-Total	56 (77.8)	0	5 (6.9)	10 (13.9)	41 (56.9)
White blood cell count decreased	43 (59.7)	4 (5.6)	1 (1.4)	8 (11.1)	30 (41.7)
Neutrophil count decreased	34 (47.2)	1 (1.4)	2 (2.8)	3 (4.2)	28 (38.9)
Platelet count decreased	25 (34.7)	3 (4.2)	2 (2.8)	3 (4.2)	17 (23.6)
Alanine aminotransferase increased	24 (33.3)	3 (4.2)	4 (5.6)	16 (22.2)	1 (1.4)
Aspartate aminotransferase increased	21 (29.2)	4 (5.6)	5 (6.9)	9 (12.5)	3 (4.2)

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	19 (26.4)	1 (1.4)	3 (4.2)	7 (9.7)	8 (11.1)
Blood bilirubin increased	10 (13.9)	2 (2.8)	3 (4.2)	4 (5.6)	1 (1.4)
International normalised ratio increased	10 (13.9)	8 (11.1)	1 (1.4)	1 (1.4)	0
Blood creatinine increased	8 (11.1)	5 (6.9)	2 (2.8)	1 (1.4)	0
Prothrombin time prolonged	8 (11.1)	5 (6.9)	2 (2.8)	1 (1.4)	0
Blood fibrinogen decreased	3 (4.2)	0	1 (1.4)	2 (2.8)	0
C-reactive protein increased	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Blood urea increased	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Blood lactic acid increased	1 (1.4)	0	0	0	1 (1.4)
Metabolism and nutrition disorders					
-Total	48 (66.7)	7 (9.7)	12 (16.7)	21 (29.2)	8 (11.1)
Decreased appetite	30 (41.7)	7 (9.7)	10 (13.9)	13 (18.1)	0
Hypokalaemia	22 (30.6)	4 (5.6)	4 (5.6)	9 (12.5)	5 (6.9)
Hypophosphataemia	12 (16.7)	3 (4.2)	1 (1.4)	7 (9.7)	1 (1.4)
Hyperglycaemia	10 (13.9)	0	4 (5.6)	5 (6.9)	1 (1.4)
Hyperphosphataemia	9 (12.5)	8 (11.1)	1 (1.4)	0	0
Hyperuricaemia	7 (9.7)	5 (6.9)	0	1 (1.4)	1 (1.4)

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fluid overload	6 (8.3)	1 (1.4)	4 (5.6)	1 (1.4)	0
Hypernatraemia	6 (8.3)	1 (1.4)	1 (1.4)	1 (1.4)	3 (4.2)
Hypoalbuminaemia	6 (8.3)	1 (1.4)	3 (4.2)	1 (1.4)	1 (1.4)
Acidosis	1 (1.4)	1 (1.4)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	24 (33.3)	11 (15.3)	7 (9.7)	6 (8.3)	0
Pain in extremity	18 (25.0)	8 (11.1)	5 (6.9)	5 (6.9)	0
Arthralgia	8 (11.1)	4 (5.6)	2 (2.8)	2 (2.8)	0
Neck pain	3 (4.2)	1 (1.4)	2 (2.8)	0	0
Bone pain	1 (1.4)	0	1 (1.4)	0	0
Nervous system disorders					
-Total	31 (43.1)	15 (20.8)	10 (13.9)	6 (8.3)	0
Headache	29 (40.3)	13 (18.1)	10 (13.9)	6 (8.3)	0
Dizziness	5 (6.9)	5 (6.9)	0	0	0
Psychiatric disorders					
-Total	19 (26.4)	6 (8.3)	11 (15.3)	2 (2.8)	0
Anxiety	9 (12.5)	3 (4.2)	5 (6.9)	1 (1.4)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	7 (9.7)	2 (2.8)	5 (6.9)	0	0
Delirium	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Insomnia	2 (2.8)	0	2 (2.8)	0	0
Irritability	2 (2.8)	2 (2.8)	0	0	0
Renal and urinary disorders					
-Total	14 (19.4)	3 (4.2)	1 (1.4)	6 (8.3)	4 (5.6)
Acute kidney injury	11 (15.3)	2 (2.8)	1 (1.4)	5 (6.9)	3 (4.2)
Haematuria	5 (6.9)	1 (1.4)	2 (2.8)	1 (1.4)	1 (1.4)
Respiratory, thoracic and mediastinal disorders					
-Total	38 (52.8)	12 (16.7)	7 (9.7)	12 (16.7)	7 (9.7)
Cough	15 (20.8)	12 (16.7)	2 (2.8)	1 (1.4)	0
Hypoxia	14 (19.4)	0	3 (4.2)	8 (11.1)	3 (4.2)
Epistaxis	13 (18.1)	4 (5.6)	3 (4.2)	5 (6.9)	1 (1.4)
Pleural effusion	8 (11.1)	1 (1.4)	5 (6.9)	2 (2.8)	0
Oropharyngeal pain	7 (9.7)	4 (5.6)	2 (2.8)	1 (1.4)	0
Pulmonary oedema	7 (9.7)	1 (1.4)	0	3 (4.2)	3 (4.2)
Tachypnoea	7 (9.7)	3 (4.2)	2 (2.8)	2 (2.8)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nasal congestion	6 (8.3)	6 (8.3)	0	0	0
Rhinorrhoea	6 (8.3)	5 (6.9)	1 (1.4)	0	0
Dyspnoea	4 (5.6)	1 (1.4)	1 (1.4)	2 (2.8)	0
Respiratory distress	1 (1.4)	0	0	0	1 (1.4)
Skin and subcutaneous tissue disorders					
-Total	16 (22.2)	13 (18.1)	3 (4.2)	0	0
Rash	10 (13.9)	7 (9.7)	3 (4.2)	0	0
Hyperhidrosis	3 (4.2)	3 (4.2)	0	0	0
Rash papular	3 (4.2)	3 (4.2)	0	0	0
Papule	1 (1.4)	1 (1.4)	0	0	0
Vascular disorders					
-Total	31 (43.1)	3 (4.2)	4 (5.6)	15 (20.8)	9 (12.5)
Hypotension	23 (31.9)	1 (1.4)	0	13 (18.1)	9 (12.5)
Hypertension	14 (19.4)	4 (5.6)	7 (9.7)	3 (4.2)	0
Flushing	1 (1.4)	1 (1.4)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188h
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	0	1 (100)	0
Blood and lymphatic system disorders					
-Total	1 (100)	0	0	1 (100)	0
Anaemia	1 (100)	0	0	1 (100)	0
Febrile neutropenia	1 (100)	0	0	1 (100)	0
Cardiac disorders					
-Total	1 (100)	0	1 (100)	0	0
Tachycardia	1 (100)	0	1 (100)	0	0
Gastrointestinal disorders					
-Total	1 (100)	0	1 (100)	0	0
Haematemesis	1 (100)	0	1 (100)	0	0

Hypodiploidy: Yes

	All patients N=1				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (100)	0	1 (100)	0	0
Vomiting	1 (100)	0	1 (100)	0	0
Immune system disorders					
-Total	1 (100)	0	1 (100)	0	0
Cytokine release syndrome	1 (100)	0	1 (100)	0	0
Investigations					
-Total	1 (100)	0	0	1 (100)	0
Activated partial thromboplastin time prolonged	1 (100)	0	1 (100)	0	0
Aspartate aminotransferase increased	1 (100)	0	1 (100)	0	0
Blood phosphorus increased	1 (100)	1 (100)	0	0	0
International normalised ratio increased	1 (100)	1 (100)	0	0	0
Neutrophil count decreased	1 (100)	0	0	1 (100)	0
Platelet count decreased	1 (100)	0	0	1 (100)	0
White blood cell count decreased	1 (100)	1 (100)	0	0	0
Nervous system disorders					
-Total	1 (100)	0	1 (100)	0	0

Hypodiploidy: Yes

Group term Preferred term	All patients N=1 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Encephalopathy	1 (100)	0	1 (100)	0	0
Psychiatric disorders					
-Total	1 (100)	0	1 (100)	0	0
Insomnia	1 (100)	0	1 (100)	0	0
Mental status changes	1 (100)	1 (100)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	1 (100)	0	1 (100)	0	0
Rash erythematous	1 (100)	0	1 (100)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188h
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	71 (95.9)	1 (1.4)	3 (4.1)	13 (17.6)	54 (73.0)
Blood and lymphatic system disorders					
-Total	62 (83.8)	0	2 (2.7)	39 (52.7)	21 (28.4)
Anaemia	40 (54.1)	2 (2.7)	7 (9.5)	30 (40.5)	1 (1.4)
Febrile neutropenia	37 (50.0)	0	0	36 (48.6)	1 (1.4)
Neutropenia	19 (25.7)	0	0	4 (5.4)	15 (20.3)
Thrombocytopenia	17 (23.0)	0	1 (1.4)	6 (8.1)	10 (13.5)
Cardiac disorders					
-Total	16 (21.6)	9 (12.2)	5 (6.8)	2 (2.7)	0
Tachycardia	16 (21.6)	9 (12.2)	5 (6.8)	2 (2.7)	0
Gastrointestinal disorders					

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	52 (70.3)	15 (20.3)	26 (35.1)	11 (14.9)	0
Nausea	35 (47.3)	8 (10.8)	20 (27.0)	7 (9.5)	0
Vomiting	32 (43.2)	17 (23.0)	11 (14.9)	4 (5.4)	0
Diarrhoea	27 (36.5)	14 (18.9)	10 (13.5)	3 (4.1)	0
Abdominal pain	18 (24.3)	6 (8.1)	8 (10.8)	4 (5.4)	0
Constipation	14 (18.9)	11 (14.9)	3 (4.1)	0	0
Haematemesis	1 (1.4)	1 (1.4)	0	0	0
General disorders and administration site conditions					
-Total	47 (63.5)	16 (21.6)	20 (27.0)	10 (13.5)	1 (1.4)
Pyrexia	36 (48.6)	12 (16.2)	15 (20.3)	8 (10.8)	1 (1.4)
Fatigue	21 (28.4)	15 (20.3)	4 (5.4)	2 (2.7)	0
Chills	12 (16.2)	10 (13.5)	2 (2.7)	0	0
Pain	8 (10.8)	1 (1.4)	4 (5.4)	3 (4.1)	0
Immune system disorders					
-Total	57 (77.0)	5 (6.8)	30 (40.5)	11 (14.9)	11 (14.9)
Cytokine release syndrome	49 (66.2)	6 (8.1)	24 (32.4)	8 (10.8)	11 (14.9)
Hypogammaglobulinaemia	33 (44.6)	4 (5.4)	24 (32.4)	5 (6.8)	0

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	11 (14.9)	5 (6.8)	5 (6.8)	1 (1.4)	0
Upper respiratory tract infection	11 (14.9)	5 (6.8)	5 (6.8)	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	8 (10.8)	1 (1.4)	4 (5.4)	3 (4.1)	0
Procedural pain	8 (10.8)	1 (1.4)	4 (5.4)	3 (4.1)	0
Investigations					
-Total	58 (78.4)	0	5 (6.8)	9 (12.2)	44 (59.5)
White blood cell count decreased	43 (58.1)	3 (4.1)	1 (1.4)	8 (10.8)	31 (41.9)
Neutrophil count decreased	34 (45.9)	1 (1.4)	2 (2.7)	2 (2.7)	29 (39.2)
Alanine aminotransferase increased	26 (35.1)	3 (4.1)	4 (5.4)	18 (24.3)	1 (1.4)
Platelet count decreased	25 (33.8)	3 (4.1)	2 (2.7)	3 (4.1)	17 (23.0)
Aspartate aminotransferase increased	23 (31.1)	5 (6.8)	4 (5.4)	9 (12.2)	5 (6.8)
Lymphocyte count decreased	19 (25.7)	1 (1.4)	3 (4.1)	7 (9.5)	8 (10.8)
Blood bilirubin increased	10 (13.5)	2 (2.7)	3 (4.1)	4 (5.4)	1 (1.4)
International normalised ratio increased	10 (13.5)	8 (10.8)	1 (1.4)	1 (1.4)	0

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	9 (12.2)	5 (6.8)	2 (2.7)	2 (2.7)	0
Prothrombin time prolonged	9 (12.2)	5 (6.8)	3 (4.1)	1 (1.4)	0
Activated partial thromboplastin time prolonged	5 (6.8)	3 (4.1)	2 (2.7)	0	0
Blood phosphorus increased	1 (1.4)	1 (1.4)	0	0	0
Metabolism and nutrition disorders					
-Total	48 (64.9)	7 (9.5)	12 (16.2)	21 (28.4)	8 (10.8)
Decreased appetite	32 (43.2)	7 (9.5)	10 (13.5)	15 (20.3)	0
Hypokalaemia	24 (32.4)	5 (6.8)	4 (5.4)	10 (13.5)	5 (6.8)
Hypophosphataemia	14 (18.9)	4 (5.4)	1 (1.4)	8 (10.8)	1 (1.4)
Hyperglycaemia	10 (13.5)	0	4 (5.4)	5 (6.8)	1 (1.4)
Hyperphosphataemia	9 (12.2)	8 (10.8)	1 (1.4)	0	0
Hyperuricaemia	8 (10.8)	5 (6.8)	0	1 (1.4)	2 (2.7)
Musculoskeletal and connective tissue disorders					
-Total	22 (29.7)	10 (13.5)	6 (8.1)	6 (8.1)	0
Pain in extremity	18 (24.3)	8 (10.8)	5 (6.8)	5 (6.8)	0
Arthralgia	8 (10.8)	4 (5.4)	2 (2.7)	2 (2.7)	0
Nervous system disorders					

Hypodiploidy: No

	All patients N=74				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	32 (43.2)	14 (18.9)	11 (14.9)	7 (9.5)	0
Headache	31 (41.9)	14 (18.9)	11 (14.9)	6 (8.1)	0
Encephalopathy	3 (4.1)	1 (1.4)	0	2 (2.7)	0
Psychiatric disorders					
-Total	20 (27.0)	6 (8.1)	12 (16.2)	2 (2.7)	0
Anxiety	10 (13.5)	3 (4.1)	6 (8.1)	1 (1.4)	0
Confusional state	8 (10.8)	3 (4.1)	5 (6.8)	0	0
Insomnia	3 (4.1)	0	3 (4.1)	0	0
Mental status changes	3 (4.1)	2 (2.7)	0	1 (1.4)	0
Renal and urinary disorders					
-Total	12 (16.2)	2 (2.7)	1 (1.4)	5 (6.8)	4 (5.4)
Acute kidney injury	12 (16.2)	2 (2.7)	1 (1.4)	5 (6.8)	4 (5.4)
Respiratory, thoracic and mediastinal disorders					
-Total	37 (50.0)	10 (13.5)	6 (8.1)	13 (17.6)	8 (10.8)
Cough	16 (21.6)	13 (17.6)	2 (2.7)	1 (1.4)	0
Hypoxia	16 (21.6)	0	3 (4.1)	9 (12.2)	4 (5.4)
Epistaxis	14 (18.9)	4 (5.4)	4 (5.4)	5 (6.8)	1 (1.4)

Hypodiploidy: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Pleural effusion	10 (13.5)	1 (1.4)	6 (8.1)	3 (4.1)	0
Pulmonary oedema	9 (12.2)	1 (1.4)	0	4 (5.4)	4 (5.4)
Oropharyngeal pain	8 (10.8)	5 (6.8)	2 (2.7)	1 (1.4)	0
Tachypnoea	8 (10.8)	3 (4.1)	2 (2.7)	3 (4.1)	0
Skin and subcutaneous tissue disorders					
-Total	13 (17.6)	8 (10.8)	5 (6.8)	0	0
Rash	10 (13.5)	7 (9.5)	3 (4.1)	0	0
Rash erythematous	4 (5.4)	2 (2.7)	2 (2.7)	0	0
Vascular disorders					
-Total	33 (44.6)	3 (4.1)	4 (5.4)	15 (20.3)	11 (14.9)
Hypotension	25 (33.8)	1 (1.4)	0	13 (17.6)	11 (14.9)
Hypertension	16 (21.6)	4 (5.4)	9 (12.2)	3 (4.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188i
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	0	1 (25.0)	3 (75.0)
Blood and lymphatic system disorders					
-Total	4 (100)	0	1 (25.0)	1 (25.0)	2 (50.0)
Anaemia	4 (100)	0	2 (50.0)	2 (50.0)	0
Febrile neutropenia	3 (75.0)	0	0	3 (75.0)	0
Neutropenia	2 (50.0)	0	0	0	2 (50.0)
Lymphopenia	1 (25.0)	0	1 (25.0)	0	0
Cardiac disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Cardiac dysfunction	1 (25.0)	1 (25.0)	0	0	0
Sinus tachycardia	1 (25.0)	0	1 (25.0)	0	0

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (25.0)	1 (25.0)	0	0	0
Endocrine disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Cushingoid	1 (25.0)	1 (25.0)	0	0	0
Eye disorders					
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Dry eye	1 (25.0)	0	1 (25.0)	0	0
Eye irritation	1 (25.0)	1 (25.0)	0	0	0
Gastrointestinal disorders					
-Total	3 (75.0)	1 (25.0)	1 (25.0)	1 (25.0)	0
Diarrhoea	3 (75.0)	2 (50.0)	1 (25.0)	0	0
Abdominal pain	2 (50.0)	2 (50.0)	0	0	0
Nausea	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Vomiting	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Abdominal distension	1 (25.0)	0	1 (25.0)	0	0
Abdominal tenderness	1 (25.0)	1 (25.0)	0	0	0
Colitis	1 (25.0)	0	0	1 (25.0)	0
Constipation	1 (25.0)	1 (25.0)	0	0	0

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dry mouth	1 (25.0)	1 (25.0)	0	0	0
Gastrooesophageal reflux disease	1 (25.0)	1 (25.0)	0	0	0
General disorders and administration site conditions					
-Total	4 (100)	2 (50.0)	1 (25.0)	1 (25.0)	0
Fatigue	4 (100)	4 (100)	0	0	0
Cyst	1 (25.0)	0	0	1 (25.0)	0
Pain	1 (25.0)	0	1 (25.0)	0	0
Pyrexia	1 (25.0)	1 (25.0)	0	0	0
Hepatobiliary disorders					
-Total	1 (25.0)	0	0	1 (25.0)	0
Cholecystitis	1 (25.0)	0	0	1 (25.0)	0
Immune system disorders					
-Total	4 (100)	0	3 (75.0)	1 (25.0)	0
Hypogammaglobulinaemia	4 (100)	0	4 (100)	0	0
Cytokine release syndrome	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Infections and infestations					
-Total	3 (75.0)	1 (25.0)	0	2 (50.0)	0

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Clostridium difficile infection	1 (25.0)	0	1 (25.0)	0	0
Cytomegalovirus infection	1 (25.0)	1 (25.0)	0	0	0
Cytomegalovirus viraemia	1 (25.0)	0	1 (25.0)	0	0
Enterococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Gastroenteritis	1 (25.0)	0	0	1 (25.0)	0
Gingivitis	1 (25.0)	1 (25.0)	0	0	0
Herpes zoster	1 (25.0)	0	0	1 (25.0)	0
Otitis media acute	1 (25.0)	0	1 (25.0)	0	0
Parainfluenzae virus infection	1 (25.0)	1 (25.0)	0	0	0
Pharyngitis	1 (25.0)	0	1 (25.0)	0	0
Sinusitis	1 (25.0)	0	1 (25.0)	0	0
Streptococcal bacteraemia	1 (25.0)	0	0	1 (25.0)	0
Streptococcal infection	1 (25.0)	0	1 (25.0)	0	0
Upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0
Viral infection	1 (25.0)	1 (25.0)	0	0	0
Injury, poisoning and procedural complications					

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (50.0)	1 (25.0)	1 (25.0)	0	0
Contusion	1 (25.0)	1 (25.0)	0	0	0
Infusion related reaction	1 (25.0)	0	1 (25.0)	0	0
Procedural pain	1 (25.0)	0	1 (25.0)	0	0
Procedural site reaction	1 (25.0)	1 (25.0)	0	0	0
Investigations					
-Total	4 (100)	0	1 (25.0)	0	3 (75.0)
Neutrophil count decreased	4 (100)	0	1 (25.0)	0	3 (75.0)
White blood cell count decreased	4 (100)	0	1 (25.0)	1 (25.0)	2 (50.0)
Alanine aminotransferase increased	3 (75.0)	0	1 (25.0)	2 (50.0)	0
Lymphocyte count decreased	3 (75.0)	0	1 (25.0)	1 (25.0)	1 (25.0)
Aspartate aminotransferase increased	2 (50.0)	1 (25.0)	0	1 (25.0)	0
International normalised ratio increased	2 (50.0)	2 (50.0)	0	0	0
Platelet count decreased	2 (50.0)	0	1 (25.0)	0	1 (25.0)
Activated partial thromboplastin time prolonged	1 (25.0)	1 (25.0)	0	0	0
Blood bilirubin increased	1 (25.0)	0	1 (25.0)	0	0

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	1 (25.0)	1 (25.0)	0	0	0
Blood fibrinogen decreased	1 (25.0)	0	1 (25.0)	0	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0	0	0
Blood uric acid increased	1 (25.0)	1 (25.0)	0	0	0
Coronavirus test positive	1 (25.0)	1 (25.0)	0	0	0
Pulmonary function test decreased	1 (25.0)	0	1 (25.0)	0	0
Metabolism and nutrition disorders					
-Total	4 (100)	0	0	4 (100)	0
Decreased appetite	2 (50.0)	0	1 (25.0)	1 (25.0)	0
Hyperglycaemia	2 (50.0)	0	0	2 (50.0)	0
Hyperphosphataemia	2 (50.0)	2 (50.0)	0	0	0
Hyperuricaemia	2 (50.0)	2 (50.0)	0	0	0
Dehydration	1 (25.0)	0	0	1 (25.0)	0
Hypokalaemia	1 (25.0)	0	0	1 (25.0)	0
Musculoskeletal and connective tissue disorders					
-Total	4 (100)	2 (50.0)	2 (50.0)	0	0

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Arthralgia	2 (50.0)	2 (50.0)	0	0	0
Joint range of motion decreased	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal chest pain	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal pain	1 (25.0)	0	1 (25.0)	0	0
Myalgia	1 (25.0)	1 (25.0)	0	0	0
Osteonecrosis	1 (25.0)	0	1 (25.0)	0	0
Pain in extremity	1 (25.0)	1 (25.0)	0	0	0
Pain in jaw	1 (25.0)	1 (25.0)	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (25.0)	0	1 (25.0)	0	0
Skin papilloma	1 (25.0)	0	1 (25.0)	0	0
Nervous system disorders					
-Total	3 (75.0)	2 (50.0)	1 (25.0)	0	0
Headache	3 (75.0)	3 (75.0)	0	0	0
Dizziness	1 (25.0)	1 (25.0)	0	0	0
Neuralgia	1 (25.0)	0	1 (25.0)	0	0
Psychiatric disorders					

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (25.0)	0	1 (25.0)	0	0
Insomnia	1 (25.0)	0	1 (25.0)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	3 (75.0)	1 (25.0)	0	1 (25.0)	1 (25.0)
Idiopathic pneumonia syndrome	1 (25.0)	0	0	0	1 (25.0)
Pulmonary oedema	1 (25.0)	0	0	1 (25.0)	0
Rhinorrhoea	1 (25.0)	1 (25.0)	0	0	0
Tachypnoea	1 (25.0)	1 (25.0)	0	0	0
Wheezing	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (75.0)	2 (50.0)	1 (25.0)	0	0
Petechiae	1 (25.0)	1 (25.0)	0	0	0
Pruritus generalised	1 (25.0)	1 (25.0)	0	0	0
Rash	1 (25.0)	0	1 (25.0)	0	0
Rash follicular	1 (25.0)	1 (25.0)	0	0	0
Rash papular	1 (25.0)	1 (25.0)	0	0	0
Vascular disorders					

BCR-ABL1-like: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (25.0)	0	0	0	1 (25.0)
Hypotension	1 (25.0)	0	0	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188i
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	69 (97.2)	1 (1.4)	3 (4.2)	14 (19.7)	51 (71.8)
Blood and lymphatic system disorders					
-Total	59 (83.1)	0	1 (1.4)	38 (53.5)	20 (28.2)
Anaemia	37 (52.1)	2 (2.8)	5 (7.0)	29 (40.8)	1 (1.4)
Febrile neutropenia	35 (49.3)	0	0	34 (47.9)	1 (1.4)
Neutropenia	17 (23.9)	0	0	4 (5.6)	13 (18.3)
Thrombocytopenia	17 (23.9)	0	1 (1.4)	6 (8.5)	10 (14.1)
Lymphopenia	5 (7.0)	0	1 (1.4)	1 (1.4)	3 (4.2)
Cardiac disorders					
-Total	21 (29.6)	10 (14.1)	7 (9.9)	4 (5.6)	0
Tachycardia	16 (22.5)	8 (11.3)	6 (8.5)	2 (2.8)	0

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	6 (8.5)	3 (4.2)	1 (1.4)	2 (2.8)	0
Eye disorders					
-Total	1 (1.4)	1 (1.4)	0	0	0
Dry eye	1 (1.4)	1 (1.4)	0	0	0
Gastrointestinal disorders					
-Total	51 (71.8)	14 (19.7)	25 (35.2)	12 (16.9)	0
Nausea	34 (47.9)	7 (9.9)	20 (28.2)	7 (9.9)	0
Vomiting	31 (43.7)	16 (22.5)	11 (15.5)	4 (5.6)	0
Diarrhoea	24 (33.8)	12 (16.9)	9 (12.7)	3 (4.2)	0
Abdominal pain	16 (22.5)	4 (5.6)	8 (11.3)	4 (5.6)	0
Constipation	13 (18.3)	10 (14.1)	3 (4.2)	0	0
Colitis	3 (4.2)	1 (1.4)	0	2 (2.8)	0
Abdominal distension	1 (1.4)	0	1 (1.4)	0	0
General disorders and administration site conditions					
-Total	43 (60.6)	13 (18.3)	19 (26.8)	10 (14.1)	1 (1.4)
Pyrexia	35 (49.3)	11 (15.5)	15 (21.1)	8 (11.3)	1 (1.4)
Fatigue	17 (23.9)	11 (15.5)	4 (5.6)	2 (2.8)	0

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	12 (16.9)	10 (14.1)	2 (2.8)	0	0
Pain	7 (9.9)	1 (1.4)	3 (4.2)	3 (4.2)	0
Immune system disorders					
-Total	54 (76.1)	5 (7.0)	28 (39.4)	10 (14.1)	11 (15.5)
Cytokine release syndrome	48 (67.6)	6 (8.5)	24 (33.8)	7 (9.9)	11 (15.5)
Hypogammaglobulinaemia	29 (40.8)	4 (5.6)	20 (28.2)	5 (7.0)	0
Infections and infestations					
-Total	25 (35.2)	5 (7.0)	14 (19.7)	6 (8.5)	0
Upper respiratory tract infection	10 (14.1)	4 (5.6)	5 (7.0)	1 (1.4)	0
Clostridium difficile infection	5 (7.0)	0	4 (5.6)	1 (1.4)	0
Gastroenteritis	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Sinusitis	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Parainfluenzae virus infection	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Viral infection	2 (2.8)	1 (1.4)	1 (1.4)	0	0
Bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Cytomegalovirus infection	1 (1.4)	1 (1.4)	0	0	0
Enterococcal bacteraemia	1 (1.4)	0	0	1 (1.4)	0
Otitis media acute	1 (1.4)	0	1 (1.4)	0	0

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal infection	1 (1.4)	0	0	1 (1.4)	0
Injury, poisoning and procedural complications					
-Total	10 (14.1)	3 (4.2)	4 (5.6)	3 (4.2)	0
Procedural pain	7 (9.9)	1 (1.4)	3 (4.2)	3 (4.2)	0
Infusion related reaction	4 (5.6)	2 (2.8)	2 (2.8)	0	0
Contusion	2 (2.8)	2 (2.8)	0	0	0
Investigations					
-Total	55 (77.5)	0	4 (5.6)	10 (14.1)	41 (57.7)
White blood cell count decreased	40 (56.3)	4 (5.6)	0	7 (9.9)	29 (40.8)
Neutrophil count decreased	31 (43.7)	1 (1.4)	1 (1.4)	3 (4.2)	26 (36.6)
Platelet count decreased	24 (33.8)	3 (4.2)	1 (1.4)	4 (5.6)	16 (22.5)
Alanine aminotransferase increased	23 (32.4)	3 (4.2)	3 (4.2)	16 (22.5)	1 (1.4)
Aspartate aminotransferase increased	22 (31.0)	4 (5.6)	5 (7.0)	8 (11.3)	5 (7.0)
Lymphocyte count decreased	16 (22.5)	1 (1.4)	2 (2.8)	6 (8.5)	7 (9.9)
Blood bilirubin increased	9 (12.7)	2 (2.8)	2 (2.8)	4 (5.6)	1 (1.4)
International normalised ratio increased	9 (12.7)	7 (9.9)	1 (1.4)	1 (1.4)	0

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Prothrombin time prolonged	9 (12.7)	5 (7.0)	3 (4.2)	1 (1.4)	0
Blood creatinine increased	8 (11.3)	4 (5.6)	2 (2.8)	2 (2.8)	0
Activated partial thromboplastin time prolonged	5 (7.0)	2 (2.8)	3 (4.2)	0	0
Blood fibrinogen decreased	4 (5.6)	0	1 (1.4)	2 (2.8)	1 (1.4)
Blood immunoglobulin m decreased	4 (5.6)	4 (5.6)	0	0	0
Blood immunoglobulin a decreased	2 (2.8)	2 (2.8)	0	0	0
Blood uric acid increased	2 (2.8)	2 (2.8)	0	0	0
Metabolism and nutrition disorders					
-Total	46 (64.8)	5 (7.0)	13 (18.3)	20 (28.2)	8 (11.3)
Decreased appetite	30 (42.3)	7 (9.9)	9 (12.7)	14 (19.7)	0
Hypokalaemia	23 (32.4)	5 (7.0)	4 (5.6)	9 (12.7)	5 (7.0)
Hypophosphataemia	14 (19.7)	4 (5.6)	1 (1.4)	8 (11.3)	1 (1.4)
Hyperglycaemia	8 (11.3)	0	4 (5.6)	3 (4.2)	1 (1.4)
Hyperphosphataemia	7 (9.9)	6 (8.5)	1 (1.4)	0	0
Dehydration	6 (8.5)	1 (1.4)	2 (2.8)	3 (4.2)	0
Hyperuricaemia	6 (8.5)	3 (4.2)	0	1 (1.4)	2 (2.8)
Musculoskeletal and connective tissue disorders					

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	28 (39.4)	12 (16.9)	9 (12.7)	7 (9.9)	0
Pain in extremity	17 (23.9)	7 (9.9)	5 (7.0)	5 (7.0)	0
Arthralgia	6 (8.5)	2 (2.8)	2 (2.8)	2 (2.8)	0
Myalgia	5 (7.0)	3 (4.2)	1 (1.4)	1 (1.4)	0
Pain in jaw	4 (5.6)	1 (1.4)	3 (4.2)	0	0
Musculoskeletal pain	3 (4.2)	2 (2.8)	0	1 (1.4)	0
Musculoskeletal chest pain	2 (2.8)	2 (2.8)	0	0	0
Joint range of motion decreased	1 (1.4)	1 (1.4)	0	0	0
Nervous system disorders					
-Total	30 (42.3)	13 (18.3)	11 (15.5)	6 (8.5)	0
Headache	28 (39.4)	11 (15.5)	11 (15.5)	6 (8.5)	0
Dizziness	5 (7.0)	5 (7.0)	0	0	0
Psychiatric disorders					
-Total	18 (25.4)	5 (7.0)	12 (16.9)	1 (1.4)	0
Anxiety	10 (14.1)	3 (4.2)	6 (8.5)	1 (1.4)	0
Confusional state	8 (11.3)	3 (4.2)	5 (7.0)	0	0
Insomnia	3 (4.2)	0	3 (4.2)	0	0
Renal and urinary disorders					

BCR-ABL1-like: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (16.9)	2 (2.8)	1 (1.4)	5 (7.0)	4 (5.6)
Acute kidney injury	12 (16.9)	2 (2.8)	1 (1.4)	5 (7.0)	4 (5.6)
Respiratory, thoracic and mediastinal disorders					
-Total	36 (50.7)	9 (12.7)	7 (9.9)	12 (16.9)	8 (11.3)
Cough	16 (22.5)	13 (18.3)	2 (2.8)	1 (1.4)	0
Hypoxia	16 (22.5)	0	3 (4.2)	9 (12.7)	4 (5.6)
Epistaxis	14 (19.7)	4 (5.6)	4 (5.6)	5 (7.0)	1 (1.4)
Pleural effusion	10 (14.1)	1 (1.4)	6 (8.5)	3 (4.2)	0
Oropharyngeal pain	8 (11.3)	5 (7.0)	2 (2.8)	1 (1.4)	0
Pulmonary oedema	8 (11.3)	1 (1.4)	0	3 (4.2)	4 (5.6)
Tachypnoea	7 (9.9)	2 (2.8)	2 (2.8)	3 (4.2)	0
Rhinorrhoea	6 (8.5)	5 (7.0)	1 (1.4)	0	0
Skin and subcutaneous tissue disorders					
-Total	14 (19.7)	11 (15.5)	3 (4.2)	0	0
Rash	9 (12.7)	7 (9.9)	2 (2.8)	0	0
Petechiae	3 (4.2)	2 (2.8)	1 (1.4)	0	0
Rash papular	3 (4.2)	3 (4.2)	0	0	0

BCR-ABL1-like: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	32 (45.1)	3 (4.2)	4 (5.6)	15 (21.1)	10 (14.1)
Hypotension	24 (33.8)	1 (1.4)	0	13 (18.3)	10 (14.1)
Hypertension	16 (22.5)	4 (5.6)	9 (12.7)	3 (4.2)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188j
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (100)	0	3 (13.6)	3 (13.6)	16 (72.7)
Blood and lymphatic system disorders					
-Total	17 (77.3)	0	0	8 (36.4)	9 (40.9)
Febrile neutropenia	11 (50.0)	0	0	11 (50.0)	0
Neutropenia	9 (40.9)	0	0	1 (4.5)	8 (36.4)
Anaemia	8 (36.4)	1 (4.5)	1 (4.5)	6 (27.3)	0
Thrombocytopenia	3 (13.6)	0	0	0	3 (13.6)
Disseminated intravascular coagulation	1 (4.5)	0	0	1 (4.5)	0
Cardiac disorders					
-Total	7 (31.8)	3 (13.6)	2 (9.1)	2 (9.1)	0
Tachycardia	4 (18.2)	2 (9.1)	1 (4.5)	1 (4.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Eye disorders					
-Total	6 (27.3)	4 (18.2)	2 (9.1)	0	0
Periorbital oedema	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Vision blurred	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Gastrointestinal disorders					
-Total	19 (86.4)	6 (27.3)	9 (40.9)	4 (18.2)	0
Vomiting	13 (59.1)	7 (31.8)	4 (18.2)	2 (9.1)	0
Diarrhoea	12 (54.5)	5 (22.7)	5 (22.7)	2 (9.1)	0
Nausea	12 (54.5)	4 (18.2)	6 (27.3)	2 (9.1)	0
Constipation	6 (27.3)	5 (22.7)	1 (4.5)	0	0
Abdominal pain	5 (22.7)	2 (9.1)	2 (9.1)	1 (4.5)	0
General disorders and administration site conditions					
-Total	16 (72.7)	4 (18.2)	9 (40.9)	3 (13.6)	0
Pyrexia	14 (63.6)	4 (18.2)	8 (36.4)	2 (9.1)	0
Fatigue	7 (31.8)	4 (18.2)	2 (9.1)	1 (4.5)	0
Chills	4 (18.2)	4 (18.2)	0	0	0
Pain	4 (18.2)	1 (4.5)	2 (9.1)	1 (4.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site pain	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Hepatobiliary disorders					
-Total	3 (13.6)	0	1 (4.5)	2 (9.1)	0
Hyperbilirubinaemia	3 (13.6)	0	1 (4.5)	2 (9.1)	0
Immune system disorders					
-Total	18 (81.8)	0	9 (40.9)	4 (18.2)	5 (22.7)
Cytokine release syndrome	18 (81.8)	1 (4.5)	9 (40.9)	3 (13.6)	5 (22.7)
Hypogammaglobulinaemia	12 (54.5)	2 (9.1)	7 (31.8)	3 (13.6)	0
Infections and infestations					
-Total	10 (45.5)	6 (27.3)	3 (13.6)	1 (4.5)	0
Upper respiratory tract infection	6 (27.3)	3 (13.6)	3 (13.6)	0	0
Gastroenteritis	4 (18.2)	1 (4.5)	2 (9.1)	1 (4.5)	0
Rhinovirus infection	3 (13.6)	3 (13.6)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (4.5)	0	1 (4.5)	0	0
Procedural pain	1 (4.5)	0	1 (4.5)	0	0
Investigations					
-Total	16 (72.7)	0	1 (4.5)	3 (13.6)	12 (54.5)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	12 (54.5)	1 (4.5)	0	0	11 (50.0)
Neutrophil count decreased	9 (40.9)	1 (4.5)	0	1 (4.5)	7 (31.8)
Alanine aminotransferase increased	8 (36.4)	1 (4.5)	1 (4.5)	6 (27.3)	0
Aspartate aminotransferase increased	6 (27.3)	2 (9.1)	1 (4.5)	1 (4.5)	2 (9.1)
Platelet count decreased	6 (27.3)	1 (4.5)	0	0	5 (22.7)
Blood creatinine increased	5 (22.7)	2 (9.1)	1 (4.5)	2 (9.1)	0
Lymphocyte count decreased	5 (22.7)	0	1 (4.5)	3 (13.6)	1 (4.5)
Prothrombin time prolonged	4 (18.2)	2 (9.1)	1 (4.5)	1 (4.5)	0
Blood bilirubin increased	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
International normalised ratio increased	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Metabolism and nutrition disorders					
-Total	20 (90.9)	1 (4.5)	6 (27.3)	9 (40.9)	4 (18.2)
Decreased appetite	12 (54.5)	2 (9.1)	5 (22.7)	5 (22.7)	0
Hypokalaemia	6 (27.3)	1 (4.5)	1 (4.5)	2 (9.1)	2 (9.1)
Hypophosphataemia	5 (22.7)	2 (9.1)	0	3 (13.6)	0
Dehydration	3 (13.6)	0	0	3 (13.6)	0
Fluid overload	3 (13.6)	0	3 (13.6)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	3 (13.6)	0	1 (4.5)	0	2 (9.1)
Hyperglycaemia	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Hyperphosphataemia	2 (9.1)	2 (9.1)	0	0	0
Hyperuricaemia	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Musculoskeletal and connective tissue disorders					
-Total	8 (36.4)	5 (22.7)	3 (13.6)	0	0
Pain in extremity	7 (31.8)	4 (18.2)	3 (13.6)	0	0
Arthralgia	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Nervous system disorders					
-Total	8 (36.4)	4 (18.2)	3 (13.6)	1 (4.5)	0
Headache	8 (36.4)	4 (18.2)	3 (13.6)	1 (4.5)	0
Psychiatric disorders					
-Total	5 (22.7)	2 (9.1)	3 (13.6)	0	0
Anxiety	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Irritability	3 (13.6)	3 (13.6)	0	0	0
Confusional state	2 (9.1)	0	2 (9.1)	0	0
Renal and urinary disorders					
-Total	5 (22.7)	1 (4.5)	0	1 (4.5)	3 (13.6)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	5 (22.7)	1 (4.5)	0	1 (4.5)	3 (13.6)
Respiratory, thoracic and mediastinal disorders					
-Total	14 (63.6)	6 (27.3)	1 (4.5)	4 (18.2)	3 (13.6)
Cough	8 (36.4)	7 (31.8)	1 (4.5)	0	0
Hypoxia	5 (22.7)	0	1 (4.5)	2 (9.1)	2 (9.1)
Pulmonary oedema	5 (22.7)	1 (4.5)	0	3 (13.6)	1 (4.5)
Epistaxis	4 (18.2)	1 (4.5)	1 (4.5)	2 (9.1)	0
Pleural effusion	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Tachypnoea	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Nasal congestion	1 (4.5)	1 (4.5)	0	0	0
Oropharyngeal pain	1 (4.5)	1 (4.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (31.8)	4 (18.2)	3 (13.6)	0	0
Rash	4 (18.2)	2 (9.1)	2 (9.1)	0	0
Rash maculo-papular	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Vascular disorders					
-Total	12 (54.5)	3 (13.6)	0	4 (18.2)	5 (22.7)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	10 (45.5)	1 (4.5)	0	4 (18.2)	5 (22.7)
Hypertension	4 (18.2)	2 (9.1)	1 (4.5)	1 (4.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188j
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (94.3)	1 (1.9)	0	11 (20.8)	38 (71.7)
Blood and lymphatic system disorders					
-Total	46 (86.8)	0	2 (3.8)	32 (60.4)	12 (22.6)
Anaemia	33 (62.3)	1 (1.9)	6 (11.3)	25 (47.2)	1 (1.9)
Febrile neutropenia	27 (50.9)	0	0	26 (49.1)	1 (1.9)
Thrombocytopenia	14 (26.4)	0	1 (1.9)	6 (11.3)	7 (13.2)
Neutropenia	10 (18.9)	0	0	3 (5.7)	7 (13.2)
Disseminated intravascular coagulation	6 (11.3)	0	2 (3.8)	3 (5.7)	1 (1.9)
Cardiac disorders					
-Total	16 (30.2)	8 (15.1)	6 (11.3)	2 (3.8)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	13 (24.5)	7 (13.2)	5 (9.4)	1 (1.9)	0
Sinus tachycardia	4 (7.5)	2 (3.8)	1 (1.9)	1 (1.9)	0
Eye disorders					
-Total	1 (1.9)	0	1 (1.9)	0	0
Periorbital oedema	1 (1.9)	1 (1.9)	0	0	0
Vision blurred	1 (1.9)	0	1 (1.9)	0	0
Gastrointestinal disorders					
-Total	34 (64.2)	9 (17.0)	18 (34.0)	7 (13.2)	0
Nausea	24 (45.3)	4 (7.5)	15 (28.3)	5 (9.4)	0
Vomiting	20 (37.7)	10 (18.9)	8 (15.1)	2 (3.8)	0
Diarrhoea	15 (28.3)	9 (17.0)	5 (9.4)	1 (1.9)	0
Abdominal pain	13 (24.5)	4 (7.5)	6 (11.3)	3 (5.7)	0
Constipation	8 (15.1)	6 (11.3)	2 (3.8)	0	0
General disorders and administration site conditions					
-Total	34 (64.2)	13 (24.5)	13 (24.5)	7 (13.2)	1 (1.9)
Pyrexia	22 (41.5)	8 (15.1)	7 (13.2)	6 (11.3)	1 (1.9)
Fatigue	14 (26.4)	11 (20.8)	2 (3.8)	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Chills	8 (15.1)	6 (11.3)	2 (3.8)	0	0
Catheter site pain	4 (7.5)	0	4 (7.5)	0	0
Pain	4 (7.5)	0	2 (3.8)	2 (3.8)	0
Hepatobiliary disorders					
-Total	3 (5.7)	0	1 (1.9)	2 (3.8)	0
Hyperbilirubinaemia	3 (5.7)	0	1 (1.9)	2 (3.8)	0
Immune system disorders					
-Total	40 (75.5)	5 (9.4)	22 (41.5)	7 (13.2)	6 (11.3)
Cytokine release syndrome	32 (60.4)	5 (9.4)	16 (30.2)	5 (9.4)	6 (11.3)
Hypogammaglobulinaemia	21 (39.6)	2 (3.8)	17 (32.1)	2 (3.8)	0
Infections and infestations					
-Total	9 (17.0)	4 (7.5)	4 (7.5)	1 (1.9)	0
Upper respiratory tract infection	5 (9.4)	2 (3.8)	2 (3.8)	1 (1.9)	0
Rhinovirus infection	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Gastroenteritis	1 (1.9)	0	1 (1.9)	0	0
Injury, poisoning and procedural complications					
-Total	7 (13.2)	1 (1.9)	3 (5.7)	3 (5.7)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural pain	7 (13.2)	1 (1.9)	3 (5.7)	3 (5.7)	0
Investigations					
-Total	43 (81.1)	0	4 (7.5)	7 (13.2)	32 (60.4)
White blood cell count decreased	32 (60.4)	3 (5.7)	1 (1.9)	8 (15.1)	20 (37.7)
Neutrophil count decreased	26 (49.1)	0	2 (3.8)	2 (3.8)	22 (41.5)
Platelet count decreased	20 (37.7)	2 (3.8)	2 (3.8)	4 (7.5)	12 (22.6)
Alanine aminotransferase increased	18 (34.0)	2 (3.8)	3 (5.7)	12 (22.6)	1 (1.9)
Aspartate aminotransferase increased	18 (34.0)	3 (5.7)	4 (7.5)	8 (15.1)	3 (5.7)
Lymphocyte count decreased	14 (26.4)	1 (1.9)	2 (3.8)	4 (7.5)	7 (13.2)
International normalised ratio increased	8 (15.1)	7 (13.2)	1 (1.9)	0	0
Blood bilirubin increased	7 (13.2)	1 (1.9)	2 (3.8)	3 (5.7)	1 (1.9)
Prothrombin time prolonged	5 (9.4)	3 (5.7)	2 (3.8)	0	0
Blood creatinine increased	4 (7.5)	3 (5.7)	1 (1.9)	0	0
Metabolism and nutrition disorders					
-Total	32 (60.4)	4 (7.5)	7 (13.2)	16 (30.2)	5 (9.4)
Decreased appetite	20 (37.7)	5 (9.4)	5 (9.4)	10 (18.9)	0
Hypokalaemia	18 (34.0)	4 (7.5)	3 (5.7)	8 (15.1)	3 (5.7)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	9 (17.0)	2 (3.8)	1 (1.9)	5 (9.4)	1 (1.9)
Hyperglycaemia	8 (15.1)	0	3 (5.7)	4 (7.5)	1 (1.9)
Hyperphosphataemia	7 (13.2)	6 (11.3)	1 (1.9)	0	0
Hyperuricaemia	6 (11.3)	5 (9.4)	0	0	1 (1.9)
Dehydration	4 (7.5)	1 (1.9)	2 (3.8)	1 (1.9)	0
Fluid overload	4 (7.5)	1 (1.9)	2 (3.8)	1 (1.9)	0
Hypernatraemia	4 (7.5)	1 (1.9)	1 (1.9)	1 (1.9)	1 (1.9)
Musculoskeletal and connective tissue disorders					
-Total	14 (26.4)	5 (9.4)	3 (5.7)	6 (11.3)	0
Pain in extremity	11 (20.8)	4 (7.5)	2 (3.8)	5 (9.4)	0
Arthralgia	6 (11.3)	3 (5.7)	1 (1.9)	2 (3.8)	0
Nervous system disorders					
-Total	23 (43.4)	10 (18.9)	8 (15.1)	5 (9.4)	0
Headache	23 (43.4)	10 (18.9)	8 (15.1)	5 (9.4)	0
Psychiatric disorders					
-Total	12 (22.6)	4 (7.5)	7 (13.2)	1 (1.9)	0
Anxiety	7 (13.2)	2 (3.8)	4 (7.5)	1 (1.9)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	6 (11.3)	3 (5.7)	3 (5.7)	0	0
Renal and urinary disorders					
-Total	7 (13.2)	1 (1.9)	1 (1.9)	4 (7.5)	1 (1.9)
Acute kidney injury	7 (13.2)	1 (1.9)	1 (1.9)	4 (7.5)	1 (1.9)
Respiratory, thoracic and mediastinal disorders					
-Total	25 (47.2)	6 (11.3)	5 (9.4)	9 (17.0)	5 (9.4)
Hypoxia	11 (20.8)	0	2 (3.8)	7 (13.2)	2 (3.8)
Epistaxis	10 (18.9)	3 (5.7)	3 (5.7)	3 (5.7)	1 (1.9)
Cough	8 (15.1)	6 (11.3)	1 (1.9)	1 (1.9)	0
Pleural effusion	8 (15.1)	1 (1.9)	5 (9.4)	2 (3.8)	0
Oropharyngeal pain	7 (13.2)	4 (7.5)	2 (3.8)	1 (1.9)	0
Nasal congestion	6 (11.3)	6 (11.3)	0	0	0
Tachypnoea	6 (11.3)	2 (3.8)	2 (3.8)	2 (3.8)	0
Pulmonary oedema	4 (7.5)	0	0	1 (1.9)	3 (5.7)
Skin and subcutaneous tissue disorders					
-Total	8 (15.1)	6 (11.3)	1 (1.9)	1 (1.9)	0
Rash	6 (11.3)	5 (9.4)	1 (1.9)	0	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

Group term Preferred term	All patients N=53 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash maculo-papular	2 (3.8)	1 (1.9)	0	1 (1.9)	0
Vascular disorders					
-Total	21 (39.6)	0	4 (7.5)	11 (20.8)	6 (11.3)
Hypotension	15 (28.3)	0	0	9 (17.0)	6 (11.3)
Hypertension	12 (22.6)	2 (3.8)	8 (15.1)	2 (3.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188k
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=75				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	72 (96.0)	1 (1.3)	3 (4.0)	14 (18.7)	54 (72.0)
Blood and lymphatic system disorders					
-Total	63 (84.0)	0	2 (2.7)	40 (53.3)	21 (28.0)
Anaemia	41 (54.7)	2 (2.7)	7 (9.3)	31 (41.3)	1 (1.3)
Febrile neutropenia	38 (50.7)	0	0	37 (49.3)	1 (1.3)
Neutropenia	19 (25.3)	0	0	4 (5.3)	15 (20.0)
Thrombocytopenia	17 (22.7)	0	1 (1.3)	6 (8.0)	10 (13.3)
Cardiac disorders					
-Total	17 (22.7)	9 (12.0)	6 (8.0)	2 (2.7)	0
Tachycardia	17 (22.7)	9 (12.0)	6 (8.0)	2 (2.7)	0
Gastrointestinal disorders					

Region: US

	All patients N=75				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	53 (70.7)	15 (20.0)	27 (36.0)	11 (14.7)	0
Nausea	36 (48.0)	8 (10.7)	21 (28.0)	7 (9.3)	0
Vomiting	33 (44.0)	17 (22.7)	12 (16.0)	4 (5.3)	0
Diarrhoea	27 (36.0)	14 (18.7)	10 (13.3)	3 (4.0)	0
Abdominal pain	18 (24.0)	6 (8.0)	8 (10.7)	4 (5.3)	0
Constipation	14 (18.7)	11 (14.7)	3 (4.0)	0	0
General disorders and administration site conditions					
-Total	47 (62.7)	16 (21.3)	20 (26.7)	10 (13.3)	1 (1.3)
Pyrexia	36 (48.0)	12 (16.0)	15 (20.0)	8 (10.7)	1 (1.3)
Fatigue	21 (28.0)	15 (20.0)	4 (5.3)	2 (2.7)	0
Chills	12 (16.0)	10 (13.3)	2 (2.7)	0	0
Pain	8 (10.7)	1 (1.3)	4 (5.3)	3 (4.0)	0
Immune system disorders					
-Total	58 (77.3)	5 (6.7)	31 (41.3)	11 (14.7)	11 (14.7)
Cytokine release syndrome	50 (66.7)	6 (8.0)	25 (33.3)	8 (10.7)	11 (14.7)
Hypogammaglobulinaemia	33 (44.0)	4 (5.3)	24 (32.0)	5 (6.7)	0
Infections and infestations					

Region: US

	All patients N=75				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (14.7)	5 (6.7)	5 (6.7)	1 (1.3)	0
Upper respiratory tract infection	11 (14.7)	5 (6.7)	5 (6.7)	1 (1.3)	0
Injury, poisoning and procedural complications					
-Total	8 (10.7)	1 (1.3)	4 (5.3)	3 (4.0)	0
Procedural pain	8 (10.7)	1 (1.3)	4 (5.3)	3 (4.0)	0
Investigations					
-Total	59 (78.7)	0	5 (6.7)	10 (13.3)	44 (58.7)
White blood cell count decreased	44 (58.7)	4 (5.3)	1 (1.3)	8 (10.7)	31 (41.3)
Neutrophil count decreased	35 (46.7)	1 (1.3)	2 (2.7)	3 (4.0)	29 (38.7)
Alanine aminotransferase increased	26 (34.7)	3 (4.0)	4 (5.3)	18 (24.0)	1 (1.3)
Platelet count decreased	26 (34.7)	3 (4.0)	2 (2.7)	4 (5.3)	17 (22.7)
Aspartate aminotransferase increased	24 (32.0)	5 (6.7)	5 (6.7)	9 (12.0)	5 (6.7)
Lymphocyte count decreased	19 (25.3)	1 (1.3)	3 (4.0)	7 (9.3)	8 (10.7)
International normalised ratio increased	11 (14.7)	9 (12.0)	1 (1.3)	1 (1.3)	0
Blood bilirubin increased	10 (13.3)	2 (2.7)	3 (4.0)	4 (5.3)	1 (1.3)
Blood creatinine increased	9 (12.0)	5 (6.7)	2 (2.7)	2 (2.7)	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Prothrombin time prolonged	9 (12.0)	5 (6.7)	3 (4.0)	1 (1.3)	0
Metabolism and nutrition disorders					
-Total	48 (64.0)	7 (9.3)	12 (16.0)	21 (28.0)	8 (10.7)
Decreased appetite	32 (42.7)	7 (9.3)	10 (13.3)	15 (20.0)	0
Hypokalaemia	24 (32.0)	5 (6.7)	4 (5.3)	10 (13.3)	5 (6.7)
Hypophosphataemia	14 (18.7)	4 (5.3)	1 (1.3)	8 (10.7)	1 (1.3)
Hyperglycaemia	10 (13.3)	0	4 (5.3)	5 (6.7)	1 (1.3)
Hyperphosphataemia	9 (12.0)	8 (10.7)	1 (1.3)	0	0
Hyperuricaemia	8 (10.7)	5 (6.7)	0	1 (1.3)	2 (2.7)
Musculoskeletal and connective tissue disorders					
-Total	22 (29.3)	10 (13.3)	6 (8.0)	6 (8.0)	0
Pain in extremity	18 (24.0)	8 (10.7)	5 (6.7)	5 (6.7)	0
Arthralgia	8 (10.7)	4 (5.3)	2 (2.7)	2 (2.7)	0
Nervous system disorders					
-Total	31 (41.3)	14 (18.7)	11 (14.7)	6 (8.0)	0
Headache	31 (41.3)	14 (18.7)	11 (14.7)	6 (8.0)	0
Psychiatric disorders					

Region: US

	All patients N=75				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	16 (21.3)	5 (6.7)	10 (13.3)	1 (1.3)	0
Anxiety	10 (13.3)	3 (4.0)	6 (8.0)	1 (1.3)	0
Confusional state	8 (10.7)	3 (4.0)	5 (6.7)	0	0
Renal and urinary disorders					
-Total	12 (16.0)	2 (2.7)	1 (1.3)	5 (6.7)	4 (5.3)
Acute kidney injury	12 (16.0)	2 (2.7)	1 (1.3)	5 (6.7)	4 (5.3)
Respiratory, thoracic and mediastinal disorders					
-Total	37 (49.3)	10 (13.3)	6 (8.0)	13 (17.3)	8 (10.7)
Cough	16 (21.3)	13 (17.3)	2 (2.7)	1 (1.3)	0
Hypoxia	16 (21.3)	0	3 (4.0)	9 (12.0)	4 (5.3)
Epistaxis	14 (18.7)	4 (5.3)	4 (5.3)	5 (6.7)	1 (1.3)
Pleural effusion	10 (13.3)	1 (1.3)	6 (8.0)	3 (4.0)	0
Pulmonary oedema	9 (12.0)	1 (1.3)	0	4 (5.3)	4 (5.3)
Oropharyngeal pain	8 (10.7)	5 (6.7)	2 (2.7)	1 (1.3)	0
Tachypnoea	8 (10.7)	3 (4.0)	2 (2.7)	3 (4.0)	0
Skin and subcutaneous tissue disorders					
-Total	10 (13.3)	7 (9.3)	3 (4.0)	0	0

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	10 (13.3)	7 (9.3)	3 (4.0)	0	0
Vascular disorders					
-Total	33 (44.0)	3 (4.0)	4 (5.3)	15 (20.0)	11 (14.7)
Hypotension	25 (33.3)	1 (1.3)	0	13 (17.3)	11 (14.7)
Hypertension	16 (21.3)	4 (5.3)	9 (12.0)	3 (4.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188l
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	0	9 (28.1)	23 (71.9)
Blood and lymphatic system disorders					
-Total	29 (90.6)	0	1 (3.1)	22 (68.8)	6 (18.8)
Anaemia	20 (62.5)	1 (3.1)	3 (9.4)	16 (50.0)	0
Febrile neutropenia	16 (50.0)	0	0	16 (50.0)	0
Thrombocytopenia	7 (21.9)	0	0	4 (12.5)	3 (9.4)
Neutropenia	4 (12.5)	0	0	1 (3.1)	3 (9.4)
Cardiac disorders					
-Total	12 (37.5)	5 (15.6)	5 (15.6)	2 (6.3)	0
Tachycardia	8 (25.0)	4 (12.5)	3 (9.4)	1 (3.1)	0
Sinus tachycardia	5 (15.6)	2 (6.3)	2 (6.3)	1 (3.1)	0

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	22 (68.8)	4 (12.5)	12 (37.5)	6 (18.8)	0
Nausea	16 (50.0)	5 (15.6)	9 (28.1)	2 (6.3)	0
Vomiting	14 (43.8)	9 (28.1)	3 (9.4)	2 (6.3)	0
Diarrhoea	13 (40.6)	6 (18.8)	6 (18.8)	1 (3.1)	0
Abdominal pain	11 (34.4)	4 (12.5)	6 (18.8)	1 (3.1)	0
Constipation	5 (15.6)	5 (15.6)	0	0	0
Stomatitis	5 (15.6)	1 (3.1)	1 (3.1)	3 (9.4)	0
General disorders and administration site conditions					
-Total	22 (68.8)	11 (34.4)	9 (28.1)	2 (6.3)	0
Pyrexia	16 (50.0)	9 (28.1)	6 (18.8)	1 (3.1)	0
Fatigue	10 (31.3)	8 (25.0)	1 (3.1)	1 (3.1)	0
Chills	5 (15.6)	5 (15.6)	0	0	0
Oedema peripheral	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Pain	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Catheter site pain	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Immune system disorders					

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	24 (75.0)	4 (12.5)	13 (40.6)	5 (15.6)	2 (6.3)
Cytokine release syndrome	20 (62.5)	3 (9.4)	11 (34.4)	4 (12.5)	2 (6.3)
Hypogammaglobulinaemia	14 (43.8)	3 (9.4)	10 (31.3)	1 (3.1)	0
Infections and infestations					
-Total	11 (34.4)	2 (6.3)	5 (15.6)	4 (12.5)	0
Upper respiratory tract infection	6 (18.8)	4 (12.5)	1 (3.1)	1 (3.1)	0
Clostridium difficile infection	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Urinary tract infection	4 (12.5)	0	2 (6.3)	2 (6.3)	0
Pneumonia	2 (6.3)	0	2 (6.3)	0	0
Injury, poisoning and procedural complications					
-Total	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Procedural pain	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Investigations					
-Total	26 (81.3)	0	3 (9.4)	3 (9.4)	20 (62.5)
Neutrophil count decreased	19 (59.4)	1 (3.1)	1 (3.1)	0	17 (53.1)
White blood cell count decreased	19 (59.4)	1 (3.1)	1 (3.1)	4 (12.5)	13 (40.6)
Alanine aminotransferase increased	17 (53.1)	3 (9.4)	2 (6.3)	11 (34.4)	1 (3.1)

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	16 (50.0)	5 (15.6)	2 (6.3)	6 (18.8)	3 (9.4)
Platelet count decreased	14 (43.8)	2 (6.3)	1 (3.1)	1 (3.1)	10 (31.3)
Lymphocyte count decreased	9 (28.1)	0	2 (6.3)	3 (9.4)	4 (12.5)
Blood bilirubin increased	7 (21.9)	2 (6.3)	2 (6.3)	2 (6.3)	1 (3.1)
International normalised ratio increased	7 (21.9)	6 (18.8)	1 (3.1)	0	0
Blood creatinine increased	6 (18.8)	4 (12.5)	1 (3.1)	1 (3.1)	0
Prothrombin time prolonged	6 (18.8)	4 (12.5)	2 (6.3)	0	0
Blood immunoglobulin m decreased	4 (12.5)	4 (12.5)	0	0	0
Metabolism and nutrition disorders					
-Total	23 (71.9)	2 (6.3)	7 (21.9)	10 (31.3)	4 (12.5)
Decreased appetite	15 (46.9)	4 (12.5)	4 (12.5)	7 (21.9)	0
Hypokalaemia	12 (37.5)	2 (6.3)	1 (3.1)	5 (15.6)	4 (12.5)
Hyperphosphataemia	8 (25.0)	7 (21.9)	1 (3.1)	0	0
Hypophosphataemia	7 (21.9)	2 (6.3)	1 (3.1)	4 (12.5)	0
Hyperglycaemia	6 (18.8)	0	2 (6.3)	3 (9.4)	1 (3.1)
Hypocalcaemia	5 (15.6)	2 (6.3)	1 (3.1)	1 (3.1)	1 (3.1)
Hyperuricaemia	4 (12.5)	4 (12.5)	0	0	0

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	4 (12.5)	0	3 (9.4)	0	1 (3.1)
Hypernatraemia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Hypomagnesaemia	1 (3.1)	1 (3.1)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	14 (43.8)	7 (21.9)	4 (12.5)	3 (9.4)	0
Pain in extremity	7 (21.9)	3 (9.4)	2 (6.3)	2 (6.3)	0
Myalgia	6 (18.8)	4 (12.5)	1 (3.1)	1 (3.1)	0
Arthralgia	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Nervous system disorders					
-Total	16 (50.0)	6 (18.8)	6 (18.8)	4 (12.5)	0
Headache	15 (46.9)	5 (15.6)	6 (18.8)	4 (12.5)	0
Dizziness	4 (12.5)	4 (12.5)	0	0	0
Psychiatric disorders					
-Total	6 (18.8)	1 (3.1)	4 (12.5)	1 (3.1)	0
Anxiety	5 (15.6)	1 (3.1)	3 (9.4)	1 (3.1)	0
Confusional state	2 (6.3)	0	2 (6.3)	0	0
Renal and urinary disorders					

Prior SCT therapy: Yes

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (9.4)	2 (6.3)	0	0	1 (3.1)
Acute kidney injury	3 (9.4)	2 (6.3)	0	0	1 (3.1)
Respiratory, thoracic and mediastinal disorders					
-Total	19 (59.4)	7 (21.9)	4 (12.5)	6 (18.8)	2 (6.3)
Cough	8 (25.0)	7 (21.9)	1 (3.1)	0	0
Hypoxia	8 (25.0)	0	3 (9.4)	3 (9.4)	2 (6.3)
Epistaxis	7 (21.9)	3 (9.4)	1 (3.1)	3 (9.4)	0
Pleural effusion	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Rhinitis allergic	4 (12.5)	4 (12.5)	0	0	0
Oropharyngeal pain	3 (9.4)	3 (9.4)	0	0	0
Tachypnoea	3 (9.4)	1 (3.1)	1 (3.1)	1 (3.1)	0
Nasal congestion	2 (6.3)	2 (6.3)	0	0	0
Rhinorrhoea	2 (6.3)	2 (6.3)	0	0	0
Pulmonary oedema	1 (3.1)	0	0	1 (3.1)	0
Skin and subcutaneous tissue disorders					
-Total	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Rash	5 (15.6)	4 (12.5)	1 (3.1)	0	0

Prior SCT therapy: Yes

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	16 (50.0)	3 (9.4)	1 (3.1)	9 (28.1)	3 (9.4)
Hypotension	11 (34.4)	1 (3.1)	0	7 (21.9)	3 (9.4)
Hypertension	8 (25.0)	2 (6.3)	3 (9.4)	3 (9.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188l
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (93.0)	1 (2.3)	3 (7.0)	5 (11.6)	31 (72.1)
Blood and lymphatic system disorders					
-Total	34 (79.1)	0	1 (2.3)	18 (41.9)	15 (34.9)
Febrile neutropenia	22 (51.2)	0	0	21 (48.8)	1 (2.3)
Anaemia	21 (48.8)	1 (2.3)	4 (9.3)	15 (34.9)	1 (2.3)
Neutropenia	15 (34.9)	0	0	3 (7.0)	12 (27.9)
Thrombocytopenia	10 (23.3)	0	1 (2.3)	2 (4.7)	7 (16.3)
Cardiac disorders					
-Total	11 (25.6)	6 (14.0)	3 (7.0)	2 (4.7)	0
Tachycardia	9 (20.9)	5 (11.6)	3 (7.0)	1 (2.3)	0
Sinus tachycardia	2 (4.7)	1 (2.3)	0	1 (2.3)	0

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	32 (74.4)	10 (23.3)	15 (34.9)	6 (14.0)	1 (2.3)
Nausea	20 (46.5)	3 (7.0)	12 (27.9)	5 (11.6)	0
Vomiting	19 (44.2)	8 (18.6)	9 (20.9)	2 (4.7)	0
Diarrhoea	14 (32.6)	8 (18.6)	4 (9.3)	2 (4.7)	0
Constipation	9 (20.9)	6 (14.0)	3 (7.0)	0	0
Abdominal pain	7 (16.3)	2 (4.7)	2 (4.7)	3 (7.0)	0
Stomatitis	2 (4.7)	1 (2.3)	0	0	1 (2.3)
General disorders and administration site conditions					
-Total	28 (65.1)	6 (14.0)	12 (27.9)	9 (20.9)	1 (2.3)
Pyrexia	20 (46.5)	3 (7.0)	9 (20.9)	7 (16.3)	1 (2.3)
Fatigue	11 (25.6)	7 (16.3)	3 (7.0)	1 (2.3)	0
Chills	7 (16.3)	5 (11.6)	2 (4.7)	0	0
Catheter site pain	5 (11.6)	1 (2.3)	4 (9.3)	0	0
Pain	4 (9.3)	0	2 (4.7)	2 (4.7)	0
Oedema peripheral	1 (2.3)	0	0	1 (2.3)	0
Immune system disorders					

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	34 (79.1)	1 (2.3)	18 (41.9)	6 (14.0)	9 (20.9)
Cytokine release syndrome	30 (69.8)	3 (7.0)	14 (32.6)	4 (9.3)	9 (20.9)
Hypogammaglobulinaemia	19 (44.2)	1 (2.3)	14 (32.6)	4 (9.3)	0
Infections and infestations					
-Total	15 (34.9)	1 (2.3)	11 (25.6)	2 (4.7)	1 (2.3)
Gastroenteritis	5 (11.6)	1 (2.3)	3 (7.0)	1 (2.3)	0
Pneumonia	5 (11.6)	0	3 (7.0)	1 (2.3)	1 (2.3)
Upper respiratory tract infection	5 (11.6)	1 (2.3)	4 (9.3)	0	0
Clostridium difficile infection	2 (4.7)	0	2 (4.7)	0	0
Urinary tract infection	1 (2.3)	0	1 (2.3)	0	0
Injury, poisoning and procedural complications					
-Total	4 (9.3)	1 (2.3)	1 (2.3)	2 (4.7)	0
Procedural pain	4 (9.3)	1 (2.3)	1 (2.3)	2 (4.7)	0
Investigations					
-Total	33 (76.7)	0	2 (4.7)	7 (16.3)	24 (55.8)
White blood cell count decreased	25 (58.1)	3 (7.0)	0	4 (9.3)	18 (41.9)
Neutrophil count decreased	16 (37.2)	0	1 (2.3)	3 (7.0)	12 (27.9)

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	12 (27.9)	1 (2.3)	1 (2.3)	3 (7.0)	7 (16.3)
Lymphocyte count decreased	10 (23.3)	1 (2.3)	1 (2.3)	4 (9.3)	4 (9.3)
Alanine aminotransferase increased	9 (20.9)	0	2 (4.7)	7 (16.3)	0
Aspartate aminotransferase increased	8 (18.6)	0	3 (7.0)	3 (7.0)	2 (4.7)
International normalised ratio increased	4 (9.3)	3 (7.0)	0	1 (2.3)	0
Blood bilirubin increased	3 (7.0)	0	1 (2.3)	2 (4.7)	0
Blood creatinine increased	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)	0
Prothrombin time prolonged	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)	0
Blood immunoglobulin m decreased	1 (2.3)	1 (2.3)	0	0	0
Metabolism and nutrition disorders					
-Total	26 (60.5)	4 (9.3)	6 (14.0)	11 (25.6)	5 (11.6)
Decreased appetite	17 (39.5)	3 (7.0)	6 (14.0)	8 (18.6)	0
Hypokalaemia	12 (27.9)	3 (7.0)	3 (7.0)	5 (11.6)	1 (2.3)
Hypophosphataemia	7 (16.3)	2 (4.7)	0	4 (9.3)	1 (2.3)
Hypernatraemia	5 (11.6)	1 (2.3)	2 (4.7)	0	2 (4.7)
Hypomagnesaemia	5 (11.6)	4 (9.3)	1 (2.3)	0	0
Hyperglycaemia	4 (9.3)	0	2 (4.7)	2 (4.7)	0

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	4 (9.3)	1 (2.3)	0	1 (2.3)	2 (4.7)
Hypoalbuminaemia	3 (7.0)	1 (2.3)	1 (2.3)	1 (2.3)	0
Hypocalcaemia	2 (4.7)	1 (2.3)	0	0	1 (2.3)
Hyperphosphataemia	1 (2.3)	1 (2.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	12 (27.9)	5 (11.6)	3 (7.0)	4 (9.3)	0
Pain in extremity	11 (25.6)	5 (11.6)	3 (7.0)	3 (7.0)	0
Arthralgia	4 (9.3)	1 (2.3)	1 (2.3)	2 (4.7)	0
Nervous system disorders					
-Total	17 (39.5)	10 (23.3)	5 (11.6)	2 (4.7)	0
Headache	16 (37.2)	9 (20.9)	5 (11.6)	2 (4.7)	0
Dizziness	2 (4.7)	2 (4.7)	0	0	0
Psychiatric disorders					
-Total	10 (23.3)	4 (9.3)	6 (14.0)	0	0
Confusional state	6 (14.0)	3 (7.0)	3 (7.0)	0	0
Anxiety	5 (11.6)	2 (4.7)	3 (7.0)	0	0
Renal and urinary disorders					

Prior SCT therapy: No

	All patients N=43				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (20.9)	0	1 (2.3)	5 (11.6)	3 (7.0)
Acute kidney injury	9 (20.9)	0	1 (2.3)	5 (11.6)	3 (7.0)
Respiratory, thoracic and mediastinal disorders					
-Total	23 (53.5)	6 (14.0)	4 (9.3)	7 (16.3)	6 (14.0)
Cough	8 (18.6)	6 (14.0)	1 (2.3)	1 (2.3)	0
Hypoxia	8 (18.6)	0	0	6 (14.0)	2 (4.7)
Pulmonary oedema	8 (18.6)	1 (2.3)	0	3 (7.0)	4 (9.3)
Epistaxis	7 (16.3)	1 (2.3)	3 (7.0)	2 (4.7)	1 (2.3)
Pleural effusion	6 (14.0)	0	4 (9.3)	2 (4.7)	0
Nasal congestion	5 (11.6)	5 (11.6)	0	0	0
Oropharyngeal pain	5 (11.6)	2 (4.7)	2 (4.7)	1 (2.3)	0
Rhinorrhoea	5 (11.6)	4 (9.3)	1 (2.3)	0	0
Tachypnoea	5 (11.6)	2 (4.7)	1 (2.3)	2 (4.7)	0
Rhinitis allergic	1 (2.3)	0	1 (2.3)	0	0
Skin and subcutaneous tissue disorders					
-Total	5 (11.6)	3 (7.0)	2 (4.7)	0	0
Rash	5 (11.6)	3 (7.0)	2 (4.7)	0	0

Prior SCT therapy: No

Group term Preferred term	All patients N=43 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	17 (39.5)	0	3 (7.0)	6 (14.0)	8 (18.6)
Hypotension	14 (32.6)	0	0	6 (14.0)	8 (18.6)
Hypertension	8 (18.6)	2 (4.7)	6 (14.0)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188m
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (94.4)	0	2 (11.1)	4 (22.2)	11 (61.1)
Blood and lymphatic system disorders					
-Total	13 (72.2)	0	1 (5.6)	8 (44.4)	4 (22.2)
Febrile neutropenia	10 (55.6)	0	0	10 (55.6)	0
Anaemia	7 (38.9)	1 (5.6)	2 (11.1)	4 (22.2)	0
Neutropenia	3 (16.7)	0	0	1 (5.6)	2 (11.1)
Thrombocytopenia	3 (16.7)	0	1 (5.6)	0	2 (11.1)
Cardiac disorders					
-Total	3 (16.7)	3 (16.7)	0	0	0
Tachycardia	2 (11.1)	2 (11.1)	0	0	0
Sinus tachycardia	1 (5.6)	1 (5.6)	0	0	0

Eligibility for SCT: Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	12 (66.7)	1 (5.6)	8 (44.4)	3 (16.7)	0
Nausea	8 (44.4)	0	6 (33.3)	2 (11.1)	0
Vomiting	6 (33.3)	2 (11.1)	3 (16.7)	1 (5.6)	0
Constipation	4 (22.2)	3 (16.7)	1 (5.6)	0	0
Diarrhoea	4 (22.2)	2 (11.1)	1 (5.6)	1 (5.6)	0
Abdominal pain	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Stomatitis	1 (5.6)	0	0	1 (5.6)	0
General disorders and administration site conditions					
-Total	8 (44.4)	2 (11.1)	3 (16.7)	3 (16.7)	0
Pyrexia	6 (33.3)	1 (5.6)	2 (11.1)	3 (16.7)	0
Catheter site pain	2 (11.1)	0	2 (11.1)	0	0
Fatigue	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Chills	1 (5.6)	1 (5.6)	0	0	0
Pain	1 (5.6)	0	0	1 (5.6)	0
Immune system disorders					
-Total	14 (77.8)	0	10 (55.6)	3 (16.7)	1 (5.6)

Eligibility for SCT: Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	13 (72.2)	0	10 (55.6)	2 (11.1)	1 (5.6)
Hypogammaglobulinaemia	8 (44.4)	1 (5.6)	6 (33.3)	1 (5.6)	0
Infections and infestations					
-Total	11 (61.1)	1 (5.6)	5 (27.8)	4 (22.2)	1 (5.6)
Viral upper respiratory tract infection	3 (16.7)	2 (11.1)	0	1 (5.6)	0
Conjunctivitis	2 (11.1)	0	2 (11.1)	0	0
Device related infection	2 (11.1)	0	0	2 (11.1)	0
Escherichia urinary tract infection	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Influenza	2 (11.1)	0	2 (11.1)	0	0
Pneumonia	2 (11.1)	0	0	1 (5.6)	1 (5.6)
Urinary tract infection	2 (11.1)	0	2 (11.1)	0	0
Injury, poisoning and procedural complications					
-Total	4 (22.2)	1 (5.6)	3 (16.7)	0	0
Procedural pain	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Radiation skin injury	2 (11.1)	0	2 (11.1)	0	0
Investigations					
-Total	13 (72.2)	0	1 (5.6)	2 (11.1)	10 (55.6)

Eligibility for SCT: Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	12 (66.7)	2 (11.1)	0	2 (11.1)	8 (44.4)
Neutrophil count decreased	8 (44.4)	1 (5.6)	0	2 (11.1)	5 (27.8)
Lymphocyte count decreased	6 (33.3)	1 (5.6)	1 (5.6)	2 (11.1)	2 (11.1)
Platelet count decreased	5 (27.8)	1 (5.6)	0	1 (5.6)	3 (16.7)
Blood bilirubin increased	3 (16.7)	1 (5.6)	1 (5.6)	1 (5.6)	0
Alanine aminotransferase increased	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Serum ferritin increased	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Aspartate aminotransferase increased	1 (5.6)	0	1 (5.6)	0	0
Blood creatinine increased	1 (5.6)	1 (5.6)	0	0	0
International normalised ratio increased	1 (5.6)	1 (5.6)	0	0	0
Prothrombin time prolonged	1 (5.6)	1 (5.6)	0	0	0
Metabolism and nutrition disorders					
-Total	11 (61.1)	2 (11.1)	3 (16.7)	4 (22.2)	2 (11.1)
Decreased appetite	8 (44.4)	2 (11.1)	4 (22.2)	2 (11.1)	0
Hypokalaemia	5 (27.8)	2 (11.1)	1 (5.6)	2 (11.1)	0
Dehydration	2 (11.1)	0	1 (5.6)	1 (5.6)	0
Hyperglycaemia	2 (11.1)	0	1 (5.6)	1 (5.6)	0

Eligibility for SCT: Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	2 (11.1)	2 (11.1)	0	0	0
Hyperuricaemia	2 (11.1)	1 (5.6)	0	0	1 (5.6)
Hypomagnesaemia	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Hypophosphataemia	2 (11.1)	1 (5.6)	0	0	1 (5.6)
Tumour lysis syndrome	2 (11.1)	0	0	2 (11.1)	0
Fluid overload	1 (5.6)	0	1 (5.6)	0	0
Hypoalbuminaemia	1 (5.6)	0	0	1 (5.6)	0
Hypocalcaemia	1 (5.6)	0	0	0	1 (5.6)
Musculoskeletal and connective tissue disorders					
-Total	10 (55.6)	4 (22.2)	5 (27.8)	1 (5.6)	0
Pain in extremity	6 (33.3)	3 (16.7)	2 (11.1)	1 (5.6)	0
Arthralgia	4 (22.2)	2 (11.1)	2 (11.1)	0	0
Muscular weakness	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Neck pain	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Pain in jaw	2 (11.1)	0	2 (11.1)	0	0
Nervous system disorders					
-Total	3 (16.7)	2 (11.1)	1 (5.6)	0	0

Eligibility for SCT: Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	3 (16.7)	2 (11.1)	1 (5.6)	0	0
Psychiatric disorders					
-Total	1 (5.6)	0	1 (5.6)	0	0
Confusional state	1 (5.6)	0	1 (5.6)	0	0
Renal and urinary disorders					
-Total	1 (5.6)	0	0	1 (5.6)	0
Acute kidney injury	1 (5.6)	0	0	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders					
-Total	9 (50.0)	2 (11.1)	4 (22.2)	3 (16.7)	0
Cough	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Epistaxis	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Hypoxia	3 (16.7)	0	1 (5.6)	2 (11.1)	0
Nasal congestion	3 (16.7)	3 (16.7)	0	0	0
Pleural effusion	3 (16.7)	0	2 (11.1)	1 (5.6)	0
Rhinorrhoea	2 (11.1)	1 (5.6)	1 (5.6)	0	0
Oropharyngeal pain	1 (5.6)	1 (5.6)	0	0	0
Pulmonary oedema	1 (5.6)	0	0	1 (5.6)	0

Eligibility for SCT: Yes

	All patients N=18				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	1 (5.6)	1 (5.6)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (16.7)	3 (16.7)	0	0	0
Rash erythematous	2 (11.1)	2 (11.1)	0	0	0
Rash	1 (5.6)	1 (5.6)	0	0	0
Vascular disorders					
-Total	6 (33.3)	1 (5.6)	2 (11.1)	2 (11.1)	1 (5.6)
Hypertension	3 (16.7)	1 (5.6)	2 (11.1)	0	0
Hypotension	3 (16.7)	0	0	2 (11.1)	1 (5.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188m
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	56 (98.2)	1 (1.8)	1 (1.8)	11 (19.3)	43 (75.4)
Blood and lymphatic system disorders					
-Total	50 (87.7)	0	1 (1.8)	31 (54.4)	18 (31.6)
Anaemia	34 (59.6)	1 (1.8)	5 (8.8)	27 (47.4)	1 (1.8)
Febrile neutropenia	28 (49.1)	0	0	27 (47.4)	1 (1.8)
Neutropenia	16 (28.1)	0	0	3 (5.3)	13 (22.8)
Thrombocytopenia	14 (24.6)	0	0	6 (10.5)	8 (14.0)
Disseminated intravascular coagulation	7 (12.3)	0	2 (3.5)	4 (7.0)	1 (1.8)
Lymphopenia	6 (10.5)	0	2 (3.5)	1 (1.8)	3 (5.3)
Cardiac disorders					

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	20 (35.1)	8 (14.0)	8 (14.0)	4 (7.0)	0
Tachycardia	15 (26.3)	7 (12.3)	6 (10.5)	2 (3.5)	0
Sinus tachycardia	6 (10.5)	2 (3.5)	2 (3.5)	2 (3.5)	0
Gastrointestinal disorders					
-Total	42 (73.7)	13 (22.8)	19 (33.3)	9 (15.8)	1 (1.8)
Nausea	28 (49.1)	8 (14.0)	15 (26.3)	5 (8.8)	0
Vomiting	27 (47.4)	15 (26.3)	9 (15.8)	3 (5.3)	0
Diarrhoea	23 (40.4)	12 (21.1)	9 (15.8)	2 (3.5)	0
Abdominal pain	16 (28.1)	6 (10.5)	7 (12.3)	3 (5.3)	0
Constipation	10 (17.5)	8 (14.0)	2 (3.5)	0	0
Stomatitis	6 (10.5)	2 (3.5)	1 (1.8)	2 (3.5)	1 (1.8)
General disorders and administration site conditions					
-Total	42 (73.7)	15 (26.3)	19 (33.3)	7 (12.3)	1 (1.8)
Pyrexia	30 (52.6)	11 (19.3)	13 (22.8)	5 (8.8)	1 (1.8)
Fatigue	19 (33.3)	14 (24.6)	3 (5.3)	2 (3.5)	0
Chills	11 (19.3)	9 (15.8)	2 (3.5)	0	0
Pain	7 (12.3)	1 (1.8)	4 (7.0)	2 (3.5)	0

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site pain	5 (8.8)	2 (3.5)	3 (5.3)	0	0
Hepatobiliary disorders					
-Total	6 (10.5)	0	2 (3.5)	4 (7.0)	0
Hyperbilirubinaemia	6 (10.5)	0	2 (3.5)	4 (7.0)	0
Immune system disorders					
-Total	44 (77.2)	5 (8.8)	21 (36.8)	8 (14.0)	10 (17.5)
Cytokine release syndrome	37 (64.9)	6 (10.5)	15 (26.3)	6 (10.5)	10 (17.5)
Hypogammaglobulinaemia	25 (43.9)	3 (5.3)	18 (31.6)	4 (7.0)	0
Infections and infestations					
-Total	21 (36.8)	3 (5.3)	13 (22.8)	5 (8.8)	0
Upper respiratory tract infection	11 (19.3)	5 (8.8)	5 (8.8)	1 (1.8)	0
Pneumonia	5 (8.8)	0	5 (8.8)	0	0
Device related infection	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Urinary tract infection	3 (5.3)	0	1 (1.8)	2 (3.5)	0
Influenza	2 (3.5)	1 (1.8)	1 (1.8)	0	0
Escherichia urinary tract infection	1 (1.8)	0	0	1 (1.8)	0
Viral upper respiratory tract infection	1 (1.8)	0	1 (1.8)	0	0

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications					
-Total	6 (10.5)	0	3 (5.3)	3 (5.3)	0
Procedural pain	6 (10.5)	0	3 (5.3)	3 (5.3)	0
Investigations					
-Total	46 (80.7)	0	4 (7.0)	8 (14.0)	34 (59.6)
White blood cell count decreased	32 (56.1)	2 (3.5)	1 (1.8)	6 (10.5)	23 (40.4)
Neutrophil count decreased	27 (47.4)	0	2 (3.5)	1 (1.8)	24 (42.1)
Alanine aminotransferase increased	24 (42.1)	3 (5.3)	3 (5.3)	17 (29.8)	1 (1.8)
Aspartate aminotransferase increased	23 (40.4)	5 (8.8)	4 (7.0)	9 (15.8)	5 (8.8)
Platelet count decreased	21 (36.8)	2 (3.5)	2 (3.5)	3 (5.3)	14 (24.6)
Lymphocyte count decreased	13 (22.8)	0	2 (3.5)	5 (8.8)	6 (10.5)
International normalised ratio increased	10 (17.5)	8 (14.0)	1 (1.8)	1 (1.8)	0
Blood creatinine increased	8 (14.0)	4 (7.0)	2 (3.5)	2 (3.5)	0
Prothrombin time prolonged	8 (14.0)	4 (7.0)	3 (5.3)	1 (1.8)	0
Blood bilirubin increased	7 (12.3)	1 (1.8)	2 (3.5)	3 (5.3)	1 (1.8)

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Activated partial thromboplastin time prolonged	6 (10.5)	3 (5.3)	3 (5.3)	0	0
Serum ferritin increased	1 (1.8)	0	1 (1.8)	0	0
Metabolism and nutrition disorders					
-Total	43 (75.4)	2 (3.5)	10 (17.5)	24 (42.1)	7 (12.3)
Decreased appetite	24 (42.1)	5 (8.8)	6 (10.5)	13 (22.8)	0
Hypokalaemia	19 (33.3)	3 (5.3)	3 (5.3)	8 (14.0)	5 (8.8)
Hypophosphataemia	12 (21.1)	3 (5.3)	1 (1.8)	8 (14.0)	0
Hyperglycaemia	8 (14.0)	0	3 (5.3)	4 (7.0)	1 (1.8)
Hypernatraemia	7 (12.3)	1 (1.8)	2 (3.5)	1 (1.8)	3 (5.3)
Hyperphosphataemia	7 (12.3)	6 (10.5)	1 (1.8)	0	0
Fluid overload	6 (10.5)	1 (1.8)	4 (7.0)	1 (1.8)	0
Hyperuricaemia	6 (10.5)	4 (7.0)	0	1 (1.8)	1 (1.8)
Hypoalbuminaemia	6 (10.5)	1 (1.8)	4 (7.0)	0	1 (1.8)
Hypocalcaemia	6 (10.5)	3 (5.3)	1 (1.8)	1 (1.8)	1 (1.8)
Dehydration	5 (8.8)	1 (1.8)	1 (1.8)	3 (5.3)	0
Hypomagnesaemia	4 (7.0)	4 (7.0)	0	0	0
Tumour lysis syndrome	3 (5.3)	0	0	3 (5.3)	0

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders					
-Total	20 (35.1)	9 (15.8)	5 (8.8)	6 (10.5)	0
Pain in extremity	12 (21.1)	5 (8.8)	3 (5.3)	4 (7.0)	0
Myalgia	6 (10.5)	4 (7.0)	1 (1.8)	1 (1.8)	0
Arthralgia	4 (7.0)	2 (3.5)	0	2 (3.5)	0
Pain in jaw	3 (5.3)	2 (3.5)	1 (1.8)	0	0
Neck pain	2 (3.5)	0	2 (3.5)	0	0
Muscular weakness	1 (1.8)	1 (1.8)	0	0	0
Nervous system disorders					
-Total	28 (49.1)	12 (21.1)	10 (17.5)	6 (10.5)	0
Headache	28 (49.1)	12 (21.1)	10 (17.5)	6 (10.5)	0
Psychiatric disorders					
-Total	15 (26.3)	5 (8.8)	9 (15.8)	1 (1.8)	0
Anxiety	10 (17.5)	3 (5.3)	6 (10.5)	1 (1.8)	0
Confusional state	7 (12.3)	3 (5.3)	4 (7.0)	0	0
Renal and urinary disorders					
-Total	14 (24.6)	3 (5.3)	1 (1.8)	5 (8.8)	5 (8.8)

Eligibility for SCT: No

	All patients N=57				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	11 (19.3)	2 (3.5)	1 (1.8)	4 (7.0)	4 (7.0)
Haematuria	6 (10.5)	1 (1.8)	2 (3.5)	2 (3.5)	1 (1.8)
Respiratory, thoracic and mediastinal disorders					
-Total	31 (54.4)	10 (17.5)	3 (5.3)	10 (17.5)	8 (14.0)
Cough	13 (22.8)	12 (21.1)	0	1 (1.8)	0
Hypoxia	13 (22.8)	0	2 (3.5)	7 (12.3)	4 (7.0)
Epistaxis	11 (19.3)	3 (5.3)	2 (3.5)	5 (8.8)	1 (1.8)
Pulmonary oedema	8 (14.0)	1 (1.8)	0	3 (5.3)	4 (7.0)
Oropharyngeal pain	7 (12.3)	4 (7.0)	2 (3.5)	1 (1.8)	0
Pleural effusion	7 (12.3)	1 (1.8)	4 (7.0)	2 (3.5)	0
Tachypnoea	7 (12.3)	2 (3.5)	2 (3.5)	3 (5.3)	0
Rhinorrhoea	5 (8.8)	5 (8.8)	0	0	0
Nasal congestion	4 (7.0)	4 (7.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (19.3)	5 (8.8)	6 (10.5)	0	0
Rash	9 (15.8)	6 (10.5)	3 (5.3)	0	0
Rash erythematous	3 (5.3)	0	3 (5.3)	0	0

Eligibility for SCT: No

Group term Preferred term	All patients N=57 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders					
-Total	27 (47.4)	2 (3.5)	2 (3.5)	13 (22.8)	10 (17.5)
Hypotension	22 (38.6)	1 (1.8)	0	11 (19.3)	10 (17.5)
Hypertension	13 (22.8)	3 (5.3)	7 (12.3)	3 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188n
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (100)	0	0	6 (27.3)	16 (72.7)
Blood and lymphatic system disorders					
-Total	22 (100)	0	0	15 (68.2)	7 (31.8)
Anaemia	14 (63.6)	1 (4.5)	2 (9.1)	11 (50.0)	0
Febrile neutropenia	12 (54.5)	0	0	12 (54.5)	0
Neutropenia	7 (31.8)	0	0	2 (9.1)	5 (22.7)
Thrombocytopenia	6 (27.3)	0	0	3 (13.6)	3 (13.6)
Disseminated intravascular coagulation	3 (13.6)	0	1 (4.5)	1 (4.5)	1 (4.5)
Cardiac disorders					
-Total	4 (18.2)	1 (4.5)	2 (9.1)	1 (4.5)	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Sinus tachycardia	1 (4.5)	0	0	1 (4.5)	0
Gastrointestinal disorders					
-Total	18 (81.8)	5 (22.7)	8 (36.4)	5 (22.7)	0
Vomiting	13 (59.1)	8 (36.4)	3 (13.6)	2 (9.1)	0
Nausea	11 (50.0)	4 (18.2)	5 (22.7)	2 (9.1)	0
Abdominal pain	7 (31.8)	2 (9.1)	2 (9.1)	3 (13.6)	0
Diarrhoea	6 (27.3)	2 (9.1)	2 (9.1)	2 (9.1)	0
Constipation	4 (18.2)	3 (13.6)	1 (4.5)	0	0
Stomatitis	4 (18.2)	1 (4.5)	1 (4.5)	2 (9.1)	0
Oral pain	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
General disorders and administration site conditions					
-Total	14 (63.6)	7 (31.8)	4 (18.2)	3 (13.6)	0
Pyrexia	10 (45.5)	5 (22.7)	3 (13.6)	2 (9.1)	0
Fatigue	6 (27.3)	5 (22.7)	1 (4.5)	0	0
Catheter site pain	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Chills	2 (9.1)	2 (9.1)	0	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Immune system disorders					
-Total	18 (81.8)	1 (4.5)	11 (50.0)	4 (18.2)	2 (9.1)
Cytokine release syndrome	16 (72.7)	0	11 (50.0)	3 (13.6)	2 (9.1)
Hypogammaglobulinaemia	13 (59.1)	2 (9.1)	10 (45.5)	1 (4.5)	0
Infections and infestations					
-Total	9 (40.9)	3 (13.6)	6 (27.3)	0	0
Upper respiratory tract infection	5 (22.7)	1 (4.5)	4 (18.2)	0	0
Viral infection	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Pneumonia	1 (4.5)	0	1 (4.5)	0	0
Injury, poisoning and procedural complications					
-Total	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Procedural pain	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Investigations					
-Total	21 (95.5)	0	2 (9.1)	5 (22.7)	14 (63.6)
White blood cell count decreased	14 (63.6)	2 (9.1)	0	2 (9.1)	10 (45.5)
Neutrophil count decreased	12 (54.5)	1 (4.5)	0	2 (9.1)	9 (40.9)

Baseline bone marrow tumor burden: Low

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	8 (36.4)	1 (4.5)	1 (4.5)	3 (13.6)	3 (13.6)
Aspartate aminotransferase increased	7 (31.8)	0	3 (13.6)	2 (9.1)	2 (9.1)
Platelet count decreased	7 (31.8)	2 (9.1)	0	1 (4.5)	4 (18.2)
Alanine aminotransferase increased	6 (27.3)	1 (4.5)	1 (4.5)	3 (13.6)	1 (4.5)
Blood bilirubin increased	5 (22.7)	2 (9.1)	0	2 (9.1)	1 (4.5)
International normalised ratio increased	5 (22.7)	4 (18.2)	1 (4.5)	0	0
Blood creatinine increased	3 (13.6)	3 (13.6)	0	0	0
Prothrombin time prolonged	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Metabolism and nutrition disorders					
-Total	12 (54.5)	1 (4.5)	2 (9.1)	7 (31.8)	2 (9.1)
Decreased appetite	8 (36.4)	1 (4.5)	3 (13.6)	4 (18.2)	0
Dehydration	4 (18.2)	0	1 (4.5)	3 (13.6)	0
Hypokalaemia	3 (13.6)	1 (4.5)	0	1 (4.5)	1 (4.5)
Hypophosphataemia	3 (13.6)	1 (4.5)	0	2 (9.1)	0
Hyperphosphataemia	2 (9.1)	2 (9.1)	0	0	0
Hypernatraemia	1 (4.5)	0	0	0	1 (4.5)
Hyperuricaemia	1 (4.5)	0	0	0	1 (4.5)

Baseline bone marrow tumor burden: Low

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	1 (4.5)	0	1 (4.5)	0	0
Hypocalcaemia	1 (4.5)	1 (4.5)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	12 (54.5)	6 (27.3)	2 (9.1)	4 (18.2)	0
Pain in extremity	8 (36.4)	4 (18.2)	2 (9.1)	2 (9.1)	0
Arthralgia	4 (18.2)	1 (4.5)	1 (4.5)	2 (9.1)	0
Myalgia	3 (13.6)	2 (9.1)	0	1 (4.5)	0
Nervous system disorders					
-Total	14 (63.6)	5 (22.7)	6 (27.3)	2 (9.1)	1 (4.5)
Headache	8 (36.4)	3 (13.6)	3 (13.6)	2 (9.1)	0
Encephalopathy	3 (13.6)	1 (4.5)	1 (4.5)	1 (4.5)	0
Peroneal nerve palsy	3 (13.6)	2 (9.1)	1 (4.5)	0	0
Seizure	3 (13.6)	0	1 (4.5)	1 (4.5)	1 (4.5)
Psychiatric disorders					
-Total	6 (27.3)	4 (18.2)	2 (9.1)	0	0
Anxiety	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Depression	3 (13.6)	3 (13.6)	0	0	0

Baseline bone marrow tumor burden: Low

	All patients N=22				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Confusional state	1 (4.5)	1 (4.5)	0	0	0
Renal and urinary disorders					
-Total	1 (4.5)	0	0	1 (4.5)	0
Acute kidney injury	1 (4.5)	0	0	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (50.0)	4 (18.2)	2 (9.1)	4 (18.2)	1 (4.5)
Cough	6 (27.3)	4 (18.2)	1 (4.5)	1 (4.5)	0
Hypoxia	5 (22.7)	0	2 (9.1)	3 (13.6)	0
Nasal congestion	3 (13.6)	3 (13.6)	0	0	0
Oropharyngeal pain	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Pleural effusion	2 (9.1)	1 (4.5)	0	1 (4.5)	0
Pulmonary oedema	2 (9.1)	0	0	1 (4.5)	1 (4.5)
Tachypnoea	2 (9.1)	0	1 (4.5)	1 (4.5)	0
Epistaxis	1 (4.5)	0	0	1 (4.5)	0
Skin and subcutaneous tissue disorders					
-Total	8 (36.4)	5 (22.7)	3 (13.6)	0	0
Erythema	4 (18.2)	4 (18.2)	0	0	0

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=22 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Alopecia	3 (13.6)	1 (4.5)	2 (9.1)	0	0
Rash	2 (9.1)	1 (4.5)	1 (4.5)	0	0
Vascular disorders					
-Total	10 (45.5)	1 (4.5)	2 (9.1)	5 (22.7)	2 (9.1)
Hypertension	7 (31.8)	2 (9.1)	4 (18.2)	1 (4.5)	0
Hypotension	6 (27.3)	0	0	4 (18.2)	2 (9.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188n
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (94.3)	1 (1.9)	3 (5.7)	8 (15.1)	38 (71.7)
Blood and lymphatic system disorders					
-Total	41 (77.4)	0	2 (3.8)	25 (47.2)	14 (26.4)
Anaemia	27 (50.9)	1 (1.9)	5 (9.4)	20 (37.7)	1 (1.9)
Febrile neutropenia	26 (49.1)	0	0	25 (47.2)	1 (1.9)
Neutropenia	12 (22.6)	0	0	2 (3.8)	10 (18.9)
Thrombocytopenia	11 (20.8)	0	1 (1.9)	3 (5.7)	7 (13.2)
Disseminated intravascular coagulation	4 (7.5)	0	1 (1.9)	3 (5.7)	0
Cardiac disorders					
-Total	19 (35.8)	10 (18.9)	6 (11.3)	3 (5.7)	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	14 (26.4)	8 (15.1)	4 (7.5)	2 (3.8)	0
Sinus tachycardia	6 (11.3)	3 (5.7)	2 (3.8)	1 (1.9)	0
Gastrointestinal disorders					
-Total	36 (67.9)	8 (15.1)	19 (35.8)	8 (15.1)	1 (1.9)
Nausea	25 (47.2)	4 (7.5)	16 (30.2)	5 (9.4)	0
Diarrhoea	21 (39.6)	12 (22.6)	8 (15.1)	1 (1.9)	0
Vomiting	20 (37.7)	9 (17.0)	9 (17.0)	2 (3.8)	0
Abdominal pain	11 (20.8)	4 (7.5)	6 (11.3)	1 (1.9)	0
Constipation	10 (18.9)	8 (15.1)	2 (3.8)	0	0
Stomatitis	3 (5.7)	1 (1.9)	0	1 (1.9)	1 (1.9)
General disorders and administration site conditions					
-Total	36 (67.9)	10 (18.9)	18 (34.0)	7 (13.2)	1 (1.9)
Pyrexia	26 (49.1)	7 (13.2)	12 (22.6)	6 (11.3)	1 (1.9)
Fatigue	15 (28.3)	10 (18.9)	3 (5.7)	2 (3.8)	0
Chills	10 (18.9)	8 (15.1)	2 (3.8)	0	0
Pain	6 (11.3)	1 (1.9)	3 (5.7)	2 (3.8)	0
Catheter site pain	4 (7.5)	1 (1.9)	3 (5.7)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	40 (75.5)	4 (7.5)	20 (37.7)	7 (13.2)	9 (17.0)
Cytokine release syndrome	34 (64.2)	6 (11.3)	14 (26.4)	5 (9.4)	9 (17.0)
Hypogammaglobulinaemia	20 (37.7)	2 (3.8)	14 (26.4)	4 (7.5)	0
Infections and infestations					
-Total	15 (28.3)	1 (1.9)	10 (18.9)	3 (5.7)	1 (1.9)
Clostridium difficile infection	6 (11.3)	0	5 (9.4)	1 (1.9)	0
Pneumonia	6 (11.3)	0	4 (7.5)	1 (1.9)	1 (1.9)
Upper respiratory tract infection	6 (11.3)	4 (7.5)	1 (1.9)	1 (1.9)	0
Injury, poisoning and procedural complications					
-Total	6 (11.3)	1 (1.9)	3 (5.7)	2 (3.8)	0
Procedural pain	6 (11.3)	1 (1.9)	3 (5.7)	2 (3.8)	0
Investigations					
-Total	38 (71.7)	0	3 (5.7)	5 (9.4)	30 (56.6)
White blood cell count decreased	30 (56.6)	2 (3.8)	1 (1.9)	6 (11.3)	21 (39.6)
Neutrophil count decreased	23 (43.4)	0	2 (3.8)	1 (1.9)	20 (37.7)
Alanine aminotransferase increased	20 (37.7)	2 (3.8)	3 (5.7)	15 (28.3)	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	19 (35.8)	1 (1.9)	2 (3.8)	3 (5.7)	13 (24.5)
Aspartate aminotransferase increased	17 (32.1)	5 (9.4)	2 (3.8)	7 (13.2)	3 (5.7)
Lymphocyte count decreased	11 (20.8)	0	2 (3.8)	4 (7.5)	5 (9.4)
Prothrombin time prolonged	7 (13.2)	4 (7.5)	2 (3.8)	1 (1.9)	0
Blood creatinine increased	6 (11.3)	2 (3.8)	2 (3.8)	2 (3.8)	0
International normalised ratio increased	6 (11.3)	5 (9.4)	0	1 (1.9)	0
Blood bilirubin increased	5 (9.4)	0	3 (5.7)	2 (3.8)	0
Metabolism and nutrition disorders					
-Total	39 (73.6)	4 (7.5)	11 (20.8)	17 (32.1)	7 (13.2)
Decreased appetite	24 (45.3)	6 (11.3)	7 (13.2)	11 (20.8)	0
Hypokalaemia	21 (39.6)	4 (7.5)	4 (7.5)	9 (17.0)	4 (7.5)
Hypophosphataemia	11 (20.8)	3 (5.7)	1 (1.9)	6 (11.3)	1 (1.9)
Hyperglycaemia	10 (18.9)	0	4 (7.5)	5 (9.4)	1 (1.9)
Hyperphosphataemia	7 (13.2)	6 (11.3)	1 (1.9)	0	0
Hyperuricaemia	7 (13.2)	5 (9.4)	0	1 (1.9)	1 (1.9)
Hypernatraemia	6 (11.3)	1 (1.9)	2 (3.8)	1 (1.9)	2 (3.8)
Hypoalbuminaemia	6 (11.3)	1 (1.9)	3 (5.7)	1 (1.9)	1 (1.9)

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypocalcaemia	6 (11.3)	2 (3.8)	1 (1.9)	1 (1.9)	2 (3.8)
Dehydration	3 (5.7)	1 (1.9)	1 (1.9)	1 (1.9)	0
Musculoskeletal and connective tissue disorders					
-Total	14 (26.4)	6 (11.3)	5 (9.4)	3 (5.7)	0
Pain in extremity	10 (18.9)	4 (7.5)	3 (5.7)	3 (5.7)	0
Arthralgia	4 (7.5)	3 (5.7)	1 (1.9)	0	0
Myalgia	3 (5.7)	2 (3.8)	1 (1.9)	0	0
Nervous system disorders					
-Total	25 (47.2)	12 (22.6)	7 (13.2)	6 (11.3)	0
Headache	23 (43.4)	11 (20.8)	8 (15.1)	4 (7.5)	0
Dizziness	6 (11.3)	6 (11.3)	0	0	0
Seizure	2 (3.8)	0	1 (1.9)	1 (1.9)	0
Encephalopathy	1 (1.9)	0	0	1 (1.9)	0
Psychiatric disorders					
-Total	12 (22.6)	3 (5.7)	8 (15.1)	1 (1.9)	0
Anxiety	7 (13.2)	2 (3.8)	4 (7.5)	1 (1.9)	0
Confusional state	7 (13.2)	2 (3.8)	5 (9.4)	0	0

Baseline bone marrow tumor burden: High

	All patients N=53				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Depression	2 (3.8)	0	2 (3.8)	0	0
Renal and urinary disorders					
-Total	14 (26.4)	3 (5.7)	1 (1.9)	5 (9.4)	5 (9.4)
Acute kidney injury	11 (20.8)	2 (3.8)	1 (1.9)	4 (7.5)	4 (7.5)
Haematuria	6 (11.3)	1 (1.9)	2 (3.8)	2 (3.8)	1 (1.9)
Respiratory, thoracic and mediastinal disorders					
-Total	28 (52.8)	8 (15.1)	4 (7.5)	9 (17.0)	7 (13.2)
Epistaxis	13 (24.5)	4 (7.5)	4 (7.5)	4 (7.5)	1 (1.9)
Hypoxia	11 (20.8)	0	1 (1.9)	6 (11.3)	4 (7.5)
Cough	10 (18.9)	9 (17.0)	1 (1.9)	0	0
Pleural effusion	8 (15.1)	0	6 (11.3)	2 (3.8)	0
Pulmonary oedema	7 (13.2)	1 (1.9)	0	3 (5.7)	3 (5.7)
Oropharyngeal pain	6 (11.3)	5 (9.4)	1 (1.9)	0	0
Tachypnoea	6 (11.3)	3 (5.7)	1 (1.9)	2 (3.8)	0
Nasal congestion	4 (7.5)	4 (7.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	9 (17.0)	7 (13.2)	2 (3.8)	0	0

Baseline bone marrow tumor burden: High

Group term Preferred term	All patients N=53 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	8 (15.1)	6 (11.3)	2 (3.8)	0	0
Alopecia	1 (1.9)	1 (1.9)	0	0	0
Erythema	1 (1.9)	1 (1.9)	0	0	0
Vascular disorders					
-Total	23 (43.4)	2 (3.8)	2 (3.8)	10 (18.9)	9 (17.0)
Hypotension	19 (35.8)	1 (1.9)	0	9 (17.0)	9 (17.0)
Hypertension	9 (17.0)	2 (3.8)	5 (9.4)	2 (3.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188o
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	0	1 (14.3)	5 (71.4)
Blood and lymphatic system disorders					
-Total	5 (71.4)	0	0	2 (28.6)	3 (42.9)
Febrile neutropenia	4 (57.1)	0	0	3 (42.9)	1 (14.3)
Anaemia	3 (42.9)	0	0	3 (42.9)	0
Neutropenia	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Leukopenia	1 (14.3)	0	0	0	1 (14.3)
Lymphadenopathy	1 (14.3)	0	1 (14.3)	0	0
Lymphopenia	1 (14.3)	0	0	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	0	0	1 (14.3)
Cardiac disorders					

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Bradycardia	1 (14.3)	0	1 (14.3)	0	0
Pericardial effusion	1 (14.3)	0	1 (14.3)	0	0
Tachycardia	1 (14.3)	1 (14.3)	0	0	0
Ear and labyrinth disorders					
-Total	1 (14.3)	0	1 (14.3)	0	0
Tympanic membrane perforation	1 (14.3)	0	1 (14.3)	0	0
Eye disorders					
-Total	1 (14.3)	1 (14.3)	0	0	0
Conjunctival haemorrhage	1 (14.3)	1 (14.3)	0	0	0
Periorbital oedema	1 (14.3)	1 (14.3)	0	0	0
Gastrointestinal disorders					
-Total	4 (57.1)	0	3 (42.9)	1 (14.3)	0
Nausea	3 (42.9)	1 (14.3)	2 (28.6)	0	0
Vomiting	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Abdominal pain	1 (14.3)	0	1 (14.3)	0	0
Colitis	1 (14.3)	1 (14.3)	0	0	0
Constipation	1 (14.3)	0	1 (14.3)	0	0

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphagia	1 (14.3)	0	0	1 (14.3)	0
Pancreatic failure	1 (14.3)	0	1 (14.3)	0	0
Perianal erythema	1 (14.3)	0	1 (14.3)	0	0
General disorders and administration site conditions					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Pyrexia	2 (28.6)	0	2 (28.6)	0	0
Acquired gene mutation	1 (14.3)	1 (14.3)	0	0	0
Chills	1 (14.3)	0	1 (14.3)	0	0
Face oedema	1 (14.3)	0	0	1 (14.3)	0
Localised oedema	1 (14.3)	0	0	1 (14.3)	0
Malaise	1 (14.3)	0	1 (14.3)	0	0
Mucosal haemorrhage	1 (14.3)	0	1 (14.3)	0	0
Multiple organ dysfunction syndrome	1 (14.3)	0	0	1 (14.3)	0
Oedema peripheral	1 (14.3)	0	0	1 (14.3)	0
Hepatobiliary disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Hyperbilirubinaemia	2 (28.6)	0	1 (14.3)	1 (14.3)	0

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders					
-Total	5 (71.4)	1 (14.3)	1 (14.3)	2 (28.6)	1 (14.3)
Cytokine release syndrome	4 (57.1)	2 (28.6)	1 (14.3)	0	1 (14.3)
Hypogammaglobulinaemia	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Anaphylactic reaction	2 (28.6)	0	0	2 (28.6)	0
Immunodeficiency	1 (14.3)	0	1 (14.3)	0	0
Seasonal allergy	1 (14.3)	1 (14.3)	0	0	0
Infections and infestations					
-Total	4 (57.1)	0	0	4 (57.1)	0
Pneumonia	2 (28.6)	0	2 (28.6)	0	0
Sinusitis	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Device related infection	1 (14.3)	0	0	1 (14.3)	0
Escherichia bacteraemia	1 (14.3)	0	0	1 (14.3)	0
Escherichia infection	1 (14.3)	0	0	1 (14.3)	0
Gastroenteritis	1 (14.3)	0	1 (14.3)	0	0
Haemophilus infection	1 (14.3)	0	1 (14.3)	0	0
Otitis media	1 (14.3)	0	0	1 (14.3)	0
Otitis media acute	1 (14.3)	0	1 (14.3)	0	0

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal infection	1 (14.3)	0	0	1 (14.3)	0
Subcutaneous abscess	1 (14.3)	0	1 (14.3)	0	0
Upper respiratory tract infection	1 (14.3)	1 (14.3)	0	0	0
Viral upper respiratory tract infection	1 (14.3)	0	0	1 (14.3)	0
Injury, poisoning and procedural complications					
-Total	4 (57.1)	1 (14.3)	1 (14.3)	2 (28.6)	0
Procedural pain	2 (28.6)	0	0	2 (28.6)	0
Arthropod bite	1 (14.3)	1 (14.3)	0	0	0
Extradural haematoma	1 (14.3)	0	0	1 (14.3)	0
Procedural complication	1 (14.3)	1 (14.3)	0	0	0
Radiation skin injury	1 (14.3)	0	1 (14.3)	0	0
Subdural haematoma	1 (14.3)	0	0	1 (14.3)	0
Investigations					
-Total	4 (57.1)	0	0	0	4 (57.1)
Alanine aminotransferase increased	3 (42.9)	0	0	3 (42.9)	0
Aspartate aminotransferase increased	3 (42.9)	0	1 (14.3)	1 (14.3)	1 (14.3)
White blood cell count decreased	3 (42.9)	0	0	1 (14.3)	2 (28.6)

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
C-reactive protein increased	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Neutrophil count decreased	2 (28.6)	0	0	0	2 (28.6)
Platelet count decreased	2 (28.6)	0	0	1 (14.3)	1 (14.3)
Activated partial thromboplastin time prolonged	1 (14.3)	1 (14.3)	0	0	0
Blood alkaline phosphatase increased	1 (14.3)	1 (14.3)	0	0	0
Blood bilirubin increased	1 (14.3)	0	0	1 (14.3)	0
Blood creatinine increased	1 (14.3)	0	0	1 (14.3)	0
Blood fibrinogen decreased	1 (14.3)	0	0	0	1 (14.3)
Blood lactate dehydrogenase increased	1 (14.3)	1 (14.3)	0	0	0
Blood lactic acid increased	1 (14.3)	0	1 (14.3)	0	0
Blood phosphorus decreased	1 (14.3)	1 (14.3)	0	0	0
Blood urea increased	1 (14.3)	0	0	1 (14.3)	0
Lymphocyte count decreased	1 (14.3)	0	0	0	1 (14.3)
Protein total decreased	1 (14.3)	0	0	1 (14.3)	0
Serum ferritin increased	1 (14.3)	0	1 (14.3)	0	0
Metabolism and nutrition disorders					

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (57.1)	0	0	3 (42.9)	1 (14.3)
Decreased appetite	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Hypokalaemia	2 (28.6)	0	0	2 (28.6)	0
Tumour lysis syndrome	2 (28.6)	0	0	2 (28.6)	0
Acidosis	1 (14.3)	0	0	1 (14.3)	0
Fluid overload	1 (14.3)	0	1 (14.3)	0	0
Hyperalbuminaemia	1 (14.3)	1 (14.3)	0	0	0
Hypercalcaemia	1 (14.3)	1 (14.3)	0	0	0
Hyperchloraemia	1 (14.3)	1 (14.3)	0	0	0
Hyperglycaemia	1 (14.3)	0	0	1 (14.3)	0
Hyperkalaemia	1 (14.3)	0	1 (14.3)	0	0
Hypermagnesaemia	1 (14.3)	1 (14.3)	0	0	0
Hypernatraemia	1 (14.3)	0	1 (14.3)	0	0
Hyperuricaemia	1 (14.3)	0	0	0	1 (14.3)
Hypoalbuminaemia	1 (14.3)	0	1 (14.3)	0	0
Hypophosphataemia	1 (14.3)	1 (14.3)	0	0	0
Iron overload	1 (14.3)	0	0	1 (14.3)	0
Malnutrition	1 (14.3)	0	1 (14.3)	0	0

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolic alkalosis	1 (14.3)	1 (14.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	4 (57.1)	1 (14.3)	2 (28.6)	1 (14.3)	0
Arthralgia	1 (14.3)	1 (14.3)	0	0	0
Back pain	1 (14.3)	1 (14.3)	0	0	0
Bone pain	1 (14.3)	0	0	1 (14.3)	0
Muscle spasms	1 (14.3)	1 (14.3)	0	0	0
Muscular weakness	1 (14.3)	0	1 (14.3)	0	0
Musculoskeletal chest pain	1 (14.3)	1 (14.3)	0	0	0
Pain in extremity	1 (14.3)	0	1 (14.3)	0	0
Pain in jaw	1 (14.3)	0	1 (14.3)	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
-Total	1 (14.3)	0	0	0	1 (14.3)
Glioblastoma multiforme	1 (14.3)	0	0	0	1 (14.3)
Nervous system disorders					
-Total	4 (57.1)	0	2 (28.6)	2 (28.6)	0
Dysarthria	1 (14.3)	0	1 (14.3)	0	0

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (14.3)	0	0	1 (14.3)	0
Hypotonia	1 (14.3)	0	1 (14.3)	0	0
Seizure	1 (14.3)	0	0	1 (14.3)	0
Somnolence	1 (14.3)	1 (14.3)	0	0	0
Product issues					
-Total	1 (14.3)	1 (14.3)	0	0	0
Device occlusion	1 (14.3)	1 (14.3)	0	0	0
Psychiatric disorders					
-Total	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Delirium	1 (14.3)	0	1 (14.3)	0	0
Insomnia	1 (14.3)	0	1 (14.3)	0	0
Irritability	1 (14.3)	1 (14.3)	0	0	0
Mental status changes	1 (14.3)	0	0	1 (14.3)	0
Renal and urinary disorders					
-Total	1 (14.3)	0	0	1 (14.3)	0
Renal impairment	1 (14.3)	0	0	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders					

Baseline extramedullary disease presence: Yes

	All patients N=7				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (57.1)	2 (28.6)	0	1 (14.3)	1 (14.3)
Epistaxis	2 (28.6)	0	1 (14.3)	1 (14.3)	0
Cough	1 (14.3)	1 (14.3)	0	0	0
Hypoxia	1 (14.3)	0	0	1 (14.3)	0
Oropharyngeal plaque	1 (14.3)	1 (14.3)	0	0	0
Pleural effusion	1 (14.3)	0	0	1 (14.3)	0
Pulmonary oedema	1 (14.3)	0	0	1 (14.3)	0
Respiratory distress	1 (14.3)	0	0	0	1 (14.3)
Rhinorrhoea	1 (14.3)	1 (14.3)	0	0	0
Tachypnoea	1 (14.3)	0	0	1 (14.3)	0
Skin and subcutaneous tissue disorders					
-Total	2 (28.6)	1 (14.3)	1 (14.3)	0	0
Dermatitis	1 (14.3)	1 (14.3)	0	0	0
Hyperhidrosis	1 (14.3)	1 (14.3)	0	0	0
Papule	1 (14.3)	1 (14.3)	0	0	0
Pruritus	1 (14.3)	1 (14.3)	0	0	0
Rash	1 (14.3)	0	1 (14.3)	0	0

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=7 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash papular	1 (14.3)	1 (14.3)	0	0	0
Urticaria	1 (14.3)	0	1 (14.3)	0	0
Vascular disorders					
-Total	1 (14.3)	0	0	0	1 (14.3)
Capillary leak syndrome	1 (14.3)	0	0	0	1 (14.3)
Flushing	1 (14.3)	1 (14.3)	0	0	0
Hypertension	1 (14.3)	0	1 (14.3)	0	0
Hypotension	1 (14.3)	0	0	0	1 (14.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188o
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	67 (98.5)	1 (1.5)	2 (2.9)	15 (22.1)	49 (72.1)
Blood and lymphatic system disorders					
-Total	58 (85.3)	0	2 (2.9)	37 (54.4)	19 (27.9)
Anaemia	38 (55.9)	2 (2.9)	7 (10.3)	28 (41.2)	1 (1.5)
Febrile neutropenia	34 (50.0)	0	0	34 (50.0)	0
Neutropenia	17 (25.0)	0	0	3 (4.4)	14 (20.6)
Thrombocytopenia	16 (23.5)	0	1 (1.5)	6 (8.8)	9 (13.2)
Disseminated intravascular coagulation	7 (10.3)	0	2 (2.9)	4 (5.9)	1 (1.5)
Lymphopenia	5 (7.4)	0	2 (2.9)	1 (1.5)	2 (2.9)
Cardiac disorders					

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	24 (35.3)	10 (14.7)	10 (14.7)	3 (4.4)	1 (1.5)
Tachycardia	16 (23.5)	8 (11.8)	6 (8.8)	2 (2.9)	0
Sinus tachycardia	7 (10.3)	3 (4.4)	2 (2.9)	2 (2.9)	0
Pericardial effusion	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Bradycardia	2 (2.9)	1 (1.5)	0	0	1 (1.5)
Eye disorders					
-Total	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Periorbital oedema	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Conjunctival haemorrhage	2 (2.9)	2 (2.9)	0	0	0
Gastrointestinal disorders					
-Total	51 (75.0)	13 (19.1)	23 (33.8)	14 (20.6)	1 (1.5)
Nausea	33 (48.5)	7 (10.3)	19 (27.9)	7 (10.3)	0
Vomiting	31 (45.6)	16 (23.5)	11 (16.2)	4 (5.9)	0
Diarrhoea	27 (39.7)	14 (20.6)	10 (14.7)	3 (4.4)	0
Abdominal pain	17 (25.0)	6 (8.8)	7 (10.3)	4 (5.9)	0
Constipation	13 (19.1)	11 (16.2)	2 (2.9)	0	0
Stomatitis	7 (10.3)	2 (2.9)	1 (1.5)	3 (4.4)	1 (1.5)
Colitis	3 (4.4)	0	0	3 (4.4)	0

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dysphagia	1 (1.5)	0	1 (1.5)	0	0
General disorders and administration site conditions					
-Total	49 (72.1)	17 (25.0)	18 (26.5)	10 (14.7)	4 (5.9)
Pyrexia	34 (50.0)	12 (17.6)	13 (19.1)	8 (11.8)	1 (1.5)
Fatigue	21 (30.9)	15 (22.1)	4 (5.9)	2 (2.9)	0
Chills	11 (16.2)	10 (14.7)	1 (1.5)	0	0
Pain	8 (11.8)	1 (1.5)	4 (5.9)	3 (4.4)	0
Catheter site pain	7 (10.3)	2 (2.9)	5 (7.4)	0	0
Oedema peripheral	4 (5.9)	3 (4.4)	1 (1.5)	0	0
Malaise	3 (4.4)	1 (1.5)	2 (2.9)	0	0
Multiple organ dysfunction syndrome	3 (4.4)	0	0	0	3 (4.4)
Face oedema	1 (1.5)	0	1 (1.5)	0	0
Hepatobiliary disorders					
-Total	4 (5.9)	0	1 (1.5)	3 (4.4)	0
Hyperbilirubinaemia	4 (5.9)	0	1 (1.5)	3 (4.4)	0
Immune system disorders					
-Total	53 (77.9)	3 (4.4)	29 (42.6)	11 (16.2)	10 (14.7)

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	46 (67.6)	4 (5.9)	24 (35.3)	8 (11.8)	10 (14.7)
Hypogammaglobulinaemia	29 (42.6)	3 (4.4)	22 (32.4)	4 (5.9)	0
Seasonal allergy	1 (1.5)	1 (1.5)	0	0	0
Infections and infestations					
-Total	26 (38.2)	5 (7.4)	13 (19.1)	7 (10.3)	1 (1.5)
Upper respiratory tract infection	10 (14.7)	4 (5.9)	5 (7.4)	1 (1.5)	0
Pneumonia	5 (7.4)	0	3 (4.4)	1 (1.5)	1 (1.5)
Device related infection	4 (5.9)	0	1 (1.5)	3 (4.4)	0
Gastroenteritis	4 (5.9)	1 (1.5)	2 (2.9)	1 (1.5)	0
Otitis media	3 (4.4)	0	3 (4.4)	0	0
Sinusitis	3 (4.4)	0	3 (4.4)	0	0
Viral upper respiratory tract infection	3 (4.4)	2 (2.9)	1 (1.5)	0	0
Escherichia bacteraemia	1 (1.5)	0	0	1 (1.5)	0
Otitis media acute	1 (1.5)	0	1 (1.5)	0	0
Streptococcal infection	1 (1.5)	0	1 (1.5)	0	0
Injury, poisoning and procedural complications					
-Total	8 (11.8)	1 (1.5)	6 (8.8)	1 (1.5)	0

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural pain	6 (8.8)	1 (1.5)	4 (5.9)	1 (1.5)	0
Radiation skin injury	1 (1.5)	0	1 (1.5)	0	0
Subdural haematoma	1 (1.5)	0	1 (1.5)	0	0
Investigations					
-Total	55 (80.9)	0	5 (7.4)	10 (14.7)	40 (58.8)
White blood cell count decreased	41 (60.3)	4 (5.9)	1 (1.5)	7 (10.3)	29 (42.6)
Neutrophil count decreased	33 (48.5)	1 (1.5)	2 (2.9)	3 (4.4)	27 (39.7)
Platelet count decreased	24 (35.3)	3 (4.4)	2 (2.9)	3 (4.4)	16 (23.5)
Alanine aminotransferase increased	23 (33.8)	3 (4.4)	4 (5.9)	15 (22.1)	1 (1.5)
Aspartate aminotransferase increased	21 (30.9)	5 (7.4)	4 (5.9)	8 (11.8)	4 (5.9)
Lymphocyte count decreased	18 (26.5)	1 (1.5)	3 (4.4)	7 (10.3)	7 (10.3)
International normalised ratio increased	11 (16.2)	9 (13.2)	1 (1.5)	1 (1.5)	0
Blood bilirubin increased	9 (13.2)	2 (2.9)	3 (4.4)	3 (4.4)	1 (1.5)
Prothrombin time prolonged	9 (13.2)	5 (7.4)	3 (4.4)	1 (1.5)	0
Blood creatinine increased	8 (11.8)	5 (7.4)	2 (2.9)	1 (1.5)	0
Activated partial thromboplastin time prolonged	5 (7.4)	2 (2.9)	3 (4.4)	0	0

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	4 (5.9)	0	2 (2.9)	2 (2.9)	0
Blood lactate dehydrogenase increased	2 (2.9)	0	0	2 (2.9)	0
Blood urea increased	2 (2.9)	1 (1.5)	1 (1.5)	0	0
C-reactive protein increased	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Serum ferritin increased	2 (2.9)	0	1 (1.5)	1 (1.5)	0
Blood lactic acid increased	1 (1.5)	0	0	0	1 (1.5)
Metabolism and nutrition disorders					
-Total	50 (73.5)	4 (5.9)	13 (19.1)	25 (36.8)	8 (11.8)
Decreased appetite	30 (44.1)	7 (10.3)	9 (13.2)	14 (20.6)	0
Hypokalaemia	22 (32.4)	5 (7.4)	4 (5.9)	8 (11.8)	5 (7.4)
Hypophosphataemia	13 (19.1)	3 (4.4)	1 (1.5)	8 (11.8)	1 (1.5)
Hyperglycaemia	9 (13.2)	0	4 (5.9)	4 (5.9)	1 (1.5)
Hyperphosphataemia	9 (13.2)	8 (11.8)	1 (1.5)	0	0
Dehydration	7 (10.3)	1 (1.5)	2 (2.9)	4 (5.9)	0
Hyperuricaemia	7 (10.3)	5 (7.4)	0	1 (1.5)	1 (1.5)
Hypocalcaemia	7 (10.3)	3 (4.4)	1 (1.5)	1 (1.5)	2 (2.9)
Fluid overload	6 (8.8)	1 (1.5)	4 (5.9)	1 (1.5)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypernatraemia	6 (8.8)	1 (1.5)	1 (1.5)	1 (1.5)	3 (4.4)
Hypoalbuminaemia	6 (8.8)	1 (1.5)	3 (4.4)	1 (1.5)	1 (1.5)
Tumour lysis syndrome	3 (4.4)	0	0	3 (4.4)	0
Hyperkalaemia	2 (2.9)	1 (1.5)	0	1 (1.5)	0
Acidosis	1 (1.5)	1 (1.5)	0	0	0
Malnutrition	1 (1.5)	0	0	1 (1.5)	0
Musculoskeletal and connective tissue disorders					
-Total	25 (36.8)	12 (17.6)	6 (8.8)	7 (10.3)	0
Pain in extremity	17 (25.0)	8 (11.8)	4 (5.9)	5 (7.4)	0
Arthralgia	7 (10.3)	3 (4.4)	2 (2.9)	2 (2.9)	0
Pain in jaw	4 (5.9)	2 (2.9)	2 (2.9)	0	0
Back pain	3 (4.4)	1 (1.5)	0	2 (2.9)	0
Muscle spasms	2 (2.9)	2 (2.9)	0	0	0
Muscular weakness	2 (2.9)	2 (2.9)	0	0	0
Musculoskeletal chest pain	2 (2.9)	2 (2.9)	0	0	0
Bone pain	1 (1.5)	0	1 (1.5)	0	0
Nervous system disorders					

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	32 (47.1)	14 (20.6)	12 (17.6)	5 (7.4)	1 (1.5)
Headache	30 (44.1)	14 (20.6)	11 (16.2)	5 (7.4)	0
Seizure	4 (5.9)	0	2 (2.9)	1 (1.5)	1 (1.5)
Dysarthria	1 (1.5)	1 (1.5)	0	0	0
Somnolence	1 (1.5)	0	1 (1.5)	0	0
Product issues					
-Total	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Device occlusion	2 (2.9)	1 (1.5)	1 (1.5)	0	0
Psychiatric disorders					
-Total	21 (30.9)	7 (10.3)	12 (17.6)	2 (2.9)	0
Anxiety	10 (14.7)	3 (4.4)	6 (8.8)	1 (1.5)	0
Confusional state	8 (11.8)	3 (4.4)	5 (7.4)	0	0
Delirium	4 (5.9)	2 (2.9)	1 (1.5)	1 (1.5)	0
Insomnia	3 (4.4)	0	3 (4.4)	0	0
Mental status changes	3 (4.4)	3 (4.4)	0	0	0
Irritability	2 (2.9)	2 (2.9)	0	0	0
Renal and urinary disorders					
-Total	12 (17.6)	2 (2.9)	1 (1.5)	5 (7.4)	4 (5.9)

Baseline extramedullary disease presence: No

	All patients N=68				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	12 (17.6)	2 (2.9)	1 (1.5)	5 (7.4)	4 (5.9)
Respiratory, thoracic and mediastinal disorders					
-Total	37 (54.4)	11 (16.2)	7 (10.3)	11 (16.2)	8 (11.8)
Cough	15 (22.1)	12 (17.6)	2 (2.9)	1 (1.5)	0
Hypoxia	15 (22.1)	0	3 (4.4)	8 (11.8)	4 (5.9)
Epistaxis	12 (17.6)	4 (5.9)	3 (4.4)	4 (5.9)	1 (1.5)
Pleural effusion	9 (13.2)	1 (1.5)	6 (8.8)	2 (2.9)	0
Oropharyngeal pain	8 (11.8)	5 (7.4)	2 (2.9)	1 (1.5)	0
Pulmonary oedema	8 (11.8)	1 (1.5)	0	3 (4.4)	4 (5.9)
Nasal congestion	7 (10.3)	7 (10.3)	0	0	0
Tachypnoea	7 (10.3)	3 (4.4)	2 (2.9)	2 (2.9)	0
Rhinorrhoea	6 (8.8)	5 (7.4)	1 (1.5)	0	0
Respiratory distress	1 (1.5)	0	0	0	1 (1.5)
Skin and subcutaneous tissue disorders					
-Total	17 (25.0)	15 (22.1)	2 (2.9)	0	0
Rash	9 (13.2)	7 (10.3)	2 (2.9)	0	0
Pruritus	4 (5.9)	4 (5.9)	0	0	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=68 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hyperhidrosis	3 (4.4)	3 (4.4)	0	0	0
Rash papular	3 (4.4)	3 (4.4)	0	0	0
Papule	1 (1.5)	1 (1.5)	0	0	0
Vascular disorders					
-Total	32 (47.1)	3 (4.4)	4 (5.9)	15 (22.1)	10 (14.7)
Hypotension	24 (35.3)	1 (1.5)	0	13 (19.1)	10 (14.7)
Hypertension	15 (22.1)	4 (5.9)	8 (11.8)	3 (4.4)	0
Flushing	1 (1.5)	1 (1.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188p
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	1 (25.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders					
-Total	3 (75.0)	0	0	2 (50.0)	1 (25.0)
Anaemia	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Febrile neutropenia	2 (50.0)	0	0	2 (50.0)	0
Neutropenia	1 (25.0)	0	0	0	1 (25.0)
Thrombocytopenia	1 (25.0)	0	0	1 (25.0)	0
Cardiac disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Bradycardia	1 (25.0)	1 (25.0)	0	0	0
Eye disorders					

Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (25.0)	1 (25.0)	0	0	0
Ocular hyperaemia	1 (25.0)	1 (25.0)	0	0	0
Gastrointestinal disorders					
-Total	3 (75.0)	1 (25.0)	0	2 (50.0)	0
Vomiting	2 (50.0)	2 (50.0)	0	0	0
Constipation	1 (25.0)	1 (25.0)	0	0	0
Enterocolitis	1 (25.0)	0	0	1 (25.0)	0
Gastrointestinal haemorrhage	1 (25.0)	1 (25.0)	0	0	0
Nausea	1 (25.0)	0	1 (25.0)	0	0
Stomatitis	1 (25.0)	0	0	1 (25.0)	0
General disorders and administration site conditions					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Fatigue	1 (25.0)	1 (25.0)	0	0	0
Influenza like illness	1 (25.0)	1 (25.0)	0	0	0
Pyrexia	1 (25.0)	0	0	1 (25.0)	0
Immune system disorders					
-Total	3 (75.0)	1 (25.0)	2 (50.0)	0	0

Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	3 (75.0)	1 (25.0)	2 (50.0)	0	0
Hypogammaglobulinaemia	1 (25.0)	0	1 (25.0)	0	0
Infections and infestations					
-Total	3 (75.0)	0	2 (50.0)	1 (25.0)	0
Conjunctivitis	1 (25.0)	0	1 (25.0)	0	0
Corona virus infection	1 (25.0)	0	0	1 (25.0)	0
Fungal skin infection	1 (25.0)	1 (25.0)	0	0	0
Metapneumovirus infection	1 (25.0)	0	1 (25.0)	0	0
Rash pustular	1 (25.0)	0	1 (25.0)	0	0
Respiratory syncytial virus infection	1 (25.0)	0	0	1 (25.0)	0
Viral infection	1 (25.0)	0	1 (25.0)	0	0
Viral upper respiratory tract infection	1 (25.0)	1 (25.0)	0	0	0
Injury, poisoning and procedural complications					
-Total	1 (25.0)	0	1 (25.0)	0	0
Radiation skin injury	1 (25.0)	0	1 (25.0)	0	0
Skin laceration	1 (25.0)	0	1 (25.0)	0	0
Investigations					

Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (75.0)	0	1 (25.0)	0	2 (50.0)
Lymphocyte count decreased	3 (75.0)	1 (25.0)	1 (25.0)	0	1 (25.0)
Neutrophil count decreased	2 (50.0)	1 (25.0)	0	0	1 (25.0)
White blood cell count decreased	2 (50.0)	1 (25.0)	0	0	1 (25.0)
Blood bilirubin increased	1 (25.0)	1 (25.0)	0	0	0
Blood creatinine increased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin a decreased	1 (25.0)	1 (25.0)	0	0	0
Blood immunoglobulin m decreased	1 (25.0)	1 (25.0)	0	0	0
Fibrin d dimer increased	1 (25.0)	1 (25.0)	0	0	0
Platelet count decreased	1 (25.0)	1 (25.0)	0	0	0
Metabolism and nutrition disorders					
-Total	1 (25.0)	1 (25.0)	0	0	0
Decreased appetite	1 (25.0)	1 (25.0)	0	0	0
Hyperphosphataemia	1 (25.0)	1 (25.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	2 (50.0)	2 (50.0)	0	0	0
Arthralgia	1 (25.0)	1 (25.0)	0	0	0

Down syndrome: Yes

	All patients N=4				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	1 (25.0)	1 (25.0)	0	0	0
Nervous system disorders					
-Total	1 (25.0)	0	1 (25.0)	0	0
Headache	1 (25.0)	0	1 (25.0)	0	0
Tremor	1 (25.0)	1 (25.0)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	2 (50.0)	0	2 (50.0)	0	0
Cough	1 (25.0)	0	1 (25.0)	0	0
Hypoxia	1 (25.0)	0	1 (25.0)	0	0
Nasal congestion	1 (25.0)	1 (25.0)	0	0	0
Rhinorrhoea	1 (25.0)	0	1 (25.0)	0	0
Skin and subcutaneous tissue disorders					
-Total	3 (75.0)	3 (75.0)	0	0	0
Dermatitis diaper	1 (25.0)	1 (25.0)	0	0	0
Dry skin	1 (25.0)	1 (25.0)	0	0	0
Erythema	1 (25.0)	1 (25.0)	0	0	0
Rash maculo-papular	1 (25.0)	1 (25.0)	0	0	0

Down syndrome: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash papular	1 (25.0)	1 (25.0)	0	0	0
Vascular disorders					
-Total	2 (50.0)	1 (25.0)	0	1 (25.0)	0
Hypertension	1 (25.0)	1 (25.0)	0	0	0
Hypotension	1 (25.0)	0	0	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188p
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	68 (95.8)	0	3 (4.2)	13 (18.3)	52 (73.2)
Blood and lymphatic system disorders					
-Total	60 (84.5)	0	2 (2.8)	38 (53.5)	20 (28.2)
Anaemia	39 (54.9)	1 (1.4)	7 (9.9)	30 (42.3)	1 (1.4)
Febrile neutropenia	36 (50.7)	0	0	35 (49.3)	1 (1.4)
Neutropenia	18 (25.4)	0	0	4 (5.6)	14 (19.7)
Thrombocytopenia	16 (22.5)	0	1 (1.4)	5 (7.0)	10 (14.1)
Cardiac disorders					
-Total	19 (26.8)	9 (12.7)	7 (9.9)	2 (2.8)	1 (1.4)
Tachycardia	17 (23.9)	9 (12.7)	6 (8.5)	2 (2.8)	0
Bradycardia	2 (2.8)	0	1 (1.4)	0	1 (1.4)

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders					
-Total	52 (73.2)	13 (18.3)	26 (36.6)	12 (16.9)	1 (1.4)
Nausea	35 (49.3)	8 (11.3)	20 (28.2)	7 (9.9)	0
Vomiting	31 (43.7)	15 (21.1)	12 (16.9)	4 (5.6)	0
Diarrhoea	27 (38.0)	14 (19.7)	10 (14.1)	3 (4.2)	0
Abdominal pain	18 (25.4)	6 (8.5)	8 (11.3)	4 (5.6)	0
Constipation	13 (18.3)	10 (14.1)	3 (4.2)	0	0
Stomatitis	6 (8.5)	2 (2.8)	1 (1.4)	2 (2.8)	1 (1.4)
Gastrointestinal haemorrhage	2 (2.8)	1 (1.4)	0	1 (1.4)	0
General disorders and administration site conditions					
-Total	46 (64.8)	16 (22.5)	20 (28.2)	9 (12.7)	1 (1.4)
Pyrexia	35 (49.3)	12 (16.9)	15 (21.1)	7 (9.9)	1 (1.4)
Fatigue	20 (28.2)	14 (19.7)	4 (5.6)	2 (2.8)	0
Chills	12 (16.9)	10 (14.1)	2 (2.8)	0	0
Pain	8 (11.3)	1 (1.4)	4 (5.6)	3 (4.2)	0
Influenza like illness	1 (1.4)	1 (1.4)	0	0	0
Immune system disorders					

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	55 (77.5)	4 (5.6)	29 (40.8)	11 (15.5)	11 (15.5)
Cytokine release syndrome	47 (66.2)	5 (7.0)	23 (32.4)	8 (11.3)	11 (15.5)
Hypogammaglobulinaemia	32 (45.1)	4 (5.6)	23 (32.4)	5 (7.0)	0
Infections and infestations					
-Total	18 (25.4)	8 (11.3)	8 (11.3)	2 (2.8)	0
Upper respiratory tract infection	11 (15.5)	5 (7.0)	5 (7.0)	1 (1.4)	0
Viral upper respiratory tract infection	3 (4.2)	1 (1.4)	1 (1.4)	1 (1.4)	0
Viral infection	2 (2.8)	2 (2.8)	0	0	0
Conjunctivitis	1 (1.4)	0	1 (1.4)	0	0
Fungal skin infection	1 (1.4)	0	1 (1.4)	0	0
Respiratory syncytial virus infection	1 (1.4)	0	1 (1.4)	0	0
Injury, poisoning and procedural complications					
-Total	9 (12.7)	1 (1.4)	5 (7.0)	3 (4.2)	0
Procedural pain	8 (11.3)	1 (1.4)	4 (5.6)	3 (4.2)	0
Radiation skin injury	1 (1.4)	0	1 (1.4)	0	0
Investigations					
-Total	56 (78.9)	0	4 (5.6)	10 (14.1)	42 (59.2)

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	42 (59.2)	3 (4.2)	1 (1.4)	8 (11.3)	30 (42.3)
Neutrophil count decreased	33 (46.5)	0	2 (2.8)	3 (4.2)	28 (39.4)
Alanine aminotransferase increased	26 (36.6)	3 (4.2)	4 (5.6)	18 (25.4)	1 (1.4)
Platelet count decreased	25 (35.2)	2 (2.8)	2 (2.8)	4 (5.6)	17 (23.9)
Aspartate aminotransferase increased	24 (33.8)	5 (7.0)	5 (7.0)	9 (12.7)	5 (7.0)
Lymphocyte count decreased	16 (22.5)	0	2 (2.8)	7 (9.9)	7 (9.9)
International normalised ratio increased	11 (15.5)	9 (12.7)	1 (1.4)	1 (1.4)	0
Blood bilirubin increased	9 (12.7)	1 (1.4)	3 (4.2)	4 (5.6)	1 (1.4)
Prothrombin time prolonged	9 (12.7)	5 (7.0)	3 (4.2)	1 (1.4)	0
Blood creatinine increased	8 (11.3)	4 (5.6)	2 (2.8)	2 (2.8)	0
Blood immunoglobulin m decreased	4 (5.6)	4 (5.6)	0	0	0
Blood immunoglobulin a decreased	2 (2.8)	2 (2.8)	0	0	0
Metabolism and nutrition disorders					
-Total	47 (66.2)	6 (8.5)	12 (16.9)	21 (29.6)	8 (11.3)
Decreased appetite	31 (43.7)	6 (8.5)	10 (14.1)	15 (21.1)	0
Hypokalaemia	24 (33.8)	5 (7.0)	4 (5.6)	10 (14.1)	5 (7.0)
Hypophosphataemia	14 (19.7)	4 (5.6)	1 (1.4)	8 (11.3)	1 (1.4)

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	10 (14.1)	0	4 (5.6)	5 (7.0)	1 (1.4)
Hyperphosphataemia	8 (11.3)	7 (9.9)	1 (1.4)	0	0
Hyperuricaemia	8 (11.3)	5 (7.0)	0	1 (1.4)	2 (2.8)
Musculoskeletal and connective tissue disorders					
-Total	20 (28.2)	8 (11.3)	6 (8.5)	6 (8.5)	0
Pain in extremity	17 (23.9)	7 (9.9)	5 (7.0)	5 (7.0)	0
Arthralgia	7 (9.9)	3 (4.2)	2 (2.8)	2 (2.8)	0
Nervous system disorders					
-Total	30 (42.3)	14 (19.7)	10 (14.1)	6 (8.5)	0
Headache	30 (42.3)	14 (19.7)	10 (14.1)	6 (8.5)	0
Tremor	1 (1.4)	1 (1.4)	0	0	0
Psychiatric disorders					
-Total	16 (22.5)	5 (7.0)	10 (14.1)	1 (1.4)	0
Anxiety	10 (14.1)	3 (4.2)	6 (8.5)	1 (1.4)	0
Confusional state	8 (11.3)	3 (4.2)	5 (7.0)	0	0
Renal and urinary disorders					
-Total	12 (16.9)	2 (2.8)	1 (1.4)	5 (7.0)	4 (5.6)

Down syndrome: No

	All patients N=71				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	12 (16.9)	2 (2.8)	1 (1.4)	5 (7.0)	4 (5.6)
Respiratory, thoracic and mediastinal disorders					
-Total	38 (53.5)	12 (16.9)	5 (7.0)	13 (18.3)	8 (11.3)
Cough	15 (21.1)	13 (18.3)	1 (1.4)	1 (1.4)	0
Hypoxia	15 (21.1)	0	2 (2.8)	9 (12.7)	4 (5.6)
Epistaxis	14 (19.7)	4 (5.6)	4 (5.6)	5 (7.0)	1 (1.4)
Pleural effusion	10 (14.1)	1 (1.4)	6 (8.5)	3 (4.2)	0
Pulmonary oedema	9 (12.7)	1 (1.4)	0	4 (5.6)	4 (5.6)
Oropharyngeal pain	8 (11.3)	5 (7.0)	2 (2.8)	1 (1.4)	0
Tachypnoea	8 (11.3)	3 (4.2)	2 (2.8)	3 (4.2)	0
Nasal congestion	6 (8.5)	6 (8.5)	0	0	0
Rhinorrhoea	6 (8.5)	6 (8.5)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	20 (28.2)	15 (21.1)	4 (5.6)	1 (1.4)	0
Rash	10 (14.1)	7 (9.9)	3 (4.2)	0	0
Dry skin	4 (5.6)	4 (5.6)	0	0	0
Erythema	4 (5.6)	4 (5.6)	0	0	0

Down syndrome: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash maculo-papular	4 (5.6)	2 (2.8)	1 (1.4)	1 (1.4)	0
Rash papular	3 (4.2)	3 (4.2)	0	0	0
Vascular disorders					
-Total	31 (43.7)	2 (2.8)	4 (5.6)	14 (19.7)	11 (15.5)
Hypotension	24 (33.8)	1 (1.4)	0	12 (16.9)	11 (15.5)
Hypertension	15 (21.1)	3 (4.2)	9 (12.7)	3 (4.2)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188q
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	0	1 (3.1)	6 (18.8)	25 (78.1)
Blood and lymphatic system disorders					
-Total	29 (90.6)	0	1 (3.1)	20 (62.5)	8 (25.0)
Febrile neutropenia	18 (56.3)	0	0	17 (53.1)	1 (3.1)
Anaemia	17 (53.1)	1 (3.1)	2 (6.3)	14 (43.8)	0
Neutropenia	7 (21.9)	0	0	2 (6.3)	5 (15.6)
Thrombocytopenia	4 (12.5)	0	1 (3.1)	2 (6.3)	1 (3.1)
Disseminated intravascular coagulation	2 (6.3)	0	0	2 (6.3)	0
Lymphopenia	1 (3.1)	0	0	0	1 (3.1)
Cardiac disorders					

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (25.0)	6 (18.8)	2 (6.3)	0	0
Tachycardia	6 (18.8)	5 (15.6)	1 (3.1)	0	0
Sinus tachycardia	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Gastrointestinal disorders					
-Total	28 (87.5)	9 (28.1)	13 (40.6)	6 (18.8)	0
Nausea	19 (59.4)	3 (9.4)	13 (40.6)	3 (9.4)	0
Vomiting	17 (53.1)	9 (28.1)	5 (15.6)	3 (9.4)	0
Diarrhoea	12 (37.5)	6 (18.8)	4 (12.5)	2 (6.3)	0
Constipation	10 (31.3)	8 (25.0)	2 (6.3)	0	0
Abdominal pain	9 (28.1)	3 (9.4)	5 (15.6)	1 (3.1)	0
Colitis	1 (3.1)	0	0	1 (3.1)	0
General disorders and administration site conditions					
-Total	21 (65.6)	5 (15.6)	9 (28.1)	7 (21.9)	0
Pyrexia	17 (53.1)	4 (12.5)	7 (21.9)	6 (18.8)	0
Fatigue	7 (21.9)	5 (15.6)	2 (6.3)	0	0
Catheter site pain	5 (15.6)	0	5 (15.6)	0	0
Oedema peripheral	4 (12.5)	3 (9.4)	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	2 (6.3)	0	1 (3.1)	1 (3.1)	0
Chills	1 (3.1)	0	1 (3.1)	0	0
Immune system disorders					
-Total	29 (90.6)	1 (3.1)	18 (56.3)	5 (15.6)	5 (15.6)
Cytokine release syndrome	25 (78.1)	3 (9.4)	15 (46.9)	2 (6.3)	5 (15.6)
Hypogammaglobulinaemia	19 (59.4)	1 (3.1)	15 (46.9)	3 (9.4)	0
Infections and infestations					
-Total	19 (59.4)	3 (9.4)	10 (31.3)	6 (18.8)	0
Upper respiratory tract infection	6 (18.8)	2 (6.3)	4 (12.5)	0	0
Clostridium difficile infection	5 (15.6)	0	4 (12.5)	1 (3.1)	0
Rhinovirus infection	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Device related infection	4 (12.5)	0	0	4 (12.5)	0
Pneumonia	2 (6.3)	0	2 (6.3)	0	0
Clostridium difficile colitis	1 (3.1)	0	0	1 (3.1)	0
Injury, poisoning and procedural complications					
-Total	6 (18.8)	0	3 (9.4)	3 (9.4)	0
Procedural pain	6 (18.8)	0	3 (9.4)	3 (9.4)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	30 (93.8)	0	1 (3.1)	5 (15.6)	24 (75.0)
White blood cell count decreased	25 (78.1)	1 (3.1)	0	5 (15.6)	19 (59.4)
Neutrophil count decreased	18 (56.3)	1 (3.1)	0	2 (6.3)	15 (46.9)
Platelet count decreased	14 (43.8)	1 (3.1)	0	2 (6.3)	11 (34.4)
Alanine aminotransferase increased	11 (34.4)	1 (3.1)	1 (3.1)	9 (28.1)	0
Lymphocyte count decreased	11 (34.4)	0	1 (3.1)	5 (15.6)	5 (15.6)
Aspartate aminotransferase increased	10 (31.3)	3 (9.4)	1 (3.1)	5 (15.6)	1 (3.1)
Blood bilirubin increased	5 (15.6)	1 (3.1)	1 (3.1)	3 (9.4)	0
Blood creatinine increased	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Prothrombin time prolonged	3 (9.4)	3 (9.4)	0	0	0
International normalised ratio increased	1 (3.1)	1 (3.1)	0	0	0
Metabolism and nutrition disorders					
-Total	23 (71.9)	2 (6.3)	7 (21.9)	10 (31.3)	4 (12.5)
Decreased appetite	14 (43.8)	3 (9.4)	7 (21.9)	4 (12.5)	0
Hypokalaemia	12 (37.5)	3 (9.4)	1 (3.1)	6 (18.8)	2 (6.3)
Hypophosphataemia	7 (21.9)	3 (9.4)	0	4 (12.5)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	5 (15.6)	1 (3.1)	2 (6.3)	2 (6.3)	0
Hyperglycaemia	5 (15.6)	0	2 (6.3)	3 (9.4)	0
Hypocalcaemia	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Hyperphosphataemia	3 (9.4)	3 (9.4)	0	0	0
Hyperuricaemia	3 (9.4)	2 (6.3)	0	0	1 (3.1)
Hypernatraemia	1 (3.1)	0	0	0	1 (3.1)
Musculoskeletal and connective tissue disorders					
-Total	14 (43.8)	5 (15.6)	6 (18.8)	3 (9.4)	0
Pain in extremity	10 (31.3)	4 (12.5)	5 (15.6)	1 (3.1)	0
Arthralgia	5 (15.6)	2 (6.3)	2 (6.3)	1 (3.1)	0
Myalgia	1 (3.1)	0	0	1 (3.1)	0
Nervous system disorders					
-Total	19 (59.4)	8 (25.0)	7 (21.9)	4 (12.5)	0
Headache	18 (56.3)	7 (21.9)	7 (21.9)	4 (12.5)	0
Dizziness	2 (6.3)	2 (6.3)	0	0	0
Psychiatric disorders					
-Total	10 (31.3)	5 (15.6)	5 (15.6)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	5 (15.6)	2 (6.3)	3 (9.4)	0	0
Depression	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Confusional state	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Renal and urinary disorders					
-Total	6 (18.8)	2 (6.3)	1 (3.1)	3 (9.4)	0
Acute kidney injury	5 (15.6)	2 (6.3)	1 (3.1)	2 (6.3)	0
Haematuria	1 (3.1)	0	0	1 (3.1)	0
Respiratory, thoracic and mediastinal disorders					
-Total	18 (56.3)	8 (25.0)	4 (12.5)	6 (18.8)	0
Cough	8 (25.0)	7 (21.9)	1 (3.1)	0	0
Epistaxis	8 (25.0)	3 (9.4)	1 (3.1)	4 (12.5)	0
Hypoxia	5 (15.6)	0	2 (6.3)	3 (9.4)	0
Nasal congestion	3 (9.4)	3 (9.4)	0	0	0
Oropharyngeal pain	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Rhinorrhoea	3 (9.4)	3 (9.4)	0	0	0
Tachypnoea	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Pleural effusion	1 (3.1)	0	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	1 (3.1)	1 (3.1)	0	0	0
Rhinitis allergic	1 (3.1)	0	1 (3.1)	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (34.4)	9 (28.1)	2 (6.3)	0	0
Pruritus	5 (15.6)	5 (15.6)	0	0	0
Rash	5 (15.6)	3 (9.4)	2 (6.3)	0	0
Dry skin	4 (12.5)	4 (12.5)	0	0	0
Rash maculo-papular	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	12 (37.5)	3 (9.4)	3 (9.4)	5 (15.6)	1 (3.1)
Hypertension	9 (28.1)	4 (12.5)	3 (9.4)	2 (6.3)	0
Hypotension	5 (15.6)	1 (3.1)	0	3 (9.4)	1 (3.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188q
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	1 (3.1)	0	8 (25.0)	23 (71.9)
Blood and lymphatic system disorders					
-Total	29 (90.6)	0	1 (3.1)	17 (53.1)	11 (34.4)
Anaemia	20 (62.5)	1 (3.1)	5 (15.6)	13 (40.6)	1 (3.1)
Febrile neutropenia	18 (56.3)	0	0	18 (56.3)	0
Neutropenia	10 (31.3)	0	0	2 (6.3)	8 (25.0)
Thrombocytopenia	9 (28.1)	0	0	3 (9.4)	6 (18.8)
Lymphopenia	4 (12.5)	0	2 (6.3)	1 (3.1)	1 (3.1)
Disseminated intravascular coagulation	2 (6.3)	0	2 (6.3)	0	0
Cardiac disorders					

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (43.8)	5 (15.6)	6 (18.8)	3 (9.4)	0
Tachycardia	11 (34.4)	4 (12.5)	5 (15.6)	2 (6.3)	0
Sinus tachycardia	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Eye disorders					
-Total	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Periorbital oedema	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Gastrointestinal disorders					
-Total	21 (65.6)	6 (18.8)	11 (34.4)	4 (12.5)	0
Diarrhoea	14 (43.8)	8 (25.0)	6 (18.8)	0	0
Nausea	14 (43.8)	5 (15.6)	6 (18.8)	3 (9.4)	0
Vomiting	13 (40.6)	8 (25.0)	5 (15.6)	0	0
Abdominal pain	7 (21.9)	3 (9.4)	3 (9.4)	1 (3.1)	0
Constipation	3 (9.4)	2 (6.3)	1 (3.1)	0	0
Colitis	1 (3.1)	1 (3.1)	0	0	0
General disorders and administration site conditions					
-Total	25 (78.1)	12 (37.5)	9 (28.1)	3 (9.4)	1 (3.1)
Pyrexia	16 (50.0)	8 (25.0)	6 (18.8)	1 (3.1)	1 (3.1)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	14 (43.8)	10 (31.3)	2 (6.3)	2 (6.3)	0
Chills	10 (31.3)	9 (28.1)	1 (3.1)	0	0
Pain	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Catheter site pain	2 (6.3)	2 (6.3)	0	0	0
Multiple organ dysfunction syndrome	1 (3.1)	0	0	1 (3.1)	0
Oedema peripheral	1 (3.1)	0	0	1 (3.1)	0
Immune system disorders					
-Total	29 (90.6)	4 (12.5)	13 (40.6)	6 (18.8)	6 (18.8)
Cytokine release syndrome	25 (78.1)	3 (9.4)	10 (31.3)	6 (18.8)	6 (18.8)
Hypogammaglobulinaemia	14 (43.8)	3 (9.4)	9 (28.1)	2 (6.3)	0
Infections and infestations					
-Total	15 (46.9)	1 (3.1)	10 (31.3)	4 (12.5)	0
Upper respiratory tract infection	5 (15.6)	3 (9.4)	1 (3.1)	1 (3.1)	0
Clostridium difficile colitis	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Otitis media	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Pneumonia	4 (12.5)	0	3 (9.4)	1 (3.1)	0
Clostridium difficile infection	1 (3.1)	0	1 (3.1)	0	0
Device related infection	1 (3.1)	0	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rhinovirus infection	1 (3.1)	1 (3.1)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Procedural pain	2 (6.3)	1 (3.1)	1 (3.1)	0	0
Investigations					
-Total	25 (78.1)	0	4 (12.5)	5 (15.6)	16 (50.0)
White blood cell count decreased	18 (56.3)	3 (9.4)	1 (3.1)	3 (9.4)	11 (34.4)
Neutrophil count decreased	15 (46.9)	0	2 (6.3)	1 (3.1)	12 (37.5)
Alanine aminotransferase increased	14 (43.8)	2 (6.3)	3 (9.4)	9 (28.1)	0
Aspartate aminotransferase increased	13 (40.6)	2 (6.3)	4 (12.5)	4 (12.5)	3 (9.4)
Platelet count decreased	11 (34.4)	2 (6.3)	2 (6.3)	2 (6.3)	5 (15.6)
International normalised ratio increased	9 (28.1)	8 (25.0)	0	1 (3.1)	0
Lymphocyte count decreased	8 (25.0)	1 (3.1)	2 (6.3)	2 (6.3)	3 (9.4)
Blood creatinine increased	6 (18.8)	3 (9.4)	1 (3.1)	2 (6.3)	0
Prothrombin time prolonged	6 (18.8)	2 (6.3)	3 (9.4)	1 (3.1)	0
Blood fibrinogen decreased	5 (15.6)	0	2 (6.3)	2 (6.3)	1 (3.1)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	4 (12.5)	1 (3.1)	2 (6.3)	1 (3.1)	0
Metabolism and nutrition disorders					
-Total	23 (71.9)	3 (9.4)	4 (12.5)	14 (43.8)	2 (6.3)
Decreased appetite	17 (53.1)	4 (12.5)	3 (9.4)	10 (31.3)	0
Hypokalaemia	9 (28.1)	2 (6.3)	3 (9.4)	4 (12.5)	0
Hyperphosphataemia	6 (18.8)	5 (15.6)	1 (3.1)	0	0
Hypophosphataemia	6 (18.8)	1 (3.1)	1 (3.1)	3 (9.4)	1 (3.1)
Hyperuricaemia	5 (15.6)	3 (9.4)	0	1 (3.1)	1 (3.1)
Hypoalbuminaemia	5 (15.6)	1 (3.1)	3 (9.4)	1 (3.1)	0
Hypernatraemia	3 (9.4)	1 (3.1)	2 (6.3)	0	0
Hyperglycaemia	2 (6.3)	0	0	2 (6.3)	0
Hypocalcaemia	2 (6.3)	0	0	1 (3.1)	1 (3.1)
Dehydration	1 (3.1)	0	0	1 (3.1)	0
Musculoskeletal and connective tissue disorders					
-Total	12 (37.5)	8 (25.0)	2 (6.3)	2 (6.3)	0
Pain in extremity	6 (18.8)	4 (12.5)	0	2 (6.3)	0
Myalgia	5 (15.6)	4 (12.5)	1 (3.1)	0	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal pain	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Arthralgia	2 (6.3)	2 (6.3)	0	0	0
Nervous system disorders					
-Total	13 (40.6)	8 (25.0)	4 (12.5)	1 (3.1)	0
Headache	12 (37.5)	7 (21.9)	4 (12.5)	1 (3.1)	0
Dizziness	4 (12.5)	4 (12.5)	0	0	0
Psychiatric disorders					
-Total	7 (21.9)	2 (6.3)	4 (12.5)	1 (3.1)	0
Anxiety	5 (15.6)	1 (3.1)	3 (9.4)	1 (3.1)	0
Confusional state	4 (12.5)	2 (6.3)	2 (6.3)	0	0
Depression	1 (3.1)	0	1 (3.1)	0	0
Renal and urinary disorders					
-Total	6 (18.8)	0	0	2 (6.3)	4 (12.5)
Acute kidney injury	5 (15.6)	0	0	2 (6.3)	3 (9.4)
Haematuria	4 (12.5)	0	2 (6.3)	1 (3.1)	1 (3.1)
Respiratory, thoracic and mediastinal disorders					
-Total	19 (59.4)	5 (15.6)	4 (12.5)	5 (15.6)	5 (15.6)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cough	7 (21.9)	6 (18.8)	1 (3.1)	0	0
Hypoxia	7 (21.9)	0	1 (3.1)	3 (9.4)	3 (9.4)
Pleural effusion	7 (21.9)	1 (3.1)	4 (12.5)	2 (6.3)	0
Pulmonary oedema	6 (18.8)	0	0	4 (12.5)	2 (6.3)
Epistaxis	5 (15.6)	1 (3.1)	2 (6.3)	1 (3.1)	1 (3.1)
Nasal congestion	4 (12.5)	4 (12.5)	0	0	0
Oropharyngeal pain	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Rhinitis allergic	4 (12.5)	4 (12.5)	0	0	0
Rhinorrhoea	4 (12.5)	3 (9.4)	1 (3.1)	0	0
Tachypnoea	4 (12.5)	2 (6.3)	0	2 (6.3)	0
Skin and subcutaneous tissue disorders					
-Total	9 (28.1)	6 (18.8)	2 (6.3)	1 (3.1)	0
Rash	5 (15.6)	4 (12.5)	1 (3.1)	0	0
Rash maculo-papular	4 (12.5)	2 (6.3)	1 (3.1)	1 (3.1)	0
Dry skin	1 (3.1)	1 (3.1)	0	0	0
Vascular disorders					
-Total	15 (46.9)	0	1 (3.1)	7 (21.9)	7 (21.9)

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=32 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	14 (43.8)	0	0	7 (21.9)	7 (21.9)
Hypertension	6 (18.8)	0	5 (15.6)	1 (3.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188q
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	0	1 (9.1)	1 (9.1)	6 (54.5)
Blood and lymphatic system disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	0	0	4 (36.4)	0
Thrombocytopenia	4 (36.4)	0	0	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	0	0	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	0	0	2 (18.2)	0
Neutropenia	2 (18.2)	0	0	0	2 (18.2)
Lymphopenia	1 (9.1)	0	0	0	1 (9.1)
Cardiac disorders					

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (9.1)	0	0	1 (9.1)	0
Sinus tachycardia	1 (9.1)	0	0	1 (9.1)	0
Gastrointestinal disorders					
-Total	5 (45.5)	0	2 (18.2)	3 (27.3)	0
Nausea	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Vomiting	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Abdominal pain	2 (18.2)	0	0	2 (18.2)	0
Colitis	2 (18.2)	0	0	2 (18.2)	0
Constipation	1 (9.1)	1 (9.1)	0	0	0
Diarrhoea	1 (9.1)	0	0	1 (9.1)	0
General disorders and administration site conditions					
-Total	5 (45.5)	0	1 (9.1)	1 (9.1)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	0	0	3 (27.3)
Pyrexia	3 (27.3)	0	2 (18.2)	1 (9.1)	0
Pain	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Chills	1 (9.1)	1 (9.1)	0	0	0
Infections and infestations					

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (27.3)	0	0	0	3 (27.3)
Klebsiella sepsis	2 (18.2)	0	0	0	2 (18.2)
Clostridium difficile colitis	1 (9.1)	0	0	1 (9.1)	0
Pneumonia	1 (9.1)	0	0	0	1 (9.1)
Investigations					
-Total	4 (36.4)	0	0	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	0	0	2 (18.2)
Alanine aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	0	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	0	0	1 (9.1)
International normalised ratio increased	1 (9.1)	0	1 (9.1)	0	0
Platelet count decreased	1 (9.1)	0	0	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	0	0	1 (9.1)
Metabolism and nutrition disorders					
-Total	5 (45.5)	0	2 (18.2)	0	3 (27.3)
Hyperglycaemia	3 (27.3)	0	2 (18.2)	0	1 (9.1)
Hypernatraemia	3 (27.3)	0	0	1 (9.1)	2 (18.2)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	3 (27.3)	0	0	0	3 (27.3)
Hypoalbuminaemia	2 (18.2)	0	1 (9.1)	0	1 (9.1)
Decreased appetite	1 (9.1)	0	0	1 (9.1)	0
Dehydration	1 (9.1)	0	0	1 (9.1)	0
Hypocalcaemia	1 (9.1)	0	0	0	1 (9.1)
Hypophosphataemia	1 (9.1)	0	0	1 (9.1)	0
Musculoskeletal and connective tissue disorders					
-Total	2 (18.2)	0	0	2 (18.2)	0
Pain in extremity	2 (18.2)	0	0	2 (18.2)	0
Arthralgia	1 (9.1)	0	0	1 (9.1)	0
Nervous system disorders					
-Total	1 (9.1)	0	0	1 (9.1)	0
Headache	1 (9.1)	0	0	1 (9.1)	0
Psychiatric disorders					
-Total	1 (9.1)	0	1 (9.1)	0	0
Confusional state	1 (9.1)	0	1 (9.1)	0	0
Renal and urinary disorders					

Time since enrollment to CTL019 infusion: Missing

	All patients N=11				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (27.3)	1 (9.1)	0	1 (9.1)	1 (9.1)
Acute kidney injury	2 (18.2)	0	0	1 (9.1)	1 (9.1)
Haematuria	1 (9.1)	1 (9.1)	0	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	5 (45.5)	0	0	2 (18.2)	3 (27.3)
Hypoxia	4 (36.4)	0	0	3 (27.3)	1 (9.1)
Pleural effusion	2 (18.2)	0	1 (9.1)	1 (9.1)	0
Pulmonary oedema	2 (18.2)	0	0	0	2 (18.2)
Cough	1 (9.1)	0	0	1 (9.1)	0
Epistaxis	1 (9.1)	0	1 (9.1)	0	0
Oropharyngeal pain	1 (9.1)	0	0	1 (9.1)	0
Tachypnoea	1 (9.1)	0	0	1 (9.1)	0
Vascular disorders					
-Total	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Hypotension	6 (54.5)	0	0	3 (27.3)	3 (27.3)
Hypertension	1 (9.1)	0	1 (9.1)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188r
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	0	0	1 (12.5)	7 (87.5)
Blood and lymphatic system disorders					
-Total	7 (87.5)	0	0	5 (62.5)	2 (25.0)
Anaemia	5 (62.5)	1 (12.5)	0	3 (37.5)	1 (12.5)
Febrile neutropenia	5 (62.5)	0	0	5 (62.5)	0
Neutropenia	2 (25.0)	0	0	0	2 (25.0)
Thrombocytopenia	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Cardiac disorders					
-Total	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Left ventricular dysfunction	2 (25.0)	0	0	2 (25.0)	0
Tachycardia	2 (25.0)	1 (12.5)	0	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Palpitations	1 (12.5)	1 (12.5)	0	0	0
Pericardial effusion	1 (12.5)	1 (12.5)	0	0	0
Endocrine disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Adrenal insufficiency	1 (12.5)	1 (12.5)	0	0	0
Eye disorders					
-Total	1 (12.5)	1 (12.5)	0	0	0
Eye pain	1 (12.5)	1 (12.5)	0	0	0
Gastrointestinal disorders					
-Total	7 (87.5)	2 (25.0)	1 (12.5)	3 (37.5)	1 (12.5)
Nausea	5 (62.5)	1 (12.5)	2 (25.0)	2 (25.0)	0
Vomiting	5 (62.5)	3 (37.5)	2 (25.0)	0	0
Diarrhoea	4 (50.0)	3 (37.5)	1 (12.5)	0	0
Abdominal pain	3 (37.5)	2 (25.0)	1 (12.5)	0	0
Oral pain	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Stomatitis	2 (25.0)	1 (12.5)	0	0	1 (12.5)
Constipation	1 (12.5)	1 (12.5)	0	0	0
Dyspepsia	1 (12.5)	0	1 (12.5)	0	0

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterocolitis	1 (12.5)	0	0	1 (12.5)	0
General disorders and administration site conditions					
-Total	6 (75.0)	1 (12.5)	1 (12.5)	3 (37.5)	1 (12.5)
Pyrexia	5 (62.5)	1 (12.5)	1 (12.5)	2 (25.0)	1 (12.5)
Fatigue	3 (37.5)	2 (25.0)	0	1 (12.5)	0
Pain	2 (25.0)	0	0	2 (25.0)	0
Asthenia	1 (12.5)	1 (12.5)	0	0	0
Catheter site pain	1 (12.5)	0	1 (12.5)	0	0
Chills	1 (12.5)	1 (12.5)	0	0	0
Hepatobiliary disorders					
-Total	1 (12.5)	0	1 (12.5)	0	0
Hepatomegaly	1 (12.5)	0	1 (12.5)	0	0
Immune system disorders					
-Total	7 (87.5)	0	4 (50.0)	0	3 (37.5)
Cytokine release syndrome	5 (62.5)	0	2 (25.0)	0	3 (37.5)
Hypogammaglobulinaemia	4 (50.0)	0	4 (50.0)	0	0
Graft versus host disease	1 (12.5)	0	1 (12.5)	0	0

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations					
-Total	6 (75.0)	1 (12.5)	2 (25.0)	1 (12.5)	2 (25.0)
Upper respiratory tract infection	2 (25.0)	0	2 (25.0)	0	0
Viral infection	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Cellulitis	1 (12.5)	0	0	1 (12.5)	0
Clostridium difficile infection	1 (12.5)	0	1 (12.5)	0	0
Corona virus infection	1 (12.5)	0	0	1 (12.5)	0
Ear infection	1 (12.5)	1 (12.5)	0	0	0
Gastroenteritis	1 (12.5)	0	1 (12.5)	0	0
Human polyomavirus infection	1 (12.5)	0	0	0	1 (12.5)
Oral herpes	1 (12.5)	0	0	1 (12.5)	0
Pneumonia	1 (12.5)	0	0	0	1 (12.5)
Respiratory syncytial virus infection	1 (12.5)	0	0	1 (12.5)	0
Rhinovirus infection	1 (12.5)	1 (12.5)	0	0	0
Skin infection	1 (12.5)	0	1 (12.5)	0	0
Tinea capitis	1 (12.5)	1 (12.5)	0	0	0
Injury, poisoning and procedural complications					

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (37.5)	1 (12.5)	0	2 (25.0)	0
Contusion	1 (12.5)	1 (12.5)	0	0	0
Infusion related reaction	1 (12.5)	0	1 (12.5)	0	0
Procedural nausea	1 (12.5)	0	1 (12.5)	0	0
Procedural pain	1 (12.5)	0	0	1 (12.5)	0
Sunburn	1 (12.5)	1 (12.5)	0	0	0
Tracheal haemorrhage	1 (12.5)	0	0	1 (12.5)	0
Wound	1 (12.5)	1 (12.5)	0	0	0
Investigations					
-Total	7 (87.5)	0	1 (12.5)	2 (25.0)	4 (50.0)
Neutrophil count decreased	4 (50.0)	0	1 (12.5)	0	3 (37.5)
White blood cell count decreased	4 (50.0)	1 (12.5)	0	0	3 (37.5)
Blood magnesium decreased	2 (25.0)	1 (12.5)	0	1 (12.5)	0
Lymphocyte count decreased	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Activated partial thromboplastin time prolonged	1 (12.5)	1 (12.5)	0	0	0
Aspartate aminotransferase increased	1 (12.5)	0	0	0	1 (12.5)
Blood bilirubin increased	1 (12.5)	0	0	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood creatinine increased	1 (12.5)	0	1 (12.5)	0	0
Blood fibrinogen decreased	1 (12.5)	0	1 (12.5)	0	0
Blood immunoglobulin m decreased	1 (12.5)	1 (12.5)	0	0	0
Blood phosphorus increased	1 (12.5)	1 (12.5)	0	0	0
Blood uric acid increased	1 (12.5)	1 (12.5)	0	0	0
Cardiac murmur	1 (12.5)	1 (12.5)	0	0	0
Fibrin d dimer increased	1 (12.5)	1 (12.5)	0	0	0
International normalised ratio increased	1 (12.5)	1 (12.5)	0	0	0
Prothrombin time prolonged	1 (12.5)	0	1 (12.5)	0	0
Weight decreased	1 (12.5)	1 (12.5)	0	0	0
Metabolism and nutrition disorders					
-Total	5 (62.5)	1 (12.5)	3 (37.5)	1 (12.5)	0
Decreased appetite	3 (37.5)	1 (12.5)	1 (12.5)	1 (12.5)	0
Hypokalaemia	3 (37.5)	2 (25.0)	1 (12.5)	0	0
Dehydration	1 (12.5)	0	1 (12.5)	0	0
Hypernatraemia	1 (12.5)	0	1 (12.5)	0	0
Hypoalbuminaemia	1 (12.5)	1 (12.5)	0	0	0

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypomagnesaemia	1 (12.5)	1 (12.5)	0	0	0
Hypophosphataemia	1 (12.5)	0	0	1 (12.5)	0
Vitamin d deficiency	1 (12.5)	0	1 (12.5)	0	0
Musculoskeletal and connective tissue disorders					
-Total	6 (75.0)	3 (37.5)	1 (12.5)	2 (25.0)	0
Pain in extremity	4 (50.0)	3 (37.5)	0	1 (12.5)	0
Arthralgia	1 (12.5)	0	0	1 (12.5)	0
Muscular weakness	1 (12.5)	1 (12.5)	0	0	0
Neck pain	1 (12.5)	0	1 (12.5)	0	0
Pain in jaw	1 (12.5)	1 (12.5)	0	0	0
Nervous system disorders					
-Total	5 (62.5)	3 (37.5)	2 (25.0)	0	0
Headache	4 (50.0)	2 (25.0)	2 (25.0)	0	0
Dizziness	1 (12.5)	1 (12.5)	0	0	0
Dysgeusia	1 (12.5)	1 (12.5)	0	0	0
Peroneal nerve palsy	1 (12.5)	1 (12.5)	0	0	0
Psychiatric disorders					

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (62.5)	1 (12.5)	4 (50.0)	0	0
Confusional state	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Depression	3 (37.5)	2 (25.0)	1 (12.5)	0	0
Anxiety	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Delirium	1 (12.5)	1 (12.5)	0	0	0
Insomnia	1 (12.5)	0	1 (12.5)	0	0
Sleep disorder	1 (12.5)	0	1 (12.5)	0	0
Renal and urinary disorders					
-Total	2 (25.0)	0	0	0	2 (25.0)
Haematuria	2 (25.0)	0	0	1 (12.5)	1 (12.5)
Acute kidney injury	1 (12.5)	0	0	0	1 (12.5)
Cystitis haemorrhagic	1 (12.5)	0	0	0	1 (12.5)
Oliguria	1 (12.5)	0	0	1 (12.5)	0
Renal failure	1 (12.5)	0	0	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders					
-Total	7 (87.5)	2 (25.0)	1 (12.5)	1 (12.5)	3 (37.5)
Cough	3 (37.5)	3 (37.5)	0	0	0

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	3 (37.5)	0	1 (12.5)	1 (12.5)	1 (12.5)
Hypoxia	3 (37.5)	0	0	2 (25.0)	1 (12.5)
Rhinorrhoea	3 (37.5)	2 (25.0)	1 (12.5)	0	0
Nasal congestion	2 (25.0)	2 (25.0)	0	0	0
Oropharyngeal pain	2 (25.0)	1 (12.5)	1 (12.5)	0	0
Pleural effusion	2 (25.0)	0	2 (25.0)	0	0
Aspiration	1 (12.5)	0	0	0	1 (12.5)
Dyspnoea	1 (12.5)	0	0	0	1 (12.5)
Haemoptysis	1 (12.5)	0	0	0	1 (12.5)
Interstitial lung disease	1 (12.5)	0	0	0	1 (12.5)
Pharyngeal erythema	1 (12.5)	1 (12.5)	0	0	0
Pharyngeal lesion	1 (12.5)	0	0	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	0	0	1 (12.5)
Respiratory failure	1 (12.5)	0	0	0	1 (12.5)
Skin and subcutaneous tissue disorders					
-Total	4 (50.0)	3 (37.5)	1 (12.5)	0	0
Erythema	2 (25.0)	2 (25.0)	0	0	0

Number of previous relapses: 0

	All patients N=8				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alopecia	1 (12.5)	0	1 (12.5)	0	0
Dermatitis diaper	1 (12.5)	1 (12.5)	0	0	0
Dry skin	1 (12.5)	1 (12.5)	0	0	0
Livedo reticularis	1 (12.5)	1 (12.5)	0	0	0
Rash erythematous	1 (12.5)	0	1 (12.5)	0	0
Rash maculo-papular	1 (12.5)	1 (12.5)	0	0	0
Rash papular	1 (12.5)	1 (12.5)	0	0	0
Vascular disorders					
-Total	6 (75.0)	0	1 (12.5)	2 (25.0)	3 (37.5)
Hypotension	5 (62.5)	0	0	2 (25.0)	3 (37.5)
Hypertension	3 (37.5)	1 (12.5)	2 (25.0)	0	0
Haematoma	1 (12.5)	0	1 (12.5)	0	0
Hot flush	1 (12.5)	1 (12.5)	0	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188r
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (95.7)	1 (4.3)	2 (8.7)	3 (13.0)	16 (69.6)
Blood and lymphatic system disorders					
-Total	18 (78.3)	0	0	12 (52.2)	6 (26.1)
Febrile neutropenia	13 (56.5)	0	0	13 (56.5)	0
Anaemia	11 (47.8)	0	1 (4.3)	10 (43.5)	0
Neutropenia	5 (21.7)	0	0	1 (4.3)	4 (17.4)
Disseminated intravascular coagulation	4 (17.4)	0	1 (4.3)	3 (13.0)	0
Lymphopenia	3 (13.0)	0	0	0	3 (13.0)
Thrombocytopenia	3 (13.0)	0	0	1 (4.3)	2 (8.7)
Cardiac disorders					

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (39.1)	3 (13.0)	5 (21.7)	1 (4.3)	0
Tachycardia	5 (21.7)	3 (13.0)	2 (8.7)	0	0
Sinus tachycardia	3 (13.0)	1 (4.3)	1 (4.3)	1 (4.3)	0
Pericardial effusion	2 (8.7)	0	2 (8.7)	0	0
Endocrine disorders					
-Total	1 (4.3)	0	1 (4.3)	0	0
Adrenal insufficiency	1 (4.3)	0	1 (4.3)	0	0
Gastrointestinal disorders					
-Total	18 (78.3)	3 (13.0)	9 (39.1)	6 (26.1)	0
Nausea	13 (56.5)	3 (13.0)	7 (30.4)	3 (13.0)	0
Vomiting	10 (43.5)	4 (17.4)	4 (17.4)	2 (8.7)	0
Diarrhoea	8 (34.8)	4 (17.4)	3 (13.0)	1 (4.3)	0
Constipation	7 (30.4)	7 (30.4)	0	0	0
Abdominal pain	6 (26.1)	1 (4.3)	3 (13.0)	2 (8.7)	0
Colitis	1 (4.3)	1 (4.3)	0	0	0
Stomatitis	1 (4.3)	0	0	1 (4.3)	0
General disorders and administration site conditions					

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (60.9)	4 (17.4)	5 (21.7)	5 (21.7)	0
Pyrexia	10 (43.5)	2 (8.7)	4 (17.4)	4 (17.4)	0
Fatigue	5 (21.7)	5 (21.7)	0	0	0
Oedema peripheral	3 (13.0)	1 (4.3)	1 (4.3)	1 (4.3)	0
Catheter site pain	2 (8.7)	0	2 (8.7)	0	0
Chills	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Generalised oedema	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Pain	2 (8.7)	0	2 (8.7)	0	0
Multiple organ dysfunction syndrome	1 (4.3)	0	0	1 (4.3)	0
Hepatobiliary disorders					
-Total	2 (8.7)	0	0	2 (8.7)	0
Hyperbilirubinaemia	2 (8.7)	0	0	2 (8.7)	0
Immune system disorders					
-Total	17 (73.9)	2 (8.7)	7 (30.4)	3 (13.0)	5 (21.7)
Cytokine release syndrome	16 (69.6)	2 (8.7)	7 (30.4)	2 (8.7)	5 (21.7)
Hypogammaglobulinaemia	10 (43.5)	1 (4.3)	7 (30.4)	2 (8.7)	0
Infections and infestations					
-Total	15 (65.2)	1 (4.3)	7 (30.4)	7 (30.4)	0

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia	4 (17.4)	0	3 (13.0)	1 (4.3)	0
Gastroenteritis	3 (13.0)	0	2 (8.7)	1 (4.3)	0
Influenza	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Clostridium difficile infection	2 (8.7)	0	2 (8.7)	0	0
Device related infection	2 (8.7)	0	0	2 (8.7)	0
Otitis media	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Rhinovirus infection	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Upper respiratory tract infection	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Urinary tract infection	2 (8.7)	0	1 (4.3)	1 (4.3)	0
Clostridium difficile colitis	1 (4.3)	0	0	1 (4.3)	0
Oral herpes	1 (4.3)	0	1 (4.3)	0	0
Respiratory syncytial virus infection	1 (4.3)	0	1 (4.3)	0	0
Viral infection	1 (4.3)	1 (4.3)	0	0	0
Injury, poisoning and procedural complications					
-Total	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Contusion	1 (4.3)	1 (4.3)	0	0	0
Procedural pain	1 (4.3)	0	1 (4.3)	0	0

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations					
-Total	17 (73.9)	0	0	3 (13.0)	14 (60.9)
White blood cell count decreased	14 (60.9)	2 (8.7)	0	3 (13.0)	9 (39.1)
Neutrophil count decreased	10 (43.5)	0	0	2 (8.7)	8 (34.8)
Platelet count decreased	9 (39.1)	0	2 (8.7)	1 (4.3)	6 (26.1)
Alanine aminotransferase increased	7 (30.4)	1 (4.3)	2 (8.7)	4 (17.4)	0
Aspartate aminotransferase increased	7 (30.4)	1 (4.3)	2 (8.7)	3 (13.0)	1 (4.3)
Lymphocyte count decreased	6 (26.1)	0	0	3 (13.0)	3 (13.0)
Blood creatinine increased	4 (17.4)	2 (8.7)	1 (4.3)	1 (4.3)	0
Activated partial thromboplastin time prolonged	3 (13.0)	1 (4.3)	2 (8.7)	0	0
Blood bilirubin increased	3 (13.0)	0	2 (8.7)	1 (4.3)	0
International normalised ratio increased	3 (13.0)	3 (13.0)	0	0	0
Prothrombin time prolonged	3 (13.0)	3 (13.0)	0	0	0
Blood fibrinogen decreased	1 (4.3)	0	0	0	1 (4.3)
Blood immunoglobulin a decreased	1 (4.3)	1 (4.3)	0	0	0
Blood immunoglobulin m decreased	1 (4.3)	1 (4.3)	0	0	0

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood phosphorus increased	1 (4.3)	1 (4.3)	0	0	0
Blood uric acid increased	1 (4.3)	1 (4.3)	0	0	0
Transaminases increased	1 (4.3)	0	0	1 (4.3)	0
Weight decreased	1 (4.3)	1 (4.3)	0	0	0
Weight increased	1 (4.3)	1 (4.3)	0	0	0
Metabolism and nutrition disorders					
-Total	16 (69.6)	2 (8.7)	3 (13.0)	6 (26.1)	5 (21.7)
Decreased appetite	11 (47.8)	3 (13.0)	3 (13.0)	5 (21.7)	0
Hypokalaemia	6 (26.1)	1 (4.3)	0	3 (13.0)	2 (8.7)
Hyperglycaemia	5 (21.7)	0	3 (13.0)	2 (8.7)	0
Hyperphosphataemia	4 (17.4)	4 (17.4)	0	0	0
Fluid overload	3 (13.0)	0	2 (8.7)	1 (4.3)	0
Hypernatraemia	3 (13.0)	1 (4.3)	1 (4.3)	0	1 (4.3)
Hyperuricaemia	3 (13.0)	1 (4.3)	0	0	2 (8.7)
Hypophosphataemia	3 (13.0)	1 (4.3)	0	2 (8.7)	0
Dehydration	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Hypocalcaemia	2 (8.7)	2 (8.7)	0	0	0
Vitamin d deficiency	2 (8.7)	1 (4.3)	1 (4.3)	0	0

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	1 (4.3)	0	1 (4.3)	0	0
Hypomagnesaemia	1 (4.3)	1 (4.3)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	7 (30.4)	1 (4.3)	4 (17.4)	2 (8.7)	0
Arthralgia	4 (17.4)	2 (8.7)	1 (4.3)	1 (4.3)	0
Pain in extremity	4 (17.4)	1 (4.3)	2 (8.7)	1 (4.3)	0
Back pain	3 (13.0)	1 (4.3)	0	2 (8.7)	0
Musculoskeletal chest pain	3 (13.0)	3 (13.0)	0	0	0
Muscular weakness	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Musculoskeletal pain	1 (4.3)	0	1 (4.3)	0	0
Neck pain	1 (4.3)	0	1 (4.3)	0	0
Nervous system disorders					
-Total	13 (56.5)	5 (21.7)	5 (21.7)	2 (8.7)	1 (4.3)
Headache	12 (52.2)	5 (21.7)	5 (21.7)	2 (8.7)	0
Seizure	3 (13.0)	0	1 (4.3)	1 (4.3)	1 (4.3)
Dizziness	1 (4.3)	1 (4.3)	0	0	0
Psychiatric disorders					

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (26.1)	2 (8.7)	4 (17.4)	0	0
Anxiety	2 (8.7)	0	2 (8.7)	0	0
Delirium	2 (8.7)	0	2 (8.7)	0	0
Depression	2 (8.7)	1 (4.3)	1 (4.3)	0	0
Insomnia	2 (8.7)	0	2 (8.7)	0	0
Confusional state	1 (4.3)	1 (4.3)	0	0	0
Irritability	1 (4.3)	1 (4.3)	0	0	0
Renal and urinary disorders					
-Total	7 (30.4)	2 (8.7)	1 (4.3)	4 (17.4)	0
Acute kidney injury	6 (26.1)	2 (8.7)	1 (4.3)	3 (13.0)	0
Haematuria	1 (4.3)	0	0	1 (4.3)	0
Oliguria	1 (4.3)	0	0	1 (4.3)	0
Respiratory, thoracic and mediastinal disorders					
-Total	12 (52.2)	4 (17.4)	1 (4.3)	5 (21.7)	2 (8.7)
Epistaxis	5 (21.7)	2 (8.7)	1 (4.3)	2 (8.7)	0
Hypoxia	5 (21.7)	0	1 (4.3)	4 (17.4)	0
Pulmonary oedema	5 (21.7)	1 (4.3)	0	2 (8.7)	2 (8.7)

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachypnoea	5 (21.7)	2 (8.7)	1 (4.3)	2 (8.7)	0
Cough	4 (17.4)	3 (13.0)	0	1 (4.3)	0
Oropharyngeal pain	3 (13.0)	1 (4.3)	1 (4.3)	1 (4.3)	0
Pleural effusion	3 (13.0)	0	2 (8.7)	1 (4.3)	0
Haemoptysis	2 (8.7)	1 (4.3)	0	1 (4.3)	0
Nasal congestion	2 (8.7)	2 (8.7)	0	0	0
Dyspnoea	1 (4.3)	0	0	1 (4.3)	0
Respiratory failure	1 (4.3)	0	0	0	1 (4.3)
Rhinorrhoea	1 (4.3)	1 (4.3)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	11 (47.8)	9 (39.1)	2 (8.7)	0	0
Dry skin	4 (17.4)	4 (17.4)	0	0	0
Rash	4 (17.4)	3 (13.0)	1 (4.3)	0	0
Hyperhidrosis	3 (13.0)	3 (13.0)	0	0	0
Petechiae	3 (13.0)	3 (13.0)	0	0	0
Rash erythematous	3 (13.0)	2 (8.7)	1 (4.3)	0	0
Erythema	1 (4.3)	1 (4.3)	0	0	0

Number of previous relapses: 1

	All patients N=23				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Rash papular	1 (4.3)	1 (4.3)	0	0	0
Vascular disorders					
-Total	7 (30.4)	0	0	3 (13.0)	4 (17.4)
Hypotension	6 (26.1)	0	0	2 (8.7)	4 (17.4)
Hypertension	4 (17.4)	1 (4.3)	2 (8.7)	1 (4.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188r
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (95.8)	0	1 (4.2)	5 (20.8)	17 (70.8)
Blood and lymphatic system disorders					
-Total	20 (83.3)	0	1 (4.2)	10 (41.7)	9 (37.5)
Anaemia	12 (50.0)	0	5 (20.8)	7 (29.2)	0
Febrile neutropenia	12 (50.0)	0	0	11 (45.8)	1 (4.2)
Neutropenia	8 (33.3)	0	0	2 (8.3)	6 (25.0)
Thrombocytopenia	6 (25.0)	0	1 (4.2)	0	5 (20.8)
Lymphopenia	2 (8.3)	0	1 (4.2)	1 (4.2)	0
Disseminated intravascular coagulation	1 (4.2)	0	1 (4.2)	0	0
Cardiac disorders					

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (25.0)	2 (8.3)	3 (12.5)	1 (4.2)	0
Tachycardia	5 (20.8)	2 (8.3)	3 (12.5)	0	0
Left ventricular dysfunction	1 (4.2)	0	0	1 (4.2)	0
Palpitations	1 (4.2)	1 (4.2)	0	0	0
Sinus tachycardia	1 (4.2)	0	1 (4.2)	0	0
Endocrine disorders					
-Total	1 (4.2)	0	1 (4.2)	0	0
Adrenal insufficiency	1 (4.2)	0	1 (4.2)	0	0
Eye disorders					
-Total	2 (8.3)	0	2 (8.3)	0	0
Eye pain	2 (8.3)	0	2 (8.3)	0	0
Gastrointestinal disorders					
-Total	16 (66.7)	5 (20.8)	8 (33.3)	3 (12.5)	0
Nausea	11 (45.8)	2 (8.3)	7 (29.2)	2 (8.3)	0
Vomiting	10 (41.7)	5 (20.8)	3 (12.5)	2 (8.3)	0
Diarrhoea	8 (33.3)	4 (16.7)	3 (12.5)	1 (4.2)	0
Constipation	5 (20.8)	2 (8.3)	3 (12.5)	0	0
Abdominal pain	3 (12.5)	1 (4.2)	1 (4.2)	1 (4.2)	0

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspepsia	1 (4.2)	0	1 (4.2)	0	0
Oral pain	1 (4.2)	0	1 (4.2)	0	0
Stomatitis	1 (4.2)	0	1 (4.2)	0	0
General disorders and administration site conditions					
-Total	16 (66.7)	6 (25.0)	9 (37.5)	1 (4.2)	0
Pyrexia	10 (41.7)	3 (12.5)	6 (25.0)	1 (4.2)	0
Chills	6 (25.0)	5 (20.8)	1 (4.2)	0	0
Fatigue	6 (25.0)	3 (12.5)	3 (12.5)	0	0
Catheter site pain	3 (12.5)	1 (4.2)	2 (8.3)	0	0
Malaise	3 (12.5)	1 (4.2)	2 (8.3)	0	0
Asthenia	1 (4.2)	0	1 (4.2)	0	0
Pain	1 (4.2)	0	1 (4.2)	0	0
Hepatobiliary disorders					
-Total	3 (12.5)	1 (4.2)	2 (8.3)	0	0
Hyperbilirubinaemia	2 (8.3)	0	2 (8.3)	0	0
Hepatomegaly	1 (4.2)	1 (4.2)	0	0	0
Immune system disorders					

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	20 (83.3)	0	13 (54.2)	6 (25.0)	1 (4.2)
Cytokine release syndrome	18 (75.0)	1 (4.2)	12 (50.0)	4 (16.7)	1 (4.2)
Hypogammaglobulinaemia	12 (50.0)	1 (4.2)	8 (33.3)	3 (12.5)	0
Infections and infestations					
-Total	12 (50.0)	2 (8.3)	8 (33.3)	2 (8.3)	0
Clostridium difficile colitis	3 (12.5)	1 (4.2)	1 (4.2)	1 (4.2)	0
Rhinovirus infection	3 (12.5)	3 (12.5)	0	0	0
Pneumonia	2 (8.3)	0	2 (8.3)	0	0
Upper respiratory tract infection	2 (8.3)	0	2 (8.3)	0	0
Clostridium difficile infection	1 (4.2)	0	1 (4.2)	0	0
Device related infection	1 (4.2)	0	0	1 (4.2)	0
Gastroenteritis	1 (4.2)	1 (4.2)	0	0	0
Influenza	1 (4.2)	0	1 (4.2)	0	0
Oral herpes	1 (4.2)	0	1 (4.2)	0	0
Urinary tract infection	1 (4.2)	0	1 (4.2)	0	0
Injury, poisoning and procedural complications					
-Total	4 (16.7)	2 (8.3)	1 (4.2)	1 (4.2)	0

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural pain	3 (12.5)	1 (4.2)	1 (4.2)	1 (4.2)	0
Infusion related reaction	2 (8.3)	2 (8.3)	0	0	0
Investigations					
-Total	20 (83.3)	0	0	6 (25.0)	14 (58.3)
White blood cell count decreased	16 (66.7)	0	0	4 (16.7)	12 (50.0)
Alanine aminotransferase increased	11 (45.8)	1 (4.2)	0	10 (41.7)	0
Neutrophil count decreased	9 (37.5)	0	0	1 (4.2)	8 (33.3)
Platelet count decreased	9 (37.5)	2 (8.3)	0	3 (12.5)	4 (16.7)
Aspartate aminotransferase increased	8 (33.3)	2 (8.3)	1 (4.2)	5 (20.8)	0
Lymphocyte count decreased	5 (20.8)	0	0	3 (12.5)	2 (8.3)
Prothrombin time prolonged	4 (16.7)	2 (8.3)	1 (4.2)	1 (4.2)	0
Transaminases increased	3 (12.5)	3 (12.5)	0	0	0
Weight decreased	3 (12.5)	0	3 (12.5)	0	0
Blood bilirubin increased	2 (8.3)	0	1 (4.2)	1 (4.2)	0
Blood fibrinogen decreased	2 (8.3)	0	0	2 (8.3)	0
International normalised ratio increased	2 (8.3)	1 (4.2)	0	1 (4.2)	0
Blood creatinine increased	1 (4.2)	1 (4.2)	0	0	0

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood immunoglobulin m decreased	1 (4.2)	1 (4.2)	0	0	0
Metabolism and nutrition disorders					
-Total	17 (70.8)	1 (4.2)	4 (16.7)	10 (41.7)	2 (8.3)
Decreased appetite	11 (45.8)	1 (4.2)	4 (16.7)	6 (25.0)	0
Hypokalaemia	7 (29.2)	1 (4.2)	2 (8.3)	3 (12.5)	1 (4.2)
Hypophosphataemia	6 (25.0)	1 (4.2)	0	4 (16.7)	1 (4.2)
Hypomagnesaemia	3 (12.5)	2 (8.3)	1 (4.2)	0	0
Dehydration	2 (8.3)	0	1 (4.2)	1 (4.2)	0
Fluid overload	2 (8.3)	0	2 (8.3)	0	0
Hyperphosphataemia	2 (8.3)	2 (8.3)	0	0	0
Hyperuricaemia	2 (8.3)	1 (4.2)	0	1 (4.2)	0
Hyperglycaemia	1 (4.2)	0	0	1 (4.2)	0
Hypernatraemia	1 (4.2)	0	0	0	1 (4.2)
Hypoalbuminaemia	1 (4.2)	0	0	1 (4.2)	0
Hypocalcaemia	1 (4.2)	0	0	0	1 (4.2)
Musculoskeletal and connective tissue disorders					
-Total	8 (33.3)	4 (16.7)	3 (12.5)	1 (4.2)	0

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	4 (16.7)	2 (8.3)	1 (4.2)	1 (4.2)	0
Pain in jaw	2 (8.3)	0	2 (8.3)	0	0
Arthralgia	1 (4.2)	0	1 (4.2)	0	0
Musculoskeletal pain	1 (4.2)	1 (4.2)	0	0	0
Myalgia	1 (4.2)	1 (4.2)	0	0	0
Neck pain	1 (4.2)	1 (4.2)	0	0	0
Nervous system disorders					
-Total	12 (50.0)	6 (25.0)	3 (12.5)	3 (12.5)	0
Headache	8 (33.3)	4 (16.7)	1 (4.2)	3 (12.5)	0
Dizziness	2 (8.3)	2 (8.3)	0	0	0
Peroneal nerve palsy	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Seizure	1 (4.2)	0	1 (4.2)	0	0
Psychiatric disorders					
-Total	6 (25.0)	3 (12.5)	3 (12.5)	0	0
Confusional state	3 (12.5)	1 (4.2)	2 (8.3)	0	0
Anxiety	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Delirium	1 (4.2)	1 (4.2)	0	0	0
Renal and urinary disorders					

Number of previous relapses: 2

	All patients N=24				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (16.7)	0	0	2 (8.3)	2 (8.3)
Acute kidney injury	4 (16.7)	0	0	2 (8.3)	2 (8.3)
Haematuria	1 (4.2)	0	1 (4.2)	0	0
Respiratory, thoracic and mediastinal disorders					
-Total	11 (45.8)	3 (12.5)	4 (16.7)	1 (4.2)	3 (12.5)
Cough	5 (20.8)	4 (16.7)	1 (4.2)	0	0
Hypoxia	3 (12.5)	0	1 (4.2)	1 (4.2)	1 (4.2)
Rhinitis allergic	3 (12.5)	2 (8.3)	1 (4.2)	0	0
Epistaxis	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Pleural effusion	2 (8.3)	1 (4.2)	0	1 (4.2)	0
Pulmonary oedema	2 (8.3)	0	0	1 (4.2)	1 (4.2)
Respiratory failure	2 (8.3)	0	0	0	2 (8.3)
Rhinorrhoea	2 (8.3)	2 (8.3)	0	0	0
Nasal congestion	1 (4.2)	1 (4.2)	0	0	0
Oropharyngeal pain	1 (4.2)	1 (4.2)	0	0	0
Tachypnoea	1 (4.2)	1 (4.2)	0	0	0
Skin and subcutaneous tissue disorders					

Number of previous relapses: 2

Group term Preferred term	All patients N=24 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	7 (29.2)	3 (12.5)	3 (12.5)	1 (4.2)	0
Alopecia	3 (12.5)	2 (8.3)	1 (4.2)	0	0
Erythema	2 (8.3)	2 (8.3)	0	0	0
Rash	2 (8.3)	1 (4.2)	1 (4.2)	0	0
Rash maculo-papular	2 (8.3)	0	1 (4.2)	1 (4.2)	0
Hyperhidrosis	1 (4.2)	1 (4.2)	0	0	0
Vascular disorders					
-Total	8 (33.3)	1 (4.2)	2 (8.3)	3 (12.5)	2 (8.3)
Hypotension	5 (20.8)	0	0	3 (12.5)	2 (8.3)
Hypertension	4 (16.7)	1 (4.2)	3 (12.5)	0	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 188r
Adverse events in at least 10% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime during the study by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (100)	0	0	6 (30.0)	14 (70.0)
Blood and lymphatic system disorders					
-Total	18 (90.0)	0	1 (5.0)	12 (60.0)	5 (25.0)
Anaemia	13 (65.0)	1 (5.0)	1 (5.0)	11 (55.0)	0
Febrile neutropenia	8 (40.0)	0	0	8 (40.0)	0
Thrombocytopenia	6 (30.0)	0	0	4 (20.0)	2 (10.0)
Neutropenia	4 (20.0)	0	0	1 (5.0)	3 (15.0)
Disseminated intravascular coagulation	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Lymphopenia	1 (5.0)	0	1 (5.0)	0	0
Cardiac disorders					

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (40.0)	4 (20.0)	2 (10.0)	2 (10.0)	0
Tachycardia	5 (25.0)	3 (15.0)	1 (5.0)	1 (5.0)	0
Sinus tachycardia	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Pericardial effusion	1 (5.0)	0	1 (5.0)	0	0
Ear and labyrinth disorders					
-Total	2 (10.0)	2 (10.0)	0	0	0
Ear pain	2 (10.0)	2 (10.0)	0	0	0
Gastrointestinal disorders					
-Total	14 (70.0)	3 (15.0)	7 (35.0)	4 (20.0)	0
Vomiting	8 (40.0)	5 (25.0)	3 (15.0)	0	0
Diarrhoea	7 (35.0)	3 (15.0)	3 (15.0)	1 (5.0)	0
Nausea	7 (35.0)	2 (10.0)	5 (25.0)	0	0
Abdominal pain	6 (30.0)	2 (10.0)	3 (15.0)	1 (5.0)	0
Colitis	3 (15.0)	0	0	3 (15.0)	0
Stomatitis	3 (15.0)	1 (5.0)	0	2 (10.0)	0
Abdominal distension	2 (10.0)	0	2 (10.0)	0	0
Constipation	1 (5.0)	1 (5.0)	0	0	0

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions					
-Total	16 (80.0)	6 (30.0)	5 (25.0)	2 (10.0)	3 (15.0)
Pyrexia	11 (55.0)	6 (30.0)	4 (20.0)	1 (5.0)	0
Fatigue	7 (35.0)	5 (25.0)	1 (5.0)	1 (5.0)	0
Chills	3 (15.0)	3 (15.0)	0	0	0
Multiple organ dysfunction syndrome	3 (15.0)	0	0	0	3 (15.0)
Pain	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Generalised oedema	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Oedema peripheral	2 (10.0)	2 (10.0)	0	0	0
Catheter site pain	1 (5.0)	1 (5.0)	0	0	0
Malaise	1 (5.0)	0	1 (5.0)	0	0
Hepatobiliary disorders					
-Total	2 (10.0)	0	0	2 (10.0)	0
Hyperbilirubinaemia	2 (10.0)	0	0	2 (10.0)	0
Hepatomegaly	1 (5.0)	0	1 (5.0)	0	0
Immune system disorders					
-Total	15 (75.0)	4 (20.0)	7 (35.0)	2 (10.0)	2 (10.0)

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	11 (55.0)	3 (15.0)	4 (20.0)	2 (10.0)	2 (10.0)
Hypogammaglobulinaemia	7 (35.0)	2 (10.0)	5 (25.0)	0	0
Graft versus host disease	1 (5.0)	1 (5.0)	0	0	0
Infections and infestations					
-Total	13 (65.0)	1 (5.0)	4 (20.0)	6 (30.0)	2 (10.0)
Upper respiratory tract infection	5 (25.0)	4 (20.0)	0	1 (5.0)	0
Bacteraemia	2 (10.0)	0	0	2 (10.0)	0
Clostridium difficile colitis	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Clostridium difficile infection	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Device related infection	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Enterococcal bacteraemia	2 (10.0)	0	0	2 (10.0)	0
Fungal skin infection	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Klebsiella sepsis	2 (10.0)	0	0	0	2 (10.0)
Otitis media	2 (10.0)	0	2 (10.0)	0	0
Urinary tract infection	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Vulvovaginal candidiasis	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Ear infection	1 (5.0)	0	1 (5.0)	0	0
Oral herpes	1 (5.0)	0	1 (5.0)	0	0

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin infection	1 (5.0)	0	1 (5.0)	0	0
Injury, poisoning and procedural complications					
-Total	6 (30.0)	1 (5.0)	4 (20.0)	1 (5.0)	0
Procedural pain	3 (15.0)	0	2 (10.0)	1 (5.0)	0
Infusion related reaction	2 (10.0)	0	2 (10.0)	0	0
Subdural haematoma	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Contusion	1 (5.0)	1 (5.0)	0	0	0
Investigations					
-Total	15 (75.0)	0	3 (15.0)	0	12 (60.0)
Neutrophil count decreased	12 (60.0)	1 (5.0)	1 (5.0)	0	10 (50.0)
White blood cell count decreased	10 (50.0)	1 (5.0)	1 (5.0)	1 (5.0)	7 (35.0)
Alanine aminotransferase increased	8 (40.0)	1 (5.0)	2 (10.0)	4 (20.0)	1 (5.0)
Aspartate aminotransferase increased	8 (40.0)	2 (10.0)	2 (10.0)	1 (5.0)	3 (15.0)
Platelet count decreased	8 (40.0)	1 (5.0)	0	0	7 (35.0)
Lymphocyte count decreased	6 (30.0)	0	2 (10.0)	1 (5.0)	3 (15.0)
International normalised ratio increased	5 (25.0)	4 (20.0)	1 (5.0)	0	0

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	4 (20.0)	2 (10.0)	0	1 (5.0)	1 (5.0)
Blood creatinine increased	3 (15.0)	2 (10.0)	0	1 (5.0)	0
Activated partial thromboplastin time prolonged	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Blood immunoglobulin a decreased	2 (10.0)	2 (10.0)	0	0	0
Blood immunoglobulin m decreased	2 (10.0)	2 (10.0)	0	0	0
Weight increased	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Blood fibrinogen decreased	1 (5.0)	0	1 (5.0)	0	0
Blood uric acid increased	1 (5.0)	1 (5.0)	0	0	0
Prothrombin time prolonged	1 (5.0)	0	1 (5.0)	0	0
Metabolism and nutrition disorders					
-Total	14 (70.0)	1 (5.0)	3 (15.0)	8 (40.0)	2 (10.0)
Hypokalaemia	8 (40.0)	1 (5.0)	1 (5.0)	4 (20.0)	2 (10.0)
Decreased appetite	7 (35.0)	2 (10.0)	2 (10.0)	3 (15.0)	0
Hyperglycaemia	4 (20.0)	0	1 (5.0)	2 (10.0)	1 (5.0)
Hypoalbuminaemia	4 (20.0)	0	3 (15.0)	0	1 (5.0)
Hypocalcaemia	4 (20.0)	1 (5.0)	1 (5.0)	1 (5.0)	1 (5.0)
Hypophosphataemia	4 (20.0)	2 (10.0)	1 (5.0)	1 (5.0)	0

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperphosphataemia	3 (15.0)	2 (10.0)	1 (5.0)	0	0
Hyperuricaemia	3 (15.0)	3 (15.0)	0	0	0
Dehydration	2 (10.0)	0	0	2 (10.0)	0
Fluid overload	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Hypernatraemia	2 (10.0)	0	0	1 (5.0)	1 (5.0)
Hypoglycaemia	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Hypomagnesaemia	1 (5.0)	1 (5.0)	0	0	0
Vitamin d deficiency	1 (5.0)	1 (5.0)	0	0	0
Musculoskeletal and connective tissue disorders					
-Total	14 (70.0)	8 (40.0)	3 (15.0)	3 (15.0)	0
Pain in extremity	6 (30.0)	2 (10.0)	2 (10.0)	2 (10.0)	0
Myalgia	5 (25.0)	3 (15.0)	1 (5.0)	1 (5.0)	0
Muscle spasms	3 (15.0)	3 (15.0)	0	0	0
Arthralgia	2 (10.0)	2 (10.0)	0	0	0
Joint range of motion decreased	2 (10.0)	2 (10.0)	0	0	0
Musculoskeletal pain	2 (10.0)	1 (5.0)	0	1 (5.0)	0
Pain in jaw	2 (10.0)	1 (5.0)	1 (5.0)	0	0

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Back pain	1 (5.0)	1 (5.0)	0	0	0
Neck pain	1 (5.0)	0	1 (5.0)	0	0
Nervous system disorders					
-Total	8 (40.0)	4 (20.0)	2 (10.0)	2 (10.0)	0
Headache	7 (35.0)	3 (15.0)	3 (15.0)	1 (5.0)	0
Dizziness	2 (10.0)	2 (10.0)	0	0	0
Seizure	1 (5.0)	0	0	1 (5.0)	0
Psychiatric disorders					
-Total	6 (30.0)	1 (5.0)	3 (15.0)	2 (10.0)	0
Anxiety	4 (20.0)	1 (5.0)	2 (10.0)	1 (5.0)	0
Irritability	2 (10.0)	2 (10.0)	0	0	0
Confusional state	1 (5.0)	0	1 (5.0)	0	0
Delirium	1 (5.0)	0	0	1 (5.0)	0
Insomnia	1 (5.0)	0	1 (5.0)	0	0
Renal and urinary disorders					
-Total	3 (15.0)	1 (5.0)	0	1 (5.0)	1 (5.0)
Haematuria	2 (10.0)	1 (5.0)	1 (5.0)	0	0
Acute kidney injury	1 (5.0)	0	0	0	1 (5.0)

Number of previous relapses: >=3

	All patients N=20				
Group term Preferred term	**All grades n (%)**	**Grade 1 n (%)**	**Grade 2 n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cystitis haemorrhagic	1 (5.0)	0	0	1 (5.0)	0
Oliguria	1 (5.0)	0	0	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders					
-Total	12 (60.0)	4 (20.0)	2 (10.0)	4 (20.0)	2 (10.0)
Hypoxia	5 (25.0)	0	1 (5.0)	2 (10.0)	2 (10.0)
Cough	4 (20.0)	3 (15.0)	1 (5.0)	0	0
Epistaxis	4 (20.0)	1 (5.0)	1 (5.0)	2 (10.0)	0
Dyspnoea	3 (15.0)	1 (5.0)	1 (5.0)	1 (5.0)	0
Pleural effusion	3 (15.0)	0	2 (10.0)	1 (5.0)	0
Nasal congestion	2 (10.0)	2 (10.0)	0	0	0
Oropharyngeal pain	2 (10.0)	2 (10.0)	0	0	0
Rhinitis allergic	2 (10.0)	2 (10.0)	0	0	0
Tachypnoea	2 (10.0)	0	1 (5.0)	1 (5.0)	0
Pulmonary oedema	1 (5.0)	0	0	1 (5.0)	0
Rhinorrhoea	1 (5.0)	1 (5.0)	0	0	0
Skin and subcutaneous tissue disorders					
-Total	7 (35.0)	5 (25.0)	2 (10.0)	0	0

Number of previous relapses: >=3

Group term Preferred term	All patients N=20 All grades n (%)	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)
Rash	4 (20.0)	3 (15.0)	1 (5.0)	0	0
Rash maculo-papular	2 (10.0)	2 (10.0)	0	0	0
Rash papular	2 (10.0)	2 (10.0)	0	0	0
Petechiae	1 (5.0)	0	1 (5.0)	0	0
Rash erythematous	1 (5.0)	0	1 (5.0)	0	0
Vascular disorders					
-Total	12 (60.0)	2 (10.0)	1 (5.0)	7 (35.0)	2 (10.0)
Hypotension	9 (45.0)	1 (5.0)	0	6 (30.0)	2 (10.0)
Hypertension	5 (25.0)	1 (5.0)	2 (10.0)	2 (10.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: <10 years

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (70.0)	2 (10.0)	12 (60.0)
Blood and lymphatic system disorders			
-Total	9 (45.0)	8 (40.0)	1 (5.0)
Febrile neutropenia	6 (30.0)	6 (30.0)	0
Anaemia	4 (20.0)	4 (20.0)	0
Disseminated intravascular coagulation	1 (5.0)	1 (5.0)	0
Thrombocytopenia	1 (5.0)	0	1 (5.0)
Gastrointestinal disorders			
-Total	5 (25.0)	5 (25.0)	0
Nausea	2 (10.0)	2 (10.0)	0

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ascites	1 (5.0)	1 (5.0)	0
Dysphagia	1 (5.0)	1 (5.0)	0
Ileus	1 (5.0)	1 (5.0)	0
Pancreatitis	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	3 (15.0)	3 (15.0)	0
Pyrexia	2 (10.0)	2 (10.0)	0
Face oedema	1 (5.0)	1 (5.0)	0
Localised oedema	1 (5.0)	1 (5.0)	0
Multiple organ dysfunction syndrome	1 (5.0)	1 (5.0)	0
Oedema peripheral	1 (5.0)	1 (5.0)	0
Hepatobiliary disorders			
-Total	1 (5.0)	1 (5.0)	0
Hyperbilirubinaemia	1 (5.0)	1 (5.0)	0
Immune system disorders			
-Total	6 (30.0)	3 (15.0)	3 (15.0)
Cytokine release syndrome	6 (30.0)	3 (15.0)	3 (15.0)

Timing: within 8 weeks post infusion, Age: <10 years

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	1 (5.0)	1 (5.0)	0
Infections and infestations			
-Total	4 (20.0)	3 (15.0)	1 (5.0)
Catheter site infection	1 (5.0)	1 (5.0)	0
Clostridium difficile colitis	1 (5.0)	1 (5.0)	0
Pneumonia	1 (5.0)	1 (5.0)	0
Septic embolus	1 (5.0)	0	1 (5.0)
Investigations			
-Total	13 (65.0)	3 (15.0)	10 (50.0)
Neutrophil count decreased	7 (35.0)	1 (5.0)	6 (30.0)
White blood cell count decreased	7 (35.0)	2 (10.0)	5 (25.0)
Aspartate aminotransferase increased	5 (25.0)	3 (15.0)	2 (10.0)
Alanine aminotransferase increased	4 (20.0)	4 (20.0)	0
Platelet count decreased	3 (15.0)	0	3 (15.0)
Blood fibrinogen decreased	2 (10.0)	1 (5.0)	1 (5.0)
Lipase increased	2 (10.0)	0	2 (10.0)
Lymphocyte count decreased	2 (10.0)	1 (5.0)	1 (5.0)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (5.0)	1 (5.0)	0
Blood creatinine increased	1 (5.0)	1 (5.0)	0
Blood lactic acid increased	1 (5.0)	0	1 (5.0)
Blood urea increased	1 (5.0)	1 (5.0)	0
International normalised ratio increased	1 (5.0)	1 (5.0)	0
Protein total decreased	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	7 (35.0)	6 (30.0)	1 (5.0)
Hypokalaemia	5 (25.0)	5 (25.0)	0
Decreased appetite	3 (15.0)	3 (15.0)	0
Hypophosphataemia	3 (15.0)	2 (10.0)	1 (5.0)
Acidosis	1 (5.0)	1 (5.0)	0
Hypertriglyceridaemia	1 (5.0)	1 (5.0)	0
Hypoalbuminaemia	1 (5.0)	1 (5.0)	0
Hyponatraemia	1 (5.0)	1 (5.0)	0
Malnutrition	1 (5.0)	1 (5.0)	0
Nervous system disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Embolic stroke	1 (5.0)	0	1 (5.0)
Seizure	1 (5.0)	1 (5.0)	0
Renal and urinary disorders			
-Total	2 (10.0)	2 (10.0)	0
Acute kidney injury	1 (5.0)	1 (5.0)	0
Renal impairment	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (25.0)	3 (15.0)	2 (10.0)
Hypoxia	3 (15.0)	3 (15.0)	0
Pleural effusion	2 (10.0)	2 (10.0)	0
Pulmonary oedema	2 (10.0)	2 (10.0)	0
Epistaxis	1 (5.0)	1 (5.0)	0
Respiratory distress	1 (5.0)	0	1 (5.0)
Respiratory failure	1 (5.0)	0	1 (5.0)
Vascular disorders			
-Total	5 (25.0)	2 (10.0)	3 (15.0)
Hypotension	4 (20.0)	1 (5.0)	3 (15.0)
Capillary leak syndrome	1 (5.0)	0	1 (5.0)

Timing: within 8 weeks post infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Embolism	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (88.2)	8 (23.5)	22 (64.7)
Blood and lymphatic system disorders			
-Total	22 (64.7)	16 (47.1)	6 (17.6)
Febrile neutropenia	14 (41.2)	14 (41.2)	0
Anaemia	12 (35.3)	11 (32.4)	1 (2.9)
Neutropenia	5 (14.7)	1 (2.9)	4 (11.8)
Thrombocytopenia	4 (11.8)	2 (5.9)	2 (5.9)
Lymphopenia	2 (5.9)	1 (2.9)	1 (2.9)
Disseminated intravascular coagulation	1 (2.9)	1 (2.9)	0
Cardiac disorders			

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.9)	1 (2.9)	0
Tachycardia	1 (2.9)	1 (2.9)	0
Gastrointestinal disorders			
-Total	3 (8.8)	3 (8.8)	0
Vomiting	2 (5.9)	2 (5.9)	0
Diarrhoea	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			
-Total	4 (11.8)	3 (8.8)	1 (2.9)
Pain	2 (5.9)	2 (5.9)	0
Pyrexia	2 (5.9)	1 (2.9)	1 (2.9)
Hepatobiliary disorders			
-Total	1 (2.9)	1 (2.9)	0
Hyperbilirubinaemia	1 (2.9)	1 (2.9)	0
Immune system disorders			
-Total	13 (38.2)	8 (23.5)	5 (14.7)
Cytokine release syndrome	10 (29.4)	5 (14.7)	5 (14.7)
Hypogammaglobulinaemia	3 (8.8)	3 (8.8)	0
Investigations			

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	22 (64.7)	5 (14.7)	17 (50.0)
Neutrophil count decreased	15 (44.1)	3 (8.8)	12 (35.3)
White blood cell count decreased	15 (44.1)	6 (17.6)	9 (26.5)
Platelet count decreased	10 (29.4)	2 (5.9)	8 (23.5)
Lymphocyte count decreased	8 (23.5)	5 (14.7)	3 (8.8)
Alanine aminotransferase increased	7 (20.6)	7 (20.6)	0
Aspartate aminotransferase increased	5 (14.7)	4 (11.8)	1 (2.9)
Blood bilirubin increased	1 (2.9)	1 (2.9)	0
Blood creatinine increased	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders			
-Total	11 (32.4)	11 (32.4)	0
Decreased appetite	6 (17.6)	6 (17.6)	0
Hypophosphataemia	3 (8.8)	3 (8.8)	0
Hypokalaemia	2 (5.9)	2 (5.9)	0
Dehydration	1 (2.9)	1 (2.9)	0
Hyponatraemia	1 (2.9)	1 (2.9)	0

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (2.9)	1 (2.9)	0
Nervous system disorders			
-Total	3 (8.8)	3 (8.8)	0
Encephalopathy	2 (5.9)	2 (5.9)	0
Headache	2 (5.9)	2 (5.9)	0
Renal and urinary disorders			
-Total	3 (8.8)	1 (2.9)	2 (5.9)
Acute kidney injury	2 (5.9)	1 (2.9)	1 (2.9)
Oliguria	2 (5.9)	2 (5.9)	0
Haematuria	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (11.8)	1 (2.9)	3 (8.8)
Epistaxis	3 (8.8)	2 (5.9)	1 (2.9)
Hypoxia	2 (5.9)	1 (2.9)	1 (2.9)
Pulmonary oedema	2 (5.9)	1 (2.9)	1 (2.9)
Respiratory failure	2 (5.9)	0	2 (5.9)
Dyspnoea	1 (2.9)	1 (2.9)	0
Vascular disorders			

Timing: within 8 weeks post infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (26.5)	5 (14.7)	4 (11.8)
Hypotension	9 (26.5)	5 (14.7)	4 (11.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: within 8 weeks post infusion, Age: >=18

		All patients N=10	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (100)	4 (40.0)	6 (60.0)
Blood and lymphatic system disorders			
-Total	7 (70.0)	3 (30.0)	4 (40.0)
Anaemia	3 (30.0)	3 (30.0)	0
Neutropenia	3 (30.0)	2 (20.0)	1 (10.0)
Thrombocytopenia	3 (30.0)	0	3 (30.0)
Febrile neutropenia	2 (20.0)	2 (20.0)	0
Pancytopenia	1 (10.0)	0	1 (10.0)
Cardiac disorders			
-Total	1 (10.0)	1 (10.0)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (10.0)	1 (10.0)	0
Tachycardia	1 (10.0)	1 (10.0)	0
Gastrointestinal disorders			
-Total	2 (20.0)	2 (20.0)	0
Abdominal pain	1 (10.0)	1 (10.0)	0
Intestinal obstruction	1 (10.0)	1 (10.0)	0
Nausea	1 (10.0)	1 (10.0)	0
Vomiting	1 (10.0)	1 (10.0)	0
General disorders and administration site conditions			
-Total	2 (20.0)	2 (20.0)	0
Pyrexia	2 (20.0)	2 (20.0)	0
Immune system disorders			
-Total	3 (30.0)	0	3 (30.0)
Cytokine release syndrome	3 (30.0)	0	3 (30.0)
Infections and infestations			
-Total	1 (10.0)	1 (10.0)	0
Urinary tract infection enterococcal	1 (10.0)	1 (10.0)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (10.0)	1 (10.0)	0
Tracheal haemorrhage	1 (10.0)	1 (10.0)	0
Investigations			
-Total	8 (80.0)	4 (40.0)	4 (40.0)
White blood cell count decreased	4 (40.0)	2 (20.0)	2 (20.0)
Aspartate aminotransferase increased	1 (10.0)	0	1 (10.0)
Blood fibrinogen decreased	1 (10.0)	1 (10.0)	0
C-reactive protein increased	1 (10.0)	1 (10.0)	0
Lymphocyte count decreased	1 (10.0)	0	1 (10.0)
Neutrophil count decreased	1 (10.0)	0	1 (10.0)
Platelet count decreased	1 (10.0)	0	1 (10.0)
Prothrombin time prolonged	1 (10.0)	1 (10.0)	0
Metabolism and nutrition disorders			
-Total	5 (50.0)	4 (40.0)	1 (10.0)
Decreased appetite	3 (30.0)	3 (30.0)	0
Dehydration	1 (10.0)	1 (10.0)	0

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	1 (10.0)	1 (10.0)	0
Hyperuricaemia	1 (10.0)	0	1 (10.0)
Hypophosphataemia	1 (10.0)	1 (10.0)	0
Psychiatric disorders			
-Total	1 (10.0)	1 (10.0)	0
Anxiety	1 (10.0)	1 (10.0)	0
Renal and urinary disorders			
-Total	2 (20.0)	0	2 (20.0)
Acute kidney injury	2 (20.0)	0	2 (20.0)
Haematuria	1 (10.0)	1 (10.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (20.0)	0	2 (20.0)
Hypoxia	2 (20.0)	0	2 (20.0)
Dyspnoea	1 (10.0)	0	1 (10.0)
Interstitial lung disease	1 (10.0)	0	1 (10.0)
Pulmonary oedema	1 (10.0)	0	1 (10.0)
Skin and subcutaneous tissue disorders			

Timing: within 8 weeks post infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (10.0)	1 (10.0)	0
Rash maculo-papular	1 (10.0)	1 (10.0)	0
Vascular disorders			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Hypotension	2 (20.0)	1 (10.0)	1 (10.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (33.3)	5 (27.8)	1 (5.6)
Blood and lymphatic system disorders			
-Total	1 (5.6)	0	1 (5.6)
Leukopenia	1 (5.6)	0	1 (5.6)
Gastrointestinal disorders			
-Total	1 (5.6)	1 (5.6)	0
Enterocolitis	1 (5.6)	1 (5.6)	0
Immune system disorders			
-Total	1 (5.6)	1 (5.6)	0
Hypogammaglobulinaemia	1 (5.6)	1 (5.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: <10 years

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	3 (16.7)	3 (16.7)	0
Corona virus infection	1 (5.6)	1 (5.6)	0
Enterovirus infection	1 (5.6)	1 (5.6)	0
Parainfluenzae virus infection	1 (5.6)	1 (5.6)	0
Respiratory syncytial virus infection	1 (5.6)	1 (5.6)	0
Rotavirus infection	1 (5.6)	1 (5.6)	0
Investigations			
-Total	2 (11.1)	2 (11.1)	0
Neutrophil count decreased	1 (5.6)	1 (5.6)	0
White blood cell count decreased	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	2 (11.1)	2 (11.1)	0
Dehydration	1 (5.6)	1 (5.6)	0
Tumour lysis syndrome	1 (5.6)	1 (5.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (45.2)	9 (29.0)	5 (16.1)
Blood and lymphatic system disorders			
-Total	6 (19.4)	3 (9.7)	3 (9.7)
Neutropenia	4 (12.9)	1 (3.2)	3 (9.7)
Febrile neutropenia	3 (9.7)	3 (9.7)	0
Anaemia	1 (3.2)	1 (3.2)	0
Thrombocytopenia	1 (3.2)	1 (3.2)	0
Gastrointestinal disorders			
-Total	1 (3.2)	1 (3.2)	0
Nausea	1 (3.2)	1 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (3.2)	1 (3.2)	0
General disorders and administration site conditions			
-Total	1 (3.2)	1 (3.2)	0
Pyrexia	1 (3.2)	1 (3.2)	0
Infections and infestations			
-Total	2 (6.5)	2 (6.5)	0
Urinary tract infection	2 (6.5)	2 (6.5)	0
Investigations			
-Total	9 (29.0)	6 (19.4)	3 (9.7)
Neutrophil count decreased	4 (12.9)	2 (6.5)	2 (6.5)
Alanine aminotransferase increased	2 (6.5)	2 (6.5)	0
Aspartate aminotransferase increased	2 (6.5)	2 (6.5)	0
Blood bilirubin increased	1 (3.2)	1 (3.2)	0
White blood cell count decreased	1 (3.2)	0	1 (3.2)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	1 (3.2)	0	1 (3.2)
Hyperglycaemia	1 (3.2)	1 (3.2)	0
Hypokalaemia	1 (3.2)	0	1 (3.2)
Hypophosphataemia	1 (3.2)	1 (3.2)	0
Renal and urinary disorders			
-Total	2 (6.5)	2 (6.5)	0
Acute kidney injury	1 (3.2)	1 (3.2)	0
Haematuria	1 (3.2)	1 (3.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.5)	2 (6.5)	0
Epistaxis	1 (3.2)	1 (3.2)	0
Pulmonary oedema	1 (3.2)	1 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (57.1)	1 (14.3)	3 (42.9)
Gastrointestinal disorders			
-Total	1 (14.3)	1 (14.3)	0
Abdominal pain	1 (14.3)	1 (14.3)	0
Diarrhoea	1 (14.3)	1 (14.3)	0
Nausea	1 (14.3)	1 (14.3)	0
Vomiting	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Bacterial sepsis	1 (14.3)	0	1 (14.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Age: >=18

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (14.3)	1 (14.3)	0
Sepsis	1 (14.3)	0	1 (14.3)
Investigations			
-Total	1 (14.3)	0	1 (14.3)
Neutrophil count decreased	1 (14.3)	0	1 (14.3)
Reproductive system and breast disorders			
-Total	1 (14.3)	1 (14.3)	0
Vaginal haemorrhage	1 (14.3)	1 (14.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: <10 years

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (36.4)	2 (18.2)	2 (18.2)
General disorders and administration site conditions			
-Total	1 (9.1)	1 (9.1)	0
Cyst	1 (9.1)	1 (9.1)	0
Infections and infestations			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Campylobacter infection	1 (9.1)	1 (9.1)	0
Clostridium difficile infection	1 (9.1)	1 (9.1)	0
Otitis media	1 (9.1)	1 (9.1)	0
Respiratory tract infection	1 (9.1)	0	1 (9.1)

Timing: >1 year post-CTL019 infusion, Age: <10 years

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory tract infection viral	1 (9.1)	1 (9.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (9.1)	0	1 (9.1)
Glioblastoma multiforme	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	1 (9.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

		All patients N=22	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (27.3)	4 (18.2)	2 (9.1)
Blood and lymphatic system disorders			
-Total	1 (4.5)	0	1 (4.5)
Febrile neutropenia	1 (4.5)	0	1 (4.5)
Infections and infestations			
-Total	1 (4.5)	1 (4.5)	0
Urinary tract infection	1 (4.5)	1 (4.5)	0
Investigations			
-Total	4 (18.2)	3 (13.6)	1 (4.5)

Timing: >1 year post-CTL019 infusion, Age: >=10 years to <18 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	3 (13.6)	2 (9.1)	1 (4.5)
Alanine aminotransferase increased	1 (4.5)	1 (4.5)	0
Lymphocyte count decreased	1 (4.5)	1 (4.5)	0
Platelet count decreased	1 (4.5)	1 (4.5)	0
Metabolism and nutrition disorders			
-Total	1 (4.5)	1 (4.5)	0
Hypokalaemia	1 (4.5)	1 (4.5)	0
Renal and urinary disorders			
-Total	1 (4.5)	1 (4.5)	0
Acute kidney injury	1 (4.5)	1 (4.5)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: >1 year post-CTL019 infusion, Age: >=18

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Investigations			
-Total	1 (100)	1 (100)	0
Alanine aminotransferase increased	1 (100)	1 (100)	0
Aspartate aminotransferase increased	1 (100)	1 (100)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (85.0)	3 (15.0)	14 (70.0)
Blood and lymphatic system disorders			
-Total	10 (50.0)	8 (40.0)	2 (10.0)
Febrile neutropenia	6 (30.0)	6 (30.0)	0
Anaemia	4 (20.0)	4 (20.0)	0
Disseminated intravascular coagulation	1 (5.0)	1 (5.0)	0
Leukopenia	1 (5.0)	0	1 (5.0)
Thrombocytopenia	1 (5.0)	0	1 (5.0)
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (30.0)	6 (30.0)	0
Nausea	2 (10.0)	2 (10.0)	0
Ascites	1 (5.0)	1 (5.0)	0
Dysphagia	1 (5.0)	1 (5.0)	0
Enterocolitis	1 (5.0)	1 (5.0)	0
Ileus	1 (5.0)	1 (5.0)	0
Pancreatitis	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	4 (20.0)	4 (20.0)	0
Pyrexia	2 (10.0)	2 (10.0)	0
Cyst	1 (5.0)	1 (5.0)	0
Face oedema	1 (5.0)	1 (5.0)	0
Localised oedema	1 (5.0)	1 (5.0)	0
Multiple organ dysfunction syndrome	1 (5.0)	1 (5.0)	0
Oedema peripheral	1 (5.0)	1 (5.0)	0
Hepatobiliary disorders			
-Total	1 (5.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	1 (5.0)	1 (5.0)	0
Immune system disorders			
-Total	6 (30.0)	3 (15.0)	3 (15.0)
Cytokine release syndrome	6 (30.0)	3 (15.0)	3 (15.0)
Hypogammaglobulinaemia	2 (10.0)	2 (10.0)	0
Infections and infestations			
-Total	8 (40.0)	6 (30.0)	2 (10.0)
Campylobacter infection	1 (5.0)	1 (5.0)	0
Catheter site infection	1 (5.0)	1 (5.0)	0
Clostridium difficile colitis	1 (5.0)	1 (5.0)	0
Clostridium difficile infection	1 (5.0)	1 (5.0)	0
Corona virus infection	1 (5.0)	1 (5.0)	0
Enterovirus infection	1 (5.0)	1 (5.0)	0
Otitis media	1 (5.0)	1 (5.0)	0
Parainfluenzae virus infection	1 (5.0)	1 (5.0)	0
Pneumonia	1 (5.0)	1 (5.0)	0
Respiratory syncytial virus infection	1 (5.0)	1 (5.0)	0
Respiratory tract infection	1 (5.0)	0	1 (5.0)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (5.0)	1 (5.0)	0
Rotavirus infection	1 (5.0)	1 (5.0)	0
Septic embolus	1 (5.0)	0	1 (5.0)
Investigations			
-Total	14 (70.0)	4 (20.0)	10 (50.0)
White blood cell count decreased	8 (40.0)	3 (15.0)	5 (25.0)
Neutrophil count decreased	7 (35.0)	1 (5.0)	6 (30.0)
Aspartate aminotransferase increased	5 (25.0)	3 (15.0)	2 (10.0)
Alanine aminotransferase increased	4 (20.0)	4 (20.0)	0
Platelet count decreased	3 (15.0)	0	3 (15.0)
Blood fibrinogen decreased	2 (10.0)	1 (5.0)	1 (5.0)
Lipase increased	2 (10.0)	0	2 (10.0)
Lymphocyte count decreased	2 (10.0)	1 (5.0)	1 (5.0)
Blood bilirubin increased	1 (5.0)	1 (5.0)	0
Blood creatinine increased	1 (5.0)	1 (5.0)	0
Blood lactic acid increased	1 (5.0)	0	1 (5.0)
Blood urea increased	1 (5.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
International normalised ratio increased	1 (5.0)	1 (5.0)	0
Protein total decreased	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	8 (40.0)	7 (35.0)	1 (5.0)
Hypokalaemia	5 (25.0)	5 (25.0)	0
Decreased appetite	3 (15.0)	3 (15.0)	0
Hypophosphataemia	3 (15.0)	2 (10.0)	1 (5.0)
Acidosis	1 (5.0)	1 (5.0)	0
Dehydration	1 (5.0)	1 (5.0)	0
Hypertriglyceridaemia	1 (5.0)	1 (5.0)	0
Hypoalbuminaemia	1 (5.0)	1 (5.0)	0
Hyponatraemia	1 (5.0)	1 (5.0)	0
Malnutrition	1 (5.0)	1 (5.0)	0
Tumour lysis syndrome	1 (5.0)	1 (5.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (5.0)	0	1 (5.0)
Glioblastoma multiforme	1 (5.0)	0	1 (5.0)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	3 (15.0)	2 (10.0)	1 (5.0)
Seizure	2 (10.0)	2 (10.0)	0
Embolic stroke	1 (5.0)	0	1 (5.0)
Renal and urinary disorders			
-Total	2 (10.0)	2 (10.0)	0
Acute kidney injury	1 (5.0)	1 (5.0)	0
Renal impairment	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (25.0)	3 (15.0)	2 (10.0)
Hypoxia	3 (15.0)	3 (15.0)	0
Pleural effusion	2 (10.0)	2 (10.0)	0
Pulmonary oedema	2 (10.0)	2 (10.0)	0
Epistaxis	1 (5.0)	1 (5.0)	0
Respiratory distress	1 (5.0)	0	1 (5.0)
Respiratory failure	1 (5.0)	0	1 (5.0)
Vascular disorders			
-Total	5 (25.0)	2 (10.0)	3 (15.0)

Timing: Any time post CTL019 infusion, Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	4 (20.0)	1 (5.0)	3 (15.0)
Capillary leak syndrome	1 (5.0)	0	1 (5.0)
Embolism	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (94.1)	7 (20.6)	25 (73.5)
Blood and lymphatic system disorders			
-Total	26 (76.5)	16 (47.1)	10 (29.4)
Febrile neutropenia	16 (47.1)	15 (44.1)	1 (2.9)
Anaemia	13 (38.2)	12 (35.3)	1 (2.9)
Neutropenia	8 (23.5)	1 (2.9)	7 (20.6)
Thrombocytopenia	5 (14.7)	3 (8.8)	2 (5.9)
Lymphopenia	2 (5.9)	1 (2.9)	1 (2.9)
Disseminated intravascular coagulation	1 (2.9)	1 (2.9)	0

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders			
-Total	1 (2.9)	1 (2.9)	0
Tachycardia	1 (2.9)	1 (2.9)	0
Gastrointestinal disorders			
-Total	3 (8.8)	3 (8.8)	0
Vomiting	2 (5.9)	2 (5.9)	0
Diarrhoea	1 (2.9)	1 (2.9)	0
Nausea	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			
-Total	5 (14.7)	4 (11.8)	1 (2.9)
Pyrexia	3 (8.8)	2 (5.9)	1 (2.9)
Pain	2 (5.9)	2 (5.9)	0
Hepatobiliary disorders			
-Total	1 (2.9)	1 (2.9)	0
Hyperbilirubinaemia	1 (2.9)	1 (2.9)	0
Immune system disorders			
-Total	13 (38.2)	8 (23.5)	5 (14.7)
Cytokine release syndrome	10 (29.4)	5 (14.7)	5 (14.7)

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	3 (8.8)	3 (8.8)	0
Infections and infestations			
-Total	2 (5.9)	2 (5.9)	0
Urinary tract infection	2 (5.9)	2 (5.9)	0
Investigations			
-Total	25 (73.5)	6 (17.6)	19 (55.9)
White blood cell count decreased	18 (52.9)	7 (20.6)	11 (32.4)
Neutrophil count decreased	16 (47.1)	3 (8.8)	13 (38.2)
Platelet count decreased	11 (32.4)	3 (8.8)	8 (23.5)
Alanine aminotransferase increased	9 (26.5)	9 (26.5)	0
Lymphocyte count decreased	9 (26.5)	6 (17.6)	3 (8.8)
Aspartate aminotransferase increased	5 (14.7)	4 (11.8)	1 (2.9)
Blood bilirubin increased	2 (5.9)	2 (5.9)	0
Blood creatinine increased	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders			

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (38.2)	12 (35.3)	1 (2.9)
Decreased appetite	6 (17.6)	6 (17.6)	0
Hypokalaemia	4 (11.8)	3 (8.8)	1 (2.9)
Hypophosphataemia	4 (11.8)	4 (11.8)	0
Dehydration	1 (2.9)	1 (2.9)	0
Hyperglycaemia	1 (2.9)	1 (2.9)	0
Hyponatraemia	1 (2.9)	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	1 (2.9)	0
Nervous system disorders			
-Total	3 (8.8)	3 (8.8)	0
Encephalopathy	2 (5.9)	2 (5.9)	0
Headache	2 (5.9)	2 (5.9)	0
Renal and urinary disorders			
-Total	6 (17.6)	4 (11.8)	2 (5.9)
Acute kidney injury	4 (11.8)	3 (8.8)	1 (2.9)
Haematuria	2 (5.9)	1 (2.9)	1 (2.9)
Oliguria	2 (5.9)	2 (5.9)	0
Respiratory, thoracic and mediastinal disorders			

Timing: Any time post CTL019 infusion, Age: >=10 years to <18 years

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (17.6)	3 (8.8)	3 (8.8)
Epistaxis	4 (11.8)	3 (8.8)	1 (2.9)
Pulmonary oedema	3 (8.8)	2 (5.9)	1 (2.9)
Hypoxia	2 (5.9)	1 (2.9)	1 (2.9)
Respiratory failure	2 (5.9)	0	2 (5.9)
Dyspnoea	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	9 (26.5)	5 (14.7)	4 (11.8)
Hypotension	9 (26.5)	5 (14.7)	4 (11.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189a
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Age
Safety Set

Timing: Any time post CTL019 infusion, Age: >=18

		All patients N=10	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (100)	2 (20.0)	8 (80.0)
Blood and lymphatic system disorders			
-Total	7 (70.0)	3 (30.0)	4 (40.0)
Anaemia	3 (30.0)	3 (30.0)	0
Neutropenia	3 (30.0)	2 (20.0)	1 (10.0)
Thrombocytopenia	3 (30.0)	0	3 (30.0)
Febrile neutropenia	2 (20.0)	2 (20.0)	0
Pancytopenia	1 (10.0)	0	1 (10.0)
Cardiac disorders			
-Total	1 (10.0)	1 (10.0)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (10.0)	1 (10.0)	0
Tachycardia	1 (10.0)	1 (10.0)	0
Gastrointestinal disorders			
-Total	2 (20.0)	2 (20.0)	0
Nausea	2 (20.0)	2 (20.0)	0
Abdominal pain	1 (10.0)	1 (10.0)	0
Diarrhoea	1 (10.0)	1 (10.0)	0
Intestinal obstruction	1 (10.0)	1 (10.0)	0
Vomiting	1 (10.0)	1 (10.0)	0
General disorders and administration site conditions			
-Total	2 (20.0)	2 (20.0)	0
Pyrexia	2 (20.0)	2 (20.0)	0
Immune system disorders			
-Total	3 (30.0)	0	3 (30.0)
Cytokine release syndrome	3 (30.0)	0	3 (30.0)
Infections and infestations			
-Total	3 (30.0)	1 (10.0)	2 (20.0)
Bacterial sepsis	1 (10.0)	0	1 (10.0)

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cholecystitis infective	1 (10.0)	1 (10.0)	0
Sepsis	1 (10.0)	0	1 (10.0)
Urinary tract infection enterococcal	1 (10.0)	1 (10.0)	0
Injury, poisoning and procedural complications			
-Total	1 (10.0)	1 (10.0)	0
Tracheal haemorrhage	1 (10.0)	1 (10.0)	0
Investigations			
-Total	9 (90.0)	4 (40.0)	5 (50.0)
White blood cell count decreased	4 (40.0)	2 (20.0)	2 (20.0)
Aspartate aminotransferase increased	2 (20.0)	1 (10.0)	1 (10.0)
Neutrophil count decreased	2 (20.0)	0	2 (20.0)
Alanine aminotransferase increased	1 (10.0)	1 (10.0)	0
Blood fibrinogen decreased	1 (10.0)	1 (10.0)	0
C-reactive protein increased	1 (10.0)	1 (10.0)	0
Lymphocyte count decreased	1 (10.0)	0	1 (10.0)
Platelet count decreased	1 (10.0)	0	1 (10.0)
Prothrombin time prolonged	1 (10.0)	1 (10.0)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	5 (50.0)	4 (40.0)	1 (10.0)
Decreased appetite	3 (30.0)	3 (30.0)	0
Dehydration	1 (10.0)	1 (10.0)	0
Hyperglycaemia	1 (10.0)	1 (10.0)	0
Hyperuricaemia	1 (10.0)	0	1 (10.0)
Hypophosphataemia	1 (10.0)	1 (10.0)	0
Psychiatric disorders			
-Total	1 (10.0)	1 (10.0)	0
Anxiety	1 (10.0)	1 (10.0)	0
Renal and urinary disorders			
-Total	2 (20.0)	0	2 (20.0)
Acute kidney injury	2 (20.0)	0	2 (20.0)
Haematuria	1 (10.0)	1 (10.0)	0
Reproductive system and breast disorders			
-Total	1 (10.0)	1 (10.0)	0
Vaginal haemorrhage	1 (10.0)	1 (10.0)	0

Timing: Any time post CTL019 infusion, Age: >=18

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	2 (20.0)	0	2 (20.0)
Hypoxia	2 (20.0)	0	2 (20.0)
Dyspnoea	1 (10.0)	0	1 (10.0)
Interstitial lung disease	1 (10.0)	0	1 (10.0)
Pulmonary oedema	1 (10.0)	0	1 (10.0)
Skin and subcutaneous tissue disorders			
-Total	1 (10.0)	1 (10.0)	0
Rash maculo-papular	1 (10.0)	1 (10.0)	0
Vascular disorders			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Hypotension	2 (20.0)	1 (10.0)	1 (10.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189b
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (76.7)	7 (23.3)	16 (53.3)
Blood and lymphatic system disorders			
-Total	17 (56.7)	13 (43.3)	4 (13.3)
Febrile neutropenia	10 (33.3)	10 (33.3)	0
Anaemia	8 (26.7)	8 (26.7)	0
Neutropenia	4 (13.3)	2 (6.7)	2 (6.7)
Thrombocytopenia	4 (13.3)	1 (3.3)	3 (10.0)
Cardiac disorders			
-Total	2 (6.7)	2 (6.7)	0
Tachycardia	2 (6.7)	2 (6.7)	0

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	1 (3.3)	1 (3.3)	0
Nausea	1 (3.3)	1 (3.3)	0
General disorders and administration site conditions			
-Total	5 (16.7)	5 (16.7)	0
Pyrexia	3 (10.0)	3 (10.0)	0
Pain	2 (6.7)	2 (6.7)	0
Hepatobiliary disorders			
-Total	2 (6.7)	2 (6.7)	0
Hyperbilirubinaemia	2 (6.7)	2 (6.7)	0
Immune system disorders			
-Total	10 (33.3)	4 (13.3)	6 (20.0)
Cytokine release syndrome	9 (30.0)	3 (10.0)	6 (20.0)
Hypogammaglobulinaemia	1 (3.3)	1 (3.3)	0
Investigations			
-Total	16 (53.3)	3 (10.0)	13 (43.3)
Neutrophil count decreased	10 (33.3)	2 (6.7)	8 (26.7)
White blood cell count decreased	10 (33.3)	4 (13.3)	6 (20.0)

Timing: within 8 weeks post infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	6 (20.0)	3 (10.0)	3 (10.0)
Alanine aminotransferase increased	5 (16.7)	5 (16.7)	0
Platelet count decreased	5 (16.7)	1 (3.3)	4 (13.3)
Lymphocyte count decreased	3 (10.0)	1 (3.3)	2 (6.7)
Blood creatinine increased	2 (6.7)	2 (6.7)	0
Blood bilirubin increased	1 (3.3)	1 (3.3)	0
Blood fibrinogen decreased	1 (3.3)	0	1 (3.3)
Metabolism and nutrition disorders			
-Total	10 (33.3)	10 (33.3)	0
Decreased appetite	6 (20.0)	6 (20.0)	0
Hypophosphataemia	4 (13.3)	4 (13.3)	0
Hypokalaemia	3 (10.0)	3 (10.0)	0
Dehydration	1 (3.3)	1 (3.3)	0
Renal and urinary disorders			
-Total	2 (6.7)	0	2 (6.7)
Acute kidney injury	2 (6.7)	0	2 (6.7)
Haematuria	1 (3.3)	1 (3.3)	0

Timing: within 8 weeks post infusion, Gender: Male

Group term Preferred term	All patients N=30 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (13.3)	2 (6.7)	2 (6.7)
Hypoxia	3 (10.0)	1 (3.3)	2 (6.7)
Pulmonary oedema	3 (10.0)	2 (6.7)	1 (3.3)
Dyspnoea	2 (6.7)	1 (3.3)	1 (3.3)
Epistaxis	2 (6.7)	2 (6.7)	0
Vascular disorders			
-Total	9 (30.0)	5 (16.7)	4 (13.3)
Hypotension	9 (30.0)	5 (16.7)	4 (13.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189b
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: within 8 weeks post infusion, Gender: Female

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (85.3)	6 (17.6)	23 (67.6)
Blood and lymphatic system disorders			
-Total	20 (58.8)	15 (44.1)	5 (14.7)
Febrile neutropenia	12 (35.3)	12 (35.3)	0
Anaemia	11 (32.4)	10 (29.4)	1 (2.9)
Neutropenia	4 (11.8)	1 (2.9)	3 (8.8)
Thrombocytopenia	4 (11.8)	1 (2.9)	3 (8.8)
Gastrointestinal disorders			
-Total	6 (17.6)	6 (17.6)	0
Vomiting	3 (8.8)	3 (8.8)	0

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (5.9)	2 (5.9)	0
Diarrhoea	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			
-Total	3 (8.8)	2 (5.9)	1 (2.9)
Pyrexia	3 (8.8)	2 (5.9)	1 (2.9)
Immune system disorders			
-Total	12 (35.3)	7 (20.6)	5 (14.7)
Cytokine release syndrome	10 (29.4)	5 (14.7)	5 (14.7)
Hypogammaglobulinaemia	3 (8.8)	3 (8.8)	0
Investigations			
-Total	26 (76.5)	8 (23.5)	18 (52.9)
White blood cell count decreased	16 (47.1)	6 (17.6)	10 (29.4)
Neutrophil count decreased	13 (38.2)	2 (5.9)	11 (32.4)
Platelet count decreased	9 (26.5)	1 (2.9)	8 (23.5)
Lymphocyte count decreased	8 (23.5)	5 (14.7)	3 (8.8)
Alanine aminotransferase increased	6 (17.6)	6 (17.6)	0
Aspartate aminotransferase increased	5 (14.7)	4 (11.8)	1 (2.9)

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	2 (5.9)	2 (5.9)	0
Blood bilirubin increased	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders			
-Total	11 (32.4)	10 (29.4)	1 (2.9)
Decreased appetite	6 (17.6)	6 (17.6)	0
Hypokalaemia	4 (11.8)	4 (11.8)	0
Hypophosphataemia	3 (8.8)	2 (5.9)	1 (2.9)
Dehydration	1 (2.9)	1 (2.9)	0
Hyperglycaemia	1 (2.9)	1 (2.9)	0
Tumour lysis syndrome	1 (2.9)	1 (2.9)	0
Renal and urinary disorders			
-Total	4 (11.8)	2 (5.9)	2 (5.9)
Acute kidney injury	3 (8.8)	2 (5.9)	1 (2.9)
Haematuria	1 (2.9)	0	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (20.6)	3 (8.8)	4 (11.8)
Hypoxia	4 (11.8)	3 (8.8)	1 (2.9)
Respiratory failure	3 (8.8)	0	3 (8.8)

Timing: within 8 weeks post infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	2 (5.9)	1 (2.9)	1 (2.9)
Pulmonary oedema	2 (5.9)	1 (2.9)	1 (2.9)
Vascular disorders			
-Total	6 (17.6)	2 (5.9)	4 (11.8)
Hypotension	6 (17.6)	2 (5.9)	4 (11.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189b
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

		All patients N=27	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (29.6)	5 (18.5)	3 (11.1)
Blood and lymphatic system disorders			
-Total	5 (18.5)	2 (7.4)	3 (11.1)
Neutropenia	4 (14.8)	1 (3.7)	3 (11.1)
Febrile neutropenia	2 (7.4)	2 (7.4)	0
Thrombocytopenia	1 (3.7)	1 (3.7)	0
Immune system disorders			
-Total	1 (3.7)	1 (3.7)	0
Hypogammaglobulinaemia	1 (3.7)	1 (3.7)	0
Investigations			

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Male

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (18.5)	3 (11.1)	2 (7.4)
Neutrophil count decreased	2 (7.4)	1 (3.7)	1 (3.7)
Alanine aminotransferase increased	1 (3.7)	1 (3.7)	0
Blood bilirubin increased	1 (3.7)	1 (3.7)	0
White blood cell count decreased	1 (3.7)	0	1 (3.7)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (7.4)	2 (7.4)	0
Epistaxis	1 (3.7)	1 (3.7)	0
Pulmonary oedema	1 (3.7)	1 (3.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189b
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

		All patients N=29	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (44.8)	10 (34.5)	3 (10.3)
Blood and lymphatic system disorders			
-Total	1 (3.4)	1 (3.4)	0
Anaemia	1 (3.4)	1 (3.4)	0
Febrile neutropenia	1 (3.4)	1 (3.4)	0
Gastrointestinal disorders			
-Total	2 (6.9)	2 (6.9)	0
Nausea	2 (6.9)	2 (6.9)	0
Vomiting	2 (6.9)	2 (6.9)	0
Diarrhoea	1 (3.4)	1 (3.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (3.4)	1 (3.4)	0
Pyrexia	1 (3.4)	1 (3.4)	0
Investigations			
-Total	7 (24.1)	5 (17.2)	2 (6.9)
Neutrophil count decreased	4 (13.8)	2 (6.9)	2 (6.9)
Aspartate aminotransferase increased	2 (6.9)	2 (6.9)	0
Alanine aminotransferase increased	1 (3.4)	1 (3.4)	0
White blood cell count decreased	1 (3.4)	1 (3.4)	0
Metabolism and nutrition disorders			
-Total	3 (10.3)	2 (6.9)	1 (3.4)
Dehydration	1 (3.4)	1 (3.4)	0
Hyperglycaemia	1 (3.4)	1 (3.4)	0
Hypokalaemia	1 (3.4)	0	1 (3.4)
Hypophosphataemia	1 (3.4)	1 (3.4)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Gender: Female

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (3.4)	1 (3.4)	0
Renal and urinary disorders			
-Total	2 (6.9)	2 (6.9)	0
Acute kidney injury	1 (3.4)	1 (3.4)	0
Haematuria	1 (3.4)	1 (3.4)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189b
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Male

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (20.0)	3 (15.0)	1 (5.0)
Investigations			
-Total	4 (20.0)	3 (15.0)	1 (5.0)
White blood cell count decreased	2 (10.0)	1 (5.0)	1 (5.0)
Alanine aminotransferase increased	1 (5.0)	1 (5.0)	0
Aspartate aminotransferase increased	1 (5.0)	1 (5.0)	0
Lymphocyte count decreased	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189b
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: >1 year post-CTL019 infusion, Gender: Female

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (14.3)	1 (7.1)	1 (7.1)
Blood and lymphatic system disorders			
-Total	1 (7.1)	0	1 (7.1)
Febrile neutropenia	1 (7.1)	0	1 (7.1)
Investigations			
-Total	1 (7.1)	1 (7.1)	0
Alanine aminotransferase increased	1 (7.1)	1 (7.1)	0
Platelet count decreased	1 (7.1)	1 (7.1)	0
White blood cell count decreased	1 (7.1)	1 (7.1)	0

Timing: >1 year post-CTL019 infusion, Gender: Female

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	1 (7.1)	1 (7.1)	0
Hypokalaemia	1 (7.1)	1 (7.1)	0
Renal and urinary disorders			
-Total	1 (7.1)	1 (7.1)	0
Acute kidney injury	1 (7.1)	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189b
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Male

		All patients N=30	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (83.3)	6 (20.0)	19 (63.3)
Blood and lymphatic system disorders			
-Total	20 (66.7)	13 (43.3)	7 (23.3)
Febrile neutropenia	10 (33.3)	10 (33.3)	0
Anaemia	8 (26.7)	8 (26.7)	0
Neutropenia	7 (23.3)	2 (6.7)	5 (16.7)
Thrombocytopenia	5 (16.7)	2 (6.7)	3 (10.0)
Cardiac disorders			
-Total	2 (6.7)	2 (6.7)	0
Tachycardia	2 (6.7)	2 (6.7)	0

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	1 (3.3)	1 (3.3)	0
Nausea	1 (3.3)	1 (3.3)	0
General disorders and administration site conditions			
-Total	5 (16.7)	5 (16.7)	0
Pyrexia	3 (10.0)	3 (10.0)	0
Pain	2 (6.7)	2 (6.7)	0
Hepatobiliary disorders			
-Total	2 (6.7)	2 (6.7)	0
Hyperbilirubinaemia	2 (6.7)	2 (6.7)	0
Immune system disorders			
-Total	10 (33.3)	4 (13.3)	6 (20.0)
Cytokine release syndrome	9 (30.0)	3 (10.0)	6 (20.0)
Hypogammaglobulinaemia	2 (6.7)	2 (6.7)	0
Investigations			
-Total	20 (66.7)	5 (16.7)	15 (50.0)
White blood cell count decreased	12 (40.0)	4 (13.3)	8 (26.7)
Neutrophil count decreased	11 (36.7)	2 (6.7)	9 (30.0)

Timing: Any time post CTL019 infusion, Gender: Male

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	7 (23.3)	4 (13.3)	3 (10.0)
Alanine aminotransferase increased	6 (20.0)	6 (20.0)	0
Platelet count decreased	5 (16.7)	1 (3.3)	4 (13.3)
Lymphocyte count decreased	4 (13.3)	2 (6.7)	2 (6.7)
Blood bilirubin increased	2 (6.7)	2 (6.7)	0
Blood creatinine increased	2 (6.7)	2 (6.7)	0
Blood fibrinogen decreased	1 (3.3)	0	1 (3.3)
Metabolism and nutrition disorders			
-Total	10 (33.3)	10 (33.3)	0
Decreased appetite	6 (20.0)	6 (20.0)	0
Hypophosphataemia	4 (13.3)	4 (13.3)	0
Hypokalaemia	3 (10.0)	3 (10.0)	0
Dehydration	1 (3.3)	1 (3.3)	0
Renal and urinary disorders			
-Total	2 (6.7)	0	2 (6.7)
Acute kidney injury	2 (6.7)	0	2 (6.7)
Haematuria	1 (3.3)	1 (3.3)	0

Timing: Any time post CTL019 infusion, Gender: Male

Group term Preferred term	All patients N=30 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (20.0)	4 (13.3)	2 (6.7)
Pulmonary oedema	4 (13.3)	3 (10.0)	1 (3.3)
Epistaxis	3 (10.0)	3 (10.0)	0
Hypoxia	3 (10.0)	1 (3.3)	2 (6.7)
Dyspnoea	2 (6.7)	1 (3.3)	1 (3.3)
Vascular disorders			
-Total	9 (30.0)	5 (16.7)	4 (13.3)
Hypotension	9 (30.0)	5 (16.7)	4 (13.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189b
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Gender
Safety Set

Timing: Any time post CTL019 infusion, Gender: Female

		All patients N=34	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (88.2)	6 (17.6)	24 (70.6)
Blood and lymphatic system disorders			
-Total	21 (61.8)	15 (44.1)	6 (17.6)
Febrile neutropenia	14 (41.2)	13 (38.2)	1 (2.9)
Anaemia	12 (35.3)	11 (32.4)	1 (2.9)
Neutropenia	4 (11.8)	1 (2.9)	3 (8.8)
Thrombocytopenia	4 (11.8)	1 (2.9)	3 (8.8)
Gastrointestinal disorders			
-Total	6 (17.6)	6 (17.6)	0
Nausea	4 (11.8)	4 (11.8)	0

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	3 (8.8)	3 (8.8)	0
Diarrhoea	2 (5.9)	2 (5.9)	0
General disorders and administration site conditions			
-Total	4 (11.8)	3 (8.8)	1 (2.9)
Pyrexia	4 (11.8)	3 (8.8)	1 (2.9)
Immune system disorders			
-Total	12 (35.3)	7 (20.6)	5 (14.7)
Cytokine release syndrome	10 (29.4)	5 (14.7)	5 (14.7)
Hypogammaglobulinaemia	3 (8.8)	3 (8.8)	0
Investigations			
-Total	27 (79.4)	8 (23.5)	19 (55.9)
White blood cell count decreased	18 (52.9)	8 (23.5)	10 (29.4)
Neutrophil count decreased	14 (41.2)	2 (5.9)	12 (35.3)
Platelet count decreased	10 (29.4)	2 (5.9)	8 (23.5)
Alanine aminotransferase increased	8 (23.5)	8 (23.5)	0
Lymphocyte count decreased	8 (23.5)	5 (14.7)	3 (8.8)
Aspartate aminotransferase increased	5 (14.7)	4 (11.8)	1 (2.9)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	2 (5.9)	2 (5.9)	0
Blood bilirubin increased	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders			
-Total	14 (41.2)	12 (35.3)	2 (5.9)
Decreased appetite	6 (17.6)	6 (17.6)	0
Hypokalaemia	6 (17.6)	5 (14.7)	1 (2.9)
Hypophosphataemia	4 (11.8)	3 (8.8)	1 (2.9)
Dehydration	2 (5.9)	2 (5.9)	0
Hyperglycaemia	2 (5.9)	2 (5.9)	0
Tumour lysis syndrome	2 (5.9)	2 (5.9)	0
Renal and urinary disorders			
-Total	7 (20.6)	5 (14.7)	2 (5.9)
Acute kidney injury	5 (14.7)	4 (11.8)	1 (2.9)
Haematuria	2 (5.9)	1 (2.9)	1 (2.9)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (20.6)	3 (8.8)	4 (11.8)
Hypoxia	4 (11.8)	3 (8.8)	1 (2.9)
Respiratory failure	3 (8.8)	0	3 (8.8)

Timing: Any time post CTL019 infusion, Gender: Female

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	2 (5.9)	1 (2.9)	1 (2.9)
Pulmonary oedema	2 (5.9)	1 (2.9)	1 (2.9)
Vascular disorders			
-Total	6 (17.6)	2 (5.9)	4 (11.8)
Hypotension	6 (17.6)	2 (5.9)	4 (11.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: White

		All patients N=52	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (80.8)	9 (17.3)	33 (63.5)
Blood and lymphatic system disorders			
-Total	32 (61.5)	23 (44.2)	9 (17.3)
Febrile neutropenia	19 (36.5)	19 (36.5)	0
Anaemia	15 (28.8)	14 (26.9)	1 (1.9)
Neutropenia	8 (15.4)	3 (5.8)	5 (9.6)
Thrombocytopenia	8 (15.4)	2 (3.8)	6 (11.5)
Lymphopenia	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders			
-Total	6 (11.5)	6 (11.5)	0

Timing: within 8 weeks post infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	3 (5.8)	3 (5.8)	0
Vomiting	3 (5.8)	3 (5.8)	0
General disorders and administration site conditions			
-Total	6 (11.5)	5 (9.6)	1 (1.9)
Pyrexia	6 (11.5)	5 (9.6)	1 (1.9)
Immune system disorders			
-Total	20 (38.5)	10 (19.2)	10 (19.2)
Cytokine release syndrome	17 (32.7)	7 (13.5)	10 (19.2)
Hypogammaglobulinaemia	4 (7.7)	4 (7.7)	0
Investigations			
-Total	34 (65.4)	8 (15.4)	26 (50.0)
White blood cell count decreased	20 (38.5)	7 (13.5)	13 (25.0)
Neutrophil count decreased	19 (36.5)	4 (7.7)	15 (28.8)
Platelet count decreased	12 (23.1)	2 (3.8)	10 (19.2)
Alanine aminotransferase increased	10 (19.2)	10 (19.2)	0
Aspartate aminotransferase increased	9 (17.3)	5 (9.6)	4 (7.7)
Lymphocyte count decreased	9 (17.3)	5 (9.6)	4 (7.7)

Timing: within 8 weeks post infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	3 (5.8)	2 (3.8)	1 (1.9)
Blood bilirubin increased	2 (3.8)	2 (3.8)	0
Metabolism and nutrition disorders			
-Total	18 (34.6)	17 (32.7)	1 (1.9)
Decreased appetite	11 (21.2)	11 (21.2)	0
Hypokalaemia	7 (13.5)	7 (13.5)	0
Hypophosphataemia	7 (13.5)	6 (11.5)	1 (1.9)
Dehydration	1 (1.9)	1 (1.9)	0
Renal and urinary disorders			
-Total	5 (9.6)	1 (1.9)	4 (7.7)
Acute kidney injury	4 (7.7)	1 (1.9)	3 (5.8)
Haematuria	2 (3.8)	1 (1.9)	1 (1.9)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (17.3)	4 (7.7)	5 (9.6)
Hypoxia	7 (13.5)	4 (7.7)	3 (5.8)
Pulmonary oedema	4 (7.7)	3 (5.8)	1 (1.9)
Epistaxis	3 (5.8)	2 (3.8)	1 (1.9)
Respiratory failure	2 (3.8)	0	2 (3.8)

Timing: within 8 weeks post infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	14 (26.9)	7 (13.5)	7 (13.5)
Hypotension	14 (26.9)	7 (13.5)	7 (13.5)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (60.0)	2 (40.0)	1 (20.0)
Blood and lymphatic system disorders			
-Total	2 (40.0)	2 (40.0)	0
Anaemia	2 (40.0)	2 (40.0)	0
Febrile neutropenia	1 (20.0)	1 (20.0)	0
Infections and infestations			
-Total	1 (20.0)	1 (20.0)	0
Gastroenteritis	1 (20.0)	1 (20.0)	0
Investigations			
-Total	2 (40.0)	1 (20.0)	1 (20.0)

Timing: within 8 weeks post infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (20.0)	1 (20.0)	0
Neutrophil count decreased	1 (20.0)	0	1 (20.0)
White blood cell count decreased	1 (20.0)	1 (20.0)	0
Metabolism and nutrition disorders			
-Total	1 (20.0)	1 (20.0)	0
Dehydration	1 (20.0)	1 (20.0)	0
Vascular disorders			
-Total	1 (20.0)	1 (20.0)	0
Embolism	1 (20.0)	1 (20.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: within 8 weeks post infusion, Race: Other

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	2 (28.6)	5 (71.4)
Blood and lymphatic system disorders			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Anaemia	2 (28.6)	2 (28.6)	0
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Lymphopenia	1 (14.3)	0	1 (14.3)
General disorders and administration site conditions			
-Total	1 (14.3)	1 (14.3)	0
Physical deconditioning	1 (14.3)	1 (14.3)	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Cytokine release syndrome	2 (28.6)	1 (14.3)	1 (14.3)
Injury, poisoning and procedural complications			
-Total	1 (14.3)	0	1 (14.3)
Transfusion related complication	1 (14.3)	0	1 (14.3)
Investigations			
-Total	6 (85.7)	2 (28.6)	4 (57.1)
White blood cell count decreased	5 (71.4)	2 (28.6)	3 (42.9)
Neutrophil count decreased	3 (42.9)	0	3 (42.9)
Lymphocyte count decreased	2 (28.6)	1 (14.3)	1 (14.3)
Platelet count decreased	2 (28.6)	0	2 (28.6)
Alanine aminotransferase increased	1 (14.3)	1 (14.3)	0
Aspartate aminotransferase increased	1 (14.3)	1 (14.3)	0
Haemoglobin decreased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	2 (28.6)	2 (28.6)	0

Timing: within 8 weeks post infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	1 (14.3)	1 (14.3)	0
Tumour lysis syndrome	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	1 (14.3)	1 (14.3)	0
Acute kidney injury	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Epistaxis	1 (14.3)	1 (14.3)	0
Pulmonary oedema	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)
Skin and subcutaneous tissue disorders			
-Total	1 (14.3)	1 (14.3)	0
Ecchymosis	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	1 (14.3)	0	1 (14.3)
Hypotension	1 (14.3)	0	1 (14.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

		All patients N=44	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (40.9)	14 (31.8)	4 (9.1)
Blood and lymphatic system disorders			
-Total	4 (9.1)	2 (4.5)	2 (4.5)
Neutropenia	3 (6.8)	1 (2.3)	2 (4.5)
Febrile neutropenia	1 (2.3)	1 (2.3)	0
Thrombocytopenia	1 (2.3)	1 (2.3)	0
Gastrointestinal disorders			
-Total	2 (4.5)	2 (4.5)	0
Nausea	2 (4.5)	2 (4.5)	0
Vomiting	2 (4.5)	2 (4.5)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (2.3)	1 (2.3)	0
Pyrexia	1 (2.3)	1 (2.3)	0
Immune system disorders			
-Total	1 (2.3)	1 (2.3)	0
Hypogammaglobulinaemia	1 (2.3)	1 (2.3)	0
Investigations			
-Total	10 (22.7)	8 (18.2)	2 (4.5)
Neutrophil count decreased	4 (9.1)	3 (6.8)	1 (2.3)
Alanine aminotransferase increased	2 (4.5)	2 (4.5)	0
Aspartate aminotransferase increased	2 (4.5)	2 (4.5)	0
White blood cell count decreased	2 (4.5)	1 (2.3)	1 (2.3)
Blood bilirubin increased	1 (2.3)	1 (2.3)	0
Metabolism and nutrition disorders			
-Total	3 (6.8)	2 (4.5)	1 (2.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: White

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (2.3)	1 (2.3)	0
Hypokalaemia	1 (2.3)	0	1 (2.3)
Hypophosphataemia	1 (2.3)	1 (2.3)	0
Tumour lysis syndrome	1 (2.3)	1 (2.3)	0
Renal and urinary disorders			
-Total	2 (4.5)	2 (4.5)	0
Acute kidney injury	1 (2.3)	1 (2.3)	0
Haematuria	1 (2.3)	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (2.3)	1 (2.3)	0
Epistaxis	1 (2.3)	1 (2.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (20.0)	0	1 (20.0)
Blood and lymphatic system disorders			
-Total	1 (20.0)	0	1 (20.0)
Febrile neutropenia	1 (20.0)	1 (20.0)	0
Neutropenia	1 (20.0)	0	1 (20.0)
Infections and infestations			
-Total	1 (20.0)	1 (20.0)	0
Herpes zoster	1 (20.0)	1 (20.0)	0
Investigations			
-Total	1 (20.0)	0	1 (20.0)

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	1 (20.0)	0	1 (20.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (20.0)	1 (20.0)	0
Pulmonary oedema	1 (20.0)	1 (20.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (42.9)	1 (14.3)	2 (28.6)
Blood and lymphatic system disorders			
-Total	1 (14.3)	1 (14.3)	0
Anaemia	1 (14.3)	1 (14.3)	0
Febrile neutropenia	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Sepsis	1 (14.3)	0	1 (14.3)
Vascular device infection	1 (14.3)	1 (14.3)	0
Investigations			

Timing: >8 weeks to 1 year post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (14.3)	0	1 (14.3)
Neutrophil count decreased	1 (14.3)	0	1 (14.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: White

		All patients N=28	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (14.3)	3 (10.7)	1 (3.6)
Investigations			
-Total	3 (10.7)	2 (7.1)	1 (3.6)
Alanine aminotransferase increased	1 (3.6)	1 (3.6)	0
Aspartate aminotransferase increased	1 (3.6)	1 (3.6)	0
Lymphocyte count decreased	1 (3.6)	1 (3.6)	0
White blood cell count decreased	1 (3.6)	0	1 (3.6)
Metabolism and nutrition disorders			
-Total	1 (3.6)	1 (3.6)	0

Timing: >1 year post-CTL019 infusion, Race: White

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	1 (3.6)	1 (3.6)	0
Renal and urinary disorders			
-Total	1 (3.6)	1 (3.6)	0
Acute kidney injury	1 (3.6)	1 (3.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Asian

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	1 (50.0)	1 (50.0)
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)
Respiratory tract infection	1 (50.0)	0	1 (50.0)
Investigations			
-Total	1 (50.0)	1 (50.0)	0
White blood cell count decreased	1 (50.0)	1 (50.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: >1 year post-CTL019 infusion, Race: Other

		All patients N=4	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	1 (25.0)	1 (25.0)
Blood and lymphatic system disorders			
-Total	1 (25.0)	0	1 (25.0)
Febrile neutropenia	1 (25.0)	0	1 (25.0)
Injury, poisoning and procedural complications			
-Total	1 (25.0)	1 (25.0)	0
Procedural pain	1 (25.0)	1 (25.0)	0
Investigations			
-Total	1 (25.0)	1 (25.0)	0

Timing: >1 year post-CTL019 infusion, Race: Other

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (25.0)	1 (25.0)	0
Platelet count decreased	1 (25.0)	1 (25.0)	0
White blood cell count decreased	1 (25.0)	1 (25.0)	0
Reproductive system and breast disorders			
-Total	1 (25.0)	1 (25.0)	0
Ovarian failure	1 (25.0)	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: White

		All patients N=52	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (86.5)	9 (17.3)	36 (69.2)
Blood and lymphatic system disorders			
-Total	35 (67.3)	24 (46.2)	11 (21.2)
Febrile neutropenia	19 (36.5)	19 (36.5)	0
Anaemia	15 (28.8)	14 (26.9)	1 (1.9)
Neutropenia	10 (19.2)	3 (5.8)	7 (13.5)
Thrombocytopenia	9 (17.3)	3 (5.8)	6 (11.5)
Lymphopenia	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders			
-Total	6 (11.5)	6 (11.5)	0

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	5 (9.6)	5 (9.6)	0
Vomiting	3 (5.8)	3 (5.8)	0
General disorders and administration site conditions			
-Total	7 (13.5)	6 (11.5)	1 (1.9)
Pyrexia	7 (13.5)	6 (11.5)	1 (1.9)
Immune system disorders			
-Total	20 (38.5)	10 (19.2)	10 (19.2)
Cytokine release syndrome	17 (32.7)	7 (13.5)	10 (19.2)
Hypogammaglobulinaemia	5 (9.6)	5 (9.6)	0
Investigations			
-Total	38 (73.1)	10 (19.2)	28 (53.8)
White blood cell count decreased	22 (42.3)	7 (13.5)	15 (28.8)
Neutrophil count decreased	20 (38.5)	4 (7.7)	16 (30.8)
Alanine aminotransferase increased	12 (23.1)	12 (23.1)	0
Platelet count decreased	12 (23.1)	2 (3.8)	10 (19.2)
Aspartate aminotransferase increased	10 (19.2)	6 (11.5)	4 (7.7)
Lymphocyte count decreased	10 (19.2)	6 (11.5)	4 (7.7)

Timing: Any time post CTL019 infusion, Race: White

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	3 (5.8)	3 (5.8)	0
Blood fibrinogen decreased	3 (5.8)	2 (3.8)	1 (1.9)
Metabolism and nutrition disorders			
-Total	21 (40.4)	19 (36.5)	2 (3.8)
Decreased appetite	11 (21.2)	11 (21.2)	0
Hypokalaemia	9 (17.3)	8 (15.4)	1 (1.9)
Hypophosphataemia	8 (15.4)	7 (13.5)	1 (1.9)
Dehydration	2 (3.8)	2 (3.8)	0
Tumour lysis syndrome	1 (1.9)	1 (1.9)	0
Renal and urinary disorders			
-Total	8 (15.4)	4 (7.7)	4 (7.7)
Acute kidney injury	6 (11.5)	3 (5.8)	3 (5.8)
Haematuria	3 (5.8)	2 (3.8)	1 (1.9)
Respiratory, thoracic and mediastinal disorders			
-Total	10 (19.2)	5 (9.6)	5 (9.6)
Hypoxia	7 (13.5)	4 (7.7)	3 (5.8)
Epistaxis	4 (7.7)	3 (5.8)	1 (1.9)
Pulmonary oedema	4 (7.7)	3 (5.8)	1 (1.9)

Timing: Any time post CTL019 infusion, Race: White

Group term Preferred term	All patients N=52 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	2 (3.8)	0	2 (3.8)
Vascular disorders			
-Total	14 (26.9)	7 (13.5)	7 (13.5)
Hypotension	14 (26.9)	7 (13.5)	7 (13.5)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Asian

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	1 (20.0)	3 (60.0)
Blood and lymphatic system disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Anaemia	2 (40.0)	2 (40.0)	0
Febrile neutropenia	1 (20.0)	1 (20.0)	0
Neutropenia	1 (20.0)	0	1 (20.0)
Infections and infestations			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Gastroenteritis	1 (20.0)	1 (20.0)	0
Herpes zoster	1 (20.0)	1 (20.0)	0

Timing: Any time post CTL019 infusion, Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection	1 (20.0)	0	1 (20.0)
Investigations			
-Total	3 (60.0)	1 (20.0)	2 (40.0)
Neutrophil count decreased	2 (40.0)	0	2 (40.0)
White blood cell count decreased	2 (40.0)	2 (40.0)	0
Aspartate aminotransferase increased	1 (20.0)	1 (20.0)	0
Metabolism and nutrition disorders			
-Total	1 (20.0)	1 (20.0)	0
Dehydration	1 (20.0)	1 (20.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (20.0)	1 (20.0)	0
Pulmonary oedema	1 (20.0)	1 (20.0)	0
Vascular disorders			
-Total	1 (20.0)	1 (20.0)	0
Embolism	1 (20.0)	1 (20.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189c
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Race
Safety Set

Timing: Any time post CTL019 infusion, Race: Other

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (100)	1 (14.3)	6 (85.7)
Blood and lymphatic system disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Febrile neutropenia	4 (57.1)	3 (42.9)	1 (14.3)
Anaemia	3 (42.9)	3 (42.9)	0
Lymphopenia	1 (14.3)	0	1 (14.3)
General disorders and administration site conditions			
-Total	1 (14.3)	1 (14.3)	0
Physical deconditioning	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Cytokine release syndrome	2 (28.6)	1 (14.3)	1 (14.3)
Infections and infestations			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Sepsis	1 (14.3)	0	1 (14.3)
Vascular device infection	1 (14.3)	1 (14.3)	0
Injury, poisoning and procedural complications			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Procedural pain	1 (14.3)	1 (14.3)	0
Transfusion related complication	1 (14.3)	0	1 (14.3)
Investigations			
-Total	6 (85.7)	2 (28.6)	4 (57.1)
White blood cell count decreased	6 (85.7)	3 (42.9)	3 (42.9)
Neutrophil count decreased	3 (42.9)	0	3 (42.9)
Platelet count decreased	3 (42.9)	1 (14.3)	2 (28.6)
Alanine aminotransferase increased	2 (28.6)	2 (28.6)	0

Timing: Any time post CTL019 infusion, Race: Other

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	2 (28.6)	1 (14.3)	1 (14.3)
Aspartate aminotransferase increased	1 (14.3)	1 (14.3)	0
Haemoglobin decreased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	2 (28.6)	2 (28.6)	0
Decreased appetite	1 (14.3)	1 (14.3)	0
Tumour lysis syndrome	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	1 (14.3)	1 (14.3)	0
Acute kidney injury	1 (14.3)	1 (14.3)	0
Reproductive system and breast disorders			
-Total	1 (14.3)	1 (14.3)	0
Ovarian failure	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Epistaxis	1 (14.3)	1 (14.3)	0
Pulmonary oedema	1 (14.3)	0	1 (14.3)

Timing: Any time post CTL019 infusion, Race: Other

Group term Preferred term	All patients N=7 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory failure	1 (14.3)	0	1 (14.3)
Skin and subcutaneous tissue disorders			
-Total	1 (14.3)	1 (14.3)	0
Ecchymosis	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	1 (14.3)	0	1 (14.3)
Hypotension	1 (14.3)	0	1 (14.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189d
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

		All patients N=25	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (88.0)	5 (20.0)	17 (68.0)
Blood and lymphatic system disorders			
-Total	17 (68.0)	15 (60.0)	2 (8.0)
Febrile neutropenia	14 (56.0)	14 (56.0)	0
Anaemia	6 (24.0)	6 (24.0)	0
Neutropenia	2 (8.0)	2 (8.0)	0
Thrombocytopenia	2 (8.0)	0	2 (8.0)
Gastrointestinal disorders			
-Total	1 (4.0)	1 (4.0)	0
Vomiting	1 (4.0)	1 (4.0)	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	2 (8.0)	2 (8.0)	0
Pyrexia	2 (8.0)	2 (8.0)	0
Immune system disorders			
-Total	7 (28.0)	4 (16.0)	3 (12.0)
Cytokine release syndrome	6 (24.0)	3 (12.0)	3 (12.0)
Hypogammaglobulinaemia	1 (4.0)	1 (4.0)	0
Investigations			
-Total	19 (76.0)	4 (16.0)	15 (60.0)
White blood cell count decreased	15 (60.0)	6 (24.0)	9 (36.0)
Neutrophil count decreased	13 (52.0)	2 (8.0)	11 (44.0)
Alanine aminotransferase increased	6 (24.0)	6 (24.0)	0
Lymphocyte count decreased	6 (24.0)	4 (16.0)	2 (8.0)
Platelet count decreased	4 (16.0)	0	4 (16.0)
Aspartate aminotransferase increased	3 (12.0)	3 (12.0)	0
Blood fibrinogen decreased	1 (4.0)	1 (4.0)	0

Timing: within 8 weeks post infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	6 (24.0)	5 (20.0)	1 (4.0)
Decreased appetite	3 (12.0)	3 (12.0)	0
Hypokalaemia	2 (8.0)	2 (8.0)	0
Hypophosphataemia	1 (4.0)	0	1 (4.0)
Tumour lysis syndrome	1 (4.0)	1 (4.0)	0
Renal and urinary disorders			
-Total	2 (8.0)	2 (8.0)	0
Acute kidney injury	2 (8.0)	2 (8.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (8.0)	0	2 (8.0)
Pulmonary oedema	2 (8.0)	1 (4.0)	1 (4.0)
Respiratory failure	2 (8.0)	0	2 (8.0)
Vascular disorders			
-Total	5 (20.0)	4 (16.0)	1 (4.0)
Hypotension	5 (20.0)	4 (16.0)	1 (4.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189d
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (76.9)	8 (20.5)	22 (56.4)
Blood and lymphatic system disorders			
-Total	20 (51.3)	13 (33.3)	7 (17.9)
Anaemia	13 (33.3)	12 (30.8)	1 (2.6)
Febrile neutropenia	8 (20.5)	8 (20.5)	0
Neutropenia	6 (15.4)	1 (2.6)	5 (12.8)
Thrombocytopenia	6 (15.4)	2 (5.1)	4 (10.3)
Cardiac disorders			
-Total	2 (5.1)	2 (5.1)	0
Tachycardia	2 (5.1)	2 (5.1)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	5 (12.8)	5 (12.8)	0
Nausea	3 (7.7)	3 (7.7)	0
Vomiting	2 (5.1)	2 (5.1)	0
General disorders and administration site conditions			
-Total	6 (15.4)	5 (12.8)	1 (2.6)
Pyrexia	4 (10.3)	3 (7.7)	1 (2.6)
Pain	2 (5.1)	2 (5.1)	0
Hepatobiliary disorders			
-Total	2 (5.1)	2 (5.1)	0
Hyperbilirubinaemia	2 (5.1)	2 (5.1)	0
Immune system disorders			
-Total	15 (38.5)	7 (17.9)	8 (20.5)
Cytokine release syndrome	13 (33.3)	5 (12.8)	8 (20.5)
Hypogammaglobulinaemia	3 (7.7)	3 (7.7)	0
Investigations			
-Total	23 (59.0)	7 (17.9)	16 (41.0)
White blood cell count decreased	11 (28.2)	4 (10.3)	7 (17.9)

Timing: within 8 weeks post infusion, Ethnicity: Other

		All patients N=39	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	10 (25.6)	2 (5.1)	8 (20.5)
Platelet count decreased	10 (25.6)	2 (5.1)	8 (20.5)
Aspartate aminotransferase increased	8 (20.5)	4 (10.3)	4 (10.3)
Alanine aminotransferase increased	5 (12.8)	5 (12.8)	0
Lymphocyte count decreased	5 (12.8)	2 (5.1)	3 (7.7)
Blood bilirubin increased	2 (5.1)	2 (5.1)	0
Blood creatinine increased	2 (5.1)	2 (5.1)	0
Blood fibrinogen decreased	2 (5.1)	1 (2.6)	1 (2.6)
Metabolism and nutrition disorders			
-Total	15 (38.5)	15 (38.5)	0
Decreased appetite	9 (23.1)	9 (23.1)	0
Hypophosphataemia	6 (15.4)	6 (15.4)	0
Hypokalaemia	5 (12.8)	5 (12.8)	0
Dehydration	2 (5.1)	2 (5.1)	0
Hyponatraemia	2 (5.1)	2 (5.1)	0
Nervous system disorders			
-Total	3 (7.7)	3 (7.7)	0

Timing: within 8 weeks post infusion, Ethnicity: Other

		All patients N=39	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	2 (5.1)	2 (5.1)	0
Seizure	1 (2.6)	1 (2.6)	0
Renal and urinary disorders			
-Total	4 (10.3)	0	4 (10.3)
Acute kidney injury	3 (7.7)	0	3 (7.7)
Haematuria	2 (5.1)	1 (2.6)	1 (2.6)
Oliguria	2 (5.1)	2 (5.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	9 (23.1)	5 (12.8)	4 (10.3)
Hypoxia	7 (17.9)	4 (10.3)	3 (7.7)
Epistaxis	4 (10.3)	3 (7.7)	1 (2.6)
Pulmonary oedema	3 (7.7)	2 (5.1)	1 (2.6)
Dyspnoea	2 (5.1)	1 (2.6)	1 (2.6)
Respiratory failure	1 (2.6)	0	1 (2.6)
Vascular disorders			
-Total	10 (25.6)	3 (7.7)	7 (17.9)
Hypotension	10 (25.6)	3 (7.7)	7 (17.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189d
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=23	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (43.5)	7 (30.4)	3 (13.0)
Blood and lymphatic system disorders			
-Total	3 (13.0)	2 (8.7)	1 (4.3)
Febrile neutropenia	2 (8.7)	2 (8.7)	0
Neutropenia	2 (8.7)	1 (4.3)	1 (4.3)
Anaemia	1 (4.3)	1 (4.3)	0
Gastrointestinal disorders			
-Total	1 (4.3)	1 (4.3)	0
Nausea	1 (4.3)	1 (4.3)	0
Vomiting	1 (4.3)	1 (4.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	2 (8.7)	2 (8.7)	0
Urinary tract infection	2 (8.7)	2 (8.7)	0
Investigations			
-Total	6 (26.1)	5 (21.7)	1 (4.3)
Neutrophil count decreased	4 (17.4)	3 (13.0)	1 (4.3)
Aspartate aminotransferase increased	2 (8.7)	2 (8.7)	0
Alanine aminotransferase increased	1 (4.3)	1 (4.3)	0
Metabolism and nutrition disorders			
-Total	2 (8.7)	1 (4.3)	1 (4.3)
Hypokalaemia	1 (4.3)	0	1 (4.3)
Hypophosphataemia	1 (4.3)	1 (4.3)	0
Tumour lysis syndrome	1 (4.3)	1 (4.3)	0
Renal and urinary disorders			
-Total	2 (8.7)	2 (8.7)	0
Acute kidney injury	1 (4.3)	1 (4.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=23	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	1 (4.3)	1 (4.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189d
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (33.3)	8 (24.2)	3 (9.1)
Blood and lymphatic system disorders			
-Total	3 (9.1)	1 (3.0)	2 (6.1)
Neutropenia	2 (6.1)	0	2 (6.1)
Febrile neutropenia	1 (3.0)	1 (3.0)	0
Thrombocytopenia	1 (3.0)	1 (3.0)	0
Gastrointestinal disorders			
-Total	1 (3.0)	1 (3.0)	0
Nausea	1 (3.0)	1 (3.0)	0
Vomiting	1 (3.0)	1 (3.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (3.0)	1 (3.0)	0
Pyrexia	1 (3.0)	1 (3.0)	0
Immune system disorders			
-Total	1 (3.0)	1 (3.0)	0
Hypogammaglobulinaemia	1 (3.0)	1 (3.0)	0
Investigations			
-Total	6 (18.2)	3 (9.1)	3 (9.1)
Neutrophil count decreased	2 (6.1)	0	2 (6.1)
White blood cell count decreased	2 (6.1)	1 (3.0)	1 (3.0)
Alanine aminotransferase increased	1 (3.0)	1 (3.0)	0
Blood bilirubin increased	1 (3.0)	1 (3.0)	0
Metabolism and nutrition disorders			
-Total	1 (3.0)	1 (3.0)	0
Dehydration	1 (3.0)	1 (3.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Ethnicity: Other

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.1)	2 (6.1)	0
Epistaxis	1 (3.0)	1 (3.0)	0
Pulmonary oedema	1 (3.0)	1 (3.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189d
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=17	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (17.6)	1 (5.9)	2 (11.8)
Blood and lymphatic system disorders			
-Total	1 (5.9)	0	1 (5.9)
Febrile neutropenia	1 (5.9)	0	1 (5.9)
Infections and infestations			
-Total	1 (5.9)	1 (5.9)	0
Urinary tract infection	1 (5.9)	1 (5.9)	0
Investigations			
-Total	2 (11.8)	1 (5.9)	1 (5.9)

Timing: >1 year post-CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	2 (11.8)	1 (5.9)	1 (5.9)
Alanine aminotransferase increased	1 (5.9)	1 (5.9)	0
Platelet count decreased	1 (5.9)	1 (5.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189d
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

		All patients N=17	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (29.4)	5 (29.4)	0
Investigations			
-Total	3 (17.6)	3 (17.6)	0
Alanine aminotransferase increased	1 (5.9)	1 (5.9)	0
Aspartate aminotransferase increased	1 (5.9)	1 (5.9)	0
Lymphocyte count decreased	1 (5.9)	1 (5.9)	0
White blood cell count decreased	1 (5.9)	1 (5.9)	0
Metabolism and nutrition disorders			
-Total	1 (5.9)	1 (5.9)	0

Timing: >1 year post-CTL019 infusion, Ethnicity: Other

	All patients N=17		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	1 (5.9)	1 (5.9)	0
Nervous system disorders			
-Total	1 (5.9)	1 (5.9)	0
Seizure	1 (5.9)	1 (5.9)	0
Renal and urinary disorders			
-Total	1 (5.9)	1 (5.9)	0
Acute kidney injury	1 (5.9)	1 (5.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189d
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

		All patients N=25	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (92.0)	4 (16.0)	19 (76.0)
Blood and lymphatic system disorders			
-Total	19 (76.0)	15 (60.0)	4 (16.0)
Febrile neutropenia	16 (64.0)	15 (60.0)	1 (4.0)
Anaemia	7 (28.0)	7 (28.0)	0
Neutropenia	3 (12.0)	2 (8.0)	1 (4.0)
Thrombocytopenia	2 (8.0)	0	2 (8.0)
Gastrointestinal disorders			
-Total	1 (4.0)	1 (4.0)	0
Nausea	1 (4.0)	1 (4.0)	0

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (4.0)	1 (4.0)	0
General disorders and administration site conditions			
-Total	2 (8.0)	2 (8.0)	0
Pyrexia	2 (8.0)	2 (8.0)	0
Immune system disorders			
-Total	7 (28.0)	4 (16.0)	3 (12.0)
Cytokine release syndrome	6 (24.0)	3 (12.0)	3 (12.0)
Hypogammaglobulinaemia	1 (4.0)	1 (4.0)	0
Infections and infestations			
-Total	2 (8.0)	2 (8.0)	0
Urinary tract infection	2 (8.0)	2 (8.0)	0
Investigations			
-Total	19 (76.0)	3 (12.0)	16 (64.0)
White blood cell count decreased	16 (64.0)	6 (24.0)	10 (40.0)
Neutrophil count decreased	14 (56.0)	2 (8.0)	12 (48.0)
Alanine aminotransferase increased	7 (28.0)	7 (28.0)	0
Lymphocyte count decreased	6 (24.0)	4 (16.0)	2 (8.0)

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	5 (20.0)	1 (4.0)	4 (16.0)
Aspartate aminotransferase increased	3 (12.0)	3 (12.0)	0
Blood fibrinogen decreased	1 (4.0)	1 (4.0)	0
Metabolism and nutrition disorders			
-Total	7 (28.0)	5 (20.0)	2 (8.0)
Decreased appetite	3 (12.0)	3 (12.0)	0
Hypokalaemia	3 (12.0)	2 (8.0)	1 (4.0)
Hypophosphataemia	2 (8.0)	1 (4.0)	1 (4.0)
Tumour lysis syndrome	2 (8.0)	2 (8.0)	0
Renal and urinary disorders			
-Total	4 (16.0)	4 (16.0)	0
Acute kidney injury	3 (12.0)	3 (12.0)	0
Haematuria	1 (4.0)	1 (4.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (8.0)	0	2 (8.0)
Pulmonary oedema	2 (8.0)	1 (4.0)	1 (4.0)
Respiratory failure	2 (8.0)	0	2 (8.0)

Timing: Any time post CTL019 infusion, Ethnicity: Hispanic or Latino

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	5 (20.0)	4 (16.0)	1 (4.0)
Hypotension	5 (20.0)	4 (16.0)	1 (4.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189d
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Safety Set

Timing: Any time post CTL019 infusion, Ethnicity: Other

		All patients N=39	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (84.6)	9 (23.1)	24 (61.5)
Blood and lymphatic system disorders			
-Total	22 (56.4)	13 (33.3)	9 (23.1)
Anaemia	13 (33.3)	12 (30.8)	1 (2.6)
Febrile neutropenia	8 (20.5)	8 (20.5)	0
Neutropenia	8 (20.5)	1 (2.6)	7 (17.9)
Thrombocytopenia	7 (17.9)	3 (7.7)	4 (10.3)
Cardiac disorders			
-Total	2 (5.1)	2 (5.1)	0
Tachycardia	2 (5.1)	2 (5.1)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	5 (12.8)	5 (12.8)	0
Nausea	4 (10.3)	4 (10.3)	0
Vomiting	2 (5.1)	2 (5.1)	0
General disorders and administration site conditions			
-Total	7 (17.9)	6 (15.4)	1 (2.6)
Pyrexia	5 (12.8)	4 (10.3)	1 (2.6)
Pain	2 (5.1)	2 (5.1)	0
Hepatobiliary disorders			
-Total	2 (5.1)	2 (5.1)	0
Hyperbilirubinaemia	2 (5.1)	2 (5.1)	0
Immune system disorders			
-Total	15 (38.5)	7 (17.9)	8 (20.5)
Cytokine release syndrome	13 (33.3)	5 (12.8)	8 (20.5)
Hypogammaglobulinaemia	4 (10.3)	4 (10.3)	0
Investigations			
-Total	28 (71.8)	10 (25.6)	18 (46.2)
White blood cell count decreased	14 (35.9)	6 (15.4)	8 (20.5)

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	11 (28.2)	2 (5.1)	9 (23.1)
Platelet count decreased	10 (25.6)	2 (5.1)	8 (20.5)
Aspartate aminotransferase increased	9 (23.1)	5 (12.8)	4 (10.3)
Alanine aminotransferase increased	7 (17.9)	7 (17.9)	0
Lymphocyte count decreased	6 (15.4)	3 (7.7)	3 (7.7)
Blood bilirubin increased	3 (7.7)	3 (7.7)	0
Blood creatinine increased	2 (5.1)	2 (5.1)	0
Blood fibrinogen decreased	2 (5.1)	1 (2.6)	1 (2.6)
Metabolism and nutrition disorders			
-Total	17 (43.6)	17 (43.6)	0
Decreased appetite	9 (23.1)	9 (23.1)	0
Hypokalaemia	6 (15.4)	6 (15.4)	0
Hypophosphataemia	6 (15.4)	6 (15.4)	0
Dehydration	3 (7.7)	3 (7.7)	0
Hyponatraemia	2 (5.1)	2 (5.1)	0
Nervous system disorders			
-Total	4 (10.3)	4 (10.3)	0

Timing: Any time post CTL019 infusion, Ethnicity: Other

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	2 (5.1)	2 (5.1)	0
Seizure	2 (5.1)	2 (5.1)	0
Renal and urinary disorders			
-Total	5 (12.8)	1 (2.6)	4 (10.3)
Acute kidney injury	4 (10.3)	1 (2.6)	3 (7.7)
Haematuria	2 (5.1)	1 (2.6)	1 (2.6)
Oliguria	2 (5.1)	2 (5.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	11 (28.2)	7 (17.9)	4 (10.3)
Hypoxia	7 (17.9)	4 (10.3)	3 (7.7)
Epistaxis	5 (12.8)	4 (10.3)	1 (2.6)
Pulmonary oedema	4 (10.3)	3 (7.7)	1 (2.6)
Dyspnoea	2 (5.1)	1 (2.6)	1 (2.6)
Respiratory failure	1 (2.6)	0	1 (2.6)
Vascular disorders			
-Total	10 (25.6)	3 (7.7)	7 (17.9)
Hypotension	10 (25.6)	3 (7.7)	7 (17.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189e
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	6 (85.7)
Blood and lymphatic system disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Anaemia	2 (28.6)	1 (14.3)	1 (14.3)
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Neutropenia	2 (28.6)	0	2 (28.6)
Thrombocytopenia	2 (28.6)	1 (14.3)	1 (14.3)
Cardiac disorders			
-Total	1 (14.3)	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	1 (14.3)	0

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	1 (14.3)	1 (14.3)	0
Nausea	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Pyrexia	2 (28.6)	1 (14.3)	1 (14.3)
Pain	1 (14.3)	1 (14.3)	0
Immune system disorders			
-Total	3 (42.9)	0	3 (42.9)
Cytokine release syndrome	3 (42.9)	0	3 (42.9)
Injury, poisoning and procedural complications			
-Total	1 (14.3)	1 (14.3)	0
Tracheal haemorrhage	1 (14.3)	1 (14.3)	0
Investigations			
-Total	5 (71.4)	1 (14.3)	4 (57.1)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	3 (42.9)	0	3 (42.9)
White blood cell count decreased	3 (42.9)	1 (14.3)	2 (28.6)
Aspartate aminotransferase increased	1 (14.3)	0	1 (14.3)
Blood magnesium decreased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	1 (14.3)	1 (14.3)	0
Decreased appetite	1 (14.3)	1 (14.3)	0
Hypophosphataemia	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (14.3)	1 (14.3)	0
Arthralgia	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	2 (28.6)	0	2 (28.6)

Timing: within 8 weeks post infusion, Response status at study entry: Primary refractory

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Haematuria	2 (28.6)	1 (14.3)	1 (14.3)
Acute kidney injury	1 (14.3)	0	1 (14.3)
Oliguria	1 (14.3)	1 (14.3)	0
Renal failure	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (28.6)	0	2 (28.6)
Hypoxia	2 (28.6)	1 (14.3)	1 (14.3)
Dyspnoea	1 (14.3)	0	1 (14.3)
Epistaxis	1 (14.3)	0	1 (14.3)
Haemoptysis	1 (14.3)	0	1 (14.3)
Interstitial lung disease	1 (14.3)	0	1 (14.3)
Pulmonary oedema	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)
Vascular disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Hypotension	4 (57.1)	2 (28.6)	2 (28.6)

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189e
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

		All patients N=57	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (80.7)	13 (22.8)	33 (57.9)
Blood and lymphatic system disorders			
-Total	33 (57.9)	26 (45.6)	7 (12.3)
Febrile neutropenia	20 (35.1)	20 (35.1)	0
Anaemia	17 (29.8)	17 (29.8)	0
Neutropenia	6 (10.5)	3 (5.3)	3 (5.3)
Thrombocytopenia	6 (10.5)	1 (1.8)	5 (8.8)
Cardiac disorders			
-Total	1 (1.8)	1 (1.8)	0
Tachycardia	1 (1.8)	1 (1.8)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	5 (8.8)	5 (8.8)	0
Vomiting	3 (5.3)	3 (5.3)	0
Nausea	2 (3.5)	2 (3.5)	0
General disorders and administration site conditions			
-Total	5 (8.8)	5 (8.8)	0
Pyrexia	4 (7.0)	4 (7.0)	0
Pain	1 (1.8)	1 (1.8)	0
Immune system disorders			
-Total	19 (33.3)	11 (19.3)	8 (14.0)
Cytokine release syndrome	16 (28.1)	8 (14.0)	8 (14.0)
Hypogammaglobulinaemia	4 (7.0)	4 (7.0)	0
Investigations			
-Total	38 (66.7)	11 (19.3)	27 (47.4)
White blood cell count decreased	23 (40.4)	9 (15.8)	14 (24.6)

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	20 (35.1)	4 (7.0)	16 (28.1)
Platelet count decreased	14 (24.6)	2 (3.5)	12 (21.1)
Alanine aminotransferase increased	11 (19.3)	11 (19.3)	0
Lymphocyte count decreased	11 (19.3)	6 (10.5)	5 (8.8)
Aspartate aminotransferase increased	10 (17.5)	7 (12.3)	3 (5.3)
Blood fibrinogen decreased	3 (5.3)	2 (3.5)	1 (1.8)
Blood bilirubin increased	2 (3.5)	2 (3.5)	0
Metabolism and nutrition disorders			
-Total	19 (33.3)	18 (31.6)	1 (1.8)
Decreased appetite	11 (19.3)	11 (19.3)	0
Hypokalaemia	7 (12.3)	7 (12.3)	0
Hypophosphataemia	6 (10.5)	5 (8.8)	1 (1.8)
Dehydration	2 (3.5)	2 (3.5)	0

Timing: within 8 weeks post infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	4 (7.0)	2 (3.5)	2 (3.5)
Acute kidney injury	4 (7.0)	2 (3.5)	2 (3.5)
Oliguria	1 (1.8)	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	9 (15.8)	5 (8.8)	4 (7.0)
Hypoxia	5 (8.8)	3 (5.3)	2 (3.5)
Pulmonary oedema	4 (7.0)	3 (5.3)	1 (1.8)
Epistaxis	3 (5.3)	3 (5.3)	0
Respiratory failure	2 (3.5)	0	2 (3.5)
Dyspnoea	1 (1.8)	1 (1.8)	0
Vascular disorders			
-Total	11 (19.3)	5 (8.8)	6 (10.5)
Hypotension	11 (19.3)	5 (8.8)	6 (10.5)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189e
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (40.0)	2 (40.0)	0
Gastrointestinal disorders			
-Total	2 (40.0)	2 (40.0)	0
Enterocolitis	1 (20.0)	1 (20.0)	0
Oral pain	1 (20.0)	1 (20.0)	0
Infections and infestations			
-Total	1 (20.0)	1 (20.0)	0
Corona virus infection	1 (20.0)	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (20.0)	1 (20.0)	0
Investigations			
-Total	1 (20.0)	1 (20.0)	0
Blood bilirubin increased	1 (20.0)	1 (20.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (20.0)	1 (20.0)	0
Epistaxis	1 (20.0)	1 (20.0)	0
Pharyngeal lesion	1 (20.0)	1 (20.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189e
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (37.3)	13 (25.5)	6 (11.8)
Blood and lymphatic system disorders			
-Total	6 (11.8)	3 (5.9)	3 (5.9)
Neutropenia	4 (7.8)	1 (2.0)	3 (5.9)
Febrile neutropenia	3 (5.9)	3 (5.9)	0
Anaemia	1 (2.0)	1 (2.0)	0
Thrombocytopenia	1 (2.0)	1 (2.0)	0
Gastrointestinal disorders			
-Total	2 (3.9)	2 (3.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (3.9)	2 (3.9)	0
Vomiting	2 (3.9)	2 (3.9)	0
General disorders and administration site conditions			
-Total	1 (2.0)	1 (2.0)	0
Pyrexia	1 (2.0)	1 (2.0)	0
Immune system disorders			
-Total	1 (2.0)	1 (2.0)	0
Hypogammaglobulinaemia	1 (2.0)	1 (2.0)	0
Investigations			
-Total	11 (21.6)	7 (13.7)	4 (7.8)
Neutrophil count decreased	6 (11.8)	3 (5.9)	3 (5.9)
Alanine aminotransferase increased	2 (3.9)	2 (3.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	2 (3.9)	2 (3.9)	0
White blood cell count decreased	2 (3.9)	1 (2.0)	1 (2.0)
Metabolism and nutrition disorders			
-Total	2 (3.9)	1 (2.0)	1 (2.0)
Dehydration	1 (2.0)	1 (2.0)	0
Hypokalaemia	1 (2.0)	0	1 (2.0)
Hypophosphataemia	1 (2.0)	1 (2.0)	0
Renal and urinary disorders			
-Total	2 (3.9)	2 (3.9)	0
Acute kidney injury	1 (2.0)	1 (2.0)	0
Haematuria	1 (2.0)	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (2.0)	1 (2.0)	0
Pulmonary oedema	1 (2.0)	1 (2.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189e
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (20.0)	0	1 (20.0)
Investigations			
-Total	1 (20.0)	0	1 (20.0)
White blood cell count decreased	1 (20.0)	0	1 (20.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189e
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

		All patients N=29	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (17.2)	4 (13.8)	1 (3.4)
Blood and lymphatic system disorders			
-Total	1 (3.4)	0	1 (3.4)
Febrile neutropenia	1 (3.4)	0	1 (3.4)
Investigations			
-Total	4 (13.8)	4 (13.8)	0
Alanine aminotransferase increased	2 (6.9)	2 (6.9)	0
White blood cell count decreased	2 (6.9)	2 (6.9)	0

Timing: >1 year post-CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (3.4)	1 (3.4)	0
Lymphocyte count decreased	1 (3.4)	1 (3.4)	0
Platelet count decreased	1 (3.4)	1 (3.4)	0
Metabolism and nutrition disorders			
-Total	1 (3.4)	1 (3.4)	0
Hypokalaemia	1 (3.4)	1 (3.4)	0
Renal and urinary disorders			
-Total	1 (3.4)	1 (3.4)	0
Acute kidney injury	1 (3.4)	1 (3.4)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189e
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	6 (85.7)
Blood and lymphatic system disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Anaemia	2 (28.6)	1 (14.3)	1 (14.3)
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Neutropenia	2 (28.6)	0	2 (28.6)
Thrombocytopenia	2 (28.6)	1 (14.3)	1 (14.3)
Cardiac disorders			
-Total	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (14.3)	1 (14.3)	0
Tachycardia	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	3 (42.9)	3 (42.9)	0
Enterocolitis	1 (14.3)	1 (14.3)	0
Nausea	1 (14.3)	1 (14.3)	0
Oral pain	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Pyrexia	2 (28.6)	1 (14.3)	1 (14.3)
Pain	1 (14.3)	1 (14.3)	0
Immune system disorders			
-Total	3 (42.9)	0	3 (42.9)
Cytokine release syndrome	3 (42.9)	0	3 (42.9)
Infections and infestations			

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (14.3)	1 (14.3)	0
Corona virus infection	1 (14.3)	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	1 (14.3)	0
Injury, poisoning and procedural complications			
-Total	1 (14.3)	1 (14.3)	0
Tracheal haemorrhage	1 (14.3)	1 (14.3)	0
Investigations			
-Total	6 (85.7)	2 (28.6)	4 (57.1)
Neutrophil count decreased	3 (42.9)	0	3 (42.9)
White blood cell count decreased	3 (42.9)	0	3 (42.9)
Aspartate aminotransferase increased	1 (14.3)	0	1 (14.3)
Blood bilirubin increased	1 (14.3)	1 (14.3)	0
Blood magnesium decreased	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	1 (14.3)	1 (14.3)	0
Decreased appetite	1 (14.3)	1 (14.3)	0
Hypophosphataemia	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (14.3)	1 (14.3)	0
Arthralgia	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	2 (28.6)	0	2 (28.6)
Haematuria	2 (28.6)	1 (14.3)	1 (14.3)
Acute kidney injury	1 (14.3)	0	1 (14.3)
Oliguria	1 (14.3)	1 (14.3)	0
Renal failure	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)

Timing: Any time post CTL019 infusion, Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	2 (28.6)	1 (14.3)	1 (14.3)
Hypoxia	2 (28.6)	1 (14.3)	1 (14.3)
Dyspnoea	1 (14.3)	0	1 (14.3)
Haemoptysis	1 (14.3)	0	1 (14.3)
Interstitial lung disease	1 (14.3)	0	1 (14.3)
Pharyngeal lesion	1 (14.3)	1 (14.3)	0
Pulmonary oedema	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)
Vascular disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Hypotension	4 (57.1)	2 (28.6)	2 (28.6)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189e
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Safety Set

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	49 (86.0)	12 (21.1)	37 (64.9)
Blood and lymphatic system disorders			
-Total	37 (64.9)	26 (45.6)	11 (19.3)
Febrile neutropenia	22 (38.6)	21 (36.8)	1 (1.8)
Anaemia	18 (31.6)	18 (31.6)	0
Neutropenia	9 (15.8)	3 (5.3)	6 (10.5)
Thrombocytopenia	7 (12.3)	2 (3.5)	5 (8.8)
Cardiac disorders			
-Total	1 (1.8)	1 (1.8)	0
Tachycardia	1 (1.8)	1 (1.8)	0

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	5 (8.8)	5 (8.8)	0
Nausea	4 (7.0)	4 (7.0)	0
Vomiting	3 (5.3)	3 (5.3)	0
General disorders and administration site conditions			
-Total	6 (10.5)	6 (10.5)	0
Pyrexia	5 (8.8)	5 (8.8)	0
Pain	1 (1.8)	1 (1.8)	0
Immune system disorders			
-Total	19 (33.3)	11 (19.3)	8 (14.0)
Cytokine release syndrome	16 (28.1)	8 (14.0)	8 (14.0)
Hypogammaglobulinaemia	5 (8.8)	5 (8.8)	0
Investigations			
-Total	42 (73.7)	12 (21.1)	30 (52.6)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	27 (47.4)	12 (21.1)	15 (26.3)
Neutrophil count decreased	22 (38.6)	4 (7.0)	18 (31.6)
Platelet count decreased	15 (26.3)	3 (5.3)	12 (21.1)
Alanine aminotransferase increased	14 (24.6)	14 (24.6)	0
Lymphocyte count decreased	12 (21.1)	7 (12.3)	5 (8.8)
Aspartate aminotransferase increased	11 (19.3)	8 (14.0)	3 (5.3)
Blood fibrinogen decreased	3 (5.3)	2 (3.5)	1 (1.8)
Blood bilirubin increased	2 (3.5)	2 (3.5)	0
Metabolism and nutrition disorders			
-Total	22 (38.6)	20 (35.1)	2 (3.5)
Decreased appetite	11 (19.3)	11 (19.3)	0
Hypokalaemia	9 (15.8)	8 (14.0)	1 (1.8)

Timing: Any time post CTL019 infusion, Response status at study entry: Relapsed disease

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	7 (12.3)	6 (10.5)	1 (1.8)
Dehydration	3 (5.3)	3 (5.3)	0
Renal and urinary disorders			
-Total	7 (12.3)	5 (8.8)	2 (3.5)
Acute kidney injury	6 (10.5)	4 (7.0)	2 (3.5)
Haematuria	1 (1.8)	1 (1.8)	0
Oliguria	1 (1.8)	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	10 (17.5)	6 (10.5)	4 (7.0)
Hypoxia	5 (8.8)	3 (5.3)	2 (3.5)
Pulmonary oedema	5 (8.8)	4 (7.0)	1 (1.8)
Epistaxis	3 (5.3)	3 (5.3)	0
Respiratory failure	2 (3.5)	0	2 (3.5)
Dyspnoea	1 (1.8)	1 (1.8)	0
Vascular disorders			
-Total	11 (19.3)	5 (8.8)	6 (10.5)
Hypotension	11 (19.3)	5 (8.8)	6 (10.5)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189f
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (83.9)	13 (21.0)	39 (62.9)
Blood and lymphatic system disorders			
-Total	37 (59.7)	28 (45.2)	9 (14.5)
Febrile neutropenia	22 (35.5)	22 (35.5)	0
Anaemia	19 (30.6)	18 (29.0)	1 (1.6)
Neutropenia	8 (12.9)	3 (4.8)	5 (8.1)
Thrombocytopenia	8 (12.9)	2 (3.2)	6 (9.7)
Gastrointestinal disorders			
-Total	3 (4.8)	3 (4.8)	0
Nausea	3 (4.8)	3 (4.8)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	6 (9.7)	5 (8.1)	1 (1.6)
Pyrexia	6 (9.7)	5 (8.1)	1 (1.6)
Immune system disorders			
-Total	22 (35.5)	11 (17.7)	11 (17.7)
Cytokine release syndrome	19 (30.6)	8 (12.9)	11 (17.7)
Hypogammaglobulinaemia	4 (6.5)	4 (6.5)	0
Investigations			
-Total	41 (66.1)	10 (16.1)	31 (50.0)
White blood cell count decreased	26 (41.9)	10 (16.1)	16 (25.8)
Neutrophil count decreased	23 (37.1)	4 (6.5)	19 (30.6)
Platelet count decreased	14 (22.6)	2 (3.2)	12 (19.4)
Alanine aminotransferase increased	11 (17.7)	11 (17.7)	0

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	11 (17.7)	7 (11.3)	4 (6.5)
Lymphocyte count decreased	11 (17.7)	6 (9.7)	5 (8.1)
Metabolism and nutrition disorders			
-Total	18 (29.0)	17 (27.4)	1 (1.6)
Decreased appetite	12 (19.4)	12 (19.4)	0
Hypokalaemia	7 (11.3)	7 (11.3)	0
Hypophosphataemia	7 (11.3)	6 (9.7)	1 (1.6)
Renal and urinary disorders			
-Total	5 (8.1)	2 (3.2)	3 (4.8)
Acute kidney injury	5 (8.1)	2 (3.2)	3 (4.8)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (17.7)	6 (9.7)	5 (8.1)
Hypoxia	7 (11.3)	4 (6.5)	3 (4.8)
Pulmonary oedema	5 (8.1)	3 (4.8)	2 (3.2)
Epistaxis	4 (6.5)	3 (4.8)	1 (1.6)

Timing: within 8 weeks post infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	15 (24.2)	7 (11.3)	8 (12.9)
Hypotension	15 (24.2)	7 (11.3)	8 (12.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189f
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
Blood and lymphatic system disorders			
-Total	1 (50.0)	0	1 (50.0)
Eosinophilia	1 (50.0)	1 (50.0)	0
Neutropenia	1 (50.0)	0	1 (50.0)
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	1 (50.0)	0
Urinary tract infection	1 (50.0)	1 (50.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189f
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (33.3)	13 (24.1)	5 (9.3)
Blood and lymphatic system disorders			
-Total	5 (9.3)	3 (5.6)	2 (3.7)
Febrile neutropenia	3 (5.6)	3 (5.6)	0
Neutropenia	3 (5.6)	1 (1.9)	2 (3.7)
Anaemia	1 (1.9)	1 (1.9)	0
Thrombocytopenia	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders			
-Total	2 (3.7)	2 (3.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (3.7)	2 (3.7)	0
General disorders and administration site conditions			
-Total	1 (1.9)	1 (1.9)	0
Pyrexia	1 (1.9)	1 (1.9)	0
Immune system disorders			
-Total	1 (1.9)	1 (1.9)	0
Hypogammaglobulinaemia	1 (1.9)	1 (1.9)	0
Infections and infestations			
-Total	1 (1.9)	1 (1.9)	0
Urinary tract infection	1 (1.9)	1 (1.9)	0
Investigations			
-Total	11 (20.4)	7 (13.0)	4 (7.4)
Neutrophil count decreased	6 (11.1)	3 (5.6)	3 (5.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	2 (3.7)	2 (3.7)	0
Aspartate aminotransferase increased	2 (3.7)	2 (3.7)	0
White blood cell count decreased	2 (3.7)	1 (1.9)	1 (1.9)
Metabolism and nutrition disorders			
-Total	1 (1.9)	0	1 (1.9)
Hypokalaemia	1 (1.9)	0	1 (1.9)
Hypophosphataemia	1 (1.9)	1 (1.9)	0
Renal and urinary disorders			
-Total	1 (1.9)	1 (1.9)	0
Acute kidney injury	1 (1.9)	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.7)	2 (3.7)	0
Epistaxis	1 (1.9)	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	1 (1.9)	1 (1.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189f
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Infections and infestations			
-Total	1 (100)	1 (100)	0
Cellulitis of male external genital organ	1 (100)	1 (100)	0
Urinary tract infection	1 (100)	1 (100)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189f
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=33	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (18.2)	4 (12.1)	2 (6.1)
Blood and lymphatic system disorders			
-Total	1 (3.0)	0	1 (3.0)
Febrile neutropenia	1 (3.0)	0	1 (3.0)
Investigations			
-Total	5 (15.2)	4 (12.1)	1 (3.0)
White blood cell count decreased	3 (9.1)	2 (6.1)	1 (3.0)
Alanine aminotransferase increased	2 (6.1)	2 (6.1)	0

Timing: >1 year post-CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (3.0)	1 (3.0)	0
Lymphocyte count decreased	1 (3.0)	1 (3.0)	0
Platelet count decreased	1 (3.0)	1 (3.0)	0
Metabolism and nutrition disorders			
-Total	1 (3.0)	1 (3.0)	0
Hypokalaemia	1 (3.0)	1 (3.0)	0
Renal and urinary disorders			
-Total	1 (3.0)	1 (3.0)	0
Acute kidney injury	1 (3.0)	1 (3.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189f
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
Blood and lymphatic system disorders			
-Total	1 (50.0)	0	1 (50.0)
Eosinophilia	1 (50.0)	1 (50.0)	0
Neutropenia	1 (50.0)	0	1 (50.0)
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	1 (50.0)	0
Urinary tract infection	1 (50.0)	1 (50.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189f
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Safety Set

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	54 (87.1)	12 (19.4)	42 (67.7)
Blood and lymphatic system disorders			
-Total	40 (64.5)	28 (45.2)	12 (19.4)
Febrile neutropenia	24 (38.7)	23 (37.1)	1 (1.6)
Anaemia	20 (32.3)	19 (30.6)	1 (1.6)
Neutropenia	10 (16.1)	3 (4.8)	7 (11.3)
Thrombocytopenia	9 (14.5)	3 (4.8)	6 (9.7)
Gastrointestinal disorders			
-Total	5 (8.1)	5 (8.1)	0
Nausea	5 (8.1)	5 (8.1)	0

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

		All patients N=62	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	7 (11.3)	6 (9.7)	1 (1.6)
Pyrexia	7 (11.3)	6 (9.7)	1 (1.6)
Immune system disorders			
-Total	22 (35.5)	11 (17.7)	11 (17.7)
Cytokine release syndrome	19 (30.6)	8 (12.9)	11 (17.7)
Hypogammaglobulinaemia	5 (8.1)	5 (8.1)	0
Infections and infestations			
-Total	1 (1.6)	1 (1.6)	0
Urinary tract infection	1 (1.6)	1 (1.6)	0
Investigations			
-Total	45 (72.6)	11 (17.7)	34 (54.8)
White blood cell count decreased	30 (48.4)	12 (19.4)	18 (29.0)
Neutrophil count decreased	25 (40.3)	4 (6.5)	21 (33.9)

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	15 (24.2)	3 (4.8)	12 (19.4)
Alanine aminotransferase increased	14 (22.6)	14 (22.6)	0
Aspartate aminotransferase increased	12 (19.4)	8 (12.9)	4 (6.5)
Lymphocyte count decreased	12 (19.4)	7 (11.3)	5 (8.1)
Metabolism and nutrition disorders			
-Total	20 (32.3)	18 (29.0)	2 (3.2)
Decreased appetite	12 (19.4)	12 (19.4)	0
Hypokalaemia	9 (14.5)	8 (12.9)	1 (1.6)
Hypophosphataemia	8 (12.9)	7 (11.3)	1 (1.6)
Renal and urinary disorders			
-Total	7 (11.3)	4 (6.5)	3 (4.8)
Acute kidney injury	7 (11.3)	4 (6.5)	3 (4.8)
Respiratory, thoracic and mediastinal disorders			

Timing: Any time post CTL019 infusion, Philadelphia chromosome/BCR-ABL: Negative

	All patients N=62		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (21.0)	8 (12.9)	5 (8.1)
Hypoxia	7 (11.3)	4 (6.5)	3 (4.8)
Pulmonary oedema	6 (9.7)	4 (6.5)	2 (3.2)
Epistaxis	5 (8.1)	4 (6.5)	1 (1.6)
Vascular disorders			
-Total	15 (24.2)	7 (11.3)	8 (12.9)
Hypotension	15 (24.2)	7 (11.3)	8 (12.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189g
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Anaemia	2 (66.7)	2 (66.7)	0
Neutropenia	1 (33.3)	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	1 (33.3)
Cardiac disorders			
-Total	1 (33.3)	1 (33.3)	0
Left ventricular dysfunction	1 (33.3)	1 (33.3)	0
Tachycardia	1 (33.3)	1 (33.3)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	2 (66.7)	2 (66.7)	0
Dysphagia	1 (33.3)	1 (33.3)	0
Nausea	1 (33.3)	1 (33.3)	0
General disorders and administration site conditions			
-Total	2 (66.7)	2 (66.7)	0
Face oedema	1 (33.3)	1 (33.3)	0
Localised oedema	1 (33.3)	1 (33.3)	0
Multiple organ dysfunction syndrome	1 (33.3)	1 (33.3)	0
Oedema peripheral	1 (33.3)	1 (33.3)	0
Pyrexia	1 (33.3)	1 (33.3)	0
Hepatobiliary disorders			
-Total	1 (33.3)	1 (33.3)	0
Hyperbilirubinaemia	1 (33.3)	1 (33.3)	0
Immune system disorders			
-Total	2 (66.7)	0	2 (66.7)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cytokine release syndrome	2 (66.7)	0	2 (66.7)
Injury, poisoning and procedural complications			
-Total	1 (33.3)	1 (33.3)	0
Tracheal haemorrhage	1 (33.3)	1 (33.3)	0
Investigations			
-Total	3 (100)	1 (33.3)	2 (66.7)
Aspartate aminotransferase increased	2 (66.7)	0	2 (66.7)
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0
Blood creatinine increased	1 (33.3)	1 (33.3)	0
Blood fibrinogen decreased	1 (33.3)	0	1 (33.3)
Blood urea increased	1 (33.3)	1 (33.3)	0
Neutrophil count decreased	1 (33.3)	1 (33.3)	0
Platelet count decreased	1 (33.3)	1 (33.3)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Protein total decreased	1 (33.3)	1 (33.3)	0
White blood cell count decreased	1 (33.3)	1 (33.3)	0
Metabolism and nutrition disorders			
-Total	2 (66.7)	2 (66.7)	0
Acidosis	1 (33.3)	1 (33.3)	0
Decreased appetite	1 (33.3)	1 (33.3)	0
Hypokalaemia	1 (33.3)	1 (33.3)	0
Hypophosphataemia	1 (33.3)	1 (33.3)	0
Renal and urinary disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Acute kidney injury	1 (33.3)	0	1 (33.3)
Haematuria	1 (33.3)	1 (33.3)	0
Renal impairment	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (66.7)	0	2 (66.7)
Pulmonary oedema	2 (66.7)	1 (33.3)	1 (33.3)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dyspnoea	1 (33.3)	0	1 (33.3)
Hypoxia	1 (33.3)	0	1 (33.3)
Interstitial lung disease	1 (33.3)	0	1 (33.3)
Pleural effusion	1 (33.3)	1 (33.3)	0
Respiratory distress	1 (33.3)	0	1 (33.3)
Vascular disorders			
-Total	2 (66.7)	0	2 (66.7)
Hypotension	2 (66.7)	0	2 (66.7)
Capillary leak syndrome	1 (33.3)	0	1 (33.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189g
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	49 (80.3)	12 (19.7)	37 (60.7)
Blood and lymphatic system disorders			
-Total	35 (57.4)	27 (44.3)	8 (13.1)
Febrile neutropenia	22 (36.1)	22 (36.1)	0
Anaemia	17 (27.9)	16 (26.2)	1 (1.6)
Neutropenia	7 (11.5)	3 (4.9)	4 (6.6)
Thrombocytopenia	7 (11.5)	2 (3.3)	5 (8.2)
Cardiac disorders			
-Total	1 (1.6)	1 (1.6)	0
Tachycardia	1 (1.6)	1 (1.6)	0

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	2 (3.3)	2 (3.3)	0
Nausea	2 (3.3)	2 (3.3)	0
General disorders and administration site conditions			
-Total	5 (8.2)	4 (6.6)	1 (1.6)
Pyrexia	5 (8.2)	4 (6.6)	1 (1.6)
Hepatobiliary disorders			
-Total	1 (1.6)	1 (1.6)	0
Hyperbilirubinaemia	1 (1.6)	1 (1.6)	0
Immune system disorders			
-Total	20 (32.8)	11 (18.0)	9 (14.8)
Cytokine release syndrome	17 (27.9)	8 (13.1)	9 (14.8)
Hypogammaglobulinaemia	4 (6.6)	4 (6.6)	0
Investigations			
-Total	39 (63.9)	10 (16.4)	29 (47.5)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	25 (41.0)	9 (14.8)	16 (26.2)
Neutrophil count decreased	22 (36.1)	3 (4.9)	19 (31.1)
Platelet count decreased	13 (21.3)	1 (1.6)	12 (19.7)
Lymphocyte count decreased	11 (18.0)	6 (9.8)	5 (8.2)
Alanine aminotransferase increased	10 (16.4)	10 (16.4)	0
Aspartate aminotransferase increased	9 (14.8)	7 (11.5)	2 (3.3)
Blood fibrinogen decreased	2 (3.3)	2 (3.3)	0
Blood creatinine increased	1 (1.6)	1 (1.6)	0
Metabolism and nutrition disorders			
-Total	16 (26.2)	15 (24.6)	1 (1.6)
Decreased appetite	11 (18.0)	11 (18.0)	0
Hypokalaemia	6 (9.8)	6 (9.8)	0
Hypophosphataemia	6 (9.8)	5 (8.2)	1 (1.6)

Timing: within 8 weeks post infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	5 (8.2)	2 (3.3)	3 (4.9)
Acute kidney injury	4 (6.6)	2 (3.3)	2 (3.3)
Haematuria	1 (1.6)	0	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (14.8)	5 (8.2)	4 (6.6)
Hypoxia	6 (9.8)	4 (6.6)	2 (3.3)
Epistaxis	4 (6.6)	3 (4.9)	1 (1.6)
Pulmonary oedema	3 (4.9)	2 (3.3)	1 (1.6)
Dyspnoea	1 (1.6)	1 (1.6)	0
Pleural effusion	1 (1.6)	1 (1.6)	0
Vascular disorders			
-Total	13 (21.3)	7 (11.5)	6 (9.8)
Hypotension	13 (21.3)	7 (11.5)	6 (9.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189g
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	0	1 (50.0)
Blood and lymphatic system disorders			
-Total	1 (50.0)	0	1 (50.0)
Leukopenia	1 (50.0)	0	1 (50.0)
Immune system disorders			
-Total	1 (50.0)	1 (50.0)	0
Hypogammaglobulinaemia	1 (50.0)	1 (50.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189g
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (33.3)	12 (22.2)	6 (11.1)
Blood and lymphatic system disorders			
-Total	6 (11.1)	3 (5.6)	3 (5.6)
Neutropenia	4 (7.4)	1 (1.9)	3 (5.6)
Febrile neutropenia	3 (5.6)	3 (5.6)	0
Anaemia	1 (1.9)	1 (1.9)	0
Thrombocytopenia	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders			
-Total	2 (3.7)	2 (3.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (3.7)	2 (3.7)	0
General disorders and administration site conditions			
-Total	1 (1.9)	1 (1.9)	0
Pyrexia	1 (1.9)	1 (1.9)	0
Investigations			
-Total	11 (20.4)	7 (13.0)	4 (7.4)
Neutrophil count decreased	6 (11.1)	3 (5.6)	3 (5.6)
Alanine aminotransferase increased	2 (3.7)	2 (3.7)	0
Aspartate aminotransferase increased	2 (3.7)	2 (3.7)	0
White blood cell count decreased	2 (3.7)	1 (1.9)	1 (1.9)
Metabolism and nutrition disorders			
-Total	1 (1.9)	0	1 (1.9)
Hypokalaemia	1 (1.9)	0	1 (1.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	1 (1.9)	1 (1.9)	0
Renal and urinary disorders			
-Total	2 (3.7)	2 (3.7)	0
Acute kidney injury	1 (1.9)	1 (1.9)	0
Haematuria	1 (1.9)	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.7)	2 (3.7)	0
Epistaxis	1 (1.9)	1 (1.9)	0
Pulmonary oedema	1 (1.9)	1 (1.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189g
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (18.2)	4 (12.1)	2 (6.1)
Blood and lymphatic system disorders			
-Total	1 (3.0)	0	1 (3.0)
Febrile neutropenia	1 (3.0)	0	1 (3.0)
Investigations			
-Total	5 (15.2)	4 (12.1)	1 (3.0)
White blood cell count decreased	3 (9.1)	2 (6.1)	1 (3.0)
Alanine aminotransferase increased	2 (6.1)	2 (6.1)	0

Timing: >1 year post-CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (3.0)	1 (3.0)	0
Lymphocyte count decreased	1 (3.0)	1 (3.0)	0
Platelet count decreased	1 (3.0)	1 (3.0)	0
Metabolism and nutrition disorders			
-Total	1 (3.0)	1 (3.0)	0
Hypokalaemia	1 (3.0)	1 (3.0)	0
Renal and urinary disorders			
-Total	1 (3.0)	1 (3.0)	0
Acute kidney injury	1 (3.0)	1 (3.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189g
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	1 (33.3)	2 (66.7)
Blood and lymphatic system disorders			
-Total	3 (100)	1 (33.3)	2 (66.7)
Anaemia	2 (66.7)	2 (66.7)	0
Leukopenia	1 (33.3)	0	1 (33.3)
Neutropenia	1 (33.3)	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	1 (33.3)
Cardiac disorders			
-Total	1 (33.3)	1 (33.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Left ventricular dysfunction	1 (33.3)	1 (33.3)	0
Tachycardia	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders			
-Total	2 (66.7)	2 (66.7)	0
Dysphagia	1 (33.3)	1 (33.3)	0
Nausea	1 (33.3)	1 (33.3)	0
General disorders and administration site conditions			
-Total	2 (66.7)	2 (66.7)	0
Face oedema	1 (33.3)	1 (33.3)	0
Localised oedema	1 (33.3)	1 (33.3)	0
Multiple organ dysfunction syndrome	1 (33.3)	1 (33.3)	0
Oedema peripheral	1 (33.3)	1 (33.3)	0
Pyrexia	1 (33.3)	1 (33.3)	0
Hepatobiliary disorders			
-Total	1 (33.3)	1 (33.3)	0
Hyperbilirubinaemia	1 (33.3)	1 (33.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	2 (66.7)	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	2 (66.7)
Hypogammaglobulinaemia	1 (33.3)	1 (33.3)	0
Injury, poisoning and procedural complications			
-Total	1 (33.3)	1 (33.3)	0
Tracheal haemorrhage	1 (33.3)	1 (33.3)	0
Investigations			
-Total	3 (100)	1 (33.3)	2 (66.7)
Aspartate aminotransferase increased	2 (66.7)	0	2 (66.7)
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0
Blood creatinine increased	1 (33.3)	1 (33.3)	0
Blood fibrinogen decreased	1 (33.3)	0	1 (33.3)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood urea increased	1 (33.3)	1 (33.3)	0
Neutrophil count decreased	1 (33.3)	1 (33.3)	0
Platelet count decreased	1 (33.3)	1 (33.3)	0
Protein total decreased	1 (33.3)	1 (33.3)	0
White blood cell count decreased	1 (33.3)	1 (33.3)	0
Metabolism and nutrition disorders			
-Total	2 (66.7)	2 (66.7)	0
Acidosis	1 (33.3)	1 (33.3)	0
Decreased appetite	1 (33.3)	1 (33.3)	0
Hypokalaemia	1 (33.3)	1 (33.3)	0
Hypophosphataemia	1 (33.3)	1 (33.3)	0
Renal and urinary disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Acute kidney injury	1 (33.3)	0	1 (33.3)
Haematuria	1 (33.3)	1 (33.3)	0
Renal impairment	1 (33.3)	1 (33.3)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	2 (66.7)	0	2 (66.7)
Pulmonary oedema	2 (66.7)	1 (33.3)	1 (33.3)
Dyspnoea	1 (33.3)	0	1 (33.3)
Hypoxia	1 (33.3)	0	1 (33.3)
Interstitial lung disease	1 (33.3)	0	1 (33.3)
Pleural effusion	1 (33.3)	1 (33.3)	0
Respiratory distress	1 (33.3)	0	1 (33.3)
Vascular disorders			
-Total	2 (66.7)	0	2 (66.7)
Hypotension	2 (66.7)	0	2 (66.7)
Capillary leak syndrome	1 (33.3)	0	1 (33.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189g
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Safety Set

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

		All patients N=61	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (85.2)	11 (18.0)	41 (67.2)
Blood and lymphatic system disorders			
-Total	39 (63.9)	27 (44.3)	12 (19.7)
Febrile neutropenia	24 (39.3)	23 (37.7)	1 (1.6)
Anaemia	18 (29.5)	17 (27.9)	1 (1.6)
Neutropenia	10 (16.4)	3 (4.9)	7 (11.5)
Thrombocytopenia	8 (13.1)	3 (4.9)	5 (8.2)
Cardiac disorders			
-Total	1 (1.6)	1 (1.6)	0
Tachycardia	1 (1.6)	1 (1.6)	0

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	4 (6.6)	4 (6.6)	0
Nausea	4 (6.6)	4 (6.6)	0
General disorders and administration site conditions			
-Total	6 (9.8)	5 (8.2)	1 (1.6)
Pyrexia	6 (9.8)	5 (8.2)	1 (1.6)
Hepatobiliary disorders			
-Total	1 (1.6)	1 (1.6)	0
Hyperbilirubinaemia	1 (1.6)	1 (1.6)	0
Immune system disorders			
-Total	20 (32.8)	11 (18.0)	9 (14.8)
Cytokine release syndrome	17 (27.9)	8 (13.1)	9 (14.8)
Hypogammaglobulinaemia	4 (6.6)	4 (6.6)	0
Investigations			
-Total	43 (70.5)	11 (18.0)	32 (52.5)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	29 (47.5)	11 (18.0)	18 (29.5)
Neutrophil count decreased	24 (39.3)	3 (4.9)	21 (34.4)
Platelet count decreased	14 (23.0)	2 (3.3)	12 (19.7)
Alanine aminotransferase increased	13 (21.3)	13 (21.3)	0
Lymphocyte count decreased	12 (19.7)	7 (11.5)	5 (8.2)
Aspartate aminotransferase increased	10 (16.4)	8 (13.1)	2 (3.3)
Blood fibrinogen decreased	2 (3.3)	2 (3.3)	0
Blood creatinine increased	1 (1.6)	1 (1.6)	0
Metabolism and nutrition disorders			
-Total	18 (29.5)	16 (26.2)	2 (3.3)
Decreased appetite	11 (18.0)	11 (18.0)	0
Hypokalaemia	8 (13.1)	7 (11.5)	1 (1.6)
Hypophosphataemia	7 (11.5)	6 (9.8)	1 (1.6)

Timing: Any time post CTL019 infusion, Mixed-lineage leukemia rearrangement: No

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	8 (13.1)	5 (8.2)	3 (4.9)
Acute kidney injury	6 (9.8)	4 (6.6)	2 (3.3)
Haematuria	2 (3.3)	1 (1.6)	1 (1.6)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (18.0)	7 (11.5)	4 (6.6)
Hypoxia	6 (9.8)	4 (6.6)	2 (3.3)
Epistaxis	5 (8.2)	4 (6.6)	1 (1.6)
Pulmonary oedema	4 (6.6)	3 (4.9)	1 (1.6)
Dyspnoea	1 (1.6)	1 (1.6)	0
Pleural effusion	1 (1.6)	1 (1.6)	0
Vascular disorders			
-Total	13 (21.3)	7 (11.5)	6 (9.8)
Hypotension	13 (21.3)	7 (11.5)	6 (9.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189h
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Blood and lymphatic system disorders			
-Total	1 (100)	1 (100)	0
Anaemia	1 (100)	1 (100)	0
Febrile neutropenia	1 (100)	1 (100)	0
Investigations			
-Total	1 (100)	1 (100)	0
Neutrophil count decreased	1 (100)	1 (100)	0
Platelet count decreased	1 (100)	1 (100)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189h
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (81.0)	12 (19.0)	39 (61.9)
Blood and lymphatic system disorders			
-Total	36 (57.1)	27 (42.9)	9 (14.3)
Febrile neutropenia	21 (33.3)	21 (33.3)	0
Anaemia	18 (28.6)	17 (27.0)	1 (1.6)
Neutropenia	8 (12.7)	3 (4.8)	5 (7.9)
Thrombocytopenia	8 (12.7)	2 (3.2)	6 (9.5)
Gastrointestinal disorders			
-Total	3 (4.8)	3 (4.8)	0
Nausea	3 (4.8)	3 (4.8)	0

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	6 (9.5)	5 (7.9)	1 (1.6)
Pyrexia	6 (9.5)	5 (7.9)	1 (1.6)
Immune system disorders			
-Total	22 (34.9)	11 (17.5)	11 (17.5)
Cytokine release syndrome	19 (30.2)	8 (12.7)	11 (17.5)
Hypogammaglobulinaemia	4 (6.3)	4 (6.3)	0
Investigations			
-Total	40 (63.5)	9 (14.3)	31 (49.2)
White blood cell count decreased	26 (41.3)	10 (15.9)	16 (25.4)
Neutrophil count decreased	22 (34.9)	3 (4.8)	19 (30.2)
Platelet count decreased	13 (20.6)	1 (1.6)	12 (19.0)
Alanine aminotransferase increased	11 (17.5)	11 (17.5)	0
Aspartate aminotransferase increased	11 (17.5)	7 (11.1)	4 (6.3)
Lymphocyte count decreased	11 (17.5)	6 (9.5)	5 (7.9)
Metabolism and nutrition disorders			
-Total	18 (28.6)	17 (27.0)	1 (1.6)

Timing: within 8 weeks post infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	12 (19.0)	12 (19.0)	0
Hypokalaemia	7 (11.1)	7 (11.1)	0
Hypophosphataemia	7 (11.1)	6 (9.5)	1 (1.6)
Renal and urinary disorders			
-Total	5 (7.9)	2 (3.2)	3 (4.8)
Acute kidney injury	5 (7.9)	2 (3.2)	3 (4.8)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (17.5)	6 (9.5)	5 (7.9)
Hypoxia	7 (11.1)	4 (6.3)	3 (4.8)
Pulmonary oedema	5 (7.9)	3 (4.8)	2 (3.2)
Epistaxis	4 (6.3)	3 (4.8)	1 (1.6)
Vascular disorders			
-Total	15 (23.8)	7 (11.1)	8 (12.7)
Hypotension	15 (23.8)	7 (11.1)	8 (12.7)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189h
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

		All patients N=55	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (34.5)	13 (23.6)	6 (10.9)
Blood and lymphatic system disorders			
-Total	6 (10.9)	3 (5.5)	3 (5.5)
Neutropenia	4 (7.3)	1 (1.8)	3 (5.5)
Febrile neutropenia	3 (5.5)	3 (5.5)	0
Anaemia	1 (1.8)	1 (1.8)	0
Thrombocytopenia	1 (1.8)	1 (1.8)	0
Gastrointestinal disorders			
-Total	2 (3.6)	2 (3.6)	0
Nausea	2 (3.6)	2 (3.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (1.8)	1 (1.8)	0
Pyrexia	1 (1.8)	1 (1.8)	0
Immune system disorders			
-Total	1 (1.8)	1 (1.8)	0
Hypogammaglobulinaemia	1 (1.8)	1 (1.8)	0
Investigations			
-Total	11 (20.0)	7 (12.7)	4 (7.3)
Neutrophil count decreased	6 (10.9)	3 (5.5)	3 (5.5)
Alanine aminotransferase increased	2 (3.6)	2 (3.6)	0
Aspartate aminotransferase increased	2 (3.6)	2 (3.6)	0
White blood cell count decreased	2 (3.6)	1 (1.8)	1 (1.8)
Metabolism and nutrition disorders			
-Total	1 (1.8)	0	1 (1.8)
Hypokalaemia	1 (1.8)	0	1 (1.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Hypodiploidy: No

	All patients N=55		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	1 (1.8)	1 (1.8)	0
Renal and urinary disorders			
-Total	1 (1.8)	1 (1.8)	0
Acute kidney injury	1 (1.8)	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.6)	2 (3.6)	0
Epistaxis	1 (1.8)	1 (1.8)	0
Pulmonary oedema	1 (1.8)	1 (1.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189h
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (18.2)	4 (12.1)	2 (6.1)
Blood and lymphatic system disorders			
-Total	1 (3.0)	0	1 (3.0)
Febrile neutropenia	1 (3.0)	0	1 (3.0)
Investigations			
-Total	5 (15.2)	4 (12.1)	1 (3.0)
White blood cell count decreased	3 (9.1)	2 (6.1)	1 (3.0)
Alanine aminotransferase increased	2 (6.1)	2 (6.1)	0

Timing: >1 year post-CTL019 infusion, Hypodiploidy: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (3.0)	1 (3.0)	0
Lymphocyte count decreased	1 (3.0)	1 (3.0)	0
Platelet count decreased	1 (3.0)	1 (3.0)	0
Metabolism and nutrition disorders			
-Total	1 (3.0)	1 (3.0)	0
Hypokalaemia	1 (3.0)	1 (3.0)	0
Renal and urinary disorders			
-Total	1 (3.0)	1 (3.0)	0
Acute kidney injury	1 (3.0)	1 (3.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189h
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: Yes

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Blood and lymphatic system disorders			
-Total	1 (100)	1 (100)	0
Anaemia	1 (100)	1 (100)	0
Febrile neutropenia	1 (100)	1 (100)	0
Investigations			
-Total	1 (100)	1 (100)	0
Neutrophil count decreased	1 (100)	1 (100)	0
Platelet count decreased	1 (100)	1 (100)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189h
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Safety Set

Timing: Any time post CTL019 infusion, Hypodiploidy: No

		All patients N=63	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	54 (85.7)	11 (17.5)	43 (68.3)
Blood and lymphatic system disorders			
-Total	40 (63.5)	27 (42.9)	13 (20.6)
Febrile neutropenia	23 (36.5)	22 (34.9)	1 (1.6)
Anaemia	19 (30.2)	18 (28.6)	1 (1.6)
Neutropenia	11 (17.5)	3 (4.8)	8 (12.7)
Thrombocytopenia	9 (14.3)	3 (4.8)	6 (9.5)
Gastrointestinal disorders			
-Total	5 (7.9)	5 (7.9)	0
Nausea	5 (7.9)	5 (7.9)	0

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	7 (11.1)	6 (9.5)	1 (1.6)
Pyrexia	7 (11.1)	6 (9.5)	1 (1.6)
Immune system disorders			
-Total	22 (34.9)	11 (17.5)	11 (17.5)
Cytokine release syndrome	19 (30.2)	8 (12.7)	11 (17.5)
Hypogammaglobulinaemia	5 (7.9)	5 (7.9)	0
Investigations			
-Total	44 (69.8)	10 (15.9)	34 (54.0)
White blood cell count decreased	30 (47.6)	12 (19.0)	18 (28.6)
Neutrophil count decreased	24 (38.1)	3 (4.8)	21 (33.3)
Alanine aminotransferase increased	14 (22.2)	14 (22.2)	0
Platelet count decreased	14 (22.2)	2 (3.2)	12 (19.0)
Aspartate aminotransferase increased	12 (19.0)	8 (12.7)	4 (6.3)
Lymphocyte count decreased	12 (19.0)	7 (11.1)	5 (7.9)

Timing: Any time post CTL019 infusion, Hypodiploidy: No

	All patients N=63		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	20 (31.7)	18 (28.6)	2 (3.2)
Decreased appetite	12 (19.0)	12 (19.0)	0
Hypokalaemia	9 (14.3)	8 (12.7)	1 (1.6)
Hypophosphataemia	8 (12.7)	7 (11.1)	1 (1.6)
Renal and urinary disorders			
-Total	7 (11.1)	4 (6.3)	3 (4.8)
Acute kidney injury	7 (11.1)	4 (6.3)	3 (4.8)
Respiratory, thoracic and mediastinal disorders			
-Total	13 (20.6)	8 (12.7)	5 (7.9)
Hypoxia	7 (11.1)	4 (6.3)	3 (4.8)
Pulmonary oedema	6 (9.5)	4 (6.3)	2 (3.2)
Epistaxis	5 (7.9)	4 (6.3)	1 (1.6)
Vascular disorders			
-Total	15 (23.8)	7 (11.1)	8 (12.7)
Hypotension	15 (23.8)	7 (11.1)	8 (12.7)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189i
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

		All patients N=4	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	1 (25.0)	1 (25.0)
Blood and lymphatic system disorders			
-Total	2 (50.0)	2 (50.0)	0
Febrile neutropenia	2 (50.0)	2 (50.0)	0
Anaemia	1 (25.0)	1 (25.0)	0
Immune system disorders			
-Total	1 (25.0)	1 (25.0)	0
Cytokine release syndrome	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	1 (25.0)	1 (25.0)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastroenteritis	1 (25.0)	1 (25.0)	0
Investigations			
-Total	1 (25.0)	0	1 (25.0)
Alanine aminotransferase increased	1 (25.0)	1 (25.0)	0
Aspartate aminotransferase increased	1 (25.0)	1 (25.0)	0
Lymphocyte count decreased	1 (25.0)	1 (25.0)	0
Neutrophil count decreased	1 (25.0)	0	1 (25.0)
White blood cell count decreased	1 (25.0)	1 (25.0)	0
Metabolism and nutrition disorders			
-Total	2 (50.0)	2 (50.0)	0
Decreased appetite	1 (25.0)	1 (25.0)	0
Dehydration	1 (25.0)	1 (25.0)	0
Vascular disorders			
-Total	1 (25.0)	0	1 (25.0)
Hypotension	1 (25.0)	0	1 (25.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189i
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

		All patients N=60	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	50 (83.3)	12 (20.0)	38 (63.3)
Blood and lymphatic system disorders			
-Total	35 (58.3)	26 (43.3)	9 (15.0)
Febrile neutropenia	20 (33.3)	20 (33.3)	0
Anaemia	18 (30.0)	17 (28.3)	1 (1.7)
Neutropenia	8 (13.3)	3 (5.0)	5 (8.3)
Thrombocytopenia	8 (13.3)	2 (3.3)	6 (10.0)
Gastrointestinal disorders			
-Total	6 (10.0)	6 (10.0)	0
Nausea	3 (5.0)	3 (5.0)	0

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	3 (5.0)	3 (5.0)	0
General disorders and administration site conditions			
-Total	6 (10.0)	5 (8.3)	1 (1.7)
Pyrexia	6 (10.0)	5 (8.3)	1 (1.7)
Immune system disorders			
-Total	21 (35.0)	10 (16.7)	11 (18.3)
Cytokine release syndrome	18 (30.0)	7 (11.7)	11 (18.3)
Hypogammaglobulinaemia	4 (6.7)	4 (6.7)	0
Investigations			
-Total	41 (68.3)	11 (18.3)	30 (50.0)
White blood cell count decreased	25 (41.7)	9 (15.0)	16 (26.7)
Neutrophil count decreased	22 (36.7)	4 (6.7)	18 (30.0)
Platelet count decreased	14 (23.3)	2 (3.3)	12 (20.0)
Alanine aminotransferase increased	10 (16.7)	10 (16.7)	0
Aspartate aminotransferase increased	10 (16.7)	6 (10.0)	4 (6.7)
Lymphocyte count decreased	10 (16.7)	5 (8.3)	5 (8.3)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	3 (5.0)	2 (3.3)	1 (1.7)
Blood bilirubin increased	2 (3.3)	2 (3.3)	0
Metabolism and nutrition disorders			
-Total	18 (30.0)	17 (28.3)	1 (1.7)
Decreased appetite	11 (18.3)	11 (18.3)	0
Hypokalaemia	7 (11.7)	7 (11.7)	0
Hypophosphataemia	7 (11.7)	6 (10.0)	1 (1.7)
Dehydration	1 (1.7)	1 (1.7)	0
Renal and urinary disorders			
-Total	6 (10.0)	2 (3.3)	4 (6.7)
Acute kidney injury	5 (8.3)	2 (3.3)	3 (5.0)
Haematuria	2 (3.3)	1 (1.7)	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (18.3)	5 (8.3)	6 (10.0)
Hypoxia	7 (11.7)	4 (6.7)	3 (5.0)
Pulmonary oedema	5 (8.3)	3 (5.0)	2 (3.3)
Epistaxis	4 (6.7)	3 (5.0)	1 (1.7)

Timing: within 8 weeks post infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	3 (5.0)	0	3 (5.0)
Vascular disorders			
-Total	14 (23.3)	7 (11.7)	7 (11.7)
Hypotension	14 (23.3)	7 (11.7)	7 (11.7)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189i
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

		All patients N=4	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	1 (25.0)	1 (25.0)
Blood and lymphatic system disorders			
-Total	1 (25.0)	0	1 (25.0)
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Neutropenia	1 (25.0)	0	1 (25.0)
Infections and infestations			
-Total	1 (25.0)	1 (25.0)	0
Herpes zoster	1 (25.0)	1 (25.0)	0
Investigations			
-Total	2 (50.0)	1 (25.0)	1 (25.0)

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (50.0)	1 (25.0)	1 (25.0)
Aspartate aminotransferase increased	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Pulmonary oedema	1 (25.0)	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189i
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (34.6)	13 (25.0)	5 (9.6)
Blood and lymphatic system disorders			
-Total	5 (9.6)	3 (5.8)	2 (3.8)
Neutropenia	3 (5.8)	1 (1.9)	2 (3.8)
Febrile neutropenia	2 (3.8)	2 (3.8)	0
Anaemia	1 (1.9)	1 (1.9)	0
Thrombocytopenia	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders			
-Total	2 (3.8)	2 (3.8)	0
Nausea	2 (3.8)	2 (3.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	2 (3.8)	2 (3.8)	0
General disorders and administration site conditions			
-Total	1 (1.9)	1 (1.9)	0
Pyrexia	1 (1.9)	1 (1.9)	0
Immune system disorders			
-Total	1 (1.9)	1 (1.9)	0
Hypogammaglobulinaemia	1 (1.9)	1 (1.9)	0
Investigations			
-Total	10 (19.2)	7 (13.5)	3 (5.8)
Neutrophil count decreased	4 (7.7)	2 (3.8)	2 (3.8)
Alanine aminotransferase increased	2 (3.8)	2 (3.8)	0
White blood cell count decreased	2 (3.8)	1 (1.9)	1 (1.9)
Aspartate aminotransferase increased	1 (1.9)	1 (1.9)	0
Blood bilirubin increased	1 (1.9)	1 (1.9)	0
Metabolism and nutrition disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, BCR-ABL1-like: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (3.8)	1 (1.9)	1 (1.9)
Dehydration	1 (1.9)	1 (1.9)	0
Hypokalaemia	1 (1.9)	0	1 (1.9)
Hypophosphataemia	1 (1.9)	1 (1.9)	0
Renal and urinary disorders			
-Total	2 (3.8)	2 (3.8)	0
Acute kidney injury	1 (1.9)	1 (1.9)	0
Haematuria	1 (1.9)	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (1.9)	1 (1.9)	0
Epistaxis	1 (1.9)	1 (1.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189i
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	2 (66.7)	0
General disorders and administration site conditions			
-Total	1 (33.3)	1 (33.3)	0
Cyst	1 (33.3)	1 (33.3)	0
Investigations			
-Total	1 (33.3)	1 (33.3)	0
White blood cell count decreased	1 (33.3)	1 (33.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189i
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (16.1)	3 (9.7)	2 (6.5)
Blood and lymphatic system disorders			
-Total	1 (3.2)	0	1 (3.2)
Febrile neutropenia	1 (3.2)	0	1 (3.2)
Investigations			
-Total	4 (12.9)	3 (9.7)	1 (3.2)
Alanine aminotransferase increased	2 (6.5)	2 (6.5)	0
White blood cell count decreased	2 (6.5)	1 (3.2)	1 (3.2)

Timing: >1 year post-CTL019 infusion, BCR-ABL1-like: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (3.2)	1 (3.2)	0
Lymphocyte count decreased	1 (3.2)	1 (3.2)	0
Platelet count decreased	1 (3.2)	1 (3.2)	0
Metabolism and nutrition disorders			
-Total	1 (3.2)	1 (3.2)	0
Hypokalaemia	1 (3.2)	1 (3.2)	0
Renal and urinary disorders			
-Total	1 (3.2)	1 (3.2)	0
Acute kidney injury	1 (3.2)	1 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189i
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Febrile neutropenia	2 (50.0)	2 (50.0)	0
Anaemia	1 (25.0)	1 (25.0)	0
Neutropenia	1 (25.0)	0	1 (25.0)
General disorders and administration site conditions			
-Total	1 (25.0)	1 (25.0)	0
Cyst	1 (25.0)	1 (25.0)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	1 (25.0)	1 (25.0)	0
Cytokine release syndrome	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	1 (25.0)	1 (25.0)	0
Gastroenteritis	1 (25.0)	1 (25.0)	0
Herpes zoster	1 (25.0)	1 (25.0)	0
Investigations			
-Total	2 (50.0)	0	2 (50.0)
Neutrophil count decreased	2 (50.0)	0	2 (50.0)
White blood cell count decreased	2 (50.0)	2 (50.0)	0
Alanine aminotransferase increased	1 (25.0)	1 (25.0)	0
Aspartate aminotransferase increased	1 (25.0)	1 (25.0)	0
Lymphocyte count decreased	1 (25.0)	1 (25.0)	0
Metabolism and nutrition disorders			
-Total	2 (50.0)	2 (50.0)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	1 (25.0)	1 (25.0)	0
Dehydration	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Pulmonary oedema	1 (25.0)	1 (25.0)	0
Vascular disorders			
-Total	1 (25.0)	0	1 (25.0)
Hypotension	1 (25.0)	0	1 (25.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189i
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Safety Set

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	53 (88.3)	12 (20.0)	41 (68.3)
Blood and lymphatic system disorders			
-Total	39 (65.0)	27 (45.0)	12 (20.0)
Febrile neutropenia	22 (36.7)	21 (35.0)	1 (1.7)
Anaemia	19 (31.7)	18 (30.0)	1 (1.7)
Neutropenia	10 (16.7)	3 (5.0)	7 (11.7)
Thrombocytopenia	9 (15.0)	3 (5.0)	6 (10.0)
Gastrointestinal disorders			
-Total	6 (10.0)	6 (10.0)	0
Nausea	5 (8.3)	5 (8.3)	0

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	3 (5.0)	3 (5.0)	0
General disorders and administration site conditions			
-Total	7 (11.7)	6 (10.0)	1 (1.7)
Pyrexia	7 (11.7)	6 (10.0)	1 (1.7)
Immune system disorders			
-Total	21 (35.0)	10 (16.7)	11 (18.3)
Cytokine release syndrome	18 (30.0)	7 (11.7)	11 (18.3)
Hypogammaglobulinaemia	5 (8.3)	5 (8.3)	0
Investigations			
-Total	45 (75.0)	13 (21.7)	32 (53.3)
White blood cell count decreased	28 (46.7)	10 (16.7)	18 (30.0)
Neutrophil count decreased	23 (38.3)	4 (6.7)	19 (31.7)
Platelet count decreased	15 (25.0)	3 (5.0)	12 (20.0)
Alanine aminotransferase increased	13 (21.7)	13 (21.7)	0
Aspartate aminotransferase increased	11 (18.3)	7 (11.7)	4 (6.7)
Lymphocyte count decreased	11 (18.3)	6 (10.0)	5 (8.3)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	3 (5.0)	3 (5.0)	0
Blood fibrinogen decreased	3 (5.0)	2 (3.3)	1 (1.7)
Metabolism and nutrition disorders			
-Total	21 (35.0)	19 (31.7)	2 (3.3)
Decreased appetite	11 (18.3)	11 (18.3)	0
Hypokalaemia	9 (15.0)	8 (13.3)	1 (1.7)
Hypophosphataemia	8 (13.3)	7 (11.7)	1 (1.7)
Dehydration	2 (3.3)	2 (3.3)	0
Renal and urinary disorders			
-Total	9 (15.0)	5 (8.3)	4 (6.7)
Acute kidney injury	7 (11.7)	4 (6.7)	3 (5.0)
Haematuria	3 (5.0)	2 (3.3)	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
-Total	12 (20.0)	6 (10.0)	6 (10.0)
Hypoxia	7 (11.7)	4 (6.7)	3 (5.0)
Epistaxis	5 (8.3)	4 (6.7)	1 (1.7)
Pulmonary oedema	5 (8.3)	3 (5.0)	2 (3.3)

Timing: Any time post CTL019 infusion, BCR-ABL1-like: No

Group term Preferred term	All grades n (%)	All patients N=60 Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	3 (5.0)	0	3 (5.0)
Vascular disorders			
-Total	14 (23.3)	7 (11.7)	7 (11.7)
Hypotension	14 (23.3)	7 (11.7)	7 (11.7)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189j
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	16 (84.2)	3 (15.8)	13 (68.4)
Blood and lymphatic system disorders			
-Total	12 (63.2)	8 (42.1)	4 (21.1)
Febrile neutropenia	8 (42.1)	8 (42.1)	0
Anaemia	6 (31.6)	6 (31.6)	0
Thrombocytopenia	2 (10.5)	0	2 (10.5)
Disseminated intravascular coagulation	1 (5.3)	1 (5.3)	0
Lymphopenia	1 (5.3)	0	1 (5.3)
Neutropenia	1 (5.3)	1 (5.3)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pancytopenia	1 (5.3)	0	1 (5.3)
Cardiac disorders			
-Total	1 (5.3)	1 (5.3)	0
Tachycardia	1 (5.3)	1 (5.3)	0
Gastrointestinal disorders			
-Total	6 (31.6)	6 (31.6)	0
Vomiting	2 (10.5)	2 (10.5)	0
Abdominal pain	1 (5.3)	1 (5.3)	0
Diarrhoea	1 (5.3)	1 (5.3)	0
Dysphagia	1 (5.3)	1 (5.3)	0
Intestinal obstruction	1 (5.3)	1 (5.3)	0
Mouth haemorrhage	1 (5.3)	1 (5.3)	0
Nausea	1 (5.3)	1 (5.3)	0
General disorders and administration site conditions			
-Total	4 (21.1)	4 (21.1)	0
Pyrexia	2 (10.5)	2 (10.5)	0
Face oedema	1 (5.3)	1 (5.3)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fatigue	1 (5.3)	1 (5.3)	0
Localised oedema	1 (5.3)	1 (5.3)	0
Multiple organ dysfunction syndrome	1 (5.3)	1 (5.3)	0
Oedema peripheral	1 (5.3)	1 (5.3)	0
Pain	1 (5.3)	1 (5.3)	0
Hepatobiliary disorders			
-Total	2 (10.5)	2 (10.5)	0
Hyperbilirubinaemia	2 (10.5)	2 (10.5)	0
Immune system disorders			
-Total	9 (47.4)	4 (21.1)	5 (26.3)
Cytokine release syndrome	8 (42.1)	3 (15.8)	5 (26.3)
Hypogammaglobulinaemia	2 (10.5)	2 (10.5)	0
Infections and infestations			
-Total	4 (21.1)	3 (15.8)	1 (5.3)
Gastroenteritis	1 (5.3)	1 (5.3)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Septic embolus	1 (5.3)	0	1 (5.3)
Staphylococcal infection	1 (5.3)	1 (5.3)	0
Urinary tract infection enterococcal	1 (5.3)	1 (5.3)	0
Injury, poisoning and procedural complications			
-Total	1 (5.3)	0	1 (5.3)
Transfusion related complication	1 (5.3)	0	1 (5.3)
Investigations			
-Total	13 (68.4)	3 (15.8)	10 (52.6)
White blood cell count decreased	7 (36.8)	0	7 (36.8)
Neutrophil count decreased	6 (31.6)	1 (5.3)	5 (26.3)
Alanine aminotransferase increased	5 (26.3)	5 (26.3)	0
Platelet count decreased	5 (26.3)	0	5 (26.3)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	3 (15.8)	1 (5.3)	2 (10.5)
Blood creatinine increased	2 (10.5)	2 (10.5)	0
Blood fibrinogen decreased	2 (10.5)	1 (5.3)	1 (5.3)
Lymphocyte count decreased	2 (10.5)	2 (10.5)	0
Blood bilirubin increased	1 (5.3)	1 (5.3)	0
Blood urea increased	1 (5.3)	1 (5.3)	0
Haemoglobin decreased	1 (5.3)	1 (5.3)	0
International normalised ratio increased	1 (5.3)	1 (5.3)	0
Protein total decreased	1 (5.3)	1 (5.3)	0
Prothrombin time prolonged	1 (5.3)	1 (5.3)	0
Metabolism and nutrition disorders			
-Total	10 (52.6)	9 (47.4)	1 (5.3)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	4 (21.1)	4 (21.1)	0
Dehydration	2 (10.5)	2 (10.5)	0
Hypokalaemia	2 (10.5)	2 (10.5)	0
Hypophosphataemia	2 (10.5)	2 (10.5)	0
Acidosis	1 (5.3)	1 (5.3)	0
Hyperglycaemia	1 (5.3)	1 (5.3)	0
Hypernatraemia	1 (5.3)	0	1 (5.3)
Hypocalcaemia	1 (5.3)	1 (5.3)	0
Hyponatraemia	1 (5.3)	1 (5.3)	0
Malnutrition	1 (5.3)	1 (5.3)	0
Nervous system disorders			
-Total	4 (21.1)	3 (15.8)	1 (5.3)
Embolic stroke	1 (5.3)	0	1 (5.3)
Encephalopathy	1 (5.3)	1 (5.3)	0
Headache	1 (5.3)	1 (5.3)	0
Seizure	1 (5.3)	1 (5.3)	0
Renal and urinary disorders			

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (15.8)	1 (5.3)	2 (10.5)
Acute kidney injury	2 (10.5)	0	2 (10.5)
Oliguria	1 (5.3)	1 (5.3)	0
Renal impairment	1 (5.3)	1 (5.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (26.3)	2 (10.5)	3 (15.8)
Hypoxia	3 (15.8)	1 (5.3)	2 (10.5)
Epistaxis	2 (10.5)	2 (10.5)	0
Pulmonary oedema	2 (10.5)	2 (10.5)	0
Dyspnoea	1 (5.3)	1 (5.3)	0
Pleural effusion	1 (5.3)	1 (5.3)	0
Respiratory distress	1 (5.3)	0	1 (5.3)
Vascular disorders			
-Total	6 (31.6)	2 (10.5)	4 (21.1)
Hypotension	6 (31.6)	2 (10.5)	4 (21.1)
Capillary leak syndrome	1 (5.3)	0	1 (5.3)
Hypertension	1 (5.3)	1 (5.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189j
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (80.0)	9 (20.0)	27 (60.0)
Blood and lymphatic system disorders			
-Total	26 (57.8)	19 (42.2)	7 (15.6)
Febrile neutropenia	14 (31.1)	14 (31.1)	0
Anaemia	13 (28.9)	12 (26.7)	1 (2.2)
Neutropenia	7 (15.6)	2 (4.4)	5 (11.1)
Thrombocytopenia	6 (13.3)	2 (4.4)	4 (8.9)
Disseminated intravascular coagulation	1 (2.2)	1 (2.2)	0
Lymphopenia	1 (2.2)	1 (2.2)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders			
-Total	1 (2.2)	1 (2.2)	0
Tachycardia	1 (2.2)	1 (2.2)	0
Gastrointestinal disorders			
-Total	3 (6.7)	3 (6.7)	0
Nausea	2 (4.4)	2 (4.4)	0
Vomiting	1 (2.2)	1 (2.2)	0
General disorders and administration site conditions			
-Total	5 (11.1)	4 (8.9)	1 (2.2)
Pyrexia	4 (8.9)	3 (6.7)	1 (2.2)
Pain	1 (2.2)	1 (2.2)	0
Immune system disorders			
-Total	13 (28.9)	7 (15.6)	6 (13.3)
Cytokine release syndrome	11 (24.4)	5 (11.1)	6 (13.3)

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	2 (4.4)	2 (4.4)	0
Investigations			
-Total	29 (64.4)	8 (17.8)	21 (46.7)
White blood cell count decreased	19 (42.2)	10 (22.2)	9 (20.0)
Neutrophil count decreased	17 (37.8)	3 (6.7)	14 (31.1)
Lymphocyte count decreased	9 (20.0)	4 (8.9)	5 (11.1)
Platelet count decreased	9 (20.0)	2 (4.4)	7 (15.6)
Aspartate aminotransferase increased	8 (17.8)	6 (13.3)	2 (4.4)
Alanine aminotransferase increased	6 (13.3)	6 (13.3)	0
Blood bilirubin increased	1 (2.2)	1 (2.2)	0
Blood fibrinogen decreased	1 (2.2)	1 (2.2)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	12 (26.7)	11 (24.4)	1 (2.2)
Decreased appetite	8 (17.8)	8 (17.8)	0
Hypokalaemia	5 (11.1)	5 (11.1)	0
Hypophosphataemia	5 (11.1)	4 (8.9)	1 (2.2)
Hyponatraemia	1 (2.2)	1 (2.2)	0
Nervous system disorders			
-Total	1 (2.2)	1 (2.2)	0
Encephalopathy	1 (2.2)	1 (2.2)	0
Headache	1 (2.2)	1 (2.2)	0
Renal and urinary disorders			
-Total	4 (8.9)	2 (4.4)	2 (4.4)
Acute kidney injury	3 (6.7)	2 (4.4)	1 (2.2)
Haematuria	2 (4.4)	1 (2.2)	1 (2.2)
Oliguria	1 (2.2)	1 (2.2)	0

Timing: within 8 weeks post infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	6 (13.3)	2 (4.4)	4 (8.9)
Hypoxia	4 (8.9)	3 (6.7)	1 (2.2)
Pulmonary oedema	3 (6.7)	1 (2.2)	2 (4.4)
Respiratory failure	3 (6.7)	0	3 (6.7)
Epistaxis	2 (4.4)	1 (2.2)	1 (2.2)
Dyspnoea	1 (2.2)	0	1 (2.2)
Pleural effusion	1 (2.2)	1 (2.2)	0
Vascular disorders			
-Total	9 (20.0)	5 (11.1)	4 (8.9)
Hypotension	9 (20.0)	5 (11.1)	4 (8.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189j
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Group term **Preferred term**
Number of patients with at least one AE
Blood and lymphatic system disorders
-Total
Neutropenia
Eosinophilia
Febrile neutropenia
Leukopenia
Gastrointestinal disorders
-Total
Abdominal pain
Diarrhoea

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Group term **Preferred term**
Nausea
Vomiting
Immune system disorders
-Total
Hypogammaglobulinaemia
Infections and infestations
-Total
Bacterial sepsis
Cellulitis of male external genital organ
Enterovirus infection
Herpes zoster
Rotavirus infection
Urinary tract infection
Vascular device infection
Investigations
-Total
Neutrophil count decreased
White blood cell count decreased
Metabolism and nutrition disorders

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

Group term **Preferred term**
-Total
Dehydration
Renal and urinary disorders
-Total
Acute kidney injury
Reproductive system and breast disorders
-Total
Vaginal haemorrhage
Respiratory, thoracic and mediastinal disorders
-Total
Acute respiratory failure
Pulmonary oedema

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients **N=18**	
All grades **n (%)**	**Grade 3** **n (%)**	**Grade 4** **n (%)**
9 (50.0)	2 (11.1)	7 (38.9)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

All patients N=18		
All grades n (%)	**Grade 3 n (%)**	**Grade 4 n (%)**
4 (22.2)	0	4 (22.2)
3 (16.7)	0	3 (16.7)
1 (5.6)	1 (5.6)	0
1 (5.6)	1 (5.6)	0
1 (5.6)	0	1 (5.6)
1 (5.6)	1 (5.6)	0
1 (5.6)	1 (5.6)	0
1 (5.6)	1 (5.6)	0
1 (5.6)	1 (5.6)	0
1 (5.6)	1 (5.6)	0
1 (5.6)	1 (5.6)	0
1 (5.6)	1 (5.6)	0
5 (27.8)	4 (22.2)	1 (5.6)
1 (5.6)	0	1 (5.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

All patients N=18		
All grades n (%)	**Grade 3 n (%)**	**Grade 4 n (%)**
1 (5.6)	1 (5.6)	0
1 (5.6)	1 (5.6)	0
1 (5.6)	1 (5.6)	0
1 (5.6)	1 (5.6)	0
1 (5.6)	1 (5.6)	0
1 (5.6)	1 (5.6)	0
4 (22.2)	1 (5.6)	3 (16.7)
3 (16.7)	1 (5.6)	2 (11.1)
1 (5.6)	0	1 (5.6)
1 (5.6)	1 (5.6)	0
1 (5.6)	1 (5.6)	0
1 (5.6)	1 (5.6)	0
1 (5.6)	1 (5.6)	0
1 (5.6)	1 (5.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18	
All grades n (%)	**Grade 3 n (%)**	**Grade 4 n (%)**
1 (5.6)	1 (5.6)	0
2 (11.1)	1 (5.6)	1 (5.6)
1 (5.6)	0	1 (5.6)
1 (5.6)	1 (5.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189j
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Group term **Preferred term**
Number of patients with at least one AE
Blood and lymphatic system disorders
-Total
Febrile neutropenia
Anaemia
Neutropenia
Thrombocytopenia
Gastrointestinal disorders
-Total
Nausea
Vomiting

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Group term **Preferred term**
General disorders and administration site conditions
-Total
Pyrexia
Infections and infestations
-Total
Urinary tract infection
Investigations
-Total
Neutrophil count decreased
Alanine aminotransferase increased
Aspartate aminotransferase increased
Blood bilirubin increased
White blood cell count decreased
Metabolism and nutrition disorders
-Total
Hyperglycaemia
Hypokalaemia
Hypophosphataemia
Renal and urinary disorders

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Group term Preferred term	All patients N=38		
	All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	11 (28.9)	9 (23.7)	2 (5.3)
Haematuria	3 (7.9)	3 (7.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (5.3)	2 (5.3)	0
Epistaxis	1 (2.6)	1 (2.6)	0
Pleural effusion	1 (2.6)	1 (2.6)	0
Pneumonitis	1 (2.6)	1 (2.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

All patients N=38		
All grades n (%)	**Grade 3 n (%)**	**Grade 4 n (%)**
1 (2.6)	1 (2.6)	0
1 (2.6)	1 (2.6)	0
1 (2.6)	1 (2.6)	0
1 (2.6)	1 (2.6)	0
1 (2.6)	1 (2.6)	0
1 (2.6)	1 (2.6)	0
1 (2.6)	1 (2.6)	0
8 (21.1)	7 (18.4)	1 (2.6)
3 (7.9)	2 (5.3)	1 (2.6)
2 (5.3)	2 (5.3)	0
2 (5.3)	2 (5.3)	0
1 (2.6)	1 (2.6)	0
1 (2.6)	1 (2.6)	0
1 (2.6)	0	1 (2.6)

Timing: >8 weeks to 1 year post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

All patients N=38		
All grades n (%)	**Grade 3 n (%)**	**Grade 4 n (%)**
1 (2.6)	1 (2.6)	0
1 (2.6)	0	1 (2.6)
1 (2.6)	1 (2.6)	0
1 (2.6)	1 (2.6)	0
1 (2.6)	1 (2.6)	0
1 (2.6)	1 (2.6)	0
1 (2.6)	1 (2.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189j
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (45.5)	4 (36.4)	1 (9.1)
Infections and infestations			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Campylobacter infection	1 (9.1)	1 (9.1)	0
Cellulitis of male external genital organ	1 (9.1)	1 (9.1)	0
Clostridium difficile infection	1 (9.1)	1 (9.1)	0
Respiratory tract infection	1 (9.1)	0	1 (9.1)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (9.1)	1 (9.1)	0
Urinary tract infection	1 (9.1)	1 (9.1)	0
Investigations			
-Total	2 (18.2)	2 (18.2)	0
Lymphocyte count decreased	1 (9.1)	1 (9.1)	0
White blood cell count decreased	1 (9.1)	1 (9.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189j
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (21.7)	3 (13.0)	2 (8.7)
Blood and lymphatic system disorders			
-Total	1 (4.3)	0	1 (4.3)
Febrile neutropenia	1 (4.3)	0	1 (4.3)
Investigations			
-Total	3 (13.0)	2 (8.7)	1 (4.3)
Alanine aminotransferase increased	2 (8.7)	2 (8.7)	0
White blood cell count decreased	2 (8.7)	1 (4.3)	1 (4.3)

Timing: >1 year post-CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (4.3)	1 (4.3)	0
Platelet count decreased	1 (4.3)	1 (4.3)	0
Metabolism and nutrition disorders			
-Total	1 (4.3)	1 (4.3)	0
Hypokalaemia	1 (4.3)	1 (4.3)	0
Nervous system disorders			
-Total	1 (4.3)	1 (4.3)	0
Seizure	1 (4.3)	1 (4.3)	0
Renal and urinary disorders			
-Total	1 (4.3)	1 (4.3)	0
Acute kidney injury	1 (4.3)	1 (4.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189j
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (94.7)	1 (5.3)	17 (89.5)
Blood and lymphatic system disorders			
-Total	15 (78.9)	7 (36.8)	8 (42.1)
Febrile neutropenia	8 (42.1)	8 (42.1)	0
Anaemia	6 (31.6)	6 (31.6)	0
Neutropenia	4 (21.1)	1 (5.3)	3 (15.8)
Thrombocytopenia	2 (10.5)	0	2 (10.5)
Disseminated intravascular coagulation	1 (5.3)	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Eosinophilia	1 (5.3)	1 (5.3)	0
Leukopenia	1 (5.3)	0	1 (5.3)
Lymphopenia	1 (5.3)	0	1 (5.3)
Pancytopenia	1 (5.3)	0	1 (5.3)
Cardiac disorders			
-Total	1 (5.3)	1 (5.3)	0
Tachycardia	1 (5.3)	1 (5.3)	0
Gastrointestinal disorders			
-Total	6 (31.6)	6 (31.6)	0
Diarrhoea	2 (10.5)	2 (10.5)	0
Nausea	2 (10.5)	2 (10.5)	0
Vomiting	2 (10.5)	2 (10.5)	0
Abdominal pain	1 (5.3)	1 (5.3)	0
Dysphagia	1 (5.3)	1 (5.3)	0
Intestinal obstruction	1 (5.3)	1 (5.3)	0
Mouth haemorrhage	1 (5.3)	1 (5.3)	0
General disorders and administration site conditions			

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (21.1)	4 (21.1)	0
Pyrexia	2 (10.5)	2 (10.5)	0
Face oedema	1 (5.3)	1 (5.3)	0
Fatigue	1 (5.3)	1 (5.3)	0
Localised oedema	1 (5.3)	1 (5.3)	0
Multiple organ dysfunction syndrome	1 (5.3)	1 (5.3)	0
Oedema peripheral	1 (5.3)	1 (5.3)	0
Pain	1 (5.3)	1 (5.3)	0
Hepatobiliary disorders			
-Total	2 (10.5)	2 (10.5)	0
Hyperbilirubinaemia	2 (10.5)	2 (10.5)	0
Immune system disorders			
-Total	9 (47.4)	4 (21.1)	5 (26.3)
Cytokine release syndrome	8 (42.1)	3 (15.8)	5 (26.3)
Hypogammaglobulinaemia	3 (15.8)	3 (15.8)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	8 (42.1)	5 (26.3)	3 (15.8)
Bacterial sepsis	1 (5.3)	0	1 (5.3)
Campylobacter infection	1 (5.3)	1 (5.3)	0
Cellulitis of male external genital organ	1 (5.3)	1 (5.3)	0
Clostridium difficile infection	1 (5.3)	1 (5.3)	0
Enterovirus infection	1 (5.3)	1 (5.3)	0
Gastroenteritis	1 (5.3)	1 (5.3)	0
Herpes zoster	1 (5.3)	1 (5.3)	0
Respiratory tract infection	1 (5.3)	0	1 (5.3)
Respiratory tract infection viral	1 (5.3)	1 (5.3)	0
Rotavirus infection	1 (5.3)	1 (5.3)	0
Septic embolus	1 (5.3)	0	1 (5.3)
Staphylococcal infection	1 (5.3)	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection	1 (5.3)	1 (5.3)	0
Urinary tract infection enterococcal	1 (5.3)	1 (5.3)	0
Vascular device infection	1 (5.3)	1 (5.3)	0
Injury, poisoning and procedural complications			
-Total	1 (5.3)	0	1 (5.3)
Transfusion related complication	1 (5.3)	0	1 (5.3)
Investigations			
-Total	15 (78.9)	3 (15.8)	12 (63.2)
White blood cell count decreased	9 (47.4)	1 (5.3)	8 (42.1)
Neutrophil count decreased	7 (36.8)	1 (5.3)	6 (31.6)
Alanine aminotransferase increased	5 (26.3)	5 (26.3)	0
Platelet count decreased	5 (26.3)	0	5 (26.3)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	3 (15.8)	1 (5.3)	2 (10.5)
Lymphocyte count decreased	3 (15.8)	3 (15.8)	0
Blood creatinine increased	2 (10.5)	2 (10.5)	0
Blood fibrinogen decreased	2 (10.5)	1 (5.3)	1 (5.3)
Blood bilirubin increased	1 (5.3)	1 (5.3)	0
Blood urea increased	1 (5.3)	1 (5.3)	0
Haemoglobin decreased	1 (5.3)	1 (5.3)	0
International normalised ratio increased	1 (5.3)	1 (5.3)	0
Protein total decreased	1 (5.3)	1 (5.3)	0
Prothrombin time prolonged	1 (5.3)	1 (5.3)	0
Metabolism and nutrition disorders			

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	11 (57.9)	10 (52.6)	1 (5.3)
Decreased appetite	4 (21.1)	4 (21.1)	0
Dehydration	3 (15.8)	3 (15.8)	0
Hypokalaemia	2 (10.5)	2 (10.5)	0
Hypophosphataemia	2 (10.5)	2 (10.5)	0
Acidosis	1 (5.3)	1 (5.3)	0
Hyperglycaemia	1 (5.3)	1 (5.3)	0
Hypernatraemia	1 (5.3)	0	1 (5.3)
Hypocalcaemia	1 (5.3)	1 (5.3)	0
Hyponatraemia	1 (5.3)	1 (5.3)	0
Malnutrition	1 (5.3)	1 (5.3)	0
Nervous system disorders			
-Total	4 (21.1)	3 (15.8)	1 (5.3)
Embolic stroke	1 (5.3)	0	1 (5.3)
Encephalopathy	1 (5.3)	1 (5.3)	0
Headache	1 (5.3)	1 (5.3)	0
Seizure	1 (5.3)	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	4 (21.1)	2 (10.5)	2 (10.5)
Acute kidney injury	3 (15.8)	1 (5.3)	2 (10.5)
Oliguria	1 (5.3)	1 (5.3)	0
Renal impairment	1 (5.3)	1 (5.3)	0
Reproductive system and breast disorders			
-Total	1 (5.3)	1 (5.3)	0
Vaginal haemorrhage	1 (5.3)	1 (5.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (36.8)	3 (15.8)	4 (21.1)
Hypoxia	3 (15.8)	1 (5.3)	2 (10.5)
Pulmonary oedema	3 (15.8)	3 (15.8)	0
Epistaxis	2 (10.5)	2 (10.5)	0
Acute respiratory failure	1 (5.3)	0	1 (5.3)
Dyspnoea	1 (5.3)	1 (5.3)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	1 (5.3)	1 (5.3)	0
Respiratory distress	1 (5.3)	0	1 (5.3)
Vascular disorders			
-Total	6 (31.6)	2 (10.5)	4 (21.1)
Hypotension	6 (31.6)	2 (10.5)	4 (21.1)
Capillary leak syndrome	1 (5.3)	0	1 (5.3)
Hypertension	1 (5.3)	1 (5.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189j
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Safety Set

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	39 (86.7)	11 (24.4)	28 (62.2)
Blood and lymphatic system disorders			
-Total	28 (62.2)	20 (44.4)	8 (17.8)
Febrile neutropenia	16 (35.6)	15 (33.3)	1 (2.2)
Anaemia	14 (31.1)	13 (28.9)	1 (2.2)
Neutropenia	7 (15.6)	2 (4.4)	5 (11.1)
Thrombocytopenia	7 (15.6)	3 (6.7)	4 (8.9)
Disseminated intravascular coagulation	1 (2.2)	1 (2.2)	0

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (2.2)	1 (2.2)	0
Cardiac disorders			
-Total	1 (2.2)	1 (2.2)	0
Tachycardia	1 (2.2)	1 (2.2)	0
Gastrointestinal disorders			
-Total	3 (6.7)	3 (6.7)	0
Nausea	3 (6.7)	3 (6.7)	0
Vomiting	1 (2.2)	1 (2.2)	0
General disorders and administration site conditions			
-Total	6 (13.3)	5 (11.1)	1 (2.2)
Pyrexia	5 (11.1)	4 (8.9)	1 (2.2)
Pain	1 (2.2)	1 (2.2)	0
Immune system disorders			
-Total	13 (28.9)	7 (15.6)	6 (13.3)
Cytokine release syndrome	11 (24.4)	5 (11.1)	6 (13.3)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	2 (4.4)	2 (4.4)	0
Infections and infestations			
-Total	1 (2.2)	1 (2.2)	0
Urinary tract infection	1 (2.2)	1 (2.2)	0
Investigations			
-Total	32 (71.1)	10 (22.2)	22 (48.9)
White blood cell count decreased	21 (46.7)	11 (24.4)	10 (22.2)
Neutrophil count decreased	18 (40.0)	3 (6.7)	15 (33.3)
Platelet count decreased	10 (22.2)	3 (6.7)	7 (15.6)
Alanine aminotransferase increased	9 (20.0)	9 (20.0)	0
Aspartate aminotransferase increased	9 (20.0)	7 (15.6)	2 (4.4)
Lymphocyte count decreased	9 (20.0)	4 (8.9)	5 (11.1)

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	2 (4.4)	2 (4.4)	0
Blood fibrinogen decreased	1 (2.2)	1 (2.2)	0
Metabolism and nutrition disorders			
-Total	14 (31.1)	12 (26.7)	2 (4.4)
Decreased appetite	8 (17.8)	8 (17.8)	0
Hypokalaemia	7 (15.6)	6 (13.3)	1 (2.2)
Hypophosphataemia	6 (13.3)	5 (11.1)	1 (2.2)
Hyperglycaemia	1 (2.2)	1 (2.2)	0
Hyponatraemia	1 (2.2)	1 (2.2)	0
Nervous system disorders			
-Total	2 (4.4)	2 (4.4)	0
Encephalopathy	1 (2.2)	1 (2.2)	0
Headache	1 (2.2)	1 (2.2)	0
Seizure	1 (2.2)	1 (2.2)	0
Renal and urinary disorders			

Timing: Any time post CTL019 infusion, Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (13.3)	4 (8.9)	2 (4.4)
Acute kidney injury	4 (8.9)	3 (6.7)	1 (2.2)
Haematuria	3 (6.7)	2 (4.4)	1 (2.2)
Oliguria	1 (2.2)	1 (2.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (15.6)	3 (6.7)	4 (8.9)
Hypoxia	4 (8.9)	3 (6.7)	1 (2.2)
Epistaxis	3 (6.7)	2 (4.4)	1 (2.2)
Pulmonary oedema	3 (6.7)	1 (2.2)	2 (4.4)
Respiratory failure	3 (6.7)	0	3 (6.7)
Dyspnoea	1 (2.2)	0	1 (2.2)
Pleural effusion	1 (2.2)	1 (2.2)	0
Vascular disorders			
-Total	9 (20.0)	5 (11.1)	4 (8.9)
Hypotension	9 (20.0)	5 (11.1)	4 (8.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189k
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: within 8 weeks post infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (81.3)	13 (20.3)	39 (60.9)
Blood and lymphatic system disorders			
-Total	37 (57.8)	28 (43.8)	9 (14.1)
Febrile neutropenia	22 (34.4)	22 (34.4)	0
Anaemia	19 (29.7)	18 (28.1)	1 (1.6)
Neutropenia	8 (12.5)	3 (4.7)	5 (7.8)
Thrombocytopenia	8 (12.5)	2 (3.1)	6 (9.4)
Gastrointestinal disorders			
-Total	3 (4.7)	3 (4.7)	0
Nausea	3 (4.7)	3 (4.7)	0

Timing: within 8 weeks post infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	6 (9.4)	5 (7.8)	1 (1.6)
Pyrexia	6 (9.4)	5 (7.8)	1 (1.6)
Immune system disorders			
-Total	22 (34.4)	11 (17.2)	11 (17.2)
Cytokine release syndrome	19 (29.7)	8 (12.5)	11 (17.2)
Hypogammaglobulinaemia	4 (6.3)	4 (6.3)	0
Investigations			
-Total	41 (64.1)	10 (15.6)	31 (48.4)
White blood cell count decreased	26 (40.6)	10 (15.6)	16 (25.0)
Neutrophil count decreased	23 (35.9)	4 (6.3)	19 (29.7)
Platelet count decreased	14 (21.9)	2 (3.1)	12 (18.8)
Alanine aminotransferase increased	11 (17.2)	11 (17.2)	0
Aspartate aminotransferase increased	11 (17.2)	7 (10.9)	4 (6.3)
Lymphocyte count decreased	11 (17.2)	6 (9.4)	5 (7.8)
Metabolism and nutrition disorders			
-Total	18 (28.1)	17 (26.6)	1 (1.6)

Timing: within 8 weeks post infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	12 (18.8)	12 (18.8)	0
Hypokalaemia	7 (10.9)	7 (10.9)	0
Hypophosphataemia	7 (10.9)	6 (9.4)	1 (1.6)
Renal and urinary disorders			
-Total	5 (7.8)	2 (3.1)	3 (4.7)
Acute kidney injury	5 (7.8)	2 (3.1)	3 (4.7)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (17.2)	6 (9.4)	5 (7.8)
Hypoxia	7 (10.9)	4 (6.3)	3 (4.7)
Pulmonary oedema	5 (7.8)	3 (4.7)	2 (3.1)
Epistaxis	4 (6.3)	3 (4.7)	1 (1.6)
Vascular disorders			
-Total	15 (23.4)	7 (10.9)	8 (12.5)
Hypotension	15 (23.4)	7 (10.9)	8 (12.5)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189k
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

		All patients N=56	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (33.9)	13 (23.2)	6 (10.7)
Blood and lymphatic system disorders			
-Total	6 (10.7)	3 (5.4)	3 (5.4)
Neutropenia	4 (7.1)	1 (1.8)	3 (5.4)
Febrile neutropenia	3 (5.4)	3 (5.4)	0
Anaemia	1 (1.8)	1 (1.8)	0
Thrombocytopenia	1 (1.8)	1 (1.8)	0
Gastrointestinal disorders			
-Total	2 (3.6)	2 (3.6)	0
Nausea	2 (3.6)	2 (3.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (1.8)	1 (1.8)	0
Pyrexia	1 (1.8)	1 (1.8)	0
Immune system disorders			
-Total	1 (1.8)	1 (1.8)	0
Hypogammaglobulinaemia	1 (1.8)	1 (1.8)	0
Investigations			
-Total	11 (19.6)	7 (12.5)	4 (7.1)
Neutrophil count decreased	6 (10.7)	3 (5.4)	3 (5.4)
Alanine aminotransferase increased	2 (3.6)	2 (3.6)	0
Aspartate aminotransferase increased	2 (3.6)	2 (3.6)	0
White blood cell count decreased	2 (3.6)	1 (1.8)	1 (1.8)
Metabolism and nutrition disorders			
-Total	1 (1.8)	0	1 (1.8)
Hypokalaemia	1 (1.8)	0	1 (1.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Region: US

	All patients N=56		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	1 (1.8)	1 (1.8)	0
Renal and urinary disorders			
-Total	1 (1.8)	1 (1.8)	0
Acute kidney injury	1 (1.8)	1 (1.8)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.6)	2 (3.6)	0
Epistaxis	1 (1.8)	1 (1.8)	0
Pulmonary oedema	1 (1.8)	1 (1.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189k
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (17.6)	4 (11.8)	2 (5.9)
Blood and lymphatic system disorders			
-Total	1 (2.9)	0	1 (2.9)
Febrile neutropenia	1 (2.9)	0	1 (2.9)
Investigations			
-Total	5 (14.7)	4 (11.8)	1 (2.9)
White blood cell count decreased	3 (8.8)	2 (5.9)	1 (2.9)
Alanine aminotransferase increased	2 (5.9)	2 (5.9)	0

Timing: >1 year post-CTL019 infusion, Region: US

	All patients N=34		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (2.9)	1 (2.9)	0
Lymphocyte count decreased	1 (2.9)	1 (2.9)	0
Platelet count decreased	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders			
-Total	1 (2.9)	1 (2.9)	0
Hypokalaemia	1 (2.9)	1 (2.9)	0
Renal and urinary disorders			
-Total	1 (2.9)	1 (2.9)	0
Acute kidney injury	1 (2.9)	1 (2.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189k
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Region
Safety Set

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	55 (85.9)	12 (18.8)	43 (67.2)
Blood and lymphatic system disorders			
-Total	41 (64.1)	28 (43.8)	13 (20.3)
Febrile neutropenia	24 (37.5)	23 (35.9)	1 (1.6)
Anaemia	20 (31.3)	19 (29.7)	1 (1.6)
Neutropenia	11 (17.2)	3 (4.7)	8 (12.5)
Thrombocytopenia	9 (14.1)	3 (4.7)	6 (9.4)
Gastrointestinal disorders			
-Total	5 (7.8)	5 (7.8)	0
Nausea	5 (7.8)	5 (7.8)	0

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	7 (10.9)	6 (9.4)	1 (1.6)
Pyrexia	7 (10.9)	6 (9.4)	1 (1.6)
Immune system disorders			
-Total	22 (34.4)	11 (17.2)	11 (17.2)
Cytokine release syndrome	19 (29.7)	8 (12.5)	11 (17.2)
Hypogammaglobulinaemia	5 (7.8)	5 (7.8)	0
Investigations			
-Total	45 (70.3)	11 (17.2)	34 (53.1)
White blood cell count decreased	30 (46.9)	12 (18.8)	18 (28.1)
Neutrophil count decreased	25 (39.1)	4 (6.3)	21 (32.8)
Platelet count decreased	15 (23.4)	3 (4.7)	12 (18.8)
Alanine aminotransferase increased	14 (21.9)	14 (21.9)	0
Aspartate aminotransferase increased	12 (18.8)	8 (12.5)	4 (6.3)
Lymphocyte count decreased	12 (18.8)	7 (10.9)	5 (7.8)
Metabolism and nutrition disorders			
-Total	20 (31.3)	18 (28.1)	2 (3.1)

Timing: Any time post CTL019 infusion, Region: US

	All patients N=64		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	12 (18.8)	12 (18.8)	0
Hypokalaemia	9 (14.1)	8 (12.5)	1 (1.6)
Hypophosphataemia	8 (12.5)	7 (10.9)	1 (1.6)
Renal and urinary disorders			
-Total	7 (10.9)	4 (6.3)	3 (4.7)
Acute kidney injury	7 (10.9)	4 (6.3)	3 (4.7)
Respiratory, thoracic and mediastinal disorders			
-Total	13 (20.3)	8 (12.5)	5 (7.8)
Hypoxia	7 (10.9)	4 (6.3)	3 (4.7)
Pulmonary oedema	6 (9.4)	4 (6.3)	2 (3.1)
Epistaxis	5 (7.8)	4 (6.3)	1 (1.6)
Vascular disorders			
-Total	15 (23.4)	7 (10.9)	8 (12.5)
Hypotension	15 (23.4)	7 (10.9)	8 (12.5)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189l
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (75.0)	7 (25.0)	14 (50.0)
Blood and lymphatic system disorders			
-Total	16 (57.1)	14 (50.0)	2 (7.1)
Anaemia	9 (32.1)	9 (32.1)	0
Febrile neutropenia	9 (32.1)	9 (32.1)	0
Thrombocytopenia	2 (7.1)	1 (3.6)	1 (3.6)
Neutropenia	1 (3.6)	0	1 (3.6)
Gastrointestinal disorders			
-Total	3 (10.7)	3 (10.7)	0
Vomiting	2 (7.1)	2 (7.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

		All patients N=28	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (3.6)	1 (3.6)	0
General disorders and administration site conditions			
-Total	1 (3.6)	1 (3.6)	0
Pyrexia	1 (3.6)	1 (3.6)	0
Immune system disorders			
-Total	7 (25.0)	5 (17.9)	2 (7.1)
Cytokine release syndrome	6 (21.4)	4 (14.3)	2 (7.1)
Hypogammaglobulinaemia	1 (3.6)	1 (3.6)	0
Investigations			
-Total	18 (64.3)	5 (17.9)	13 (46.4)
White blood cell count decreased	14 (50.0)	7 (25.0)	7 (25.0)
Neutrophil count decreased	11 (39.3)	1 (3.6)	10 (35.7)
Platelet count decreased	8 (28.6)	1 (3.6)	7 (25.0)
Aspartate aminotransferase increased	7 (25.0)	5 (17.9)	2 (7.1)
Alanine aminotransferase increased	6 (21.4)	6 (21.4)	0
Lymphocyte count decreased	5 (17.9)	4 (14.3)	1 (3.6)

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	2 (7.1)	2 (7.1)	0
Metabolism and nutrition disorders			
-Total	7 (25.0)	7 (25.0)	0
Decreased appetite	5 (17.9)	5 (17.9)	0
Hypokalaemia	3 (10.7)	3 (10.7)	0
Hypophosphataemia	3 (10.7)	3 (10.7)	0
Hyponatraemia	2 (7.1)	2 (7.1)	0
Nervous system disorders			
-Total	3 (10.7)	3 (10.7)	0
Headache	2 (7.1)	2 (7.1)	0
Seizure	1 (3.6)	1 (3.6)	0
Renal and urinary disorders			
-Total	1 (3.6)	0	1 (3.6)
Acute kidney injury	1 (3.6)	0	1 (3.6)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (10.7)	2 (7.1)	1 (3.6)
Epistaxis	2 (7.1)	2 (7.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	2 (7.1)	1 (3.6)	1 (3.6)
Pulmonary oedema	1 (3.6)	1 (3.6)	0
Vascular disorders			
-Total	5 (17.9)	2 (7.1)	3 (10.7)
Hypotension	5 (17.9)	2 (7.1)	3 (10.7)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189l
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: within 8 weeks post infusion, Prior SCT therapy: No

		All patients N=36	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (86.1)	6 (16.7)	25 (69.4)
Blood and lymphatic system disorders			
-Total	21 (58.3)	14 (38.9)	7 (19.4)
Febrile neutropenia	13 (36.1)	13 (36.1)	0
Anaemia	10 (27.8)	9 (25.0)	1 (2.8)
Neutropenia	7 (19.4)	3 (8.3)	4 (11.1)
Thrombocytopenia	6 (16.7)	1 (2.8)	5 (13.9)
Disseminated intravascular coagulation	2 (5.6)	2 (5.6)	0
Gastrointestinal disorders			
-Total	4 (11.1)	4 (11.1)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (5.6)	2 (5.6)	0
Diarrhoea	1 (2.8)	1 (2.8)	0
Vomiting	1 (2.8)	1 (2.8)	0
General disorders and administration site conditions			
-Total	5 (13.9)	4 (11.1)	1 (2.8)
Pyrexia	5 (13.9)	4 (11.1)	1 (2.8)
Immune system disorders			
-Total	15 (41.7)	6 (16.7)	9 (25.0)
Cytokine release syndrome	13 (36.1)	4 (11.1)	9 (25.0)
Hypogammaglobulinaemia	3 (8.3)	3 (8.3)	0
Investigations			
-Total	24 (66.7)	6 (16.7)	18 (50.0)
Neutrophil count decreased	12 (33.3)	3 (8.3)	9 (25.0)
White blood cell count decreased	12 (33.3)	3 (8.3)	9 (25.0)
Lymphocyte count decreased	6 (16.7)	2 (5.6)	4 (11.1)
Platelet count decreased	6 (16.7)	1 (2.8)	5 (13.9)
Alanine aminotransferase increased	5 (13.9)	5 (13.9)	0

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	4 (11.1)	2 (5.6)	2 (5.6)
Blood fibrinogen decreased	3 (8.3)	2 (5.6)	1 (2.8)
Lipase increased	2 (5.6)	0	2 (5.6)
Metabolism and nutrition disorders			
-Total	14 (38.9)	13 (36.1)	1 (2.8)
Decreased appetite	7 (19.4)	7 (19.4)	0
Hypokalaemia	4 (11.1)	4 (11.1)	0
Hypophosphataemia	4 (11.1)	3 (8.3)	1 (2.8)
Dehydration	2 (5.6)	2 (5.6)	0
Tumour lysis syndrome	1 (2.8)	1 (2.8)	0
Renal and urinary disorders			
-Total	5 (13.9)	2 (5.6)	3 (8.3)
Acute kidney injury	4 (11.1)	2 (5.6)	2 (5.6)
Haematuria	2 (5.6)	1 (2.8)	1 (2.8)
Respiratory, thoracic and mediastinal disorders			
-Total	8 (22.2)	3 (8.3)	5 (13.9)
Hypoxia	5 (13.9)	3 (8.3)	2 (5.6)

Timing: within 8 weeks post infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	4 (11.1)	2 (5.6)	2 (5.6)
Respiratory failure	3 (8.3)	0	3 (8.3)
Epistaxis	2 (5.6)	1 (2.8)	1 (2.8)
Pleural effusion	2 (5.6)	2 (5.6)	0
Vascular disorders			
-Total	10 (27.8)	5 (13.9)	5 (13.9)
Hypotension	10 (27.8)	5 (13.9)	5 (13.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189l
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

		All patients N=25	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (36.0)	5 (20.0)	4 (16.0)
Blood and lymphatic system disorders			
-Total	3 (12.0)	2 (8.0)	1 (4.0)
Anaemia	1 (4.0)	1 (4.0)	0
Febrile neutropenia	1 (4.0)	1 (4.0)	0
Neutropenia	1 (4.0)	0	1 (4.0)
Thrombocytopenia	1 (4.0)	1 (4.0)	0
Gastrointestinal disorders			
-Total	1 (4.0)	1 (4.0)	0
Nausea	1 (4.0)	1 (4.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (4.0)	1 (4.0)	0
Infections and infestations			
-Total	2 (8.0)	2 (8.0)	0
Urinary tract infection	2 (8.0)	2 (8.0)	0
Investigations			
-Total	5 (20.0)	3 (12.0)	2 (8.0)
Neutrophil count decreased	3 (12.0)	1 (4.0)	2 (8.0)
Aspartate aminotransferase increased	2 (8.0)	2 (8.0)	0
Alanine aminotransferase increased	1 (4.0)	1 (4.0)	0
Metabolism and nutrition disorders			
-Total	2 (8.0)	1 (4.0)	1 (4.0)
Dehydration	1 (4.0)	1 (4.0)	0
Hypokalaemia	1 (4.0)	0	1 (4.0)
Hypophosphataemia	1 (4.0)	1 (4.0)	0
Renal and urinary disorders			
-Total	1 (4.0)	1 (4.0)	0
Haematuria	1 (4.0)	1 (4.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189l
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (38.7)	10 (32.3)	2 (6.5)
Blood and lymphatic system disorders			
-Total	3 (9.7)	1 (3.2)	2 (6.5)
Neutropenia	3 (9.7)	1 (3.2)	2 (6.5)
Febrile neutropenia	2 (6.5)	2 (6.5)	0
Gastrointestinal disorders			
-Total	1 (3.2)	1 (3.2)	0
Diarrhoea	1 (3.2)	1 (3.2)	0
Nausea	1 (3.2)	1 (3.2)	0
Vomiting	1 (3.2)	1 (3.2)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (3.2)	1 (3.2)	0
Pyrexia	1 (3.2)	1 (3.2)	0
Immune system disorders			
-Total	1 (3.2)	1 (3.2)	0
Hypogammaglobulinaemia	1 (3.2)	1 (3.2)	0
Investigations			
-Total	7 (22.6)	5 (16.1)	2 (6.5)
Neutrophil count decreased	3 (9.7)	2 (6.5)	1 (3.2)
White blood cell count decreased	2 (6.5)	1 (3.2)	1 (3.2)
Alanine aminotransferase increased	1 (3.2)	1 (3.2)	0
Blood bilirubin increased	1 (3.2)	1 (3.2)	0
Metabolism and nutrition disorders			
-Total	1 (3.2)	1 (3.2)	0
Tumour lysis syndrome	1 (3.2)	1 (3.2)	0
Renal and urinary disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Prior SCT therapy: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (3.2)	1 (3.2)	0
Acute kidney injury	1 (3.2)	1 (3.2)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.5)	2 (6.5)	0
Epistaxis	1 (3.2)	1 (3.2)	0
Pulmonary oedema	1 (3.2)	1 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189l
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (21.4)	3 (21.4)	0
Infections and infestations			
-Total	1 (7.1)	1 (7.1)	0
Urinary tract infection	1 (7.1)	1 (7.1)	0
Investigations			
-Total	1 (7.1)	1 (7.1)	0
Alanine aminotransferase increased	1 (7.1)	1 (7.1)	0
Aspartate aminotransferase increased	1 (7.1)	1 (7.1)	0
Nervous system disorders			

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (7.1)	1 (7.1)	0
Seizure	1 (7.1)	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189l
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (25.0)	3 (15.0)	2 (10.0)
Blood and lymphatic system disorders			
-Total	1 (5.0)	0	1 (5.0)
Febrile neutropenia	1 (5.0)	0	1 (5.0)
Investigations			
-Total	4 (20.0)	3 (15.0)	1 (5.0)
White blood cell count decreased	3 (15.0)	2 (10.0)	1 (5.0)
Alanine aminotransferase increased	1 (5.0)	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Prior SCT therapy: No

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (5.0)	1 (5.0)	0
Platelet count decreased	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	1 (5.0)	1 (5.0)	0
Hypokalaemia	1 (5.0)	1 (5.0)	0
Renal and urinary disorders			
-Total	1 (5.0)	1 (5.0)	0
Acute kidney injury	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189l
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

		All patients N=28	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (85.7)	8 (28.6)	16 (57.1)
Blood and lymphatic system disorders			
-Total	19 (67.9)	16 (57.1)	3 (10.7)
Anaemia	10 (35.7)	10 (35.7)	0
Febrile neutropenia	10 (35.7)	10 (35.7)	0
Thrombocytopenia	3 (10.7)	2 (7.1)	1 (3.6)
Neutropenia	2 (7.1)	0	2 (7.1)
Gastrointestinal disorders			
-Total	3 (10.7)	3 (10.7)	0
Nausea	2 (7.1)	2 (7.1)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	2 (7.1)	2 (7.1)	0
General disorders and administration site conditions			
-Total	1 (3.6)	1 (3.6)	0
Pyrexia	1 (3.6)	1 (3.6)	0
Immune system disorders			
-Total	7 (25.0)	5 (17.9)	2 (7.1)
Cytokine release syndrome	6 (21.4)	4 (14.3)	2 (7.1)
Hypogammaglobulinaemia	1 (3.6)	1 (3.6)	0
Infections and infestations			
-Total	2 (7.1)	2 (7.1)	0
Urinary tract infection	2 (7.1)	2 (7.1)	0
Investigations			
-Total	19 (67.9)	5 (17.9)	14 (50.0)
White blood cell count decreased	14 (50.0)	7 (25.0)	7 (25.0)
Neutrophil count decreased	12 (42.9)	1 (3.6)	11 (39.3)
Alanine aminotransferase increased	8 (28.6)	8 (28.6)	0

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	8 (28.6)	6 (21.4)	2 (7.1)
Platelet count decreased	8 (28.6)	1 (3.6)	7 (25.0)
Lymphocyte count decreased	5 (17.9)	4 (14.3)	1 (3.6)
Blood bilirubin increased	2 (7.1)	2 (7.1)	0
Metabolism and nutrition disorders			
-Total	9 (32.1)	8 (28.6)	1 (3.6)
Decreased appetite	5 (17.9)	5 (17.9)	0
Hypokalaemia	4 (14.3)	3 (10.7)	1 (3.6)
Hypophosphataemia	4 (14.3)	4 (14.3)	0
Hyponatraemia	2 (7.1)	2 (7.1)	0
Dehydration	1 (3.6)	1 (3.6)	0
Nervous system disorders			
-Total	4 (14.3)	4 (14.3)	0
Headache	2 (7.1)	2 (7.1)	0
Seizure	2 (7.1)	2 (7.1)	0
Renal and urinary disorders			
-Total	2 (7.1)	1 (3.6)	1 (3.6)

Timing: Any time post CTL019 infusion, Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (3.6)	0	1 (3.6)
Haematuria	1 (3.6)	1 (3.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (10.7)	2 (7.1)	1 (3.6)
Epistaxis	2 (7.1)	2 (7.1)	0
Hypoxia	2 (7.1)	1 (3.6)	1 (3.6)
Pulmonary oedema	1 (3.6)	1 (3.6)	0
Vascular disorders			
-Total	5 (17.9)	2 (7.1)	3 (10.7)
Hypotension	5 (17.9)	2 (7.1)	3 (10.7)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189l
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Safety Set

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (88.9)	5 (13.9)	27 (75.0)
Blood and lymphatic system disorders			
-Total	22 (61.1)	12 (33.3)	10 (27.8)
Febrile neutropenia	14 (38.9)	13 (36.1)	1 (2.8)
Anaemia	10 (27.8)	9 (25.0)	1 (2.8)
Neutropenia	9 (25.0)	3 (8.3)	6 (16.7)
Thrombocytopenia	6 (16.7)	1 (2.8)	5 (13.9)
Disseminated intravascular coagulation	2 (5.6)	2 (5.6)	0
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (11.1)	4 (11.1)	0
Nausea	3 (8.3)	3 (8.3)	0
Diarrhoea	2 (5.6)	2 (5.6)	0
Vomiting	1 (2.8)	1 (2.8)	0
General disorders and administration site conditions			
-Total	6 (16.7)	5 (13.9)	1 (2.8)
Pyrexia	6 (16.7)	5 (13.9)	1 (2.8)
Immune system disorders			
-Total	15 (41.7)	6 (16.7)	9 (25.0)
Cytokine release syndrome	13 (36.1)	4 (11.1)	9 (25.0)
Hypogammaglobulinaemia	4 (11.1)	4 (11.1)	0
Investigations			
-Total	28 (77.8)	8 (22.2)	20 (55.6)
White blood cell count decreased	16 (44.4)	5 (13.9)	11 (30.6)
Neutrophil count decreased	13 (36.1)	3 (8.3)	10 (27.8)
Lymphocyte count decreased	7 (19.4)	3 (8.3)	4 (11.1)
Platelet count decreased	7 (19.4)	2 (5.6)	5 (13.9)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	6 (16.7)	6 (16.7)	0
Aspartate aminotransferase increased	4 (11.1)	2 (5.6)	2 (5.6)
Blood fibrinogen decreased	3 (8.3)	2 (5.6)	1 (2.8)
Lipase increased	2 (5.6)	0	2 (5.6)
Blood bilirubin increased	1 (2.8)	1 (2.8)	0
Metabolism and nutrition disorders			
-Total	15 (41.7)	14 (38.9)	1 (2.8)
Decreased appetite	7 (19.4)	7 (19.4)	0
Hypokalaemia	5 (13.9)	5 (13.9)	0
Hypophosphataemia	4 (11.1)	3 (8.3)	1 (2.8)
Dehydration	2 (5.6)	2 (5.6)	0
Tumour lysis syndrome	2 (5.6)	2 (5.6)	0
Renal and urinary disorders			
-Total	7 (19.4)	4 (11.1)	3 (8.3)
Acute kidney injury	6 (16.7)	4 (11.1)	2 (5.6)
Haematuria	2 (5.6)	1 (2.8)	1 (2.8)

Timing: Any time post CTL019 infusion, Prior SCT therapy: No

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	10 (27.8)	5 (13.9)	5 (13.9)
Hypoxia	5 (13.9)	3 (8.3)	2 (5.6)
Pulmonary oedema	5 (13.9)	3 (8.3)	2 (5.6)
Epistaxis	3 (8.3)	2 (5.6)	1 (2.8)
Respiratory failure	3 (8.3)	0	3 (8.3)
Pleural effusion	2 (5.6)	2 (5.6)	0
Vascular disorders			
-Total	10 (27.8)	5 (13.9)	5 (13.9)
Hypotension	10 (27.8)	5 (13.9)	5 (13.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189m
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (92.9)	4 (28.6)	9 (64.3)
Blood and lymphatic system disorders			
-Total	11 (78.6)	8 (57.1)	3 (21.4)
Febrile neutropenia	9 (64.3)	9 (64.3)	0
Anaemia	2 (14.3)	2 (14.3)	0
Thrombocytopenia	2 (14.3)	0	2 (14.3)
Neutropenia	1 (7.1)	1 (7.1)	0
Pancytopenia	1 (7.1)	0	1 (7.1)
Gastrointestinal disorders			
-Total	3 (21.4)	3 (21.4)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (7.1)	1 (7.1)	0
Ascites	1 (7.1)	1 (7.1)	0
Intestinal obstruction	1 (7.1)	1 (7.1)	0
Nausea	1 (7.1)	1 (7.1)	0
Pancreatitis	1 (7.1)	1 (7.1)	0
Vomiting	1 (7.1)	1 (7.1)	0
General disorders and administration site conditions			
-Total	1 (7.1)	1 (7.1)	0
Pyrexia	1 (7.1)	1 (7.1)	0
Immune system disorders			
-Total	4 (28.6)	3 (21.4)	1 (7.1)
Cytokine release syndrome	3 (21.4)	2 (14.3)	1 (7.1)
Hypogammaglobulinaemia	1 (7.1)	1 (7.1)	0
Infections and infestations			
-Total	3 (21.4)	3 (21.4)	0
Catheter site infection	1 (7.1)	1 (7.1)	0
Pneumonia	1 (7.1)	1 (7.1)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Urinary tract infection enterococcal	1 (7.1)	1 (7.1)	0
Investigations			
-Total	11 (78.6)	3 (21.4)	8 (57.1)
Neutrophil count decreased	7 (50.0)	2 (14.3)	5 (35.7)
White blood cell count decreased	7 (50.0)	1 (7.1)	6 (42.9)
Lymphocyte count decreased	4 (28.6)	2 (14.3)	2 (14.3)
Platelet count decreased	3 (21.4)	0	3 (21.4)
Alanine aminotransferase increased	1 (7.1)	1 (7.1)	0
Blood fibrinogen decreased	1 (7.1)	1 (7.1)	0
C-reactive protein increased	1 (7.1)	1 (7.1)	0
Lipase increased	1 (7.1)	0	1 (7.1)
Metabolism and nutrition disorders			
-Total	6 (42.9)	4 (28.6)	2 (14.3)
Decreased appetite	2 (14.3)	2 (14.3)	0
Hypokalaemia	2 (14.3)	2 (14.3)	0
Dehydration	1 (7.1)	1 (7.1)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	1 (7.1)	0	1 (7.1)
Hypoalbuminaemia	1 (7.1)	1 (7.1)	0
Hypophosphataemia	1 (7.1)	0	1 (7.1)
Renal and urinary disorders			
-Total	1 (7.1)	1 (7.1)	0
Acute kidney injury	1 (7.1)	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Hypoxia	1 (7.1)	1 (7.1)	0
Pleural effusion	1 (7.1)	1 (7.1)	0
Pulmonary oedema	1 (7.1)	1 (7.1)	0
Respiratory failure	1 (7.1)	0	1 (7.1)
Vascular disorders			
-Total	2 (14.3)	2 (14.3)	0
Hypotension	2 (14.3)	2 (14.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189m
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: within 8 weeks post infusion, Eligibility for SCT: No

		All patients N=50	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (80.0)	10 (20.0)	30 (60.0)
Blood and lymphatic system disorders			
-Total	27 (54.0)	20 (40.0)	7 (14.0)
Anaemia	17 (34.0)	16 (32.0)	1 (2.0)
Febrile neutropenia	13 (26.0)	13 (26.0)	0
Neutropenia	7 (14.0)	2 (4.0)	5 (10.0)
Thrombocytopenia	6 (12.0)	2 (4.0)	4 (8.0)
Gastrointestinal disorders			
-Total	5 (10.0)	5 (10.0)	0
Nausea	2 (4.0)	2 (4.0)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	2 (4.0)	2 (4.0)	0
Diarrhoea	1 (2.0)	1 (2.0)	0
General disorders and administration site conditions			
-Total	5 (10.0)	4 (8.0)	1 (2.0)
Pyrexia	5 (10.0)	4 (8.0)	1 (2.0)
Immune system disorders			
-Total	18 (36.0)	8 (16.0)	10 (20.0)
Cytokine release syndrome	16 (32.0)	6 (12.0)	10 (20.0)
Hypogammaglobulinaemia	3 (6.0)	3 (6.0)	0
Investigations			
-Total	32 (64.0)	9 (18.0)	23 (46.0)
White blood cell count decreased	19 (38.0)	9 (18.0)	10 (20.0)
Neutrophil count decreased	16 (32.0)	2 (4.0)	14 (28.0)
Aspartate aminotransferase increased	11 (22.0)	7 (14.0)	4 (8.0)
Platelet count decreased	11 (22.0)	2 (4.0)	9 (18.0)
Alanine aminotransferase increased	10 (20.0)	10 (20.0)	0

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	7 (14.0)	4 (8.0)	3 (6.0)
Blood bilirubin increased	2 (4.0)	2 (4.0)	0
Blood fibrinogen decreased	2 (4.0)	1 (2.0)	1 (2.0)
Lipase increased	1 (2.0)	0	1 (2.0)
Metabolism and nutrition disorders			
-Total	16 (32.0)	16 (32.0)	0
Decreased appetite	10 (20.0)	10 (20.0)	0
Hypophosphataemia	6 (12.0)	6 (12.0)	0
Hypokalaemia	5 (10.0)	5 (10.0)	0
Dehydration	1 (2.0)	1 (2.0)	0
Tumour lysis syndrome	1 (2.0)	1 (2.0)	0
Renal and urinary disorders			
-Total	5 (10.0)	1 (2.0)	4 (8.0)
Acute kidney injury	4 (8.0)	1 (2.0)	3 (6.0)
Haematuria	2 (4.0)	1 (2.0)	1 (2.0)
Respiratory, thoracic and mediastinal disorders			
-Total	9 (18.0)	4 (8.0)	5 (10.0)

Timing: within 8 weeks post infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	6 (12.0)	3 (6.0)	3 (6.0)
Epistaxis	4 (8.0)	3 (6.0)	1 (2.0)
Pulmonary oedema	4 (8.0)	2 (4.0)	2 (4.0)
Respiratory failure	2 (4.0)	0	2 (4.0)
Pleural effusion	1 (2.0)	1 (2.0)	0
Vascular disorders			
-Total	13 (26.0)	5 (10.0)	8 (16.0)
Hypotension	13 (26.0)	5 (10.0)	8 (16.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189m
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

		All patients N=12	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (75.0)	8 (66.7)	1 (8.3)
Blood and lymphatic system disorders			
-Total	1 (8.3)	1 (8.3)	0
Anaemia	1 (8.3)	1 (8.3)	0
Febrile neutropenia	1 (8.3)	1 (8.3)	0
Gastrointestinal disorders			
-Total	2 (16.7)	2 (16.7)	0
Abdominal pain	1 (8.3)	1 (8.3)	0
Diarrhoea	1 (8.3)	1 (8.3)	0
Enterocolitis	1 (8.3)	1 (8.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

		All patients N=12	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	1 (8.3)	1 (8.3)	0
Vomiting	1 (8.3)	1 (8.3)	0
Infections and infestations			
-Total	4 (33.3)	3 (25.0)	1 (8.3)
Bacterial sepsis	1 (8.3)	0	1 (8.3)
Corona virus infection	1 (8.3)	1 (8.3)	0
Parainfluenzae virus infection	1 (8.3)	1 (8.3)	0
Respiratory syncytial virus infection	1 (8.3)	1 (8.3)	0
Viral upper respiratory tract infection	1 (8.3)	1 (8.3)	0
Investigations			
-Total	3 (25.0)	3 (25.0)	0
Neutrophil count decreased	2 (16.7)	2 (16.7)	0
White blood cell count decreased	1 (8.3)	1 (8.3)	0
Metabolism and nutrition disorders			
-Total	2 (16.7)	2 (16.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=12		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Iron overload	1 (8.3)	1 (8.3)	0
Tumour lysis syndrome	1 (8.3)	1 (8.3)	0
Reproductive system and breast disorders			
-Total	1 (8.3)	1 (8.3)	0
Vaginal haemorrhage	1 (8.3)	1 (8.3)	0
Skin and subcutaneous tissue disorders			
-Total	1 (8.3)	1 (8.3)	0
Dermatitis acneiform	1 (8.3)	1 (8.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189m
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

		All patients N=44	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (34.1)	9 (20.5)	6 (13.6)
Blood and lymphatic system disorders			
-Total	5 (11.4)	2 (4.5)	3 (6.8)
Neutropenia	4 (9.1)	1 (2.3)	3 (6.8)
Febrile neutropenia	2 (4.5)	2 (4.5)	0
Thrombocytopenia	1 (2.3)	1 (2.3)	0
Gastrointestinal disorders			
-Total	1 (2.3)	1 (2.3)	0
Nausea	1 (2.3)	1 (2.3)	0
Vomiting	1 (2.3)	1 (2.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (2.3)	1 (2.3)	0
Pyrexia	1 (2.3)	1 (2.3)	0
Immune system disorders			
-Total	1 (2.3)	1 (2.3)	0
Hypogammaglobulinaemia	1 (2.3)	1 (2.3)	0
Investigations			
-Total	9 (20.5)	5 (11.4)	4 (9.1)
Neutrophil count decreased	4 (9.1)	1 (2.3)	3 (6.8)
Alanine aminotransferase increased	2 (4.5)	2 (4.5)	0
Aspartate aminotransferase increased	2 (4.5)	2 (4.5)	0
Blood bilirubin increased	1 (2.3)	1 (2.3)	0
White blood cell count decreased	1 (2.3)	0	1 (2.3)
Metabolism and nutrition disorders			
-Total	2 (4.5)	1 (2.3)	1 (2.3)

Timing: >8 weeks to 1 year post CTL019 infusion, Eligibility for SCT: No

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (2.3)	1 (2.3)	0
Hypokalaemia	1 (2.3)	0	1 (2.3)
Hypophosphataemia	1 (2.3)	1 (2.3)	0
Renal and urinary disorders			
-Total	2 (4.5)	2 (4.5)	0
Acute kidney injury	1 (2.3)	1 (2.3)	0
Haematuria	1 (2.3)	1 (2.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (4.5)	2 (4.5)	0
Epistaxis	1 (2.3)	1 (2.3)	0
Pulmonary oedema	1 (2.3)	1 (2.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189m
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: Yes

		All patients N=9	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (22.2)	1 (11.1)	1 (11.1)
Infections and infestations			
-Total	1 (11.1)	0	1 (11.1)
Respiratory tract infection	1 (11.1)	0	1 (11.1)
Reproductive system and breast disorders			
-Total	1 (11.1)	1 (11.1)	0
Ovarian failure	1 (11.1)	1 (11.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189m
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

		All patients N=25	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (24.0)	4 (16.0)	2 (8.0)
Blood and lymphatic system disorders			
-Total	1 (4.0)	0	1 (4.0)
Febrile neutropenia	1 (4.0)	0	1 (4.0)
Investigations			
-Total	5 (20.0)	4 (16.0)	1 (4.0)
White blood cell count decreased	3 (12.0)	2 (8.0)	1 (4.0)
Alanine aminotransferase increased	2 (8.0)	2 (8.0)	0

Timing: >1 year post-CTL019 infusion, Eligibility for SCT: No

	All patients N=25		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (4.0)	1 (4.0)	0
Lymphocyte count decreased	1 (4.0)	1 (4.0)	0
Platelet count decreased	1 (4.0)	1 (4.0)	0
Metabolism and nutrition disorders			
-Total	1 (4.0)	1 (4.0)	0
Hypokalaemia	1 (4.0)	1 (4.0)	0
Renal and urinary disorders			
-Total	1 (4.0)	1 (4.0)	0
Acute kidney injury	1 (4.0)	1 (4.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189m
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

		All patients N=14	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (100)	4 (28.6)	10 (71.4)
Blood and lymphatic system disorders			
-Total	12 (85.7)	9 (64.3)	3 (21.4)
Febrile neutropenia	10 (71.4)	10 (71.4)	0
Anaemia	3 (21.4)	3 (21.4)	0
Thrombocytopenia	2 (14.3)	0	2 (14.3)
Neutropenia	1 (7.1)	1 (7.1)	0
Pancytopenia	1 (7.1)	0	1 (7.1)
Gastrointestinal disorders			
-Total	4 (28.6)	4 (28.6)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (14.3)	2 (14.3)	0
Abdominal pain	1 (7.1)	1 (7.1)	0
Ascites	1 (7.1)	1 (7.1)	0
Diarrhoea	1 (7.1)	1 (7.1)	0
Enterocolitis	1 (7.1)	1 (7.1)	0
Intestinal obstruction	1 (7.1)	1 (7.1)	0
Pancreatitis	1 (7.1)	1 (7.1)	0
Vomiting	1 (7.1)	1 (7.1)	0
General disorders and administration site conditions			
-Total	1 (7.1)	1 (7.1)	0
Pyrexia	1 (7.1)	1 (7.1)	0
Immune system disorders			
-Total	4 (28.6)	3 (21.4)	1 (7.1)
Cytokine release syndrome	3 (21.4)	2 (14.3)	1 (7.1)
Hypogammaglobulinaemia	1 (7.1)	1 (7.1)	0
Infections and infestations			
-Total	6 (42.9)	4 (28.6)	2 (14.3)
Bacterial sepsis	1 (7.1)	0	1 (7.1)

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Catheter site infection	1 (7.1)	1 (7.1)	0
Corona virus infection	1 (7.1)	1 (7.1)	0
Parainfluenzae virus infection	1 (7.1)	1 (7.1)	0
Pneumonia	1 (7.1)	1 (7.1)	0
Respiratory syncytial virus infection	1 (7.1)	1 (7.1)	0
Respiratory tract infection	1 (7.1)	0	1 (7.1)
Urinary tract infection enterococcal	1 (7.1)	1 (7.1)	0
Viral upper respiratory tract infection	1 (7.1)	1 (7.1)	0
Investigations			
-Total	12 (85.7)	4 (28.6)	8 (57.1)
White blood cell count decreased	8 (57.1)	2 (14.3)	6 (42.9)
Neutrophil count decreased	7 (50.0)	2 (14.3)	5 (35.7)
Lymphocyte count decreased	4 (28.6)	2 (14.3)	2 (14.3)
Platelet count decreased	3 (21.4)	0	3 (21.4)
Alanine aminotransferase increased	1 (7.1)	1 (7.1)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	1 (7.1)	1 (7.1)	0
C-reactive protein increased	1 (7.1)	1 (7.1)	0
Lipase increased	1 (7.1)	0	1 (7.1)
Metabolism and nutrition disorders			
-Total	6 (42.9)	4 (28.6)	2 (14.3)
Decreased appetite	2 (14.3)	2 (14.3)	0
Hypokalaemia	2 (14.3)	2 (14.3)	0
Dehydration	1 (7.1)	1 (7.1)	0
Hyperuricaemia	1 (7.1)	0	1 (7.1)
Hypoalbuminaemia	1 (7.1)	1 (7.1)	0
Hypophosphataemia	1 (7.1)	0	1 (7.1)
Iron overload	1 (7.1)	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	1 (7.1)	0
Renal and urinary disorders			
-Total	1 (7.1)	1 (7.1)	0
Acute kidney injury	1 (7.1)	1 (7.1)	0
Reproductive system and breast disorders			

Timing: Any time post CTL019 infusion, Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (14.3)	2 (14.3)	0
Ovarian failure	1 (7.1)	1 (7.1)	0
Vaginal haemorrhage	1 (7.1)	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Hypoxia	1 (7.1)	1 (7.1)	0
Pleural effusion	1 (7.1)	1 (7.1)	0
Pulmonary oedema	1 (7.1)	1 (7.1)	0
Respiratory failure	1 (7.1)	0	1 (7.1)
Skin and subcutaneous tissue disorders			
-Total	1 (7.1)	1 (7.1)	0
Dermatitis acneiform	1 (7.1)	1 (7.1)	0
Vascular disorders			
-Total	2 (14.3)	2 (14.3)	0
Hypotension	2 (14.3)	2 (14.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189m
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Safety Set

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	42 (84.0)	8 (16.0)	34 (68.0)
Blood and lymphatic system disorders			
-Total	30 (60.0)	19 (38.0)	11 (22.0)
Anaemia	17 (34.0)	16 (32.0)	1 (2.0)
Febrile neutropenia	14 (28.0)	13 (26.0)	1 (2.0)
Neutropenia	10 (20.0)	2 (4.0)	8 (16.0)
Thrombocytopenia	7 (14.0)	3 (6.0)	4 (8.0)
Gastrointestinal disorders			
-Total	5 (10.0)	5 (10.0)	0
Nausea	3 (6.0)	3 (6.0)	0

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	2 (4.0)	2 (4.0)	0
Diarrhoea	1 (2.0)	1 (2.0)	0
General disorders and administration site conditions			
-Total	6 (12.0)	5 (10.0)	1 (2.0)
Pyrexia	6 (12.0)	5 (10.0)	1 (2.0)
Immune system disorders			
-Total	18 (36.0)	8 (16.0)	10 (20.0)
Cytokine release syndrome	16 (32.0)	6 (12.0)	10 (20.0)
Hypogammaglobulinaemia	4 (8.0)	4 (8.0)	0
Investigations			
-Total	36 (72.0)	10 (20.0)	26 (52.0)
White blood cell count decreased	22 (44.0)	10 (20.0)	12 (24.0)
Neutrophil count decreased	18 (36.0)	2 (4.0)	16 (32.0)
Alanine aminotransferase increased	13 (26.0)	13 (26.0)	0
Aspartate aminotransferase increased	12 (24.0)	8 (16.0)	4 (8.0)
Platelet count decreased	12 (24.0)	3 (6.0)	9 (18.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	8 (16.0)	5 (10.0)	3 (6.0)
Blood bilirubin increased	3 (6.0)	3 (6.0)	0
Blood fibrinogen decreased	2 (4.0)	1 (2.0)	1 (2.0)
Lipase increased	1 (2.0)	0	1 (2.0)
Metabolism and nutrition disorders			
-Total	19 (38.0)	18 (36.0)	1 (2.0)
Decreased appetite	10 (20.0)	10 (20.0)	0
Hypokalaemia	7 (14.0)	6 (12.0)	1 (2.0)
Hypophosphataemia	7 (14.0)	7 (14.0)	0
Dehydration	2 (4.0)	2 (4.0)	0
Tumour lysis syndrome	1 (2.0)	1 (2.0)	0
Renal and urinary disorders			
-Total	8 (16.0)	4 (8.0)	4 (8.0)
Acute kidney injury	6 (12.0)	3 (6.0)	3 (6.0)
Haematuria	3 (6.0)	2 (4.0)	1 (2.0)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (22.0)	6 (12.0)	5 (10.0)

Timing: Any time post CTL019 infusion, Eligibility for SCT: No

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	6 (12.0)	3 (6.0)	3 (6.0)
Epistaxis	5 (10.0)	4 (8.0)	1 (2.0)
Pulmonary oedema	5 (10.0)	3 (6.0)	2 (4.0)
Respiratory failure	2 (4.0)	0	2 (4.0)
Pleural effusion	1 (2.0)	1 (2.0)	0
Vascular disorders			
-Total	13 (26.0)	5 (10.0)	8 (16.0)
Hypotension	13 (26.0)	5 (10.0)	8 (16.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189n
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (90.0)	7 (35.0)	11 (55.0)
Blood and lymphatic system disorders			
-Total	14 (70.0)	12 (60.0)	2 (10.0)
Febrile neutropenia	9 (45.0)	9 (45.0)	0
Anaemia	5 (25.0)	5 (25.0)	0
Neutropenia	3 (15.0)	2 (10.0)	1 (5.0)
Lymphopenia	1 (5.0)	1 (5.0)	0
Pancytopenia	1 (5.0)	0	1 (5.0)
Gastrointestinal disorders			
-Total	1 (5.0)	1 (5.0)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (5.0)	1 (5.0)	0
Intestinal obstruction	1 (5.0)	1 (5.0)	0
Vomiting	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	2 (10.0)	2 (10.0)	0
Pain	1 (5.0)	1 (5.0)	0
Pyrexia	1 (5.0)	1 (5.0)	0
Immune system disorders			
-Total	6 (30.0)	4 (20.0)	2 (10.0)
Cytokine release syndrome	5 (25.0)	3 (15.0)	2 (10.0)
Hypogammaglobulinaemia	1 (5.0)	1 (5.0)	0
Infections and infestations			
-Total	2 (10.0)	2 (10.0)	0
Gastroenteritis	1 (5.0)	1 (5.0)	0
Urinary tract infection enterococcal	1 (5.0)	1 (5.0)	0
Investigations			

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	13 (65.0)	3 (15.0)	10 (50.0)
Neutrophil count decreased	8 (40.0)	2 (10.0)	6 (30.0)
White blood cell count decreased	8 (40.0)	3 (15.0)	5 (25.0)
Lymphocyte count decreased	5 (25.0)	2 (10.0)	3 (15.0)
Platelet count decreased	4 (20.0)	1 (5.0)	3 (15.0)
Alanine aminotransferase increased	2 (10.0)	2 (10.0)	0
Aspartate aminotransferase increased	2 (10.0)	1 (5.0)	1 (5.0)
Blood bilirubin increased	1 (5.0)	1 (5.0)	0
Blood lactic acid increased	1 (5.0)	0	1 (5.0)
Metabolism and nutrition disorders			
-Total	8 (40.0)	7 (35.0)	1 (5.0)
Decreased appetite	3 (15.0)	3 (15.0)	0
Dehydration	2 (10.0)	2 (10.0)	0
Hypophosphataemia	2 (10.0)	2 (10.0)	0
Hyperuricaemia	1 (5.0)	0	1 (5.0)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	1 (5.0)	1 (5.0)	0
Hyponatraemia	1 (5.0)	1 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (5.0)	1 (5.0)	0
Arthralgia	1 (5.0)	1 (5.0)	0
Nervous system disorders			
-Total	1 (5.0)	1 (5.0)	0
Encephalopathy	1 (5.0)	1 (5.0)	0
Headache	1 (5.0)	1 (5.0)	0
Skin and subcutaneous tissue disorders			
-Total	1 (5.0)	1 (5.0)	0
Rash maculo-papular	1 (5.0)	1 (5.0)	0
Vascular disorders			
-Total	5 (25.0)	4 (20.0)	1 (5.0)
Hypotension	4 (20.0)	3 (15.0)	1 (5.0)
Embolism	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189n
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	34 (77.3)	6 (13.6)	28 (63.6)
Blood and lymphatic system disorders			
-Total	24 (54.5)	15 (34.1)	9 (20.5)
Anaemia	14 (31.8)	13 (29.5)	1 (2.3)
Febrile neutropenia	13 (29.5)	13 (29.5)	0
Thrombocytopenia	8 (18.2)	2 (4.5)	6 (13.6)
Neutropenia	5 (11.4)	1 (2.3)	4 (9.1)
Lymphopenia	1 (2.3)	0	1 (2.3)
Gastrointestinal disorders			
-Total	6 (13.6)	6 (13.6)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	3 (6.8)	3 (6.8)	0
Vomiting	2 (4.5)	2 (4.5)	0
Diarrhoea	1 (2.3)	1 (2.3)	0
General disorders and administration site conditions			
-Total	6 (13.6)	5 (11.4)	1 (2.3)
Pyrexia	5 (11.4)	4 (9.1)	1 (2.3)
Pain	1 (2.3)	1 (2.3)	0
Immune system disorders			
-Total	16 (36.4)	7 (15.9)	9 (20.5)
Cytokine release syndrome	14 (31.8)	5 (11.4)	9 (20.5)
Hypogammaglobulinaemia	3 (6.8)	3 (6.8)	0
Investigations			
-Total	29 (65.9)	8 (18.2)	21 (47.7)
White blood cell count decreased	18 (40.9)	7 (15.9)	11 (25.0)
Neutrophil count decreased	15 (34.1)	2 (4.5)	13 (29.5)

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	10 (22.7)	1 (2.3)	9 (20.5)
Alanine aminotransferase increased	9 (20.5)	9 (20.5)	0
Aspartate aminotransferase increased	9 (20.5)	6 (13.6)	3 (6.8)
Lymphocyte count decreased	6 (13.6)	4 (9.1)	2 (4.5)
Blood fibrinogen decreased	3 (6.8)	2 (4.5)	1 (2.3)
Blood bilirubin increased	1 (2.3)	1 (2.3)	0
Metabolism and nutrition disorders			
-Total	13 (29.5)	12 (27.3)	1 (2.3)
Decreased appetite	9 (20.5)	9 (20.5)	0
Hypokalaemia	6 (13.6)	6 (13.6)	0
Hypophosphataemia	5 (11.4)	4 (9.1)	1 (2.3)
Hyponatraemia	1 (2.3)	1 (2.3)	0
Nervous system disorders			
-Total	3 (6.8)	3 (6.8)	0
Encephalopathy	1 (2.3)	1 (2.3)	0

Timing: within 8 weeks post infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	1 (2.3)	1 (2.3)	0
Seizure	1 (2.3)	1 (2.3)	0
Renal and urinary disorders			
-Total	6 (13.6)	2 (4.5)	4 (9.1)
Acute kidney injury	5 (11.4)	2 (4.5)	3 (6.8)
Haematuria	2 (4.5)	1 (2.3)	1 (2.3)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (25.0)	5 (11.4)	6 (13.6)
Hypoxia	7 (15.9)	4 (9.1)	3 (6.8)
Pulmonary oedema	5 (11.4)	3 (6.8)	2 (4.5)
Epistaxis	4 (9.1)	3 (6.8)	1 (2.3)
Respiratory failure	3 (6.8)	0	3 (6.8)
Vascular disorders			
-Total	11 (25.0)	4 (9.1)	7 (15.9)
Hypotension	11 (25.0)	4 (9.1)	7 (15.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189n
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (55.0)	7 (35.0)	4 (20.0)
Blood and lymphatic system disorders			
-Total	4 (20.0)	2 (10.0)	2 (10.0)
Neutropenia	3 (15.0)	1 (5.0)	2 (10.0)
Febrile neutropenia	2 (10.0)	2 (10.0)	0
Thrombocytopenia	1 (5.0)	1 (5.0)	0
Gastrointestinal disorders			
-Total	3 (15.0)	3 (15.0)	0
Abdominal pain	1 (5.0)	1 (5.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (5.0)	1 (5.0)	0
Enterocolitis	1 (5.0)	1 (5.0)	0
Nausea	1 (5.0)	1 (5.0)	0
Oral pain	1 (5.0)	1 (5.0)	0
Vomiting	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	1 (5.0)	1 (5.0)	0
Pyrexia	1 (5.0)	1 (5.0)	0
Infections and infestations			
-Total	5 (25.0)	4 (20.0)	1 (5.0)
Bacterial sepsis	1 (5.0)	0	1 (5.0)
Cholecystitis infective	1 (5.0)	1 (5.0)	0
Corona virus infection	1 (5.0)	1 (5.0)	0
Herpes zoster	1 (5.0)	1 (5.0)	0
Respiratory syncytial virus infection	1 (5.0)	1 (5.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular device infection	1 (5.0)	1 (5.0)	0
Investigations			
-Total	6 (30.0)	3 (15.0)	3 (15.0)
Neutrophil count decreased	3 (15.0)	1 (5.0)	2 (10.0)
Alanine aminotransferase increased	1 (5.0)	1 (5.0)	0
Blood bilirubin increased	1 (5.0)	1 (5.0)	0
White blood cell count decreased	1 (5.0)	0	1 (5.0)
Reproductive system and breast disorders			
-Total	1 (5.0)	1 (5.0)	0
Vaginal haemorrhage	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (10.0)	2 (10.0)	0
Epistaxis	1 (5.0)	1 (5.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pharyngeal lesion	1 (5.0)	1 (5.0)	0
Pulmonary oedema	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189n
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (30.6)	8 (22.2)	3 (8.3)
Blood and lymphatic system disorders			
-Total	2 (5.6)	1 (2.8)	1 (2.8)
Anaemia	1 (2.8)	1 (2.8)	0
Febrile neutropenia	1 (2.8)	1 (2.8)	0
Neutropenia	1 (2.8)	0	1 (2.8)
Gastrointestinal disorders			
-Total	1 (2.8)	1 (2.8)	0
Nausea	1 (2.8)	1 (2.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (2.8)	1 (2.8)	0
Immune system disorders			
-Total	1 (2.8)	1 (2.8)	0
Hypogammaglobulinaemia	1 (2.8)	1 (2.8)	0
Investigations			
-Total	6 (16.7)	5 (13.9)	1 (2.8)
Neutrophil count decreased	3 (8.3)	2 (5.6)	1 (2.8)
Aspartate aminotransferase increased	2 (5.6)	2 (5.6)	0
Alanine aminotransferase increased	1 (2.8)	1 (2.8)	0
White blood cell count decreased	1 (2.8)	1 (2.8)	0
Metabolism and nutrition disorders			
-Total	2 (5.6)	1 (2.8)	1 (2.8)

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=36		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (2.8)	1 (2.8)	0
Hypokalaemia	1 (2.8)	0	1 (2.8)
Hypophosphataemia	1 (2.8)	1 (2.8)	0
Renal and urinary disorders			
-Total	2 (5.6)	2 (5.6)	0
Acute kidney injury	1 (2.8)	1 (2.8)	0
Haematuria	1 (2.8)	1 (2.8)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189n
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (35.7)	3 (21.4)	2 (14.3)
Infections and infestations			
-Total	1 (7.1)	1 (7.1)	0
Otitis media	1 (7.1)	1 (7.1)	0
Investigations			
-Total	4 (28.6)	3 (21.4)	1 (7.1)
White blood cell count decreased	2 (14.3)	1 (7.1)	1 (7.1)
Alanine aminotransferase increased	1 (7.1)	1 (7.1)	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (7.1)	1 (7.1)	0
Lymphocyte count decreased	1 (7.1)	1 (7.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (7.1)	0	1 (7.1)
Glioblastoma multiforme	1 (7.1)	0	1 (7.1)
Nervous system disorders			
-Total	1 (7.1)	1 (7.1)	0
Seizure	1 (7.1)	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189n
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (10.0)	1 (5.0)	1 (5.0)
Blood and lymphatic system disorders			
-Total	1 (5.0)	0	1 (5.0)
Febrile neutropenia	1 (5.0)	0	1 (5.0)
Investigations			
-Total	1 (5.0)	1 (5.0)	0
Alanine aminotransferase increased	1 (5.0)	1 (5.0)	0
Platelet count decreased	1 (5.0)	1 (5.0)	0

Timing: >1 year post-CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	1 (5.0)	1 (5.0)	0
Hypokalaemia	1 (5.0)	1 (5.0)	0
Renal and urinary disorders			
-Total	1 (5.0)	1 (5.0)	0
Acute kidney injury	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189n
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (100)	6 (30.0)	14 (70.0)
Blood and lymphatic system disorders			
-Total	16 (80.0)	12 (60.0)	4 (20.0)
Febrile neutropenia	9 (45.0)	9 (45.0)	0
Anaemia	5 (25.0)	5 (25.0)	0
Neutropenia	5 (25.0)	2 (10.0)	3 (15.0)
Lymphopenia	1 (5.0)	1 (5.0)	0
Pancytopenia	1 (5.0)	0	1 (5.0)
Thrombocytopenia	1 (5.0)	1 (5.0)	0
Gastrointestinal disorders			

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (15.0)	3 (15.0)	0
Abdominal pain	1 (5.0)	1 (5.0)	0
Diarrhoea	1 (5.0)	1 (5.0)	0
Enterocolitis	1 (5.0)	1 (5.0)	0
Intestinal obstruction	1 (5.0)	1 (5.0)	0
Nausea	1 (5.0)	1 (5.0)	0
Oral pain	1 (5.0)	1 (5.0)	0
Vomiting	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	3 (15.0)	3 (15.0)	0
Pyrexia	2 (10.0)	2 (10.0)	0
Pain	1 (5.0)	1 (5.0)	0
Immune system disorders			
-Total	6 (30.0)	4 (20.0)	2 (10.0)
Cytokine release syndrome	5 (25.0)	3 (15.0)	2 (10.0)
Hypogammaglobulinaemia	1 (5.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	6 (30.0)	5 (25.0)	1 (5.0)
Bacterial sepsis	1 (5.0)	0	1 (5.0)
Cholecystitis infective	1 (5.0)	1 (5.0)	0
Corona virus infection	1 (5.0)	1 (5.0)	0
Gastroenteritis	1 (5.0)	1 (5.0)	0
Herpes zoster	1 (5.0)	1 (5.0)	0
Otitis media	1 (5.0)	1 (5.0)	0
Respiratory syncytial virus infection	1 (5.0)	1 (5.0)	0
Urinary tract infection enterococcal	1 (5.0)	1 (5.0)	0
Vascular device infection	1 (5.0)	1 (5.0)	0
Investigations			
-Total	17 (85.0)	5 (25.0)	12 (60.0)
White blood cell count decreased	10 (50.0)	3 (15.0)	7 (35.0)
Neutrophil count decreased	9 (45.0)	2 (10.0)	7 (35.0)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	6 (30.0)	3 (15.0)	3 (15.0)
Platelet count decreased	4 (20.0)	1 (5.0)	3 (15.0)
Alanine aminotransferase increased	3 (15.0)	3 (15.0)	0
Aspartate aminotransferase increased	3 (15.0)	2 (10.0)	1 (5.0)
Blood bilirubin increased	2 (10.0)	2 (10.0)	0
Blood lactic acid increased	1 (5.0)	0	1 (5.0)
Metabolism and nutrition disorders			
-Total	8 (40.0)	7 (35.0)	1 (5.0)
Decreased appetite	3 (15.0)	3 (15.0)	0
Dehydration	2 (10.0)	2 (10.0)	0
Hypophosphataemia	2 (10.0)	2 (10.0)	0
Hyperuricaemia	1 (5.0)	0	1 (5.0)
Hypokalaemia	1 (5.0)	1 (5.0)	0
Hyponatraemia	1 (5.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	1 (5.0)	1 (5.0)	0
Arthralgia	1 (5.0)	1 (5.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (5.0)	0	1 (5.0)
Glioblastoma multiforme	1 (5.0)	0	1 (5.0)
Nervous system disorders			
-Total	2 (10.0)	2 (10.0)	0
Encephalopathy	1 (5.0)	1 (5.0)	0
Headache	1 (5.0)	1 (5.0)	0
Seizure	1 (5.0)	1 (5.0)	0
Reproductive system and breast disorders			
-Total	1 (5.0)	1 (5.0)	0
Vaginal haemorrhage	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: Low

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (10.0)	2 (10.0)	0
Epistaxis	1 (5.0)	1 (5.0)	0
Pharyngeal lesion	1 (5.0)	1 (5.0)	0
Pulmonary oedema	1 (5.0)	1 (5.0)	0
Skin and subcutaneous tissue disorders			
-Total	1 (5.0)	1 (5.0)	0
Rash maculo-papular	1 (5.0)	1 (5.0)	0
Vascular disorders			
-Total	5 (25.0)	4 (20.0)	1 (5.0)
Hypotension	4 (20.0)	3 (15.0)	1 (5.0)
Embolism	1 (5.0)	1 (5.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189n
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Safety Set

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (81.8)	6 (13.6)	30 (68.2)
Blood and lymphatic system disorders			
-Total	26 (59.1)	15 (34.1)	11 (25.0)
Anaemia	15 (34.1)	14 (31.8)	1 (2.3)
Febrile neutropenia	15 (34.1)	14 (31.8)	1 (2.3)
Thrombocytopenia	8 (18.2)	2 (4.5)	6 (13.6)
Neutropenia	6 (13.6)	1 (2.3)	5 (11.4)
Lymphopenia	1 (2.3)	0	1 (2.3)
Gastrointestinal disorders			
-Total	6 (13.6)	6 (13.6)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	4 (9.1)	4 (9.1)	0
Vomiting	2 (4.5)	2 (4.5)	0
Diarrhoea	1 (2.3)	1 (2.3)	0
General disorders and administration site conditions			
-Total	6 (13.6)	5 (11.4)	1 (2.3)
Pyrexia	5 (11.4)	4 (9.1)	1 (2.3)
Pain	1 (2.3)	1 (2.3)	0
Immune system disorders			
-Total	16 (36.4)	7 (15.9)	9 (20.5)
Cytokine release syndrome	14 (31.8)	5 (11.4)	9 (20.5)
Hypogammaglobulinaemia	4 (9.1)	4 (9.1)	0
Investigations			
-Total	30 (68.2)	8 (18.2)	22 (50.0)
White blood cell count decreased	20 (45.5)	9 (20.5)	11 (25.0)
Neutrophil count decreased	16 (36.4)	2 (4.5)	14 (31.8)

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	11 (25.0)	11 (25.0)	0
Platelet count decreased	11 (25.0)	2 (4.5)	9 (20.5)
Aspartate aminotransferase increased	9 (20.5)	6 (13.6)	3 (6.8)
Lymphocyte count decreased	6 (13.6)	4 (9.1)	2 (4.5)
Blood fibrinogen decreased	3 (6.8)	2 (4.5)	1 (2.3)
Blood bilirubin increased	1 (2.3)	1 (2.3)	0
Metabolism and nutrition disorders			
-Total	16 (36.4)	14 (31.8)	2 (4.5)
Decreased appetite	9 (20.5)	9 (20.5)	0
Hypokalaemia	8 (18.2)	7 (15.9)	1 (2.3)
Hypophosphataemia	6 (13.6)	5 (11.4)	1 (2.3)
Dehydration	1 (2.3)	1 (2.3)	0
Hyponatraemia	1 (2.3)	1 (2.3)	0
Nervous system disorders			
-Total	3 (6.8)	3 (6.8)	0

Timing: Any time post CTL019 infusion, Baseline bone marrow tumor burden: High

	All patients N=44		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Encephalopathy	1 (2.3)	1 (2.3)	0
Headache	1 (2.3)	1 (2.3)	0
Seizure	1 (2.3)	1 (2.3)	0
Renal and urinary disorders			
-Total	9 (20.5)	5 (11.4)	4 (9.1)
Acute kidney injury	7 (15.9)	4 (9.1)	3 (6.8)
Haematuria	3 (6.8)	2 (4.5)	1 (2.3)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (25.0)	5 (11.4)	6 (13.6)
Hypoxia	7 (15.9)	4 (9.1)	3 (6.8)
Pulmonary oedema	5 (11.4)	3 (6.8)	2 (4.5)
Epistaxis	4 (9.1)	3 (6.8)	1 (2.3)
Respiratory failure	3 (6.8)	0	3 (6.8)
Vascular disorders			
-Total	11 (25.0)	4 (9.1)	7 (15.9)
Hypotension	11 (25.0)	4 (9.1)	7 (15.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189o
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	4 (80.0)
Blood and lymphatic system disorders			
-Total	2 (40.0)	2 (40.0)	0
Anaemia	2 (40.0)	2 (40.0)	0
Febrile neutropenia	1 (20.0)	1 (20.0)	0
Gastrointestinal disorders			
-Total	1 (20.0)	1 (20.0)	0
Dysphagia	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (20.0)	1 (20.0)	0
Face oedema	1 (20.0)	1 (20.0)	0
Localised oedema	1 (20.0)	1 (20.0)	0
Multiple organ dysfunction syndrome	1 (20.0)	1 (20.0)	0
Oedema peripheral	1 (20.0)	1 (20.0)	0
Hepatobiliary disorders			
-Total	1 (20.0)	1 (20.0)	0
Hyperbilirubinaemia	1 (20.0)	1 (20.0)	0
Immune system disorders			
-Total	1 (20.0)	0	1 (20.0)
Cytokine release syndrome	1 (20.0)	0	1 (20.0)
Investigations			
-Total	4 (80.0)	0	4 (80.0)
Alanine aminotransferase increased	2 (40.0)	2 (40.0)	0
Aspartate aminotransferase increased	2 (40.0)	1 (20.0)	1 (20.0)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (40.0)	0	2 (40.0)
White blood cell count decreased	2 (40.0)	0	2 (40.0)
Blood creatinine increased	1 (20.0)	1 (20.0)	0
Blood fibrinogen decreased	1 (20.0)	0	1 (20.0)
Blood urea increased	1 (20.0)	1 (20.0)	0
Lymphocyte count decreased	1 (20.0)	0	1 (20.0)
Platelet count decreased	1 (20.0)	0	1 (20.0)
Protein total decreased	1 (20.0)	1 (20.0)	0
Metabolism and nutrition disorders			
-Total	2 (40.0)	2 (40.0)	0
Hypokalaemia	2 (40.0)	2 (40.0)	0
Acidosis	1 (20.0)	1 (20.0)	0
Renal and urinary disorders			
-Total	1 (20.0)	1 (20.0)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal impairment	1 (20.0)	1 (20.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (20.0)	0	1 (20.0)
Pleural effusion	1 (20.0)	1 (20.0)	0
Pulmonary oedema	1 (20.0)	1 (20.0)	0
Respiratory distress	1 (20.0)	0	1 (20.0)
Vascular disorders			
-Total	1 (20.0)	0	1 (20.0)
Capillary leak syndrome	1 (20.0)	0	1 (20.0)
Hypotension	1 (20.0)	0	1 (20.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189o
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (81.4)	13 (22.0)	35 (59.3)
Blood and lymphatic system disorders			
-Total	35 (59.3)	26 (44.1)	9 (15.3)
Febrile neutropenia	21 (35.6)	21 (35.6)	0
Anaemia	17 (28.8)	16 (27.1)	1 (1.7)
Neutropenia	8 (13.6)	3 (5.1)	5 (8.5)
Thrombocytopenia	8 (13.6)	2 (3.4)	6 (10.2)
Gastrointestinal disorders			
-Total	6 (10.2)	6 (10.2)	0
Nausea	3 (5.1)	3 (5.1)	0

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	3 (5.1)	3 (5.1)	0
General disorders and administration site conditions			
-Total	6 (10.2)	5 (8.5)	1 (1.7)
Pyrexia	6 (10.2)	5 (8.5)	1 (1.7)
Hepatobiliary disorders			
-Total	1 (1.7)	1 (1.7)	0
Hyperbilirubinaemia	1 (1.7)	1 (1.7)	0
Immune system disorders			
-Total	21 (35.6)	11 (18.6)	10 (16.9)
Cytokine release syndrome	18 (30.5)	8 (13.6)	10 (16.9)
Hypogammaglobulinaemia	4 (6.8)	4 (6.8)	0
Investigations			
-Total	38 (64.4)	11 (18.6)	27 (45.8)
White blood cell count decreased	24 (40.7)	10 (16.9)	14 (23.7)
Neutrophil count decreased	21 (35.6)	4 (6.8)	17 (28.8)

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	13 (22.0)	2 (3.4)	11 (18.6)
Lymphocyte count decreased	10 (16.9)	6 (10.2)	4 (6.8)
Alanine aminotransferase increased	9 (15.3)	9 (15.3)	0
Aspartate aminotransferase increased	9 (15.3)	6 (10.2)	3 (5.1)
Blood bilirubin increased	2 (3.4)	2 (3.4)	0
Blood fibrinogen decreased	2 (3.4)	2 (3.4)	0
Blood creatinine increased	1 (1.7)	1 (1.7)	0
Metabolism and nutrition disorders			
-Total	18 (30.5)	17 (28.8)	1 (1.7)
Decreased appetite	12 (20.3)	12 (20.3)	0
Hypophosphataemia	7 (11.9)	6 (10.2)	1 (1.7)
Hypokalaemia	5 (8.5)	5 (8.5)	0
Dehydration	2 (3.4)	2 (3.4)	0
Nervous system disorders			

Timing: within 8 weeks post infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.7)	1 (1.7)	0
Seizure	1 (1.7)	1 (1.7)	0
Renal and urinary disorders			
-Total	6 (10.2)	2 (3.4)	4 (6.8)
Acute kidney injury	5 (8.5)	2 (3.4)	3 (5.1)
Haematuria	2 (3.4)	1 (1.7)	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
-Total	10 (16.9)	4 (6.8)	6 (10.2)
Hypoxia	7 (11.9)	4 (6.8)	3 (5.1)
Epistaxis	4 (6.8)	3 (5.1)	1 (1.7)
Pulmonary oedema	4 (6.8)	2 (3.4)	2 (3.4)
Respiratory failure	3 (5.1)	0	3 (5.1)
Pleural effusion	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	14 (23.7)	7 (11.9)	7 (11.9)
Hypotension	14 (23.7)	7 (11.9)	7 (11.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189o
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (40.0)	1 (20.0)	1 (20.0)
Blood and lymphatic system disorders			
-Total	1 (20.0)	0	1 (20.0)
Leukopenia	1 (20.0)	0	1 (20.0)
Immune system disorders			
-Total	1 (20.0)	1 (20.0)	0
Hypogammaglobulinaemia	1 (20.0)	1 (20.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	1 (20.0)	1 (20.0)	0
Viral upper respiratory tract infection	1 (20.0)	1 (20.0)	0
Metabolism and nutrition disorders			
-Total	1 (20.0)	1 (20.0)	0
Iron overload	1 (20.0)	1 (20.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189o
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (37.3)	13 (25.5)	6 (11.8)
Blood and lymphatic system disorders			
-Total	6 (11.8)	3 (5.9)	3 (5.9)
Neutropenia	4 (7.8)	1 (2.0)	3 (5.9)
Febrile neutropenia	3 (5.9)	3 (5.9)	0
Anaemia	1 (2.0)	1 (2.0)	0
Thrombocytopenia	1 (2.0)	1 (2.0)	0
Gastrointestinal disorders			
-Total	2 (3.9)	2 (3.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (3.9)	2 (3.9)	0
Vomiting	2 (3.9)	2 (3.9)	0
General disorders and administration site conditions			
-Total	1 (2.0)	1 (2.0)	0
Pyrexia	1 (2.0)	1 (2.0)	0
Investigations			
-Total	12 (23.5)	8 (15.7)	4 (7.8)
Neutrophil count decreased	6 (11.8)	3 (5.9)	3 (5.9)
Alanine aminotransferase increased	2 (3.9)	2 (3.9)	0
Aspartate aminotransferase increased	2 (3.9)	2 (3.9)	0
White blood cell count decreased	2 (3.9)	1 (2.0)	1 (2.0)
Blood bilirubin increased	1 (2.0)	1 (2.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=51		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	2 (3.9)	1 (2.0)	1 (2.0)
Dehydration	1 (2.0)	1 (2.0)	0
Hypokalaemia	1 (2.0)	0	1 (2.0)
Hypophosphataemia	1 (2.0)	1 (2.0)	0
Renal and urinary disorders			
-Total	2 (3.9)	2 (3.9)	0
Acute kidney injury	1 (2.0)	1 (2.0)	0
Haematuria	1 (2.0)	1 (2.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.9)	2 (3.9)	0
Epistaxis	1 (2.0)	1 (2.0)	0
Pulmonary oedema	1 (2.0)	1 (2.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189o
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	2 (66.7)
Blood and lymphatic system disorders			
-Total	1 (33.3)	0	1 (33.3)
Febrile neutropenia	1 (33.3)	0	1 (33.3)
Infections and infestations			
-Total	1 (33.3)	1 (33.3)	0
Otitis media	1 (33.3)	1 (33.3)	0
Injury, poisoning and procedural complications			
-Total	1 (33.3)	1 (33.3)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural pain	1 (33.3)	1 (33.3)	0
Investigations			
-Total	1 (33.3)	1 (33.3)	0
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0
Platelet count decreased	1 (33.3)	1 (33.3)	0
White blood cell count decreased	1 (33.3)	1 (33.3)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (33.3)	0	1 (33.3)
Glioblastoma multiforme	1 (33.3)	0	1 (33.3)
Nervous system disorders			
-Total	1 (33.3)	1 (33.3)	0
Seizure	1 (33.3)	1 (33.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189o
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (16.1)	4 (12.9)	1 (3.2)
Investigations			
-Total	4 (12.9)	3 (9.7)	1 (3.2)
White blood cell count decreased	2 (6.5)	1 (3.2)	1 (3.2)
Alanine aminotransferase increased	1 (3.2)	1 (3.2)	0
Aspartate aminotransferase increased	1 (3.2)	1 (3.2)	0

Timing: >1 year post-CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (3.2)	1 (3.2)	0
Metabolism and nutrition disorders			
-Total	1 (3.2)	1 (3.2)	0
Hypokalaemia	1 (3.2)	1 (3.2)	0
Renal and urinary disorders			
-Total	1 (3.2)	1 (3.2)	0
Acute kidney injury	1 (3.2)	1 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189o
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (100)	0	5 (100)
Blood and lymphatic system disorders			
-Total	3 (60.0)	1 (20.0)	2 (40.0)
Anaemia	2 (40.0)	2 (40.0)	0
Febrile neutropenia	2 (40.0)	1 (20.0)	1 (20.0)
Leukopenia	1 (20.0)	0	1 (20.0)
Gastrointestinal disorders			
-Total	1 (20.0)	1 (20.0)	0
Dysphagia	1 (20.0)	1 (20.0)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (20.0)	1 (20.0)	0
Face oedema	1 (20.0)	1 (20.0)	0
Localised oedema	1 (20.0)	1 (20.0)	0
Multiple organ dysfunction syndrome	1 (20.0)	1 (20.0)	0
Oedema peripheral	1 (20.0)	1 (20.0)	0
Hepatobiliary disorders			
-Total	1 (20.0)	1 (20.0)	0
Hyperbilirubinaemia	1 (20.0)	1 (20.0)	0
Immune system disorders			
-Total	1 (20.0)	0	1 (20.0)
Cytokine release syndrome	1 (20.0)	0	1 (20.0)
Hypogammaglobulinaemia	1 (20.0)	1 (20.0)	0
Infections and infestations			
-Total	2 (40.0)	2 (40.0)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Otitis media	1 (20.0)	1 (20.0)	0
Viral upper respiratory tract infection	1 (20.0)	1 (20.0)	0
Injury, poisoning and procedural complications			
-Total	1 (20.0)	1 (20.0)	0
Procedural pain	1 (20.0)	1 (20.0)	0
Investigations			
-Total	4 (80.0)	0	4 (80.0)
Alanine aminotransferase increased	3 (60.0)	3 (60.0)	0
White blood cell count decreased	3 (60.0)	1 (20.0)	2 (40.0)
Aspartate aminotransferase increased	2 (40.0)	1 (20.0)	1 (20.0)
Neutrophil count decreased	2 (40.0)	0	2 (40.0)
Platelet count decreased	2 (40.0)	1 (20.0)	1 (20.0)
Blood creatinine increased	1 (20.0)	1 (20.0)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	1 (20.0)	0	1 (20.0)
Blood urea increased	1 (20.0)	1 (20.0)	0
Lymphocyte count decreased	1 (20.0)	0	1 (20.0)
Protein total decreased	1 (20.0)	1 (20.0)	0
Metabolism and nutrition disorders			
-Total	2 (40.0)	2 (40.0)	0
Hypokalaemia	2 (40.0)	2 (40.0)	0
Acidosis	1 (20.0)	1 (20.0)	0
Iron overload	1 (20.0)	1 (20.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (20.0)	0	1 (20.0)
Glioblastoma multiforme	1 (20.0)	0	1 (20.0)
Nervous system disorders			
-Total	1 (20.0)	1 (20.0)	0
Seizure	1 (20.0)	1 (20.0)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: Yes

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	1 (20.0)	1 (20.0)	0
Renal impairment	1 (20.0)	1 (20.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (20.0)	0	1 (20.0)
Pleural effusion	1 (20.0)	1 (20.0)	0
Pulmonary oedema	1 (20.0)	1 (20.0)	0
Respiratory distress	1 (20.0)	0	1 (20.0)
Vascular disorders			
-Total	1 (20.0)	0	1 (20.0)
Capillary leak syndrome	1 (20.0)	0	1 (20.0)
Hypotension	1 (20.0)	0	1 (20.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189o
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Safety Set

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

		All patients N=59	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	51 (86.4)	12 (20.3)	39 (66.1)
Blood and lymphatic system disorders			
-Total	39 (66.1)	27 (45.8)	12 (20.3)
Febrile neutropenia	22 (37.3)	22 (37.3)	0
Anaemia	18 (30.5)	17 (28.8)	1 (1.7)
Neutropenia	11 (18.6)	3 (5.1)	8 (13.6)
Thrombocytopenia	9 (15.3)	3 (5.1)	6 (10.2)
Gastrointestinal disorders			
-Total	6 (10.2)	6 (10.2)	0
Nausea	5 (8.5)	5 (8.5)	0

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	3 (5.1)	3 (5.1)	0
General disorders and administration site conditions			
-Total	7 (11.9)	6 (10.2)	1 (1.7)
Pyrexia	7 (11.9)	6 (10.2)	1 (1.7)
Hepatobiliary disorders			
-Total	1 (1.7)	1 (1.7)	0
Hyperbilirubinaemia	1 (1.7)	1 (1.7)	0
Immune system disorders			
-Total	21 (35.6)	11 (18.6)	10 (16.9)
Cytokine release syndrome	18 (30.5)	8 (13.6)	10 (16.9)
Hypogammaglobulinaemia	4 (6.8)	4 (6.8)	0
Investigations			
-Total	43 (72.9)	13 (22.0)	30 (50.8)
White blood cell count decreased	27 (45.8)	11 (18.6)	16 (27.1)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	23 (39.0)	4 (6.8)	19 (32.2)
Platelet count decreased	13 (22.0)	2 (3.4)	11 (18.6)
Alanine aminotransferase increased	11 (18.6)	11 (18.6)	0
Lymphocyte count decreased	11 (18.6)	7 (11.9)	4 (6.8)
Aspartate aminotransferase increased	10 (16.9)	7 (11.9)	3 (5.1)
Blood bilirubin increased	3 (5.1)	3 (5.1)	0
Blood fibrinogen decreased	2 (3.4)	2 (3.4)	0
Blood creatinine increased	1 (1.7)	1 (1.7)	0
Metabolism and nutrition disorders			
-Total	21 (35.6)	19 (32.2)	2 (3.4)
Decreased appetite	12 (20.3)	12 (20.3)	0
Hypophosphataemia	8 (13.6)	7 (11.9)	1 (1.7)
Hypokalaemia	7 (11.9)	6 (10.2)	1 (1.7)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	3 (5.1)	3 (5.1)	0
Nervous system disorders			
-Total	1 (1.7)	1 (1.7)	0
Seizure	1 (1.7)	1 (1.7)	0
Renal and urinary disorders			
-Total	9 (15.3)	5 (8.5)	4 (6.8)
Acute kidney injury	7 (11.9)	4 (6.8)	3 (5.1)
Haematuria	3 (5.1)	2 (3.4)	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
-Total	12 (20.3)	6 (10.2)	6 (10.2)
Hypoxia	7 (11.9)	4 (6.8)	3 (5.1)
Epistaxis	5 (8.5)	4 (6.8)	1 (1.7)
Pulmonary oedema	5 (8.5)	3 (5.1)	2 (3.4)
Respiratory failure	3 (5.1)	0	3 (5.1)
Pleural effusion	1 (1.7)	1 (1.7)	0
Vascular disorders			
-Total	14 (23.7)	7 (11.9)	7 (11.9)

Timing: Any time post CTL019 infusion, Baseline extramedullary disease presence: No

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	14 (23.7)	7 (11.9)	7 (11.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189p
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: Yes

		All patients N=4	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Febrile neutropenia	2 (50.0)	2 (50.0)	0
Neutropenia	1 (25.0)	0	1 (25.0)
Investigations			
-Total	2 (50.0)	0	2 (50.0)
Lymphocyte count decreased	1 (25.0)	0	1 (25.0)
Neutrophil count decreased	1 (25.0)	0	1 (25.0)
White blood cell count decreased	1 (25.0)	0	1 (25.0)

Timing: within 8 weeks post infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	1 (25.0)	1 (25.0)	0
Hypotension	1 (25.0)	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189p
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: within 8 weeks post infusion, Down syndrome: No

		All patients N=60	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	49 (81.7)	12 (20.0)	37 (61.7)
Blood and lymphatic system disorders			
-Total	34 (56.7)	26 (43.3)	8 (13.3)
Febrile neutropenia	20 (33.3)	20 (33.3)	0
Anaemia	19 (31.7)	18 (30.0)	1 (1.7)
Thrombocytopenia	8 (13.3)	2 (3.3)	6 (10.0)
Neutropenia	7 (11.7)	3 (5.0)	4 (6.7)
Gastrointestinal disorders			
-Total	6 (10.0)	6 (10.0)	0
Nausea	3 (5.0)	3 (5.0)	0

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	3 (5.0)	3 (5.0)	0
General disorders and administration site conditions			
-Total	6 (10.0)	5 (8.3)	1 (1.7)
Pyrexia	6 (10.0)	5 (8.3)	1 (1.7)
Immune system disorders			
-Total	22 (36.7)	11 (18.3)	11 (18.3)
Cytokine release syndrome	19 (31.7)	8 (13.3)	11 (18.3)
Hypogammaglobulinaemia	4 (6.7)	4 (6.7)	0
Investigations			
-Total	40 (66.7)	11 (18.3)	29 (48.3)
White blood cell count decreased	25 (41.7)	10 (16.7)	15 (25.0)
Neutrophil count decreased	22 (36.7)	4 (6.7)	18 (30.0)
Platelet count decreased	14 (23.3)	2 (3.3)	12 (20.0)
Alanine aminotransferase increased	11 (18.3)	11 (18.3)	0
Aspartate aminotransferase increased	11 (18.3)	7 (11.7)	4 (6.7)
Lymphocyte count decreased	10 (16.7)	6 (10.0)	4 (6.7)

Timing: within 8 weeks post infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood fibrinogen decreased	3 (5.0)	2 (3.3)	1 (1.7)
Blood bilirubin increased	2 (3.3)	2 (3.3)	0
Metabolism and nutrition disorders			
-Total	20 (33.3)	19 (31.7)	1 (1.7)
Decreased appetite	12 (20.0)	12 (20.0)	0
Hypokalaemia	7 (11.7)	7 (11.7)	0
Hypophosphataemia	7 (11.7)	6 (10.0)	1 (1.7)
Dehydration	2 (3.3)	2 (3.3)	0
Renal and urinary disorders			
-Total	6 (10.0)	2 (3.3)	4 (6.7)
Acute kidney injury	5 (8.3)	2 (3.3)	3 (5.0)
Haematuria	2 (3.3)	1 (1.7)	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
-Total	11 (18.3)	5 (8.3)	6 (10.0)
Hypoxia	7 (11.7)	4 (6.7)	3 (5.0)
Pulmonary oedema	5 (8.3)	3 (5.0)	2 (3.3)
Epistaxis	4 (6.7)	3 (5.0)	1 (1.7)

Timing: within 8 weeks post infusion, Down syndrome: No

Group term Preferred term	All patients N=60 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory failure	3 (5.0)	0	3 (5.0)
Vascular disorders			
-Total	14 (23.3)	6 (10.0)	8 (13.3)
Hypotension	14 (23.3)	6 (10.0)	8 (13.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189p
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

		All patients N=4	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	2 (50.0)	0
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Enterocolitis	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
-Total	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	1 (25.0)	1 (25.0)	0
Corona virus infection	1 (25.0)	1 (25.0)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory syncytial virus infection	1 (25.0)	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189p
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (36.5)	13 (25.0)	6 (11.5)
Blood and lymphatic system disorders			
-Total	6 (11.5)	3 (5.8)	3 (5.8)
Neutropenia	4 (7.7)	1 (1.9)	3 (5.8)
Febrile neutropenia	3 (5.8)	3 (5.8)	0
Anaemia	1 (1.9)	1 (1.9)	0
Thrombocytopenia	1 (1.9)	1 (1.9)	0
Gastrointestinal disorders			
-Total	2 (3.8)	2 (3.8)	0
Nausea	2 (3.8)	2 (3.8)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	2 (3.8)	2 (3.8)	0
Immune system disorders			
-Total	1 (1.9)	1 (1.9)	0
Hypogammaglobulinaemia	1 (1.9)	1 (1.9)	0
Investigations			
-Total	12 (23.1)	8 (15.4)	4 (7.7)
Neutrophil count decreased	6 (11.5)	3 (5.8)	3 (5.8)
Alanine aminotransferase increased	2 (3.8)	2 (3.8)	0
Aspartate aminotransferase increased	2 (3.8)	2 (3.8)	0
White blood cell count decreased	2 (3.8)	1 (1.9)	1 (1.9)
Blood bilirubin increased	1 (1.9)	1 (1.9)	0
Metabolism and nutrition disorders			
-Total	2 (3.8)	1 (1.9)	1 (1.9)
Dehydration	1 (1.9)	1 (1.9)	0
Hypokalaemia	1 (1.9)	0	1 (1.9)
Hypophosphataemia	1 (1.9)	1 (1.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Down syndrome: No

	All patients N=52		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Renal and urinary disorders			
-Total	2 (3.8)	2 (3.8)	0
Acute kidney injury	1 (1.9)	1 (1.9)	0
Haematuria	1 (1.9)	1 (1.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.8)	2 (3.8)	0
Epistaxis	1 (1.9)	1 (1.9)	0
Pulmonary oedema	1 (1.9)	1 (1.9)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189p
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: >1 year post-CTL019 infusion, Down syndrome: No

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (19.4)	4 (12.9)	2 (6.5)
Blood and lymphatic system disorders			
-Total	1 (3.2)	0	1 (3.2)
Febrile neutropenia	1 (3.2)	0	1 (3.2)
Investigations			
-Total	5 (16.1)	4 (12.9)	1 (3.2)
White blood cell count decreased	3 (9.7)	2 (6.5)	1 (3.2)
Alanine aminotransferase increased	2 (6.5)	2 (6.5)	0

Timing: >1 year post-CTL019 infusion, Down syndrome: No

	All patients N=31		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	1 (3.2)	1 (3.2)	0
Lymphocyte count decreased	1 (3.2)	1 (3.2)	0
Platelet count decreased	1 (3.2)	1 (3.2)	0
Metabolism and nutrition disorders			
-Total	1 (3.2)	1 (3.2)	0
Hypokalaemia	1 (3.2)	1 (3.2)	0
Renal and urinary disorders			
-Total	1 (3.2)	1 (3.2)	0
Acute kidney injury	1 (3.2)	1 (3.2)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189p
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Febrile neutropenia	2 (50.0)	2 (50.0)	0
Neutropenia	1 (25.0)	0	1 (25.0)
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Enterocolitis	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			

Timing: Any time post CTL019 infusion, Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	1 (25.0)	1 (25.0)	0
Corona virus infection	1 (25.0)	1 (25.0)	0
Respiratory syncytial virus infection	1 (25.0)	1 (25.0)	0
Investigations			
-Total	2 (50.0)	0	2 (50.0)
Lymphocyte count decreased	1 (25.0)	0	1 (25.0)
Neutrophil count decreased	1 (25.0)	0	1 (25.0)
White blood cell count decreased	1 (25.0)	0	1 (25.0)
Vascular disorders			
-Total	1 (25.0)	1 (25.0)	0
Hypotension	1 (25.0)	1 (25.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the

All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189p
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Safety Set

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	52 (86.7)	11 (18.3)	41 (68.3)
Blood and lymphatic system disorders			
-Total	38 (63.3)	26 (43.3)	12 (20.0)
Febrile neutropenia	22 (36.7)	21 (35.0)	1 (1.7)
Anaemia	20 (33.3)	19 (31.7)	1 (1.7)
Neutropenia	10 (16.7)	3 (5.0)	7 (11.7)
Thrombocytopenia	9 (15.0)	3 (5.0)	6 (10.0)
Gastrointestinal disorders			
-Total	6 (10.0)	6 (10.0)	0
Nausea	5 (8.3)	5 (8.3)	0

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	3 (5.0)	3 (5.0)	0
General disorders and administration site conditions			
-Total	6 (10.0)	5 (8.3)	1 (1.7)
Pyrexia	6 (10.0)	5 (8.3)	1 (1.7)
Immune system disorders			
-Total	22 (36.7)	11 (18.3)	11 (18.3)
Cytokine release syndrome	19 (31.7)	8 (13.3)	11 (18.3)
Hypogammaglobulinaemia	5 (8.3)	5 (8.3)	0
Investigations			
-Total	45 (75.0)	13 (21.7)	32 (53.3)
White blood cell count decreased	29 (48.3)	12 (20.0)	17 (28.3)
Neutrophil count decreased	24 (40.0)	4 (6.7)	20 (33.3)
Platelet count decreased	15 (25.0)	3 (5.0)	12 (20.0)
Alanine aminotransferase increased	14 (23.3)	14 (23.3)	0
Aspartate aminotransferase increased	12 (20.0)	8 (13.3)	4 (6.7)
Lymphocyte count decreased	11 (18.3)	7 (11.7)	4 (6.7)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	3 (5.0)	3 (5.0)	0
Blood fibrinogen decreased	3 (5.0)	2 (3.3)	1 (1.7)
Metabolism and nutrition disorders			
-Total	23 (38.3)	21 (35.0)	2 (3.3)
Decreased appetite	12 (20.0)	12 (20.0)	0
Hypokalaemia	9 (15.0)	8 (13.3)	1 (1.7)
Hypophosphataemia	8 (13.3)	7 (11.7)	1 (1.7)
Dehydration	3 (5.0)	3 (5.0)	0
Renal and urinary disorders			
-Total	9 (15.0)	5 (8.3)	4 (6.7)
Acute kidney injury	7 (11.7)	4 (6.7)	3 (5.0)
Haematuria	3 (5.0)	2 (3.3)	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
-Total	13 (21.7)	7 (11.7)	6 (10.0)
Hypoxia	7 (11.7)	4 (6.7)	3 (5.0)
Pulmonary oedema	6 (10.0)	4 (6.7)	2 (3.3)
Epistaxis	5 (8.3)	4 (6.7)	1 (1.7)

Timing: Any time post CTL019 infusion, Down syndrome: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	3 (5.0)	0	3 (5.0)
Vascular disorders			
-Total	14 (23.3)	6 (10.0)	8 (13.3)
Hypotension	14 (23.3)	6 (10.0)	8 (13.3)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189q
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (87.5)	7 (21.9)	21 (65.6)
Blood and lymphatic system disorders			
-Total	18 (56.3)	16 (50.0)	2 (6.3)
Febrile neutropenia	10 (31.3)	10 (31.3)	0
Anaemia	9 (28.1)	9 (28.1)	0
Disseminated intravascular coagulation	2 (6.3)	2 (6.3)	0
Neutropenia	2 (6.3)	1 (3.1)	1 (3.1)
Thrombocytopenia	1 (3.1)	0	1 (3.1)
Gastrointestinal disorders			
-Total	5 (15.6)	5 (15.6)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	3 (9.4)	3 (9.4)	0
Diarrhoea	1 (3.1)	1 (3.1)	0
Nausea	1 (3.1)	1 (3.1)	0
General disorders and administration site conditions			
-Total	4 (12.5)	4 (12.5)	0
Pyrexia	4 (12.5)	4 (12.5)	0
Immune system disorders			
-Total	10 (31.3)	5 (15.6)	5 (15.6)
Cytokine release syndrome	7 (21.9)	2 (6.3)	5 (15.6)
Hypogammaglobulinaemia	3 (9.4)	3 (9.4)	0
Investigations			
-Total	24 (75.0)	5 (15.6)	19 (59.4)
White blood cell count decreased	17 (53.1)	7 (21.9)	10 (31.3)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	14 (43.8)	3 (9.4)	11 (34.4)
Platelet count decreased	9 (28.1)	1 (3.1)	8 (25.0)
Lymphocyte count decreased	6 (18.8)	3 (9.4)	3 (9.4)
Aspartate aminotransferase increased	5 (15.6)	4 (12.5)	1 (3.1)
Alanine aminotransferase increased	4 (12.5)	4 (12.5)	0
Blood bilirubin increased	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			
-Total	7 (21.9)	7 (21.9)	0
Hypokalaemia	4 (12.5)	4 (12.5)	0
Decreased appetite	3 (9.4)	3 (9.4)	0
Hypophosphataemia	3 (9.4)	3 (9.4)	0
Dehydration	1 (3.1)	1 (3.1)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	3 (9.4)	3 (9.4)	0
Epistaxis	2 (6.3)	2 (6.3)	0
Hypoxia	2 (6.3)	2 (6.3)	0
Vascular disorders			
-Total	4 (12.5)	3 (9.4)	1 (3.1)
Hypotension	4 (12.5)	3 (9.4)	1 (3.1)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189q
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (75.0)	6 (18.8)	18 (56.3)
Blood and lymphatic system disorders			
-Total	19 (59.4)	12 (37.5)	7 (21.9)
Febrile neutropenia	12 (37.5)	12 (37.5)	0
Anaemia	10 (31.3)	9 (28.1)	1 (3.1)
Thrombocytopenia	7 (21.9)	2 (6.3)	5 (15.6)
Neutropenia	6 (18.8)	2 (6.3)	4 (12.5)
Cardiac disorders			
-Total	2 (6.3)	2 (6.3)	0
Tachycardia	2 (6.3)	2 (6.3)	0

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	2 (6.3)	2 (6.3)	0
Nausea	2 (6.3)	2 (6.3)	0
General disorders and administration site conditions			
-Total	2 (6.3)	1 (3.1)	1 (3.1)
Pyrexia	2 (6.3)	1 (3.1)	1 (3.1)
Hepatobiliary disorders			
-Total	2 (6.3)	2 (6.3)	0
Hyperbilirubinaemia	2 (6.3)	2 (6.3)	0
Immune system disorders			
-Total	12 (37.5)	6 (18.8)	6 (18.8)
Cytokine release syndrome	12 (37.5)	6 (18.8)	6 (18.8)
Hypogammaglobulinaemia	1 (3.1)	1 (3.1)	0
Investigations			
-Total	18 (56.3)	6 (18.8)	12 (37.5)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	9 (28.1)	1 (3.1)	8 (25.0)
White blood cell count decreased	9 (28.1)	3 (9.4)	6 (18.8)
Alanine aminotransferase increased	7 (21.9)	7 (21.9)	0
Aspartate aminotransferase increased	6 (18.8)	3 (9.4)	3 (9.4)
Lymphocyte count decreased	5 (15.6)	3 (9.4)	2 (6.3)
Platelet count decreased	5 (15.6)	1 (3.1)	4 (12.5)
Blood fibrinogen decreased	3 (9.4)	2 (6.3)	1 (3.1)
Blood creatinine increased	2 (6.3)	2 (6.3)	0
Blood bilirubin increased	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			
-Total	14 (43.8)	13 (40.6)	1 (3.1)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	9 (28.1)	9 (28.1)	0
Hypophosphataemia	4 (12.5)	3 (9.4)	1 (3.1)
Hypokalaemia	3 (9.4)	3 (9.4)	0
Dehydration	1 (3.1)	1 (3.1)	0
Tumour lysis syndrome	1 (3.1)	1 (3.1)	0
Renal and urinary disorders			
-Total	6 (18.8)	2 (6.3)	4 (12.5)
Acute kidney injury	5 (15.6)	2 (6.3)	3 (9.4)
Haematuria	2 (6.3)	1 (3.1)	1 (3.1)
Oliguria	2 (6.3)	2 (6.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	8 (25.0)	2 (6.3)	6 (18.8)
Hypoxia	5 (15.6)	2 (6.3)	3 (9.4)
Pulmonary oedema	5 (15.6)	3 (9.4)	2 (6.3)
Respiratory failure	3 (9.4)	0	3 (9.4)
Dyspnoea	2 (6.3)	1 (3.1)	1 (3.1)
Epistaxis	2 (6.3)	1 (3.1)	1 (3.1)

Timing: within 8 weeks post infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	2 (6.3)	2 (6.3)	0
Vascular disorders			
-Total	11 (34.4)	4 (12.5)	7 (21.9)
Hypotension	11 (34.4)	4 (12.5)	7 (21.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189q
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (37.9)	9 (31.0)	2 (6.9)
Blood and lymphatic system disorders			
-Total	2 (6.9)	1 (3.4)	1 (3.4)
Anaemia	1 (3.4)	1 (3.4)	0
Febrile neutropenia	1 (3.4)	1 (3.4)	0
Neutropenia	1 (3.4)	0	1 (3.4)
Gastrointestinal disorders			
-Total	2 (6.9)	2 (6.9)	0
Nausea	2 (6.9)	2 (6.9)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	2 (6.9)	2 (6.9)	0
Diarrhoea	1 (3.4)	1 (3.4)	0
General disorders and administration site conditions			
-Total	1 (3.4)	1 (3.4)	0
Pyrexia	1 (3.4)	1 (3.4)	0
Investigations			
-Total	6 (20.7)	5 (17.2)	1 (3.4)
Neutrophil count decreased	2 (6.9)	2 (6.9)	0
White blood cell count decreased	2 (6.9)	1 (3.4)	1 (3.4)
Aspartate aminotransferase increased	1 (3.4)	1 (3.4)	0
Blood bilirubin increased	1 (3.4)	1 (3.4)	0
Metabolism and nutrition disorders			
-Total	2 (6.9)	1 (3.4)	1 (3.4)

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (3.4)	1 (3.4)	0
Hypokalaemia	1 (3.4)	0	1 (3.4)
Hypophosphataemia	1 (3.4)	1 (3.4)	0
Renal and urinary disorders			
-Total	2 (6.9)	2 (6.9)	0
Acute kidney injury	1 (3.4)	1 (3.4)	0
Haematuria	1 (3.4)	1 (3.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.4)	1 (3.4)	0
Epistaxis	1 (3.4)	1 (3.4)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189q
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (37.0)	6 (22.2)	4 (14.8)
Blood and lymphatic system disorders			
-Total	4 (14.8)	2 (7.4)	2 (7.4)
Neutropenia	3 (11.1)	1 (3.7)	2 (7.4)
Febrile neutropenia	2 (7.4)	2 (7.4)	0
Thrombocytopenia	1 (3.7)	1 (3.7)	0
Immune system disorders			
-Total	1 (3.7)	1 (3.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	1 (3.7)	1 (3.7)	0
Investigations			
-Total	6 (22.2)	3 (11.1)	3 (11.1)
Neutrophil count decreased	4 (14.8)	1 (3.7)	3 (11.1)
Alanine aminotransferase increased	2 (7.4)	2 (7.4)	0
Aspartate aminotransferase increased	1 (3.7)	1 (3.7)	0
Metabolism and nutrition disorders			
-Total	1 (3.7)	1 (3.7)	0
Tumour lysis syndrome	1 (3.7)	1 (3.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.7)	1 (3.7)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=27		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pulmonary oedema	1 (3.7)	1 (3.7)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189q
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (22.2)	2 (11.1)	2 (11.1)
Blood and lymphatic system disorders			
-Total	1 (5.6)	0	1 (5.6)
Febrile neutropenia	1 (5.6)	0	1 (5.6)
Investigations			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
White blood cell count decreased	2 (11.1)	1 (5.6)	1 (5.6)
Alanine aminotransferase increased	1 (5.6)	1 (5.6)	0

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (5.6)	1 (5.6)	0
Platelet count decreased	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	1 (5.6)	1 (5.6)	0
Hypokalaemia	1 (5.6)	1 (5.6)	0
Renal and urinary disorders			
-Total	1 (5.6)	1 (5.6)	0
Acute kidney injury	1 (5.6)	1 (5.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189q
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: >1 year post-CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (12.5)	2 (12.5)	0
Investigations			
-Total	2 (12.5)	2 (12.5)	0
Alanine aminotransferase increased	1 (6.3)	1 (6.3)	0
Aspartate aminotransferase increased	1 (6.3)	1 (6.3)	0
White blood cell count decreased	1 (6.3)	1 (6.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189q
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	29 (90.6)	7 (21.9)	22 (68.8)
Blood and lymphatic system disorders			
-Total	20 (62.5)	16 (50.0)	4 (12.5)
Febrile neutropenia	12 (37.5)	11 (34.4)	1 (3.1)
Anaemia	10 (31.3)	10 (31.3)	0
Neutropenia	3 (9.4)	1 (3.1)	2 (6.3)
Disseminated intravascular coagulation	2 (6.3)	2 (6.3)	0
Thrombocytopenia	1 (3.1)	0	1 (3.1)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	5 (15.6)	5 (15.6)	0
Nausea	3 (9.4)	3 (9.4)	0
Vomiting	3 (9.4)	3 (9.4)	0
Diarrhoea	2 (6.3)	2 (6.3)	0
General disorders and administration site conditions			
-Total	5 (15.6)	5 (15.6)	0
Pyrexia	5 (15.6)	5 (15.6)	0
Immune system disorders			
-Total	10 (31.3)	5 (15.6)	5 (15.6)
Cytokine release syndrome	7 (21.9)	2 (6.3)	5 (15.6)
Hypogammaglobulinaemia	3 (9.4)	3 (9.4)	0
Investigations			
-Total	27 (84.4)	7 (21.9)	20 (62.5)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	20 (62.5)	8 (25.0)	12 (37.5)
Neutrophil count decreased	14 (43.8)	3 (9.4)	11 (34.4)
Platelet count decreased	10 (31.3)	2 (6.3)	8 (25.0)
Lymphocyte count decreased	7 (21.9)	4 (12.5)	3 (9.4)
Alanine aminotransferase increased	5 (15.6)	5 (15.6)	0
Aspartate aminotransferase increased	5 (15.6)	4 (12.5)	1 (3.1)
Blood bilirubin increased	2 (6.3)	2 (6.3)	0
Metabolism and nutrition disorders			
-Total	10 (31.3)	9 (28.1)	1 (3.1)
Hypokalaemia	6 (18.8)	5 (15.6)	1 (3.1)
Hypophosphataemia	4 (12.5)	4 (12.5)	0
Decreased appetite	3 (9.4)	3 (9.4)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	2 (6.3)	2 (6.3)	0
Renal and urinary disorders			
-Total	3 (9.4)	3 (9.4)	0
Acute kidney injury	2 (6.3)	2 (6.3)	0
Haematuria	1 (3.1)	1 (3.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (12.5)	4 (12.5)	0
Epistaxis	3 (9.4)	3 (9.4)	0
Hypoxia	2 (6.3)	2 (6.3)	0
Vascular disorders			
-Total	4 (12.5)	3 (9.4)	1 (3.1)
Hypotension	4 (12.5)	3 (9.4)	1 (3.1)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189q
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Safety Set

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	26 (81.3)	5 (15.6)	21 (65.6)
Blood and lymphatic system disorders			
-Total	21 (65.6)	12 (37.5)	9 (28.1)
Febrile neutropenia	12 (37.5)	12 (37.5)	0
Anaemia	10 (31.3)	9 (28.1)	1 (3.1)
Neutropenia	8 (25.0)	2 (6.3)	6 (18.8)
Thrombocytopenia	8 (25.0)	3 (9.4)	5 (15.6)
Cardiac disorders			
-Total	2 (6.3)	2 (6.3)	0
Tachycardia	2 (6.3)	2 (6.3)	0

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	2 (6.3)	2 (6.3)	0
Nausea	2 (6.3)	2 (6.3)	0
General disorders and administration site conditions			
-Total	2 (6.3)	1 (3.1)	1 (3.1)
Pyrexia	2 (6.3)	1 (3.1)	1 (3.1)
Hepatobiliary disorders			
-Total	2 (6.3)	2 (6.3)	0
Hyperbilirubinaemia	2 (6.3)	2 (6.3)	0
Immune system disorders			
-Total	12 (37.5)	6 (18.8)	6 (18.8)
Cytokine release syndrome	12 (37.5)	6 (18.8)	6 (18.8)
Hypogammaglobulinaemia	2 (6.3)	2 (6.3)	0
Investigations			

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	20 (62.5)	6 (18.8)	14 (43.8)
Neutrophil count decreased	11 (34.4)	1 (3.1)	10 (31.3)
White blood cell count decreased	10 (31.3)	4 (12.5)	6 (18.8)
Alanine aminotransferase increased	9 (28.1)	9 (28.1)	0
Aspartate aminotransferase increased	7 (21.9)	4 (12.5)	3 (9.4)
Lymphocyte count decreased	5 (15.6)	3 (9.4)	2 (6.3)
Platelet count decreased	5 (15.6)	1 (3.1)	4 (12.5)
Blood fibrinogen decreased	3 (9.4)	2 (6.3)	1 (3.1)
Blood creatinine increased	2 (6.3)	2 (6.3)	0
Blood bilirubin increased	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	14 (43.8)	13 (40.6)	1 (3.1)
Decreased appetite	9 (28.1)	9 (28.1)	0
Hypophosphataemia	4 (12.5)	3 (9.4)	1 (3.1)
Hypokalaemia	3 (9.4)	3 (9.4)	0
Tumour lysis syndrome	2 (6.3)	2 (6.3)	0
Dehydration	1 (3.1)	1 (3.1)	0
Renal and urinary disorders			
-Total	6 (18.8)	2 (6.3)	4 (12.5)
Acute kidney injury	5 (15.6)	2 (6.3)	3 (9.4)
Haematuria	2 (6.3)	1 (3.1)	1 (3.1)
Oliguria	2 (6.3)	2 (6.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	9 (28.1)	3 (9.4)	6 (18.8)
Pulmonary oedema	6 (18.8)	4 (12.5)	2 (6.3)
Hypoxia	5 (15.6)	2 (6.3)	3 (9.4)
Respiratory failure	3 (9.4)	0	3 (9.4)
Dyspnoea	2 (6.3)	1 (3.1)	1 (3.1)

Timing: Any time post CTL019 infusion, Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	2 (6.3)	1 (3.1)	1 (3.1)
Pleural effusion	2 (6.3)	2 (6.3)	0
Vascular disorders			
-Total	11 (34.4)	4 (12.5)	7 (21.9)
Hypotension	11 (34.4)	4 (12.5)	7 (21.9)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 0

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	6 (85.7)
Blood and lymphatic system disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Anaemia	2 (28.6)	1 (14.3)	1 (14.3)
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Neutropenia	2 (28.6)	0	2 (28.6)
Thrombocytopenia	2 (28.6)	1 (14.3)	1 (14.3)
Cardiac disorders			
-Total	1 (14.3)	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	1 (14.3)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	1 (14.3)	1 (14.3)	0
Nausea	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Pyrexia	2 (28.6)	1 (14.3)	1 (14.3)
Pain	1 (14.3)	1 (14.3)	0
Immune system disorders			
-Total	3 (42.9)	0	3 (42.9)
Cytokine release syndrome	3 (42.9)	0	3 (42.9)
Injury, poisoning and procedural complications			
-Total	1 (14.3)	1 (14.3)	0
Tracheal haemorrhage	1 (14.3)	1 (14.3)	0
Investigations			
-Total	5 (71.4)	1 (14.3)	4 (57.1)
Neutrophil count decreased	3 (42.9)	0	3 (42.9)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	3 (42.9)	1 (14.3)	2 (28.6)
Aspartate aminotransferase increased	1 (14.3)	0	1 (14.3)
Blood magnesium decreased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	1 (14.3)	1 (14.3)	0
Decreased appetite	1 (14.3)	1 (14.3)	0
Hypophosphataemia	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (14.3)	1 (14.3)	0
Arthralgia	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	2 (28.6)	0	2 (28.6)
Haematuria	2 (28.6)	1 (14.3)	1 (14.3)
Acute kidney injury	1 (14.3)	0	1 (14.3)
Oliguria	1 (14.3)	1 (14.3)	0
Renal failure	1 (14.3)	0	1 (14.3)

Timing: within 8 weeks post infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	2 (28.6)	0	2 (28.6)
Hypoxia	2 (28.6)	1 (14.3)	1 (14.3)
Dyspnoea	1 (14.3)	0	1 (14.3)
Epistaxis	1 (14.3)	0	1 (14.3)
Haemoptysis	1 (14.3)	0	1 (14.3)
Interstitial lung disease	1 (14.3)	0	1 (14.3)
Pulmonary oedema	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)
Vascular disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Hypotension	4 (57.1)	2 (28.6)	2 (28.6)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 1

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (85.0)	5 (25.0)	12 (60.0)
Blood and lymphatic system disorders			
-Total	12 (60.0)	10 (50.0)	2 (10.0)
Febrile neutropenia	9 (45.0)	9 (45.0)	0
Anaemia	6 (30.0)	6 (30.0)	0
Disseminated intravascular coagulation	2 (10.0)	2 (10.0)	0
Neutropenia	2 (10.0)	1 (5.0)	1 (5.0)
Lymphopenia	1 (5.0)	0	1 (5.0)
Gastrointestinal disorders			
-Total	5 (25.0)	5 (25.0)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Diarrhoea	1 (5.0)	1 (5.0)	0
Dysphagia	1 (5.0)	1 (5.0)	0
Ileus	1 (5.0)	1 (5.0)	0
Nausea	1 (5.0)	1 (5.0)	0
Vomiting	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	5 (25.0)	5 (25.0)	0
Pyrexia	3 (15.0)	3 (15.0)	0
Face oedema	1 (5.0)	1 (5.0)	0
Localised oedema	1 (5.0)	1 (5.0)	0
Multiple organ dysfunction syndrome	1 (5.0)	1 (5.0)	0
Oedema peripheral	1 (5.0)	1 (5.0)	0
Physical deconditioning	1 (5.0)	1 (5.0)	0
Hepatobiliary disorders			
-Total	1 (5.0)	1 (5.0)	0
Hyperbilirubinaemia	1 (5.0)	1 (5.0)	0
Immune system disorders			

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (40.0)	3 (15.0)	5 (25.0)
Cytokine release syndrome	7 (35.0)	2 (10.0)	5 (25.0)
Hypogammaglobulinaemia	1 (5.0)	1 (5.0)	0
Infections and infestations			
-Total	4 (20.0)	4 (20.0)	0
Clostridium difficile colitis	1 (5.0)	1 (5.0)	0
Gastroenteritis	1 (5.0)	1 (5.0)	0
Pneumonia	1 (5.0)	1 (5.0)	0
Staphylococcal infection	1 (5.0)	1 (5.0)	0
Injury, poisoning and procedural complications			
-Total	1 (5.0)	0	1 (5.0)
Transfusion related complication	1 (5.0)	0	1 (5.0)
Investigations			
-Total	15 (75.0)	4 (20.0)	11 (55.0)
Neutrophil count decreased	8 (40.0)	2 (10.0)	6 (30.0)
White blood cell count decreased	8 (40.0)	4 (20.0)	4 (20.0)
Platelet count decreased	7 (35.0)	1 (5.0)	6 (30.0)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	6 (30.0)	3 (15.0)	3 (15.0)
Alanine aminotransferase increased	4 (20.0)	4 (20.0)	0
Aspartate aminotransferase increased	4 (20.0)	3 (15.0)	1 (5.0)
Blood creatinine increased	1 (5.0)	1 (5.0)	0
Blood fibrinogen decreased	1 (5.0)	0	1 (5.0)
Blood urea increased	1 (5.0)	1 (5.0)	0
Haemoglobin decreased	1 (5.0)	1 (5.0)	0
Lipase increased	1 (5.0)	0	1 (5.0)
Protein total decreased	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	9 (45.0)	7 (35.0)	2 (10.0)
Decreased appetite	3 (15.0)	3 (15.0)	0
Hypokalaemia	3 (15.0)	3 (15.0)	0
Acidosis	1 (5.0)	1 (5.0)	0
Dehydration	1 (5.0)	1 (5.0)	0
Hypernatraemia	1 (5.0)	0	1 (5.0)
Hypertriglyceridaemia	1 (5.0)	1 (5.0)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperuricaemia	1 (5.0)	0	1 (5.0)
Hypophosphataemia	1 (5.0)	1 (5.0)	0
Tumour lysis syndrome	1 (5.0)	1 (5.0)	0
Nervous system disorders			
-Total	1 (5.0)	1 (5.0)	0
Encephalopathy	1 (5.0)	1 (5.0)	0
Renal and urinary disorders			
-Total	2 (10.0)	2 (10.0)	0
Acute kidney injury	1 (5.0)	1 (5.0)	0
Renal impairment	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (25.0)	3 (15.0)	2 (10.0)
Epistaxis	2 (10.0)	2 (10.0)	0
Hypoxia	2 (10.0)	2 (10.0)	0
Pulmonary oedema	2 (10.0)	1 (5.0)	1 (5.0)
Pleural effusion	1 (5.0)	1 (5.0)	0
Respiratory distress	1 (5.0)	0	1 (5.0)
Respiratory failure	1 (5.0)	0	1 (5.0)

Timing: within 8 weeks post infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Skin and subcutaneous tissue disorders			
-Total	1 (5.0)	1 (5.0)	0
Ecchymosis	1 (5.0)	1 (5.0)	0
Vascular disorders			
-Total	4 (20.0)	1 (5.0)	3 (15.0)
Hypotension	4 (20.0)	1 (5.0)	3 (15.0)
Capillary leak syndrome	1 (5.0)	0	1 (5.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: 2

		All patients N=21	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (90.5)	7 (33.3)	12 (57.1)
Blood and lymphatic system disorders			
-Total	13 (61.9)	9 (42.9)	4 (19.0)
Febrile neutropenia	8 (38.1)	8 (38.1)	0
Anaemia	5 (23.8)	5 (23.8)	0
Thrombocytopenia	4 (19.0)	0	4 (19.0)
Neutropenia	3 (14.3)	2 (9.5)	1 (4.8)
Lymphopenia	1 (4.8)	1 (4.8)	0
Gastrointestinal disorders			
-Total	3 (14.3)	3 (14.3)	0

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	2 (9.5)	2 (9.5)	0
Nausea	1 (4.8)	1 (4.8)	0
Immune system disorders			
-Total	7 (33.3)	6 (28.6)	1 (4.8)
Cytokine release syndrome	5 (23.8)	4 (19.0)	1 (4.8)
Hypogammaglobulinaemia	3 (14.3)	3 (14.3)	0
Investigations			
-Total	15 (71.4)	7 (33.3)	8 (38.1)
White blood cell count decreased	10 (47.6)	3 (14.3)	7 (33.3)
Neutrophil count decreased	7 (33.3)	2 (9.5)	5 (23.8)
Alanine aminotransferase increased	5 (23.8)	5 (23.8)	0
Aspartate aminotransferase increased	3 (14.3)	3 (14.3)	0
Lymphocyte count decreased	3 (14.3)	1 (4.8)	2 (9.5)
Platelet count decreased	3 (14.3)	1 (4.8)	2 (9.5)
Blood fibrinogen decreased	2 (9.5)	2 (9.5)	0
Blood bilirubin increased	1 (4.8)	1 (4.8)	0
Lipase increased	1 (4.8)	0	1 (4.8)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	9 (42.9)	8 (38.1)	1 (4.8)
Decreased appetite	6 (28.6)	6 (28.6)	0
Hypophosphataemia	4 (19.0)	3 (14.3)	1 (4.8)
Hypokalaemia	2 (9.5)	2 (9.5)	0
Hyponatraemia	2 (9.5)	2 (9.5)	0
Dehydration	1 (4.8)	1 (4.8)	0
Hyperglycaemia	1 (4.8)	1 (4.8)	0
Nervous system disorders			
-Total	2 (9.5)	2 (9.5)	0
Headache	2 (9.5)	2 (9.5)	0
Encephalopathy	1 (4.8)	1 (4.8)	0
Renal and urinary disorders			
-Total	2 (9.5)	1 (4.8)	1 (4.8)
Acute kidney injury	2 (9.5)	1 (4.8)	1 (4.8)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (14.3)	1 (4.8)	2 (9.5)

Timing: within 8 weeks post infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	2 (9.5)	1 (4.8)	1 (4.8)
Pleural effusion	1 (4.8)	1 (4.8)	0
Pulmonary oedema	1 (4.8)	1 (4.8)	0
Respiratory failure	1 (4.8)	0	1 (4.8)
Vascular disorders			
-Total	4 (19.0)	3 (14.3)	1 (4.8)
Hypotension	4 (19.0)	3 (14.3)	1 (4.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

		All patients N=16	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (68.8)	2 (12.5)	9 (56.3)
Blood and lymphatic system disorders			
-Total	8 (50.0)	6 (37.5)	2 (12.5)
Anaemia	6 (37.5)	6 (37.5)	0
Febrile neutropenia	3 (18.8)	3 (18.8)	0
Thrombocytopenia	2 (12.5)	1 (6.3)	1 (6.3)
Neutropenia	1 (6.3)	0	1 (6.3)
Cardiac disorders			
-Total	1 (6.3)	1 (6.3)	0
Tachycardia	1 (6.3)	1 (6.3)	0

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	1 (6.3)	1 (6.3)	0
Mouth haemorrhage	1 (6.3)	1 (6.3)	0
General disorders and administration site conditions			
-Total	2 (12.5)	2 (12.5)	0
Fatigue	1 (6.3)	1 (6.3)	0
Pain	1 (6.3)	1 (6.3)	0
Pyrexia	1 (6.3)	1 (6.3)	0
Hepatobiliary disorders			
-Total	1 (6.3)	1 (6.3)	0
Hyperbilirubinaemia	1 (6.3)	1 (6.3)	0
Immune system disorders			
-Total	4 (25.0)	2 (12.5)	2 (12.5)
Cytokine release syndrome	4 (25.0)	2 (12.5)	2 (12.5)
Investigations			
-Total	8 (50.0)	0	8 (50.0)
Neutrophil count decreased	5 (31.3)	0	5 (31.3)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

		All patients N=16	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	5 (31.3)	2 (12.5)	3 (18.8)
Platelet count decreased	4 (25.0)	0	4 (25.0)
Aspartate aminotransferase increased	3 (18.8)	1 (6.3)	2 (12.5)
Alanine aminotransferase increased	2 (12.5)	2 (12.5)	0
Lymphocyte count decreased	2 (12.5)	2 (12.5)	0
Blood bilirubin increased	1 (6.3)	1 (6.3)	0
Blood creatinine increased	1 (6.3)	1 (6.3)	0
Blood lactic acid increased	1 (6.3)	0	1 (6.3)
Metabolism and nutrition disorders			
-Total	4 (25.0)	4 (25.0)	0
Decreased appetite	2 (12.5)	2 (12.5)	0
Hypokalaemia	2 (12.5)	2 (12.5)	0
Hypocalcaemia	1 (6.3)	1 (6.3)	0
Hypophosphataemia	1 (6.3)	1 (6.3)	0
Nervous system disorders			

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (6.3)	1 (6.3)	0
Seizure	1 (6.3)	1 (6.3)	0
Psychiatric disorders			
-Total	1 (6.3)	1 (6.3)	0
Anxiety	1 (6.3)	1 (6.3)	0
Renal and urinary disorders			
-Total	1 (6.3)	0	1 (6.3)
Acute kidney injury	1 (6.3)	0	1 (6.3)
Oliguria	1 (6.3)	1 (6.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Dyspnoea	1 (6.3)	1 (6.3)	0
Epistaxis	1 (6.3)	1 (6.3)	0
Hypoxia	1 (6.3)	0	1 (6.3)
Pulmonary oedema	1 (6.3)	1 (6.3)	0
Tachypnoea	1 (6.3)	1 (6.3)	0
Vascular disorders			
-Total	4 (25.0)	2 (12.5)	2 (12.5)

Timing: within 8 weeks post infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	3 (18.8)	1 (6.3)	2 (12.5)
Embolism	1 (6.3)	1 (6.3)	0
Hypertension	1 (6.3)	1 (6.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (40.0)	2 (40.0)	0
Gastrointestinal disorders			
-Total	2 (40.0)	2 (40.0)	0
Enterocolitis	1 (20.0)	1 (20.0)	0
Oral pain	1 (20.0)	1 (20.0)	0
Infections and infestations			
-Total	1 (20.0)	1 (20.0)	0
Corona virus infection	1 (20.0)	1 (20.0)	0
Respiratory syncytial virus infection	1 (20.0)	1 (20.0)	0
Investigations			

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 0

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (20.0)	1 (20.0)	0
Blood bilirubin increased	1 (20.0)	1 (20.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (20.0)	1 (20.0)	0
Epistaxis	1 (20.0)	1 (20.0)	0
Pharyngeal lesion	1 (20.0)	1 (20.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

		All patients N=19	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (52.6)	5 (26.3)	5 (26.3)
Blood and lymphatic system disorders			
-Total	3 (15.8)	1 (5.3)	2 (10.5)
Febrile neutropenia	2 (10.5)	2 (10.5)	0
Anaemia	1 (5.3)	1 (5.3)	0
Leukopenia	1 (5.3)	0	1 (5.3)
Neutropenia	1 (5.3)	0	1 (5.3)
Gastrointestinal disorders			
-Total	1 (5.3)	1 (5.3)	0
Nausea	1 (5.3)	1 (5.3)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vomiting	1 (5.3)	1 (5.3)	0
General disorders and administration site conditions			
-Total	1 (5.3)	1 (5.3)	0
Pyrexia	1 (5.3)	1 (5.3)	0
Immune system disorders			
-Total	1 (5.3)	1 (5.3)	0
Hypogammaglobulinaemia	1 (5.3)	1 (5.3)	0
Infections and infestations			
-Total	4 (21.1)	3 (15.8)	1 (5.3)
Escherichia urinary tract infection	1 (5.3)	1 (5.3)	0
Herpes zoster	1 (5.3)	1 (5.3)	0
Sepsis	1 (5.3)	0	1 (5.3)
Urinary tract infection	1 (5.3)	1 (5.3)	0
Viral upper respiratory tract infection	1 (5.3)	1 (5.3)	0
Investigations			

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (21.1)	3 (15.8)	1 (5.3)
Neutrophil count decreased	3 (15.8)	2 (10.5)	1 (5.3)
Aspartate aminotransferase increased	2 (10.5)	2 (10.5)	0
Metabolism and nutrition disorders			
-Total	2 (10.5)	1 (5.3)	1 (5.3)
Hyperglycaemia	1 (5.3)	1 (5.3)	0
Hypokalaemia	1 (5.3)	0	1 (5.3)
Hypophosphataemia	1 (5.3)	1 (5.3)	0
Iron overload	1 (5.3)	1 (5.3)	0
Renal and urinary disorders			
-Total	2 (10.5)	2 (10.5)	0
Acute kidney injury	1 (5.3)	1 (5.3)	0
Haematuria	1 (5.3)	1 (5.3)	0
Nephrolithiasis	1 (5.3)	1 (5.3)	0
Respiratory, thoracic and mediastinal disorders			

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 1

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (10.5)	1 (5.3)	1 (5.3)
Acute respiratory failure	1 (5.3)	0	1 (5.3)
Pulmonary oedema	1 (5.3)	1 (5.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

		All patients N=18	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (38.9)	5 (27.8)	2 (11.1)
Blood and lymphatic system disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Neutropenia	2 (11.1)	1 (5.6)	1 (5.6)
Febrile neutropenia	1 (5.6)	1 (5.6)	0
Gastrointestinal disorders			
-Total	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	1 (5.6)	0
Nausea	1 (5.6)	1 (5.6)	0
Vomiting	1 (5.6)	1 (5.6)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: 2

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	5 (27.8)	3 (16.7)	2 (11.1)
Neutrophil count decreased	2 (11.1)	1 (5.6)	1 (5.6)
White blood cell count decreased	2 (11.1)	1 (5.6)	1 (5.6)
Alanine aminotransferase increased	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	1 (5.6)	1 (5.6)	0
Tumour lysis syndrome	1 (5.6)	1 (5.6)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (35.7)	3 (21.4)	2 (14.3)
Blood and lymphatic system disorders			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Eosinophilia	1 (7.1)	1 (7.1)	0
Neutropenia	1 (7.1)	0	1 (7.1)
Thrombocytopenia	1 (7.1)	1 (7.1)	0
Infections and infestations			
-Total	4 (28.6)	4 (28.6)	0
Cellulitis of male external genital organ	1 (7.1)	1 (7.1)	0

Timing: >8 weeks to 1 year post CTL019 infusion, Number of previous relapses: >=3

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterovirus infection	1 (7.1)	1 (7.1)	0
Rotavirus infection	1 (7.1)	1 (7.1)	0
Upper respiratory tract infection	1 (7.1)	1 (7.1)	0
Urinary tract infection	1 (7.1)	1 (7.1)	0
Vascular device infection	1 (7.1)	1 (7.1)	0
Investigations			
-Total	2 (14.3)	1 (7.1)	1 (7.1)
Alanine aminotransferase increased	1 (7.1)	1 (7.1)	0
Neutrophil count decreased	1 (7.1)	0	1 (7.1)
Metabolism and nutrition disorders			
-Total	1 (7.1)	1 (7.1)	0
Dehydration	1 (7.1)	1 (7.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 0

		All patients N=5	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (20.0)	0	1 (20.0)
Investigations			
-Total	1 (20.0)	0	1 (20.0)
White blood cell count decreased	1 (20.0)	0	1 (20.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (27.3)	2 (18.2)	1 (9.1)
Infections and infestations			
-Total	1 (9.1)	1 (9.1)	0
Otitis media	1 (9.1)	1 (9.1)	0
Investigations			
-Total	1 (9.1)	1 (9.1)	0
White blood cell count decreased	1 (9.1)	1 (9.1)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 1

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (9.1)	0	1 (9.1)
Glioblastoma multiforme	1 (9.1)	0	1 (9.1)
Nervous system disorders			
-Total	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	1 (9.1)	0
Reproductive system and breast disorders			
-Total	1 (9.1)	1 (9.1)	0
Ovarian failure	1 (9.1)	1 (9.1)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

		All patients N=10	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (40.0)	3 (30.0)	1 (10.0)
Blood and lymphatic system disorders			
-Total	1 (10.0)	0	1 (10.0)
Febrile neutropenia	1 (10.0)	0	1 (10.0)
Investigations			
-Total	3 (30.0)	3 (30.0)	0
Alanine aminotransferase increased	2 (20.0)	2 (20.0)	0
Aspartate aminotransferase increased	1 (10.0)	1 (10.0)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: 2

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (10.0)	1 (10.0)	0
Platelet count decreased	1 (10.0)	1 (10.0)	0
White blood cell count decreased	1 (10.0)	1 (10.0)	0
Metabolism and nutrition disorders			
-Total	1 (10.0)	1 (10.0)	0
Hypokalaemia	1 (10.0)	1 (10.0)	0
Renal and urinary disorders			
-Total	1 (10.0)	1 (10.0)	0
Acute kidney injury	1 (10.0)	1 (10.0)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

		All patients N=8	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (37.5)	3 (37.5)	0
General disorders and administration site conditions			
-Total	1 (12.5)	1 (12.5)	0
Cyst	1 (12.5)	1 (12.5)	0
Infections and infestations			
-Total	2 (25.0)	2 (25.0)	0
Campylobacter infection	1 (12.5)	1 (12.5)	0
Cellulitis of male external genital organ	1 (12.5)	1 (12.5)	0
Clostridium difficile infection	1 (12.5)	1 (12.5)	0

Timing: >1 year post-CTL019 infusion, Number of previous relapses: >=3

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory tract infection viral	1 (12.5)	1 (12.5)	0
Urinary tract infection	1 (12.5)	1 (12.5)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

		All patients N=7	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	6 (85.7)
Blood and lymphatic system disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Anaemia	2 (28.6)	1 (14.3)	1 (14.3)
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Neutropenia	2 (28.6)	0	2 (28.6)
Thrombocytopenia	2 (28.6)	1 (14.3)	1 (14.3)
Cardiac disorders			
-Total	1 (14.3)	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	3 (42.9)	3 (42.9)	0
Enterocolitis	1 (14.3)	1 (14.3)	0
Nausea	1 (14.3)	1 (14.3)	0
Oral pain	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Pyrexia	2 (28.6)	1 (14.3)	1 (14.3)
Pain	1 (14.3)	1 (14.3)	0
Immune system disorders			
-Total	3 (42.9)	0	3 (42.9)
Cytokine release syndrome	3 (42.9)	0	3 (42.9)
Infections and infestations			
-Total	1 (14.3)	1 (14.3)	0
Corona virus infection	1 (14.3)	1 (14.3)	0
Respiratory syncytial virus infection	1 (14.3)	1 (14.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (14.3)	1 (14.3)	0
Tracheal haemorrhage	1 (14.3)	1 (14.3)	0
Investigations			
-Total	6 (85.7)	2 (28.6)	4 (57.1)
Neutrophil count decreased	3 (42.9)	0	3 (42.9)
White blood cell count decreased	3 (42.9)	0	3 (42.9)
Aspartate aminotransferase increased	1 (14.3)	0	1 (14.3)
Blood bilirubin increased	1 (14.3)	1 (14.3)	0
Blood magnesium decreased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	1 (14.3)	1 (14.3)	0
Decreased appetite	1 (14.3)	1 (14.3)	0
Hypophosphataemia	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (14.3)	1 (14.3)	0
Arthralgia	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	2 (28.6)	0	2 (28.6)
Haematuria	2 (28.6)	1 (14.3)	1 (14.3)
Acute kidney injury	1 (14.3)	0	1 (14.3)
Oliguria	1 (14.3)	1 (14.3)	0
Renal failure	1 (14.3)	0	1 (14.3)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Epistaxis	2 (28.6)	1 (14.3)	1 (14.3)
Hypoxia	2 (28.6)	1 (14.3)	1 (14.3)
Dyspnoea	1 (14.3)	0	1 (14.3)
Haemoptysis	1 (14.3)	0	1 (14.3)
Interstitial lung disease	1 (14.3)	0	1 (14.3)
Pharyngeal lesion	1 (14.3)	1 (14.3)	0
Pulmonary oedema	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)

Timing: Any time post CTL019 infusion, Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Vascular disorders			
-Total	4 (57.1)	2 (28.6)	2 (28.6)
Hypotension	4 (57.1)	2 (28.6)	2 (28.6)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

		All patients N=20	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (90.0)	3 (15.0)	15 (75.0)
Blood and lymphatic system disorders			
-Total	14 (70.0)	10 (50.0)	4 (20.0)
Febrile neutropenia	10 (50.0)	10 (50.0)	0
Anaemia	7 (35.0)	7 (35.0)	0
Neutropenia	3 (15.0)	1 (5.0)	2 (10.0)
Disseminated intravascular coagulation	2 (10.0)	2 (10.0)	0
Leukopenia	1 (5.0)	0	1 (5.0)
Lymphopenia	1 (5.0)	0	1 (5.0)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	5 (25.0)	5 (25.0)	0
Nausea	2 (10.0)	2 (10.0)	0
Diarrhoea	1 (5.0)	1 (5.0)	0
Dysphagia	1 (5.0)	1 (5.0)	0
Ileus	1 (5.0)	1 (5.0)	0
Vomiting	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	6 (30.0)	6 (30.0)	0
Pyrexia	4 (20.0)	4 (20.0)	0
Face oedema	1 (5.0)	1 (5.0)	0
Localised oedema	1 (5.0)	1 (5.0)	0
Multiple organ dysfunction syndrome	1 (5.0)	1 (5.0)	0
Oedema peripheral	1 (5.0)	1 (5.0)	0
Physical deconditioning	1 (5.0)	1 (5.0)	0
Hepatobiliary disorders			
-Total	1 (5.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	1 (5.0)	1 (5.0)	0
Immune system disorders			
-Total	8 (40.0)	3 (15.0)	5 (25.0)
Cytokine release syndrome	7 (35.0)	2 (10.0)	5 (25.0)
Hypogammaglobulinaemia	2 (10.0)	2 (10.0)	0
Infections and infestations			
-Total	8 (40.0)	7 (35.0)	1 (5.0)
Clostridium difficile colitis	1 (5.0)	1 (5.0)	0
Escherichia urinary tract infection	1 (5.0)	1 (5.0)	0
Gastroenteritis	1 (5.0)	1 (5.0)	0
Herpes zoster	1 (5.0)	1 (5.0)	0
Otitis media	1 (5.0)	1 (5.0)	0
Pneumonia	1 (5.0)	1 (5.0)	0
Sepsis	1 (5.0)	0	1 (5.0)
Staphylococcal infection	1 (5.0)	1 (5.0)	0
Urinary tract infection	1 (5.0)	1 (5.0)	0
Viral upper respiratory tract infection	1 (5.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Injury, poisoning and procedural complications			
-Total	1 (5.0)	0	1 (5.0)
Transfusion related complication	1 (5.0)	0	1 (5.0)
Investigations			
-Total	16 (80.0)	4 (20.0)	12 (60.0)
Neutrophil count decreased	9 (45.0)	2 (10.0)	7 (35.0)
White blood cell count decreased	9 (45.0)	5 (25.0)	4 (20.0)
Platelet count decreased	7 (35.0)	1 (5.0)	6 (30.0)
Lymphocyte count decreased	6 (30.0)	3 (15.0)	3 (15.0)
Alanine aminotransferase increased	4 (20.0)	4 (20.0)	0
Aspartate aminotransferase increased	4 (20.0)	3 (15.0)	1 (5.0)
Blood creatinine increased	1 (5.0)	1 (5.0)	0
Blood fibrinogen decreased	1 (5.0)	0	1 (5.0)
Blood urea increased	1 (5.0)	1 (5.0)	0
Haemoglobin decreased	1 (5.0)	1 (5.0)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lipase increased	1 (5.0)	0	1 (5.0)
Protein total decreased	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	10 (50.0)	7 (35.0)	3 (15.0)
Hypokalaemia	4 (20.0)	3 (15.0)	1 (5.0)
Decreased appetite	3 (15.0)	3 (15.0)	0
Hypophosphataemia	2 (10.0)	2 (10.0)	0
Acidosis	1 (5.0)	1 (5.0)	0
Dehydration	1 (5.0)	1 (5.0)	0
Hyperglycaemia	1 (5.0)	1 (5.0)	0
Hypernatraemia	1 (5.0)	0	1 (5.0)
Hypertriglyceridaemia	1 (5.0)	1 (5.0)	0
Hyperuricaemia	1 (5.0)	0	1 (5.0)
Iron overload	1 (5.0)	1 (5.0)	0
Tumour lysis syndrome	1 (5.0)	1 (5.0)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (5.0)	0	1 (5.0)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Glioblastoma multiforme	1 (5.0)	0	1 (5.0)
Nervous system disorders			
-Total	2 (10.0)	2 (10.0)	0
Encephalopathy	1 (5.0)	1 (5.0)	0
Seizure	1 (5.0)	1 (5.0)	0
Renal and urinary disorders			
-Total	4 (20.0)	4 (20.0)	0
Acute kidney injury	2 (10.0)	2 (10.0)	0
Haematuria	1 (5.0)	1 (5.0)	0
Nephrolithiasis	1 (5.0)	1 (5.0)	0
Renal impairment	1 (5.0)	1 (5.0)	0
Reproductive system and breast disorders			
-Total	1 (5.0)	1 (5.0)	0
Ovarian failure	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (35.0)	4 (20.0)	3 (15.0)
Pulmonary oedema	3 (15.0)	2 (10.0)	1 (5.0)

Timing: Any time post CTL019 infusion, Number of previous relapses: 1

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Epistaxis	2 (10.0)	2 (10.0)	0
Hypoxia	2 (10.0)	2 (10.0)	0
Acute respiratory failure	1 (5.0)	0	1 (5.0)
Pleural effusion	1 (5.0)	1 (5.0)	0
Respiratory distress	1 (5.0)	0	1 (5.0)
Respiratory failure	1 (5.0)	0	1 (5.0)
Skin and subcutaneous tissue disorders			
-Total	1 (5.0)	1 (5.0)	0
Ecchymosis	1 (5.0)	1 (5.0)	0
Vascular disorders			
-Total	4 (20.0)	1 (5.0)	3 (15.0)
Hypotension	4 (20.0)	1 (5.0)	3 (15.0)
Capillary leak syndrome	1 (5.0)	0	1 (5.0)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

		All patients N=21	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (95.2)	6 (28.6)	14 (66.7)
Blood and lymphatic system disorders			
-Total	14 (66.7)	8 (38.1)	6 (28.6)
Febrile neutropenia	9 (42.9)	8 (38.1)	1 (4.8)
Anaemia	5 (23.8)	5 (23.8)	0
Neutropenia	4 (19.0)	2 (9.5)	2 (9.5)
Thrombocytopenia	4 (19.0)	0	4 (19.0)
Lymphopenia	1 (4.8)	1 (4.8)	0
Gastrointestinal disorders			
-Total	3 (14.3)	3 (14.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (9.5)	2 (9.5)	0
Vomiting	2 (9.5)	2 (9.5)	0
Diarrhoea	1 (4.8)	1 (4.8)	0
Immune system disorders			
-Total	7 (33.3)	6 (28.6)	1 (4.8)
Cytokine release syndrome	5 (23.8)	4 (19.0)	1 (4.8)
Hypogammaglobulinaemia	3 (14.3)	3 (14.3)	0
Investigations			
-Total	18 (85.7)	8 (38.1)	10 (47.6)
White blood cell count decreased	13 (61.9)	5 (23.8)	8 (38.1)
Neutrophil count decreased	8 (38.1)	2 (9.5)	6 (28.6)
Alanine aminotransferase increased	7 (33.3)	7 (33.3)	0
Aspartate aminotransferase increased	4 (19.0)	4 (19.0)	0
Lymphocyte count decreased	4 (19.0)	2 (9.5)	2 (9.5)
Platelet count decreased	4 (19.0)	2 (9.5)	2 (9.5)
Blood fibrinogen decreased	2 (9.5)	2 (9.5)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	1 (4.8)	1 (4.8)	0
Lipase increased	1 (4.8)	0	1 (4.8)
Metabolism and nutrition disorders			
-Total	10 (47.6)	9 (42.9)	1 (4.8)
Decreased appetite	6 (28.6)	6 (28.6)	0
Hypophosphataemia	4 (19.0)	3 (14.3)	1 (4.8)
Hypokalaemia	3 (14.3)	3 (14.3)	0
Hyponatraemia	2 (9.5)	2 (9.5)	0
Dehydration	1 (4.8)	1 (4.8)	0
Hyperglycaemia	1 (4.8)	1 (4.8)	0
Tumour lysis syndrome	1 (4.8)	1 (4.8)	0
Nervous system disorders			
-Total	2 (9.5)	2 (9.5)	0
Headache	2 (9.5)	2 (9.5)	0
Encephalopathy	1 (4.8)	1 (4.8)	0
Renal and urinary disorders			
-Total	3 (14.3)	2 (9.5)	1 (4.8)
Acute kidney injury	3 (14.3)	2 (9.5)	1 (4.8)

Timing: Any time post CTL019 infusion, Number of previous relapses: 2

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	3 (14.3)	1 (4.8)	2 (9.5)
Hypoxia	2 (9.5)	1 (4.8)	1 (4.8)
Pleural effusion	1 (4.8)	1 (4.8)	0
Pulmonary oedema	1 (4.8)	1 (4.8)	0
Respiratory failure	1 (4.8)	0	1 (4.8)
Vascular disorders			
-Total	4 (19.0)	3 (14.3)	1 (4.8)
Hypotension	4 (19.0)	3 (14.3)	1 (4.8)

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 189r
Severe adverse events (AE CTCAE Grade 3/4) post CTL019 infusion that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of study drug relationship, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Safety Set

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

		All patients N=16	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (87.5)	4 (25.0)	10 (62.5)
Blood and lymphatic system disorders			
-Total	10 (62.5)	7 (43.8)	3 (18.8)
Anaemia	6 (37.5)	6 (37.5)	0
Febrile neutropenia	3 (18.8)	3 (18.8)	0
Thrombocytopenia	3 (18.8)	2 (12.5)	1 (6.3)
Neutropenia	2 (12.5)	0	2 (12.5)
Eosinophilia	1 (6.3)	1 (6.3)	0
Cardiac disorders			
-Total	1 (6.3)	1 (6.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (6.3)	1 (6.3)	0
Gastrointestinal disorders			
-Total	1 (6.3)	1 (6.3)	0
Mouth haemorrhage	1 (6.3)	1 (6.3)	0
General disorders and administration site conditions			
-Total	3 (18.8)	3 (18.8)	0
Cyst	1 (6.3)	1 (6.3)	0
Fatigue	1 (6.3)	1 (6.3)	0
Pain	1 (6.3)	1 (6.3)	0
Pyrexia	1 (6.3)	1 (6.3)	0
Hepatobiliary disorders			
-Total	1 (6.3)	1 (6.3)	0
Hyperbilirubinaemia	1 (6.3)	1 (6.3)	0
Immune system disorders			
-Total	4 (25.0)	2 (12.5)	2 (12.5)
Cytokine release syndrome	4 (25.0)	2 (12.5)	2 (12.5)
Infections and infestations			
-Total	4 (25.0)	4 (25.0)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Campylobacter infection	1 (6.3)	1 (6.3)	0
Cellulitis of male external genital organ	1 (6.3)	1 (6.3)	0
Clostridium difficile infection	1 (6.3)	1 (6.3)	0
Enterovirus infection	1 (6.3)	1 (6.3)	0
Respiratory tract infection viral	1 (6.3)	1 (6.3)	0
Rotavirus infection	1 (6.3)	1 (6.3)	0
Upper respiratory tract infection	1 (6.3)	1 (6.3)	0
Urinary tract infection	1 (6.3)	1 (6.3)	0
Vascular device infection	1 (6.3)	1 (6.3)	0
Investigations			
-Total	8 (50.0)	0	8 (50.0)
Neutrophil count decreased	5 (31.3)	0	5 (31.3)
White blood cell count decreased	5 (31.3)	2 (12.5)	3 (18.8)
Platelet count decreased	4 (25.0)	0	4 (25.0)
Alanine aminotransferase increased	3 (18.8)	3 (18.8)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	3 (18.8)	1 (6.3)	2 (12.5)
Lymphocyte count decreased	2 (12.5)	2 (12.5)	0
Blood bilirubin increased	1 (6.3)	1 (6.3)	0
Blood creatinine increased	1 (6.3)	1 (6.3)	0
Blood lactic acid increased	1 (6.3)	0	1 (6.3)
Metabolism and nutrition disorders			
-Total	5 (31.3)	5 (31.3)	0
Decreased appetite	2 (12.5)	2 (12.5)	0
Hypokalaemia	2 (12.5)	2 (12.5)	0
Dehydration	1 (6.3)	1 (6.3)	0
Hypocalcaemia	1 (6.3)	1 (6.3)	0
Hypophosphataemia	1 (6.3)	1 (6.3)	0
Nervous system disorders			
-Total	1 (6.3)	1 (6.3)	0
Seizure	1 (6.3)	1 (6.3)	0
Psychiatric disorders			
-Total	1 (6.3)	1 (6.3)	0

Timing: Any time post CTL019 infusion, Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Anxiety	1 (6.3)	1 (6.3)	0
Renal and urinary disorders			
-Total	1 (6.3)	0	1 (6.3)
Acute kidney injury	1 (6.3)	0	1 (6.3)
Oliguria	1 (6.3)	1 (6.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (12.5)	1 (6.3)	1 (6.3)
Dyspnoea	1 (6.3)	1 (6.3)	0
Epistaxis	1 (6.3)	1 (6.3)	0
Hypoxia	1 (6.3)	0	1 (6.3)
Pulmonary oedema	1 (6.3)	1 (6.3)	0
Tachypnoea	1 (6.3)	1 (6.3)	0
Vascular disorders			
-Total	4 (25.0)	2 (12.5)	2 (12.5)
Hypotension	3 (18.8)	1 (6.3)	2 (12.5)
Embolism	1 (6.3)	1 (6.3)	0
Hypertension	1 (6.3)	1 (6.3)	0

- A patient with multiple adverse events within a group term is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- Preferred terms are presented within group term in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190a
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (63.6)	6 (27.3)	8 (36.4)
Blood and lymphatic system disorders			
-Total	12 (54.5)	8 (36.4)	4 (18.2)
Anaemia	6 (27.3)	6 (27.3)	0
Febrile neutropenia	5 (22.7)	5 (22.7)	0
Thrombocytopenia	3 (13.6)	1 (4.5)	2 (9.1)
Neutropenia	2 (9.1)	0	2 (9.1)
Gastrointestinal disorders			
-Total	1 (4.5)	1 (4.5)	0
Colitis	1 (4.5)	1 (4.5)	0
Infections and infestations			

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (9.1)	2 (9.1)	0
Device related infection	1 (4.5)	1 (4.5)	0
Enterococcal bacteraemia	1 (4.5)	1 (4.5)	0
Investigations			
-Total	6 (27.3)	1 (4.5)	5 (22.7)
Neutrophil count decreased	4 (18.2)	0	4 (18.2)
Platelet count decreased	3 (13.6)	0	3 (13.6)
White blood cell count decreased	3 (13.6)	0	3 (13.6)
Alanine aminotransferase increased	1 (4.5)	1 (4.5)	0
Aspartate aminotransferase increased	1 (4.5)	1 (4.5)	0
Metabolism and nutrition disorders			
-Total	3 (13.6)	2 (9.1)	1 (4.5)
Hyperuricaemia	2 (9.1)	1 (4.5)	1 (4.5)
Decreased appetite	1 (4.5)	1 (4.5)	0
Hyperglycaemia	1 (4.5)	1 (4.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190a
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (71.8)	15 (38.5)	13 (33.3)
Blood and lymphatic system disorders			
-Total	20 (51.3)	16 (41.0)	4 (10.3)
Febrile neutropenia	12 (30.8)	12 (30.8)	0
Anaemia	8 (20.5)	8 (20.5)	0
Thrombocytopenia	4 (10.3)	1 (2.6)	3 (7.7)
Neutropenia	2 (5.1)	1 (2.6)	1 (2.6)
Disseminated intravascular coagulation	1 (2.6)	1 (2.6)	0
Pancytopenia	1 (2.6)	0	1 (2.6)
Cardiac disorders			

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.6)	1 (2.6)	0
Sinus tachycardia	1 (2.6)	1 (2.6)	0
Gastrointestinal disorders			
-Total	6 (15.4)	5 (12.8)	1 (2.6)
Stomatitis	4 (10.3)	3 (7.7)	1 (2.6)
Abdominal pain	2 (5.1)	2 (5.1)	0
Colitis	2 (5.1)	2 (5.1)	0
Nausea	1 (2.6)	1 (2.6)	0
General disorders and administration site conditions			
-Total	1 (2.6)	0	1 (2.6)
Multiple organ dysfunction syndrome	1 (2.6)	0	1 (2.6)
Infections and infestations			
-Total	5 (12.8)	4 (10.3)	1 (2.6)
Device related infection	2 (5.1)	2 (5.1)	0
Staphylococcal bacteraemia	2 (5.1)	2 (5.1)	0
Klebsiella sepsis	1 (2.6)	0	1 (2.6)
Injury, poisoning and procedural complications			

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (5.1)	2 (5.1)	0
Procedural pain	2 (5.1)	2 (5.1)	0
Investigations			
-Total	14 (35.9)	4 (10.3)	10 (25.6)
Platelet count decreased	6 (15.4)	1 (2.6)	5 (12.8)
White blood cell count decreased	5 (12.8)	1 (2.6)	4 (10.3)
Alanine aminotransferase increased	4 (10.3)	4 (10.3)	0
Neutrophil count decreased	4 (10.3)	0	4 (10.3)
Aspartate aminotransferase increased	2 (5.1)	2 (5.1)	0
Electrocardiogram qt prolonged	1 (2.6)	1 (2.6)	0
Metabolism and nutrition disorders			
-Total	6 (15.4)	4 (10.3)	2 (5.1)
Hyperglycaemia	3 (7.7)	2 (5.1)	1 (2.6)
Hypokalaemia	3 (7.7)	1 (2.6)	2 (5.1)
Decreased appetite	2 (5.1)	2 (5.1)	0
Dehydration	2 (5.1)	2 (5.1)	0
Hypernatraemia	2 (5.1)	1 (2.6)	1 (2.6)

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	3 (7.7)	3 (7.7)	0
Pain in extremity	2 (5.1)	2 (5.1)	0
Back pain	1 (2.6)	1 (2.6)	0
Nervous system disorders			
-Total	3 (7.7)	3 (7.7)	0
Headache	3 (7.7)	3 (7.7)	0
Renal and urinary disorders			
-Total	3 (7.7)	1 (2.6)	2 (5.1)
Cystitis haemorrhagic	2 (5.1)	1 (2.6)	1 (2.6)
Acute kidney injury	1 (2.6)	0	1 (2.6)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (5.1)	0	2 (5.1)
Hypoxia	1 (2.6)	0	1 (2.6)
Pulmonary oedema	1 (2.6)	0	1 (2.6)
Vascular disorders			
-Total	5 (12.8)	4 (10.3)	1 (2.6)

Age: >=10 years to <18 years

Group term Preferred term	All patients N=39 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	5 (12.8)	4 (10.3)	1 (2.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190a
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (85.7)	5 (35.7)	7 (50.0)
Blood and lymphatic system disorders			
-Total	7 (50.0)	4 (28.6)	3 (21.4)
Anaemia	5 (35.7)	5 (35.7)	0
Thrombocytopenia	3 (21.4)	1 (7.1)	2 (14.3)
Neutropenia	2 (14.3)	0	2 (14.3)
Disseminated intravascular coagulation	1 (7.1)	1 (7.1)	0
Febrile neutropenia	1 (7.1)	1 (7.1)	0
Lymphopenia	1 (7.1)	0	1 (7.1)
Pancytopenia	1 (7.1)	0	1 (7.1)

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Cardiac disorders			
-Total	4 (28.6)	2 (14.3)	2 (14.3)
Bradycardia	1 (7.1)	0	1 (7.1)
Cardiovascular insufficiency	1 (7.1)	0	1 (7.1)
Left ventricular dysfunction	1 (7.1)	1 (7.1)	0
Right ventricular dysfunction	1 (7.1)	1 (7.1)	0
Sinus tachycardia	1 (7.1)	1 (7.1)	0
Tachycardia	1 (7.1)	1 (7.1)	0
Ventricular tachycardia	1 (7.1)	1 (7.1)	0
Gastrointestinal disorders			
-Total	2 (14.3)	2 (14.3)	0
Nausea	2 (14.3)	2 (14.3)	0
Abdominal pain	1 (7.1)	1 (7.1)	0
Haematochezia	1 (7.1)	1 (7.1)	0
Vomiting	1 (7.1)	1 (7.1)	0
General disorders and administration site conditions			
-Total	5 (35.7)	4 (28.6)	1 (7.1)

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pyrexia	2 (14.3)	2 (14.3)	0
Multiple organ dysfunction syndrome	1 (7.1)	0	1 (7.1)
Non-cardiac chest pain	1 (7.1)	1 (7.1)	0
Pain	1 (7.1)	1 (7.1)	0
Physical deconditioning	1 (7.1)	1 (7.1)	0
Hepatobiliary disorders			
-Total	2 (14.3)	2 (14.3)	0
Hyperbilirubinaemia	2 (14.3)	2 (14.3)	0
Infections and infestations			
-Total	6 (42.9)	2 (14.3)	4 (28.6)
Abscess limb	1 (7.1)	1 (7.1)	0
Enterococcal bacteraemia	1 (7.1)	1 (7.1)	0
Escherichia sepsis	1 (7.1)	0	1 (7.1)
Klebsiella sepsis	1 (7.1)	0	1 (7.1)
Pneumonia	1 (7.1)	0	1 (7.1)
Serratia infection	1 (7.1)	1 (7.1)	0
Staphylococcal sepsis	1 (7.1)	0	1 (7.1)
Investigations			

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	5 (35.7)	2 (14.3)	3 (21.4)
Blood lactate dehydrogenase increased	2 (14.3)	2 (14.3)	0
White blood cell count decreased	2 (14.3)	0	2 (14.3)
Computerised tomogram thorax abnormal	1 (7.1)	1 (7.1)	0
Electrocardiogram qt prolonged	1 (7.1)	1 (7.1)	0
Neutrophil count decreased	1 (7.1)	0	1 (7.1)
Platelet count decreased	1 (7.1)	0	1 (7.1)
Serum ferritin increased	1 (7.1)	1 (7.1)	0
Transaminases increased	1 (7.1)	1 (7.1)	0
Metabolism and nutrition disorders			
-Total	2 (14.3)	2 (14.3)	0
Fluid overload	1 (7.1)	1 (7.1)	0
Hyperkalaemia	1 (7.1)	1 (7.1)	0
Hypokalaemia	1 (7.1)	1 (7.1)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (28.6)	4 (28.6)	0

Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	3 (21.4)	3 (21.4)	0
Arthralgia	1 (7.1)	1 (7.1)	0
Back pain	1 (7.1)	1 (7.1)	0
Musculoskeletal pain	1 (7.1)	1 (7.1)	0
Myopathy	1 (7.1)	1 (7.1)	0
Myositis	1 (7.1)	1 (7.1)	0
Nervous system disorders			
-Total	1 (7.1)	0	1 (7.1)
Headache	1 (7.1)	1 (7.1)	0
Hyporesponsive to stimuli	1 (7.1)	1 (7.1)	0
Seizure	1 (7.1)	0	1 (7.1)
Psychiatric disorders			
-Total	1 (7.1)	1 (7.1)	0
Agitation	1 (7.1)	1 (7.1)	0
Renal and urinary disorders			
-Total	1 (7.1)	1 (7.1)	0
Acute kidney injury	1 (7.1)	1 (7.1)	0
Oliguria	1 (7.1)	1 (7.1)	0

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (14.3)	0	2 (14.3)
Hypoxia	2 (14.3)	2 (14.3)	0
Aspiration	1 (7.1)	0	1 (7.1)
Cough	1 (7.1)	1 (7.1)	0
Dyspnoea	1 (7.1)	1 (7.1)	0
Haemoptysis	1 (7.1)	1 (7.1)	0
Oropharyngeal pain	1 (7.1)	1 (7.1)	0
Pulmonary alveolar haemorrhage	1 (7.1)	0	1 (7.1)
Pulmonary hypertension	1 (7.1)	1 (7.1)	0
Pulmonary oedema	1 (7.1)	0	1 (7.1)
Respiratory distress	1 (7.1)	0	1 (7.1)
Tachypnoea	1 (7.1)	1 (7.1)	0
Vascular disorders			
-Total	3 (21.4)	1 (7.1)	2 (14.3)
Hypotension	2 (14.3)	0	2 (14.3)
Hypertension	1 (7.1)	1 (7.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190b
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (70.0)	15 (37.5)	13 (32.5)
Blood and lymphatic system disorders			
-Total	21 (52.5)	15 (37.5)	6 (15.0)
Anaemia	11 (27.5)	11 (27.5)	0
Febrile neutropenia	9 (22.5)	9 (22.5)	0
Thrombocytopenia	6 (15.0)	1 (2.5)	5 (12.5)
Neutropenia	3 (7.5)	0	3 (7.5)
Disseminated intravascular coagulation	2 (5.0)	2 (5.0)	0
Cardiac disorders			
-Total	2 (5.0)	2 (5.0)	0

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Sinus tachycardia	2 (5.0)	2 (5.0)	0
Gastrointestinal disorders			
-Total	5 (12.5)	5 (12.5)	0
Abdominal pain	2 (5.0)	2 (5.0)	0
Colitis	2 (5.0)	2 (5.0)	0
Nausea	2 (5.0)	2 (5.0)	0
Stomatitis	2 (5.0)	2 (5.0)	0
General disorders and administration site conditions			
-Total	4 (10.0)	2 (5.0)	2 (5.0)
Multiple organ dysfunction syndrome	2 (5.0)	0	2 (5.0)
Pyrexia	2 (5.0)	2 (5.0)	0
Infections and infestations			
-Total	3 (7.5)	1 (2.5)	2 (5.0)
Klebsiella sepsis	2 (5.0)	0	2 (5.0)
Device related infection	1 (2.5)	1 (2.5)	0
Injury, poisoning and procedural complications			
-Total	2 (5.0)	2 (5.0)	0

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Procedural pain	2 (5.0)	2 (5.0)	0
Investigations			
-Total	13 (32.5)	4 (10.0)	9 (22.5)
Neutrophil count decreased	4 (10.0)	0	4 (10.0)
Platelet count decreased	4 (10.0)	1 (2.5)	3 (7.5)
White blood cell count decreased	4 (10.0)	0	4 (10.0)
Aspartate aminotransferase increased	2 (5.0)	2 (5.0)	0
Blood lactate dehydrogenase increased	2 (5.0)	2 (5.0)	0
Electrocardiogram qt prolonged	2 (5.0)	2 (5.0)	0
Alanine aminotransferase increased	1 (2.5)	1 (2.5)	0
Metabolism and nutrition disorders			
-Total	8 (20.0)	6 (15.0)	2 (5.0)
Hypokalaemia	3 (7.5)	1 (2.5)	2 (5.0)
Decreased appetite	2 (5.0)	2 (5.0)	0
Dehydration	2 (5.0)	2 (5.0)	0
Hyperglycaemia	2 (5.0)	1 (2.5)	1 (2.5)
Hypernatraemia	2 (5.0)	1 (2.5)	1 (2.5)

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	2 (5.0)	2 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (7.5)	3 (7.5)	0
Pain in extremity	3 (7.5)	3 (7.5)	0
Nervous system disorders			
-Total	2 (5.0)	2 (5.0)	0
Headache	2 (5.0)	2 (5.0)	0
Renal and urinary disorders			
-Total	2 (5.0)	1 (2.5)	1 (2.5)
Acute kidney injury	2 (5.0)	1 (2.5)	1 (2.5)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (10.0)	1 (2.5)	3 (7.5)
Hypoxia	3 (7.5)	2 (5.0)	1 (2.5)
Pulmonary oedema	2 (5.0)	0	2 (5.0)
Vascular disorders			
-Total	6 (15.0)	3 (7.5)	3 (7.5)
Hypotension	6 (15.0)	3 (7.5)	3 (7.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190b
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (68.6)	10 (28.6)	14 (40.0)
Blood and lymphatic system disorders			
-Total	18 (51.4)	13 (37.1)	5 (14.3)
Febrile neutropenia	9 (25.7)	9 (25.7)	0
Anaemia	8 (22.9)	8 (22.9)	0
Thrombocytopenia	4 (11.4)	2 (5.7)	2 (5.7)
Neutropenia	3 (8.6)	1 (2.9)	2 (5.7)
Pancytopenia	2 (5.7)	0	2 (5.7)
Gastrointestinal disorders			
-Total	4 (11.4)	3 (8.6)	1 (2.9)
Stomatitis	2 (5.7)	1 (2.9)	1 (2.9)

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (2.9)	1 (2.9)	0
Colitis	1 (2.9)	1 (2.9)	0
Nausea	1 (2.9)	1 (2.9)	0
Hepatobiliary disorders			
-Total	2 (5.7)	2 (5.7)	0
Hyperbilirubinaemia	2 (5.7)	2 (5.7)	0
Infections and infestations			
-Total	4 (11.4)	4 (11.4)	0
Device related infection	2 (5.7)	2 (5.7)	0
Enterococcal bacteraemia	2 (5.7)	2 (5.7)	0
Investigations			
-Total	11 (31.4)	2 (5.7)	9 (25.7)
Platelet count decreased	6 (17.1)	0	6 (17.1)
White blood cell count decreased	6 (17.1)	1 (2.9)	5 (14.3)
Neutrophil count decreased	5 (14.3)	0	5 (14.3)
Alanine aminotransferase increased	4 (11.4)	4 (11.4)	0
Aspartate aminotransferase increased	1 (2.9)	1 (2.9)	0

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders			
-Total	3 (8.6)	3 (8.6)	0
Hyperglycaemia	2 (5.7)	2 (5.7)	0
Decreased appetite	1 (2.9)	1 (2.9)	0
Hypokalaemia	1 (2.9)	1 (2.9)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (5.7)	2 (5.7)	0
Pain in extremity	2 (5.7)	2 (5.7)	0
Nervous system disorders			
-Total	2 (5.7)	2 (5.7)	0
Headache	2 (5.7)	2 (5.7)	0
Vascular disorders			
-Total	1 (2.9)	1 (2.9)	0
Hypotension	1 (2.9)	1 (2.9)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
/vob/CCTL019/haq/haq_eu_5/pgm/saf/t190_gd_b2205.sas@@/main/1 29SEP20:18:22 Final

Table 190c
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	41 (68.3)	19 (31.7)	22 (36.7)
Blood and lymphatic system disorders			
-Total	31 (51.7)	23 (38.3)	8 (13.3)
Anaemia	15 (25.0)	15 (25.0)	0
Febrile neutropenia	15 (25.0)	15 (25.0)	0
Thrombocytopenia	8 (13.3)	2 (3.3)	6 (10.0)
Neutropenia	4 (6.7)	0	4 (6.7)
Disseminated intravascular coagulation	1 (1.7)	1 (1.7)	0
Cardiac disorders			
-Total	1 (1.7)	1 (1.7)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Sinus tachycardia	1 (1.7)	1 (1.7)	0
Gastrointestinal disorders			
-Total	6 (10.0)	5 (8.3)	1 (1.7)
Colitis	3 (5.0)	3 (5.0)	0
Stomatitis	3 (5.0)	2 (3.3)	1 (1.7)
Nausea	2 (3.3)	2 (3.3)	0
Abdominal pain	1 (1.7)	1 (1.7)	0
General disorders and administration site conditions			
-Total	1 (1.7)	0	1 (1.7)
Multiple organ dysfunction syndrome	1 (1.7)	0	1 (1.7)
Hepatobiliary disorders			
-Total	1 (1.7)	1 (1.7)	0
Hyperbilirubinaemia	1 (1.7)	1 (1.7)	0
Immune system disorders			
-Total	1 (1.7)	1 (1.7)	0
Anaphylactic reaction	1 (1.7)	1 (1.7)	0
Infections and infestations			

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (3.3)	1 (1.7)	1 (1.7)
Device related infection	1 (1.7)	1 (1.7)	0
Klebsiella sepsis	1 (1.7)	0	1 (1.7)
Injury, poisoning and procedural complications			
-Total	1 (1.7)	1 (1.7)	0
Procedural pain	1 (1.7)	1 (1.7)	0
Investigations			
-Total	19 (31.7)	4 (6.7)	15 (25.0)
Platelet count decreased	9 (15.0)	1 (1.7)	8 (13.3)
White blood cell count decreased	8 (13.3)	1 (1.7)	7 (11.7)
Neutrophil count decreased	7 (11.7)	0	7 (11.7)
Alanine aminotransferase increased	3 (5.0)	3 (5.0)	0
Aspartate aminotransferase increased	2 (3.3)	2 (3.3)	0
Blood lactate dehydrogenase increased	1 (1.7)	1 (1.7)	0
Electrocardiogram qt prolonged	1 (1.7)	1 (1.7)	0
Metabolism and nutrition disorders			

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (15.0)	7 (11.7)	2 (3.3)
Hyperglycaemia	4 (6.7)	3 (5.0)	1 (1.7)
Hypokalaemia	4 (6.7)	2 (3.3)	2 (3.3)
Decreased appetite	3 (5.0)	3 (5.0)	0
Dehydration	1 (1.7)	1 (1.7)	0
Tumour lysis syndrome	1 (1.7)	1 (1.7)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (6.7)	4 (6.7)	0
Pain in extremity	4 (6.7)	4 (6.7)	0
Nervous system disorders			
-Total	2 (3.3)	2 (3.3)	0
Headache	2 (3.3)	2 (3.3)	0
Renal and urinary disorders			
-Total	1 (1.7)	0	1 (1.7)
Acute kidney injury	1 (1.7)	0	1 (1.7)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (5.0)	1 (1.7)	2 (3.3)

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (3.3)	1 (1.7)	1 (1.7)
Pulmonary oedema	1 (1.7)	0	1 (1.7)
Vascular disorders			
-Total	6 (10.0)	4 (6.7)	2 (3.3)
Hypotension	6 (10.0)	4 (6.7)	2 (3.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190c
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (66.7)	3 (50.0)	1 (16.7)
Blood and lymphatic system disorders			
-Total	1 (16.7)	1 (16.7)	0
Anaemia	1 (16.7)	1 (16.7)	0
Infections and infestations			
-Total	4 (66.7)	4 (66.7)	0
Alpha haemolytic streptococcal infection	1 (16.7)	1 (16.7)	0
Device related infection	1 (16.7)	1 (16.7)	0
Escherichia infection	1 (16.7)	1 (16.7)	0
Gastroenteritis	1 (16.7)	1 (16.7)	0

Race: Asian

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Staphylococcal infection	1 (16.7)	1 (16.7)	0
Streptococcal infection	1 (16.7)	1 (16.7)	0
Investigations			
-Total	1 (16.7)	0	1 (16.7)
Neutrophil count decreased	1 (16.7)	0	1 (16.7)
Platelet count decreased	1 (16.7)	0	1 (16.7)
White blood cell count decreased	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	1 (16.7)	1 (16.7)	0
Dehydration	1 (16.7)	1 (16.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190c
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (88.9)	4 (44.4)	4 (44.4)
Blood and lymphatic system disorders			
-Total	8 (88.9)	5 (55.6)	3 (33.3)
Anaemia	3 (33.3)	3 (33.3)	0
Febrile neutropenia	3 (33.3)	3 (33.3)	0
Neutropenia	2 (22.2)	1 (11.1)	1 (11.1)
Pancytopenia	2 (22.2)	0	2 (22.2)
Thrombocytopenia	2 (22.2)	1 (11.1)	1 (11.1)
Coagulopathy	1 (11.1)	1 (11.1)	0
Disseminated intravascular coagulation	1 (11.1)	1 (11.1)	0

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphopenia	1 (11.1)	0	1 (11.1)
Cardiac disorders			
-Total	2 (22.2)	0	2 (22.2)
Bradycardia	1 (11.1)	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	1 (11.1)
Right ventricular dysfunction	1 (11.1)	1 (11.1)	0
Sinus tachycardia	1 (11.1)	1 (11.1)	0
Ventricular tachycardia	1 (11.1)	1 (11.1)	0
Gastrointestinal disorders			
-Total	3 (33.3)	3 (33.3)	0
Abdominal pain	2 (22.2)	2 (22.2)	0
Haematochezia	1 (11.1)	1 (11.1)	0
Nausea	1 (11.1)	1 (11.1)	0
Stomatitis	1 (11.1)	1 (11.1)	0
Vomiting	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			
-Total	3 (33.3)	2 (22.2)	1 (11.1)

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	1 (11.1)	0	1 (11.1)
Non-cardiac chest pain	1 (11.1)	1 (11.1)	0
Physical deconditioning	1 (11.1)	1 (11.1)	0
Hepatobiliary disorders			
-Total	1 (11.1)	1 (11.1)	0
Hyperbilirubinaemia	1 (11.1)	1 (11.1)	0
Immune system disorders			
-Total	1 (11.1)	1 (11.1)	0
Anaphylactic reaction	1 (11.1)	1 (11.1)	0
Infections and infestations			
-Total	4 (44.4)	2 (22.2)	2 (22.2)
Abscess limb	1 (11.1)	1 (11.1)	0
Device related infection	1 (11.1)	1 (11.1)	0
Escherichia urinary tract infection	1 (11.1)	1 (11.1)	0
Klebsiella sepsis	1 (11.1)	0	1 (11.1)
Staphylococcal sepsis	1 (11.1)	0	1 (11.1)
Injury, poisoning and procedural complications			

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (11.1)	1 (11.1)	0
Extradural haematoma	1 (11.1)	1 (11.1)	0
Procedural pain	1 (11.1)	1 (11.1)	0
Subdural haematoma	1 (11.1)	1 (11.1)	0
Investigations			
-Total	5 (55.6)	3 (33.3)	2 (22.2)
Alanine aminotransferase increased	2 (22.2)	2 (22.2)	0
Aspartate aminotransferase increased	1 (11.1)	1 (11.1)	0
Blood lactate dehydrogenase increased	1 (11.1)	1 (11.1)	0
Computerised tomogram thorax abnormal	1 (11.1)	1 (11.1)	0
Electrocardiogram qt prolonged	1 (11.1)	1 (11.1)	0
Neutrophil count decreased	1 (11.1)	0	1 (11.1)
Transaminases increased	1 (11.1)	1 (11.1)	0
White blood cell count decreased	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			
-Total	2 (22.2)	2 (22.2)	0

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fluid overload	1 (11.1)	1 (11.1)	0
Hyperkalaemia	1 (11.1)	1 (11.1)	0
Tumour lysis syndrome	1 (11.1)	1 (11.1)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (33.3)	3 (33.3)	0
Back pain	2 (22.2)	2 (22.2)	0
Arthralgia	1 (11.1)	1 (11.1)	0
Myopathy	1 (11.1)	1 (11.1)	0
Myositis	1 (11.1)	1 (11.1)	0
Pain in extremity	1 (11.1)	1 (11.1)	0
Nervous system disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Headache	2 (22.2)	2 (22.2)	0
Hyporesponsive to stimuli	1 (11.1)	1 (11.1)	0
Seizure	1 (11.1)	0	1 (11.1)
Psychiatric disorders			
-Total	2 (22.2)	2 (22.2)	0

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Agitation	1 (11.1)	1 (11.1)	0
Mental status changes	1 (11.1)	1 (11.1)	0
Renal and urinary disorders			
-Total	1 (11.1)	1 (11.1)	0
Acute kidney injury	1 (11.1)	1 (11.1)	0
Oliguria	1 (11.1)	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Cough	1 (11.1)	1 (11.1)	0
Dyspnoea	1 (11.1)	1 (11.1)	0
Epistaxis	1 (11.1)	1 (11.1)	0
Haemoptysis	1 (11.1)	1 (11.1)	0
Hypoxia	1 (11.1)	1 (11.1)	0
Oropharyngeal pain	1 (11.1)	1 (11.1)	0
Pulmonary alveolar haemorrhage	1 (11.1)	0	1 (11.1)
Pulmonary hypertension	1 (11.1)	1 (11.1)	0
Pulmonary oedema	1 (11.1)	0	1 (11.1)

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory distress	1 (11.1)	0	1 (11.1)
Tachypnoea	1 (11.1)	1 (11.1)	0
Vascular disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Hypertension	1 (11.1)	1 (11.1)	0
Hypotension	1 (11.1)	0	1 (11.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190d
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (66.7)	11 (36.7)	9 (30.0)
Blood and lymphatic system disorders			
-Total	16 (53.3)	13 (43.3)	3 (10.0)
Anaemia	8 (26.7)	8 (26.7)	0
Febrile neutropenia	8 (26.7)	8 (26.7)	0
Neutropenia	3 (10.0)	1 (3.3)	2 (6.7)
Thrombocytopenia	3 (10.0)	1 (3.3)	2 (6.7)
Gastrointestinal disorders			
-Total	1 (3.3)	1 (3.3)	0
Stomatitis	1 (3.3)	1 (3.3)	0
Investigations			

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (30.0)	2 (6.7)	7 (23.3)
Neutrophil count decreased	5 (16.7)	0	5 (16.7)
Platelet count decreased	4 (13.3)	1 (3.3)	3 (10.0)
White blood cell count decreased	4 (13.3)	0	4 (13.3)
Alanine aminotransferase increased	3 (10.0)	3 (10.0)	0
Metabolism and nutrition disorders			
-Total	5 (16.7)	4 (13.3)	1 (3.3)
Hyperglycaemia	3 (10.0)	3 (10.0)	0
Hypokalaemia	2 (6.7)	1 (3.3)	1 (3.3)
Hypophosphataemia	2 (6.7)	2 (6.7)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (3.3)	1 (3.3)	0
Pain in extremity	1 (3.3)	1 (3.3)	0
Nervous system disorders			
-Total	2 (6.7)	2 (6.7)	0
Headache	2 (6.7)	2 (6.7)	0
Vascular disorders			

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=30 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (10.0)	2 (6.7)	1 (3.3)
Hypotension	3 (10.0)	2 (6.7)	1 (3.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190d
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (62.2)	12 (26.7)	16 (35.6)
Blood and lymphatic system disorders			
-Total	22 (48.9)	16 (35.6)	6 (13.3)
Anaemia	11 (24.4)	11 (24.4)	0
Febrile neutropenia	10 (22.2)	10 (22.2)	0
Thrombocytopenia	7 (15.6)	2 (4.4)	5 (11.1)
Neutropenia	3 (6.7)	0	3 (6.7)
Gastrointestinal disorders			
-Total	5 (11.1)	4 (8.9)	1 (2.2)
Nausea	3 (6.7)	3 (6.7)	0
Stomatitis	3 (6.7)	2 (4.4)	1 (2.2)

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Investigations			
-Total	12 (26.7)	1 (2.2)	11 (24.4)
Platelet count decreased	6 (13.3)	0	6 (13.3)
White blood cell count decreased	6 (13.3)	1 (2.2)	5 (11.1)
Neutrophil count decreased	4 (8.9)	0	4 (8.9)
Alanine aminotransferase increased	2 (4.4)	2 (4.4)	0
Metabolism and nutrition disorders			
-Total	2 (4.4)	1 (2.2)	1 (2.2)
Hypokalaemia	2 (4.4)	1 (2.2)	1 (2.2)
Hyperglycaemia	1 (2.2)	0	1 (2.2)
Musculoskeletal and connective tissue disorders			
-Total	4 (8.9)	4 (8.9)	0
Pain in extremity	4 (8.9)	4 (8.9)	0
Nervous system disorders			
-Total	2 (4.4)	2 (4.4)	0
Headache	2 (4.4)	2 (4.4)	0
Respiratory, thoracic and mediastinal disorders			

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (6.7)	2 (4.4)	1 (2.2)
Hypoxia	3 (6.7)	2 (4.4)	1 (2.2)
Vascular disorders			
-Total	4 (8.9)	2 (4.4)	2 (4.4)
Hypotension	4 (8.9)	2 (4.4)	2 (4.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190e
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

		All patients N=8	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (87.5)	4 (50.0)	3 (37.5)
Blood and lymphatic system disorders			
-Total	5 (62.5)	5 (62.5)	0
Febrile neutropenia	3 (37.5)	3 (37.5)	0
Anaemia	2 (25.0)	2 (25.0)	0
Cardiac disorders			
-Total	1 (12.5)	1 (12.5)	0
Tachycardia	1 (12.5)	1 (12.5)	0
Gastrointestinal disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Nausea	2 (25.0)	2 (25.0)	0
Stomatitis	1 (12.5)	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	2 (25.0)	2 (25.0)	0
Fatigue	1 (12.5)	1 (12.5)	0
Pain	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Infections and infestations			
-Total	2 (25.0)	0	2 (25.0)
Cellulitis	1 (12.5)	1 (12.5)	0
Human polyomavirus infection	1 (12.5)	0	1 (12.5)
Oral herpes	1 (12.5)	1 (12.5)	0
Pneumonia	1 (12.5)	0	1 (12.5)
Injury, poisoning and procedural complications			
-Total	1 (12.5)	1 (12.5)	0
Procedural pain	1 (12.5)	1 (12.5)	0
Investigations			
-Total	1 (12.5)	0	1 (12.5)
Neutrophil count decreased	1 (12.5)	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (12.5)	0	1 (12.5)
Musculoskeletal and connective tissue disorders			
-Total	1 (12.5)	1 (12.5)	0
Pain in extremity	1 (12.5)	1 (12.5)	0
Renal and urinary disorders			
-Total	1 (12.5)	0	1 (12.5)
Cystitis haemorrhagic	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Aspiration	1 (12.5)	0	1 (12.5)
Hypoxia	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Hypotension	2 (25.0)	1 (12.5)	1 (12.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190e
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	41 (61.2)	19 (28.4)	22 (32.8)
Blood and lymphatic system disorders			
-Total	33 (49.3)	24 (35.8)	9 (13.4)
Anaemia	17 (25.4)	17 (25.4)	0
Febrile neutropenia	15 (22.4)	15 (22.4)	0
Thrombocytopenia	10 (14.9)	3 (4.5)	7 (10.4)
Neutropenia	6 (9.0)	1 (1.5)	5 (7.5)
Gastrointestinal disorders			
-Total	4 (6.0)	4 (6.0)	0
Stomatitis	3 (4.5)	3 (4.5)	0
Nausea	1 (1.5)	1 (1.5)	0

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (1.5)	1 (1.5)	0
Pyrexia	1 (1.5)	1 (1.5)	0
Injury, poisoning and procedural complications			
-Total	1 (1.5)	1 (1.5)	0
Procedural pain	1 (1.5)	1 (1.5)	0
Investigations			
-Total	20 (29.9)	3 (4.5)	17 (25.4)
Platelet count decreased	10 (14.9)	1 (1.5)	9 (13.4)
White blood cell count decreased	9 (13.4)	1 (1.5)	8 (11.9)
Neutrophil count decreased	8 (11.9)	0	8 (11.9)
Alanine aminotransferase increased	5 (7.5)	5 (7.5)	0
Metabolism and nutrition disorders			
-Total	6 (9.0)	4 (6.0)	2 (3.0)
Hyperglycaemia	4 (6.0)	3 (4.5)	1 (1.5)
Hypokalaemia	4 (6.0)	2 (3.0)	2 (3.0)
Musculoskeletal and connective tissue disorders			

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (6.0)	4 (6.0)	0
Pain in extremity	4 (6.0)	4 (6.0)	0
Nervous system disorders			
-Total	4 (6.0)	4 (6.0)	0
Headache	4 (6.0)	4 (6.0)	0
Renal and urinary disorders			
-Total	1 (1.5)	1 (1.5)	0
Cystitis haemorrhagic	1 (1.5)	1 (1.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.0)	1 (1.5)	1 (1.5)
Hypoxia	2 (3.0)	1 (1.5)	1 (1.5)
Vascular disorders			
-Total	5 (7.5)	3 (4.5)	2 (3.0)
Hypotension	5 (7.5)	3 (4.5)	2 (3.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190f
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	1 (50.0)	0
Cardiac disorders			
-Total	1 (50.0)	1 (50.0)	0
Sinus tachycardia	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Bacteraemia	1 (50.0)	1 (50.0)	0
Vascular disorders			
-Total	1 (50.0)	1 (50.0)	0
Hypotension	1 (50.0)	1 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190f
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	47 (64.4)	22 (30.1)	25 (34.2)
Blood and lymphatic system disorders			
-Total	38 (52.1)	29 (39.7)	9 (12.3)
Anaemia	19 (26.0)	19 (26.0)	0
Febrile neutropenia	18 (24.7)	18 (24.7)	0
Thrombocytopenia	10 (13.7)	3 (4.1)	7 (9.6)
Neutropenia	6 (8.2)	1 (1.4)	5 (6.8)
Cardiac disorders			
-Total	1 (1.4)	1 (1.4)	0
Sinus tachycardia	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	4 (5.5)	3 (4.1)	1 (1.4)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	4 (5.5)	3 (4.1)	1 (1.4)
Investigations			
-Total	21 (28.8)	3 (4.1)	18 (24.7)
Platelet count decreased	10 (13.7)	1 (1.4)	9 (12.3)
White blood cell count decreased	10 (13.7)	1 (1.4)	9 (12.3)
Neutrophil count decreased	9 (12.3)	0	9 (12.3)
Alanine aminotransferase increased	5 (6.8)	5 (6.8)	0
Metabolism and nutrition disorders			
-Total	6 (8.2)	4 (5.5)	2 (2.7)
Hyperglycaemia	4 (5.5)	3 (4.1)	1 (1.4)
Hypokalaemia	4 (5.5)	2 (2.7)	2 (2.7)
Musculoskeletal and connective tissue disorders			
-Total	5 (6.8)	5 (6.8)	0
Pain in extremity	5 (6.8)	5 (6.8)	0
Nervous system disorders			
-Total	4 (5.5)	4 (5.5)	0
Headache	4 (5.5)	4 (5.5)	0
Vascular disorders			

Philadelphia chromosome/BCR-ABL: Negative

Group term Preferred term	All patients N=73 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	6 (8.2)	3 (4.1)	3 (4.1)
Hypotension	6 (8.2)	3 (4.1)	3 (4.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190g
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	2 (66.7)	1 (33.3)
Blood and lymphatic system disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Febrile neutropenia	1 (33.3)	1 (33.3)	0
Leukopenia	1 (33.3)	0	1 (33.3)
Neutropenia	1 (33.3)	0	1 (33.3)
Cardiac disorders			
-Total	1 (33.3)	1 (33.3)	0
Tachycardia	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders			
-Total	1 (33.3)	1 (33.3)	0
Nausea	1 (33.3)	1 (33.3)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	1 (33.3)	1 (33.3)	0
Escherichia bacteraemia	1 (33.3)	1 (33.3)	0
Investigations			
-Total	2 (66.7)	2 (66.7)	0
Alanine aminotransferase increased	1 (33.3)	1 (33.3)	0
Aspartate aminotransferase increased	1 (33.3)	1 (33.3)	0
Metabolism and nutrition disorders			
-Total	1 (33.3)	0	1 (33.3)
Decreased appetite	1 (33.3)	1 (33.3)	0
Hyperuricaemia	1 (33.3)	0	1 (33.3)
Musculoskeletal and connective tissue disorders			
-Total	1 (33.3)	1 (33.3)	0
Bone pain	1 (33.3)	1 (33.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion,

are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.
/vob/CCTL019/haq/haq_eu_5/pgm/saf/t190_gd_b2205.sas@@/main/1 29SEP20:18:23 Final

Table 190g
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (63.9)	22 (30.6)	24 (33.3)
Blood and lymphatic system disorders			
-Total	36 (50.0)	28 (38.9)	8 (11.1)
Anaemia	19 (26.4)	19 (26.4)	0
Febrile neutropenia	17 (23.6)	17 (23.6)	0
Thrombocytopenia	10 (13.9)	3 (4.2)	7 (9.7)
Neutropenia	5 (6.9)	1 (1.4)	4 (5.6)
Gastrointestinal disorders			
-Total	5 (6.9)	4 (5.6)	1 (1.4)
Stomatitis	4 (5.6)	3 (4.2)	1 (1.4)
Nausea	2 (2.8)	2 (2.8)	0
Infections and infestations			

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.4)	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Investigations			
-Total	20 (27.8)	2 (2.8)	18 (25.0)
Platelet count decreased	10 (13.9)	1 (1.4)	9 (12.5)
White blood cell count decreased	10 (13.9)	1 (1.4)	9 (12.5)
Neutrophil count decreased	9 (12.5)	0	9 (12.5)
Alanine aminotransferase increased	4 (5.6)	4 (5.6)	0
Aspartate aminotransferase increased	2 (2.8)	2 (2.8)	0
Metabolism and nutrition disorders			
-Total	8 (11.1)	6 (8.3)	2 (2.8)
Hyperglycaemia	4 (5.6)	3 (4.2)	1 (1.4)
Hypokalaemia	4 (5.6)	2 (2.8)	2 (2.8)
Decreased appetite	2 (2.8)	2 (2.8)	0
Hyperuricaemia	1 (1.4)	1 (1.4)	0
Musculoskeletal and connective tissue disorders			
-Total	5 (6.9)	5 (6.9)	0

Mixed-lineage leukemia rearrangement: No

Group term Preferred term	All patients N=72 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pain in extremity	5 (6.9)	5 (6.9)	0
Nervous system disorders			
-Total	4 (5.6)	4 (5.6)	0
Headache	4 (5.6)	4 (5.6)	0
Vascular disorders			
-Total	7 (9.7)	4 (5.6)	3 (4.2)
Hypotension	7 (9.7)	4 (5.6)	3 (4.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190h
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Blood and lymphatic system disorders			
-Total	1 (100)	1 (100)	0
Febrile neutropenia	1 (100)	1 (100)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190h
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	47 (63.5)	22 (29.7)	25 (33.8)
Blood and lymphatic system disorders			
-Total	37 (50.0)	28 (37.8)	9 (12.2)
Anaemia	19 (25.7)	19 (25.7)	0
Febrile neutropenia	17 (23.0)	17 (23.0)	0
Thrombocytopenia	10 (13.5)	3 (4.1)	7 (9.5)
Neutropenia	6 (8.1)	1 (1.4)	5 (6.8)
Gastrointestinal disorders			
-Total	4 (5.4)	3 (4.1)	1 (1.4)
Stomatitis	4 (5.4)	3 (4.1)	1 (1.4)
Investigations			

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	21 (28.4)	3 (4.1)	18 (24.3)
Platelet count decreased	10 (13.5)	1 (1.4)	9 (12.2)
White blood cell count decreased	10 (13.5)	1 (1.4)	9 (12.2)
Neutrophil count decreased	9 (12.2)	0	9 (12.2)
Alanine aminotransferase increased	5 (6.8)	5 (6.8)	0
Metabolism and nutrition disorders			
-Total	6 (8.1)	4 (5.4)	2 (2.7)
Hyperglycaemia	4 (5.4)	3 (4.1)	1 (1.4)
Hypokalaemia	4 (5.4)	2 (2.7)	2 (2.7)
Musculoskeletal and connective tissue disorders			
-Total	5 (6.8)	5 (6.8)	0
Pain in extremity	5 (6.8)	5 (6.8)	0
Nervous system disorders			
-Total	4 (5.4)	4 (5.4)	0
Headache	4 (5.4)	4 (5.4)	0
Vascular disorders			
-Total	7 (9.5)	4 (5.4)	3 (4.1)

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypotension	7 (9.5)	4 (5.4)	3 (4.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190i
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	1 (25.0)	1 (25.0)
Blood and lymphatic system disorders			
-Total	1 (25.0)	1 (25.0)	0
Anaemia	1 (25.0)	1 (25.0)	0
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Colitis	1 (25.0)	1 (25.0)	0
Hepatobiliary disorders			
-Total	1 (25.0)	1 (25.0)	0
Cholecystitis	1 (25.0)	1 (25.0)	0
Infections and infestations			

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (50.0)	2 (50.0)	0
Enterococcal bacteraemia	1 (25.0)	1 (25.0)	0
Gastroenteritis	1 (25.0)	1 (25.0)	0
Streptococcal bacteraemia	1 (25.0)	1 (25.0)	0
Investigations			
-Total	1 (25.0)	0	1 (25.0)
Alanine aminotransferase increased	1 (25.0)	1 (25.0)	0
Lymphocyte count decreased	1 (25.0)	1 (25.0)	0
Neutrophil count decreased	1 (25.0)	0	1 (25.0)
Platelet count decreased	1 (25.0)	0	1 (25.0)
White blood cell count decreased	1 (25.0)	0	1 (25.0)
Metabolism and nutrition disorders			
-Total	2 (50.0)	2 (50.0)	0
Dehydration	1 (25.0)	1 (25.0)	0
Hyperglycaemia	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	0	1 (25.0)

BCR-ABL1-like: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Idiopathic pneumonia syndrome	1 (25.0)	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190i
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	47 (66.2)	23 (32.4)	24 (33.8)
Blood and lymphatic system disorders			
-Total	37 (52.1)	28 (39.4)	9 (12.7)
Anaemia	18 (25.4)	18 (25.4)	0
Febrile neutropenia	18 (25.4)	18 (25.4)	0
Thrombocytopenia	10 (14.1)	3 (4.2)	7 (9.9)
Neutropenia	6 (8.5)	1 (1.4)	5 (7.0)
Gastrointestinal disorders			
-Total	5 (7.0)	4 (5.6)	1 (1.4)
Stomatitis	4 (5.6)	3 (4.2)	1 (1.4)
Colitis	2 (2.8)	2 (2.8)	0

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	1 (1.4)	1 (1.4)	0
Enterococcal bacteraemia	1 (1.4)	1 (1.4)	0
Investigations			
-Total	20 (28.2)	3 (4.2)	17 (23.9)
Platelet count decreased	9 (12.7)	1 (1.4)	8 (11.3)
White blood cell count decreased	9 (12.7)	1 (1.4)	8 (11.3)
Neutrophil count decreased	8 (11.3)	0	8 (11.3)
Alanine aminotransferase increased	4 (5.6)	4 (5.6)	0
Metabolism and nutrition disorders			
-Total	6 (8.5)	4 (5.6)	2 (2.8)
Hypokalaemia	4 (5.6)	2 (2.8)	2 (2.8)
Hyperglycaemia	3 (4.2)	2 (2.8)	1 (1.4)
Dehydration	1 (1.4)	1 (1.4)	0
Musculoskeletal and connective tissue disorders			
-Total	5 (7.0)	5 (7.0)	0
Pain in extremity	5 (7.0)	5 (7.0)	0

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	4 (5.6)	4 (5.6)	0
Headache	4 (5.6)	4 (5.6)	0
Vascular disorders			
-Total	7 (9.9)	4 (5.6)	3 (4.2)
Hypotension	7 (9.9)	4 (5.6)	3 (4.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190j
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (68.2)	8 (36.4)	7 (31.8)
Blood and lymphatic system disorders			
-Total	9 (40.9)	4 (18.2)	5 (22.7)
Febrile neutropenia	5 (22.7)	5 (22.7)	0
Neutropenia	4 (18.2)	0	4 (18.2)
Thrombocytopenia	3 (13.6)	0	3 (13.6)
Anaemia	2 (9.1)	2 (9.1)	0
Gastrointestinal disorders			
-Total	2 (9.1)	2 (9.1)	0
Stomatitis	2 (9.1)	2 (9.1)	0
Infections and infestations			
-Total	2 (9.1)	2 (9.1)	0

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (9.1)	2 (9.1)	0
Investigations			
-Total	3 (13.6)	0	3 (13.6)
Platelet count decreased	2 (9.1)	0	2 (9.1)
White blood cell count decreased	2 (9.1)	0	2 (9.1)
Metabolism and nutrition disorders			
-Total	3 (13.6)	1 (4.5)	2 (9.1)
Hyperuricaemia	2 (9.1)	1 (4.5)	1 (4.5)
Hypokalaemia	1 (4.5)	0	1 (4.5)
Vascular disorders			
-Total	3 (13.6)	2 (9.1)	1 (4.5)
Hypotension	3 (13.6)	2 (9.1)	1 (4.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190j
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (66.0)	17 (32.1)	18 (34.0)
Blood and lymphatic system disorders			
-Total	29 (54.7)	25 (47.2)	4 (7.5)
Anaemia	17 (32.1)	17 (32.1)	0
Febrile neutropenia	13 (24.5)	13 (24.5)	0
Thrombocytopenia	7 (13.2)	3 (5.7)	4 (7.5)
Neutropenia	2 (3.8)	1 (1.9)	1 (1.9)
Gastrointestinal disorders			
-Total	7 (13.2)	6 (11.3)	1 (1.9)
Abdominal pain	3 (5.7)	3 (5.7)	0
Colitis	3 (5.7)	3 (5.7)	0
Nausea	3 (5.7)	3 (5.7)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	2 (3.8)	1 (1.9)	1 (1.9)
Infections and infestations			
-Total	1 (1.9)	1 (1.9)	0
Device related infection	1 (1.9)	1 (1.9)	0
Investigations			
-Total	18 (34.0)	3 (5.7)	15 (28.3)
Neutrophil count decreased	9 (17.0)	0	9 (17.0)
Platelet count decreased	8 (15.1)	1 (1.9)	7 (13.2)
White blood cell count decreased	8 (15.1)	1 (1.9)	7 (13.2)
Alanine aminotransferase increased	5 (9.4)	5 (9.4)	0
Metabolism and nutrition disorders			
-Total	5 (9.4)	4 (7.5)	1 (1.9)
Hyperglycaemia	4 (7.5)	3 (5.7)	1 (1.9)
Hypokalaemia	3 (5.7)	2 (3.8)	1 (1.9)
Musculoskeletal and connective tissue disorders			
-Total	5 (9.4)	5 (9.4)	0
Pain in extremity	5 (9.4)	5 (9.4)	0
Nervous system disorders			

Complex karyotypes II (>=5 unrelated abnormalities) : No

Group term Preferred term	All patients N=53 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	4 (7.5)	4 (7.5)	0
Headache	4 (7.5)	4 (7.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (5.7)	2 (3.8)	1 (1.9)
Hypoxia	3 (5.7)	2 (3.8)	1 (1.9)
Vascular disorders			
-Total	4 (7.5)	2 (3.8)	2 (3.8)
Hypotension	4 (7.5)	2 (3.8)	2 (3.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190k
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=75		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	48 (64.0)	23 (30.7)	25 (33.3)
Blood and lymphatic system disorders			
-Total	38 (50.7)	29 (38.7)	9 (12.0)
Anaemia	19 (25.3)	19 (25.3)	0
Febrile neutropenia	18 (24.0)	18 (24.0)	0
Thrombocytopenia	10 (13.3)	3 (4.0)	7 (9.3)
Neutropenia	6 (8.0)	1 (1.3)	5 (6.7)
Gastrointestinal disorders			
-Total	4 (5.3)	3 (4.0)	1 (1.3)
Stomatitis	4 (5.3)	3 (4.0)	1 (1.3)
Investigations			

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	21 (28.0)	3 (4.0)	18 (24.0)
Platelet count decreased	10 (13.3)	1 (1.3)	9 (12.0)
White blood cell count decreased	10 (13.3)	1 (1.3)	9 (12.0)
Neutrophil count decreased	9 (12.0)	0	9 (12.0)
Alanine aminotransferase increased	5 (6.7)	5 (6.7)	0
Metabolism and nutrition disorders			
-Total	6 (8.0)	4 (5.3)	2 (2.7)
Hyperglycaemia	4 (5.3)	3 (4.0)	1 (1.3)
Hypokalaemia	4 (5.3)	2 (2.7)	2 (2.7)
Musculoskeletal and connective tissue disorders			
-Total	5 (6.7)	5 (6.7)	0
Pain in extremity	5 (6.7)	5 (6.7)	0
Nervous system disorders			
-Total	4 (5.3)	4 (5.3)	0
Headache	4 (5.3)	4 (5.3)	0
Vascular disorders			
-Total	7 (9.3)	4 (5.3)	3 (4.0)

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	7 (9.3)	4 (5.3)	3 (4.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190l
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (68.8)	14 (43.8)	8 (25.0)
Blood and lymphatic system disorders			
-Total	16 (50.0)	13 (40.6)	3 (9.4)
Anaemia	10 (31.3)	10 (31.3)	0
Febrile neutropenia	6 (18.8)	6 (18.8)	0
Thrombocytopenia	5 (15.6)	2 (6.3)	3 (9.4)
Gastrointestinal disorders			
-Total	5 (15.6)	5 (15.6)	0
Colitis	3 (9.4)	3 (9.4)	0
Stomatitis	3 (9.4)	3 (9.4)	0

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	2 (6.3)	0	2 (6.3)
Multiple organ dysfunction syndrome	2 (6.3)	0	2 (6.3)
Hepatobiliary disorders			
-Total	2 (6.3)	2 (6.3)	0
Hyperbilirubinaemia	2 (6.3)	2 (6.3)	0
Infections and infestations			
-Total	6 (18.8)	4 (12.5)	2 (6.3)
Enterococcal bacteraemia	2 (6.3)	2 (6.3)	0
Klebsiella sepsis	2 (6.3)	0	2 (6.3)
Staphylococcal bacteraemia	2 (6.3)	2 (6.3)	0
Investigations			
-Total	9 (28.1)	2 (6.3)	7 (21.9)
Neutrophil count decreased	4 (12.5)	0	4 (12.5)
Alanine aminotransferase increased	3 (9.4)	3 (9.4)	0
Platelet count decreased	3 (9.4)	0	3 (9.4)
White blood cell count decreased	2 (6.3)	0	2 (6.3)

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	7 (21.9)	6 (18.8)	1 (3.1)
Hyperglycaemia	3 (9.4)	2 (6.3)	1 (3.1)
Decreased appetite	2 (6.3)	2 (6.3)	0
Hypokalaemia	2 (6.3)	1 (3.1)	1 (3.1)
Tumour lysis syndrome	2 (6.3)	2 (6.3)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (6.3)	2 (6.3)	0
Pain in extremity	2 (6.3)	2 (6.3)	0
Nervous system disorders			
-Total	2 (6.3)	2 (6.3)	0
Headache	2 (6.3)	2 (6.3)	0
Vascular disorders			
-Total	3 (9.4)	3 (9.4)	0
Hypotension	3 (9.4)	3 (9.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190l
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	27 (62.8)	10 (23.3)	17 (39.5)
Blood and lymphatic system disorders			
-Total	22 (51.2)	16 (37.2)	6 (14.0)
Febrile neutropenia	12 (27.9)	12 (27.9)	0
Anaemia	9 (20.9)	9 (20.9)	0
Neutropenia	6 (14.0)	1 (2.3)	5 (11.6)
Thrombocytopenia	5 (11.6)	1 (2.3)	4 (9.3)
Gastrointestinal disorders			
-Total	3 (7.0)	2 (4.7)	1 (2.3)
Nausea	3 (7.0)	3 (7.0)	0
Stomatitis	1 (2.3)	0	1 (2.3)

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	12 (27.9)	1 (2.3)	11 (25.6)
White blood cell count decreased	8 (18.6)	1 (2.3)	7 (16.3)
Platelet count decreased	7 (16.3)	1 (2.3)	6 (14.0)
Neutrophil count decreased	5 (11.6)	0	5 (11.6)
Alanine aminotransferase increased	2 (4.7)	2 (4.7)	0
Metabolism and nutrition disorders			
-Total	3 (7.0)	2 (4.7)	1 (2.3)
Hypokalaemia	2 (4.7)	1 (2.3)	1 (2.3)
Decreased appetite	1 (2.3)	1 (2.3)	0
Hyperglycaemia	1 (2.3)	1 (2.3)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (7.0)	3 (7.0)	0
Pain in extremity	3 (7.0)	3 (7.0)	0
Nervous system disorders			
-Total	2 (4.7)	2 (4.7)	0
Headache	2 (4.7)	2 (4.7)	0

Prior SCT therapy: No

Group term Preferred term	All patients N=43 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
-Total	4 (9.3)	1 (2.3)	3 (7.0)
Hypotension	4 (9.3)	1 (2.3)	3 (7.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190m
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (72.2)	7 (38.9)	6 (33.3)
Blood and lymphatic system disorders			
-Total	7 (38.9)	5 (27.8)	2 (11.1)
Anaemia	4 (22.2)	4 (22.2)	0
Febrile neutropenia	3 (16.7)	3 (16.7)	0
Neutropenia	1 (5.6)	0	1 (5.6)
Thrombocytopenia	1 (5.6)	0	1 (5.6)
Gastrointestinal disorders			
-Total	1 (5.6)	1 (5.6)	0
Stomatitis	1 (5.6)	1 (5.6)	0

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	2 (11.1)	2 (11.1)	0
Pyrexia	2 (11.1)	2 (11.1)	0
Pain	1 (5.6)	1 (5.6)	0
Infections and infestations			
-Total	7 (38.9)	6 (33.3)	1 (5.6)
Device related infection	2 (11.1)	2 (11.1)	0
Alpha haemolytic streptococcal infection	1 (5.6)	1 (5.6)	0
Bronchopulmonary aspergillosis	1 (5.6)	1 (5.6)	0
Clostridium difficile colitis	1 (5.6)	1 (5.6)	0
Escherichia infection	1 (5.6)	1 (5.6)	0
Escherichia urinary tract infection	1 (5.6)	1 (5.6)	0
Pneumonia	1 (5.6)	0	1 (5.6)
Streptococcal infection	1 (5.6)	1 (5.6)	0
Investigations			
-Total	5 (27.8)	1 (5.6)	4 (22.2)
Platelet count decreased	3 (16.7)	1 (5.6)	2 (11.1)

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	3 (16.7)	0	3 (16.7)
Neutrophil count decreased	2 (11.1)	0	2 (11.1)
Blast cell count increased	1 (5.6)	1 (5.6)	0
Blood bilirubin increased	1 (5.6)	1 (5.6)	0
Blood lactate dehydrogenase increased	1 (5.6)	1 (5.6)	0
Serum ferritin increased	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Hyperglycaemia	1 (5.6)	1 (5.6)	0
Hypocalcaemia	1 (5.6)	0	1 (5.6)
Hypokalaemia	1 (5.6)	1 (5.6)	0
Hypophosphataemia	1 (5.6)	1 (5.6)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (5.6)	1 (5.6)	0
Pain in extremity	1 (5.6)	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders			

Eligibility for SCT: Yes

Group term Preferred term	All patients N=18 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (5.6)	0	1 (5.6)
Aspiration	1 (5.6)	0	1 (5.6)
Hypoxia	1 (5.6)	1 (5.6)	0
Vascular disorders			
-Total	1 (5.6)	0	1 (5.6)
Hypotension	1 (5.6)	0	1 (5.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190m
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (64.9)	18 (31.6)	19 (33.3)
Blood and lymphatic system disorders			
-Total	31 (54.4)	24 (42.1)	7 (12.3)
Anaemia	15 (26.3)	15 (26.3)	0
Febrile neutropenia	15 (26.3)	15 (26.3)	0
Thrombocytopenia	9 (15.8)	3 (5.3)	6 (10.5)
Neutropenia	5 (8.8)	1 (1.8)	4 (7.0)
Gastrointestinal disorders			
-Total	8 (14.0)	7 (12.3)	1 (1.8)
Abdominal pain	3 (5.3)	3 (5.3)	0
Colitis	3 (5.3)	3 (5.3)	0

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	3 (5.3)	3 (5.3)	0
Stomatitis	3 (5.3)	2 (3.5)	1 (1.8)
Infections and infestations			
-Total	2 (3.5)	2 (3.5)	0
Clostridium difficile colitis	1 (1.8)	1 (1.8)	0
Device related infection	1 (1.8)	1 (1.8)	0
Investigations			
-Total	18 (31.6)	4 (7.0)	14 (24.6)
Neutrophil count decreased	7 (12.3)	0	7 (12.3)
Platelet count decreased	7 (12.3)	0	7 (12.3)
White blood cell count decreased	7 (12.3)	1 (1.8)	6 (10.5)
Alanine aminotransferase increased	5 (8.8)	5 (8.8)	0
Aspartate aminotransferase increased	3 (5.3)	3 (5.3)	0
Blood lactate dehydrogenase increased	1 (1.8)	1 (1.8)	0
Metabolism and nutrition disorders			
-Total	7 (12.3)	5 (8.8)	2 (3.5)
Decreased appetite	3 (5.3)	3 (5.3)	0

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	3 (5.3)	2 (3.5)	1 (1.8)
Hypokalaemia	3 (5.3)	1 (1.8)	2 (3.5)
Hypocalcaemia	1 (1.8)	0	1 (1.8)
Hypophosphataemia	1 (1.8)	1 (1.8)	0
Musculoskeletal and connective tissue disorders			
-Total	4 (7.0)	4 (7.0)	0
Pain in extremity	4 (7.0)	4 (7.0)	0
Nervous system disorders			
-Total	4 (7.0)	4 (7.0)	0
Headache	4 (7.0)	4 (7.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.5)	1 (1.8)	1 (1.8)
Hypoxia	2 (3.5)	1 (1.8)	1 (1.8)
Vascular disorders			
-Total	6 (10.5)	4 (7.0)	2 (3.5)
Hypotension	6 (10.5)	4 (7.0)	2 (3.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190n
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (59.1)	7 (31.8)	6 (27.3)
Blood and lymphatic system disorders			
-Total	11 (50.0)	8 (36.4)	3 (13.6)
Anaemia	7 (31.8)	7 (31.8)	0
Febrile neutropenia	4 (18.2)	4 (18.2)	0
Thrombocytopenia	4 (18.2)	1 (4.5)	3 (13.6)
Neutropenia	1 (4.5)	0	1 (4.5)
Gastrointestinal disorders			
-Total	3 (13.6)	3 (13.6)	0
Abdominal pain	2 (9.1)	2 (9.1)	0
Stomatitis	2 (9.1)	2 (9.1)	0
Investigations			

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (22.7)	0	5 (22.7)
Neutrophil count decreased	3 (13.6)	0	3 (13.6)
White blood cell count decreased	3 (13.6)	0	3 (13.6)
Platelet count decreased	1 (4.5)	0	1 (4.5)
Metabolism and nutrition disorders			
-Total	2 (9.1)	2 (9.1)	0
Dehydration	2 (9.1)	2 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (9.1)	2 (9.1)	0
Pain in extremity	2 (9.1)	2 (9.1)	0
Nervous system disorders			
-Total	1 (4.5)	1 (4.5)	0
Headache	1 (4.5)	1 (4.5)	0
Vascular disorders			
-Total	1 (4.5)	0	1 (4.5)
Hypotension	1 (4.5)	0	1 (4.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190n
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	37 (69.8)	18 (34.0)	19 (35.8)
Blood and lymphatic system disorders			
-Total	27 (50.9)	21 (39.6)	6 (11.3)
Febrile neutropenia	14 (26.4)	14 (26.4)	0
Anaemia	12 (22.6)	12 (22.6)	0
Thrombocytopenia	6 (11.3)	2 (3.8)	4 (7.5)
Neutropenia	5 (9.4)	1 (1.9)	4 (7.5)
Gastrointestinal disorders			
-Total	3 (5.7)	2 (3.8)	1 (1.9)
Stomatitis	2 (3.8)	1 (1.9)	1 (1.9)
Abdominal pain	1 (1.9)	1 (1.9)	0
Infections and infestations			

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (5.7)	3 (5.7)	0
Device related infection	3 (5.7)	3 (5.7)	0
Investigations			
-Total	17 (32.1)	4 (7.5)	13 (24.5)
Platelet count decreased	9 (17.0)	1 (1.9)	8 (15.1)
White blood cell count decreased	7 (13.2)	1 (1.9)	6 (11.3)
Neutrophil count decreased	6 (11.3)	0	6 (11.3)
Alanine aminotransferase increased	5 (9.4)	5 (9.4)	0
Aspartate aminotransferase increased	3 (5.7)	3 (5.7)	0
Metabolism and nutrition disorders			
-Total	6 (11.3)	4 (7.5)	2 (3.8)
Hyperglycaemia	4 (7.5)	3 (5.7)	1 (1.9)
Hypokalaemia	4 (7.5)	2 (3.8)	2 (3.8)
Musculoskeletal and connective tissue disorders			
-Total	3 (5.7)	3 (5.7)	0
Pain in extremity	3 (5.7)	3 (5.7)	0
Nervous system disorders			

Baseline bone marrow tumor burden: High

Group term Preferred term	All patients N=53 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	3 (5.7)	3 (5.7)	0
Headache	3 (5.7)	3 (5.7)	0
Vascular disorders			
-Total	6 (11.3)	4 (7.5)	2 (3.8)
Hypotension	6 (11.3)	4 (7.5)	2 (3.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190o
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	3 (42.9)	3 (42.9)
Blood and lymphatic system disorders			
-Total	5 (71.4)	3 (42.9)	2 (28.6)
Anaemia	2 (28.6)	2 (28.6)	0
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Neutropenia	2 (28.6)	1 (14.3)	1 (14.3)
Leukopenia	1 (14.3)	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	1 (14.3)
Immune system disorders			
-Total	2 (28.6)	2 (28.6)	0
Anaphylactic reaction	2 (28.6)	2 (28.6)	0
Infections and infestations			

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (42.9)	3 (42.9)	0
Device related infection	1 (14.3)	1 (14.3)	0
Escherichia bacteraemia	1 (14.3)	1 (14.3)	0
Escherichia infection	1 (14.3)	1 (14.3)	0
Streptococcal infection	1 (14.3)	1 (14.3)	0
Injury, poisoning and procedural complications			
-Total	1 (14.3)	1 (14.3)	0
Extradural haematoma	1 (14.3)	1 (14.3)	0
Procedural pain	1 (14.3)	1 (14.3)	0
Subdural haematoma	1 (14.3)	1 (14.3)	0
Investigations			
-Total	4 (57.1)	3 (42.9)	1 (14.3)
Alanine aminotransferase increased	2 (28.6)	2 (28.6)	0
Aspartate aminotransferase increased	2 (28.6)	2 (28.6)	0
Blood bilirubin increased	1 (14.3)	1 (14.3)	0
Platelet count decreased	1 (14.3)	0	1 (14.3)
White blood cell count decreased	1 (14.3)	0	1 (14.3)

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	4 (57.1)	3 (42.9)	1 (14.3)
Tumour lysis syndrome	2 (28.6)	2 (28.6)	0
Decreased appetite	1 (14.3)	1 (14.3)	0
Hyperglycaemia	1 (14.3)	1 (14.3)	0
Hyperuricaemia	1 (14.3)	0	1 (14.3)
Hypokalaemia	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (14.3)	1 (14.3)	0
Bone pain	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	1 (14.3)	1 (14.3)	0
Headache	1 (14.3)	1 (14.3)	0
Psychiatric disorders			
-Total	1 (14.3)	1 (14.3)	0
Mental status changes	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=7 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	1 (14.3)	1 (14.3)	0
Epistaxis	1 (14.3)	1 (14.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190o
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	45 (66.2)	23 (33.8)	22 (32.4)
Blood and lymphatic system disorders			
-Total	33 (48.5)	26 (38.2)	7 (10.3)
Anaemia	17 (25.0)	17 (25.0)	0
Febrile neutropenia	16 (23.5)	16 (23.5)	0
Thrombocytopenia	9 (13.2)	3 (4.4)	6 (8.8)
Neutropenia	4 (5.9)	0	4 (5.9)
Gastrointestinal disorders			
-Total	4 (5.9)	3 (4.4)	1 (1.5)
Stomatitis	4 (5.9)	3 (4.4)	1 (1.5)
Infections and infestations			
-Total	3 (4.4)	3 (4.4)	0

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Device related infection	2 (2.9)	2 (2.9)	0
Escherichia bacteraemia	1 (1.5)	1 (1.5)	0
Injury, poisoning and procedural complications			
-Total	1 (1.5)	1 (1.5)	0
Procedural pain	1 (1.5)	1 (1.5)	0
Investigations			
-Total	18 (26.5)	1 (1.5)	17 (25.0)
Neutrophil count decreased	9 (13.2)	0	9 (13.2)
Platelet count decreased	9 (13.2)	1 (1.5)	8 (11.8)
White blood cell count decreased	9 (13.2)	1 (1.5)	8 (11.8)
Alanine aminotransferase increased	3 (4.4)	3 (4.4)	0
Aspartate aminotransferase increased	1 (1.5)	1 (1.5)	0
Metabolism and nutrition disorders			
-Total	7 (10.3)	5 (7.4)	2 (2.9)
Hyperglycaemia	3 (4.4)	2 (2.9)	1 (1.5)
Hypokalaemia	3 (4.4)	1 (1.5)	2 (2.9)
Decreased appetite	2 (2.9)	2 (2.9)	0

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=68 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hyperuricaemia	1 (1.5)	1 (1.5)	0
Musculoskeletal and connective tissue disorders			
-Total	5 (7.4)	5 (7.4)	0
Pain in extremity	5 (7.4)	5 (7.4)	0
Nervous system disorders			
-Total	3 (4.4)	3 (4.4)	0
Headache	3 (4.4)	3 (4.4)	0
Vascular disorders			
-Total	7 (10.3)	4 (5.9)	3 (4.4)
Hypotension	7 (10.3)	4 (5.9)	3 (4.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190p
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	2 (50.0)	0
Blood and lymphatic system disorders			
-Total	2 (50.0)	2 (50.0)	0
Anaemia	1 (25.0)	1 (25.0)	0
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Stomatitis	1 (25.0)	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190p
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (64.8)	21 (29.6)	25 (35.2)
Blood and lymphatic system disorders			
-Total	36 (50.7)	27 (38.0)	9 (12.7)
Anaemia	18 (25.4)	18 (25.4)	0
Febrile neutropenia	17 (23.9)	17 (23.9)	0
Thrombocytopenia	10 (14.1)	3 (4.2)	7 (9.9)
Neutropenia	6 (8.5)	1 (1.4)	5 (7.0)
Gastrointestinal disorders			
-Total	3 (4.2)	2 (2.8)	1 (1.4)
Stomatitis	3 (4.2)	2 (2.8)	1 (1.4)
Investigations			

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	21 (29.6)	3 (4.2)	18 (25.4)
Platelet count decreased	10 (14.1)	1 (1.4)	9 (12.7)
White blood cell count decreased	10 (14.1)	1 (1.4)	9 (12.7)
Neutrophil count decreased	9 (12.7)	0	9 (12.7)
Alanine aminotransferase increased	5 (7.0)	5 (7.0)	0
Metabolism and nutrition disorders			
-Total	6 (8.5)	4 (5.6)	2 (2.8)
Hyperglycaemia	4 (5.6)	3 (4.2)	1 (1.4)
Hypokalaemia	4 (5.6)	2 (2.8)	2 (2.8)
Musculoskeletal and connective tissue disorders			
-Total	5 (7.0)	5 (7.0)	0
Pain in extremity	5 (7.0)	5 (7.0)	0
Nervous system disorders			
-Total	4 (5.6)	4 (5.6)	0
Headache	4 (5.6)	4 (5.6)	0
Vascular disorders			
-Total	7 (9.9)	4 (5.6)	3 (4.2)

Down syndrome: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	7 (9.9)	4 (5.6)	3 (4.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190q
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

		All patients N=32	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (68.8)	13 (40.6)	9 (28.1)
Blood and lymphatic system disorders			
-Total	16 (50.0)	15 (46.9)	1 (3.1)
Febrile neutropenia	9 (28.1)	9 (28.1)	0
Anaemia	6 (18.8)	6 (18.8)	0
Neutropenia	2 (6.3)	1 (3.1)	1 (3.1)
Thrombocytopenia	1 (3.1)	1 (3.1)	0
Gastrointestinal disorders			
-Total	3 (9.4)	3 (9.4)	0
Stomatitis	2 (6.3)	2 (6.3)	0
Colitis	1 (3.1)	1 (3.1)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (3.1)	1 (3.1)	0
Pyrexia	1 (3.1)	1 (3.1)	0
Infections and infestations			
-Total	4 (12.5)	4 (12.5)	0
Device related infection	3 (9.4)	3 (9.4)	0
Staphylococcal bacteraemia	1 (3.1)	1 (3.1)	0
Injury, poisoning and procedural complications			
-Total	2 (6.3)	2 (6.3)	0
Procedural pain	2 (6.3)	2 (6.3)	0
Investigations			
-Total	13 (40.6)	5 (15.6)	8 (25.0)
Platelet count decreased	6 (18.8)	0	6 (18.8)
Alanine aminotransferase increased	5 (15.6)	5 (15.6)	0
White blood cell count decreased	5 (15.6)	1 (3.1)	4 (12.5)
Neutrophil count decreased	4 (12.5)	0	4 (12.5)
Aspartate aminotransferase increased	2 (6.3)	2 (6.3)	0

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=32 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Blood lactate dehydrogenase increased	1 (3.1)	1 (3.1)	0
Electrocardiogram qt prolonged	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			
-Total	3 (9.4)	3 (9.4)	0
Hyperglycaemia	3 (9.4)	3 (9.4)	0
Decreased appetite	1 (3.1)	1 (3.1)	0
Hypokalaemia	1 (3.1)	1 (3.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (3.1)	1 (3.1)	0
Pain in extremity	1 (3.1)	1 (3.1)	0
Nervous system disorders			
-Total	3 (9.4)	3 (9.4)	0
Headache	3 (9.4)	3 (9.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190q
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	23 (71.9)	13 (40.6)	10 (31.3)
Blood and lymphatic system disorders			
-Total	17 (53.1)	12 (37.5)	5 (15.6)
Anaemia	9 (28.1)	9 (28.1)	0
Febrile neutropenia	8 (25.0)	8 (25.0)	0
Thrombocytopenia	5 (15.6)	1 (3.1)	4 (12.5)
Neutropenia	2 (6.3)	0	2 (6.3)
Cardiac disorders			
-Total	1 (3.1)	1 (3.1)	0
Sinus tachycardia	1 (3.1)	1 (3.1)	0
Gastrointestinal disorders			
-Total	3 (9.4)	2 (6.3)	1 (3.1)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nausea	2 (6.3)	2 (6.3)	0
Abdominal pain	1 (3.1)	1 (3.1)	0
Stomatitis	1 (3.1)	0	1 (3.1)
Infections and infestations			
-Total	1 (3.1)	1 (3.1)	0
Clostridium difficile colitis	1 (3.1)	1 (3.1)	0
Investigations			
-Total	7 (21.9)	1 (3.1)	6 (18.8)
White blood cell count decreased	4 (12.5)	0	4 (12.5)
Neutrophil count decreased	3 (9.4)	0	3 (9.4)
Platelet count decreased	3 (9.4)	1 (3.1)	2 (6.3)
Aspartate aminotransferase increased	1 (3.1)	1 (3.1)	0
Metabolism and nutrition disorders			
-Total	5 (15.6)	3 (9.4)	2 (6.3)
Hyperuricaemia	2 (6.3)	1 (3.1)	1 (3.1)
Decreased appetite	1 (3.1)	1 (3.1)	0
Dehydration	1 (3.1)	1 (3.1)	0
Hypocalcaemia	1 (3.1)	0	1 (3.1)

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=32 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypokalaemia	1 (3.1)	1 (3.1)	0
Hypophosphataemia	1 (3.1)	1 (3.1)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (9.4)	3 (9.4)	0
Pain in extremity	2 (6.3)	2 (6.3)	0
Back pain	1 (3.1)	1 (3.1)	0
Renal and urinary disorders			
-Total	1 (3.1)	0	1 (3.1)
Cystitis haemorrhagic	1 (3.1)	0	1 (3.1)
Vascular disorders			
-Total	2 (6.3)	2 (6.3)	0
Hypotension	2 (6.3)	2 (6.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190q
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders			
-Total	5 (45.5)	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	4 (36.4)	0
Thrombocytopenia	4 (36.4)	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	2 (18.2)	2 (18.2)	0
Neutropenia	2 (18.2)	0	2 (18.2)
Febrile neutropenia	1 (9.1)	1 (9.1)	0
Lymphopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (18.2)	0	2 (18.2)
Bradycardia	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	1 (9.1)	0
Sinus tachycardia	1 (9.1)	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	4 (36.4)	4 (36.4)	0
Abdominal pain	2 (18.2)	2 (18.2)	0
Colitis	2 (18.2)	2 (18.2)	0
Diarrhoea	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Haematochezia	1 (9.1)	1 (9.1)	0
Nausea	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
Vomiting	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	4 (36.4)	2 (18.2)	2 (18.2)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	2 (18.2)	0	2 (18.2)
Non-cardiac chest pain	1 (9.1)	1 (9.1)	0
Pain	1 (9.1)	1 (9.1)	0
Pyrexia	1 (9.1)	1 (9.1)	0
Infections and infestations			
-Total	7 (63.6)	2 (18.2)	5 (45.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Candida sepsis	1 (9.1)	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	1 (9.1)	0
Escherichia infection	1 (9.1)	1 (9.1)	0
Klebsiella infection	1 (9.1)	1 (9.1)	0
Pneumonia	1 (9.1)	0	1 (9.1)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Streptococcal infection	1 (9.1)	1 (9.1)	0
Investigations			
-Total	4 (36.4)	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	2 (18.2)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	1 (9.1)	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	1 (9.1)	0
Platelet count decreased	1 (9.1)	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	4 (36.4)	2 (18.2)	2 (18.2)
Hypernatraemia	2 (18.2)	1 (9.1)	1 (9.1)
Hypokalaemia	2 (18.2)	0	2 (18.2)
Decreased appetite	1 (9.1)	1 (9.1)	0
Dehydration	1 (9.1)	1 (9.1)	0
Fluid overload	1 (9.1)	1 (9.1)	0
Hyperglycaemia	1 (9.1)	0	1 (9.1)
Hyperkalaemia	1 (9.1)	1 (9.1)	0
Hypoalbuminaemia	1 (9.1)	0	1 (9.1)
Hypocalcaemia	1 (9.1)	0	1 (9.1)
Hypophosphataemia	1 (9.1)	1 (9.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	2 (18.2)	2 (18.2)	0
Pain in extremity	2 (18.2)	2 (18.2)	0
Arthralgia	1 (9.1)	1 (9.1)	0
Back pain	1 (9.1)	1 (9.1)	0
Nervous system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Headache	1 (9.1)	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	0	1 (9.1)
Psychiatric disorders			
-Total	1 (9.1)	1 (9.1)	0
Agitation	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Acute kidney injury	2 (18.2)	1 (9.1)	1 (9.1)
Cystitis haemorrhagic	1 (9.1)	1 (9.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oliguria	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (36.4)	0	4 (36.4)
Hypoxia	3 (27.3)	2 (18.2)	1 (9.1)
Pulmonary oedema	2 (18.2)	0	2 (18.2)
Aspiration	1 (9.1)	0	1 (9.1)
Cough	1 (9.1)	1 (9.1)	0
Dyspnoea	1 (9.1)	1 (9.1)	0
Haemoptysis	1 (9.1)	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	1 (9.1)	0
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Tachypnoea	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	5 (45.5)	2 (18.2)	3 (27.3)
Hypotension	5 (45.5)	2 (18.2)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190r
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (87.5)	4 (50.0)	3 (37.5)
Blood and lymphatic system disorders			
-Total	5 (62.5)	5 (62.5)	0
Febrile neutropenia	3 (37.5)	3 (37.5)	0
Anaemia	2 (25.0)	2 (25.0)	0
Cardiac disorders			
-Total	1 (12.5)	1 (12.5)	0
Tachycardia	1 (12.5)	1 (12.5)	0
Gastrointestinal disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Nausea	2 (25.0)	2 (25.0)	0

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Stomatitis	1 (12.5)	0	1 (12.5)
General disorders and administration site conditions			
-Total	2 (25.0)	2 (25.0)	0
Fatigue	1 (12.5)	1 (12.5)	0
Pain	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Infections and infestations			
-Total	2 (25.0)	0	2 (25.0)
Cellulitis	1 (12.5)	1 (12.5)	0
Human polyomavirus infection	1 (12.5)	0	1 (12.5)
Oral herpes	1 (12.5)	1 (12.5)	0
Pneumonia	1 (12.5)	0	1 (12.5)
Injury, poisoning and procedural complications			
-Total	1 (12.5)	1 (12.5)	0
Procedural pain	1 (12.5)	1 (12.5)	0
Investigations			
-Total	1 (12.5)	0	1 (12.5)

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	1 (12.5)	0	1 (12.5)
White blood cell count decreased	1 (12.5)	0	1 (12.5)
Musculoskeletal and connective tissue disorders			
-Total	1 (12.5)	1 (12.5)	0
Pain in extremity	1 (12.5)	1 (12.5)	0
Renal and urinary disorders			
-Total	1 (12.5)	0	1 (12.5)
Cystitis haemorrhagic	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (12.5)	0	1 (12.5)
Aspiration	1 (12.5)	0	1 (12.5)
Hypoxia	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Hypotension	2 (25.0)	1 (12.5)	1 (12.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190r
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (65.2)	7 (30.4)	8 (34.8)
Blood and lymphatic system disorders			
-Total	13 (56.5)	8 (34.8)	5 (21.7)
Febrile neutropenia	6 (26.1)	6 (26.1)	0
Anaemia	5 (21.7)	5 (21.7)	0
Neutropenia	2 (8.7)	0	2 (8.7)
Pancytopenia	2 (8.7)	0	2 (8.7)
Thrombocytopenia	2 (8.7)	0	2 (8.7)
Disseminated intravascular coagulation	1 (4.3)	1 (4.3)	0
Cardiac disorders			

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.3)	1 (4.3)	0
Sinus tachycardia	1 (4.3)	1 (4.3)	0
Gastrointestinal disorders			
-Total	3 (13.0)	3 (13.0)	0
Abdominal pain	2 (8.7)	2 (8.7)	0
Nausea	1 (4.3)	1 (4.3)	0
Stomatitis	1 (4.3)	1 (4.3)	0
Hepatobiliary disorders			
-Total	1 (4.3)	1 (4.3)	0
Hyperbilirubinaemia	1 (4.3)	1 (4.3)	0
Infections and infestations			
-Total	4 (17.4)	4 (17.4)	0
Device related infection	2 (8.7)	2 (8.7)	0
Escherichia bacteraemia	2 (8.7)	2 (8.7)	0
Staphylococcal bacteraemia	1 (4.3)	1 (4.3)	0
Investigations			
-Total	5 (21.7)	1 (4.3)	4 (17.4)
Platelet count decreased	3 (13.0)	0	3 (13.0)

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	2 (8.7)	0	2 (8.7)
Aspartate aminotransferase increased	1 (4.3)	1 (4.3)	0
Electrocardiogram qt prolonged	1 (4.3)	1 (4.3)	0
Metabolism and nutrition disorders			
-Total	5 (21.7)	5 (21.7)	0
Decreased appetite	2 (8.7)	2 (8.7)	0
Hyperglycaemia	2 (8.7)	2 (8.7)	0
Dehydration	1 (4.3)	1 (4.3)	0
Hypokalaemia	1 (4.3)	1 (4.3)	0
Tumour lysis syndrome	1 (4.3)	1 (4.3)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (8.7)	2 (8.7)	0
Back pain	2 (8.7)	2 (8.7)	0
Pain in extremity	1 (4.3)	1 (4.3)	0
Nervous system disorders			
-Total	2 (8.7)	2 (8.7)	0
Headache	2 (8.7)	2 (8.7)	0

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (4.3)	1 (4.3)	0
Hypoxia	1 (4.3)	1 (4.3)	0
Vascular disorders			
-Total	1 (4.3)	0	1 (4.3)
Hypotension	1 (4.3)	0	1 (4.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190r
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (70.8)	8 (33.3)	9 (37.5)
Blood and lymphatic system disorders			
-Total	12 (50.0)	8 (33.3)	4 (16.7)
Febrile neutropenia	7 (29.2)	7 (29.2)	0
Anaemia	5 (20.8)	5 (20.8)	0
Neutropenia	4 (16.7)	1 (4.2)	3 (12.5)
Thrombocytopenia	4 (16.7)	1 (4.2)	3 (12.5)
General disorders and administration site conditions			
-Total	1 (4.2)	1 (4.2)	0
Pyrexia	1 (4.2)	1 (4.2)	0

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	2 (8.3)	2 (8.3)	0
Clostridium difficile colitis	1 (4.2)	1 (4.2)	0
Device related infection	1 (4.2)	1 (4.2)	0
Investigations			
-Total	8 (33.3)	2 (8.3)	6 (25.0)
White blood cell count decreased	5 (20.8)	1 (4.2)	4 (16.7)
Neutrophil count decreased	4 (16.7)	0	4 (16.7)
Platelet count decreased	4 (16.7)	1 (4.2)	3 (12.5)
Alanine aminotransferase increased	3 (12.5)	3 (12.5)	0
Aspartate aminotransferase increased	1 (4.2)	1 (4.2)	0
Metabolism and nutrition disorders			
-Total	2 (8.3)	0	2 (8.3)
Hypophosphataemia	2 (8.3)	2 (8.3)	0
Hypernatraemia	1 (4.2)	0	1 (4.2)
Hypocalcaemia	1 (4.2)	0	1 (4.2)
Hypokalaemia	1 (4.2)	0	1 (4.2)

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	1 (4.2)	1 (4.2)	0
Pain in extremity	1 (4.2)	1 (4.2)	0
Nervous system disorders			
-Total	1 (4.2)	1 (4.2)	0
Headache	1 (4.2)	1 (4.2)	0
Vascular disorders			
-Total	1 (4.2)	0	1 (4.2)
Hypotension	1 (4.2)	0	1 (4.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 190r
Severe adverse events (AE CTCAE Grade 3/4) before study treatment that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (65.0)	5 (25.0)	8 (40.0)
Blood and lymphatic system disorders			
-Total	9 (45.0)	7 (35.0)	2 (10.0)
Anaemia	7 (35.0)	7 (35.0)	0
Thrombocytopenia	4 (20.0)	2 (10.0)	2 (10.0)
Febrile neutropenia	2 (10.0)	2 (10.0)	0
Disseminated intravascular coagulation	1 (5.0)	1 (5.0)	0
Cardiac disorders			
-Total	2 (10.0)	1 (5.0)	1 (5.0)
Cardiovascular insufficiency	1 (5.0)	0	1 (5.0)

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sinus tachycardia	1 (5.0)	1 (5.0)	0
Gastrointestinal disorders			
-Total	4 (20.0)	4 (20.0)	0
Colitis	3 (15.0)	3 (15.0)	0
Stomatitis	2 (10.0)	2 (10.0)	0
Abdominal pain	1 (5.0)	1 (5.0)	0
Diarrhoea	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	2 (10.0)	0	2 (10.0)
Multiple organ dysfunction syndrome	2 (10.0)	0	2 (10.0)
Hepatobiliary disorders			
-Total	2 (10.0)	2 (10.0)	0
Cholecystitis	1 (5.0)	1 (5.0)	0
Hyperbilirubinaemia	1 (5.0)	1 (5.0)	0
Infections and infestations			
-Total	8 (40.0)	5 (25.0)	3 (15.0)
Enterococcal bacteraemia	2 (10.0)	2 (10.0)	0

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella sepsis	2 (10.0)	0	2 (10.0)
Bacteraemia	1 (5.0)	1 (5.0)	0
Clostridium difficile colitis	1 (5.0)	1 (5.0)	0
Croup infectious	1 (5.0)	1 (5.0)	0
Klebsiella infection	1 (5.0)	1 (5.0)	0
Sepsis	1 (5.0)	0	1 (5.0)
Staphylococcal bacteraemia	1 (5.0)	1 (5.0)	0
Streptococcal bacteraemia	1 (5.0)	1 (5.0)	0
Injury, poisoning and procedural complications			
-Total	1 (5.0)	1 (5.0)	0
Extradural haematoma	1 (5.0)	1 (5.0)	0
Procedural pain	1 (5.0)	1 (5.0)	0
Subdural haematoma	1 (5.0)	1 (5.0)	0
Investigations			
-Total	9 (45.0)	2 (10.0)	7 (35.0)
Neutrophil count decreased	4 (20.0)	0	4 (20.0)
Platelet count decreased	3 (15.0)	0	3 (15.0)

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	2 (10.0)	2 (10.0)	0
White blood cell count decreased	2 (10.0)	0	2 (10.0)
Aspartate aminotransferase increased	1 (5.0)	1 (5.0)	0
Electrocardiogram qt prolonged	1 (5.0)	1 (5.0)	0
Lymphocyte count decreased	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	5 (25.0)	4 (20.0)	1 (5.0)
Hyperglycaemia	2 (10.0)	1 (5.0)	1 (5.0)
Hypokalaemia	2 (10.0)	1 (5.0)	1 (5.0)
Decreased appetite	1 (5.0)	1 (5.0)	0
Dehydration	1 (5.0)	1 (5.0)	0
Hypernatraemia	1 (5.0)	1 (5.0)	0
Hypoalbuminaemia	1 (5.0)	0	1 (5.0)
Hypocalcaemia	1 (5.0)	0	1 (5.0)
Tumour lysis syndrome	1 (5.0)	1 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (10.0)	2 (10.0)	0

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	2 (10.0)	2 (10.0)	0
Musculoskeletal pain	1 (5.0)	1 (5.0)	0
Nervous system disorders			
-Total	2 (10.0)	2 (10.0)	0
Headache	1 (5.0)	1 (5.0)	0
Leukoencephalopathy	1 (5.0)	1 (5.0)	0
Psychiatric disorders			
-Total	1 (5.0)	1 (5.0)	0
Mental status changes	1 (5.0)	1 (5.0)	0
Renal and urinary disorders			
-Total	1 (5.0)	1 (5.0)	0
Cystitis haemorrhagic	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (15.0)	1 (5.0)	2 (10.0)
Epistaxis	1 (5.0)	1 (5.0)	0
Hypoxia	1 (5.0)	0	1 (5.0)
Idiopathic pneumonia syndrome	1 (5.0)	0	1 (5.0)

Number of previous relapses: >=3

Group term Preferred term	All patients N=20 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
-Total	3 (15.0)	3 (15.0)	0
Hypotension	3 (15.0)	3 (15.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started prior to any study treatment, i.e. prior to lymphodepleting chemotherapy and CTL019 infusion, are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191a
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: <10 years

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (45.0)	2 (10.0)	7 (35.0)
Blood and lymphatic system disorders			
-Total	6 (30.0)	3 (15.0)	3 (15.0)
Anaemia	3 (15.0)	3 (15.0)	0
Febrile neutropenia	3 (15.0)	3 (15.0)	0
Lymphopenia	1 (5.0)	0	1 (5.0)
Neutropenia	1 (5.0)	0	1 (5.0)
Thrombocytopenia	1 (5.0)	0	1 (5.0)
Infections and infestations			
-Total	2 (10.0)	2 (10.0)	0

Age: <10 years

Group term Preferred term	All patients N=20 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Bacteraemia	1 (5.0)	1 (5.0)	0
Device related infection	1 (5.0)	1 (5.0)	0
Investigations			
-Total	8 (40.0)	2 (10.0)	6 (30.0)
White blood cell count decreased	6 (30.0)	1 (5.0)	5 (25.0)
Neutrophil count decreased	3 (15.0)	0	3 (15.0)
Lymphocyte count decreased	2 (10.0)	0	2 (10.0)
Platelet count decreased	1 (5.0)	0	1 (5.0)
Protein total decreased	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	3 (15.0)	3 (15.0)	0
Hypokalaemia	2 (10.0)	2 (10.0)	0
Hypoglycaemia	1 (5.0)	1 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (5.0)	1 (5.0)	0
Myalgia	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			

Age: <10 years

Group term Preferred term	All patients N=20 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	3 (15.0)	3 (15.0)	0
Hypoxia	2 (10.0)	2 (10.0)	0
Epistaxis	1 (5.0)	1 (5.0)	0
Tachypnoea	1 (5.0)	1 (5.0)	0
Vascular disorders			
-Total	1 (5.0)	1 (5.0)	0
Hypertension	1 (5.0)	1 (5.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191a
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (60.6)	8 (24.2)	12 (36.4)
Blood and lymphatic system disorders			
-Total	8 (24.2)	7 (21.2)	1 (3.0)
Febrile neutropenia	5 (15.2)	5 (15.2)	0
Anaemia	2 (6.1)	2 (6.1)	0
Thrombocytopenia	2 (6.1)	1 (3.0)	1 (3.0)
Neutropenia	1 (3.0)	1 (3.0)	0
Investigations			
-Total	15 (45.5)	4 (12.1)	11 (33.3)
White blood cell count decreased	11 (33.3)	2 (6.1)	9 (27.3)

Age: >=10 years to <18 years

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	7 (21.2)	0	7 (21.2)
Alanine aminotransferase increased	4 (12.1)	3 (9.1)	1 (3.0)
Lymphocyte count decreased	2 (6.1)	1 (3.0)	1 (3.0)
Platelet count decreased	2 (6.1)	2 (6.1)	0
Metabolism and nutrition disorders			
-Total	2 (6.1)	0	2 (6.1)
Hypokalaemia	2 (6.1)	0	2 (6.1)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.0)	1 (3.0)	0
Hypoxia	1 (3.0)	1 (3.0)	0
Vascular disorders			
-Total	2 (6.1)	2 (6.1)	0
Hypotension	2 (6.1)	2 (6.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191a
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set - Patients who received lymphodepleting chemotherapy

Age: >=18

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (62.5)	2 (25.0)	3 (37.5)
Blood and lymphatic system disorders			
-Total	2 (25.0)	0	2 (25.0)
Neutropenia	2 (25.0)	0	2 (25.0)
Infections and infestations			
-Total	1 (12.5)	1 (12.5)	0
Necrotising fasciitis	1 (12.5)	1 (12.5)	0
Investigations			
-Total	2 (25.0)	0	2 (25.0)
White blood cell count decreased	2 (25.0)	0	2 (25.0)

Age: >=18

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders			
-Total	2 (25.0)	2 (25.0)	0
Hyperuricaemia	1 (12.5)	1 (12.5)	0
Tumour lysis syndrome	1 (12.5)	1 (12.5)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (12.5)	1 (12.5)	0
Pain in extremity	1 (12.5)	1 (12.5)	0
Vascular disorders			
-Total	1 (12.5)	1 (12.5)	0
Hypotension	1 (12.5)	1 (12.5)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191b
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Male

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (51.7)	5 (17.2)	10 (34.5)
Blood and lymphatic system disorders			
-Total	8 (27.6)	6 (20.7)	2 (6.9)
Febrile neutropenia	5 (17.2)	5 (17.2)	0
Anaemia	2 (6.9)	2 (6.9)	0
Neutropenia	2 (6.9)	1 (3.4)	1 (3.4)
Thrombocytopenia	1 (3.4)	0	1 (3.4)
Investigations			
-Total	11 (37.9)	2 (6.9)	9 (31.0)
White blood cell count decreased	9 (31.0)	2 (6.9)	7 (24.1)

Gender: Male

Group term Preferred term	All patients N=29 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	4 (13.8)	0	4 (13.8)
Alanine aminotransferase increased	2 (6.9)	1 (3.4)	1 (3.4)
Metabolism and nutrition disorders			
-Total	2 (6.9)	1 (3.4)	1 (3.4)
Hypokalaemia	2 (6.9)	1 (3.4)	1 (3.4)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (6.9)	2 (6.9)	0
Hypoxia	2 (6.9)	2 (6.9)	0
Vascular disorders			
-Total	1 (3.4)	1 (3.4)	0
Hypotension	1 (3.4)	1 (3.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191b
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set - Patients who received lymphodepleting chemotherapy

Gender: Female

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	18 (56.3)	7 (21.9)	11 (34.4)
Blood and lymphatic system disorders			
-Total	8 (25.0)	5 (15.6)	3 (9.4)
Anaemia	3 (9.4)	3 (9.4)	0
Febrile neutropenia	3 (9.4)	3 (9.4)	0
Neutropenia	2 (6.3)	0	2 (6.3)
Thrombocytopenia	2 (6.3)	1 (3.1)	1 (3.1)
Investigations			
-Total	13 (40.6)	3 (9.4)	10 (31.3)
White blood cell count decreased	10 (31.3)	1 (3.1)	9 (28.1)

Gender: Female

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	6 (18.8)	0	6 (18.8)
Lymphocyte count decreased	4 (12.5)	1 (3.1)	3 (9.4)
Platelet count decreased	3 (9.4)	2 (6.3)	1 (3.1)
Alanine aminotransferase increased	2 (6.3)	2 (6.3)	0
Metabolism and nutrition disorders			
-Total	2 (6.3)	1 (3.1)	1 (3.1)
Hypokalaemia	2 (6.3)	1 (3.1)	1 (3.1)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.1)	1 (3.1)	0
Hypoxia	1 (3.1)	1 (3.1)	0
Vascular disorders			
-Total	2 (6.3)	2 (6.3)	0
Hypotension	2 (6.3)	2 (6.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191c
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: White

	All patients N=50		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (56.0)	11 (22.0)	17 (34.0)
Blood and lymphatic system disorders			
-Total	15 (30.0)	10 (20.0)	5 (10.0)
Febrile neutropenia	7 (14.0)	7 (14.0)	0
Anaemia	5 (10.0)	5 (10.0)	0
Neutropenia	4 (8.0)	1 (2.0)	3 (6.0)
Thrombocytopenia	3 (6.0)	1 (2.0)	2 (4.0)
Investigations			
-Total	21 (42.0)	5 (10.0)	16 (32.0)
White blood cell count decreased	16 (32.0)	3 (6.0)	13 (26.0)

Race: White

Group term Preferred term	All patients N=50 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	10 (20.0)	0	10 (20.0)
Alanine aminotransferase increased	4 (8.0)	3 (6.0)	1 (2.0)
Lymphocyte count decreased	4 (8.0)	1 (2.0)	3 (6.0)
Platelet count decreased	2 (4.0)	2 (4.0)	0
Metabolism and nutrition disorders			
-Total	3 (6.0)	2 (4.0)	1 (2.0)
Hypokalaemia	3 (6.0)	2 (4.0)	1 (2.0)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.0)	3 (6.0)	0
Hypoxia	3 (6.0)	3 (6.0)	0
Vascular disorders			
-Total	2 (4.0)	2 (4.0)	0
Hypotension	2 (4.0)	2 (4.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191c
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Asian

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (60.0)	1 (20.0)	2 (40.0)
Investigations			
-Total	2 (40.0)	0	2 (40.0)
White blood cell count decreased	2 (40.0)	0	2 (40.0)
Platelet count decreased	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
-Total	1 (20.0)	1 (20.0)	0
Hyperglycaemia	1 (20.0)	1 (20.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191c
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set - Patients who received lymphodepleting chemotherapy

Race: Other

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (50.0)	1 (16.7)	2 (33.3)
Blood and lymphatic system disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Febrile neutropenia	1 (16.7)	1 (16.7)	0
Hypofibrinogenaemia	1 (16.7)	0	1 (16.7)
Investigations			
-Total	2 (33.3)	0	2 (33.3)
Lipase increased	1 (16.7)	0	1 (16.7)
White blood cell count decreased	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			

Race: Other

Group term Preferred term	All patients N=6 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (16.7)	0	1 (16.7)
Hypokalaemia	1 (16.7)	0	1 (16.7)
Vascular disorders			
-Total	1 (16.7)	1 (16.7)	0
Hypotension	1 (16.7)	1 (16.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191d
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Hispanic or Latino

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (60.9)	4 (17.4)	10 (43.5)
Blood and lymphatic system disorders			
-Total	5 (21.7)	3 (13.0)	2 (8.7)
Febrile neutropenia	4 (17.4)	4 (17.4)	0
Anaemia	1 (4.3)	1 (4.3)	0
Neutropenia	1 (4.3)	0	1 (4.3)
Thrombocytopenia	1 (4.3)	0	1 (4.3)
Investigations			
-Total	12 (52.2)	2 (8.7)	10 (43.5)
White blood cell count decreased	10 (43.5)	2 (8.7)	8 (34.8)

Ethnicity: Hispanic or Latino

Group term Preferred term	All patients N=23 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	6 (26.1)	0	6 (26.1)
Alanine aminotransferase increased	2 (8.7)	2 (8.7)	0
Lymphocyte count decreased	1 (4.3)	0	1 (4.3)
Metabolism and nutrition disorders			
-Total	1 (4.3)	1 (4.3)	0
Hypokalaemia	1 (4.3)	1 (4.3)	0
Vascular disorders			
-Total	1 (4.3)	1 (4.3)	0
Hypotension	1 (4.3)	1 (4.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191d
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set - Patients who received lymphodepleting chemotherapy

Ethnicity: Other

	All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (50.0)	8 (21.1)	11 (28.9)
Blood and lymphatic system disorders			
-Total	11 (28.9)	8 (21.1)	3 (7.9)
Anaemia	4 (10.5)	4 (10.5)	0
Febrile neutropenia	4 (10.5)	4 (10.5)	0
Neutropenia	3 (7.9)	1 (2.6)	2 (5.3)
Thrombocytopenia	2 (5.3)	1 (2.6)	1 (2.6)
Investigations			
-Total	12 (31.6)	3 (7.9)	9 (23.7)
White blood cell count decreased	9 (23.7)	1 (2.6)	8 (21.1)

Ethnicity: Other

	All patients N=38		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	4 (10.5)	0	4 (10.5)
Lymphocyte count decreased	3 (7.9)	1 (2.6)	2 (5.3)
Platelet count decreased	3 (7.9)	2 (5.3)	1 (2.6)
Alanine aminotransferase increased	2 (5.3)	1 (2.6)	1 (2.6)
Metabolism and nutrition disorders			
-Total	3 (7.9)	1 (2.6)	2 (5.3)
Hypokalaemia	3 (7.9)	1 (2.6)	2 (5.3)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (7.9)	3 (7.9)	0
Hypoxia	3 (7.9)	3 (7.9)	0
Vascular disorders			
-Total	2 (5.3)	2 (5.3)	0
Hypotension	2 (5.3)	2 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191e
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Primary refractory

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (57.1)	1 (14.3)	3 (42.9)
Blood and lymphatic system disorders			
-Total	1 (14.3)	0	1 (14.3)
Neutropenia	1 (14.3)	0	1 (14.3)
Cardiac disorders			
-Total	1 (14.3)	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	1 (14.3)	0
Investigations			
-Total	2 (28.6)	0	2 (28.6)
Neutrophil count decreased	2 (28.6)	0	2 (28.6)
White blood cell count decreased	2 (28.6)	0	2 (28.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191e
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set - Patients who received lymphodepleting chemotherapy

Response status at study entry: Relapsed disease

		All patients N=54	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (55.6)	12 (22.2)	18 (33.3)
Blood and lymphatic system disorders			
-Total	15 (27.8)	11 (20.4)	4 (7.4)
Febrile neutropenia	8 (14.8)	8 (14.8)	0
Anaemia	5 (9.3)	5 (9.3)	0
Neutropenia	3 (5.6)	1 (1.9)	2 (3.7)
Thrombocytopenia	3 (5.6)	1 (1.9)	2 (3.7)
Investigations			
-Total	22 (40.7)	5 (9.3)	17 (31.5)
White blood cell count decreased	17 (31.5)	3 (5.6)	14 (25.9)
Neutrophil count decreased	8 (14.8)	0	8 (14.8)

Response status at study entry: Relapsed disease

	All patients N=54		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	4 (7.4)	3 (5.6)	1 (1.9)
Lymphocyte count decreased	4 (7.4)	1 (1.9)	3 (5.6)
Platelet count decreased	3 (5.6)	2 (3.7)	1 (1.9)
Metabolism and nutrition disorders			
-Total	4 (7.4)	2 (3.7)	2 (3.7)
Hypokalaemia	4 (7.4)	2 (3.7)	2 (3.7)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (5.6)	3 (5.6)	0
Hypoxia	3 (5.6)	3 (5.6)	0
Vascular disorders			
-Total	3 (5.6)	3 (5.6)	0
Hypotension	3 (5.6)	3 (5.6)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191f
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	1 (50.0)	0
Metabolism and nutrition disorders			
-Total	1 (50.0)	1 (50.0)	0
Hyperglycaemia	1 (50.0)	1 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191f
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set - Patients who received lymphodepleting chemotherapy

Philadelphia chromosome/BCR-ABL: Negative

		All patients N=59	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (55.9)	12 (20.3)	21 (35.6)
Blood and lymphatic system disorders			
-Total	16 (27.1)	11 (18.6)	5 (8.5)
Febrile neutropenia	8 (13.6)	8 (13.6)	0
Anaemia	5 (8.5)	5 (8.5)	0
Neutropenia	4 (6.8)	1 (1.7)	3 (5.1)
Thrombocytopenia	3 (5.1)	1 (1.7)	2 (3.4)
Investigations			
-Total	24 (40.7)	5 (8.5)	19 (32.2)
White blood cell count decreased	19 (32.2)	3 (5.1)	16 (27.1)
Neutrophil count decreased	10 (16.9)	0	10 (16.9)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=59		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	4 (6.8)	3 (5.1)	1 (1.7)
Lymphocyte count decreased	4 (6.8)	1 (1.7)	3 (5.1)
Platelet count decreased	3 (5.1)	2 (3.4)	1 (1.7)
Metabolism and nutrition disorders			
-Total	4 (6.8)	2 (3.4)	2 (3.4)
Hypokalaemia	4 (6.8)	2 (3.4)	2 (3.4)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (5.1)	3 (5.1)	0
Hypoxia	3 (5.1)	3 (5.1)	0
Vascular disorders			
-Total	3 (5.1)	3 (5.1)	0
Hypotension	3 (5.1)	3 (5.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191g
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	3 (100)
Blood and lymphatic system disorders			
-Total	3 (100)	1 (33.3)	2 (66.7)
Anaemia	1 (33.3)	1 (33.3)	0
Febrile neutropenia	1 (33.3)	1 (33.3)	0
Lymphopenia	1 (33.3)	0	1 (33.3)
Neutropenia	1 (33.3)	0	1 (33.3)
Investigations			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Neutrophil count decreased	1 (33.3)	0	1 (33.3)
Platelet count decreased	1 (33.3)	1 (33.3)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Protein total decreased	1 (33.3)	1 (33.3)	0
White blood cell count decreased	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	1 (33.3)	1 (33.3)	0
Hypokalaemia	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	1 (33.3)	0
Hypoxia	1 (33.3)	1 (33.3)	0
Tachypnoea	1 (33.3)	1 (33.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191g
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set - Patients who received lymphodepleting chemotherapy

Mixed-lineage leukemia rearrangement: No

	All patients N=58		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (51.7)	11 (19.0)	19 (32.8)
Blood and lymphatic system disorders			
-Total	13 (22.4)	9 (15.5)	4 (6.9)
Febrile neutropenia	7 (12.1)	7 (12.1)	0
Anaemia	4 (6.9)	4 (6.9)	0
Neutropenia	3 (5.2)	1 (1.7)	2 (3.4)
Thrombocytopenia	3 (5.2)	1 (1.7)	2 (3.4)
Investigations			
-Total	23 (39.7)	5 (8.6)	18 (31.0)
White blood cell count decreased	18 (31.0)	3 (5.2)	15 (25.9)
Neutrophil count decreased	9 (15.5)	0	9 (15.5)

Mixed-lineage leukemia rearrangement: No			
		All patients N=58	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	4 (6.9)	3 (5.2)	1 (1.7)
Lymphocyte count decreased	4 (6.9)	1 (1.7)	3 (5.2)
Platelet count decreased	2 (3.4)	1 (1.7)	1 (1.7)
Metabolism and nutrition disorders			
-Total	3 (5.2)	1 (1.7)	2 (3.4)
Hypokalaemia	3 (5.2)	1 (1.7)	2 (3.4)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.4)	2 (3.4)	0
Hypoxia	2 (3.4)	2 (3.4)	0
Vascular disorders			
-Total	3 (5.2)	3 (5.2)	0
Hypotension	3 (5.2)	3 (5.2)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191h
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Blood and lymphatic system disorders			
-Total	1 (100)	1 (100)	0
Febrile neutropenia	1 (100)	1 (100)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191h
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set - Patients who received lymphodepleting chemotherapy

Hypodiploidy: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (53.3)	11 (18.3)	21 (35.0)
Blood and lymphatic system disorders			
-Total	15 (25.0)	10 (16.7)	5 (8.3)
Febrile neutropenia	7 (11.7)	7 (11.7)	0
Anaemia	5 (8.3)	5 (8.3)	0
Neutropenia	4 (6.7)	1 (1.7)	3 (5.0)
Thrombocytopenia	3 (5.0)	1 (1.7)	2 (3.3)
Investigations			
-Total	24 (40.0)	5 (8.3)	19 (31.7)
White blood cell count decreased	19 (31.7)	3 (5.0)	16 (26.7)

Hypodiploidy: No

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	10 (16.7)	0	10 (16.7)
Alanine aminotransferase increased	4 (6.7)	3 (5.0)	1 (1.7)
Lymphocyte count decreased	4 (6.7)	1 (1.7)	3 (5.0)
Platelet count decreased	3 (5.0)	2 (3.3)	1 (1.7)
Metabolism and nutrition disorders			
-Total	4 (6.7)	2 (3.3)	2 (3.3)
Hypokalaemia	4 (6.7)	2 (3.3)	2 (3.3)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (5.0)	3 (5.0)	0
Hypoxia	3 (5.0)	3 (5.0)	0
Vascular disorders			
-Total	3 (5.0)	3 (5.0)	0
Hypotension	3 (5.0)	3 (5.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191i
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders			
-Total	1 (25.0)	0	1 (25.0)
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Neutropenia	1 (25.0)	0	1 (25.0)
Infections and infestations			
-Total	1 (25.0)	1 (25.0)	0
Bacteraemia	1 (25.0)	1 (25.0)	0
Investigations			
-Total	2 (50.0)	0	2 (50.0)

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (25.0)	0	1 (25.0)
White blood cell count decreased	1 (25.0)	0	1 (25.0)
Metabolism and nutrition disorders			
-Total	2 (50.0)	2 (50.0)	0
Hyperglycaemia	1 (25.0)	1 (25.0)	0
Hypokalaemia	1 (25.0)	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191i
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set - Patients who received lymphodepleting chemotherapy

BCR-ABL1-like: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (54.4)	12 (21.1)	19 (33.3)
Blood and lymphatic system disorders			
-Total	15 (26.3)	11 (19.3)	4 (7.0)
Febrile neutropenia	7 (12.3)	7 (12.3)	0
Anaemia	5 (8.8)	5 (8.8)	0
Neutropenia	3 (5.3)	1 (1.8)	2 (3.5)
Thrombocytopenia	3 (5.3)	1 (1.8)	2 (3.5)
Investigations			
-Total	22 (38.6)	5 (8.8)	17 (29.8)
White blood cell count decreased	18 (31.6)	3 (5.3)	15 (26.3)

BCR-ABL1-like: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	10 (17.5)	0	10 (17.5)
Alanine aminotransferase increased	4 (7.0)	3 (5.3)	1 (1.8)
Lymphocyte count decreased	3 (5.3)	1 (1.8)	2 (3.5)
Platelet count decreased	3 (5.3)	2 (3.5)	1 (1.8)
Metabolism and nutrition disorders			
-Total	3 (5.3)	1 (1.8)	2 (3.5)
Hypokalaemia	3 (5.3)	1 (1.8)	2 (3.5)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (5.3)	3 (5.3)	0
Hypoxia	3 (5.3)	3 (5.3)	0
Vascular disorders			
-Total	3 (5.3)	3 (5.3)	0
Hypotension	3 (5.3)	3 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191j
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (55.6)	2 (11.1)	8 (44.4)
Blood and lymphatic system disorders			
-Total	6 (33.3)	3 (16.7)	3 (16.7)
Neutropenia	2 (11.1)	1 (5.6)	1 (5.6)
Anaemia	1 (5.6)	1 (5.6)	0
Febrile neutropenia	1 (5.6)	1 (5.6)	0
Hypofibrinogenaemia	1 (5.6)	0	1 (5.6)
Lymphopenia	1 (5.6)	0	1 (5.6)
Pancytopenia	1 (5.6)	1 (5.6)	0
Investigations			
-Total	9 (50.0)	2 (11.1)	7 (38.9)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	6 (33.3)	0	6 (33.3)
Neutrophil count decreased	3 (16.7)	0	3 (16.7)
Alanine aminotransferase increased	2 (11.1)	2 (11.1)	0
Lipase increased	1 (5.6)	0	1 (5.6)
Lymphocyte count decreased	1 (5.6)	0	1 (5.6)
Protein total decreased	1 (5.6)	1 (5.6)	0
Metabolism and nutrition disorders			
-Total	2 (11.1)	1 (5.6)	1 (5.6)
Hypokalaemia	2 (11.1)	1 (5.6)	1 (5.6)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (5.6)	1 (5.6)	0
Hypoxia	1 (5.6)	1 (5.6)	0
Tachypnoea	1 (5.6)	1 (5.6)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.

- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191j
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set - Patients who received lymphodepleting chemotherapy

Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=43	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	24 (55.8)	10 (23.3)	14 (32.6)
Blood and lymphatic system disorders			
-Total	12 (27.9)	8 (18.6)	4 (9.3)
Febrile neutropenia	7 (16.3)	7 (16.3)	0
Anaemia	4 (9.3)	4 (9.3)	0
Thrombocytopenia	3 (7.0)	1 (2.3)	2 (4.7)
Neutropenia	2 (4.7)	0	2 (4.7)
Investigations			
-Total	17 (39.5)	4 (9.3)	13 (30.2)
White blood cell count decreased	13 (30.2)	3 (7.0)	10 (23.3)
Neutrophil count decreased	7 (16.3)	0	7 (16.3)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	3 (7.0)	1 (2.3)	2 (4.7)
Platelet count decreased	3 (7.0)	2 (4.7)	1 (2.3)
Alanine aminotransferase increased	2 (4.7)	1 (2.3)	1 (2.3)
Metabolism and nutrition disorders			
-Total	2 (4.7)	1 (2.3)	1 (2.3)
Hypokalaemia	2 (4.7)	1 (2.3)	1 (2.3)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (4.7)	2 (4.7)	0
Hypoxia	2 (4.7)	2 (4.7)	0
Vascular disorders			
-Total	3 (7.0)	3 (7.0)	0
Hypotension	3 (7.0)	3 (7.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191k
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set - Patients who received lymphodepleting chemotherapy

Region: US

	All patients N=61		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (50.8)	10 (16.4)	21 (34.4)
Blood and lymphatic system disorders			
-Total	15 (24.6)	12 (19.7)	3 (4.9)
Febrile neutropenia	8 (13.1)	8 (13.1)	0
Anaemia	5 (8.2)	5 (8.2)	0
Neutropenia	4 (6.6)	1 (1.6)	3 (4.9)
Investigations			
-Total	24 (39.3)	5 (8.2)	19 (31.1)
White blood cell count decreased	19 (31.1)	3 (4.9)	16 (26.2)
Neutrophil count decreased	10 (16.4)	0	10 (16.4)

Region: US

Group term Preferred term	All patients N=61 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Alanine aminotransferase increased	4 (6.6)	3 (4.9)	1 (1.6)
Lymphocyte count decreased	4 (6.6)	1 (1.6)	3 (4.9)
Metabolism and nutrition disorders			
-Total	4 (6.6)	2 (3.3)	2 (3.3)
Hypokalaemia	4 (6.6)	2 (3.3)	2 (3.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191l
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: Yes

	All patients N=28		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	14 (50.0)	4 (14.3)	10 (35.7)
Blood and lymphatic system disorders			
-Total	7 (25.0)	5 (17.9)	2 (7.1)
Febrile neutropenia	4 (14.3)	4 (14.3)	0
Anaemia	3 (10.7)	3 (10.7)	0
Neutropenia	2 (7.1)	1 (3.6)	1 (3.6)
Thrombocytopenia	1 (3.6)	0	1 (3.6)
Investigations			
-Total	10 (35.7)	1 (3.6)	9 (32.1)
White blood cell count decreased	7 (25.0)	1 (3.6)	6 (21.4)

Prior SCT therapy: Yes

Group term Preferred term	All patients N=28 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	5 (17.9)	0	5 (17.9)
Lymphocyte count decreased	3 (10.7)	0	3 (10.7)
Platelet count decreased	3 (10.7)	2 (7.1)	1 (3.6)
Alanine aminotransferase increased	2 (7.1)	1 (3.6)	1 (3.6)
Metabolism and nutrition disorders			
-Total	3 (10.7)	1 (3.6)	2 (7.1)
Hypokalaemia	3 (10.7)	1 (3.6)	2 (7.1)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (7.1)	2 (7.1)	0
Hypoxia	2 (7.1)	2 (7.1)	0
Vascular disorders			
-Total	2 (7.1)	2 (7.1)	0
Hypotension	2 (7.1)	2 (7.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191l
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set - Patients who received lymphodepleting chemotherapy

Prior SCT therapy: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (57.6)	8 (24.2)	11 (33.3)
Blood and lymphatic system disorders			
-Total	9 (27.3)	6 (18.2)	3 (9.1)
Febrile neutropenia	4 (12.1)	4 (12.1)	0
Anaemia	2 (6.1)	2 (6.1)	0
Neutropenia	2 (6.1)	0	2 (6.1)
Thrombocytopenia	2 (6.1)	1 (3.0)	1 (3.0)
Investigations			
-Total	14 (42.4)	4 (12.1)	10 (30.3)
White blood cell count decreased	12 (36.4)	2 (6.1)	10 (30.3)

Prior SCT therapy: No

	All patients N=33		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	5 (15.2)	0	5 (15.2)
Alanine aminotransferase increased	2 (6.1)	2 (6.1)	0
Lymphocyte count decreased	1 (3.0)	1 (3.0)	0
Metabolism and nutrition disorders			
-Total	1 (3.0)	1 (3.0)	0
Hypokalaemia	1 (3.0)	1 (3.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.0)	1 (3.0)	0
Hypoxia	1 (3.0)	1 (3.0)	0
Vascular disorders			
-Total	1 (3.0)	1 (3.0)	0
Hypotension	1 (3.0)	1 (3.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191m
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: Yes

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (64.3)	3 (21.4)	6 (42.9)
Blood and lymphatic system disorders			
-Total	3 (21.4)	1 (7.1)	2 (14.3)
Anaemia	1 (7.1)	1 (7.1)	0
Febrile neutropenia	1 (7.1)	1 (7.1)	0
Neutropenia	1 (7.1)	0	1 (7.1)
Thrombocytopenia	1 (7.1)	0	1 (7.1)
Investigations			
-Total	8 (57.1)	2 (14.3)	6 (42.9)
White blood cell count decreased	8 (57.1)	2 (14.3)	6 (42.9)

Eligibility for SCT: Yes

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	2 (14.3)	0	2 (14.3)
Metabolism and nutrition disorders			
-Total	2 (14.3)	2 (14.3)	0
Hyperuricaemia	1 (7.1)	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	1 (7.1)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191m
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set - Patients who received lymphodepleting chemotherapy

Eligibility for SCT: No

	All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	25 (53.2)	10 (21.3)	15 (31.9)
Blood and lymphatic system disorders			
-Total	13 (27.7)	10 (21.3)	3 (6.4)
Febrile neutropenia	7 (14.9)	7 (14.9)	0
Anaemia	4 (8.5)	4 (8.5)	0
Neutropenia	3 (6.4)	1 (2.1)	2 (4.3)
Thrombocytopenia	2 (4.3)	1 (2.1)	1 (2.1)
Investigations			
-Total	16 (34.0)	3 (6.4)	13 (27.7)
White blood cell count decreased	11 (23.4)	1 (2.1)	10 (21.3)

Eligibility for SCT: No

	All patients N=47		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	8 (17.0)	0	8 (17.0)
Alanine aminotransferase increased	4 (8.5)	3 (6.4)	1 (2.1)
Lymphocyte count decreased	4 (8.5)	1 (2.1)	3 (6.4)
Platelet count decreased	3 (6.4)	2 (4.3)	1 (2.1)
Metabolism and nutrition disorders			
-Total	4 (8.5)	2 (4.3)	2 (4.3)
Hypokalaemia	4 (8.5)	2 (4.3)	2 (4.3)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (6.4)	3 (6.4)	0
Hypoxia	3 (6.4)	3 (6.4)	0
Vascular disorders			
-Total	3 (6.4)	3 (6.4)	0
Hypotension	3 (6.4)	3 (6.4)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191n
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: Low

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	11 (52.4)	5 (23.8)	6 (28.6)
Blood and lymphatic system disorders			
-Total	5 (23.8)	3 (14.3)	2 (9.5)
Febrile neutropenia	3 (14.3)	3 (14.3)	0
Thrombocytopenia	2 (9.5)	1 (4.8)	1 (4.8)
Anaemia	1 (4.8)	1 (4.8)	0
Neutropenia	1 (4.8)	0	1 (4.8)
Investigations			
-Total	8 (38.1)	2 (9.5)	6 (28.6)
White blood cell count decreased	6 (28.6)	1 (4.8)	5 (23.8)
Neutrophil count decreased	3 (14.3)	0	3 (14.3)

Baseline bone marrow tumor burden: Low

	All patients N=21		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	2 (9.5)	1 (4.8)	1 (4.8)
Platelet count decreased	1 (4.8)	0	1 (4.8)
Metabolism and nutrition disorders			
-Total	1 (4.8)	0	1 (4.8)
Hypokalaemia	1 (4.8)	0	1 (4.8)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (9.5)	2 (9.5)	0
Hypoxia	2 (9.5)	2 (9.5)	0
Vascular disorders			
-Total	1 (4.8)	1 (4.8)	0
Hypotension	1 (4.8)	1 (4.8)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191n
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline bone marrow tumor burden: High

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (55.0)	7 (17.5)	15 (37.5)
Blood and lymphatic system disorders			
-Total	11 (27.5)	8 (20.0)	3 (7.5)
Febrile neutropenia	5 (12.5)	5 (12.5)	0
Anaemia	4 (10.0)	4 (10.0)	0
Neutropenia	3 (7.5)	1 (2.5)	2 (5.0)
Thrombocytopenia	1 (2.5)	0	1 (2.5)
Investigations			
-Total	16 (40.0)	3 (7.5)	13 (32.5)
White blood cell count decreased	13 (32.5)	2 (5.0)	11 (27.5)
Neutrophil count decreased	7 (17.5)	0	7 (17.5)

Baseline bone marrow tumor burden: High			
		All patients N=40	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	4 (10.0)	1 (2.5)	3 (7.5)
Alanine aminotransferase increased	2 (5.0)	2 (5.0)	0
Platelet count decreased	2 (5.0)	2 (5.0)	0
Metabolism and nutrition disorders			
-Total	3 (7.5)	2 (5.0)	1 (2.5)
Hypokalaemia	3 (7.5)	2 (5.0)	1 (2.5)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (2.5)	1 (2.5)	0
Hypoxia	1 (2.5)	1 (2.5)	0
Vascular disorders			
-Total	2 (5.0)	2 (5.0)	0
Hypotension	2 (5.0)	2 (5.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191o
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: Yes

		All patients N=4	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	0	2 (50.0)
Blood and lymphatic system disorders			
-Total	1 (25.0)	0	1 (25.0)
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Lymphopenia	1 (25.0)	0	1 (25.0)
Investigations			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Protein total decreased	1 (25.0)	1 (25.0)	0
White blood cell count decreased	1 (25.0)	0	1 (25.0)
Metabolism and nutrition disorders			
-Total	1 (25.0)	1 (25.0)	0

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=4 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypokalaemia	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Hypoxia	1 (25.0)	1 (25.0)	0
Tachypnoea	1 (25.0)	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191o
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set - Patients who received lymphodepleting chemotherapy

Baseline extramedullary disease presence: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (54.4)	11 (19.3)	20 (35.1)
Blood and lymphatic system disorders			
-Total	15 (26.3)	10 (17.5)	5 (8.8)
Febrile neutropenia	7 (12.3)	7 (12.3)	0
Anaemia	5 (8.8)	5 (8.8)	0
Neutropenia	4 (7.0)	1 (1.8)	3 (5.3)
Thrombocytopenia	3 (5.3)	1 (1.8)	2 (3.5)
Investigations			
-Total	23 (40.4)	5 (8.8)	18 (31.6)
White blood cell count decreased	18 (31.6)	3 (5.3)	15 (26.3)
Neutrophil count decreased	10 (17.5)	0	10 (17.5)

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=57 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Alanine aminotransferase increased	4 (7.0)	3 (5.3)	1 (1.8)
Lymphocyte count decreased	4 (7.0)	1 (1.8)	3 (5.3)
Platelet count decreased	3 (5.3)	2 (3.5)	1 (1.8)
Metabolism and nutrition disorders			
-Total	3 (5.3)	1 (1.8)	2 (3.5)
Hypokalaemia	3 (5.3)	1 (1.8)	2 (3.5)
Respiratory, thoracic and mediastinal disorders			
-Total	2 (3.5)	2 (3.5)	0
Hypoxia	2 (3.5)	2 (3.5)	0
Vascular disorders			
-Total	3 (5.3)	3 (5.3)	0
Hypotension	3 (5.3)	3 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191p
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (25.0)	1 (25.0)	0
Blood and lymphatic system disorders			
-Total	1 (25.0)	1 (25.0)	0
Thrombocytopenia	1 (25.0)	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191p
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set - Patients who received lymphodepleting chemotherapy

Down syndrome: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (56.1)	11 (19.3)	21 (36.8)
Blood and lymphatic system disorders			
-Total	15 (26.3)	10 (17.5)	5 (8.8)
Febrile neutropenia	8 (14.0)	8 (14.0)	0
Anaemia	5 (8.8)	5 (8.8)	0
Neutropenia	4 (7.0)	1 (1.8)	3 (5.3)
Thrombocytopenia	2 (3.5)	0	2 (3.5)
Investigations			
-Total	24 (42.1)	5 (8.8)	19 (33.3)
White blood cell count decreased	19 (33.3)	3 (5.3)	16 (28.1)

Down syndrome: No

Group term Preferred term	All patients N=57 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Neutrophil count decreased	10 (17.5)	0	10 (17.5)
Alanine aminotransferase increased	4 (7.0)	3 (5.3)	1 (1.8)
Lymphocyte count decreased	4 (7.0)	1 (1.8)	3 (5.3)
Platelet count decreased	3 (5.3)	2 (3.5)	1 (1.8)
Metabolism and nutrition disorders			
-Total	4 (7.0)	2 (3.5)	2 (3.5)
Hypokalaemia	4 (7.0)	2 (3.5)	2 (3.5)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (5.3)	3 (5.3)	0
Hypoxia	3 (5.3)	3 (5.3)	0
Vascular disorders			
-Total	3 (5.3)	3 (5.3)	0
Hypotension	3 (5.3)	3 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191q
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: > Median

		All patients N=31	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (64.5)	6 (19.4)	14 (45.2)
Blood and lymphatic system disorders			
-Total	7 (22.6)	5 (16.1)	2 (6.5)
Anaemia	3 (9.7)	3 (9.7)	0
Febrile neutropenia	2 (6.5)	2 (6.5)	0
Neutropenia	2 (6.5)	0	2 (6.5)
Thrombocytopenia	1 (3.2)	1 (3.2)	0
Investigations			
-Total	17 (54.8)	4 (12.9)	13 (41.9)
White blood cell count decreased	14 (45.2)	3 (9.7)	11 (35.5)
Neutrophil count decreased	6 (19.4)	0	6 (19.4)

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=31 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Lymphocyte count decreased	3 (9.7)	1 (3.2)	2 (6.5)
Alanine aminotransferase increased	2 (6.5)	2 (6.5)	0
Platelet count decreased	2 (6.5)	1 (3.2)	1 (3.2)
Metabolism and nutrition disorders			
-Total	2 (6.5)	1 (3.2)	1 (3.2)
Hypokalaemia	2 (6.5)	1 (3.2)	1 (3.2)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.2)	1 (3.2)	0
Hypoxia	1 (3.2)	1 (3.2)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191q
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: <=Median

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (41.4)	6 (20.7)	6 (20.7)
Blood and lymphatic system disorders			
-Total	8 (27.6)	6 (20.7)	2 (6.9)
Febrile neutropenia	5 (17.2)	5 (17.2)	0
Neutropenia	2 (6.9)	1 (3.4)	1 (3.4)
Anaemia	1 (3.4)	1 (3.4)	0
Thrombocytopenia	1 (3.4)	0	1 (3.4)
Investigations			
-Total	6 (20.7)	1 (3.4)	5 (17.2)
White blood cell count decreased	5 (17.2)	0	5 (17.2)
Neutrophil count decreased	3 (10.3)	0	3 (10.3)

Time since enrollment to CTL019 infusion: <=Median

	All patients N=29		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (3.4)	1 (3.4)	0
Lymphocyte count decreased	1 (3.4)	0	1 (3.4)
Platelet count decreased	1 (3.4)	1 (3.4)	0
Metabolism and nutrition disorders			
-Total	1 (3.4)	1 (3.4)	0
Hypokalaemia	1 (3.4)	1 (3.4)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (3.4)	1 (3.4)	0
Hypoxia	1 (3.4)	1 (3.4)	0
Vascular disorders			
-Total	2 (6.9)	2 (6.9)	0
Hypotension	2 (6.9)	2 (6.9)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191q
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set - Patients who received lymphodepleting chemotherapy

Time since enrollment to CTL019 infusion: Missing

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
Blood and lymphatic system disorders			
-Total	1 (100)	0	1 (100)
Anaemia	1 (100)	1 (100)	0
Disseminated intravascular coagulation	1 (100)	0	1 (100)
Febrile neutropenia	1 (100)	1 (100)	0
Thrombocytopenia	1 (100)	0	1 (100)
Gastrointestinal disorders			
-Total	1 (100)	1 (100)	0
Ascites	1 (100)	1 (100)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (100)	0	1 (100)
Multiple organ dysfunction syndrome	1 (100)	0	1 (100)
Hepatobiliary disorders			
-Total	1 (100)	0	1 (100)
Hepatic failure	1 (100)	0	1 (100)
Infections and infestations			
-Total	1 (100)	0	1 (100)
Staphylococcal infection	1 (100)	0	1 (100)
Investigations			
-Total	1 (100)	0	1 (100)
Alanine aminotransferase increased	1 (100)	0	1 (100)
Aspartate aminotransferase increased	1 (100)	0	1 (100)
Blood bilirubin increased	1 (100)	0	1 (100)
Neutrophil count decreased	1 (100)	0	1 (100)
Metabolism and nutrition disorders			
-Total	1 (100)	0	1 (100)

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=1 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypernatraemia	1 (100)	0	1 (100)
Hypokalaemia	1 (100)	0	1 (100)
Psychiatric disorders			
-Total	1 (100)	1 (100)	0
Delirium	1 (100)	1 (100)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (100)	1 (100)	0
Hypoxia	1 (100)	1 (100)	0
Pleural effusion	1 (100)	1 (100)	0
Vascular disorders			
-Total	1 (100)	1 (100)	0
Hypotension	1 (100)	1 (100)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191r
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 0

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (57.1)	1 (14.3)	3 (42.9)
Blood and lymphatic system disorders			
-Total	1 (14.3)	0	1 (14.3)
Neutropenia	1 (14.3)	0	1 (14.3)
Cardiac disorders			
-Total	1 (14.3)	1 (14.3)	0
Left ventricular dysfunction	1 (14.3)	1 (14.3)	0
Investigations			
-Total	2 (28.6)	0	2 (28.6)
Neutrophil count decreased	2 (28.6)	0	2 (28.6)

Number of previous relapses: 0

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
White blood cell count decreased	2 (28.6)	0	2 (28.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191r
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 1

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (63.2)	5 (26.3)	7 (36.8)
Blood and lymphatic system disorders			
-Total	6 (31.6)	4 (21.1)	2 (10.5)
Febrile neutropenia	3 (15.8)	3 (15.8)	0
Anaemia	1 (5.3)	1 (5.3)	0
Hypofibrinogenaemia	1 (5.3)	0	1 (5.3)
Lymphopenia	1 (5.3)	0	1 (5.3)
Thrombocytopenia	1 (5.3)	1 (5.3)	0
Investigations			
-Total	8 (42.1)	2 (10.5)	6 (31.6)

Number of previous relapses: 1

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	6 (31.6)	1 (5.3)	5 (26.3)
Alanine aminotransferase increased	1 (5.3)	1 (5.3)	0
Lipase increased	1 (5.3)	0	1 (5.3)
Neutrophil count decreased	1 (5.3)	0	1 (5.3)
Protein total decreased	1 (5.3)	1 (5.3)	0
Metabolism and nutrition disorders			
-Total	3 (15.8)	2 (10.5)	1 (5.3)
Hypokalaemia	2 (10.5)	1 (5.3)	1 (5.3)
Hyperuricaemia	1 (5.3)	1 (5.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (10.5)	2 (10.5)	0
Epistaxis	1 (5.3)	1 (5.3)	0
Hypoxia	1 (5.3)	1 (5.3)	0
Tachypnoea	1 (5.3)	1 (5.3)	0
Vascular disorders			
-Total	1 (5.3)	1 (5.3)	0
Hypotension	1 (5.3)	1 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191r
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: 2

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	10 (52.6)	5 (26.3)	5 (26.3)
Blood and lymphatic system disorders			
-Total	5 (26.3)	3 (15.8)	2 (10.5)
Anaemia	2 (10.5)	2 (10.5)	0
Febrile neutropenia	1 (5.3)	1 (5.3)	0
Neutropenia	1 (5.3)	0	1 (5.3)
Pancytopenia	1 (5.3)	1 (5.3)	0
Thrombocytopenia	1 (5.3)	0	1 (5.3)
Investigations			
-Total	9 (47.4)	4 (21.1)	5 (26.3)

Number of previous relapses: 2

	All patients N=19		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	6 (31.6)	1 (5.3)	5 (26.3)
Neutrophil count decreased	3 (15.8)	0	3 (15.8)
Alanine aminotransferase increased	2 (10.5)	2 (10.5)	0
Lymphocyte count decreased	1 (5.3)	1 (5.3)	0
Platelet count decreased	1 (5.3)	1 (5.3)	0
Metabolism and nutrition disorders			
-Total	1 (5.3)	1 (5.3)	0
Tumour lysis syndrome	1 (5.3)	1 (5.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused) are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 191r
Severe adverse events (AE CTCAE Grade 3/4) during lymphodepleting period that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients), regardless of relationship to lymphodepleting chemotherapy, by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set - Patients who received lymphodepleting chemotherapy

Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	12 (75.0)	5 (31.3)	7 (43.8)
Blood and lymphatic system disorders			
-Total	6 (37.5)	4 (25.0)	2 (12.5)
Febrile neutropenia	4 (25.0)	4 (25.0)	0
Anaemia	2 (12.5)	2 (12.5)	0
Neutropenia	2 (12.5)	1 (6.3)	1 (6.3)
Disseminated intravascular coagulation	1 (6.3)	0	1 (6.3)
Thrombocytopenia	1 (6.3)	0	1 (6.3)
Gastrointestinal disorders			

Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (6.3)	1 (6.3)	0
Ascites	1 (6.3)	1 (6.3)	0
General disorders and administration site conditions			
-Total	1 (6.3)	0	1 (6.3)
Multiple organ dysfunction syndrome	1 (6.3)	0	1 (6.3)
Hepatobiliary disorders			
-Total	1 (6.3)	0	1 (6.3)
Hepatic failure	1 (6.3)	0	1 (6.3)
Infections and infestations			
-Total	4 (25.0)	3 (18.8)	1 (6.3)
Bacteraemia	1 (6.3)	1 (6.3)	0
Device related infection	1 (6.3)	1 (6.3)	0
Necrotising fasciitis	1 (6.3)	1 (6.3)	0
Staphylococcal infection	1 (6.3)	0	1 (6.3)
Investigations			
-Total	7 (43.8)	0	7 (43.8)
White blood cell count decreased	5 (31.3)	1 (6.3)	4 (25.0)

Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	4 (25.0)	0	4 (25.0)
Lymphocyte count decreased	3 (18.8)	0	3 (18.8)
Platelet count decreased	2 (12.5)	1 (6.3)	1 (6.3)
Alanine aminotransferase increased	1 (6.3)	0	1 (6.3)
Aspartate aminotransferase increased	1 (6.3)	0	1 (6.3)
Blood bilirubin increased	1 (6.3)	0	1 (6.3)
Metabolism and nutrition disorders			
-Total	4 (25.0)	3 (18.8)	1 (6.3)
Hypokalaemia	2 (12.5)	1 (6.3)	1 (6.3)
Hyperglycaemia	1 (6.3)	1 (6.3)	0
Hypernatraemia	1 (6.3)	0	1 (6.3)
Hypoglycaemia	1 (6.3)	1 (6.3)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (12.5)	2 (12.5)	0
Myalgia	1 (6.3)	1 (6.3)	0
Pain in extremity	1 (6.3)	1 (6.3)	0
Psychiatric disorders			

Number of previous relapses: >=3

	All patients N=16		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (6.3)	1 (6.3)	0
Delirium	1 (6.3)	1 (6.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (12.5)	2 (12.5)	0
Hypoxia	2 (12.5)	2 (12.5)	0
Pleural effusion	1 (6.3)	1 (6.3)	0
Skin and subcutaneous tissue disorders			
-Total	1 (6.3)	1 (6.3)	0
Rash macular	1 (6.3)	1 (6.3)	0
Vascular disorders			
-Total	3 (18.8)	3 (18.8)	0
Hypotension	2 (12.5)	2 (12.5)	0
Hypertension	1 (6.3)	1 (6.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs started between the first day of lymphodepleting chemotherapy and CTL019 infusion (for patients who were infused)

are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192a
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: <10 years

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Escherichia infection	1 (50.0)	1 (50.0)	0
Streptococcal infection	1 (50.0)	1 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192a
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=10 years to <18 years

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (80.0)	0	4 (80.0)
Blood and lymphatic system disorders			
-Total	3 (60.0)	1 (20.0)	2 (40.0)
Anaemia	2 (40.0)	2 (40.0)	0
Disseminated intravascular coagulation	2 (40.0)	1 (20.0)	1 (20.0)
Febrile neutropenia	2 (40.0)	2 (40.0)	0
Thrombocytopenia	2 (40.0)	0	2 (40.0)
Neutropenia	1 (20.0)	0	1 (20.0)
Gastrointestinal disorders			
-Total	3 (60.0)	3 (60.0)	0

Age: >=10 years to <18 years

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Colitis	2 (40.0)	2 (40.0)	0
Abdominal pain	1 (20.0)	1 (20.0)	0
Ascites	1 (20.0)	1 (20.0)	0
Diarrhoea	1 (20.0)	1 (20.0)	0
Gastrointestinal haemorrhage	1 (20.0)	1 (20.0)	0
Stomatitis	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
-Total	2 (40.0)	0	2 (40.0)
Multiple organ dysfunction syndrome	2 (40.0)	0	2 (40.0)
Hepatobiliary disorders			
-Total	1 (20.0)	0	1 (20.0)
Hepatic failure	1 (20.0)	0	1 (20.0)
Infections and infestations			
-Total	4 (80.0)	0	4 (80.0)
Candida sepsis	1 (20.0)	0	1 (20.0)
Clostridium difficile colitis	1 (20.0)	1 (20.0)	0
Klebsiella infection	1 (20.0)	1 (20.0)	0

Age: >=10 years to <18 years

Group term Preferred term	All patients N=5 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Klebsiella sepsis	1 (20.0)	0	1 (20.0)
Pneumonia fungal	1 (20.0)	1 (20.0)	0
Sepsis	1 (20.0)	0	1 (20.0)
Staphylococcal bacteraemia	1 (20.0)	1 (20.0)	0
Staphylococcal infection	1 (20.0)	0	1 (20.0)
Investigations			
-Total	2 (40.0)	0	2 (40.0)
Alanine aminotransferase increased	1 (20.0)	0	1 (20.0)
Aspartate aminotransferase increased	1 (20.0)	0	1 (20.0)
Blood bilirubin increased	1 (20.0)	0	1 (20.0)
Neutrophil count decreased	1 (20.0)	0	1 (20.0)
Platelet count decreased	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
-Total	3 (60.0)	0	3 (60.0)
Hypernatraemia	3 (60.0)	1 (20.0)	2 (40.0)
Hypokalaemia	3 (60.0)	0	3 (60.0)
Decreased appetite	1 (20.0)	1 (20.0)	0

Age: >=10 years to <18 years

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (20.0)	1 (20.0)	0
Hyperglycaemia	1 (20.0)	0	1 (20.0)
Hypoalbuminaemia	1 (20.0)	0	1 (20.0)
Hypocalcaemia	1 (20.0)	0	1 (20.0)
Hypophosphataemia	1 (20.0)	1 (20.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (20.0)	1 (20.0)	0
Pain in extremity	1 (20.0)	1 (20.0)	0
Nervous system disorders			
-Total	1 (20.0)	1 (20.0)	0
Leukoencephalopathy	1 (20.0)	1 (20.0)	0
Psychiatric disorders			
-Total	1 (20.0)	1 (20.0)	0
Delirium	1 (20.0)	1 (20.0)	0
Renal and urinary disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Acute kidney injury	1 (20.0)	0	1 (20.0)

Age: >=10 years to <18 years

Group term Preferred term	All patients N=5 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Cystitis haemorrhagic	1 (20.0)	1 (20.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (60.0)	1 (20.0)	2 (40.0)
Hypoxia	2 (40.0)	1 (20.0)	1 (20.0)
Pleural effusion	1 (20.0)	1 (20.0)	0
Pulmonary oedema	1 (20.0)	0	1 (20.0)
Respiratory failure	1 (20.0)	0	1 (20.0)
Vascular disorders			
-Total	4 (80.0)	3 (60.0)	1 (20.0)
Hypotension	4 (80.0)	3 (60.0)	1 (20.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192a
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set – non – infused patients

Age: >=18

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	0	3 (75.0)
Blood and lymphatic system disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Anaemia	2 (50.0)	2 (50.0)	0
Thrombocytopenia	2 (50.0)	1 (25.0)	1 (25.0)
Disseminated intravascular coagulation	1 (25.0)	1 (25.0)	0
Lymphopenia	1 (25.0)	0	1 (25.0)
Neutropenia	1 (25.0)	0	1 (25.0)
Cardiac disorders			
-Total	2 (50.0)	0	2 (50.0)

Age: >=18

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (25.0)	0	1 (25.0)
Cardiovascular insufficiency	1 (25.0)	0	1 (25.0)
Right ventricular dysfunction	1 (25.0)	1 (25.0)	0
Sinus tachycardia	1 (25.0)	1 (25.0)	0
Ventricular tachycardia	1 (25.0)	1 (25.0)	0
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Abdominal pain	1 (25.0)	1 (25.0)	0
Haematochezia	1 (25.0)	1 (25.0)	0
Nausea	1 (25.0)	1 (25.0)	0
Vomiting	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Multiple organ dysfunction syndrome	1 (25.0)	0	1 (25.0)
Non-cardiac chest pain	1 (25.0)	1 (25.0)	0
Pain	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0

Age: >=18

Group term Preferred term	All patients N=4 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Infections and infestations			
-Total	2 (50.0)	0	2 (50.0)
Klebsiella sepsis	1 (25.0)	0	1 (25.0)
Pneumonia	1 (25.0)	0	1 (25.0)
Investigations			
-Total	2 (50.0)	0	2 (50.0)
Blood lactate dehydrogenase increased	1 (25.0)	1 (25.0)	0
Computerised tomogram thorax abnormal	1 (25.0)	1 (25.0)	0
Electrocardiogram qt prolonged	1 (25.0)	1 (25.0)	0
Neutrophil count decreased	1 (25.0)	0	1 (25.0)
White blood cell count decreased	1 (25.0)	0	1 (25.0)
Metabolism and nutrition disorders			
-Total	1 (25.0)	1 (25.0)	0
Fluid overload	1 (25.0)	1 (25.0)	0
Hyperkalaemia	1 (25.0)	1 (25.0)	0
Musculoskeletal and connective tissue disorders			

Age: >=18

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (25.0)	1 (25.0)	0
Arthralgia	1 (25.0)	1 (25.0)	0
Back pain	1 (25.0)	1 (25.0)	0
Pain in extremity	1 (25.0)	1 (25.0)	0
Nervous system disorders			
-Total	1 (25.0)	0	1 (25.0)
Headache	1 (25.0)	1 (25.0)	0
Hyporesponsive to stimuli	1 (25.0)	1 (25.0)	0
Seizure	1 (25.0)	0	1 (25.0)
Psychiatric disorders			
-Total	1 (25.0)	1 (25.0)	0
Agitation	1 (25.0)	1 (25.0)	0
Renal and urinary disorders			
-Total	1 (25.0)	1 (25.0)	0
Acute kidney injury	1 (25.0)	1 (25.0)	0
Oliguria	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			

Age: >=18

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (50.0)	0	2 (50.0)
Hypoxia	2 (50.0)	2 (50.0)	0
Aspiration	1 (25.0)	0	1 (25.0)
Cough	1 (25.0)	1 (25.0)	0
Dyspnoea	1 (25.0)	1 (25.0)	0
Haemoptysis	1 (25.0)	1 (25.0)	0
Oropharyngeal pain	1 (25.0)	1 (25.0)	0
Pulmonary alveolar haemorrhage	1 (25.0)	0	1 (25.0)
Pulmonary hypertension	1 (25.0)	1 (25.0)	0
Pulmonary oedema	1 (25.0)	0	1 (25.0)
Respiratory distress	1 (25.0)	0	1 (25.0)
Tachypnoea	1 (25.0)	1 (25.0)	0
Vascular disorders			
-Total	2 (50.0)	0	2 (50.0)
Hypotension	2 (50.0)	0	2 (50.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192b
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set – non – infused patients

Gender: Male

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (80.0)	1 (10.0)	7 (70.0)
Blood and lymphatic system disorders			
-Total	5 (50.0)	2 (20.0)	3 (30.0)
Anaemia	4 (40.0)	4 (40.0)	0
Thrombocytopenia	4 (40.0)	1 (10.0)	3 (30.0)
Disseminated intravascular coagulation	3 (30.0)	2 (20.0)	1 (10.0)
Febrile neutropenia	2 (20.0)	2 (20.0)	0
Neutropenia	2 (20.0)	0	2 (20.0)
Lymphopenia	1 (10.0)	0	1 (10.0)
Cardiac disorders			

Gender: Male

Group term Preferred term	All patients N=10 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (20.0)	0	2 (20.0)
Bradycardia	1 (10.0)	0	1 (10.0)
Cardiovascular insufficiency	1 (10.0)	0	1 (10.0)
Right ventricular dysfunction	1 (10.0)	1 (10.0)	0
Sinus tachycardia	1 (10.0)	1 (10.0)	0
Ventricular tachycardia	1 (10.0)	1 (10.0)	0
Gastrointestinal disorders			
-Total	4 (40.0)	4 (40.0)	0
Abdominal pain	2 (20.0)	2 (20.0)	0
Colitis	2 (20.0)	2 (20.0)	0
Ascites	1 (10.0)	1 (10.0)	0
Diarrhoea	1 (10.0)	1 (10.0)	0
Gastrointestinal haemorrhage	1 (10.0)	1 (10.0)	0
Haematochezia	1 (10.0)	1 (10.0)	0
Nausea	1 (10.0)	1 (10.0)	0
Stomatitis	1 (10.0)	1 (10.0)	0
Vomiting	1 (10.0)	1 (10.0)	0

Gender: Male

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	5 (50.0)	2 (20.0)	3 (30.0)
Multiple organ dysfunction syndrome	3 (30.0)	0	3 (30.0)
Non-cardiac chest pain	1 (10.0)	1 (10.0)	0
Pain	1 (10.0)	1 (10.0)	0
Pyrexia	1 (10.0)	1 (10.0)	0
Hepatobiliary disorders			
-Total	1 (10.0)	0	1 (10.0)
Hepatic failure	1 (10.0)	0	1 (10.0)
Infections and infestations			
-Total	7 (70.0)	1 (10.0)	6 (60.0)
Klebsiella sepsis	2 (20.0)	0	2 (20.0)
Candida sepsis	1 (10.0)	0	1 (10.0)
Clostridium difficile colitis	1 (10.0)	1 (10.0)	0
Escherichia infection	1 (10.0)	1 (10.0)	0
Klebsiella infection	1 (10.0)	1 (10.0)	0
Pneumonia	1 (10.0)	0	1 (10.0)

Gender: Male

Group term Preferred term	All patients N=10 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	1 (10.0)	1 (10.0)	0
Sepsis	1 (10.0)	0	1 (10.0)
Staphylococcal bacteraemia	1 (10.0)	1 (10.0)	0
Staphylococcal infection	1 (10.0)	0	1 (10.0)
Streptococcal infection	1 (10.0)	1 (10.0)	0
Investigations			
-Total	4 (40.0)	0	4 (40.0)
Neutrophil count decreased	2 (20.0)	0	2 (20.0)
Alanine aminotransferase increased	1 (10.0)	0	1 (10.0)
Aspartate aminotransferase increased	1 (10.0)	0	1 (10.0)
Blood bilirubin increased	1 (10.0)	0	1 (10.0)
Blood lactate dehydrogenase increased	1 (10.0)	1 (10.0)	0
Computerised tomogram thorax abnormal	1 (10.0)	1 (10.0)	0
Electrocardiogram qt prolonged	1 (10.0)	1 (10.0)	0
Platelet count decreased	1 (10.0)	0	1 (10.0)
White blood cell count decreased	1 (10.0)	0	1 (10.0)

Gender: Male

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	4 (40.0)	1 (10.0)	3 (30.0)
Hypernatraemia	3 (30.0)	1 (10.0)	2 (20.0)
Hypokalaemia	3 (30.0)	0	3 (30.0)
Decreased appetite	1 (10.0)	1 (10.0)	0
Dehydration	1 (10.0)	1 (10.0)	0
Fluid overload	1 (10.0)	1 (10.0)	0
Hyperglycaemia	1 (10.0)	0	1 (10.0)
Hyperkalaemia	1 (10.0)	1 (10.0)	0
Hypoalbuminaemia	1 (10.0)	0	1 (10.0)
Hypocalcaemia	1 (10.0)	0	1 (10.0)
Hypophosphataemia	1 (10.0)	1 (10.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (20.0)	2 (20.0)	0
Pain in extremity	2 (20.0)	2 (20.0)	0
Arthralgia	1 (10.0)	1 (10.0)	0
Back pain	1 (10.0)	1 (10.0)	0

Gender: Male

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Headache	1 (10.0)	1 (10.0)	0
Hyporesponsive to stimuli	1 (10.0)	1 (10.0)	0
Leukoencephalopathy	1 (10.0)	1 (10.0)	0
Seizure	1 (10.0)	0	1 (10.0)
Psychiatric disorders			
-Total	2 (20.0)	2 (20.0)	0
Agitation	1 (10.0)	1 (10.0)	0
Delirium	1 (10.0)	1 (10.0)	0
Renal and urinary disorders			
-Total	3 (30.0)	2 (20.0)	1 (10.0)
Acute kidney injury	2 (20.0)	1 (10.0)	1 (10.0)
Cystitis haemorrhagic	1 (10.0)	1 (10.0)	0
Oliguria	1 (10.0)	1 (10.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (50.0)	1 (10.0)	4 (40.0)

Gender: Male

Group term Preferred term	All patients N=10 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	4 (40.0)	3 (30.0)	1 (10.0)
Pulmonary oedema	2 (20.0)	0	2 (20.0)
Aspiration	1 (10.0)	0	1 (10.0)
Cough	1 (10.0)	1 (10.0)	0
Dyspnoea	1 (10.0)	1 (10.0)	0
Haemoptysis	1 (10.0)	1 (10.0)	0
Oropharyngeal pain	1 (10.0)	1 (10.0)	0
Pleural effusion	1 (10.0)	1 (10.0)	0
Pulmonary alveolar haemorrhage	1 (10.0)	0	1 (10.0)
Pulmonary hypertension	1 (10.0)	1 (10.0)	0
Respiratory distress	1 (10.0)	0	1 (10.0)
Respiratory failure	1 (10.0)	0	1 (10.0)
Tachypnoea	1 (10.0)	1 (10.0)	0
Vascular disorders			
-Total	6 (60.0)	3 (30.0)	3 (30.0)
Hypotension	6 (60.0)	3 (30.0)	3 (30.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192c
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: White

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (62.5)	0	5 (62.5)
Blood and lymphatic system disorders			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Anaemia	2 (25.0)	2 (25.0)	0
Disseminated intravascular coagulation	2 (25.0)	1 (12.5)	1 (12.5)
Febrile neutropenia	2 (25.0)	2 (25.0)	0
Thrombocytopenia	2 (25.0)	0	2 (25.0)
Neutropenia	1 (12.5)	0	1 (12.5)
Gastrointestinal disorders			
-Total	3 (37.5)	3 (37.5)	0

Race: White

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Colitis	2 (25.0)	2 (25.0)	0
Abdominal pain	1 (12.5)	1 (12.5)	0
Ascites	1 (12.5)	1 (12.5)	0
Diarrhoea	1 (12.5)	1 (12.5)	0
Gastrointestinal haemorrhage	1 (12.5)	1 (12.5)	0
Stomatitis	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Multiple organ dysfunction syndrome	2 (25.0)	0	2 (25.0)
Pain	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Hepatobiliary disorders			
-Total	1 (12.5)	0	1 (12.5)
Hepatic failure	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	5 (62.5)	0	5 (62.5)
Candida sepsis	1 (12.5)	0	1 (12.5)

Race: White

Group term Preferred term	All patients N=8 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Clostridium difficile colitis	1 (12.5)	1 (12.5)	0
Klebsiella infection	1 (12.5)	1 (12.5)	0
Klebsiella sepsis	1 (12.5)	0	1 (12.5)
Pneumonia	1 (12.5)	0	1 (12.5)
Pneumonia fungal	1 (12.5)	1 (12.5)	0
Sepsis	1 (12.5)	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Investigations			
-Total	2 (25.0)	0	2 (25.0)
Alanine aminotransferase increased	1 (12.5)	0	1 (12.5)
Aspartate aminotransferase increased	1 (12.5)	0	1 (12.5)
Blood bilirubin increased	1 (12.5)	0	1 (12.5)
Neutrophil count decreased	1 (12.5)	0	1 (12.5)
Platelet count decreased	1 (12.5)	0	1 (12.5)
Metabolism and nutrition disorders			
-Total	3 (37.5)	0	3 (37.5)

Race: White

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypernatraemia	3 (37.5)	1 (12.5)	2 (25.0)
Hypokalaemia	3 (37.5)	0	3 (37.5)
Decreased appetite	1 (12.5)	1 (12.5)	0
Dehydration	1 (12.5)	1 (12.5)	0
Hyperglycaemia	1 (12.5)	0	1 (12.5)
Hypoalbuminaemia	1 (12.5)	0	1 (12.5)
Hypocalcaemia	1 (12.5)	0	1 (12.5)
Hypophosphataemia	1 (12.5)	1 (12.5)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (12.5)	1 (12.5)	0
Pain in extremity	1 (12.5)	1 (12.5)	0
Nervous system disorders			
-Total	1 (12.5)	1 (12.5)	0
Leukoencephalopathy	1 (12.5)	1 (12.5)	0
Psychiatric disorders			
-Total	1 (12.5)	1 (12.5)	0
Delirium	1 (12.5)	1 (12.5)	0

Race: White

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Renal and urinary disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Acute kidney injury	1 (12.5)	0	1 (12.5)
Cystitis haemorrhagic	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Hypoxia	3 (37.5)	2 (25.0)	1 (12.5)
Aspiration	1 (12.5)	0	1 (12.5)
Pleural effusion	1 (12.5)	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	1 (12.5)
Respiratory failure	1 (12.5)	0	1 (12.5)
Vascular disorders			
-Total	5 (62.5)	3 (37.5)	2 (25.0)
Hypotension	5 (62.5)	3 (37.5)	2 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192c
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Asian

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Infections and infestations			
-Total	1 (100)	1 (100)	0
Escherichia infection	1 (100)	1 (100)	0
Streptococcal infection	1 (100)	1 (100)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192c
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set – non – infused patients

Race: Other

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Blood and lymphatic system disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Anaemia	2 (100)	2 (100)	0
Thrombocytopenia	2 (100)	1 (50.0)	1 (50.0)
Disseminated intravascular coagulation	1 (50.0)	1 (50.0)	0
Lymphopenia	1 (50.0)	0	1 (50.0)
Neutropenia	1 (50.0)	0	1 (50.0)
Cardiac disorders			
-Total	2 (100)	0	2 (100)

Race: Other

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (50.0)	0	1 (50.0)
Cardiovascular insufficiency	1 (50.0)	0	1 (50.0)
Right ventricular dysfunction	1 (50.0)	1 (50.0)	0
Sinus tachycardia	1 (50.0)	1 (50.0)	0
Ventricular tachycardia	1 (50.0)	1 (50.0)	0
Gastrointestinal disorders			
-Total	1 (50.0)	1 (50.0)	0
Abdominal pain	1 (50.0)	1 (50.0)	0
Haematochezia	1 (50.0)	1 (50.0)	0
Nausea	1 (50.0)	1 (50.0)	0
Vomiting	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	2 (100)	1 (50.0)	1 (50.0)
Multiple organ dysfunction syndrome	1 (50.0)	0	1 (50.0)
Non-cardiac chest pain	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)

Race: Other

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella sepsis	1 (50.0)	0	1 (50.0)
Investigations			
-Total	2 (100)	0	2 (100)
Blood lactate dehydrogenase increased	1 (50.0)	1 (50.0)	0
Computerised tomogram thorax abnormal	1 (50.0)	1 (50.0)	0
Electrocardiogram qt prolonged	1 (50.0)	1 (50.0)	0
Neutrophil count decreased	1 (50.0)	0	1 (50.0)
White blood cell count decreased	1 (50.0)	0	1 (50.0)
Metabolism and nutrition disorders			
-Total	1 (50.0)	1 (50.0)	0
Fluid overload	1 (50.0)	1 (50.0)	0
Hyperkalaemia	1 (50.0)	1 (50.0)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (50.0)	1 (50.0)	0
Arthralgia	1 (50.0)	1 (50.0)	0
Back pain	1 (50.0)	1 (50.0)	0

Race: Other

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	1 (50.0)	1 (50.0)	0
Nervous system disorders			
-Total	1 (50.0)	0	1 (50.0)
Headache	1 (50.0)	1 (50.0)	0
Hyporesponsive to stimuli	1 (50.0)	1 (50.0)	0
Seizure	1 (50.0)	0	1 (50.0)
Psychiatric disorders			
-Total	1 (50.0)	1 (50.0)	0
Agitation	1 (50.0)	1 (50.0)	0
Renal and urinary disorders			
-Total	1 (50.0)	1 (50.0)	0
Acute kidney injury	1 (50.0)	1 (50.0)	0
Oliguria	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (50.0)	0	1 (50.0)
Cough	1 (50.0)	1 (50.0)	0
Dyspnoea	1 (50.0)	1 (50.0)	0

Race: Other

Group term Preferred term	All patients N=2 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemoptysis	1 (50.0)	1 (50.0)	0
Hypoxia	1 (50.0)	1 (50.0)	0
Oropharyngeal pain	1 (50.0)	1 (50.0)	0
Pulmonary alveolar haemorrhage	1 (50.0)	0	1 (50.0)
Pulmonary hypertension	1 (50.0)	1 (50.0)	0
Pulmonary oedema	1 (50.0)	0	1 (50.0)
Respiratory distress	1 (50.0)	0	1 (50.0)
Tachypnoea	1 (50.0)	1 (50.0)	0
Vascular disorders			
-Total	1 (50.0)	0	1 (50.0)
Hypotension	1 (50.0)	0	1 (50.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192d
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Hispanic or Latino

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (60.0)	0	3 (60.0)
Blood and lymphatic system disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Thrombocytopenia	2 (40.0)	1 (20.0)	1 (20.0)
Anaemia	1 (20.0)	1 (20.0)	0
Febrile neutropenia	1 (20.0)	1 (20.0)	0
Neutropenia	1 (20.0)	0	1 (20.0)
Cardiac disorders			
-Total	1 (20.0)	0	1 (20.0)
Cardiovascular insufficiency	1 (20.0)	0	1 (20.0)
Gastrointestinal disorders			

Ethnicity: Hispanic or Latino

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (20.0)	1 (20.0)	0
Gastrointestinal haemorrhage	1 (20.0)	1 (20.0)	0
General disorders and administration site conditions			
-Total	1 (20.0)	0	1 (20.0)
Multiple organ dysfunction syndrome	1 (20.0)	0	1 (20.0)
Infections and infestations			
-Total	3 (60.0)	0	3 (60.0)
Candida sepsis	1 (20.0)	0	1 (20.0)
Klebsiella sepsis	1 (20.0)	0	1 (20.0)
Pneumonia fungal	1 (20.0)	1 (20.0)	0
Sepsis	1 (20.0)	0	1 (20.0)
Investigations			
-Total	1 (20.0)	0	1 (20.0)
Neutrophil count decreased	1 (20.0)	0	1 (20.0)
Metabolism and nutrition disorders			
-Total	1 (20.0)	0	1 (20.0)
Hypernatraemia	1 (20.0)	0	1 (20.0)

Ethnicity: Hispanic or Latino

	All patients N=5		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypokalaemia	1 (20.0)	0	1 (20.0)
Hypophosphataemia	1 (20.0)	1 (20.0)	0
Renal and urinary disorders			
-Total	1 (20.0)	0	1 (20.0)
Acute kidney injury	1 (20.0)	0	1 (20.0)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (20.0)	0	1 (20.0)
Pulmonary oedema	1 (20.0)	0	1 (20.0)
Respiratory failure	1 (20.0)	0	1 (20.0)
Vascular disorders			
-Total	2 (40.0)	1 (20.0)	1 (20.0)
Hypotension	2 (40.0)	1 (20.0)	1 (20.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all

grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192d
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set – non – infused patients

Ethnicity: Other

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (83.3)	1 (16.7)	4 (66.7)
Blood and lymphatic system disorders			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Anaemia	3 (50.0)	3 (50.0)	0
Disseminated intravascular coagulation	3 (50.0)	2 (33.3)	1 (16.7)
Thrombocytopenia	2 (33.3)	0	2 (33.3)
Febrile neutropenia	1 (16.7)	1 (16.7)	0
Lymphopenia	1 (16.7)	0	1 (16.7)
Neutropenia	1 (16.7)	0	1 (16.7)
Cardiac disorders			

Ethnicity: Other

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (16.7)	0	1 (16.7)
Bradycardia	1 (16.7)	0	1 (16.7)
Right ventricular dysfunction	1 (16.7)	1 (16.7)	0
Sinus tachycardia	1 (16.7)	1 (16.7)	0
Ventricular tachycardia	1 (16.7)	1 (16.7)	0
Gastrointestinal disorders			
-Total	3 (50.0)	3 (50.0)	0
Abdominal pain	2 (33.3)	2 (33.3)	0
Colitis	2 (33.3)	2 (33.3)	0
Ascites	1 (16.7)	1 (16.7)	0
Diarrhoea	1 (16.7)	1 (16.7)	0
Haematochezia	1 (16.7)	1 (16.7)	0
Nausea	1 (16.7)	1 (16.7)	0
Stomatitis	1 (16.7)	1 (16.7)	0
Vomiting	1 (16.7)	1 (16.7)	0
General disorders and administration site conditions			
-Total	4 (66.7)	2 (33.3)	2 (33.3)

Ethnicity: Other

Group term Preferred term	All patients N=6 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Multiple organ dysfunction syndrome	2 (33.3)	0	2 (33.3)
Non-cardiac chest pain	1 (16.7)	1 (16.7)	0
Pain	1 (16.7)	1 (16.7)	0
Pyrexia	1 (16.7)	1 (16.7)	0
Hepatobiliary disorders			
-Total	1 (16.7)	0	1 (16.7)
Hepatic failure	1 (16.7)	0	1 (16.7)
Infections and infestations			
-Total	4 (66.7)	1 (16.7)	3 (50.0)
Clostridium difficile colitis	1 (16.7)	1 (16.7)	0
Escherichia infection	1 (16.7)	1 (16.7)	0
Klebsiella infection	1 (16.7)	1 (16.7)	0
Klebsiella sepsis	1 (16.7)	0	1 (16.7)
Pneumonia	1 (16.7)	0	1 (16.7)
Staphylococcal bacteraemia	1 (16.7)	1 (16.7)	0
Staphylococcal infection	1 (16.7)	0	1 (16.7)
Streptococcal infection	1 (16.7)	1 (16.7)	0
Investigations			

Ethnicity: Other

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (50.0)	0	3 (50.0)
Alanine aminotransferase increased	1 (16.7)	0	1 (16.7)
Aspartate aminotransferase increased	1 (16.7)	0	1 (16.7)
Blood bilirubin increased	1 (16.7)	0	1 (16.7)
Blood lactate dehydrogenase increased	1 (16.7)	1 (16.7)	0
Computerised tomogram thorax abnormal	1 (16.7)	1 (16.7)	0
Electrocardiogram qt prolonged	1 (16.7)	1 (16.7)	0
Neutrophil count decreased	1 (16.7)	0	1 (16.7)
Platelet count decreased	1 (16.7)	0	1 (16.7)
White blood cell count decreased	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Hypernatraemia	2 (33.3)	1 (16.7)	1 (16.7)
Hypokalaemia	2 (33.3)	0	2 (33.3)
Decreased appetite	1 (16.7)	1 (16.7)	0
Dehydration	1 (16.7)	1 (16.7)	0

Ethnicity: Other

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Fluid overload	1 (16.7)	1 (16.7)	0
Hyperglycaemia	1 (16.7)	0	1 (16.7)
Hyperkalaemia	1 (16.7)	1 (16.7)	0
Hypoalbuminaemia	1 (16.7)	0	1 (16.7)
Hypocalcaemia	1 (16.7)	0	1 (16.7)
Musculoskeletal and connective tissue disorders			
-Total	2 (33.3)	2 (33.3)	0
Pain in extremity	2 (33.3)	2 (33.3)	0
Arthralgia	1 (16.7)	1 (16.7)	0
Back pain	1 (16.7)	1 (16.7)	0
Nervous system disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Headache	1 (16.7)	1 (16.7)	0
Hyporesponsive to stimuli	1 (16.7)	1 (16.7)	0
Leukoencephalopathy	1 (16.7)	1 (16.7)	0
Seizure	1 (16.7)	0	1 (16.7)
Psychiatric disorders			

Ethnicity: Other

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (33.3)	2 (33.3)	0
Agitation	1 (16.7)	1 (16.7)	0
Delirium	1 (16.7)	1 (16.7)	0
Renal and urinary disorders			
-Total	2 (33.3)	2 (33.3)	0
Acute kidney injury	1 (16.7)	1 (16.7)	0
Cystitis haemorrhagic	1 (16.7)	1 (16.7)	0
Oliguria	1 (16.7)	1 (16.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (66.7)	1 (16.7)	3 (50.0)
Hypoxia	4 (66.7)	3 (50.0)	1 (16.7)
Aspiration	1 (16.7)	0	1 (16.7)
Cough	1 (16.7)	1 (16.7)	0
Dyspnoea	1 (16.7)	1 (16.7)	0
Haemoptysis	1 (16.7)	1 (16.7)	0
Oropharyngeal pain	1 (16.7)	1 (16.7)	0
Pleural effusion	1 (16.7)	1 (16.7)	0

Ethnicity: Other

Group term Preferred term	All patients N=6 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary alveolar haemorrhage	1 (16.7)	0	1 (16.7)
Pulmonary hypertension	1 (16.7)	1 (16.7)	0
Pulmonary oedema	1 (16.7)	0	1 (16.7)
Respiratory distress	1 (16.7)	0	1 (16.7)
Tachypnoea	1 (16.7)	1 (16.7)	0
Vascular disorders			
-Total	4 (66.7)	2 (33.3)	2 (33.3)
Hypotension	4 (66.7)	2 (33.3)	2 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192e
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Primary refractory

		All patients N=1	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
General disorders and administration site conditions			
-Total	1 (100)	1 (100)	0
Pain	1 (100)	1 (100)	0
Pyrexia	1 (100)	1 (100)	0
Infections and infestations			
-Total	1 (100)	0	1 (100)
Pneumonia	1 (100)	0	1 (100)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (100)	0	1 (100)

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=1 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Aspiration	1 (100)	0	1 (100)
Hypoxia	1 (100)	1 (100)	0
Vascular disorders			
-Total	1 (100)	0	1 (100)
Hypotension	1 (100)	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192e
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set – non – infused patients

Response status at study entry: Relapsed disease

		All patients N=10	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (70.0)	1 (10.0)	6 (60.0)
Blood and lymphatic system disorders			
-Total	5 (50.0)	2 (20.0)	3 (30.0)
Anaemia	4 (40.0)	4 (40.0)	0
Thrombocytopenia	4 (40.0)	1 (10.0)	3 (30.0)
Disseminated intravascular coagulation	3 (30.0)	2 (20.0)	1 (10.0)
Febrile neutropenia	2 (20.0)	2 (20.0)	0
Neutropenia	2 (20.0)	0	2 (20.0)
Lymphopenia	1 (10.0)	0	1 (10.0)
Cardiac disorders			
-Total	2 (20.0)	0	2 (20.0)

Response status at study entry: Relapsed disease

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (10.0)	0	1 (10.0)
Cardiovascular insufficiency	1 (10.0)	0	1 (10.0)
Right ventricular dysfunction	1 (10.0)	1 (10.0)	0
Sinus tachycardia	1 (10.0)	1 (10.0)	0
Ventricular tachycardia	1 (10.0)	1 (10.0)	0
Gastrointestinal disorders			
-Total	4 (40.0)	4 (40.0)	0
Abdominal pain	2 (20.0)	2 (20.0)	0
Colitis	2 (20.0)	2 (20.0)	0
Ascites	1 (10.0)	1 (10.0)	0
Diarrhoea	1 (10.0)	1 (10.0)	0
Gastrointestinal haemorrhage	1 (10.0)	1 (10.0)	0
Haematochezia	1 (10.0)	1 (10.0)	0
Nausea	1 (10.0)	1 (10.0)	0
Stomatitis	1 (10.0)	1 (10.0)	0
Vomiting	1 (10.0)	1 (10.0)	0
General disorders and administration site conditions			
-Total	4 (40.0)	1 (10.0)	3 (30.0)

Response status at study entry: Relapsed disease

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	3 (30.0)	0	3 (30.0)
Non-cardiac chest pain	1 (10.0)	1 (10.0)	0
Hepatobiliary disorders			
-Total	1 (10.0)	0	1 (10.0)
Hepatic failure	1 (10.0)	0	1 (10.0)
Infections and infestations			
-Total	6 (60.0)	1 (10.0)	5 (50.0)
Klebsiella sepsis	2 (20.0)	0	2 (20.0)
Candida sepsis	1 (10.0)	0	1 (10.0)
Clostridium difficile colitis	1 (10.0)	1 (10.0)	0
Escherichia infection	1 (10.0)	1 (10.0)	0
Klebsiella infection	1 (10.0)	1 (10.0)	0
Pneumonia fungal	1 (10.0)	1 (10.0)	0
Sepsis	1 (10.0)	0	1 (10.0)
Staphylococcal bacteraemia	1 (10.0)	1 (10.0)	0
Staphylococcal infection	1 (10.0)	0	1 (10.0)
Streptococcal infection	1 (10.0)	1 (10.0)	0
Investigations			
-Total	4 (40.0)	0	4 (40.0)

Response status at study entry: Relapsed disease

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (20.0)	0	2 (20.0)
Alanine aminotransferase increased	1 (10.0)	0	1 (10.0)
Aspartate aminotransferase increased	1 (10.0)	0	1 (10.0)
Blood bilirubin increased	1 (10.0)	0	1 (10.0)
Blood lactate dehydrogenase increased	1 (10.0)	1 (10.0)	0
Computerised tomogram thorax abnormal	1 (10.0)	1 (10.0)	0
Electrocardiogram qt prolonged	1 (10.0)	1 (10.0)	0
Platelet count decreased	1 (10.0)	0	1 (10.0)
White blood cell count decreased	1 (10.0)	0	1 (10.0)
Metabolism and nutrition disorders			
-Total	4 (40.0)	1 (10.0)	3 (30.0)
Hypernatraemia	3 (30.0)	1 (10.0)	2 (20.0)
Hypokalaemia	3 (30.0)	0	3 (30.0)
Decreased appetite	1 (10.0)	1 (10.0)	0
Dehydration	1 (10.0)	1 (10.0)	0
Fluid overload	1 (10.0)	1 (10.0)	0
Hyperglycaemia	1 (10.0)	0	1 (10.0)

Response status at study entry: Relapsed disease

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperkalaemia	1 (10.0)	1 (10.0)	0
Hypoalbuminaemia	1 (10.0)	0	1 (10.0)
Hypocalcaemia	1 (10.0)	0	1 (10.0)
Hypophosphataemia	1 (10.0)	1 (10.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (20.0)	2 (20.0)	0
Pain in extremity	2 (20.0)	2 (20.0)	0
Arthralgia	1 (10.0)	1 (10.0)	0
Back pain	1 (10.0)	1 (10.0)	0
Nervous system disorders			
-Total	2 (20.0)	1 (10.0)	1 (10.0)
Headache	1 (10.0)	1 (10.0)	0
Hyporesponsive to stimuli	1 (10.0)	1 (10.0)	0
Leukoencephalopathy	1 (10.0)	1 (10.0)	0
Seizure	1 (10.0)	0	1 (10.0)
Psychiatric disorders			
-Total	2 (20.0)	2 (20.0)	0
Agitation	1 (10.0)	1 (10.0)	0

Response status at study entry: Relapsed disease

	All patients N=10		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Delirium	1 (10.0)	1 (10.0)	0
Renal and urinary disorders			
-Total	3 (30.0)	2 (20.0)	1 (10.0)
Acute kidney injury	2 (20.0)	1 (10.0)	1 (10.0)
Cystitis haemorrhagic	1 (10.0)	1 (10.0)	0
Oliguria	1 (10.0)	1 (10.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (40.0)	1 (10.0)	3 (30.0)
Hypoxia	3 (30.0)	2 (20.0)	1 (10.0)
Pulmonary oedema	2 (20.0)	0	2 (20.0)
Cough	1 (10.0)	1 (10.0)	0
Dyspnoea	1 (10.0)	1 (10.0)	0
Haemoptysis	1 (10.0)	1 (10.0)	0
Oropharyngeal pain	1 (10.0)	1 (10.0)	0
Pleural effusion	1 (10.0)	1 (10.0)	0
Pulmonary alveolar haemorrhage	1 (10.0)	0	1 (10.0)
Pulmonary hypertension	1 (10.0)	1 (10.0)	0
Respiratory distress	1 (10.0)	0	1 (10.0)

Response status at study entry: Relapsed disease

Group term Preferred term	All patients N=10 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Respiratory failure	1 (10.0)	0	1 (10.0)
Tachypnoea	1 (10.0)	1 (10.0)	0
Vascular disorders			
-Total	5 (50.0)	3 (30.0)	2 (20.0)
Hypotension	5 (50.0)	3 (30.0)	2 (20.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192f
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set – non – infused patients

Philadelphia chromosome/BCR-ABL: Negative

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders			
-Total	5 (45.5)	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	4 (36.4)	0
Thrombocytopenia	4 (36.4)	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	2 (18.2)	0	2 (18.2)
Lymphopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
-Total	2 (18.2)	0	2 (18.2)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	1 (9.1)	0
Sinus tachycardia	1 (9.1)	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	4 (36.4)	4 (36.4)	0
Abdominal pain	2 (18.2)	2 (18.2)	0
Colitis	2 (18.2)	2 (18.2)	0
Ascites	1 (9.1)	1 (9.1)	0
Diarrhoea	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Haematochezia	1 (9.1)	1 (9.1)	0
Nausea	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
Vomiting	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	5 (45.5)	2 (18.2)	3 (27.3)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Non-cardiac chest pain	1 (9.1)	1 (9.1)	0
Pain	1 (9.1)	1 (9.1)	0
Pyrexia	1 (9.1)	1 (9.1)	0
Hepatobiliary disorders			
-Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	7 (63.6)	1 (9.1)	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Candida sepsis	1 (9.1)	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	1 (9.1)	0
Escherichia infection	1 (9.1)	1 (9.1)	0
Klebsiella infection	1 (9.1)	1 (9.1)	0
Pneumonia	1 (9.1)	0	1 (9.1)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal infection	1 (9.1)	1 (9.1)	0
Investigations			
-Total	4 (36.4)	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	2 (18.2)
Alanine aminotransferase increased	1 (9.1)	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	1 (9.1)	0
Platelet count decreased	1 (9.1)	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Hypernatraemia	3 (27.3)	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	3 (27.3)
Decreased appetite	1 (9.1)	1 (9.1)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (9.1)	1 (9.1)	0
Fluid overload	1 (9.1)	1 (9.1)	0
Hyperglycaemia	1 (9.1)	0	1 (9.1)
Hyperkalaemia	1 (9.1)	1 (9.1)	0
Hypoalbuminaemia	1 (9.1)	0	1 (9.1)
Hypocalcaemia	1 (9.1)	0	1 (9.1)
Hypophosphataemia	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (18.2)	2 (18.2)	0
Pain in extremity	2 (18.2)	2 (18.2)	0
Arthralgia	1 (9.1)	1 (9.1)	0
Back pain	1 (9.1)	1 (9.1)	0
Nervous system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Headache	1 (9.1)	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	0	1 (9.1)

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	2 (18.2)	2 (18.2)	0
Agitation	1 (9.1)	1 (9.1)	0
Delirium	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Acute kidney injury	2 (18.2)	1 (9.1)	1 (9.1)
Cystitis haemorrhagic	1 (9.1)	1 (9.1)	0
Oliguria	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (45.5)	1 (9.1)	4 (36.4)
Hypoxia	4 (36.4)	3 (27.3)	1 (9.1)
Pulmonary oedema	2 (18.2)	0	2 (18.2)
Aspiration	1 (9.1)	0	1 (9.1)
Cough	1 (9.1)	1 (9.1)	0
Dyspnoea	1 (9.1)	1 (9.1)	0
Haemoptysis	1 (9.1)	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	1 (9.1)	0

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	1 (9.1)	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	1 (9.1)	0
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Tachypnoea	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	6 (54.5)	3 (27.3)	3 (27.3)
Hypotension	6 (54.5)	3 (27.3)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192g
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set – non – infused patients

Mixed-lineage leukemia rearrangement: No

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders			
-Total	5 (45.5)	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	4 (36.4)	0
Thrombocytopenia	4 (36.4)	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	2 (18.2)	0	2 (18.2)
Lymphopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
-Total	2 (18.2)	0	2 (18.2)

Mixed-lineage leukemia rearrangement: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	1 (9.1)	0
Sinus tachycardia	1 (9.1)	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	4 (36.4)	4 (36.4)	0
Abdominal pain	2 (18.2)	2 (18.2)	0
Colitis	2 (18.2)	2 (18.2)	0
Ascites	1 (9.1)	1 (9.1)	0
Diarrhoea	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Haematochezia	1 (9.1)	1 (9.1)	0
Nausea	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
Vomiting	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	5 (45.5)	2 (18.2)	3 (27.3)

Mixed-lineage leukemia rearrangement: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Non-cardiac chest pain	1 (9.1)	1 (9.1)	0
Pain	1 (9.1)	1 (9.1)	0
Pyrexia	1 (9.1)	1 (9.1)	0
Hepatobiliary disorders			
-Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	7 (63.6)	1 (9.1)	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Candida sepsis	1 (9.1)	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	1 (9.1)	0
Escherichia infection	1 (9.1)	1 (9.1)	0
Klebsiella infection	1 (9.1)	1 (9.1)	0
Pneumonia	1 (9.1)	0	1 (9.1)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)

Mixed-lineage leukemia rearrangement: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal infection	1 (9.1)	1 (9.1)	0
Investigations			
-Total	4 (36.4)	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	2 (18.2)
Alanine aminotransferase increased	1 (9.1)	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	1 (9.1)	0
Platelet count decreased	1 (9.1)	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Hypernatraemia	3 (27.3)	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	3 (27.3)
Decreased appetite	1 (9.1)	1 (9.1)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (9.1)	1 (9.1)	0
Fluid overload	1 (9.1)	1 (9.1)	0
Hyperglycaemia	1 (9.1)	0	1 (9.1)
Hyperkalaemia	1 (9.1)	1 (9.1)	0
Hypoalbuminaemia	1 (9.1)	0	1 (9.1)
Hypocalcaemia	1 (9.1)	0	1 (9.1)
Hypophosphataemia	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (18.2)	2 (18.2)	0
Pain in extremity	2 (18.2)	2 (18.2)	0
Arthralgia	1 (9.1)	1 (9.1)	0
Back pain	1 (9.1)	1 (9.1)	0
Nervous system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Headache	1 (9.1)	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	0	1 (9.1)

Mixed-lineage leukemia rearrangement: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	2 (18.2)	2 (18.2)	0
Agitation	1 (9.1)	1 (9.1)	0
Delirium	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Acute kidney injury	2 (18.2)	1 (9.1)	1 (9.1)
Cystitis haemorrhagic	1 (9.1)	1 (9.1)	0
Oliguria	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (45.5)	1 (9.1)	4 (36.4)
Hypoxia	4 (36.4)	3 (27.3)	1 (9.1)
Pulmonary oedema	2 (18.2)	0	2 (18.2)
Aspiration	1 (9.1)	0	1 (9.1)
Cough	1 (9.1)	1 (9.1)	0
Dyspnoea	1 (9.1)	1 (9.1)	0
Haemoptysis	1 (9.1)	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	1 (9.1)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pleural effusion	1 (9.1)	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	1 (9.1)	0
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Tachypnoea	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	6 (54.5)	3 (27.3)	3 (27.3)
Hypotension	6 (54.5)	3 (27.3)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192h
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set – non – infused patients

Hypodiploidy: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders			
-Total	5 (45.5)	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	4 (36.4)	0
Thrombocytopenia	4 (36.4)	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	2 (18.2)	0	2 (18.2)
Lymphopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			

Hypodiploidy: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (18.2)	0	2 (18.2)
Bradycardia	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	1 (9.1)	0
Sinus tachycardia	1 (9.1)	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	4 (36.4)	4 (36.4)	0
Abdominal pain	2 (18.2)	2 (18.2)	0
Colitis	2 (18.2)	2 (18.2)	0
Ascites	1 (9.1)	1 (9.1)	0
Diarrhoea	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Haematochezia	1 (9.1)	1 (9.1)	0
Nausea	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
Vomiting	1 (9.1)	1 (9.1)	0

Hypodiploidy: No

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
General disorders and administration site conditions			
-Total	5 (45.5)	2 (18.2)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Non-cardiac chest pain	1 (9.1)	1 (9.1)	0
Pain	1 (9.1)	1 (9.1)	0
Pyrexia	1 (9.1)	1 (9.1)	0
Hepatobiliary disorders			
-Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	7 (63.6)	1 (9.1)	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Candida sepsis	1 (9.1)	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	1 (9.1)	0
Escherichia infection	1 (9.1)	1 (9.1)	0
Klebsiella infection	1 (9.1)	1 (9.1)	0
Pneumonia	1 (9.1)	0	1 (9.1)

Hypodiploidy: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Streptococcal infection	1 (9.1)	1 (9.1)	0
Investigations			
-Total	4 (36.4)	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	2 (18.2)
Alanine aminotransferase increased	1 (9.1)	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	1 (9.1)	0
Platelet count decreased	1 (9.1)	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	1 (9.1)

Hypodiploidy: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Hypernatraemia	3 (27.3)	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	3 (27.3)
Decreased appetite	1 (9.1)	1 (9.1)	0
Dehydration	1 (9.1)	1 (9.1)	0
Fluid overload	1 (9.1)	1 (9.1)	0
Hyperglycaemia	1 (9.1)	0	1 (9.1)
Hyperkalaemia	1 (9.1)	1 (9.1)	0
Hypoalbuminaemia	1 (9.1)	0	1 (9.1)
Hypocalcaemia	1 (9.1)	0	1 (9.1)
Hypophosphataemia	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (18.2)	2 (18.2)	0
Pain in extremity	2 (18.2)	2 (18.2)	0
Arthralgia	1 (9.1)	1 (9.1)	0
Back pain	1 (9.1)	1 (9.1)	0

Hypodiploidy: No

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Nervous system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Headache	1 (9.1)	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	0	1 (9.1)
Psychiatric disorders			
-Total	2 (18.2)	2 (18.2)	0
Agitation	1 (9.1)	1 (9.1)	0
Delirium	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Acute kidney injury	2 (18.2)	1 (9.1)	1 (9.1)
Cystitis haemorrhagic	1 (9.1)	1 (9.1)	0
Oliguria	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (45.5)	1 (9.1)	4 (36.4)

Hypodiploidy: No

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	4 (36.4)	3 (27.3)	1 (9.1)
Pulmonary oedema	2 (18.2)	0	2 (18.2)
Aspiration	1 (9.1)	0	1 (9.1)
Cough	1 (9.1)	1 (9.1)	0
Dyspnoea	1 (9.1)	1 (9.1)	0
Haemoptysis	1 (9.1)	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	1 (9.1)	0
Pleural effusion	1 (9.1)	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	1 (9.1)	0
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Tachypnoea	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	6 (54.5)	3 (27.3)	3 (27.3)
Hypotension	6 (54.5)	3 (27.3)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192i
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set – non – infused patients

BCR-ABL1-like: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders			
-Total	5 (45.5)	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	4 (36.4)	0
Thrombocytopenia	4 (36.4)	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	2 (18.2)	0	2 (18.2)
Lymphopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			

BCR-ABL1-like: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (18.2)	0	2 (18.2)
Bradycardia	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	1 (9.1)	0
Sinus tachycardia	1 (9.1)	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	4 (36.4)	4 (36.4)	0
Abdominal pain	2 (18.2)	2 (18.2)	0
Colitis	2 (18.2)	2 (18.2)	0
Ascites	1 (9.1)	1 (9.1)	0
Diarrhoea	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Haematochezia	1 (9.1)	1 (9.1)	0
Nausea	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
Vomiting	1 (9.1)	1 (9.1)	0

BCR-ABL1-like: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	5 (45.5)	2 (18.2)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Non-cardiac chest pain	1 (9.1)	1 (9.1)	0
Pain	1 (9.1)	1 (9.1)	0
Pyrexia	1 (9.1)	1 (9.1)	0
Hepatobiliary disorders			
-Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	7 (63.6)	1 (9.1)	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Candida sepsis	1 (9.1)	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	1 (9.1)	0
Escherichia infection	1 (9.1)	1 (9.1)	0
Klebsiella infection	1 (9.1)	1 (9.1)	0
Pneumonia	1 (9.1)	0	1 (9.1)

BCR-ABL1-like: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Streptococcal infection	1 (9.1)	1 (9.1)	0
Investigations			
-Total	4 (36.4)	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	2 (18.2)
Alanine aminotransferase increased	1 (9.1)	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	1 (9.1)	0
Platelet count decreased	1 (9.1)	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	1 (9.1)

BCR-ABL1-like: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Hypernatraemia	3 (27.3)	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	3 (27.3)
Decreased appetite	1 (9.1)	1 (9.1)	0
Dehydration	1 (9.1)	1 (9.1)	0
Fluid overload	1 (9.1)	1 (9.1)	0
Hyperglycaemia	1 (9.1)	0	1 (9.1)
Hyperkalaemia	1 (9.1)	1 (9.1)	0
Hypoalbuminaemia	1 (9.1)	0	1 (9.1)
Hypocalcaemia	1 (9.1)	0	1 (9.1)
Hypophosphataemia	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (18.2)	2 (18.2)	0
Pain in extremity	2 (18.2)	2 (18.2)	0
Arthralgia	1 (9.1)	1 (9.1)	0
Back pain	1 (9.1)	1 (9.1)	0

BCR-ABL1-like: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Headache	1 (9.1)	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	0	1 (9.1)
Psychiatric disorders			
-Total	2 (18.2)	2 (18.2)	0
Agitation	1 (9.1)	1 (9.1)	0
Delirium	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Acute kidney injury	2 (18.2)	1 (9.1)	1 (9.1)
Cystitis haemorrhagic	1 (9.1)	1 (9.1)	0
Oliguria	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (45.5)	1 (9.1)	4 (36.4)

BCR-ABL1-like: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	4 (36.4)	3 (27.3)	1 (9.1)
Pulmonary oedema	2 (18.2)	0	2 (18.2)
Aspiration	1 (9.1)	0	1 (9.1)
Cough	1 (9.1)	1 (9.1)	0
Dyspnoea	1 (9.1)	1 (9.1)	0
Haemoptysis	1 (9.1)	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	1 (9.1)	0
Pleural effusion	1 (9.1)	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	1 (9.1)	0
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Tachypnoea	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	6 (54.5)	3 (27.3)	3 (27.3)
Hypotension	6 (54.5)	3 (27.3)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192j
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	0	2 (66.7)
Blood and lymphatic system disorders			
-Total	1 (33.3)	0	1 (33.3)
Febrile neutropenia	1 (33.3)	1 (33.3)	0
Neutropenia	1 (33.3)	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	1 (33.3)
Gastrointestinal disorders			
-Total	1 (33.3)	1 (33.3)	0
Gastrointestinal haemorrhage	1 (33.3)	1 (33.3)	0
Infections and infestations			
-Total	2 (66.7)	0	2 (66.7)
Candida sepsis	1 (33.3)	0	1 (33.3)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pneumonia fungal	1 (33.3)	1 (33.3)	0
Sepsis	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	1 (33.3)	0	1 (33.3)
Hypernatraemia	1 (33.3)	0	1 (33.3)
Hypokalaemia	1 (33.3)	0	1 (33.3)
Hypophosphataemia	1 (33.3)	1 (33.3)	0
Renal and urinary disorders			
-Total	1 (33.3)	0	1 (33.3)
Acute kidney injury	1 (33.3)	0	1 (33.3)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	1 (33.3)
Respiratory failure	1 (33.3)	0	1 (33.3)
Vascular disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Hypotension	2 (66.7)	1 (33.3)	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192j
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set – non – infused patients

Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=8	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (75.0)	1 (12.5)	5 (62.5)
Blood and lymphatic system disorders			
-Total	4 (50.0)	2 (25.0)	2 (25.0)
Anaemia	4 (50.0)	4 (50.0)	0
Disseminated intravascular coagulation	3 (37.5)	2 (25.0)	1 (12.5)
Thrombocytopenia	3 (37.5)	1 (12.5)	2 (25.0)
Febrile neutropenia	1 (12.5)	1 (12.5)	0
Lymphopenia	1 (12.5)	0	1 (12.5)
Neutropenia	1 (12.5)	0	1 (12.5)
Cardiac disorders			
-Total	2 (25.0)	0	2 (25.0)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (12.5)	0	1 (12.5)
Cardiovascular insufficiency	1 (12.5)	0	1 (12.5)
Right ventricular dysfunction	1 (12.5)	1 (12.5)	0
Sinus tachycardia	1 (12.5)	1 (12.5)	0
Ventricular tachycardia	1 (12.5)	1 (12.5)	0
Gastrointestinal disorders			
-Total	3 (37.5)	3 (37.5)	0
Abdominal pain	2 (25.0)	2 (25.0)	0
Colitis	2 (25.0)	2 (25.0)	0
Ascites	1 (12.5)	1 (12.5)	0
Diarrhoea	1 (12.5)	1 (12.5)	0
Haematochezia	1 (12.5)	1 (12.5)	0
Nausea	1 (12.5)	1 (12.5)	0
Stomatitis	1 (12.5)	1 (12.5)	0
Vomiting	1 (12.5)	1 (12.5)	0
General disorders and administration site conditions			
-Total	5 (62.5)	2 (25.0)	3 (37.5)
Multiple organ dysfunction syndrome	3 (37.5)	0	3 (37.5)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Non-cardiac chest pain	1 (12.5)	1 (12.5)	0
Pain	1 (12.5)	1 (12.5)	0
Pyrexia	1 (12.5)	1 (12.5)	0
Hepatobiliary disorders			
-Total	1 (12.5)	0	1 (12.5)
Hepatic failure	1 (12.5)	0	1 (12.5)
Infections and infestations			
-Total	5 (62.5)	1 (12.5)	4 (50.0)
Klebsiella sepsis	2 (25.0)	0	2 (25.0)
Clostridium difficile colitis	1 (12.5)	1 (12.5)	0
Escherichia infection	1 (12.5)	1 (12.5)	0
Klebsiella infection	1 (12.5)	1 (12.5)	0
Pneumonia	1 (12.5)	0	1 (12.5)
Staphylococcal bacteraemia	1 (12.5)	1 (12.5)	0
Staphylococcal infection	1 (12.5)	0	1 (12.5)
Streptococcal infection	1 (12.5)	1 (12.5)	0
Investigations			
-Total	4 (50.0)	0	4 (50.0)
Neutrophil count decreased	2 (25.0)	0	2 (25.0)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	1 (12.5)	0	1 (12.5)
Aspartate aminotransferase increased	1 (12.5)	0	1 (12.5)
Blood bilirubin increased	1 (12.5)	0	1 (12.5)
Blood lactate dehydrogenase increased	1 (12.5)	1 (12.5)	0
Computerised tomogram thorax abnormal	1 (12.5)	1 (12.5)	0
Electrocardiogram qt prolonged	1 (12.5)	1 (12.5)	0
Platelet count decreased	1 (12.5)	0	1 (12.5)
White blood cell count decreased	1 (12.5)	0	1 (12.5)
Metabolism and nutrition disorders			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Hypernatraemia	2 (25.0)	1 (12.5)	1 (12.5)
Hypokalaemia	2 (25.0)	0	2 (25.0)
Decreased appetite	1 (12.5)	1 (12.5)	0
Dehydration	1 (12.5)	1 (12.5)	0
Fluid overload	1 (12.5)	1 (12.5)	0
Hyperglycaemia	1 (12.5)	0	1 (12.5)
Hyperkalaemia	1 (12.5)	1 (12.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoalbuminaemia	1 (12.5)	0	1 (12.5)
Hypocalcaemia	1 (12.5)	0	1 (12.5)
Musculoskeletal and connective tissue disorders			
-Total	2 (25.0)	2 (25.0)	0
Pain in extremity	2 (25.0)	2 (25.0)	0
Arthralgia	1 (12.5)	1 (12.5)	0
Back pain	1 (12.5)	1 (12.5)	0
Nervous system disorders			
-Total	2 (25.0)	1 (12.5)	1 (12.5)
Headache	1 (12.5)	1 (12.5)	0
Hyporesponsive to stimuli	1 (12.5)	1 (12.5)	0
Leukoencephalopathy	1 (12.5)	1 (12.5)	0
Seizure	1 (12.5)	0	1 (12.5)
Psychiatric disorders			
-Total	2 (25.0)	2 (25.0)	0
Agitation	1 (12.5)	1 (12.5)	0
Delirium	1 (12.5)	1 (12.5)	0
Renal and urinary disorders			

Complex karyotypes II (>=5 unrelated abnormalities) : No

		All patients N=8	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (25.0)	2 (25.0)	0
Acute kidney injury	1 (12.5)	1 (12.5)	0
Cystitis haemorrhagic	1 (12.5)	1 (12.5)	0
Oliguria	1 (12.5)	1 (12.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Hypoxia	4 (50.0)	3 (37.5)	1 (12.5)
Aspiration	1 (12.5)	0	1 (12.5)
Cough	1 (12.5)	1 (12.5)	0
Dyspnoea	1 (12.5)	1 (12.5)	0
Haemoptysis	1 (12.5)	1 (12.5)	0
Oropharyngeal pain	1 (12.5)	1 (12.5)	0
Pleural effusion	1 (12.5)	1 (12.5)	0
Pulmonary alveolar haemorrhage	1 (12.5)	0	1 (12.5)
Pulmonary hypertension	1 (12.5)	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	1 (12.5)
Respiratory distress	1 (12.5)	0	1 (12.5)
Tachypnoea	1 (12.5)	1 (12.5)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

Group term Preferred term	All patients N=8 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Vascular disorders			
-Total	4 (50.0)	2 (25.0)	2 (25.0)
Hypotension	4 (50.0)	2 (25.0)	2 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192k
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set – non – infused patients

Region: US

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders			
-Total	5 (45.5)	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	4 (36.4)	0
Thrombocytopenia	4 (36.4)	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	2 (18.2)	0	2 (18.2)
Lymphopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			

Region: US

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	2 (18.2)	0	2 (18.2)
Bradycardia	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	1 (9.1)	0
Sinus tachycardia	1 (9.1)	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	4 (36.4)	4 (36.4)	0
Abdominal pain	2 (18.2)	2 (18.2)	0
Colitis	2 (18.2)	2 (18.2)	0
Ascites	1 (9.1)	1 (9.1)	0
Diarrhoea	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Haematochezia	1 (9.1)	1 (9.1)	0
Nausea	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
Vomiting	1 (9.1)	1 (9.1)	0

Region: US

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions			
-Total	5 (45.5)	2 (18.2)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Non-cardiac chest pain	1 (9.1)	1 (9.1)	0
Pain	1 (9.1)	1 (9.1)	0
Pyrexia	1 (9.1)	1 (9.1)	0
Hepatobiliary disorders			
-Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	7 (63.6)	1 (9.1)	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Candida sepsis	1 (9.1)	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	1 (9.1)	0
Escherichia infection	1 (9.1)	1 (9.1)	0
Klebsiella infection	1 (9.1)	1 (9.1)	0
Pneumonia	1 (9.1)	0	1 (9.1)

Region: US

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Streptococcal infection	1 (9.1)	1 (9.1)	0
Investigations			
-Total	4 (36.4)	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	2 (18.2)
Alanine aminotransferase increased	1 (9.1)	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	1 (9.1)	0
Platelet count decreased	1 (9.1)	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	1 (9.1)

Region: US

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Metabolism and nutrition disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Hypernatraemia	3 (27.3)	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	3 (27.3)
Decreased appetite	1 (9.1)	1 (9.1)	0
Dehydration	1 (9.1)	1 (9.1)	0
Fluid overload	1 (9.1)	1 (9.1)	0
Hyperglycaemia	1 (9.1)	0	1 (9.1)
Hyperkalaemia	1 (9.1)	1 (9.1)	0
Hypoalbuminaemia	1 (9.1)	0	1 (9.1)
Hypocalcaemia	1 (9.1)	0	1 (9.1)
Hypophosphataemia	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (18.2)	2 (18.2)	0
Pain in extremity	2 (18.2)	2 (18.2)	0
Arthralgia	1 (9.1)	1 (9.1)	0
Back pain	1 (9.1)	1 (9.1)	0

Region: US

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Nervous system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Headache	1 (9.1)	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	0	1 (9.1)
Psychiatric disorders			
-Total	2 (18.2)	2 (18.2)	0
Agitation	1 (9.1)	1 (9.1)	0
Delirium	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Acute kidney injury	2 (18.2)	1 (9.1)	1 (9.1)
Cystitis haemorrhagic	1 (9.1)	1 (9.1)	0
Oliguria	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (45.5)	1 (9.1)	4 (36.4)

Region: US

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypoxia	4 (36.4)	3 (27.3)	1 (9.1)
Pulmonary oedema	2 (18.2)	0	2 (18.2)
Aspiration	1 (9.1)	0	1 (9.1)
Cough	1 (9.1)	1 (9.1)	0
Dyspnoea	1 (9.1)	1 (9.1)	0
Haemoptysis	1 (9.1)	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	1 (9.1)	0
Pleural effusion	1 (9.1)	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	1 (9.1)	0
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Tachypnoea	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	6 (54.5)	3 (27.3)	3 (27.3)
Hypotension	6 (54.5)	3 (27.3)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192l
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	4 (100)
Blood and lymphatic system disorders			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Anaemia	3 (75.0)	3 (75.0)	0
Disseminated intravascular coagulation	2 (50.0)	1 (25.0)	1 (25.0)
Thrombocytopenia	2 (50.0)	1 (25.0)	1 (25.0)
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Cardiac disorders			
-Total	1 (25.0)	0	1 (25.0)
Cardiovascular insufficiency	1 (25.0)	0	1 (25.0)

Prior SCT therapy: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	2 (50.0)	2 (50.0)	0
Colitis	2 (50.0)	2 (50.0)	0
Abdominal pain	1 (25.0)	1 (25.0)	0
Ascites	1 (25.0)	1 (25.0)	0
Diarrhoea	1 (25.0)	1 (25.0)	0
Stomatitis	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
-Total	3 (75.0)	0	3 (75.0)
Multiple organ dysfunction syndrome	3 (75.0)	0	3 (75.0)
Hepatobiliary disorders			
-Total	1 (25.0)	0	1 (25.0)
Hepatic failure	1 (25.0)	0	1 (25.0)
Infections and infestations			
-Total	4 (100)	0	4 (100)
Klebsiella sepsis	2 (50.0)	0	2 (50.0)
Clostridium difficile colitis	1 (25.0)	1 (25.0)	0

Prior SCT therapy: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (25.0)	1 (25.0)	0
Sepsis	1 (25.0)	0	1 (25.0)
Staphylococcal bacteraemia	1 (25.0)	1 (25.0)	0
Staphylococcal infection	1 (25.0)	0	1 (25.0)
Investigations			
-Total	3 (75.0)	0	3 (75.0)
Neutrophil count decreased	2 (50.0)	0	2 (50.0)
Alanine aminotransferase increased	1 (25.0)	0	1 (25.0)
Aspartate aminotransferase increased	1 (25.0)	0	1 (25.0)
Blood bilirubin increased	1 (25.0)	0	1 (25.0)
Platelet count decreased	1 (25.0)	0	1 (25.0)
Metabolism and nutrition disorders			
-Total	2 (50.0)	0	2 (50.0)
Hypernatraemia	2 (50.0)	1 (25.0)	1 (25.0)
Hypokalaemia	2 (50.0)	0	2 (50.0)
Decreased appetite	1 (25.0)	1 (25.0)	0
Dehydration	1 (25.0)	1 (25.0)	0

Prior SCT therapy: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	1 (25.0)	0	1 (25.0)
Hypoalbuminaemia	1 (25.0)	0	1 (25.0)
Hypocalcaemia	1 (25.0)	0	1 (25.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (25.0)	1 (25.0)	0
Pain in extremity	1 (25.0)	1 (25.0)	0
Nervous system disorders			
-Total	1 (25.0)	1 (25.0)	0
Leukoencephalopathy	1 (25.0)	1 (25.0)	0
Psychiatric disorders			
-Total	1 (25.0)	1 (25.0)	0
Delirium	1 (25.0)	1 (25.0)	0
Renal and urinary disorders			
-Total	1 (25.0)	1 (25.0)	0
Cystitis haemorrhagic	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)

Prior SCT therapy: Yes

Group term Preferred term	All patients N=4 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (50.0)	1 (25.0)	1 (25.0)
Pleural effusion	1 (25.0)	1 (25.0)	0
Vascular disorders			
-Total	3 (75.0)	3 (75.0)	0
Hypotension	3 (75.0)	3 (75.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192l
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set – non – infused patients

Prior SCT therapy: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (57.1)	1 (14.3)	3 (42.9)
Blood and lymphatic system disorders			
-Total	2 (28.6)	0	2 (28.6)
Neutropenia	2 (28.6)	0	2 (28.6)
Thrombocytopenia	2 (28.6)	0	2 (28.6)
Anaemia	1 (14.3)	1 (14.3)	0
Disseminated intravascular coagulation	1 (14.3)	1 (14.3)	0
Febrile neutropenia	1 (14.3)	1 (14.3)	0
Lymphopenia	1 (14.3)	0	1 (14.3)
Cardiac disorders			

Prior SCT therapy: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (14.3)	0	1 (14.3)
Bradycardia	1 (14.3)	0	1 (14.3)
Right ventricular dysfunction	1 (14.3)	1 (14.3)	0
Sinus tachycardia	1 (14.3)	1 (14.3)	0
Ventricular tachycardia	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	2 (28.6)	2 (28.6)	0
Abdominal pain	1 (14.3)	1 (14.3)	0
Gastrointestinal haemorrhage	1 (14.3)	1 (14.3)	0
Haematochezia	1 (14.3)	1 (14.3)	0
Nausea	1 (14.3)	1 (14.3)	0
Vomiting	1 (14.3)	1 (14.3)	0
General disorders and administration site conditions			
-Total	2 (28.6)	2 (28.6)	0
Non-cardiac chest pain	1 (14.3)	1 (14.3)	0
Pain	1 (14.3)	1 (14.3)	0
Pyrexia	1 (14.3)	1 (14.3)	0

Prior SCT therapy: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	3 (42.9)	1 (14.3)	2 (28.6)
Candida sepsis	1 (14.3)	0	1 (14.3)
Escherichia infection	1 (14.3)	1 (14.3)	0
Pneumonia	1 (14.3)	0	1 (14.3)
Pneumonia fungal	1 (14.3)	1 (14.3)	0
Streptococcal infection	1 (14.3)	1 (14.3)	0
Investigations			
-Total	1 (14.3)	0	1 (14.3)
Blood lactate dehydrogenase increased	1 (14.3)	1 (14.3)	0
Computerised tomogram thorax abnormal	1 (14.3)	1 (14.3)	0
Electrocardiogram qt prolonged	1 (14.3)	1 (14.3)	0
White blood cell count decreased	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Fluid overload	1 (14.3)	1 (14.3)	0
Hyperkalaemia	1 (14.3)	1 (14.3)	0

Prior SCT therapy: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	1 (14.3)	0	1 (14.3)
Hypokalaemia	1 (14.3)	0	1 (14.3)
Hypophosphataemia	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (14.3)	1 (14.3)	0
Arthralgia	1 (14.3)	1 (14.3)	0
Back pain	1 (14.3)	1 (14.3)	0
Pain in extremity	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	1 (14.3)	0	1 (14.3)
Headache	1 (14.3)	1 (14.3)	0
Hyporesponsive to stimuli	1 (14.3)	1 (14.3)	0
Seizure	1 (14.3)	0	1 (14.3)
Psychiatric disorders			
-Total	1 (14.3)	1 (14.3)	0
Agitation	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			

Prior SCT therapy: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Acute kidney injury	2 (28.6)	1 (14.3)	1 (14.3)
Oliguria	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (42.9)	0	3 (42.9)
Hypoxia	2 (28.6)	2 (28.6)	0
Pulmonary oedema	2 (28.6)	0	2 (28.6)
Aspiration	1 (14.3)	0	1 (14.3)
Cough	1 (14.3)	1 (14.3)	0
Dyspnoea	1 (14.3)	1 (14.3)	0
Haemoptysis	1 (14.3)	1 (14.3)	0
Oropharyngeal pain	1 (14.3)	1 (14.3)	0
Pulmonary alveolar haemorrhage	1 (14.3)	0	1 (14.3)
Pulmonary hypertension	1 (14.3)	1 (14.3)	0
Respiratory distress	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)
Tachypnoea	1 (14.3)	1 (14.3)	0

Prior SCT therapy: No

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
-Total	3 (42.9)	0	3 (42.9)
Hypotension	3 (42.9)	0	3 (42.9)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192m
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (50.0)	1 (25.0)	1 (25.0)
General disorders and administration site conditions			
-Total	1 (25.0)	1 (25.0)	0
Pain	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Escherichia infection	1 (25.0)	1 (25.0)	0
Pneumonia	1 (25.0)	0	1 (25.0)
Streptococcal infection	1 (25.0)	1 (25.0)	0

Eligibility for SCT: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory, thoracic and mediastinal disorders			
-Total	1 (25.0)	0	1 (25.0)
Aspiration	1 (25.0)	0	1 (25.0)
Hypoxia	1 (25.0)	1 (25.0)	0
Vascular disorders			
-Total	1 (25.0)	0	1 (25.0)
Hypotension	1 (25.0)	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192m
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set – non – infused patients

Eligibility for SCT: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (85.7)	0	6 (85.7)
Blood and lymphatic system disorders			
-Total	5 (71.4)	2 (28.6)	3 (42.9)
Anaemia	4 (57.1)	4 (57.1)	0
Thrombocytopenia	4 (57.1)	1 (14.3)	3 (42.9)
Disseminated intravascular coagulation	3 (42.9)	2 (28.6)	1 (14.3)
Febrile neutropenia	2 (28.6)	2 (28.6)	0
Neutropenia	2 (28.6)	0	2 (28.6)
Lymphopenia	1 (14.3)	0	1 (14.3)
Cardiac disorders			

Eligibility for SCT: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (28.6)	0	2 (28.6)
Bradycardia	1 (14.3)	0	1 (14.3)
Cardiovascular insufficiency	1 (14.3)	0	1 (14.3)
Right ventricular dysfunction	1 (14.3)	1 (14.3)	0
Sinus tachycardia	1 (14.3)	1 (14.3)	0
Ventricular tachycardia	1 (14.3)	1 (14.3)	0
Gastrointestinal disorders			
-Total	4 (57.1)	4 (57.1)	0
Abdominal pain	2 (28.6)	2 (28.6)	0
Colitis	2 (28.6)	2 (28.6)	0
Ascites	1 (14.3)	1 (14.3)	0
Diarrhoea	1 (14.3)	1 (14.3)	0
Gastrointestinal haemorrhage	1 (14.3)	1 (14.3)	0
Haematochezia	1 (14.3)	1 (14.3)	0
Nausea	1 (14.3)	1 (14.3)	0
Stomatitis	1 (14.3)	1 (14.3)	0
Vomiting	1 (14.3)	1 (14.3)	0

Eligibility for SCT: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Multiple organ dysfunction syndrome	3 (42.9)	0	3 (42.9)
Non-cardiac chest pain	1 (14.3)	1 (14.3)	0
Hepatobiliary disorders			
-Total	1 (14.3)	0	1 (14.3)
Hepatic failure	1 (14.3)	0	1 (14.3)
Infections and infestations			
-Total	5 (71.4)	0	5 (71.4)
Klebsiella sepsis	2 (28.6)	0	2 (28.6)
Candida sepsis	1 (14.3)	0	1 (14.3)
Clostridium difficile colitis	1 (14.3)	1 (14.3)	0
Klebsiella infection	1 (14.3)	1 (14.3)	0
Pneumonia fungal	1 (14.3)	1 (14.3)	0
Sepsis	1 (14.3)	0	1 (14.3)
Staphylococcal bacteraemia	1 (14.3)	1 (14.3)	0
Staphylococcal infection	1 (14.3)	0	1 (14.3)

Eligibility for SCT: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	4 (57.1)	0	4 (57.1)
Neutrophil count decreased	2 (28.6)	0	2 (28.6)
Alanine aminotransferase increased	1 (14.3)	0	1 (14.3)
Aspartate aminotransferase increased	1 (14.3)	0	1 (14.3)
Blood bilirubin increased	1 (14.3)	0	1 (14.3)
Blood lactate dehydrogenase increased	1 (14.3)	1 (14.3)	0
Computerised tomogram thorax abnormal	1 (14.3)	1 (14.3)	0
Electrocardiogram qt prolonged	1 (14.3)	1 (14.3)	0
Platelet count decreased	1 (14.3)	0	1 (14.3)
White blood cell count decreased	1 (14.3)	0	1 (14.3)
Metabolism and nutrition disorders			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Hypernatraemia	3 (42.9)	1 (14.3)	2 (28.6)
Hypokalaemia	3 (42.9)	0	3 (42.9)
Decreased appetite	1 (14.3)	1 (14.3)	0

Eligibility for SCT: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (14.3)	1 (14.3)	0
Fluid overload	1 (14.3)	1 (14.3)	0
Hyperglycaemia	1 (14.3)	0	1 (14.3)
Hyperkalaemia	1 (14.3)	1 (14.3)	0
Hypoalbuminaemia	1 (14.3)	0	1 (14.3)
Hypocalcaemia	1 (14.3)	0	1 (14.3)
Hypophosphataemia	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (28.6)	2 (28.6)	0
Pain in extremity	2 (28.6)	2 (28.6)	0
Arthralgia	1 (14.3)	1 (14.3)	0
Back pain	1 (14.3)	1 (14.3)	0
Nervous system disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Headache	1 (14.3)	1 (14.3)	0
Hyporesponsive to stimuli	1 (14.3)	1 (14.3)	0
Leukoencephalopathy	1 (14.3)	1 (14.3)	0

Eligibility for SCT: No

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (14.3)	0	1 (14.3)
Psychiatric disorders			
-Total	2 (28.6)	2 (28.6)	0
Agitation	1 (14.3)	1 (14.3)	0
Delirium	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	3 (42.9)	2 (28.6)	1 (14.3)
Acute kidney injury	2 (28.6)	1 (14.3)	1 (14.3)
Cystitis haemorrhagic	1 (14.3)	1 (14.3)	0
Oliguria	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (57.1)	1 (14.3)	3 (42.9)
Hypoxia	3 (42.9)	2 (28.6)	1 (14.3)
Pulmonary oedema	2 (28.6)	0	2 (28.6)
Cough	1 (14.3)	1 (14.3)	0
Dyspnoea	1 (14.3)	1 (14.3)	0
Haemoptysis	1 (14.3)	1 (14.3)	0

Eligibility for SCT: No

Group term Preferred term	All patients N=7 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Oropharyngeal pain	1 (14.3)	1 (14.3)	0
Pleural effusion	1 (14.3)	1 (14.3)	0
Pulmonary alveolar haemorrhage	1 (14.3)	0	1 (14.3)
Pulmonary hypertension	1 (14.3)	1 (14.3)	0
Respiratory distress	1 (14.3)	0	1 (14.3)
Respiratory failure	1 (14.3)	0	1 (14.3)
Tachypnoea	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	5 (71.4)	3 (42.9)	2 (28.6)
Hypotension	5 (71.4)	3 (42.9)	2 (28.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192n
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: Low

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	0	2 (100)
Blood and lymphatic system disorders			
-Total	2 (100)	0	2 (100)
Anaemia	2 (100)	2 (100)	0
Disseminated intravascular coagulation	2 (100)	1 (50.0)	1 (50.0)
Thrombocytopenia	2 (100)	0	2 (100)
Febrile neutropenia	1 (50.0)	1 (50.0)	0
Lymphopenia	1 (50.0)	0	1 (50.0)
Neutropenia	1 (50.0)	0	1 (50.0)
Cardiac disorders			
-Total	1 (50.0)	0	1 (50.0)

Baseline bone marrow tumor burden: Low

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (50.0)	0	1 (50.0)
Right ventricular dysfunction	1 (50.0)	1 (50.0)	0
Sinus tachycardia	1 (50.0)	1 (50.0)	0
Ventricular tachycardia	1 (50.0)	1 (50.0)	0
Gastrointestinal disorders			
-Total	2 (100)	2 (100)	0
Abdominal pain	2 (100)	2 (100)	0
Ascites	1 (50.0)	1 (50.0)	0
Colitis	1 (50.0)	1 (50.0)	0
Diarrhoea	1 (50.0)	1 (50.0)	0
Haematochezia	1 (50.0)	1 (50.0)	0
Nausea	1 (50.0)	1 (50.0)	0
Stomatitis	1 (50.0)	1 (50.0)	0
Vomiting	1 (50.0)	1 (50.0)	0
General disorders and administration site conditions			
-Total	2 (100)	1 (50.0)	1 (50.0)
Multiple organ dysfunction syndrome	1 (50.0)	0	1 (50.0)
Non-cardiac chest pain	1 (50.0)	1 (50.0)	0

Baseline bone marrow tumor burden: Low

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders			
-Total	1 (50.0)	0	1 (50.0)
Hepatic failure	1 (50.0)	0	1 (50.0)
Infections and infestations			
-Total	1 (50.0)	0	1 (50.0)
Staphylococcal bacteraemia	1 (50.0)	1 (50.0)	0
Staphylococcal infection	1 (50.0)	0	1 (50.0)
Investigations			
-Total	2 (100)	0	2 (100)
Alanine aminotransferase increased	1 (50.0)	0	1 (50.0)
Aspartate aminotransferase increased	1 (50.0)	0	1 (50.0)
Blood bilirubin increased	1 (50.0)	0	1 (50.0)
Blood lactate dehydrogenase increased	1 (50.0)	1 (50.0)	0
Computerised tomogram thorax abnormal	1 (50.0)	1 (50.0)	0
Electrocardiogram qt prolonged	1 (50.0)	1 (50.0)	0
Neutrophil count decreased	1 (50.0)	0	1 (50.0)
White blood cell count decreased	1 (50.0)	0	1 (50.0)

Baseline bone marrow tumor burden: Low

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Decreased appetite	1 (50.0)	1 (50.0)	0
Dehydration	1 (50.0)	1 (50.0)	0
Fluid overload	1 (50.0)	1 (50.0)	0
Hyperkalaemia	1 (50.0)	1 (50.0)	0
Hypernatraemia	1 (50.0)	0	1 (50.0)
Hypokalaemia	1 (50.0)	0	1 (50.0)
Musculoskeletal and connective tissue disorders			
-Total	2 (100)	2 (100)	0
Pain in extremity	2 (100)	2 (100)	0
Arthralgia	1 (50.0)	1 (50.0)	0
Back pain	1 (50.0)	1 (50.0)	0
Nervous system disorders			
-Total	1 (50.0)	0	1 (50.0)
Headache	1 (50.0)	1 (50.0)	0
Hyporesponsive to stimuli	1 (50.0)	1 (50.0)	0
Seizure	1 (50.0)	0	1 (50.0)

Baseline bone marrow tumor burden: Low

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	2 (100)	2 (100)	0
Agitation	1 (50.0)	1 (50.0)	0
Delirium	1 (50.0)	1 (50.0)	0
Renal and urinary disorders			
-Total	2 (100)	2 (100)	0
Acute kidney injury	1 (50.0)	1 (50.0)	0
Cystitis haemorrhagic	1 (50.0)	1 (50.0)	0
Oliguria	1 (50.0)	1 (50.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Hypoxia	2 (100)	2 (100)	0
Cough	1 (50.0)	1 (50.0)	0
Dyspnoea	1 (50.0)	1 (50.0)	0
Haemoptysis	1 (50.0)	1 (50.0)	0
Oropharyngeal pain	1 (50.0)	1 (50.0)	0
Pleural effusion	1 (50.0)	1 (50.0)	0
Pulmonary alveolar haemorrhage	1 (50.0)	0	1 (50.0)

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=2 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pulmonary hypertension	1 (50.0)	1 (50.0)	0
Pulmonary oedema	1 (50.0)	0	1 (50.0)
Respiratory distress	1 (50.0)	0	1 (50.0)
Tachypnoea	1 (50.0)	1 (50.0)	0
Vascular disorders			
-Total	2 (100)	1 (50.0)	1 (50.0)
Hypotension	2 (100)	1 (50.0)	1 (50.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192n
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set – non – infused patients

Baseline bone marrow tumor burden: High

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	6 (66.7)	1 (11.1)	5 (55.6)
Blood and lymphatic system disorders			
-Total	3 (33.3)	2 (22.2)	1 (11.1)
Anaemia	2 (22.2)	2 (22.2)	0
Thrombocytopenia	2 (22.2)	1 (11.1)	1 (11.1)
Disseminated intravascular coagulation	1 (11.1)	1 (11.1)	0
Febrile neutropenia	1 (11.1)	1 (11.1)	0
Neutropenia	1 (11.1)	0	1 (11.1)
Cardiac disorders			
-Total	1 (11.1)	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	1 (11.1)

Baseline bone marrow tumor burden: High

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	2 (22.2)	2 (22.2)	0
Colitis	1 (11.1)	1 (11.1)	0
Gastrointestinal haemorrhage	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			
-Total	3 (33.3)	1 (11.1)	2 (22.2)
Multiple organ dysfunction syndrome	2 (22.2)	0	2 (22.2)
Pain	1 (11.1)	1 (11.1)	0
Pyrexia	1 (11.1)	1 (11.1)	0
Infections and infestations			
-Total	6 (66.7)	1 (11.1)	5 (55.6)
Klebsiella sepsis	2 (22.2)	0	2 (22.2)
Candida sepsis	1 (11.1)	0	1 (11.1)
Clostridium difficile colitis	1 (11.1)	1 (11.1)	0
Escherichia infection	1 (11.1)	1 (11.1)	0
Klebsiella infection	1 (11.1)	1 (11.1)	0
Pneumonia	1 (11.1)	0	1 (11.1)
Pneumonia fungal	1 (11.1)	1 (11.1)	0

Baseline bone marrow tumor burden: High

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Sepsis	1 (11.1)	0	1 (11.1)
Streptococcal infection	1 (11.1)	1 (11.1)	0
Investigations			
-Total	2 (22.2)	0	2 (22.2)
Neutrophil count decreased	1 (11.1)	0	1 (11.1)
Platelet count decreased	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			
-Total	2 (22.2)	0	2 (22.2)
Hypernatraemia	2 (22.2)	1 (11.1)	1 (11.1)
Hypokalaemia	2 (22.2)	0	2 (22.2)
Hyperglycaemia	1 (11.1)	0	1 (11.1)
Hypoalbuminaemia	1 (11.1)	0	1 (11.1)
Hypocalcaemia	1 (11.1)	0	1 (11.1)
Hypophosphataemia	1 (11.1)	1 (11.1)	0
Nervous system disorders			
-Total	1 (11.1)	1 (11.1)	0
Leukoencephalopathy	1 (11.1)	1 (11.1)	0
Renal and urinary disorders			
-Total	1 (11.1)	0	1 (11.1)

Baseline bone marrow tumor burden: High

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Acute kidney injury	1 (11.1)	0	1 (11.1)
Respiratory, thoracic and mediastinal disorders			
-Total	3 (33.3)	0	3 (33.3)
Hypoxia	2 (22.2)	1 (11.1)	1 (11.1)
Aspiration	1 (11.1)	0	1 (11.1)
Pulmonary oedema	1 (11.1)	0	1 (11.1)
Respiratory failure	1 (11.1)	0	1 (11.1)
Vascular disorders			
-Total	4 (44.4)	2 (22.2)	2 (22.2)
Hypotension	4 (44.4)	2 (22.2)	2 (22.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192o
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set – non – infused patients

Baseline extramedullary disease presence: Yes

	All patients N=2		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Escherichia infection	1 (50.0)	1 (50.0)	0
Streptococcal infection	1 (50.0)	1 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192o
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set – non – infused patients

Baseline extramedullary disease presence: No

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (77.8)	0	7 (77.8)
Blood and lymphatic system disorders			
-Total	5 (55.6)	2 (22.2)	3 (33.3)
Anaemia	4 (44.4)	4 (44.4)	0
Thrombocytopenia	4 (44.4)	1 (11.1)	3 (33.3)
Disseminated intravascular coagulation	3 (33.3)	2 (22.2)	1 (11.1)
Febrile neutropenia	2 (22.2)	2 (22.2)	0
Neutropenia	2 (22.2)	0	2 (22.2)
Lymphopenia	1 (11.1)	0	1 (11.1)
Cardiac disorders			
-Total	2 (22.2)	0	2 (22.2)

Baseline extramedullary disease presence: No

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (11.1)	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	1 (11.1)
Right ventricular dysfunction	1 (11.1)	1 (11.1)	0
Sinus tachycardia	1 (11.1)	1 (11.1)	0
Ventricular tachycardia	1 (11.1)	1 (11.1)	0
Gastrointestinal disorders			
-Total	4 (44.4)	4 (44.4)	0
Abdominal pain	2 (22.2)	2 (22.2)	0
Colitis	2 (22.2)	2 (22.2)	0
Ascites	1 (11.1)	1 (11.1)	0
Diarrhoea	1 (11.1)	1 (11.1)	0
Gastrointestinal haemorrhage	1 (11.1)	1 (11.1)	0
Haematochezia	1 (11.1)	1 (11.1)	0
Nausea	1 (11.1)	1 (11.1)	0
Stomatitis	1 (11.1)	1 (11.1)	0
Vomiting	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			
-Total	5 (55.6)	2 (22.2)	3 (33.3)

Baseline extramedullary disease presence: No

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	3 (33.3)	0	3 (33.3)
Non-cardiac chest pain	1 (11.1)	1 (11.1)	0
Pain	1 (11.1)	1 (11.1)	0
Pyrexia	1 (11.1)	1 (11.1)	0
Hepatobiliary disorders			
-Total	1 (11.1)	0	1 (11.1)
Hepatic failure	1 (11.1)	0	1 (11.1)
Infections and infestations			
-Total	6 (66.7)	0	6 (66.7)
Klebsiella sepsis	2 (22.2)	0	2 (22.2)
Candida sepsis	1 (11.1)	0	1 (11.1)
Clostridium difficile colitis	1 (11.1)	1 (11.1)	0
Klebsiella infection	1 (11.1)	1 (11.1)	0
Pneumonia	1 (11.1)	0	1 (11.1)
Pneumonia fungal	1 (11.1)	1 (11.1)	0
Sepsis	1 (11.1)	0	1 (11.1)
Staphylococcal bacteraemia	1 (11.1)	1 (11.1)	0
Staphylococcal infection	1 (11.1)	0	1 (11.1)
Investigations			

Baseline extramedullary disease presence: No

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (44.4)	0	4 (44.4)
Neutrophil count decreased	2 (22.2)	0	2 (22.2)
Alanine aminotransferase increased	1 (11.1)	0	1 (11.1)
Aspartate aminotransferase increased	1 (11.1)	0	1 (11.1)
Blood bilirubin increased	1 (11.1)	0	1 (11.1)
Blood lactate dehydrogenase increased	1 (11.1)	1 (11.1)	0
Computerised tomogram thorax abnormal	1 (11.1)	1 (11.1)	0
Electrocardiogram qt prolonged	1 (11.1)	1 (11.1)	0
Platelet count decreased	1 (11.1)	0	1 (11.1)
White blood cell count decreased	1 (11.1)	0	1 (11.1)
Metabolism and nutrition disorders			
-Total	4 (44.4)	1 (11.1)	3 (33.3)
Hypernatraemia	3 (33.3)	1 (11.1)	2 (22.2)
Hypokalaemia	3 (33.3)	0	3 (33.3)
Decreased appetite	1 (11.1)	1 (11.1)	0
Dehydration	1 (11.1)	1 (11.1)	0
Fluid overload	1 (11.1)	1 (11.1)	0

Baseline extramedullary disease presence: No

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	1 (11.1)	0	1 (11.1)
Hyperkalaemia	1 (11.1)	1 (11.1)	0
Hypoalbuminaemia	1 (11.1)	0	1 (11.1)
Hypocalcaemia	1 (11.1)	0	1 (11.1)
Hypophosphataemia	1 (11.1)	1 (11.1)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (22.2)	2 (22.2)	0
Pain in extremity	2 (22.2)	2 (22.2)	0
Arthralgia	1 (11.1)	1 (11.1)	0
Back pain	1 (11.1)	1 (11.1)	0
Nervous system disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Headache	1 (11.1)	1 (11.1)	0
Hyporesponsive to stimuli	1 (11.1)	1 (11.1)	0
Leukoencephalopathy	1 (11.1)	1 (11.1)	0
Seizure	1 (11.1)	0	1 (11.1)
Psychiatric disorders			
-Total	2 (22.2)	2 (22.2)	0

Baseline extramedullary disease presence: No

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	1 (11.1)	1 (11.1)	0
Delirium	1 (11.1)	1 (11.1)	0
Renal and urinary disorders			
-Total	3 (33.3)	2 (22.2)	1 (11.1)
Acute kidney injury	2 (22.2)	1 (11.1)	1 (11.1)
Cystitis haemorrhagic	1 (11.1)	1 (11.1)	0
Oliguria	1 (11.1)	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (55.6)	1 (11.1)	4 (44.4)
Hypoxia	4 (44.4)	3 (33.3)	1 (11.1)
Pulmonary oedema	2 (22.2)	0	2 (22.2)
Aspiration	1 (11.1)	0	1 (11.1)
Cough	1 (11.1)	1 (11.1)	0
Dyspnoea	1 (11.1)	1 (11.1)	0
Haemoptysis	1 (11.1)	1 (11.1)	0
Oropharyngeal pain	1 (11.1)	1 (11.1)	0
Pleural effusion	1 (11.1)	1 (11.1)	0
Pulmonary alveolar haemorrhage	1 (11.1)	0	1 (11.1)

Baseline extramedullary disease presence: No

Group term Preferred term	All patients N=9 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pulmonary hypertension	1 (11.1)	1 (11.1)	0
Respiratory distress	1 (11.1)	0	1 (11.1)
Respiratory failure	1 (11.1)	0	1 (11.1)
Tachypnoea	1 (11.1)	1 (11.1)	0
Vascular disorders			
-Total	6 (66.7)	3 (33.3)	3 (33.3)
Hypotension	6 (66.7)	3 (33.3)	3 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192p
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set – non – infused patients

Down syndrome: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders			
-Total	5 (45.5)	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	4 (36.4)	0
Thrombocytopenia	4 (36.4)	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	2 (18.2)	0	2 (18.2)
Lymphopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			

Down syndrome: No

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (18.2)	0	2 (18.2)
Bradycardia	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	1 (9.1)	0
Sinus tachycardia	1 (9.1)	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	4 (36.4)	4 (36.4)	0
Abdominal pain	2 (18.2)	2 (18.2)	0
Colitis	2 (18.2)	2 (18.2)	0
Ascites	1 (9.1)	1 (9.1)	0
Diarrhoea	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Haematochezia	1 (9.1)	1 (9.1)	0
Nausea	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
Vomiting	1 (9.1)	1 (9.1)	0

Down syndrome: No

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions			
-Total	5 (45.5)	2 (18.2)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Non-cardiac chest pain	1 (9.1)	1 (9.1)	0
Pain	1 (9.1)	1 (9.1)	0
Pyrexia	1 (9.1)	1 (9.1)	0
Hepatobiliary disorders			
-Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	7 (63.6)	1 (9.1)	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Candida sepsis	1 (9.1)	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	1 (9.1)	0
Escherichia infection	1 (9.1)	1 (9.1)	0
Klebsiella infection	1 (9.1)	1 (9.1)	0
Pneumonia	1 (9.1)	0	1 (9.1)

Down syndrome: No

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Streptococcal infection	1 (9.1)	1 (9.1)	0
Investigations			
-Total	4 (36.4)	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	2 (18.2)
Alanine aminotransferase increased	1 (9.1)	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	1 (9.1)	0
Platelet count decreased	1 (9.1)	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	1 (9.1)

Down syndrome: No

Group term Preferred term	All patients N=11 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Metabolism and nutrition disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Hypernatraemia	3 (27.3)	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	3 (27.3)
Decreased appetite	1 (9.1)	1 (9.1)	0
Dehydration	1 (9.1)	1 (9.1)	0
Fluid overload	1 (9.1)	1 (9.1)	0
Hyperglycaemia	1 (9.1)	0	1 (9.1)
Hyperkalaemia	1 (9.1)	1 (9.1)	0
Hypoalbuminaemia	1 (9.1)	0	1 (9.1)
Hypocalcaemia	1 (9.1)	0	1 (9.1)
Hypophosphataemia	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (18.2)	2 (18.2)	0
Pain in extremity	2 (18.2)	2 (18.2)	0
Arthralgia	1 (9.1)	1 (9.1)	0
Back pain	1 (9.1)	1 (9.1)	0

Down syndrome: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Headache	1 (9.1)	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	0	1 (9.1)
Psychiatric disorders			
-Total	2 (18.2)	2 (18.2)	0
Agitation	1 (9.1)	1 (9.1)	0
Delirium	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Acute kidney injury	2 (18.2)	1 (9.1)	1 (9.1)
Cystitis haemorrhagic	1 (9.1)	1 (9.1)	0
Oliguria	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (45.5)	1 (9.1)	4 (36.4)

Down syndrome: No

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	4 (36.4)	3 (27.3)	1 (9.1)
Pulmonary oedema	2 (18.2)	0	2 (18.2)
Aspiration	1 (9.1)	0	1 (9.1)
Cough	1 (9.1)	1 (9.1)	0
Dyspnoea	1 (9.1)	1 (9.1)	0
Haemoptysis	1 (9.1)	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	1 (9.1)	0
Pleural effusion	1 (9.1)	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	1 (9.1)	0
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Tachypnoea	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	6 (54.5)	3 (27.3)	3 (27.3)
Hypotension	6 (54.5)	3 (27.3)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192q
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set – non – infused patients

Time since enrollment to CTL019 infusion: Missing

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (72.7)	1 (9.1)	7 (63.6)
Blood and lymphatic system disorders			
-Total	5 (45.5)	2 (18.2)	3 (27.3)
Anaemia	4 (36.4)	4 (36.4)	0
Thrombocytopenia	4 (36.4)	1 (9.1)	3 (27.3)
Disseminated intravascular coagulation	3 (27.3)	2 (18.2)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Neutropenia	2 (18.2)	0	2 (18.2)
Lymphopenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			
-Total	2 (18.2)	0	2 (18.2)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	1 (9.1)	0
Sinus tachycardia	1 (9.1)	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	4 (36.4)	4 (36.4)	0
Abdominal pain	2 (18.2)	2 (18.2)	0
Colitis	2 (18.2)	2 (18.2)	0
Ascites	1 (9.1)	1 (9.1)	0
Diarrhoea	1 (9.1)	1 (9.1)	0
Gastrointestinal haemorrhage	1 (9.1)	1 (9.1)	0
Haematochezia	1 (9.1)	1 (9.1)	0
Nausea	1 (9.1)	1 (9.1)	0
Stomatitis	1 (9.1)	1 (9.1)	0
Vomiting	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	5 (45.5)	2 (18.2)	3 (27.3)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Non-cardiac chest pain	1 (9.1)	1 (9.1)	0
Pain	1 (9.1)	1 (9.1)	0
Pyrexia	1 (9.1)	1 (9.1)	0
Hepatobiliary disorders			
-Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	7 (63.6)	1 (9.1)	6 (54.5)
Klebsiella sepsis	2 (18.2)	0	2 (18.2)
Candida sepsis	1 (9.1)	0	1 (9.1)
Clostridium difficile colitis	1 (9.1)	1 (9.1)	0
Escherichia infection	1 (9.1)	1 (9.1)	0
Klebsiella infection	1 (9.1)	1 (9.1)	0
Pneumonia	1 (9.1)	0	1 (9.1)
Pneumonia fungal	1 (9.1)	1 (9.1)	0
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Streptococcal infection	1 (9.1)	1 (9.1)	0
Investigations			
-Total	4 (36.4)	0	4 (36.4)
Neutrophil count decreased	2 (18.2)	0	2 (18.2)
Alanine aminotransferase increased	1 (9.1)	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	1 (9.1)
Blood lactate dehydrogenase increased	1 (9.1)	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	1 (9.1)	0
Platelet count decreased	1 (9.1)	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Hypernatraemia	3 (27.3)	1 (9.1)	2 (18.2)
Hypokalaemia	3 (27.3)	0	3 (27.3)
Decreased appetite	1 (9.1)	1 (9.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (9.1)	1 (9.1)	0
Fluid overload	1 (9.1)	1 (9.1)	0
Hyperglycaemia	1 (9.1)	0	1 (9.1)
Hyperkalaemia	1 (9.1)	1 (9.1)	0
Hypoalbuminaemia	1 (9.1)	0	1 (9.1)
Hypocalcaemia	1 (9.1)	0	1 (9.1)
Hypophosphataemia	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (18.2)	2 (18.2)	0
Pain in extremity	2 (18.2)	2 (18.2)	0
Arthralgia	1 (9.1)	1 (9.1)	0
Back pain	1 (9.1)	1 (9.1)	0
Nervous system disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Headache	1 (9.1)	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	1 (9.1)	0
Leukoencephalopathy	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	0	1 (9.1)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	2 (18.2)	2 (18.2)	0
Agitation	1 (9.1)	1 (9.1)	0
Delirium	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	3 (27.3)	2 (18.2)	1 (9.1)
Acute kidney injury	2 (18.2)	1 (9.1)	1 (9.1)
Cystitis haemorrhagic	1 (9.1)	1 (9.1)	0
Oliguria	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (45.5)	1 (9.1)	4 (36.4)
Hypoxia	4 (36.4)	3 (27.3)	1 (9.1)
Pulmonary oedema	2 (18.2)	0	2 (18.2)
Aspiration	1 (9.1)	0	1 (9.1)
Cough	1 (9.1)	1 (9.1)	0
Dyspnoea	1 (9.1)	1 (9.1)	0
Haemoptysis	1 (9.1)	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	1 (9.1)	0

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Pleural effusion	1 (9.1)	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	1 (9.1)	0
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Tachypnoea	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	6 (54.5)	3 (27.3)	3 (27.3)
Hypotension	6 (54.5)	3 (27.3)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192r
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 0

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	0	1 (100)
General disorders and administration site conditions			
-Total	1 (100)	1 (100)	0
Pain	1 (100)	1 (100)	0
Pyrexia	1 (100)	1 (100)	0
Infections and infestations			
-Total	1 (100)	0	1 (100)
Pneumonia	1 (100)	0	1 (100)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (100)	0	1 (100)

Number of previous relapses: 0

Group term Preferred term	All patients N=1 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspiration	1 (100)	0	1 (100)
Hypoxia	1 (100)	1 (100)	0
Vascular disorders			
-Total	1 (100)	0	1 (100)
Hypotension	1 (100)	0	1 (100)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192r
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 1

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (33.3)	0	1 (33.3)
Blood and lymphatic system disorders			
-Total	1 (33.3)	0	1 (33.3)
Anaemia	1 (33.3)	1 (33.3)	0
Disseminated intravascular coagulation	1 (33.3)	1 (33.3)	0
Lymphopenia	1 (33.3)	0	1 (33.3)
Neutropenia	1 (33.3)	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	1 (33.3)
Cardiac disorders			
-Total	1 (33.3)	0	1 (33.3)

Number of previous relapses: 1

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Bradycardia	1 (33.3)	0	1 (33.3)
Right ventricular dysfunction	1 (33.3)	1 (33.3)	0
Sinus tachycardia	1 (33.3)	1 (33.3)	0
Ventricular tachycardia	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders			
-Total	1 (33.3)	1 (33.3)	0
Abdominal pain	1 (33.3)	1 (33.3)	0
Haematochezia	1 (33.3)	1 (33.3)	0
Nausea	1 (33.3)	1 (33.3)	0
Vomiting	1 (33.3)	1 (33.3)	0
General disorders and administration site conditions			
-Total	1 (33.3)	1 (33.3)	0
Non-cardiac chest pain	1 (33.3)	1 (33.3)	0
Investigations			
-Total	1 (33.3)	0	1 (33.3)
Blood lactate dehydrogenase increased	1 (33.3)	1 (33.3)	0

Number of previous relapses: 1

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Computerised tomogram thorax abnormal	1 (33.3)	1 (33.3)	0
Electrocardiogram qt prolonged	1 (33.3)	1 (33.3)	0
White blood cell count decreased	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	1 (33.3)	1 (33.3)	0
Fluid overload	1 (33.3)	1 (33.3)	0
Hyperkalaemia	1 (33.3)	1 (33.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (33.3)	1 (33.3)	0
Arthralgia	1 (33.3)	1 (33.3)	0
Back pain	1 (33.3)	1 (33.3)	0
Pain in extremity	1 (33.3)	1 (33.3)	0
Nervous system disorders			
-Total	1 (33.3)	0	1 (33.3)
Headache	1 (33.3)	1 (33.3)	0
Hyporesponsive to stimuli	1 (33.3)	1 (33.3)	0
Seizure	1 (33.3)	0	1 (33.3)

Number of previous relapses: 1

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Psychiatric disorders			
-Total	1 (33.3)	1 (33.3)	0
Agitation	1 (33.3)	1 (33.3)	0
Renal and urinary disorders			
-Total	1 (33.3)	1 (33.3)	0
Acute kidney injury	1 (33.3)	1 (33.3)	0
Oliguria	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Cough	1 (33.3)	1 (33.3)	0
Dyspnoea	1 (33.3)	1 (33.3)	0
Haemoptysis	1 (33.3)	1 (33.3)	0
Hypoxia	1 (33.3)	1 (33.3)	0
Oropharyngeal pain	1 (33.3)	1 (33.3)	0
Pulmonary alveolar haemorrhage	1 (33.3)	0	1 (33.3)
Pulmonary hypertension	1 (33.3)	1 (33.3)	0
Pulmonary oedema	1 (33.3)	0	1 (33.3)

Number of previous relapses: 1

Group term Preferred term	All patients N=3 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory distress	1 (33.3)	0	1 (33.3)
Tachypnoea	1 (33.3)	1 (33.3)	0
Vascular disorders			
-Total	1 (33.3)	0	1 (33.3)
Hypotension	1 (33.3)	0	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192r
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: 2

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (66.7)	1 (33.3)	1 (33.3)
Blood and lymphatic system disorders			
-Total	1 (33.3)	0	1 (33.3)
Febrile neutropenia	1 (33.3)	1 (33.3)	0
Neutropenia	1 (33.3)	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	1 (33.3)
Gastrointestinal disorders			
-Total	1 (33.3)	1 (33.3)	0
Gastrointestinal haemorrhage	1 (33.3)	1 (33.3)	0
Infections and infestations			

Number of previous relapses: 2

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Candida sepsis	1 (33.3)	0	1 (33.3)
Escherichia infection	1 (33.3)	1 (33.3)	0
Pneumonia fungal	1 (33.3)	1 (33.3)	0
Streptococcal infection	1 (33.3)	1 (33.3)	0
Metabolism and nutrition disorders			
-Total	1 (33.3)	0	1 (33.3)
Hypernatraemia	1 (33.3)	0	1 (33.3)
Hypokalaemia	1 (33.3)	0	1 (33.3)
Hypophosphataemia	1 (33.3)	1 (33.3)	0
Renal and urinary disorders			
-Total	1 (33.3)	0	1 (33.3)
Acute kidney injury	1 (33.3)	0	1 (33.3)
Respiratory, thoracic and mediastinal disorders			
-Total	1 (33.3)	0	1 (33.3)
Pulmonary oedema	1 (33.3)	0	1 (33.3)
Respiratory failure	1 (33.3)	0	1 (33.3)

Number of previous relapses: 2

Group term Preferred term	All patients N=3 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
-Total	1 (33.3)	0	1 (33.3)
Hypotension	1 (33.3)	0	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 192r
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set – non – infused patients

Number of previous relapses: >=3

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	0	4 (100)
Blood and lymphatic system disorders			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Anaemia	3 (75.0)	3 (75.0)	0
Disseminated intravascular coagulation	2 (50.0)	1 (25.0)	1 (25.0)
Thrombocytopenia	2 (50.0)	1 (25.0)	1 (25.0)
Febrile neutropenia	1 (25.0)	1 (25.0)	0
Cardiac disorders			
-Total	1 (25.0)	0	1 (25.0)
Cardiovascular insufficiency	1 (25.0)	0	1 (25.0)

Number of previous relapses: >=3

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	2 (50.0)	2 (50.0)	0
Colitis	2 (50.0)	2 (50.0)	0
Abdominal pain	1 (25.0)	1 (25.0)	0
Ascites	1 (25.0)	1 (25.0)	0
Diarrhoea	1 (25.0)	1 (25.0)	0
Stomatitis	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			
-Total	3 (75.0)	0	3 (75.0)
Multiple organ dysfunction syndrome	3 (75.0)	0	3 (75.0)
Hepatobiliary disorders			
-Total	1 (25.0)	0	1 (25.0)
Hepatic failure	1 (25.0)	0	1 (25.0)
Infections and infestations			
-Total	4 (100)	0	4 (100)
Klebsiella sepsis	2 (50.0)	0	2 (50.0)
Clostridium difficile colitis	1 (25.0)	1 (25.0)	0

Number of previous relapses: >=3

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Klebsiella infection	1 (25.0)	1 (25.0)	0
Sepsis	1 (25.0)	0	1 (25.0)
Staphylococcal bacteraemia	1 (25.0)	1 (25.0)	0
Staphylococcal infection	1 (25.0)	0	1 (25.0)
Investigations			
-Total	3 (75.0)	0	3 (75.0)
Neutrophil count decreased	2 (50.0)	0	2 (50.0)
Alanine aminotransferase increased	1 (25.0)	0	1 (25.0)
Aspartate aminotransferase increased	1 (25.0)	0	1 (25.0)
Blood bilirubin increased	1 (25.0)	0	1 (25.0)
Platelet count decreased	1 (25.0)	0	1 (25.0)
Metabolism and nutrition disorders			
-Total	2 (50.0)	0	2 (50.0)
Hypernatraemia	2 (50.0)	1 (25.0)	1 (25.0)
Hypokalaemia	2 (50.0)	0	2 (50.0)
Decreased appetite	1 (25.0)	1 (25.0)	0
Dehydration	1 (25.0)	1 (25.0)	0

Number of previous relapses: >=3

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperglycaemia	1 (25.0)	0	1 (25.0)
Hypoalbuminaemia	1 (25.0)	0	1 (25.0)
Hypocalcaemia	1 (25.0)	0	1 (25.0)
Musculoskeletal and connective tissue disorders			
-Total	1 (25.0)	1 (25.0)	0
Pain in extremity	1 (25.0)	1 (25.0)	0
Nervous system disorders			
-Total	1 (25.0)	1 (25.0)	0
Leukoencephalopathy	1 (25.0)	1 (25.0)	0
Psychiatric disorders			
-Total	1 (25.0)	1 (25.0)	0
Delirium	1 (25.0)	1 (25.0)	0
Renal and urinary disorders			
-Total	1 (25.0)	1 (25.0)	0
Cystitis haemorrhagic	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)

Number of previous relapses: >=3

Group term Preferred term	All patients N=4 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypoxia	2 (50.0)	1 (25.0)	1 (25.0)
Pleural effusion	1 (25.0)	1 (25.0)	0
Vascular disorders			
-Total	3 (75.0)	3 (75.0)	0
Hypotension	3 (75.0)	3 (75.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- Only AEs occured to non-infused patients are summarized.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193a
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: <10 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	17 (77.3)	4 (18.2)	13 (59.1)
Blood and lymphatic system disorders			
-Total	14 (63.6)	9 (40.9)	5 (22.7)
Febrile neutropenia	11 (50.0)	11 (50.0)	0
Anaemia	6 (27.3)	6 (27.3)	0
Thrombocytopenia	3 (13.6)	1 (4.5)	2 (9.1)
Neutropenia	2 (9.1)	0	2 (9.1)
Disseminated intravascular coagulation	1 (4.5)	1 (4.5)	0
Lymphopenia	1 (4.5)	0	1 (4.5)
Gastrointestinal disorders			

Age: <10 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (13.6)	3 (13.6)	0
Nausea	2 (9.1)	2 (9.1)	0
Colitis	1 (4.5)	1 (4.5)	0
General disorders and administration site conditions			
-Total	3 (13.6)	3 (13.6)	0
Pyrexia	2 (9.1)	2 (9.1)	0
Multiple organ dysfunction syndrome	1 (4.5)	1 (4.5)	0
Hepatobiliary disorders			
-Total	1 (4.5)	1 (4.5)	0
Hyperbilirubinaemia	1 (4.5)	1 (4.5)	0
Immune system disorders			
-Total	6 (27.3)	3 (13.6)	3 (13.6)
Cytokine release syndrome	6 (27.3)	3 (13.6)	3 (13.6)
Hypogammaglobulinaemia	2 (9.1)	2 (9.1)	0
Infections and infestations			
-Total	4 (18.2)	4 (18.2)	0
Clostridium difficile colitis	2 (9.1)	2 (9.1)	0

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Device related infection	1 (4.5)	1 (4.5)	0
Pneumonia	1 (4.5)	1 (4.5)	0
Investigations			
-Total	15 (68.2)	4 (18.2)	11 (50.0)
Neutrophil count decreased	8 (36.4)	1 (4.5)	7 (31.8)
White blood cell count decreased	8 (36.4)	1 (4.5)	7 (31.8)
Alanine aminotransferase increased	5 (22.7)	5 (22.7)	0
Aspartate aminotransferase increased	5 (22.7)	3 (13.6)	2 (9.1)
Lymphocyte count decreased	4 (18.2)	1 (4.5)	3 (13.6)
Platelet count decreased	4 (18.2)	0	4 (18.2)
Blood fibrinogen decreased	2 (9.1)	1 (4.5)	1 (4.5)
Lipase increased	2 (9.1)	0	2 (9.1)
Blood bilirubin increased	1 (4.5)	1 (4.5)	0
Metabolism and nutrition disorders			
-Total	8 (36.4)	7 (31.8)	1 (4.5)
Hypokalaemia	6 (27.3)	6 (27.3)	0
Decreased appetite	3 (13.6)	3 (13.6)	0

Age: <10 years

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	3 (13.6)	2 (9.1)	1 (4.5)
Dehydration	1 (4.5)	1 (4.5)	0
Tumour lysis syndrome	1 (4.5)	1 (4.5)	0
Nervous system disorders			
-Total	2 (9.1)	2 (9.1)	0
Seizure	2 (9.1)	2 (9.1)	0
Renal and urinary disorders			
-Total	1 (4.5)	1 (4.5)	0
Acute kidney injury	1 (4.5)	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (27.3)	4 (18.2)	2 (9.1)
Hypoxia	5 (22.7)	5 (22.7)	0
Pleural effusion	2 (9.1)	2 (9.1)	0
Pulmonary oedema	2 (9.1)	2 (9.1)	0
Epistaxis	1 (4.5)	1 (4.5)	0
Respiratory distress	1 (4.5)	0	1 (4.5)
Respiratory failure	1 (4.5)	0	1 (4.5)

Age: <10 years

Group term Preferred term	All patients N=22 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Tachypnoea	1 (4.5)	1 (4.5)	0
Vascular disorders			
-Total	4 (18.2)	1 (4.5)	3 (13.6)
Hypotension	4 (18.2)	1 (4.5)	3 (13.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193a
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	38 (97.4)	7 (17.9)	31 (79.5)
Blood and lymphatic system disorders			
-Total	34 (87.2)	22 (56.4)	12 (30.8)
Febrile neutropenia	22 (56.4)	21 (53.8)	1 (2.6)
Anaemia	16 (41.0)	15 (38.5)	1 (2.6)
Neutropenia	9 (23.1)	2 (5.1)	7 (17.9)
Thrombocytopenia	7 (17.9)	4 (10.3)	3 (7.7)
Disseminated intravascular coagulation	2 (5.1)	1 (2.6)	1 (2.6)
Lymphopenia	2 (5.1)	1 (2.6)	1 (2.6)
Pancytopenia	2 (5.1)	1 (2.6)	1 (2.6)

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders			
-Total	3 (7.7)	3 (7.7)	0
Left ventricular dysfunction	1 (2.6)	1 (2.6)	0
Sinus tachycardia	1 (2.6)	1 (2.6)	0
Tachycardia	1 (2.6)	1 (2.6)	0
Gastrointestinal disorders			
-Total	9 (23.1)	8 (20.5)	1 (2.6)
Stomatitis	3 (7.7)	2 (5.1)	1 (2.6)
Abdominal pain	2 (5.1)	2 (5.1)	0
Colitis	2 (5.1)	2 (5.1)	0
Nausea	2 (5.1)	2 (5.1)	0
Vomiting	2 (5.1)	2 (5.1)	0
Diarrhoea	1 (2.6)	1 (2.6)	0
General disorders and administration site conditions			
-Total	8 (20.5)	5 (12.8)	3 (7.7)
Pyrexia	3 (7.7)	2 (5.1)	1 (2.6)
Fatigue	2 (5.1)	2 (5.1)	0

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Multiple organ dysfunction syndrome	2 (5.1)	0	2 (5.1)
Pain	2 (5.1)	2 (5.1)	0
Physical deconditioning	1 (2.6)	1 (2.6)	0
Hepatobiliary disorders			
-Total	1 (2.6)	1 (2.6)	0
Hyperbilirubinaemia	1 (2.6)	1 (2.6)	0
Immune system disorders			
-Total	13 (33.3)	8 (20.5)	5 (12.8)
Cytokine release syndrome	10 (25.6)	5 (12.8)	5 (12.8)
Hypogammaglobulinaemia	3 (7.7)	3 (7.7)	0
Infections and infestations			
-Total	8 (20.5)	6 (15.4)	2 (5.1)
Device related infection	2 (5.1)	2 (5.1)	0
Escherichia urinary tract infection	2 (5.1)	2 (5.1)	0
Staphylococcal bacteraemia	2 (5.1)	2 (5.1)	0
Staphylococcal infection	2 (5.1)	1 (2.6)	1 (2.6)
Urinary tract infection	2 (5.1)	2 (5.1)	0
Sepsis	1 (2.6)	0	1 (2.6)

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	27 (69.2)	4 (10.3)	23 (59.0)
White blood cell count decreased	23 (59.0)	5 (12.8)	18 (46.2)
Neutrophil count decreased	19 (48.7)	2 (5.1)	17 (43.6)
Alanine aminotransferase increased	13 (33.3)	12 (30.8)	1 (2.6)
Platelet count decreased	11 (28.2)	3 (7.7)	8 (20.5)
Lymphocyte count decreased	10 (25.6)	6 (15.4)	4 (10.3)
Aspartate aminotransferase increased	7 (17.9)	5 (12.8)	2 (5.1)
Blood bilirubin increased	4 (10.3)	3 (7.7)	1 (2.6)
Electrocardiogram qt prolonged	1 (2.6)	1 (2.6)	0
Lipase increased	1 (2.6)	0	1 (2.6)
Metabolism and nutrition disorders			
-Total	18 (46.2)	13 (33.3)	5 (12.8)
Decreased appetite	7 (17.9)	7 (17.9)	0
Hypokalaemia	7 (17.9)	3 (7.7)	4 (10.3)
Hypophosphataemia	5 (12.8)	5 (12.8)	0
Hyperglycaemia	3 (7.7)	3 (7.7)	0

Age: >=10 years to <18 years

	All patients N=39		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	3 (7.7)	0	3 (7.7)
Dehydration	1 (2.6)	1 (2.6)	0
Tumour lysis syndrome	1 (2.6)	1 (2.6)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (7.7)	3 (7.7)	0
Arthralgia	1 (2.6)	1 (2.6)	0
Back pain	1 (2.6)	1 (2.6)	0
Pain in extremity	1 (2.6)	1 (2.6)	0
Nervous system disorders			
-Total	5 (12.8)	5 (12.8)	0
Headache	4 (10.3)	4 (10.3)	0
Encephalopathy	2 (5.1)	2 (5.1)	0
Renal and urinary disorders			
-Total	7 (17.9)	4 (10.3)	3 (7.7)
Acute kidney injury	5 (12.8)	3 (7.7)	2 (5.1)
Haematuria	2 (5.1)	1 (2.6)	1 (2.6)
Oliguria	2 (5.1)	2 (5.1)	0

Age: >=10 years to <18 years

Group term Preferred term	All patients N=39 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	10 (25.6)	6 (15.4)	4 (10.3)
Epistaxis	5 (12.8)	4 (10.3)	1 (2.6)
Pulmonary oedema	4 (10.3)	2 (5.1)	2 (5.1)
Hypoxia	3 (7.7)	2 (5.1)	1 (2.6)
Respiratory failure	3 (7.7)	0	3 (7.7)
Dyspnoea	1 (2.6)	1 (2.6)	0
Haemoptysis	1 (2.6)	0	1 (2.6)
Pleural effusion	1 (2.6)	1 (2.6)	0
Tachypnoea	1 (2.6)	1 (2.6)	0
Vascular disorders			
-Total	14 (35.9)	9 (23.1)	5 (12.8)
Hypotension	14 (35.9)	9 (23.1)	5 (12.8)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193a
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Age
Enrolled set

Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	13 (92.9)	2 (14.3)	11 (78.6)
Blood and lymphatic system disorders			
-Total	10 (71.4)	4 (28.6)	6 (42.9)
Anaemia	5 (35.7)	5 (35.7)	0
Neutropenia	5 (35.7)	2 (14.3)	3 (21.4)
Thrombocytopenia	4 (28.6)	0	4 (28.6)
Febrile neutropenia	3 (21.4)	3 (21.4)	0
Pancytopenia	2 (14.3)	0	2 (14.3)
Disseminated intravascular coagulation	1 (7.1)	1 (7.1)	0
Lymphopenia	1 (7.1)	0	1 (7.1)

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac disorders			
-Total	4 (28.6)	2 (14.3)	2 (14.3)
Left ventricular dysfunction	2 (14.3)	2 (14.3)	0
Bradycardia	1 (7.1)	0	1 (7.1)
Cardiovascular insufficiency	1 (7.1)	0	1 (7.1)
Right ventricular dysfunction	1 (7.1)	1 (7.1)	0
Sinus tachycardia	1 (7.1)	1 (7.1)	0
Tachycardia	1 (7.1)	1 (7.1)	0
Ventricular tachycardia	1 (7.1)	1 (7.1)	0
Gastrointestinal disorders			
-Total	3 (21.4)	3 (21.4)	0
Nausea	3 (21.4)	3 (21.4)	0
Vomiting	2 (14.3)	2 (14.3)	0
Abdominal pain	1 (7.1)	1 (7.1)	0
Diarrhoea	1 (7.1)	1 (7.1)	0
Haematochezia	1 (7.1)	1 (7.1)	0
Intestinal obstruction	1 (7.1)	1 (7.1)	0

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
General disorders and administration site conditions			
-Total	6 (42.9)	5 (35.7)	1 (7.1)
Pyrexia	3 (21.4)	3 (21.4)	0
Multiple organ dysfunction syndrome	1 (7.1)	0	1 (7.1)
Non-cardiac chest pain	1 (7.1)	1 (7.1)	0
Pain	1 (7.1)	1 (7.1)	0
Physical deconditioning	1 (7.1)	1 (7.1)	0
Hepatobiliary disorders			
-Total	1 (7.1)	1 (7.1)	0
Hyperbilirubinaemia	1 (7.1)	1 (7.1)	0
Immune system disorders			
-Total	3 (21.4)	0	3 (21.4)
Cytokine release syndrome	3 (21.4)	0	3 (21.4)
Infections and infestations			
-Total	7 (50.0)	2 (14.3)	5 (35.7)
Abscess limb	1 (7.1)	1 (7.1)	0
Bacterial sepsis	1 (7.1)	0	1 (7.1)

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Cholecystitis infective	1 (7.1)	1 (7.1)	0
Escherichia sepsis	1 (7.1)	0	1 (7.1)
Klebsiella sepsis	1 (7.1)	0	1 (7.1)
Necrotising fasciitis	1 (7.1)	1 (7.1)	0
Pneumonia	1 (7.1)	0	1 (7.1)
Sepsis	1 (7.1)	0	1 (7.1)
Staphylococcal sepsis	1 (7.1)	0	1 (7.1)
Urinary tract infection enterococcal	1 (7.1)	1 (7.1)	0
Injury, poisoning and procedural complications			
-Total	1 (7.1)	1 (7.1)	0
Tracheal haemorrhage	1 (7.1)	1 (7.1)	0
Investigations			
-Total	10 (71.4)	3 (21.4)	7 (50.0)
White blood cell count decreased	6 (42.9)	2 (14.3)	4 (28.6)
Aspartate aminotransferase increased	2 (14.3)	1 (7.1)	1 (7.1)
Neutrophil count decreased	2 (14.3)	0	2 (14.3)
Alanine aminotransferase increased	1 (7.1)	1 (7.1)	0

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood fibrinogen decreased	1 (7.1)	1 (7.1)	0
Blood lactate dehydrogenase increased	1 (7.1)	1 (7.1)	0
C-reactive protein increased	1 (7.1)	1 (7.1)	0
Computerised tomogram thorax abnormal	1 (7.1)	1 (7.1)	0
Electrocardiogram qt prolonged	1 (7.1)	1 (7.1)	0
Lymphocyte count decreased	1 (7.1)	0	1 (7.1)
Platelet count decreased	1 (7.1)	0	1 (7.1)
Prothrombin time prolonged	1 (7.1)	1 (7.1)	0
Transaminases increased	1 (7.1)	1 (7.1)	0
Metabolism and nutrition disorders			
-Total	6 (42.9)	5 (35.7)	1 (7.1)
Decreased appetite	3 (21.4)	3 (21.4)	0
Dehydration	1 (7.1)	1 (7.1)	0
Fluid overload	1 (7.1)	1 (7.1)	0
Hyperglycaemia	1 (7.1)	1 (7.1)	0
Hyperkalaemia	1 (7.1)	1 (7.1)	0
Hyperuricaemia	1 (7.1)	0	1 (7.1)

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypophosphataemia	1 (7.1)	1 (7.1)	0
Tumour lysis syndrome	1 (7.1)	1 (7.1)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (21.4)	3 (21.4)	0
Pain in extremity	2 (14.3)	2 (14.3)	0
Arthralgia	1 (7.1)	1 (7.1)	0
Back pain	1 (7.1)	1 (7.1)	0
Musculoskeletal pain	1 (7.1)	1 (7.1)	0
Myopathy	1 (7.1)	1 (7.1)	0
Myositis	1 (7.1)	1 (7.1)	0
Nervous system disorders			
-Total	1 (7.1)	0	1 (7.1)
Headache	1 (7.1)	1 (7.1)	0
Hyporesponsive to stimuli	1 (7.1)	1 (7.1)	0
Seizure	1 (7.1)	0	1 (7.1)
Psychiatric disorders			
-Total	2 (14.3)	2 (14.3)	0

Age: >=18

	All patients N=14		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Agitation	1 (7.1)	1 (7.1)	0
Anxiety	1 (7.1)	1 (7.1)	0
Renal and urinary disorders			
-Total	3 (21.4)	1 (7.1)	2 (14.3)
Acute kidney injury	3 (21.4)	1 (7.1)	2 (14.3)
Haematuria	1 (7.1)	1 (7.1)	0
Oliguria	1 (7.1)	1 (7.1)	0
Reproductive system and breast disorders			
-Total	1 (7.1)	1 (7.1)	0
Vaginal haemorrhage	1 (7.1)	1 (7.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (28.6)	0	4 (28.6)
Hypoxia	4 (28.6)	2 (14.3)	2 (14.3)
Dyspnoea	2 (14.3)	1 (7.1)	1 (7.1)
Pulmonary oedema	2 (14.3)	0	2 (14.3)
Aspiration	1 (7.1)	0	1 (7.1)
Cough	1 (7.1)	1 (7.1)	0

Age: >=18

Group term Preferred term	All patients N=14 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Haemoptysis	1 (7.1)	1 (7.1)	0
Interstitial lung disease	1 (7.1)	0	1 (7.1)
Oropharyngeal pain	1 (7.1)	1 (7.1)	0
Pulmonary alveolar haemorrhage	1 (7.1)	0	1 (7.1)
Pulmonary hypertension	1 (7.1)	1 (7.1)	0
Respiratory distress	1 (7.1)	0	1 (7.1)
Tachypnoea	1 (7.1)	1 (7.1)	0
Skin and subcutaneous tissue disorders			
-Total	1 (7.1)	1 (7.1)	0
Rash maculo-papular	1 (7.1)	1 (7.1)	0
Vascular disorders			
-Total	5 (35.7)	2 (14.3)	3 (21.4)
Hypotension	5 (35.7)	2 (14.3)	3 (21.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193b
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	35 (87.5)	9 (22.5)	26 (65.0)
Blood and lymphatic system disorders			
-Total	30 (75.0)	19 (47.5)	11 (27.5)
Febrile neutropenia	18 (45.0)	18 (45.0)	0
Anaemia	13 (32.5)	13 (32.5)	0
Neutropenia	9 (22.5)	3 (7.5)	6 (15.0)
Thrombocytopenia	8 (20.0)	2 (5.0)	6 (15.0)
Disseminated intravascular coagulation	3 (7.5)	2 (5.0)	1 (2.5)
Lymphopenia	3 (7.5)	1 (2.5)	2 (5.0)
Pancytopenia	1 (2.5)	1 (2.5)	0

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders			
-Total	4 (10.0)	4 (10.0)	0
Sinus tachycardia	2 (5.0)	2 (5.0)	0
Tachycardia	2 (5.0)	2 (5.0)	0
Left ventricular dysfunction	1 (2.5)	1 (2.5)	0
Gastrointestinal disorders			
-Total	5 (12.5)	5 (12.5)	0
Colitis	2 (5.0)	2 (5.0)	0
Nausea	2 (5.0)	2 (5.0)	0
Abdominal pain	1 (2.5)	1 (2.5)	0
Stomatitis	1 (2.5)	1 (2.5)	0
Vomiting	1 (2.5)	1 (2.5)	0
General disorders and administration site conditions			
-Total	10 (25.0)	7 (17.5)	3 (7.5)
Multiple organ dysfunction syndrome	4 (10.0)	1 (2.5)	3 (7.5)
Pyrexia	4 (10.0)	4 (10.0)	0
Pain	3 (7.5)	3 (7.5)	0

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders			
-Total	2 (5.0)	2 (5.0)	0
Hyperbilirubinaemia	2 (5.0)	2 (5.0)	0
Immune system disorders			
-Total	10 (25.0)	4 (10.0)	6 (15.0)
Cytokine release syndrome	9 (22.5)	3 (7.5)	6 (15.0)
Hypogammaglobulinaemia	2 (5.0)	2 (5.0)	0
Infections and infestations			
-Total	1 (2.5)	1 (2.5)	0
Device related infection	1 (2.5)	1 (2.5)	0
Investigations			
-Total	23 (57.5)	5 (12.5)	18 (45.0)
White blood cell count decreased	16 (40.0)	3 (7.5)	13 (32.5)
Neutrophil count decreased	12 (30.0)	2 (5.0)	10 (25.0)
Aspartate aminotransferase increased	8 (20.0)	4 (10.0)	4 (10.0)
Alanine aminotransferase increased	7 (17.5)	6 (15.0)	1 (2.5)
Platelet count decreased	5 (12.5)	1 (2.5)	4 (10.0)

Gender: Male

	All patients N=40		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood bilirubin increased	4 (10.0)	3 (7.5)	1 (2.5)
Lymphocyte count decreased	4 (10.0)	2 (5.0)	2 (5.0)
Blood creatinine increased	2 (5.0)	2 (5.0)	0
Electrocardiogram qt prolonged	2 (5.0)	2 (5.0)	0
Blood fibrinogen decreased	1 (2.5)	0	1 (2.5)
Lipase increased	1 (2.5)	0	1 (2.5)
Metabolism and nutrition disorders			
-Total	12 (30.0)	10 (25.0)	2 (5.0)
Decreased appetite	6 (15.0)	6 (15.0)	0
Hypokalaemia	5 (12.5)	3 (7.5)	2 (5.0)
Hypophosphataemia	5 (12.5)	5 (12.5)	0
Hypernatraemia	2 (5.0)	0	2 (5.0)
Dehydration	1 (2.5)	1 (2.5)	0
Hyperglycaemia	1 (2.5)	1 (2.5)	0
Tumour lysis syndrome	1 (2.5)	1 (2.5)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (5.0)	2 (5.0)	0

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Arthralgia	2 (5.0)	2 (5.0)	0
Pain in extremity	1 (2.5)	1 (2.5)	0
Nervous system disorders			
-Total	4 (10.0)	3 (7.5)	1 (2.5)
Headache	3 (7.5)	3 (7.5)	0
Seizure	2 (5.0)	1 (2.5)	1 (2.5)
Renal and urinary disorders			
-Total	4 (10.0)	1 (2.5)	3 (7.5)
Acute kidney injury	4 (10.0)	1 (2.5)	3 (7.5)
Oliguria	2 (5.0)	2 (5.0)	0
Haematuria	1 (2.5)	1 (2.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	11 (27.5)	6 (15.0)	5 (12.5)
Hypoxia	7 (17.5)	5 (12.5)	2 (5.0)
Pulmonary oedema	6 (15.0)	3 (7.5)	3 (7.5)
Epistaxis	4 (10.0)	4 (10.0)	0
Dyspnoea	3 (7.5)	2 (5.0)	1 (2.5)

Gender: Male

Group term Preferred term	All patients N=40 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pleural effusion	2 (5.0)	2 (5.0)	0
Respiratory distress	2 (5.0)	0	2 (5.0)
Tachypnoea	2 (5.0)	2 (5.0)	0
Respiratory failure	1 (2.5)	0	1 (2.5)
Vascular disorders			
-Total	15 (37.5)	8 (20.0)	7 (17.5)
Hypotension	15 (37.5)	8 (20.0)	7 (17.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193b
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Gender
Enrolled set

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	33 (94.3)	5 (14.3)	28 (80.0)
Blood and lymphatic system disorders			
-Total	28 (80.0)	16 (45.7)	12 (34.3)
Febrile neutropenia	18 (51.4)	17 (48.6)	1 (2.9)
Anaemia	14 (40.0)	13 (37.1)	1 (2.9)
Neutropenia	7 (20.0)	1 (2.9)	6 (17.1)
Thrombocytopenia	6 (17.1)	3 (8.6)	3 (8.6)
Pancytopenia	3 (8.6)	0	3 (8.6)
Disseminated intravascular coagulation	1 (2.9)	1 (2.9)	0
Lymphopenia	1 (2.9)	0	1 (2.9)

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders			
-Total	2 (5.7)	2 (5.7)	0
Left ventricular dysfunction	2 (5.7)	2 (5.7)	0
Gastrointestinal disorders			
-Total	10 (28.6)	9 (25.7)	1 (2.9)
Nausea	5 (14.3)	5 (14.3)	0
Vomiting	3 (8.6)	3 (8.6)	0
Abdominal pain	2 (5.7)	2 (5.7)	0
Diarrhoea	2 (5.7)	2 (5.7)	0
Stomatitis	2 (5.7)	1 (2.9)	1 (2.9)
Colitis	1 (2.9)	1 (2.9)	0
General disorders and administration site conditions			
-Total	6 (17.1)	5 (14.3)	1 (2.9)
Pyrexia	4 (11.4)	3 (8.6)	1 (2.9)
Physical deconditioning	2 (5.7)	2 (5.7)	0
Hepatobiliary disorders			
-Total	1 (2.9)	1 (2.9)	0

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hyperbilirubinaemia	1 (2.9)	1 (2.9)	0
Immune system disorders			
-Total	12 (34.3)	7 (20.0)	5 (14.3)
Cytokine release syndrome	10 (28.6)	5 (14.3)	5 (14.3)
Hypogammaglobulinaemia	3 (8.6)	3 (8.6)	0
Infections and infestations			
-Total	4 (11.4)	4 (11.4)	0
Device related infection	2 (5.7)	2 (5.7)	0
Escherichia urinary tract infection	2 (5.7)	2 (5.7)	0
Investigations			
-Total	29 (82.9)	6 (17.1)	23 (65.7)
White blood cell count decreased	21 (60.0)	5 (14.3)	16 (45.7)
Neutrophil count decreased	17 (48.6)	1 (2.9)	16 (45.7)
Alanine aminotransferase increased	12 (34.3)	12 (34.3)	0
Lymphocyte count decreased	11 (31.4)	5 (14.3)	6 (17.1)
Platelet count decreased	11 (31.4)	2 (5.7)	9 (25.7)
Aspartate aminotransferase increased	6 (17.1)	5 (14.3)	1 (2.9)

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Blood fibrinogen decreased	2 (5.7)	2 (5.7)	0
Lipase increased	2 (5.7)	0	2 (5.7)
Blood bilirubin increased	1 (2.9)	1 (2.9)	0
Metabolism and nutrition disorders			
-Total	18 (51.4)	14 (40.0)	4 (11.4)
Hypokalaemia	8 (22.9)	6 (17.1)	2 (5.7)
Decreased appetite	7 (20.0)	7 (20.0)	0
Hypophosphataemia	4 (11.4)	3 (8.6)	1 (2.9)
Hyperglycaemia	3 (8.6)	3 (8.6)	0
Dehydration	2 (5.7)	2 (5.7)	0
Tumour lysis syndrome	2 (5.7)	2 (5.7)	0
Hypernatraemia	1 (2.9)	0	1 (2.9)
Musculoskeletal and connective tissue disorders			
-Total	2 (5.7)	2 (5.7)	0
Pain in extremity	2 (5.7)	2 (5.7)	0
Nervous system disorders			
-Total	3 (8.6)	3 (8.6)	0

Gender: Female

	All patients N=35		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Headache	2 (5.7)	2 (5.7)	0
Seizure	1 (2.9)	1 (2.9)	0
Renal and urinary disorders			
-Total	7 (20.0)	5 (14.3)	2 (5.7)
Acute kidney injury	5 (14.3)	4 (11.4)	1 (2.9)
Haematuria	2 (5.7)	1 (2.9)	1 (2.9)
Oliguria	1 (2.9)	1 (2.9)	0
Respiratory, thoracic and mediastinal disorders			
-Total	9 (25.7)	5 (14.3)	4 (11.4)
Hypoxia	5 (14.3)	4 (11.4)	1 (2.9)
Respiratory failure	3 (8.6)	0	3 (8.6)
Epistaxis	2 (5.7)	1 (2.9)	1 (2.9)
Pulmonary oedema	2 (5.7)	1 (2.9)	1 (2.9)
Pleural effusion	1 (2.9)	1 (2.9)	0
Tachypnoea	1 (2.9)	1 (2.9)	0
Vascular disorders			
-Total	8 (22.9)	4 (11.4)	4 (11.4)

Gender: Female

Group term Preferred term	All patients N=35 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	8 (22.9)	4 (11.4)	4 (11.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193c
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	55 (91.7)	11 (18.3)	44 (73.3)
Blood and lymphatic system disorders			
-Total	48 (80.0)	31 (51.7)	17 (28.3)
Febrile neutropenia	29 (48.3)	29 (48.3)	0
Anaemia	21 (35.0)	20 (33.3)	1 (1.7)
Neutropenia	14 (23.3)	4 (6.7)	10 (16.7)
Thrombocytopenia	13 (21.7)	5 (8.3)	8 (13.3)
Disseminated intravascular coagulation	3 (5.0)	2 (3.3)	1 (1.7)
Lymphopenia	2 (3.3)	1 (1.7)	1 (1.7)
Pancytopenia	2 (3.3)	1 (1.7)	1 (1.7)

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Cardiac disorders			
-Total	4 (6.7)	4 (6.7)	0
Left ventricular dysfunction	3 (5.0)	3 (5.0)	0
Sinus tachycardia	1 (1.7)	1 (1.7)	0
Gastrointestinal disorders			
-Total	11 (18.3)	10 (16.7)	1 (1.7)
Nausea	6 (10.0)	6 (10.0)	0
Colitis	3 (5.0)	3 (5.0)	0
Vomiting	3 (5.0)	3 (5.0)	0
Abdominal pain	2 (3.3)	2 (3.3)	0
Stomatitis	2 (3.3)	1 (1.7)	1 (1.7)
General disorders and administration site conditions			
-Total	13 (21.7)	10 (16.7)	3 (5.0)
Pyrexia	8 (13.3)	7 (11.7)	1 (1.7)
Multiple organ dysfunction syndrome	3 (5.0)	1 (1.7)	2 (3.3)
Pain	3 (5.0)	3 (5.0)	0
Hepatobiliary disorders			

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	2 (3.3)	2 (3.3)	0
Hyperbilirubinaemia	2 (3.3)	2 (3.3)	0
Immune system disorders			
-Total	20 (33.3)	10 (16.7)	10 (16.7)
Cytokine release syndrome	17 (28.3)	7 (11.7)	10 (16.7)
Hypogammaglobulinaemia	5 (8.3)	5 (8.3)	0
Infections and infestations			
-Total	4 (6.7)	3 (5.0)	1 (1.7)
Device related infection	2 (3.3)	2 (3.3)	0
Escherichia urinary tract infection	1 (1.7)	1 (1.7)	0
Sepsis	1 (1.7)	0	1 (1.7)
Investigations			
-Total	42 (70.0)	9 (15.0)	33 (55.0)
White blood cell count decreased	28 (46.7)	6 (10.0)	22 (36.7)
Neutrophil count decreased	24 (40.0)	3 (5.0)	21 (35.0)
Alanine aminotransferase increased	17 (28.3)	16 (26.7)	1 (1.7)
Lymphocyte count decreased	13 (21.7)	6 (10.0)	7 (11.7)

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	12 (20.0)	7 (11.7)	5 (8.3)
Platelet count decreased	12 (20.0)	2 (3.3)	10 (16.7)
Blood bilirubin increased	5 (8.3)	4 (6.7)	1 (1.7)
Blood fibrinogen decreased	3 (5.0)	2 (3.3)	1 (1.7)
Lipase increased	2 (3.3)	0	2 (3.3)
Electrocardiogram qt prolonged	1 (1.7)	1 (1.7)	0
Metabolism and nutrition disorders			
-Total	25 (41.7)	20 (33.3)	5 (8.3)
Decreased appetite	12 (20.0)	12 (20.0)	0
Hypokalaemia	12 (20.0)	9 (15.0)	3 (5.0)
Hypophosphataemia	9 (15.0)	8 (13.3)	1 (1.7)
Hyperglycaemia	3 (5.0)	3 (5.0)	0
Hypernatraemia	3 (5.0)	0	3 (5.0)
Dehydration	2 (3.3)	2 (3.3)	0
Tumour lysis syndrome	2 (3.3)	2 (3.3)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (5.0)	3 (5.0)	0

Race: White

	All patients N=60		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain in extremity	2 (3.3)	2 (3.3)	0
Arthralgia	1 (1.7)	1 (1.7)	0
Nervous system disorders			
-Total	5 (8.3)	5 (8.3)	0
Headache	3 (5.0)	3 (5.0)	0
Seizure	2 (3.3)	2 (3.3)	0
Renal and urinary disorders			
-Total	9 (15.0)	4 (6.7)	5 (8.3)
Acute kidney injury	7 (11.7)	3 (5.0)	4 (6.7)
Haematuria	3 (5.0)	2 (3.3)	1 (1.7)
Oliguria	2 (3.3)	2 (3.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	15 (25.0)	8 (13.3)	7 (11.7)
Hypoxia	11 (18.3)	8 (13.3)	3 (5.0)
Pulmonary oedema	5 (8.3)	3 (5.0)	2 (3.3)
Epistaxis	4 (6.7)	3 (5.0)	1 (1.7)
Pleural effusion	3 (5.0)	3 (5.0)	0

Race: White

Group term Preferred term	All patients N=60 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	3 (5.0)	0	3 (5.0)
Dyspnoea	2 (3.3)	1 (1.7)	1 (1.7)
Tachypnoea	2 (3.3)	2 (3.3)	0
Haemoptysis	1 (1.7)	0	1 (1.7)
Respiratory distress	1 (1.7)	0	1 (1.7)
Vascular disorders			
-Total	20 (33.3)	11 (18.3)	9 (15.0)
Hypotension	20 (33.3)	11 (18.3)	9 (15.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193c
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Asian

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (83.3)	2 (33.3)	3 (50.0)
Blood and lymphatic system disorders			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Anaemia	2 (33.3)	2 (33.3)	0
Febrile neutropenia	1 (16.7)	1 (16.7)	0
Neutropenia	1 (16.7)	0	1 (16.7)
Infections and infestations			
-Total	2 (33.3)	1 (16.7)	1 (16.7)
Gastroenteritis	1 (16.7)	1 (16.7)	0
Herpes zoster	1 (16.7)	1 (16.7)	0
Respiratory tract infection	1 (16.7)	0	1 (16.7)

Race: Asian

	All patients N=6		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	3 (50.0)	1 (16.7)	2 (33.3)
Neutrophil count decreased	2 (33.3)	0	2 (33.3)
White blood cell count decreased	2 (33.3)	0	2 (33.3)
Aspartate aminotransferase increased	1 (16.7)	1 (16.7)	0
Platelet count decreased	1 (16.7)	0	1 (16.7)
Metabolism and nutrition disorders			
-Total	2 (33.3)	2 (33.3)	0
Dehydration	1 (16.7)	1 (16.7)	0
Hyperglycaemia	1 (16.7)	1 (16.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	1 (16.7)	1 (16.7)	0
Pulmonary oedema	1 (16.7)	1 (16.7)	0
Vascular disorders			
-Total	1 (16.7)	1 (16.7)	0
Embolism	1 (16.7)	1 (16.7)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193c
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Race
Enrolled set

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	9 (100)	0	9 (100)
Blood and lymphatic system disorders			
-Total	8 (88.9)	3 (33.3)	5 (55.6)
Febrile neutropenia	6 (66.7)	5 (55.6)	1 (11.1)
Anaemia	4 (44.4)	4 (44.4)	0
Lymphopenia	2 (22.2)	0	2 (22.2)
Pancytopenia	2 (22.2)	0	2 (22.2)
Coagulopathy	1 (11.1)	1 (11.1)	0
Disseminated intravascular coagulation	1 (11.1)	1 (11.1)	0
Hypofibrinogenaemia	1 (11.1)	0	1 (11.1)

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutropenia	1 (11.1)	0	1 (11.1)
Thrombocytopenia	1 (11.1)	0	1 (11.1)
Cardiac disorders			
-Total	2 (22.2)	0	2 (22.2)
Bradycardia	1 (11.1)	0	1 (11.1)
Cardiovascular insufficiency	1 (11.1)	0	1 (11.1)
Right ventricular dysfunction	1 (11.1)	1 (11.1)	0
Sinus tachycardia	1 (11.1)	1 (11.1)	0
Ventricular tachycardia	1 (11.1)	1 (11.1)	0
Gastrointestinal disorders			
-Total	3 (33.3)	3 (33.3)	0
Abdominal pain	1 (11.1)	1 (11.1)	0
Haematochezia	1 (11.1)	1 (11.1)	0
Nausea	1 (11.1)	1 (11.1)	0
Stomatitis	1 (11.1)	1 (11.1)	0
Vomiting	1 (11.1)	1 (11.1)	0
General disorders and administration site conditions			

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (44.4)	3 (33.3)	1 (11.1)
Physical deconditioning	2 (22.2)	2 (22.2)	0
Multiple organ dysfunction syndrome	1 (11.1)	0	1 (11.1)
Non-cardiac chest pain	1 (11.1)	1 (11.1)	0
Hepatobiliary disorders			
-Total	1 (11.1)	1 (11.1)	0
Hyperbilirubinaemia	1 (11.1)	1 (11.1)	0
Immune system disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Cytokine release syndrome	2 (22.2)	1 (11.1)	1 (11.1)
Infections and infestations			
-Total	5 (55.6)	3 (33.3)	2 (22.2)
Abscess limb	1 (11.1)	1 (11.1)	0
Device related infection	1 (11.1)	1 (11.1)	0
Escherichia urinary tract infection	1 (11.1)	1 (11.1)	0
Klebsiella sepsis	1 (11.1)	0	1 (11.1)
Sepsis	1 (11.1)	0	1 (11.1)
Staphylococcal sepsis	1 (11.1)	0	1 (11.1)

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular device infection	1 (11.1)	1 (11.1)	0
Injury, poisoning and procedural complications			
-Total	3 (33.3)	2 (22.2)	1 (11.1)
Extradural haematoma	1 (11.1)	1 (11.1)	0
Procedural pain	1 (11.1)	1 (11.1)	0
Subdural haematoma	1 (11.1)	1 (11.1)	0
Transfusion related complication	1 (11.1)	0	1 (11.1)
Investigations			
-Total	7 (77.8)	1 (11.1)	6 (66.7)
White blood cell count decreased	7 (77.8)	2 (22.2)	5 (55.6)
Neutrophil count decreased	3 (33.3)	0	3 (33.3)
Platelet count decreased	3 (33.3)	1 (11.1)	2 (22.2)
Alanine aminotransferase increased	2 (22.2)	2 (22.2)	0
Lymphocyte count decreased	2 (22.2)	1 (11.1)	1 (11.1)
Aspartate aminotransferase increased	1 (11.1)	1 (11.1)	0
Blood lactate dehydrogenase increased	1 (11.1)	1 (11.1)	0

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Computerised tomogram thorax abnormal	1 (11.1)	1 (11.1)	0
Electrocardiogram qt prolonged	1 (11.1)	1 (11.1)	0
Haemoglobin decreased	1 (11.1)	1 (11.1)	0
Lipase increased	1 (11.1)	0	1 (11.1)
Transaminases increased	1 (11.1)	1 (11.1)	0
Metabolism and nutrition disorders			
-Total	4 (44.4)	3 (33.3)	1 (11.1)
Decreased appetite	1 (11.1)	1 (11.1)	0
Fluid overload	1 (11.1)	1 (11.1)	0
Hyperkalaemia	1 (11.1)	1 (11.1)	0
Hypokalaemia	1 (11.1)	0	1 (11.1)
Tumour lysis syndrome	1 (11.1)	1 (11.1)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (33.3)	3 (33.3)	0
Back pain	2 (22.2)	2 (22.2)	0
Arthralgia	1 (11.1)	1 (11.1)	0
Myopathy	1 (11.1)	1 (11.1)	0

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Myositis	1 (11.1)	1 (11.1)	0
Pain in extremity	1 (11.1)	1 (11.1)	0
Nervous system disorders			
-Total	2 (22.2)	1 (11.1)	1 (11.1)
Headache	2 (22.2)	2 (22.2)	0
Hyporesponsive to stimuli	1 (11.1)	1 (11.1)	0
Seizure	1 (11.1)	0	1 (11.1)
Psychiatric disorders			
-Total	2 (22.2)	2 (22.2)	0
Agitation	1 (11.1)	1 (11.1)	0
Mental status changes	1 (11.1)	1 (11.1)	0
Renal and urinary disorders			
-Total	2 (22.2)	2 (22.2)	0
Acute kidney injury	2 (22.2)	2 (22.2)	0
Oliguria	1 (11.1)	1 (11.1)	0
Reproductive system and breast disorders			
-Total	1 (11.1)	1 (11.1)	0

Race: Other

	All patients N=9		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Ovarian failure	1 (11.1)	1 (11.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (44.4)	2 (22.2)	2 (22.2)
Epistaxis	2 (22.2)	2 (22.2)	0
Pulmonary oedema	2 (22.2)	0	2 (22.2)
Cough	1 (11.1)	1 (11.1)	0
Dyspnoea	1 (11.1)	1 (11.1)	0
Haemoptysis	1 (11.1)	1 (11.1)	0
Hypoxia	1 (11.1)	1 (11.1)	0
Oropharyngeal pain	1 (11.1)	1 (11.1)	0
Pulmonary alveolar haemorrhage	1 (11.1)	0	1 (11.1)
Pulmonary hypertension	1 (11.1)	1 (11.1)	0
Respiratory distress	1 (11.1)	0	1 (11.1)
Respiratory failure	1 (11.1)	0	1 (11.1)
Tachypnoea	1 (11.1)	1 (11.1)	0
Skin and subcutaneous tissue disorders			
-Total	1 (11.1)	1 (11.1)	0

Race: Other

Group term Preferred term	All patients N=9 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Ecchymosis	1 (11.1)	1 (11.1)	0
Vascular disorders			
-Total	3 (33.3)	1 (11.1)	2 (22.2)
Hypotension	3 (33.3)	1 (11.1)	2 (22.2)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193d
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	28 (93.3)	5 (16.7)	23 (76.7)
Blood and lymphatic system disorders			
-Total	26 (86.7)	19 (63.3)	7 (23.3)
Febrile neutropenia	21 (70.0)	20 (66.7)	1 (3.3)
Anaemia	10 (33.3)	10 (33.3)	0
Neutropenia	5 (16.7)	2 (6.7)	3 (10.0)
Thrombocytopenia	2 (6.7)	0	2 (6.7)
Disseminated intravascular coagulation	1 (3.3)	1 (3.3)	0
Lymphopenia	1 (3.3)	1 (3.3)	0
Pancytopenia	1 (3.3)	0	1 (3.3)

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	1 (3.3)	1 (3.3)	0
Nausea	1 (3.3)	1 (3.3)	0
Vomiting	1 (3.3)	1 (3.3)	0
General disorders and administration site conditions			
-Total	3 (10.0)	2 (6.7)	1 (3.3)
Pyrexia	2 (6.7)	2 (6.7)	0
Multiple organ dysfunction syndrome	1 (3.3)	0	1 (3.3)
Immune system disorders			
-Total	7 (23.3)	4 (13.3)	3 (10.0)
Cytokine release syndrome	6 (20.0)	3 (10.0)	3 (10.0)
Hypogammaglobulinaemia	1 (3.3)	1 (3.3)	0
Infections and infestations			
-Total	3 (10.0)	3 (10.0)	0
Escherichia urinary tract infection	2 (6.7)	2 (6.7)	0
Urinary tract infection	2 (6.7)	2 (6.7)	0
Investigations			

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	21 (70.0)	2 (6.7)	19 (63.3)
White blood cell count decreased	19 (63.3)	6 (20.0)	13 (43.3)
Neutrophil count decreased	15 (50.0)	2 (6.7)	13 (43.3)
Alanine aminotransferase increased	8 (26.7)	8 (26.7)	0
Lymphocyte count decreased	7 (23.3)	4 (13.3)	3 (10.0)
Platelet count decreased	5 (16.7)	1 (3.3)	4 (13.3)
Aspartate aminotransferase increased	3 (10.0)	3 (10.0)	0
Blood bilirubin increased	1 (3.3)	1 (3.3)	0
Metabolism and nutrition disorders			
-Total	10 (33.3)	6 (20.0)	4 (13.3)
Hypokalaemia	5 (16.7)	3 (10.0)	2 (6.7)
Decreased appetite	4 (13.3)	4 (13.3)	0
Hypophosphataemia	3 (10.0)	2 (6.7)	1 (3.3)
Tumour lysis syndrome	3 (10.0)	3 (10.0)	0
Hyperglycaemia	2 (6.7)	2 (6.7)	0
Hypernatraemia	2 (6.7)	0	2 (6.7)
Nervous system disorders			

Ethnicity: Hispanic or Latino

	All patients N=30		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (6.7)	2 (6.7)	0
Headache	2 (6.7)	2 (6.7)	0
Renal and urinary disorders			
-Total	4 (13.3)	3 (10.0)	1 (3.3)
Acute kidney injury	4 (13.3)	3 (10.0)	1 (3.3)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (13.3)	1 (3.3)	3 (10.0)
Pulmonary oedema	3 (10.0)	1 (3.3)	2 (6.7)
Respiratory failure	3 (10.0)	0	3 (10.0)
Epistaxis	1 (3.3)	1 (3.3)	0
Vascular disorders			
-Total	9 (30.0)	7 (23.3)	2 (6.7)
Hypotension	9 (30.0)	7 (23.3)	2 (6.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193d
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Ethnicity
Enrolled set

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	40 (88.9)	9 (20.0)	31 (68.9)
Blood and lymphatic system disorders			
-Total	32 (71.1)	16 (35.6)	16 (35.6)
Anaemia	17 (37.8)	16 (35.6)	1 (2.2)
Febrile neutropenia	15 (33.3)	15 (33.3)	0
Thrombocytopenia	12 (26.7)	5 (11.1)	7 (15.6)
Neutropenia	11 (24.4)	2 (4.4)	9 (20.0)
Disseminated intravascular coagulation	3 (6.7)	2 (4.4)	1 (2.2)
Lymphopenia	3 (6.7)	0	3 (6.7)
Pancytopenia	3 (6.7)	1 (2.2)	2 (4.4)

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	7 (15.6)	7 (15.6)	0
Nausea	6 (13.3)	6 (13.3)	0
Vomiting	3 (6.7)	3 (6.7)	0
General disorders and administration site conditions			
-Total	11 (24.4)	8 (17.8)	3 (6.7)
Pyrexia	6 (13.3)	5 (11.1)	1 (2.2)
Multiple organ dysfunction syndrome	3 (6.7)	1 (2.2)	2 (4.4)
Pain	3 (6.7)	3 (6.7)	0
Hepatobiliary disorders			
-Total	3 (6.7)	3 (6.7)	0
Hyperbilirubinaemia	3 (6.7)	3 (6.7)	0
Immune system disorders			
-Total	15 (33.3)	7 (15.6)	8 (17.8)
Cytokine release syndrome	13 (28.9)	5 (11.1)	8 (17.8)
Hypogammaglobulinaemia	4 (8.9)	4 (8.9)	0
Investigations			

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	30 (66.7)	8 (17.8)	22 (48.9)
White blood cell count decreased	18 (40.0)	2 (4.4)	16 (35.6)
Neutrophil count decreased	14 (31.1)	1 (2.2)	13 (28.9)
Alanine aminotransferase increased	11 (24.4)	10 (22.2)	1 (2.2)
Aspartate aminotransferase increased	11 (24.4)	6 (13.3)	5 (11.1)
Platelet count decreased	11 (24.4)	2 (4.4)	9 (20.0)
Lymphocyte count decreased	8 (17.8)	3 (6.7)	5 (11.1)
Blood bilirubin increased	4 (8.9)	3 (6.7)	1 (2.2)
Metabolism and nutrition disorders			
-Total	20 (44.4)	18 (40.0)	2 (4.4)
Decreased appetite	9 (20.0)	9 (20.0)	0
Hypokalaemia	8 (17.8)	6 (13.3)	2 (4.4)
Hypophosphataemia	6 (13.3)	6 (13.3)	0
Dehydration	3 (6.7)	3 (6.7)	0
Hyperglycaemia	2 (4.4)	2 (4.4)	0
Hypernatraemia	1 (2.2)	0	1 (2.2)
Musculoskeletal and connective tissue disorders			

Ethnicity: Other

	All patients N=45		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (6.7)	3 (6.7)	0
Pain in extremity	3 (6.7)	3 (6.7)	0
Nervous system disorders			
-Total	5 (11.1)	4 (8.9)	1 (2.2)
Headache	3 (6.7)	3 (6.7)	0
Seizure	3 (6.7)	2 (4.4)	1 (2.2)
Renal and urinary disorders			
-Total	6 (13.3)	3 (6.7)	3 (6.7)
Acute kidney injury	5 (11.1)	2 (4.4)	3 (6.7)
Oliguria	3 (6.7)	3 (6.7)	0
Respiratory, thoracic and mediastinal disorders			
-Total	16 (35.6)	11 (24.4)	5 (11.1)
Hypoxia	12 (26.7)	9 (20.0)	3 (6.7)
Epistaxis	5 (11.1)	4 (8.9)	1 (2.2)
Pulmonary oedema	5 (11.1)	3 (6.7)	2 (4.4)
Dyspnoea	3 (6.7)	2 (4.4)	1 (2.2)
Tachypnoea	3 (6.7)	3 (6.7)	0

Ethnicity: Other

Group term Preferred term	All patients N=45 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory failure	1 (2.2)	0	1 (2.2)
Vascular disorders			
-Total	14 (31.1)	5 (11.1)	9 (20.0)
Hypotension	14 (31.1)	5 (11.1)	9 (20.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193e
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Primary refractory

		All patients N=8	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	1 (12.5)	7 (87.5)
Blood and lymphatic system disorders			
-Total	6 (75.0)	4 (50.0)	2 (25.0)
Anaemia	4 (50.0)	3 (37.5)	1 (12.5)
Febrile neutropenia	4 (50.0)	4 (50.0)	0
Neutropenia	2 (25.0)	0	2 (25.0)
Thrombocytopenia	2 (25.0)	1 (12.5)	1 (12.5)
Cardiac disorders			
-Total	2 (25.0)	2 (25.0)	0
Left ventricular dysfunction	2 (25.0)	2 (25.0)	0
Tachycardia	1 (12.5)	1 (12.5)	0
Gastrointestinal disorders			

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Nausea	2 (25.0)	2 (25.0)	0
Enterocolitis	1 (12.5)	1 (12.5)	0
Oral pain	1 (12.5)	1 (12.5)	0
Stomatitis	1 (12.5)	0	1 (12.5)
General disorders and administration site conditions			
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Pyrexia	3 (37.5)	2 (25.0)	1 (12.5)
Pain	2 (25.0)	2 (25.0)	0
Fatigue	1 (12.5)	1 (12.5)	0
Immune system disorders			
-Total	3 (37.5)	0	3 (37.5)
Cytokine release syndrome	3 (37.5)	0	3 (37.5)
Infections and infestations			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Cellulitis	1 (12.5)	1 (12.5)	0
Corona virus infection	1 (12.5)	1 (12.5)	0
Human polyomavirus infection	1 (12.5)	0	1 (12.5)

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Oral herpes	1 (12.5)	1 (12.5)	0
Pneumonia	1 (12.5)	0	1 (12.5)
Respiratory syncytial virus infection	1 (12.5)	1 (12.5)	0
Injury, poisoning and procedural complications			
-Total	1 (12.5)	1 (12.5)	0
Tracheal haemorrhage	1 (12.5)	1 (12.5)	0
Investigations			
-Total	6 (75.0)	2 (25.0)	4 (50.0)
Neutrophil count decreased	3 (37.5)	0	3 (37.5)
White blood cell count decreased	3 (37.5)	0	3 (37.5)
Aspartate aminotransferase increased	1 (12.5)	0	1 (12.5)
Blood bilirubin increased	1 (12.5)	1 (12.5)	0
Blood magnesium decreased	1 (12.5)	1 (12.5)	0
Metabolism and nutrition disorders			
-Total	1 (12.5)	1 (12.5)	0
Decreased appetite	1 (12.5)	1 (12.5)	0
Hypophosphataemia	1 (12.5)	1 (12.5)	0

Response status at study entry: Primary refractory

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	2 (25.0)	2 (25.0)	0
Arthralgia	1 (12.5)	1 (12.5)	0
Pain in extremity	1 (12.5)	1 (12.5)	0
Renal and urinary disorders			
-Total	2 (25.0)	0	2 (25.0)
Haematuria	2 (25.0)	1 (12.5)	1 (12.5)
Acute kidney injury	1 (12.5)	0	1 (12.5)
Cystitis haemorrhagic	1 (12.5)	0	1 (12.5)
Oliguria	1 (12.5)	1 (12.5)	0
Renal failure	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Hypoxia	3 (37.5)	2 (25.0)	1 (12.5)
Epistaxis	2 (25.0)	1 (12.5)	1 (12.5)
Aspiration	1 (12.5)	0	1 (12.5)
Dyspnoea	1 (12.5)	0	1 (12.5)

Response status at study entry: Primary refractory

Group term Preferred term	All patients N=8 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Haemoptysis	1 (12.5)	0	1 (12.5)
Interstitial lung disease	1 (12.5)	0	1 (12.5)
Pharyngeal lesion	1 (12.5)	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	1 (12.5)
Respiratory failure	1 (12.5)	0	1 (12.5)
Vascular disorders			
-Total	5 (62.5)	2 (25.0)	3 (37.5)
Hypotension	5 (62.5)	2 (25.0)	3 (37.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193e
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Response status at study entry
Enrolled set

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	60 (89.6)	13 (19.4)	47 (70.1)
Blood and lymphatic system disorders			
-Total	52 (77.6)	31 (46.3)	21 (31.3)
Febrile neutropenia	32 (47.8)	31 (46.3)	1 (1.5)
Anaemia	23 (34.3)	23 (34.3)	0
Neutropenia	14 (20.9)	4 (6.0)	10 (14.9)
Thrombocytopenia	12 (17.9)	4 (6.0)	8 (11.9)
Disseminated intravascular coagulation	4 (6.0)	3 (4.5)	1 (1.5)
Lymphopenia	4 (6.0)	1 (1.5)	3 (4.5)
Pancytopenia	4 (6.0)	1 (1.5)	3 (4.5)
Cardiac disorders			

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (3.0)	2 (3.0)	0
Left ventricular dysfunction	1 (1.5)	1 (1.5)	0
Tachycardia	1 (1.5)	1 (1.5)	0
Gastrointestinal disorders			
-Total	8 (11.9)	8 (11.9)	0
Nausea	5 (7.5)	5 (7.5)	0
Vomiting	4 (6.0)	4 (6.0)	0
Stomatitis	2 (3.0)	2 (3.0)	0
General disorders and administration site conditions			
-Total	10 (14.9)	7 (10.4)	3 (4.5)
Pyrexia	5 (7.5)	5 (7.5)	0
Multiple organ dysfunction syndrome	4 (6.0)	1 (1.5)	3 (4.5)
Fatigue	1 (1.5)	1 (1.5)	0
Pain	1 (1.5)	1 (1.5)	0
Immune system disorders			
-Total	19 (28.4)	11 (16.4)	8 (11.9)
Cytokine release syndrome	16 (23.9)	8 (11.9)	8 (11.9)
Hypogammaglobulinaemia	5 (7.5)	5 (7.5)	0

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	1 (1.5)	1 (1.5)	0
Pneumonia	1 (1.5)	1 (1.5)	0
Investigations			
-Total	46 (68.7)	9 (13.4)	37 (55.2)
White blood cell count decreased	34 (50.7)	8 (11.9)	26 (38.8)
Neutrophil count decreased	26 (38.8)	3 (4.5)	23 (34.3)
Alanine aminotransferase increased	19 (28.4)	18 (26.9)	1 (1.5)
Platelet count decreased	16 (23.9)	3 (4.5)	13 (19.4)
Lymphocyte count decreased	15 (22.4)	7 (10.4)	8 (11.9)
Aspartate aminotransferase increased	13 (19.4)	9 (13.4)	4 (6.0)
Blood bilirubin increased	4 (6.0)	3 (4.5)	1 (1.5)
Metabolism and nutrition disorders			
-Total	24 (35.8)	19 (28.4)	5 (7.5)
Hypokalaemia	13 (19.4)	9 (13.4)	4 (6.0)
Decreased appetite	12 (17.9)	12 (17.9)	0
Hypophosphataemia	8 (11.9)	7 (10.4)	1 (1.5)
Hyperglycaemia	4 (6.0)	4 (6.0)	0

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Musculoskeletal and connective tissue disorders			
-Total	2 (3.0)	2 (3.0)	0
Pain in extremity	2 (3.0)	2 (3.0)	0
Arthralgia	1 (1.5)	1 (1.5)	0
Nervous system disorders			
-Total	5 (7.5)	5 (7.5)	0
Headache	5 (7.5)	5 (7.5)	0
Renal and urinary disorders			
-Total	9 (13.4)	6 (9.0)	3 (4.5)
Acute kidney injury	8 (11.9)	5 (7.5)	3 (4.5)
Oliguria	2 (3.0)	2 (3.0)	0
Haematuria	1 (1.5)	1 (1.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	15 (22.4)	9 (13.4)	6 (9.0)
Hypoxia	9 (13.4)	7 (10.4)	2 (3.0)
Pulmonary oedema	7 (10.4)	4 (6.0)	3 (4.5)
Epistaxis	4 (6.0)	4 (6.0)	0

Response status at study entry: Relapsed disease

	All patients N=67		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	3 (4.5)	0	3 (4.5)
Dyspnoea	2 (3.0)	2 (3.0)	0
Haemoptysis	1 (1.5)	1 (1.5)	0
Vascular disorders			
-Total	18 (26.9)	10 (14.9)	8 (11.9)
Hypotension	18 (26.9)	10 (14.9)	8 (11.9)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193f
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Positive

		All patients N=2	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	2 (100)	1 (50.0)	1 (50.0)
Blood and lymphatic system disorders			
-Total	1 (50.0)	0	1 (50.0)
Eosinophilia	1 (50.0)	1 (50.0)	0
Neutropenia	1 (50.0)	0	1 (50.0)
Cardiac disorders			
-Total	1 (50.0)	1 (50.0)	0
Sinus tachycardia	1 (50.0)	1 (50.0)	0
Infections and infestations			
-Total	1 (50.0)	1 (50.0)	0
Cellulitis of male external genital organ	1 (50.0)	1 (50.0)	0

Philadelphia chromosome/BCR-ABL: Positive

Group term Preferred term	All patients N=2 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Urinary tract infection	1 (50.0)	1 (50.0)	0
Metabolism and nutrition disorders			
-Total	1 (50.0)	1 (50.0)	0
Hyperglycaemia	1 (50.0)	1 (50.0)	0
Vascular disorders			
-Total	1 (50.0)	1 (50.0)	0
Hypotension	1 (50.0)	1 (50.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193f
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Philadelphia chromosome/BCR-ABL
Enrolled set

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	66 (90.4)	13 (17.8)	53 (72.6)
Blood and lymphatic system disorders			
-Total	57 (78.1)	35 (47.9)	22 (30.1)
Febrile neutropenia	36 (49.3)	35 (47.9)	1 (1.4)
Anaemia	27 (37.0)	26 (35.6)	1 (1.4)
Neutropenia	15 (20.5)	4 (5.5)	11 (15.1)
Thrombocytopenia	14 (19.2)	5 (6.8)	9 (12.3)
Disseminated intravascular coagulation	4 (5.5)	3 (4.1)	1 (1.4)
Lymphopenia	4 (5.5)	1 (1.4)	3 (4.1)
Pancytopenia	4 (5.5)	1 (1.4)	3 (4.1)
Cardiac disorders			

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (1.4)	1 (1.4)	0
Sinus tachycardia	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	8 (11.0)	8 (11.0)	0
Nausea	7 (9.6)	7 (9.6)	0
Vomiting	4 (5.5)	4 (5.5)	0
General disorders and administration site conditions			
-Total	12 (16.4)	8 (11.0)	4 (5.5)
Pyrexia	8 (11.0)	7 (9.6)	1 (1.4)
Multiple organ dysfunction syndrome	4 (5.5)	1 (1.4)	3 (4.1)
Immune system disorders			
-Total	22 (30.1)	11 (15.1)	11 (15.1)
Cytokine release syndrome	19 (26.0)	8 (11.0)	11 (15.1)
Hypogammaglobulinaemia	5 (6.8)	5 (6.8)	0
Infections and infestations			
-Total	1 (1.4)	1 (1.4)	0
Urinary tract infection	1 (1.4)	1 (1.4)	0
Investigations			

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	51 (69.9)	10 (13.7)	41 (56.2)
White blood cell count decreased	37 (50.7)	8 (11.0)	29 (39.7)
Neutrophil count decreased	29 (39.7)	3 (4.1)	26 (35.6)
Alanine aminotransferase increased	19 (26.0)	18 (24.7)	1 (1.4)
Platelet count decreased	16 (21.9)	3 (4.1)	13 (17.8)
Lymphocyte count decreased	15 (20.5)	7 (9.6)	8 (11.0)
Aspartate aminotransferase increased	14 (19.2)	9 (12.3)	5 (6.8)
Blood bilirubin increased	5 (6.8)	4 (5.5)	1 (1.4)
Metabolism and nutrition disorders			
-Total	24 (32.9)	19 (26.0)	5 (6.8)
Decreased appetite	13 (17.8)	13 (17.8)	0
Hypokalaemia	13 (17.8)	9 (12.3)	4 (5.5)
Hypophosphataemia	9 (12.3)	8 (11.0)	1 (1.4)
Hyperglycaemia	3 (4.1)	3 (4.1)	0
Nervous system disorders			
-Total	5 (6.8)	5 (6.8)	0
Headache	5 (6.8)	5 (6.8)	0
Renal and urinary disorders			

Philadelphia chromosome/BCR-ABL: Negative

	All patients N=73		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (12.3)	5 (6.8)	4 (5.5)
Acute kidney injury	9 (12.3)	5 (6.8)	4 (5.5)
Respiratory, thoracic and mediastinal disorders			
-Total	19 (26.0)	11 (15.1)	8 (11.0)
Hypoxia	12 (16.4)	9 (12.3)	3 (4.1)
Pulmonary oedema	8 (11.0)	4 (5.5)	4 (5.5)
Epistaxis	6 (8.2)	5 (6.8)	1 (1.4)
Respiratory failure	4 (5.5)	0	4 (5.5)
Vascular disorders			
-Total	22 (30.1)	11 (15.1)	11 (15.1)
Hypotension	22 (30.1)	11 (15.1)	11 (15.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193g
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: Yes

		All patients N=3	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (100)	0	3 (100)
Blood and lymphatic system disorders			
-Total	3 (100)	1 (33.3)	2 (66.7)
Anaemia	2 (66.7)	2 (66.7)	0
Febrile neutropenia	2 (66.7)	2 (66.7)	0
Leukopenia	1 (33.3)	0	1 (33.3)
Lymphopenia	1 (33.3)	0	1 (33.3)
Neutropenia	1 (33.3)	0	1 (33.3)
Thrombocytopenia	1 (33.3)	0	1 (33.3)
Cardiac disorders			
-Total	1 (33.3)	1 (33.3)	0
Left ventricular dysfunction	1 (33.3)	1 (33.3)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	1 (33.3)	1 (33.3)	0
Gastrointestinal disorders			
-Total	2 (66.7)	2 (66.7)	0
Dysphagia	1 (33.3)	1 (33.3)	0
Nausea	1 (33.3)	1 (33.3)	0
General disorders and administration site conditions			
-Total	2 (66.7)	2 (66.7)	0
Face oedema	1 (33.3)	1 (33.3)	0
Localised oedema	1 (33.3)	1 (33.3)	0
Multiple organ dysfunction syndrome	1 (33.3)	1 (33.3)	0
Oedema peripheral	1 (33.3)	1 (33.3)	0
Pyrexia	1 (33.3)	1 (33.3)	0
Hepatobiliary disorders			
-Total	1 (33.3)	1 (33.3)	0
Hyperbilirubinaemia	1 (33.3)	1 (33.3)	0
Immune system disorders			
-Total	2 (66.7)	0	2 (66.7)
Cytokine release syndrome	2 (66.7)	0	2 (66.7)

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	1 (33.3)	1 (33.3)	0
Infections and infestations			
-Total	1 (33.3)	1 (33.3)	0
Escherichia bacteraemia	1 (33.3)	1 (33.3)	0
Injury, poisoning and procedural complications			
-Total	1 (33.3)	1 (33.3)	0
Tracheal haemorrhage	1 (33.3)	1 (33.3)	0
Investigations			
-Total	3 (100)	0	3 (100)
Alanine aminotransferase increased	2 (66.7)	2 (66.7)	0
Aspartate aminotransferase increased	2 (66.7)	0	2 (66.7)
Blood creatinine increased	1 (33.3)	1 (33.3)	0
Blood fibrinogen decreased	1 (33.3)	0	1 (33.3)
Blood urea increased	1 (33.3)	1 (33.3)	0
Neutrophil count decreased	1 (33.3)	0	1 (33.3)
Platelet count decreased	1 (33.3)	1 (33.3)	0
Protein total decreased	1 (33.3)	1 (33.3)	0

Mixed-lineage leukemia rearrangement: Yes

	All patients N=3		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	1 (33.3)	0	1 (33.3)
Metabolism and nutrition disorders			
-Total	2 (66.7)	2 (66.7)	0
Acidosis	1 (33.3)	1 (33.3)	0
Decreased appetite	1 (33.3)	1 (33.3)	0
Hypokalaemia	1 (33.3)	1 (33.3)	0
Hypophosphataemia	1 (33.3)	1 (33.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (33.3)	1 (33.3)	0
Bone pain	1 (33.3)	1 (33.3)	0
Renal and urinary disorders			
-Total	2 (66.7)	1 (33.3)	1 (33.3)
Acute kidney injury	1 (33.3)	0	1 (33.3)
Haematuria	1 (33.3)	1 (33.3)	0
Renal impairment	1 (33.3)	1 (33.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (66.7)	0	2 (66.7)

Mixed-lineage leukemia rearrangement: Yes

Group term Preferred term	All patients N=3 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypoxia	2 (66.7)	1 (33.3)	1 (33.3)
Pulmonary oedema	2 (66.7)	1 (33.3)	1 (33.3)
Dyspnoea	1 (33.3)	0	1 (33.3)
Interstitial lung disease	1 (33.3)	0	1 (33.3)
Pleural effusion	1 (33.3)	1 (33.3)	0
Respiratory distress	1 (33.3)	0	1 (33.3)
Tachypnoea	1 (33.3)	1 (33.3)	0
Vascular disorders			
-Total	2 (66.7)	0	2 (66.7)
Hypotension	2 (66.7)	0	2 (66.7)
Capillary leak syndrome	1 (33.3)	0	1 (33.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193g
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and MLL rearrangement
Enrolled set

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	65 (90.3)	14 (19.4)	51 (70.8)
Blood and lymphatic system disorders			
-Total	55 (76.4)	34 (47.2)	21 (29.2)
Febrile neutropenia	34 (47.2)	33 (45.8)	1 (1.4)
Anaemia	25 (34.7)	24 (33.3)	1 (1.4)
Neutropenia	15 (20.8)	4 (5.6)	11 (15.3)
Thrombocytopenia	13 (18.1)	5 (6.9)	8 (11.1)
Disseminated intravascular coagulation	4 (5.6)	3 (4.2)	1 (1.4)
Pancytopenia	4 (5.6)	1 (1.4)	3 (4.2)
Lymphopenia	3 (4.2)	1 (1.4)	2 (2.8)
Cardiac disorders			

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (4.2)	3 (4.2)	0
Left ventricular dysfunction	2 (2.8)	2 (2.8)	0
Tachycardia	1 (1.4)	1 (1.4)	0
Gastrointestinal disorders			
-Total	7 (9.7)	7 (9.7)	0
Nausea	6 (8.3)	6 (8.3)	0
Vomiting	4 (5.6)	4 (5.6)	0
General disorders and administration site conditions			
-Total	10 (13.9)	6 (8.3)	4 (5.6)
Pyrexia	7 (9.7)	6 (8.3)	1 (1.4)
Multiple organ dysfunction syndrome	3 (4.2)	0	3 (4.2)
Hepatobiliary disorders			
-Total	2 (2.8)	2 (2.8)	0
Hyperbilirubinaemia	2 (2.8)	2 (2.8)	0
Immune system disorders			
-Total	20 (27.8)	11 (15.3)	9 (12.5)
Cytokine release syndrome	17 (23.6)	8 (11.1)	9 (12.5)
Hypogammaglobulinaemia	4 (5.6)	4 (5.6)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	1 (1.4)	1 (1.4)	0
Escherichia bacteraemia	1 (1.4)	1 (1.4)	0
Investigations			
-Total	49 (68.1)	11 (15.3)	38 (52.8)
White blood cell count decreased	36 (50.0)	8 (11.1)	28 (38.9)
Neutrophil count decreased	28 (38.9)	3 (4.2)	25 (34.7)
Alanine aminotransferase increased	17 (23.6)	16 (22.2)	1 (1.4)
Lymphocyte count decreased	15 (20.8)	7 (9.7)	8 (11.1)
Platelet count decreased	15 (20.8)	2 (2.8)	13 (18.1)
Aspartate aminotransferase increased	12 (16.7)	9 (12.5)	3 (4.2)
Blood bilirubin increased	5 (6.9)	4 (5.6)	1 (1.4)
Blood fibrinogen decreased	2 (2.8)	2 (2.8)	0
Blood creatinine increased	1 (1.4)	1 (1.4)	0
Metabolism and nutrition disorders			
-Total	23 (31.9)	18 (25.0)	5 (6.9)
Decreased appetite	12 (16.7)	12 (16.7)	0
Hypokalaemia	12 (16.7)	8 (11.1)	4 (5.6)

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypophosphataemia	8 (11.1)	7 (9.7)	1 (1.4)
Hyperglycaemia	4 (5.6)	4 (5.6)	0
Nervous system disorders			
-Total	5 (6.9)	5 (6.9)	0
Headache	5 (6.9)	5 (6.9)	0
Renal and urinary disorders			
-Total	10 (13.9)	6 (8.3)	4 (5.6)
Acute kidney injury	8 (11.1)	5 (6.9)	3 (4.2)
Haematuria	2 (2.8)	1 (1.4)	1 (1.4)
Respiratory, thoracic and mediastinal disorders			
-Total	18 (25.0)	11 (15.3)	7 (9.7)
Hypoxia	10 (13.9)	8 (11.1)	2 (2.8)
Epistaxis	6 (8.3)	5 (6.9)	1 (1.4)
Pulmonary oedema	6 (8.3)	3 (4.2)	3 (4.2)
Respiratory failure	4 (5.6)	0	4 (5.6)
Dyspnoea	2 (2.8)	2 (2.8)	0
Pleural effusion	2 (2.8)	2 (2.8)	0
Tachypnoea	2 (2.8)	2 (2.8)	0

Mixed-lineage leukemia rearrangement: No

	All patients N=72		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory distress	1 (1.4)	0	1 (1.4)
Vascular disorders			
-Total	21 (29.2)	12 (16.7)	9 (12.5)
Hypotension	21 (29.2)	12 (16.7)	9 (12.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193h
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: Yes

	All patients N=1		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	1 (100)	1 (100)	0
Blood and lymphatic system disorders			
-Total	1 (100)	1 (100)	0
Anaemia	1 (100)	1 (100)	0
Febrile neutropenia	1 (100)	1 (100)	0
Investigations			
-Total	1 (100)	1 (100)	0
Neutrophil count decreased	1 (100)	1 (100)	0
Platelet count decreased	1 (100)	1 (100)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and

accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193h
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Hypodiploidy
Enrolled set

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	67 (90.5)	13 (17.6)	54 (73.0)
Blood and lymphatic system disorders			
-Total	57 (77.0)	34 (45.9)	23 (31.1)
Febrile neutropenia	35 (47.3)	34 (45.9)	1 (1.4)
Anaemia	26 (35.1)	25 (33.8)	1 (1.4)
Neutropenia	16 (21.6)	4 (5.4)	12 (16.2)
Thrombocytopenia	14 (18.9)	5 (6.8)	9 (12.2)
Disseminated intravascular coagulation	4 (5.4)	3 (4.1)	1 (1.4)
Lymphopenia	4 (5.4)	1 (1.4)	3 (4.1)
Pancytopenia	4 (5.4)	1 (1.4)	3 (4.1)

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	8 (10.8)	8 (10.8)	0
Nausea	7 (9.5)	7 (9.5)	0
Vomiting	4 (5.4)	4 (5.4)	0
General disorders and administration site conditions			
-Total	12 (16.2)	8 (10.8)	4 (5.4)
Pyrexia	8 (10.8)	7 (9.5)	1 (1.4)
Multiple organ dysfunction syndrome	4 (5.4)	1 (1.4)	3 (4.1)
Immune system disorders			
-Total	22 (29.7)	11 (14.9)	11 (14.9)
Cytokine release syndrome	19 (25.7)	8 (10.8)	11 (14.9)
Hypogammaglobulinaemia	5 (6.8)	5 (6.8)	0
Investigations			
-Total	50 (67.6)	9 (12.2)	41 (55.4)
White blood cell count decreased	37 (50.0)	8 (10.8)	29 (39.2)
Neutrophil count decreased	28 (37.8)	2 (2.7)	26 (35.1)
Alanine aminotransferase increased	19 (25.7)	18 (24.3)	1 (1.4)

Hypodiploidy: No

	All patients N=74		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	15 (20.3)	7 (9.5)	8 (10.8)
Platelet count decreased	15 (20.3)	2 (2.7)	13 (17.6)
Aspartate aminotransferase increased	14 (18.9)	9 (12.2)	5 (6.8)
Blood bilirubin increased	5 (6.8)	4 (5.4)	1 (1.4)
Metabolism and nutrition disorders			
-Total	25 (33.8)	20 (27.0)	5 (6.8)
Decreased appetite	13 (17.6)	13 (17.6)	0
Hypokalaemia	13 (17.6)	9 (12.2)	4 (5.4)
Hypophosphataemia	9 (12.2)	8 (10.8)	1 (1.4)
Hyperglycaemia	4 (5.4)	4 (5.4)	0
Nervous system disorders			
-Total	5 (6.8)	5 (6.8)	0
Headache	5 (6.8)	5 (6.8)	0
Renal and urinary disorders			
-Total	9 (12.2)	5 (6.8)	4 (5.4)
Acute kidney injury	9 (12.2)	5 (6.8)	4 (5.4)
Respiratory, thoracic and mediastinal disorders			

Hypodiploidy: No

Group term Preferred term	All patients N=74 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	19 (25.7)	11 (14.9)	8 (10.8)
Hypoxia	12 (16.2)	9 (12.2)	3 (4.1)
Pulmonary oedema	8 (10.8)	4 (5.4)	4 (5.4)
Epistaxis	6 (8.1)	5 (6.8)	1 (1.4)
Respiratory failure	4 (5.4)	0	4 (5.4)
Vascular disorders			
-Total	23 (31.1)	12 (16.2)	11 (14.9)
Hypotension	23 (31.1)	12 (16.2)	11 (14.9)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193i
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	4 (100)	1 (25.0)	3 (75.0)
Blood and lymphatic system disorders			
-Total	3 (75.0)	1 (25.0)	2 (50.0)
Febrile neutropenia	3 (75.0)	3 (75.0)	0
Neutropenia	2 (50.0)	0	2 (50.0)
Anaemia	1 (25.0)	1 (25.0)	0
Gastrointestinal disorders			
-Total	1 (25.0)	1 (25.0)	0
Colitis	1 (25.0)	1 (25.0)	0
General disorders and administration site conditions			

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (25.0)	1 (25.0)	0
Cyst	1 (25.0)	1 (25.0)	0
Hepatobiliary disorders			
-Total	1 (25.0)	1 (25.0)	0
Cholecystitis	1 (25.0)	1 (25.0)	0
Immune system disorders			
-Total	1 (25.0)	1 (25.0)	0
Cytokine release syndrome	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	2 (50.0)	2 (50.0)	0
Bacteraemia	1 (25.0)	1 (25.0)	0
Gastroenteritis	1 (25.0)	1 (25.0)	0
Herpes zoster	1 (25.0)	1 (25.0)	0
Streptococcal bacteraemia	1 (25.0)	1 (25.0)	0
Investigations			
-Total	3 (75.0)	0	3 (75.0)
Alanine aminotransferase increased	2 (50.0)	2 (50.0)	0
Lymphocyte count decreased	2 (50.0)	1 (25.0)	1 (25.0)

BCR-ABL1-like: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Neutrophil count decreased	2 (50.0)	0	2 (50.0)
White blood cell count decreased	2 (50.0)	1 (25.0)	1 (25.0)
Aspartate aminotransferase increased	1 (25.0)	1 (25.0)	0
Metabolism and nutrition disorders			
-Total	4 (100)	4 (100)	0
Decreased appetite	1 (25.0)	1 (25.0)	0
Dehydration	1 (25.0)	1 (25.0)	0
Hyperglycaemia	1 (25.0)	1 (25.0)	0
Hypokalaemia	1 (25.0)	1 (25.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (50.0)	1 (25.0)	1 (25.0)
Idiopathic pneumonia syndrome	1 (25.0)	0	1 (25.0)
Pulmonary oedema	1 (25.0)	1 (25.0)	0
Vascular disorders			
-Total	1 (25.0)	0	1 (25.0)
Hypotension	1 (25.0)	0	1 (25.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193i
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and BCR-ABL1-like
Enrolled set

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	64 (90.1)	13 (18.3)	51 (71.8)
Blood and lymphatic system disorders			
-Total	55 (77.5)	34 (47.9)	21 (29.6)
Febrile neutropenia	33 (46.5)	32 (45.1)	1 (1.4)
Anaemia	26 (36.6)	25 (35.2)	1 (1.4)
Neutropenia	14 (19.7)	4 (5.6)	10 (14.1)
Thrombocytopenia	14 (19.7)	5 (7.0)	9 (12.7)
Disseminated intravascular coagulation	4 (5.6)	3 (4.2)	1 (1.4)
Lymphopenia	4 (5.6)	1 (1.4)	3 (4.2)
Pancytopenia	4 (5.6)	1 (1.4)	3 (4.2)

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	10 (14.1)	10 (14.1)	0
Nausea	7 (9.9)	7 (9.9)	0
Vomiting	4 (5.6)	4 (5.6)	0
Colitis	2 (2.8)	2 (2.8)	0
General disorders and administration site conditions			
-Total	12 (16.9)	8 (11.3)	4 (5.6)
Pyrexia	8 (11.3)	7 (9.9)	1 (1.4)
Multiple organ dysfunction syndrome	4 (5.6)	1 (1.4)	3 (4.2)
Immune system disorders			
-Total	21 (29.6)	10 (14.1)	11 (15.5)
Cytokine release syndrome	18 (25.4)	7 (9.9)	11 (15.5)
Hypogammaglobulinaemia	5 (7.0)	5 (7.0)	0
Investigations			
-Total	48 (67.6)	10 (14.1)	38 (53.5)
White blood cell count decreased	35 (49.3)	7 (9.9)	28 (39.4)
Neutrophil count decreased	27 (38.0)	3 (4.2)	24 (33.8)

BCR-ABL1-like: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	17 (23.9)	16 (22.5)	1 (1.4)
Platelet count decreased	16 (22.5)	3 (4.2)	13 (18.3)
Aspartate aminotransferase increased	13 (18.3)	8 (11.3)	5 (7.0)
Lymphocyte count decreased	13 (18.3)	6 (8.5)	7 (9.9)
Blood bilirubin increased	5 (7.0)	4 (5.6)	1 (1.4)
Metabolism and nutrition disorders			
-Total	24 (33.8)	19 (26.8)	5 (7.0)
Decreased appetite	12 (16.9)	12 (16.9)	0
Hypokalaemia	12 (16.9)	8 (11.3)	4 (5.6)
Hypophosphataemia	9 (12.7)	8 (11.3)	1 (1.4)
Hyperglycaemia	3 (4.2)	3 (4.2)	0
Dehydration	2 (2.8)	2 (2.8)	0
Nervous system disorders			
-Total	5 (7.0)	5 (7.0)	0
Headache	5 (7.0)	5 (7.0)	0
Renal and urinary disorders			
-Total	9 (12.7)	5 (7.0)	4 (5.6)

BCR-ABL1-like: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Acute kidney injury	9 (12.7)	5 (7.0)	4 (5.6)
Respiratory, thoracic and mediastinal disorders			
-Total	18 (25.4)	10 (14.1)	8 (11.3)
Hypoxia	12 (16.9)	9 (12.7)	3 (4.2)
Pulmonary oedema	7 (9.9)	3 (4.2)	4 (5.6)
Epistaxis	6 (8.5)	5 (7.0)	1 (1.4)
Respiratory failure	4 (5.6)	0	4 (5.6)
Vascular disorders			
-Total	22 (31.0)	12 (16.9)	10 (14.1)
Hypotension	22 (31.0)	12 (16.9)	10 (14.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193j
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (86.4)	3 (13.6)	16 (72.7)
Blood and lymphatic system disorders			
-Total	17 (77.3)	8 (36.4)	9 (40.9)
Febrile neutropenia	11 (50.0)	11 (50.0)	0
Neutropenia	7 (31.8)	2 (9.1)	5 (22.7)
Anaemia	6 (27.3)	6 (27.3)	0
Lymphopenia	2 (9.1)	0	2 (9.1)
Pancytopenia	2 (9.1)	1 (4.5)	1 (4.5)
Thrombocytopenia	2 (9.1)	0	2 (9.1)
Disseminated intravascular coagulation	1 (4.5)	1 (4.5)	0
Gastrointestinal disorders			

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (27.3)	6 (27.3)	0
Diarrhoea	2 (9.1)	2 (9.1)	0
Nausea	2 (9.1)	2 (9.1)	0
Stomatitis	2 (9.1)	2 (9.1)	0
Vomiting	2 (9.1)	2 (9.1)	0
General disorders and administration site conditions			
-Total	3 (13.6)	3 (13.6)	0
Pyrexia	2 (9.1)	2 (9.1)	0
Multiple organ dysfunction syndrome	1 (4.5)	1 (4.5)	0
Hepatobiliary disorders			
-Total	2 (9.1)	2 (9.1)	0
Hyperbilirubinaemia	2 (9.1)	2 (9.1)	0
Immune system disorders			
-Total	9 (40.9)	4 (18.2)	5 (22.7)
Cytokine release syndrome	8 (36.4)	3 (13.6)	5 (22.7)
Hypogammaglobulinaemia	3 (13.6)	3 (13.6)	0
Investigations			
-Total	15 (68.2)	3 (13.6)	12 (54.5)

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
White blood cell count decreased	11 (50.0)	0	11 (50.0)
Neutrophil count decreased	8 (36.4)	1 (4.5)	7 (31.8)
Alanine aminotransferase increased	6 (27.3)	6 (27.3)	0
Platelet count decreased	5 (22.7)	0	5 (22.7)
Lymphocyte count decreased	4 (18.2)	3 (13.6)	1 (4.5)
Aspartate aminotransferase increased	3 (13.6)	1 (4.5)	2 (9.1)
Blood creatinine increased	2 (9.1)	2 (9.1)	0
Blood fibrinogen decreased	2 (9.1)	1 (4.5)	1 (4.5)
Blood bilirubin increased	1 (4.5)	1 (4.5)	0
Metabolism and nutrition disorders			
-Total	12 (54.5)	9 (40.9)	3 (13.6)
Decreased appetite	4 (18.2)	4 (18.2)	0
Hypokalaemia	4 (18.2)	2 (9.1)	2 (9.1)
Dehydration	3 (13.6)	3 (13.6)	0
Hypophosphataemia	3 (13.6)	3 (13.6)	0
Hypernatraemia	2 (9.1)	0	2 (9.1)
Hyperglycaemia	1 (4.5)	1 (4.5)	0
Nervous system disorders			

Complex karyotypes II (>=5 unrelated abnormalities) : Yes

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.5)	1 (4.5)	0
Headache	1 (4.5)	1 (4.5)	0
Renal and urinary disorders			
-Total	4 (18.2)	1 (4.5)	3 (13.6)
Acute kidney injury	4 (18.2)	1 (4.5)	3 (13.6)
Respiratory, thoracic and mediastinal disorders			
-Total	7 (31.8)	4 (18.2)	3 (13.6)
Hypoxia	4 (18.2)	2 (9.1)	2 (9.1)
Pulmonary oedema	4 (18.2)	3 (13.6)	1 (4.5)
Epistaxis	2 (9.1)	2 (9.1)	0
Respiratory failure	1 (4.5)	0	1 (4.5)
Vascular disorders			
-Total	9 (40.9)	4 (18.2)	5 (22.7)
Hypotension	9 (40.9)	4 (18.2)	5 (22.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.

- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193j
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Complex Karyotypes
Enrolled set

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	49 (92.5)	11 (20.8)	38 (71.7)
Blood and lymphatic system disorders			
-Total	41 (77.4)	27 (50.9)	14 (26.4)
Febrile neutropenia	25 (47.2)	24 (45.3)	1 (1.9)
Anaemia	21 (39.6)	20 (37.7)	1 (1.9)
Thrombocytopenia	12 (22.6)	5 (9.4)	7 (13.2)
Neutropenia	9 (17.0)	2 (3.8)	7 (13.2)
Disseminated intravascular coagulation	3 (5.7)	2 (3.8)	1 (1.9)
Lymphopenia	2 (3.8)	1 (1.9)	1 (1.9)
Pancytopenia	2 (3.8)	0	2 (3.8)
Cardiac disorders			

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (5.7)	3 (5.7)	0
Left ventricular dysfunction	3 (5.7)	3 (5.7)	0
Gastrointestinal disorders			
-Total	8 (15.1)	7 (13.2)	1 (1.9)
Nausea	5 (9.4)	5 (9.4)	0
Colitis	3 (5.7)	3 (5.7)	0
Vomiting	2 (3.8)	2 (3.8)	0
Stomatitis	1 (1.9)	0	1 (1.9)
General disorders and administration site conditions			
-Total	9 (17.0)	5 (9.4)	4 (7.5)
Pyrexia	6 (11.3)	5 (9.4)	1 (1.9)
Multiple organ dysfunction syndrome	3 (5.7)	0	3 (5.7)
Hepatobiliary disorders			
-Total	1 (1.9)	1 (1.9)	0
Hyperbilirubinaemia	1 (1.9)	1 (1.9)	0
Immune system disorders			
-Total	13 (24.5)	7 (13.2)	6 (11.3)
Cytokine release syndrome	11 (20.8)	5 (9.4)	6 (11.3)

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypogammaglobulinaemia	2 (3.8)	2 (3.8)	0
Investigations			
-Total	37 (69.8)	8 (15.1)	29 (54.7)
White blood cell count decreased	26 (49.1)	8 (15.1)	18 (34.0)
Neutrophil count decreased	21 (39.6)	2 (3.8)	19 (35.8)
Alanine aminotransferase increased	13 (24.5)	12 (22.6)	1 (1.9)
Aspartate aminotransferase increased	11 (20.8)	8 (15.1)	3 (5.7)
Lymphocyte count decreased	11 (20.8)	4 (7.5)	7 (13.2)
Platelet count decreased	11 (20.8)	3 (5.7)	8 (15.1)
Blood bilirubin increased	4 (7.5)	3 (5.7)	1 (1.9)
Blood fibrinogen decreased	1 (1.9)	1 (1.9)	0
Metabolism and nutrition disorders			
-Total	18 (34.0)	15 (28.3)	3 (5.7)
Decreased appetite	9 (17.0)	9 (17.0)	0
Hypokalaemia	9 (17.0)	7 (13.2)	2 (3.8)
Hypophosphataemia	6 (11.3)	5 (9.4)	1 (1.9)
Hyperglycaemia	3 (5.7)	3 (5.7)	0
Tumour lysis syndrome	3 (5.7)	3 (5.7)	0

Complex karyotypes II (>=5 unrelated abnormalities) : No

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	1 (1.9)	0	1 (1.9)
Musculoskeletal and connective tissue disorders			
-Total	3 (5.7)	3 (5.7)	0
Pain in extremity	3 (5.7)	3 (5.7)	0
Nervous system disorders			
-Total	4 (7.5)	4 (7.5)	0
Headache	4 (7.5)	4 (7.5)	0
Renal and urinary disorders			
-Total	7 (13.2)	5 (9.4)	2 (3.8)
Acute kidney injury	5 (9.4)	4 (7.5)	1 (1.9)
Haematuria	3 (5.7)	2 (3.8)	1 (1.9)
Respiratory, thoracic and mediastinal disorders			
-Total	12 (22.6)	7 (13.2)	5 (9.4)
Hypoxia	8 (15.1)	7 (13.2)	1 (1.9)
Epistaxis	4 (7.5)	3 (5.7)	1 (1.9)
Pulmonary oedema	4 (7.5)	1 (1.9)	3 (5.7)
Respiratory failure	3 (5.7)	0	3 (5.7)

Complex karyotypes II (>=5 unrelated abnormalities) : No

Group term Preferred term	All patients N=53 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Vascular disorders			
-Total	14 (26.4)	8 (15.1)	6 (11.3)
Hypotension	14 (26.4)	8 (15.1)	6 (11.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193k
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Region
Enrolled set

Region: US

	All patients N=75		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	68 (90.7)	14 (18.7)	54 (72.0)
Blood and lymphatic system disorders			
-Total	58 (77.3)	35 (46.7)	23 (30.7)
Febrile neutropenia	36 (48.0)	35 (46.7)	1 (1.3)
Anaemia	27 (36.0)	26 (34.7)	1 (1.3)
Neutropenia	16 (21.3)	4 (5.3)	12 (16.0)
Thrombocytopenia	14 (18.7)	5 (6.7)	9 (12.0)
Disseminated intravascular coagulation	4 (5.3)	3 (4.0)	1 (1.3)
Lymphopenia	4 (5.3)	1 (1.3)	3 (4.0)
Pancytopenia	4 (5.3)	1 (1.3)	3 (4.0)

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Gastrointestinal disorders			
-Total	8 (10.7)	8 (10.7)	0
Nausea	7 (9.3)	7 (9.3)	0
Vomiting	4 (5.3)	4 (5.3)	0
General disorders and administration site conditions			
-Total	12 (16.0)	8 (10.7)	4 (5.3)
Pyrexia	8 (10.7)	7 (9.3)	1 (1.3)
Multiple organ dysfunction syndrome	4 (5.3)	1 (1.3)	3 (4.0)
Immune system disorders			
-Total	22 (29.3)	11 (14.7)	11 (14.7)
Cytokine release syndrome	19 (25.3)	8 (10.7)	11 (14.7)
Hypogammaglobulinaemia	5 (6.7)	5 (6.7)	0
Investigations			
-Total	51 (68.0)	10 (13.3)	41 (54.7)
White blood cell count decreased	37 (49.3)	8 (10.7)	29 (38.7)
Neutrophil count decreased	29 (38.7)	3 (4.0)	26 (34.7)
Alanine aminotransferase increased	19 (25.3)	18 (24.0)	1 (1.3)

Region: US

	All patients N=75		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	16 (21.3)	3 (4.0)	13 (17.3)
Lymphocyte count decreased	15 (20.0)	7 (9.3)	8 (10.7)
Aspartate aminotransferase increased	14 (18.7)	9 (12.0)	5 (6.7)
Blood bilirubin increased	5 (6.7)	4 (5.3)	1 (1.3)
Metabolism and nutrition disorders			
-Total	25 (33.3)	20 (26.7)	5 (6.7)
Decreased appetite	13 (17.3)	13 (17.3)	0
Hypokalaemia	13 (17.3)	9 (12.0)	4 (5.3)
Hypophosphataemia	9 (12.0)	8 (10.7)	1 (1.3)
Hyperglycaemia	4 (5.3)	4 (5.3)	0
Nervous system disorders			
-Total	5 (6.7)	5 (6.7)	0
Headache	5 (6.7)	5 (6.7)	0
Renal and urinary disorders			
-Total	9 (12.0)	5 (6.7)	4 (5.3)
Acute kidney injury	9 (12.0)	5 (6.7)	4 (5.3)
Respiratory, thoracic and mediastinal disorders			

Region: US

Group term Preferred term	All patients N=75 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	19 (25.3)	11 (14.7)	8 (10.7)
Hypoxia	12 (16.0)	9 (12.0)	3 (4.0)
Pulmonary oedema	8 (10.7)	4 (5.3)	4 (5.3)
Epistaxis	6 (8.0)	5 (6.7)	1 (1.3)
Respiratory failure	4 (5.3)	0	4 (5.3)
Vascular disorders			
-Total	23 (30.7)	12 (16.0)	11 (14.7)
Hypotension	23 (30.7)	12 (16.0)	11 (14.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193l
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	32 (100)	7 (21.9)	25 (78.1)
Blood and lymphatic system disorders			
-Total	27 (84.4)	19 (59.4)	8 (25.0)
Febrile neutropenia	16 (50.0)	16 (50.0)	0
Anaemia	12 (37.5)	12 (37.5)	0
Thrombocytopenia	6 (18.8)	3 (9.4)	3 (9.4)
Neutropenia	4 (12.5)	1 (3.1)	3 (9.4)
Disseminated intravascular coagulation	1 (3.1)	0	1 (3.1)
Lymphopenia	1 (3.1)	0	1 (3.1)
Pancytopenia	1 (3.1)	0	1 (3.1)

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	8 (25.0)	8 (25.0)	0
Colitis	3 (9.4)	3 (9.4)	0
Nausea	2 (6.3)	2 (6.3)	0
Stomatitis	2 (6.3)	2 (6.3)	0
Vomiting	2 (6.3)	2 (6.3)	0
General disorders and administration site conditions			
-Total	4 (12.5)	1 (3.1)	3 (9.4)
Multiple organ dysfunction syndrome	3 (9.4)	0	3 (9.4)
Pyrexia	1 (3.1)	1 (3.1)	0
Hepatobiliary disorders			
-Total	2 (6.3)	2 (6.3)	0
Hyperbilirubinaemia	2 (6.3)	2 (6.3)	0
Immune system disorders			
-Total	7 (21.9)	5 (15.6)	2 (6.3)
Cytokine release syndrome	6 (18.8)	4 (12.5)	2 (6.3)
Hypogammaglobulinaemia	1 (3.1)	1 (3.1)	0

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	8 (25.0)	6 (18.8)	2 (6.3)
Device related infection	2 (6.3)	2 (6.3)	0
Escherichia urinary tract infection	2 (6.3)	2 (6.3)	0
Sepsis	2 (6.3)	0	2 (6.3)
Staphylococcal bacteraemia	2 (6.3)	2 (6.3)	0
Urinary tract infection	2 (6.3)	2 (6.3)	0
Investigations			
-Total	21 (65.6)	3 (9.4)	18 (56.3)
White blood cell count decreased	16 (50.0)	4 (12.5)	12 (37.5)
Neutrophil count decreased	15 (46.9)	0	15 (46.9)
Alanine aminotransferase increased	12 (37.5)	11 (34.4)	1 (3.1)
Aspartate aminotransferase increased	9 (28.1)	6 (18.8)	3 (9.4)
Platelet count decreased	9 (28.1)	1 (3.1)	8 (25.0)
Lymphocyte count decreased	7 (21.9)	3 (9.4)	4 (12.5)
Blood bilirubin increased	3 (9.4)	2 (6.3)	1 (3.1)
Metabolism and nutrition disorders			

Prior SCT therapy: Yes

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (37.5)	9 (28.1)	3 (9.4)
Hypokalaemia	7 (21.9)	4 (12.5)	3 (9.4)
Decreased appetite	6 (18.8)	6 (18.8)	0
Hypophosphataemia	4 (12.5)	4 (12.5)	0
Hyperglycaemia	2 (6.3)	2 (6.3)	0
Hyponatraemia	2 (6.3)	2 (6.3)	0
Nervous system disorders			
-Total	6 (18.8)	6 (18.8)	0
Headache	4 (12.5)	4 (12.5)	0
Seizure	2 (6.3)	2 (6.3)	0
Renal and urinary disorders			
-Total	1 (3.1)	0	1 (3.1)
Acute kidney injury	1 (3.1)	0	1 (3.1)
Respiratory, thoracic and mediastinal disorders			
-Total	6 (18.8)	5 (15.6)	1 (3.1)
Hypoxia	4 (12.5)	3 (9.4)	1 (3.1)
Epistaxis	3 (9.4)	3 (9.4)	0

Prior SCT therapy: Yes

Group term Preferred term	All patients N=32 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Pulmonary oedema	1 (3.1)	1 (3.1)	0
Vascular disorders			
-Total	10 (31.3)	7 (21.9)	3 (9.4)
Hypotension	9 (28.1)	6 (18.8)	3 (9.4)
Hypertension	2 (6.3)	2 (6.3)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193l
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Prior SCT therapy
Enrolled set

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	36 (83.7)	6 (14.0)	30 (69.8)
Blood and lymphatic system disorders			
-Total	31 (72.1)	16 (37.2)	15 (34.9)
Febrile neutropenia	20 (46.5)	19 (44.2)	1 (2.3)
Anaemia	15 (34.9)	14 (32.6)	1 (2.3)
Neutropenia	12 (27.9)	3 (7.0)	9 (20.9)
Thrombocytopenia	8 (18.6)	2 (4.7)	6 (14.0)
Disseminated intravascular coagulation	3 (7.0)	3 (7.0)	0
Lymphopenia	3 (7.0)	1 (2.3)	2 (4.7)
Pancytopenia	3 (7.0)	1 (2.3)	2 (4.7)

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	5 (11.6)	4 (9.3)	1 (2.3)
Nausea	5 (11.6)	5 (11.6)	0
Vomiting	2 (4.7)	2 (4.7)	0
Stomatitis	1 (2.3)	0	1 (2.3)
General disorders and administration site conditions			
-Total	8 (18.6)	7 (16.3)	1 (2.3)
Pyrexia	7 (16.3)	6 (14.0)	1 (2.3)
Multiple organ dysfunction syndrome	1 (2.3)	1 (2.3)	0
Hepatobiliary disorders			
-Total	1 (2.3)	1 (2.3)	0
Hyperbilirubinaemia	1 (2.3)	1 (2.3)	0
Immune system disorders			
-Total	15 (34.9)	6 (14.0)	9 (20.9)
Cytokine release syndrome	13 (30.2)	4 (9.3)	9 (20.9)
Hypogammaglobulinaemia	4 (9.3)	4 (9.3)	0
Infections and infestations			

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (2.3)	1 (2.3)	0
Device related infection	1 (2.3)	1 (2.3)	0
Investigations			
-Total	31 (72.1)	8 (18.6)	23 (53.5)
White blood cell count decreased	21 (48.8)	4 (9.3)	17 (39.5)
Neutrophil count decreased	14 (32.6)	3 (7.0)	11 (25.6)
Lymphocyte count decreased	8 (18.6)	4 (9.3)	4 (9.3)
Alanine aminotransferase increased	7 (16.3)	7 (16.3)	0
Platelet count decreased	7 (16.3)	2 (4.7)	5 (11.6)
Aspartate aminotransferase increased	5 (11.6)	3 (7.0)	2 (4.7)
Blood fibrinogen decreased	3 (7.0)	2 (4.7)	1 (2.3)
Blood bilirubin increased	2 (4.7)	2 (4.7)	0
Metabolism and nutrition disorders			
-Total	14 (32.6)	12 (27.9)	2 (4.7)
Decreased appetite	7 (16.3)	7 (16.3)	0
Hypokalaemia	6 (14.0)	5 (11.6)	1 (2.3)
Hypophosphataemia	5 (11.6)	4 (9.3)	1 (2.3)

Prior SCT therapy: No

	All patients N=43		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	3 (7.0)	3 (7.0)	0
Hyperglycaemia	2 (4.7)	2 (4.7)	0
Nervous system disorders			
-Total	1 (2.3)	0	1 (2.3)
Headache	1 (2.3)	1 (2.3)	0
Seizure	1 (2.3)	0	1 (2.3)
Renal and urinary disorders			
-Total	8 (18.6)	5 (11.6)	3 (7.0)
Acute kidney injury	8 (18.6)	5 (11.6)	3 (7.0)
Respiratory, thoracic and mediastinal disorders			
-Total	13 (30.2)	6 (14.0)	7 (16.3)
Hypoxia	8 (18.6)	6 (14.0)	2 (4.7)
Pulmonary oedema	7 (16.3)	3 (7.0)	4 (9.3)
Respiratory failure	4 (9.3)	0	4 (9.3)
Epistaxis	3 (7.0)	2 (4.7)	1 (2.3)
Vascular disorders			
-Total	14 (32.6)	6 (14.0)	8 (18.6)

Prior SCT therapy: No

Group term Preferred term	All patients N=43 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Hypotension	14 (32.6)	6 (14.0)	8 (18.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193m
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	15 (83.3)	3 (16.7)	12 (66.7)
Blood and lymphatic system disorders			
-Total	12 (66.7)	8 (44.4)	4 (22.2)
Febrile neutropenia	10 (55.6)	10 (55.6)	0
Anaemia	4 (22.2)	4 (22.2)	0
Neutropenia	3 (16.7)	1 (5.6)	2 (11.1)
Thrombocytopenia	2 (11.1)	0	2 (11.1)
Pancytopenia	1 (5.6)	0	1 (5.6)
Gastrointestinal disorders			
-Total	5 (27.8)	5 (27.8)	0
Nausea	2 (11.1)	2 (11.1)	0

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Abdominal pain	1 (5.6)	1 (5.6)	0
Ascites	1 (5.6)	1 (5.6)	0
Diarrhoea	1 (5.6)	1 (5.6)	0
Enterocolitis	1 (5.6)	1 (5.6)	0
Intestinal obstruction	1 (5.6)	1 (5.6)	0
Pancreatitis	1 (5.6)	1 (5.6)	0
Stomatitis	1 (5.6)	1 (5.6)	0
Vomiting	1 (5.6)	1 (5.6)	0
General disorders and administration site conditions			
-Total	2 (11.1)	2 (11.1)	0
Pyrexia	2 (11.1)	2 (11.1)	0
Pain	1 (5.6)	1 (5.6)	0
Immune system disorders			
-Total	4 (22.2)	3 (16.7)	1 (5.6)
Cytokine release syndrome	3 (16.7)	2 (11.1)	1 (5.6)
Hypogammaglobulinaemia	1 (5.6)	1 (5.6)	0
Infections and infestations			

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	9 (50.0)	6 (33.3)	3 (16.7)
Pneumonia	2 (11.1)	1 (5.6)	1 (5.6)
Bacterial sepsis	1 (5.6)	0	1 (5.6)
Bronchopulmonary aspergillosis	1 (5.6)	1 (5.6)	0
Catheter site infection	1 (5.6)	1 (5.6)	0
Clostridium difficile colitis	1 (5.6)	1 (5.6)	0
Corona virus infection	1 (5.6)	1 (5.6)	0
Device related infection	1 (5.6)	1 (5.6)	0
Escherichia urinary tract infection	1 (5.6)	1 (5.6)	0
Parainfluenzae virus infection	1 (5.6)	1 (5.6)	0
Respiratory syncytial virus infection	1 (5.6)	1 (5.6)	0
Respiratory tract infection	1 (5.6)	0	1 (5.6)
Urinary tract infection enterococcal	1 (5.6)	1 (5.6)	0
Viral upper respiratory tract infection	1 (5.6)	1 (5.6)	0
Investigations			
-Total	12 (66.7)	2 (11.1)	10 (55.6)
White blood cell count decreased	10 (55.6)	2 (11.1)	8 (44.4)
Neutrophil count decreased	7 (38.9)	2 (11.1)	5 (27.8)

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	4 (22.2)	2 (11.1)	2 (11.1)
Platelet count decreased	3 (16.7)	0	3 (16.7)
Alanine aminotransferase increased	1 (5.6)	1 (5.6)	0
Blood bilirubin increased	1 (5.6)	1 (5.6)	0
Blood fibrinogen decreased	1 (5.6)	1 (5.6)	0
C-reactive protein increased	1 (5.6)	1 (5.6)	0
Lipase increased	1 (5.6)	0	1 (5.6)
Metabolism and nutrition disorders			
-Total	6 (33.3)	4 (22.2)	2 (11.1)
Decreased appetite	2 (11.1)	2 (11.1)	0
Hypokalaemia	2 (11.1)	2 (11.1)	0
Tumour lysis syndrome	2 (11.1)	2 (11.1)	0
Dehydration	1 (5.6)	1 (5.6)	0
Hyperglycaemia	1 (5.6)	1 (5.6)	0
Hyperuricaemia	1 (5.6)	0	1 (5.6)
Hypoalbuminaemia	1 (5.6)	1 (5.6)	0
Hypocalcaemia	1 (5.6)	0	1 (5.6)
Hypophosphataemia	1 (5.6)	0	1 (5.6)

Eligibility for SCT: Yes

	All patients N=18		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Iron overload	1 (5.6)	1 (5.6)	0
Renal and urinary disorders			
-Total	1 (5.6)	1 (5.6)	0
Acute kidney injury	1 (5.6)	1 (5.6)	0
Reproductive system and breast disorders			
-Total	2 (11.1)	2 (11.1)	0
Ovarian failure	1 (5.6)	1 (5.6)	0
Vaginal haemorrhage	1 (5.6)	1 (5.6)	0
Respiratory, thoracic and mediastinal disorders			
-Total	3 (16.7)	1 (5.6)	2 (11.1)
Hypoxia	2 (11.1)	2 (11.1)	0
Aspiration	1 (5.6)	0	1 (5.6)
Pleural effusion	1 (5.6)	1 (5.6)	0
Pulmonary oedema	1 (5.6)	1 (5.6)	0
Respiratory failure	1 (5.6)	0	1 (5.6)
Skin and subcutaneous tissue disorders			

Eligibility for SCT: Yes

Group term Preferred term	All patients N=18 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
-Total	1 (5.6)	1 (5.6)	0
Dermatitis acneiform	1 (5.6)	1 (5.6)	0
Vascular disorders			
-Total	3 (16.7)	2 (11.1)	1 (5.6)
Hypotension	3 (16.7)	2 (11.1)	1 (5.6)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193m
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Eligibility for SCT
Enrolled set

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	54 (94.7)	11 (19.3)	43 (75.4)
Blood and lymphatic system disorders			
-Total	46 (80.7)	27 (47.4)	19 (33.3)
Febrile neutropenia	26 (45.6)	25 (43.9)	1 (1.8)
Anaemia	23 (40.4)	22 (38.6)	1 (1.8)
Neutropenia	13 (22.8)	3 (5.3)	10 (17.5)
Thrombocytopenia	12 (21.1)	5 (8.8)	7 (12.3)
Disseminated intravascular coagulation	4 (7.0)	3 (5.3)	1 (1.8)
Lymphopenia	4 (7.0)	1 (1.8)	3 (5.3)
Pancytopenia	3 (5.3)	1 (1.8)	2 (3.5)

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders			
-Total	3 (5.3)	3 (5.3)	0
Left ventricular dysfunction	3 (5.3)	3 (5.3)	0
Gastrointestinal disorders			
-Total	12 (21.1)	11 (19.3)	1 (1.8)
Nausea	5 (8.8)	5 (8.8)	0
Colitis	3 (5.3)	3 (5.3)	0
Vomiting	3 (5.3)	3 (5.3)	0
Abdominal pain	2 (3.5)	2 (3.5)	0
Stomatitis	2 (3.5)	1 (1.8)	1 (1.8)
Ascites	1 (1.8)	1 (1.8)	0
Diarrhoea	1 (1.8)	1 (1.8)	0
General disorders and administration site conditions			
-Total	12 (21.1)	8 (14.0)	4 (7.0)
Pyrexia	6 (10.5)	5 (8.8)	1 (1.8)
Multiple organ dysfunction syndrome	4 (7.0)	1 (1.8)	3 (5.3)
Pain	2 (3.5)	2 (3.5)	0

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hepatobiliary disorders			
-Total	3 (5.3)	3 (5.3)	0
Hyperbilirubinaemia	3 (5.3)	3 (5.3)	0
Immune system disorders			
-Total	18 (31.6)	8 (14.0)	10 (17.5)
Cytokine release syndrome	16 (28.1)	6 (10.5)	10 (17.5)
Hypogammaglobulinaemia	4 (7.0)	4 (7.0)	0
Infections and infestations			
-Total	4 (7.0)	4 (7.0)	0
Device related infection	2 (3.5)	2 (3.5)	0
Clostridium difficile colitis	1 (1.8)	1 (1.8)	0
Escherichia urinary tract infection	1 (1.8)	1 (1.8)	0
Investigations			
-Total	40 (70.2)	9 (15.8)	31 (54.4)
White blood cell count decreased	27 (47.4)	6 (10.5)	21 (36.8)
Neutrophil count decreased	22 (38.6)	1 (1.8)	21 (36.8)
Alanine aminotransferase increased	18 (31.6)	17 (29.8)	1 (1.8)

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	14 (24.6)	9 (15.8)	5 (8.8)
Platelet count decreased	13 (22.8)	3 (5.3)	10 (17.5)
Lymphocyte count decreased	11 (19.3)	5 (8.8)	6 (10.5)
Blood bilirubin increased	4 (7.0)	3 (5.3)	1 (1.8)
Blood fibrinogen decreased	2 (3.5)	1 (1.8)	1 (1.8)
Lipase increased	2 (3.5)	0	2 (3.5)
Metabolism and nutrition disorders			
-Total	25 (43.9)	20 (35.1)	5 (8.8)
Decreased appetite	11 (19.3)	11 (19.3)	0
Hypokalaemia	11 (19.3)	7 (12.3)	4 (7.0)
Hypophosphataemia	8 (14.0)	8 (14.0)	0
Hyperglycaemia	3 (5.3)	3 (5.3)	0
Hypernatraemia	3 (5.3)	0	3 (5.3)
Dehydration	2 (3.5)	2 (3.5)	0
Hypocalcaemia	1 (1.8)	1 (1.8)	0
Tumour lysis syndrome	1 (1.8)	1 (1.8)	0
Musculoskeletal and connective tissue disorders			

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (5.3)	3 (5.3)	0
Pain in extremity	3 (5.3)	3 (5.3)	0
Nervous system disorders			
-Total	7 (12.3)	6 (10.5)	1 (1.8)
Headache	5 (8.8)	5 (8.8)	0
Seizure	3 (5.3)	2 (3.5)	1 (1.8)
Renal and urinary disorders			
-Total	10 (17.5)	5 (8.8)	5 (8.8)
Acute kidney injury	8 (14.0)	4 (7.0)	4 (7.0)
Haematuria	3 (5.3)	2 (3.5)	1 (1.8)
Oliguria	3 (5.3)	3 (5.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	17 (29.8)	10 (17.5)	7 (12.3)
Hypoxia	10 (17.5)	7 (12.3)	3 (5.3)
Pulmonary oedema	7 (12.3)	3 (5.3)	4 (7.0)
Epistaxis	6 (10.5)	5 (8.8)	1 (1.8)
Dyspnoea	3 (5.3)	2 (3.5)	1 (1.8)

Eligibility for SCT: No

	All patients N=57		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Respiratory failure	3 (5.3)	0	3 (5.3)
Tachypnoea	3 (5.3)	3 (5.3)	0
Pleural effusion	2 (3.5)	2 (3.5)	0
Vascular disorders			
-Total	20 (35.1)	10 (17.5)	10 (17.5)
Hypotension	20 (35.1)	10 (17.5)	10 (17.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193n
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	22 (100)	6 (27.3)	16 (72.7)
Blood and lymphatic system disorders			
-Total	21 (95.5)	14 (63.6)	7 (31.8)
Febrile neutropenia	11 (50.0)	11 (50.0)	0
Anaemia	10 (45.5)	10 (45.5)	0
Neutropenia	7 (31.8)	2 (9.1)	5 (22.7)
Thrombocytopenia	6 (27.3)	3 (13.6)	3 (13.6)
Disseminated intravascular coagulation	2 (9.1)	1 (4.5)	1 (4.5)
Lymphopenia	2 (9.1)	1 (4.5)	1 (4.5)
Pancytopenia	2 (9.1)	1 (4.5)	1 (4.5)
Gastrointestinal disorders			

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (13.6)	3 (13.6)	0
Abdominal pain	2 (9.1)	2 (9.1)	0
Nausea	2 (9.1)	2 (9.1)	0
Vomiting	2 (9.1)	2 (9.1)	0
General disorders and administration site conditions			
-Total	3 (13.6)	2 (9.1)	1 (4.5)
Pyrexia	2 (9.1)	2 (9.1)	0
Multiple organ dysfunction syndrome	1 (4.5)	0	1 (4.5)
Immune system disorders			
-Total	6 (27.3)	4 (18.2)	2 (9.1)
Cytokine release syndrome	5 (22.7)	3 (13.6)	2 (9.1)
Hypogammaglobulinaemia	1 (4.5)	1 (4.5)	0
Investigations			
-Total	19 (86.4)	5 (22.7)	14 (63.6)
White blood cell count decreased	12 (54.5)	2 (9.1)	10 (45.5)
Neutrophil count decreased	11 (50.0)	2 (9.1)	9 (40.9)
Lymphocyte count decreased	6 (27.3)	3 (13.6)	3 (13.6)
Platelet count decreased	5 (22.7)	1 (4.5)	4 (18.2)

Baseline bone marrow tumor burden: Low

	All patients N=22		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	4 (18.2)	3 (13.6)	1 (4.5)
Aspartate aminotransferase increased	4 (18.2)	2 (9.1)	2 (9.1)
Blood bilirubin increased	3 (13.6)	2 (9.1)	1 (4.5)
Metabolism and nutrition disorders			
-Total	8 (36.4)	7 (31.8)	1 (4.5)
Decreased appetite	3 (13.6)	3 (13.6)	0
Dehydration	2 (9.1)	2 (9.1)	0
Hypokalaemia	2 (9.1)	1 (4.5)	1 (4.5)
Hypophosphataemia	2 (9.1)	2 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (9.1)	2 (9.1)	0
Arthralgia	2 (9.1)	2 (9.1)	0
Nervous system disorders			
-Total	3 (13.6)	2 (9.1)	1 (4.5)
Headache	2 (9.1)	2 (9.1)	0
Seizure	2 (9.1)	1 (4.5)	1 (4.5)
Renal and urinary disorders			

Baseline bone marrow tumor burden: Low

Group term Preferred term	All patients N=22 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
-Total	1 (4.5)	1 (4.5)	0
Acute kidney injury	1 (4.5)	1 (4.5)	0
Respiratory, thoracic and mediastinal disorders			
-Total	5 (22.7)	4 (18.2)	1 (4.5)
Hypoxia	3 (13.6)	3 (13.6)	0
Pulmonary oedema	2 (9.1)	1 (4.5)	1 (4.5)
Epistaxis	1 (4.5)	1 (4.5)	0
Vascular disorders			
-Total	6 (27.3)	4 (18.2)	2 (9.1)
Hypotension	6 (27.3)	4 (18.2)	2 (9.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193n
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline bone marrow tumor burden
Enrolled set

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	46 (86.8)	8 (15.1)	38 (71.7)
Blood and lymphatic system disorders			
-Total	37 (69.8)	21 (39.6)	16 (30.2)
Febrile neutropenia	25 (47.2)	24 (45.3)	1 (1.9)
Anaemia	17 (32.1)	16 (30.2)	1 (1.9)
Neutropenia	9 (17.0)	2 (3.8)	7 (13.2)
Thrombocytopenia	8 (15.1)	2 (3.8)	6 (11.3)
Disseminated intravascular coagulation	2 (3.8)	2 (3.8)	0
Lymphopenia	2 (3.8)	0	2 (3.8)
Pancytopenia	2 (3.8)	0	2 (3.8)
Cardiac disorders			

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (5.7)	3 (5.7)	0
Left ventricular dysfunction	3 (5.7)	3 (5.7)	0
Gastrointestinal disorders			
-Total	7 (13.2)	7 (13.2)	0
Nausea	5 (9.4)	5 (9.4)	0
Vomiting	2 (3.8)	2 (3.8)	0
Abdominal pain	1 (1.9)	1 (1.9)	0
General disorders and administration site conditions			
-Total	9 (17.0)	6 (11.3)	3 (5.7)
Pyrexia	6 (11.3)	5 (9.4)	1 (1.9)
Multiple organ dysfunction syndrome	3 (5.7)	1 (1.9)	2 (3.8)
Hepatobiliary disorders			
-Total	3 (5.7)	3 (5.7)	0
Hyperbilirubinaemia	3 (5.7)	3 (5.7)	0
Immune system disorders			
-Total	16 (30.2)	7 (13.2)	9 (17.0)
Cytokine release syndrome	14 (26.4)	5 (9.4)	9 (17.0)
Hypogammaglobulinaemia	4 (7.5)	4 (7.5)	0

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	33 (62.3)	6 (11.3)	27 (50.9)
White blood cell count decreased	25 (47.2)	6 (11.3)	19 (35.8)
Neutrophil count decreased	18 (34.0)	1 (1.9)	17 (32.1)
Alanine aminotransferase increased	15 (28.3)	15 (28.3)	0
Platelet count decreased	11 (20.8)	2 (3.8)	9 (17.0)
Aspartate aminotransferase increased	10 (18.9)	7 (13.2)	3 (5.7)
Lymphocyte count decreased	9 (17.0)	4 (7.5)	5 (9.4)
Blood fibrinogen decreased	3 (5.7)	2 (3.8)	1 (1.9)
Lipase increased	3 (5.7)	0	3 (5.7)
Blood bilirubin increased	2 (3.8)	2 (3.8)	0
Metabolism and nutrition disorders			
-Total	21 (39.6)	17 (32.1)	4 (7.5)
Hypokalaemia	11 (20.8)	8 (15.1)	3 (5.7)
Decreased appetite	10 (18.9)	10 (18.9)	0
Hypophosphataemia	7 (13.2)	6 (11.3)	1 (1.9)
Hyperglycaemia	4 (7.5)	4 (7.5)	0
Tumour lysis syndrome	3 (5.7)	3 (5.7)	0

Baseline bone marrow tumor burden: High

	All patients N=53		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Dehydration	1 (1.9)	1 (1.9)	0
Nervous system disorders			
-Total	4 (7.5)	4 (7.5)	0
Headache	3 (5.7)	3 (5.7)	0
Seizure	1 (1.9)	1 (1.9)	0
Renal and urinary disorders			
-Total	10 (18.9)	5 (9.4)	5 (9.4)
Acute kidney injury	8 (15.1)	4 (7.5)	4 (7.5)
Haematuria	3 (5.7)	2 (3.8)	1 (1.9)
Respiratory, thoracic and mediastinal disorders			
-Total	14 (26.4)	7 (13.2)	7 (13.2)
Hypoxia	9 (17.0)	6 (11.3)	3 (5.7)
Pulmonary oedema	6 (11.3)	3 (5.7)	3 (5.7)
Epistaxis	5 (9.4)	4 (7.5)	1 (1.9)
Respiratory failure	4 (7.5)	0	4 (7.5)
Vascular disorders			
-Total	17 (32.1)	8 (15.1)	9 (17.0)
Hypotension	17 (32.1)	8 (15.1)	9 (17.0)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193o
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	5 (71.4)	0	5 (71.4)
Blood and lymphatic system disorders			
-Total	5 (71.4)	2 (28.6)	3 (42.9)
Febrile neutropenia	4 (57.1)	3 (42.9)	1 (14.3)
Anaemia	2 (28.6)	2 (28.6)	0
Leukopenia	1 (14.3)	0	1 (14.3)
Lymphopenia	1 (14.3)	0	1 (14.3)
Thrombocytopenia	1 (14.3)	0	1 (14.3)
Gastrointestinal disorders			
-Total	1 (14.3)	1 (14.3)	0
Dysphagia	1 (14.3)	1 (14.3)	0

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (14.3)	1 (14.3)	0
Face oedema	1 (14.3)	1 (14.3)	0
Localised oedema	1 (14.3)	1 (14.3)	0
Multiple organ dysfunction syndrome	1 (14.3)	1 (14.3)	0
Oedema peripheral	1 (14.3)	1 (14.3)	0
Hepatobiliary disorders			
-Total	1 (14.3)	1 (14.3)	0
Hyperbilirubinaemia	1 (14.3)	1 (14.3)	0
Immune system disorders			
-Total	1 (14.3)	0	1 (14.3)
Cytokine release syndrome	1 (14.3)	0	1 (14.3)
Hypogammaglobulinaemia	1 (14.3)	1 (14.3)	0
Infections and infestations			
-Total	3 (42.9)	3 (42.9)	0
Device related infection	1 (14.3)	1 (14.3)	0
Escherichia bacteraemia	1 (14.3)	1 (14.3)	0
Otitis media	1 (14.3)	1 (14.3)	0

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Viral upper respiratory tract infection	1 (14.3)	1 (14.3)	0
Injury, poisoning and procedural complications			
-Total	2 (28.6)	2 (28.6)	0
Extradural haematoma	1 (14.3)	1 (14.3)	0
Procedural pain	1 (14.3)	1 (14.3)	0
Subdural haematoma	1 (14.3)	1 (14.3)	0
Investigations			
-Total	4 (57.1)	0	4 (57.1)
Alanine aminotransferase increased	3 (42.9)	3 (42.9)	0
White blood cell count decreased	3 (42.9)	1 (14.3)	2 (28.6)
Aspartate aminotransferase increased	2 (28.6)	1 (14.3)	1 (14.3)
Neutrophil count decreased	2 (28.6)	0	2 (28.6)
Platelet count decreased	2 (28.6)	1 (14.3)	1 (14.3)
Blood bilirubin increased	1 (14.3)	1 (14.3)	0
Blood creatinine increased	1 (14.3)	1 (14.3)	0
Blood fibrinogen decreased	1 (14.3)	0	1 (14.3)
Blood urea increased	1 (14.3)	1 (14.3)	0

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Lymphocyte count decreased	1 (14.3)	0	1 (14.3)
Protein total decreased	1 (14.3)	1 (14.3)	0
Metabolism and nutrition disorders			
-Total	2 (28.6)	2 (28.6)	0
Hypokalaemia	2 (28.6)	2 (28.6)	0
Acidosis	1 (14.3)	1 (14.3)	0
Hyperglycaemia	1 (14.3)	1 (14.3)	0
Iron overload	1 (14.3)	1 (14.3)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (14.3)	1 (14.3)	0
Bone pain	1 (14.3)	1 (14.3)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
-Total	1 (14.3)	0	1 (14.3)
Glioblastoma multiforme	1 (14.3)	0	1 (14.3)
Nervous system disorders			
-Total	2 (28.6)	2 (28.6)	0
Headache	1 (14.3)	1 (14.3)	0

Baseline extramedullary disease presence: Yes

	All patients N=7		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Seizure	1 (14.3)	1 (14.3)	0
Psychiatric disorders			
-Total	1 (14.3)	1 (14.3)	0
Mental status changes	1 (14.3)	1 (14.3)	0
Renal and urinary disorders			
-Total	1 (14.3)	1 (14.3)	0
Renal impairment	1 (14.3)	1 (14.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	2 (28.6)	1 (14.3)	1 (14.3)
Epistaxis	1 (14.3)	1 (14.3)	0
Hypoxia	1 (14.3)	1 (14.3)	0
Pleural effusion	1 (14.3)	1 (14.3)	0
Pulmonary oedema	1 (14.3)	1 (14.3)	0
Respiratory distress	1 (14.3)	0	1 (14.3)
Tachypnoea	1 (14.3)	1 (14.3)	0
Vascular disorders			
-Total	1 (14.3)	0	1 (14.3)
Capillary leak syndrome	1 (14.3)	0	1 (14.3)

Baseline extramedullary disease presence: Yes

Group term Preferred term	All patients N=7 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Hypotension	1 (14.3)	0	1 (14.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193o
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Baseline extramedullary disease presence
Enrolled set

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	63 (92.6)	14 (20.6)	49 (72.1)
Blood and lymphatic system disorders			
-Total	53 (77.9)	33 (48.5)	20 (29.4)
Febrile neutropenia	32 (47.1)	32 (47.1)	0
Anaemia	25 (36.8)	24 (35.3)	1 (1.5)
Neutropenia	16 (23.5)	4 (5.9)	12 (17.6)
Thrombocytopenia	13 (19.1)	5 (7.4)	8 (11.8)
Disseminated intravascular coagulation	4 (5.9)	3 (4.4)	1 (1.5)
Pancytopenia	4 (5.9)	1 (1.5)	3 (4.4)
Lymphopenia	3 (4.4)	1 (1.5)	2 (2.9)
Gastrointestinal disorders			

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (11.8)	8 (11.8)	0
Nausea	7 (10.3)	7 (10.3)	0
Vomiting	4 (5.9)	4 (5.9)	0
General disorders and administration site conditions			
-Total	11 (16.2)	7 (10.3)	4 (5.9)
Pyrexia	8 (11.8)	7 (10.3)	1 (1.5)
Multiple organ dysfunction syndrome	3 (4.4)	0	3 (4.4)
Hepatobiliary disorders			
-Total	2 (2.9)	2 (2.9)	0
Hyperbilirubinaemia	2 (2.9)	2 (2.9)	0
Immune system disorders			
-Total	21 (30.9)	11 (16.2)	10 (14.7)
Cytokine release syndrome	18 (26.5)	8 (11.8)	10 (14.7)
Hypogammaglobulinaemia	4 (5.9)	4 (5.9)	0
Infections and infestations			
-Total	3 (4.4)	3 (4.4)	0
Device related infection	2 (2.9)	2 (2.9)	0
Escherichia bacteraemia	1 (1.5)	1 (1.5)	0

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Investigations			
-Total	48 (70.6)	11 (16.2)	37 (54.4)
White blood cell count decreased	34 (50.0)	7 (10.3)	27 (39.7)
Neutrophil count decreased	27 (39.7)	3 (4.4)	24 (35.3)
Alanine aminotransferase increased	16 (23.5)	15 (22.1)	1 (1.5)
Lymphocyte count decreased	14 (20.6)	7 (10.3)	7 (10.3)
Platelet count decreased	14 (20.6)	2 (2.9)	12 (17.6)
Aspartate aminotransferase increased	12 (17.6)	8 (11.8)	4 (5.9)
Blood bilirubin increased	4 (5.9)	3 (4.4)	1 (1.5)
Blood fibrinogen decreased	2 (2.9)	2 (2.9)	0
Blood creatinine increased	1 (1.5)	1 (1.5)	0
Metabolism and nutrition disorders			
-Total	23 (33.8)	18 (26.5)	5 (7.4)
Decreased appetite	13 (19.1)	13 (19.1)	0
Hypokalaemia	11 (16.2)	7 (10.3)	4 (5.9)
Hypophosphataemia	9 (13.2)	8 (11.8)	1 (1.5)
Hyperglycaemia	3 (4.4)	3 (4.4)	0
Nervous system disorders			

Baseline extramedullary disease presence: No

	All patients N=68		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	5 (7.4)	4 (5.9)	1 (1.5)
Headache	4 (5.9)	4 (5.9)	0
Seizure	2 (2.9)	1 (1.5)	1 (1.5)
Renal and urinary disorders			
-Total	9 (13.2)	5 (7.4)	4 (5.9)
Acute kidney injury	9 (13.2)	5 (7.4)	4 (5.9)
Respiratory, thoracic and mediastinal disorders			
-Total	18 (26.5)	10 (14.7)	8 (11.8)
Hypoxia	11 (16.2)	8 (11.8)	3 (4.4)
Pulmonary oedema	7 (10.3)	3 (4.4)	4 (5.9)
Epistaxis	5 (7.4)	4 (5.9)	1 (1.5)
Respiratory failure	4 (5.9)	0	4 (5.9)
Pleural effusion	2 (2.9)	2 (2.9)	0
Tachypnoea	2 (2.9)	2 (2.9)	0
Respiratory distress	1 (1.5)	0	1 (1.5)
Vascular disorders			
-Total	22 (32.4)	12 (17.6)	10 (14.7)
Hypotension	22 (32.4)	12 (17.6)	10 (14.7)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193p
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	3 (75.0)	1 (25.0)	2 (50.0)
Blood and lymphatic system disorders			
-Total	3 (75.0)	2 (50.0)	1 (25.0)
Febrile neutropenia	2 (50.0)	2 (50.0)	0
Anaemia	1 (25.0)	1 (25.0)	0
Neutropenia	1 (25.0)	0	1 (25.0)
Thrombocytopenia	1 (25.0)	1 (25.0)	0
Gastrointestinal disorders			
-Total	2 (50.0)	2 (50.0)	0
Enterocolitis	1 (25.0)	1 (25.0)	0
Stomatitis	1 (25.0)	1 (25.0)	0

Down syndrome: Yes

	All patients N=4		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
General disorders and administration site conditions			
-Total	1 (25.0)	1 (25.0)	0
Pyrexia	1 (25.0)	1 (25.0)	0
Infections and infestations			
-Total	1 (25.0)	1 (25.0)	0
Corona virus infection	1 (25.0)	1 (25.0)	0
Respiratory syncytial virus infection	1 (25.0)	1 (25.0)	0
Investigations			
-Total	2 (50.0)	0	2 (50.0)
Lymphocyte count decreased	1 (25.0)	0	1 (25.0)
Neutrophil count decreased	1 (25.0)	0	1 (25.0)
White blood cell count decreased	1 (25.0)	0	1 (25.0)
Vascular disorders			
-Total	1 (25.0)	1 (25.0)	0
Hypotension	1 (25.0)	1 (25.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193p
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Down syndrome
Enrolled set

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	65 (91.5)	13 (18.3)	52 (73.2)
Blood and lymphatic system disorders			
-Total	55 (77.5)	33 (46.5)	22 (31.0)
Febrile neutropenia	34 (47.9)	33 (46.5)	1 (1.4)
Anaemia	26 (36.6)	25 (35.2)	1 (1.4)
Neutropenia	15 (21.1)	4 (5.6)	11 (15.5)
Thrombocytopenia	13 (18.3)	4 (5.6)	9 (12.7)
Disseminated intravascular coagulation	4 (5.6)	3 (4.2)	1 (1.4)
Lymphopenia	4 (5.6)	1 (1.4)	3 (4.2)
Pancytopenia	4 (5.6)	1 (1.4)	3 (4.2)

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	9 (12.7)	8 (11.3)	1 (1.4)
Nausea	7 (9.9)	7 (9.9)	0
Vomiting	4 (5.6)	4 (5.6)	0
Stomatitis	2 (2.8)	1 (1.4)	1 (1.4)
General disorders and administration site conditions			
-Total	11 (15.5)	7 (9.9)	4 (5.6)
Pyrexia	7 (9.9)	6 (8.5)	1 (1.4)
Multiple organ dysfunction syndrome	4 (5.6)	1 (1.4)	3 (4.2)
Immune system disorders			
-Total	22 (31.0)	11 (15.5)	11 (15.5)
Cytokine release syndrome	19 (26.8)	8 (11.3)	11 (15.5)
Hypogammaglobulinaemia	5 (7.0)	5 (7.0)	0
Investigations			
-Total	49 (69.0)	10 (14.1)	39 (54.9)
White blood cell count decreased	36 (50.7)	8 (11.3)	28 (39.4)
Neutrophil count decreased	28 (39.4)	3 (4.2)	25 (35.2)

Down syndrome: No

	All patients N=71		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Alanine aminotransferase increased	19 (26.8)	18 (25.4)	1 (1.4)
Platelet count decreased	16 (22.5)	3 (4.2)	13 (18.3)
Aspartate aminotransferase increased	14 (19.7)	9 (12.7)	5 (7.0)
Lymphocyte count decreased	14 (19.7)	7 (9.9)	7 (9.9)
Blood bilirubin increased	5 (7.0)	4 (5.6)	1 (1.4)
Metabolism and nutrition disorders			
-Total	25 (35.2)	20 (28.2)	5 (7.0)
Decreased appetite	13 (18.3)	13 (18.3)	0
Hypokalaemia	13 (18.3)	9 (12.7)	4 (5.6)
Hypophosphataemia	9 (12.7)	8 (11.3)	1 (1.4)
Hyperglycaemia	4 (5.6)	4 (5.6)	0
Nervous system disorders			
-Total	5 (7.0)	5 (7.0)	0
Headache	5 (7.0)	5 (7.0)	0
Renal and urinary disorders			
-Total	9 (12.7)	5 (7.0)	4 (5.6)
Acute kidney injury	9 (12.7)	5 (7.0)	4 (5.6)

Down syndrome: No

Group term Preferred term	All patients N=71 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Respiratory, thoracic and mediastinal disorders			
-Total	19 (26.8)	11 (15.5)	8 (11.3)
Hypoxia	12 (16.9)	9 (12.7)	3 (4.2)
Pulmonary oedema	8 (11.3)	4 (5.6)	4 (5.6)
Epistaxis	6 (8.5)	5 (7.0)	1 (1.4)
Respiratory failure	4 (5.6)	0	4 (5.6)
Vascular disorders			
-Total	22 (31.0)	11 (15.5)	11 (15.5)
Hypotension	22 (31.0)	11 (15.5)	11 (15.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193q
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	30 (93.8)	4 (12.5)	26 (81.3)
Blood and lymphatic system disorders			
-Total	28 (87.5)	19 (59.4)	9 (28.1)
Febrile neutropenia	17 (53.1)	16 (50.0)	1 (3.1)
Anaemia	13 (40.6)	13 (40.6)	0
Neutropenia	6 (18.8)	1 (3.1)	5 (15.6)
Pancytopenia	3 (9.4)	1 (3.1)	2 (6.3)
Thrombocytopenia	3 (9.4)	2 (6.3)	1 (3.1)
Disseminated intravascular coagulation	2 (6.3)	2 (6.3)	0
Lymphopenia	1 (3.1)	0	1 (3.1)
Gastrointestinal disorders			

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	8 (25.0)	8 (25.0)	0
Nausea	3 (9.4)	3 (9.4)	0
Vomiting	3 (9.4)	3 (9.4)	0
Diarrhoea	2 (6.3)	2 (6.3)	0
Stomatitis	2 (6.3)	2 (6.3)	0
Abdominal pain	1 (3.1)	1 (3.1)	0
Colitis	1 (3.1)	1 (3.1)	0
General disorders and administration site conditions			
-Total	6 (18.8)	6 (18.8)	0
Pyrexia	5 (15.6)	5 (15.6)	0
Pain	1 (3.1)	1 (3.1)	0
Hepatobiliary disorders			
-Total	1 (3.1)	1 (3.1)	0
Hyperbilirubinaemia	1 (3.1)	1 (3.1)	0
Immune system disorders			
-Total	10 (31.3)	5 (15.6)	5 (15.6)
Cytokine release syndrome	7 (21.9)	2 (6.3)	5 (15.6)
Hypogammaglobulinaemia	3 (9.4)	3 (9.4)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Infections and infestations			
-Total	7 (21.9)	6 (18.8)	1 (3.1)
Device related infection	3 (9.4)	3 (9.4)	0
Escherichia urinary tract infection	2 (6.3)	2 (6.3)	0
Sepsis	1 (3.1)	0	1 (3.1)
Staphylococcal bacteraemia	1 (3.1)	1 (3.1)	0
Staphylococcal infection	1 (3.1)	1 (3.1)	0
Investigations			
-Total	29 (90.6)	5 (15.6)	24 (75.0)
White blood cell count decreased	23 (71.9)	5 (15.6)	18 (56.3)
Neutrophil count decreased	16 (50.0)	2 (6.3)	14 (43.8)
Platelet count decreased	11 (34.4)	2 (6.3)	9 (28.1)
Lymphocyte count decreased	10 (31.3)	5 (15.6)	5 (15.6)
Alanine aminotransferase increased	9 (28.1)	9 (28.1)	0
Aspartate aminotransferase increased	6 (18.8)	5 (15.6)	1 (3.1)
Blood bilirubin increased	3 (9.4)	3 (9.4)	0
Lipase increased	2 (6.3)	0	2 (6.3)
Electrocardiogram qt prolonged	1 (3.1)	1 (3.1)	0

Time since enrollment to CTL019 infusion: > Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Metabolism and nutrition disorders			
-Total	13 (40.6)	10 (31.3)	3 (9.4)
Hypokalaemia	8 (25.0)	6 (18.8)	2 (6.3)
Decreased appetite	4 (12.5)	4 (12.5)	0
Hypophosphataemia	4 (12.5)	4 (12.5)	0
Dehydration	2 (6.3)	2 (6.3)	0
Hyperglycaemia	2 (6.3)	2 (6.3)	0
Hypernatraemia	1 (3.1)	0	1 (3.1)
Tumour lysis syndrome	1 (3.1)	1 (3.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (3.1)	1 (3.1)	0
Arthralgia	1 (3.1)	1 (3.1)	0
Nervous system disorders			
-Total	4 (12.5)	4 (12.5)	0
Headache	3 (9.4)	3 (9.4)	0
Seizure	1 (3.1)	1 (3.1)	0
Renal and urinary disorders			
-Total	3 (9.4)	3 (9.4)	0

Time since enrollment to CTL019 infusion: > Median

Group term Preferred term	All patients N=32 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Acute kidney injury	2 (6.3)	2 (6.3)	0
Haematuria	1 (3.1)	1 (3.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (18.8)	6 (18.8)	0
Epistaxis	4 (12.5)	4 (12.5)	0
Hypoxia	3 (9.4)	3 (9.4)	0
Vascular disorders			
-Total	4 (12.5)	3 (9.4)	1 (3.1)
Hypotension	4 (12.5)	3 (9.4)	1 (3.1)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193q
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	31 (96.9)	9 (28.1)	22 (68.8)
Blood and lymphatic system disorders			
-Total	27 (84.4)	15 (46.9)	12 (37.5)
Febrile neutropenia	17 (53.1)	17 (53.1)	0
Anaemia	12 (37.5)	11 (34.4)	1 (3.1)
Neutropenia	9 (28.1)	3 (9.4)	6 (18.8)
Thrombocytopenia	9 (28.1)	3 (9.4)	6 (18.8)
Lymphopenia	2 (6.3)	1 (3.1)	1 (3.1)
Pancytopenia	1 (3.1)	0	1 (3.1)
Cardiac disorders			
-Total	5 (15.6)	5 (15.6)	0
Left ventricular dysfunction	3 (9.4)	3 (9.4)	0

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tachycardia	2 (6.3)	2 (6.3)	0
Sinus tachycardia	1 (3.1)	1 (3.1)	0
Gastrointestinal disorders			
-Total	5 (15.6)	4 (12.5)	1 (3.1)
Nausea	3 (9.4)	3 (9.4)	0
Abdominal pain	1 (3.1)	1 (3.1)	0
Ascites	1 (3.1)	1 (3.1)	0
Stomatitis	1 (3.1)	0	1 (3.1)
General disorders and administration site conditions			
-Total	4 (12.5)	3 (9.4)	1 (3.1)
Fatigue	2 (6.3)	2 (6.3)	0
Pyrexia	2 (6.3)	1 (3.1)	1 (3.1)
Multiple organ dysfunction syndrome	1 (3.1)	1 (3.1)	0
Pain	1 (3.1)	1 (3.1)	0
Hepatobiliary disorders			
-Total	2 (6.3)	2 (6.3)	0
Hyperbilirubinaemia	2 (6.3)	2 (6.3)	0
Immune system disorders			

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	12 (37.5)	6 (18.8)	6 (18.8)
Cytokine release syndrome	12 (37.5)	6 (18.8)	6 (18.8)
Hypogammaglobulinaemia	2 (6.3)	2 (6.3)	0
Infections and infestations			
-Total	1 (3.1)	1 (3.1)	0
Pneumonia	1 (3.1)	1 (3.1)	0
Investigations			
-Total	21 (65.6)	6 (18.8)	15 (46.9)
White blood cell count decreased	13 (40.6)	3 (9.4)	10 (31.3)
Neutrophil count decreased	12 (37.5)	1 (3.1)	11 (34.4)
Alanine aminotransferase increased	9 (28.1)	9 (28.1)	0
Aspartate aminotransferase increased	7 (21.9)	4 (12.5)	3 (9.4)
Lymphocyte count decreased	5 (15.6)	2 (6.3)	3 (9.4)
Platelet count decreased	5 (15.6)	1 (3.1)	4 (12.5)
Blood fibrinogen decreased	3 (9.4)	2 (6.3)	1 (3.1)
Blood creatinine increased	2 (6.3)	2 (6.3)	0
Blood bilirubin increased	1 (3.1)	1 (3.1)	0
Lipase increased	1 (3.1)	0	1 (3.1)

Time since enrollment to CTL019 infusion: <=Median

Group term Preferred term	All patients N=32 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Metabolism and nutrition disorders			
-Total	15 (46.9)	14 (43.8)	1 (3.1)
Decreased appetite	9 (28.1)	9 (28.1)	0
Hypophosphataemia	4 (12.5)	3 (9.4)	1 (3.1)
Hypokalaemia	3 (9.4)	3 (9.4)	0
Hyperglycaemia	2 (6.3)	2 (6.3)	0
Hypocalcaemia	2 (6.3)	1 (3.1)	1 (3.1)
Tumour lysis syndrome	2 (6.3)	2 (6.3)	0
Dehydration	1 (3.1)	1 (3.1)	0
Musculoskeletal and connective tissue disorders			
-Total	3 (9.4)	3 (9.4)	0
Pain in extremity	2 (6.3)	2 (6.3)	0
Back pain	1 (3.1)	1 (3.1)	0
Nervous system disorders			
-Total	2 (6.3)	2 (6.3)	0
Headache	1 (3.1)	1 (3.1)	0
Seizure	1 (3.1)	1 (3.1)	0
Renal and urinary disorders			

Time since enrollment to CTL019 infusion: <=Median

	All patients N=32		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	6 (18.8)	2 (6.3)	4 (12.5)
Acute kidney injury	5 (15.6)	2 (6.3)	3 (9.4)
Haematuria	2 (6.3)	1 (3.1)	1 (3.1)
Oliguria	2 (6.3)	2 (6.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	10 (31.3)	3 (9.4)	7 (21.9)
Hypoxia	6 (18.8)	3 (9.4)	3 (9.4)
Pulmonary oedema	6 (18.8)	4 (12.5)	2 (6.3)
Respiratory failure	3 (9.4)	0	3 (9.4)
Dyspnoea	2 (6.3)	1 (3.1)	1 (3.1)
Epistaxis	2 (6.3)	1 (3.1)	1 (3.1)
Pleural effusion	2 (6.3)	2 (6.3)	0
Tachypnoea	2 (6.3)	2 (6.3)	0
Haemoptysis	1 (3.1)	0	1 (3.1)
Respiratory distress	1 (3.1)	0	1 (3.1)
Vascular disorders			
-Total	14 (43.8)	7 (21.9)	7 (21.9)
Hypotension	14 (43.8)	7 (21.9)	7 (21.9)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193q
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Time since enrollment to CTL019 infusion
Enrolled set

Time since enrollment to CTL019 infusion: Missing

		All patients N=11	
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	7 (63.6)	0	7 (63.6)
Blood and lymphatic system disorders			
-Total	3 (27.3)	1 (9.1)	2 (18.2)
Anaemia	2 (18.2)	2 (18.2)	0
Disseminated intravascular coagulation	2 (18.2)	1 (9.1)	1 (9.1)
Febrile neutropenia	2 (18.2)	2 (18.2)	0
Thrombocytopenia	2 (18.2)	0	2 (18.2)
Lymphopenia	1 (9.1)	0	1 (9.1)
Neutropenia	1 (9.1)	0	1 (9.1)
Cardiac disorders			

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	2 (18.2)	0	2 (18.2)
Bradycardia	1 (9.1)	0	1 (9.1)
Cardiovascular insufficiency	1 (9.1)	0	1 (9.1)
Right ventricular dysfunction	1 (9.1)	1 (9.1)	0
Sinus tachycardia	1 (9.1)	1 (9.1)	0
Ventricular tachycardia	1 (9.1)	1 (9.1)	0
Gastrointestinal disorders			
-Total	3 (27.3)	3 (27.3)	0
Colitis	2 (18.2)	2 (18.2)	0
Abdominal pain	1 (9.1)	1 (9.1)	0
Ascites	1 (9.1)	1 (9.1)	0
Haematochezia	1 (9.1)	1 (9.1)	0
Nausea	1 (9.1)	1 (9.1)	0
Vomiting	1 (9.1)	1 (9.1)	0
General disorders and administration site conditions			
-Total	5 (45.5)	2 (18.2)	3 (27.3)
Multiple organ dysfunction syndrome	3 (27.3)	0	3 (27.3)
Non-cardiac chest pain	1 (9.1)	1 (9.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pain	1 (9.1)	1 (9.1)	0
Pyrexia	1 (9.1)	1 (9.1)	0
Hepatobiliary disorders			
-Total	1 (9.1)	0	1 (9.1)
Hepatic failure	1 (9.1)	0	1 (9.1)
Infections and infestations			
-Total	5 (45.5)	0	5 (45.5)
Candida sepsis	1 (9.1)	0	1 (9.1)
Klebsiella sepsis	1 (9.1)	0	1 (9.1)
Pneumonia	1 (9.1)	0	1 (9.1)
Sepsis	1 (9.1)	0	1 (9.1)
Staphylococcal bacteraemia	1 (9.1)	1 (9.1)	0
Staphylococcal infection	1 (9.1)	0	1 (9.1)
Investigations			
-Total	2 (18.2)	0	2 (18.2)
Alanine aminotransferase increased	1 (9.1)	0	1 (9.1)
Aspartate aminotransferase increased	1 (9.1)	0	1 (9.1)
Blood bilirubin increased	1 (9.1)	0	1 (9.1)

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Blood lactate dehydrogenase increased	1 (9.1)	1 (9.1)	0
Computerised tomogram thorax abnormal	1 (9.1)	1 (9.1)	0
Electrocardiogram qt prolonged	1 (9.1)	1 (9.1)	0
Neutrophil count decreased	1 (9.1)	0	1 (9.1)
White blood cell count decreased	1 (9.1)	0	1 (9.1)
Metabolism and nutrition disorders			
-Total	3 (27.3)	1 (9.1)	2 (18.2)
Hypernatraemia	2 (18.2)	0	2 (18.2)
Hypokalaemia	2 (18.2)	0	2 (18.2)
Fluid overload	1 (9.1)	1 (9.1)	0
Hyperkalaemia	1 (9.1)	1 (9.1)	0
Hypophosphataemia	1 (9.1)	1 (9.1)	0
Musculoskeletal and connective tissue disorders			
-Total	1 (9.1)	1 (9.1)	0
Arthralgia	1 (9.1)	1 (9.1)	0
Back pain	1 (9.1)	1 (9.1)	0
Pain in extremity	1 (9.1)	1 (9.1)	0

Time since enrollment to CTL019 infusion: Missing

	All patients N=11		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	1 (9.1)	0	1 (9.1)
Headache	1 (9.1)	1 (9.1)	0
Hyporesponsive to stimuli	1 (9.1)	1 (9.1)	0
Seizure	1 (9.1)	0	1 (9.1)
Psychiatric disorders			
-Total	2 (18.2)	2 (18.2)	0
Agitation	1 (9.1)	1 (9.1)	0
Delirium	1 (9.1)	1 (9.1)	0
Renal and urinary disorders			
-Total	2 (18.2)	1 (9.1)	1 (9.1)
Acute kidney injury	2 (18.2)	1 (9.1)	1 (9.1)
Oliguria	1 (9.1)	1 (9.1)	0
Respiratory, thoracic and mediastinal disorders			
-Total	4 (36.4)	1 (9.1)	3 (27.3)
Hypoxia	3 (27.3)	3 (27.3)	0
Pulmonary oedema	2 (18.2)	0	2 (18.2)
Aspiration	1 (9.1)	0	1 (9.1)

Time since enrollment to CTL019 infusion: Missing

Group term Preferred term	All patients N=11 All grades n (%)	 Grade 3 n (%)	 Grade 4 n (%)
Cough	1 (9.1)	1 (9.1)	0
Dyspnoea	1 (9.1)	1 (9.1)	0
Haemoptysis	1 (9.1)	1 (9.1)	0
Oropharyngeal pain	1 (9.1)	1 (9.1)	0
Pleural effusion	1 (9.1)	1 (9.1)	0
Pulmonary alveolar haemorrhage	1 (9.1)	0	1 (9.1)
Pulmonary hypertension	1 (9.1)	1 (9.1)	0
Respiratory distress	1 (9.1)	0	1 (9.1)
Respiratory failure	1 (9.1)	0	1 (9.1)
Tachypnoea	1 (9.1)	1 (9.1)	0
Vascular disorders			
-Total	5 (45.5)	2 (18.2)	3 (27.3)
Hypotension	5 (45.5)	2 (18.2)	3 (27.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.

- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193r
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	8 (100)	1 (12.5)	7 (87.5)
Blood and lymphatic system disorders			
-Total	6 (75.0)	4 (50.0)	2 (25.0)
Anaemia	4 (50.0)	3 (37.5)	1 (12.5)
Febrile neutropenia	4 (50.0)	4 (50.0)	0
Neutropenia	2 (25.0)	0	2 (25.0)
Thrombocytopenia	2 (25.0)	1 (12.5)	1 (12.5)
Cardiac disorders			
-Total	2 (25.0)	2 (25.0)	0
Left ventricular dysfunction	2 (25.0)	2 (25.0)	0
Tachycardia	1 (12.5)	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Gastrointestinal disorders			
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Nausea	2 (25.0)	2 (25.0)	0
Enterocolitis	1 (12.5)	1 (12.5)	0
Oral pain	1 (12.5)	1 (12.5)	0
Stomatitis	1 (12.5)	0	1 (12.5)
General disorders and administration site conditions			
-Total	4 (50.0)	3 (37.5)	1 (12.5)
Pyrexia	3 (37.5)	2 (25.0)	1 (12.5)
Pain	2 (25.0)	2 (25.0)	0
Fatigue	1 (12.5)	1 (12.5)	0
Immune system disorders			
-Total	3 (37.5)	0	3 (37.5)
Cytokine release syndrome	3 (37.5)	0	3 (37.5)
Infections and infestations			
-Total	3 (37.5)	1 (12.5)	2 (25.0)
Cellulitis	1 (12.5)	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Corona virus infection	1 (12.5)	1 (12.5)	0
Human polyomavirus infection	1 (12.5)	0	1 (12.5)
Oral herpes	1 (12.5)	1 (12.5)	0
Pneumonia	1 (12.5)	0	1 (12.5)
Respiratory syncytial virus infection	1 (12.5)	1 (12.5)	0
Injury, poisoning and procedural complications			
-Total	1 (12.5)	1 (12.5)	0
Tracheal haemorrhage	1 (12.5)	1 (12.5)	0
Investigations			
-Total	6 (75.0)	2 (25.0)	4 (50.0)
Neutrophil count decreased	3 (37.5)	0	3 (37.5)
White blood cell count decreased	3 (37.5)	0	3 (37.5)
Aspartate aminotransferase increased	1 (12.5)	0	1 (12.5)
Blood bilirubin increased	1 (12.5)	1 (12.5)	0
Blood magnesium decreased	1 (12.5)	1 (12.5)	0
Metabolism and nutrition disorders			
-Total	1 (12.5)	1 (12.5)	0

Number of previous relapses: 0

	All patients N=8		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Decreased appetite	1 (12.5)	1 (12.5)	0
Hypophosphataemia	1 (12.5)	1 (12.5)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (25.0)	2 (25.0)	0
Arthralgia	1 (12.5)	1 (12.5)	0
Pain in extremity	1 (12.5)	1 (12.5)	0
Renal and urinary disorders			
-Total	2 (25.0)	0	2 (25.0)
Haematuria	2 (25.0)	1 (12.5)	1 (12.5)
Acute kidney injury	1 (12.5)	0	1 (12.5)
Cystitis haemorrhagic	1 (12.5)	0	1 (12.5)
Oliguria	1 (12.5)	1 (12.5)	0
Renal failure	1 (12.5)	0	1 (12.5)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (50.0)	1 (12.5)	3 (37.5)
Hypoxia	3 (37.5)	2 (25.0)	1 (12.5)
Epistaxis	2 (25.0)	1 (12.5)	1 (12.5)

Number of previous relapses: 0

Group term Preferred term	All patients N=8 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Aspiration	1 (12.5)	0	1 (12.5)
Dyspnoea	1 (12.5)	0	1 (12.5)
Haemoptysis	1 (12.5)	0	1 (12.5)
Interstitial lung disease	1 (12.5)	0	1 (12.5)
Pharyngeal lesion	1 (12.5)	1 (12.5)	0
Pulmonary oedema	1 (12.5)	0	1 (12.5)
Respiratory failure	1 (12.5)	0	1 (12.5)
Vascular disorders			
-Total	5 (62.5)	2 (25.0)	3 (37.5)
Hypotension	5 (62.5)	2 (25.0)	3 (37.5)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193r
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	19 (82.6)	2 (8.7)	17 (73.9)
Blood and lymphatic system disorders			
-Total	19 (82.6)	11 (47.8)	8 (34.8)
Febrile neutropenia	13 (56.5)	13 (56.5)	0
Anaemia	9 (39.1)	9 (39.1)	0
Neutropenia	4 (17.4)	1 (4.3)	3 (13.0)
Disseminated intravascular coagulation	3 (13.0)	3 (13.0)	0
Lymphopenia	3 (13.0)	0	3 (13.0)
Thrombocytopenia	3 (13.0)	1 (4.3)	2 (8.7)
Pancytopenia	2 (8.7)	0	2 (8.7)

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Cardiac disorders			
-Total	1 (4.3)	1 (4.3)	0
Sinus tachycardia	1 (4.3)	1 (4.3)	0
Gastrointestinal disorders			
-Total	5 (21.7)	5 (21.7)	0
Nausea	3 (13.0)	3 (13.0)	0
Vomiting	2 (8.7)	2 (8.7)	0
Abdominal pain	1 (4.3)	1 (4.3)	0
Stomatitis	1 (4.3)	1 (4.3)	0
General disorders and administration site conditions			
-Total	7 (30.4)	7 (30.4)	0
Pyrexia	4 (17.4)	4 (17.4)	0
Physical deconditioning	2 (8.7)	2 (8.7)	0
Multiple organ dysfunction syndrome	1 (4.3)	1 (4.3)	0
Hepatobiliary disorders			
-Total	2 (8.7)	2 (8.7)	0
Hyperbilirubinaemia	2 (8.7)	2 (8.7)	0

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Immune system disorders			
-Total	8 (34.8)	3 (13.0)	5 (21.7)
Cytokine release syndrome	7 (30.4)	2 (8.7)	5 (21.7)
Hypogammaglobulinaemia	2 (8.7)	2 (8.7)	0
Infections and infestations			
-Total	8 (34.8)	7 (30.4)	1 (4.3)
Device related infection	2 (8.7)	2 (8.7)	0
Escherichia bacteraemia	2 (8.7)	2 (8.7)	0
Escherichia urinary tract infection	2 (8.7)	2 (8.7)	0
Pneumonia	1 (4.3)	1 (4.3)	0
Sepsis	1 (4.3)	0	1 (4.3)
Staphylococcal bacteraemia	1 (4.3)	1 (4.3)	0
Staphylococcal infection	1 (4.3)	1 (4.3)	0
Urinary tract infection	1 (4.3)	1 (4.3)	0
Investigations			
-Total	17 (73.9)	3 (13.0)	14 (60.9)
White blood cell count decreased	12 (52.2)	3 (13.0)	9 (39.1)
Neutrophil count decreased	10 (43.5)	2 (8.7)	8 (34.8)

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Platelet count decreased	7 (30.4)	1 (4.3)	6 (26.1)
Lymphocyte count decreased	6 (26.1)	3 (13.0)	3 (13.0)
Alanine aminotransferase increased	4 (17.4)	4 (17.4)	0
Aspartate aminotransferase increased	4 (17.4)	3 (13.0)	1 (4.3)
Lipase increased	2 (8.7)	0	2 (8.7)
Blood bilirubin increased	1 (4.3)	1 (4.3)	0
Blood creatinine increased	1 (4.3)	1 (4.3)	0
Blood fibrinogen decreased	1 (4.3)	0	1 (4.3)
Electrocardiogram qt prolonged	1 (4.3)	1 (4.3)	0
Metabolism and nutrition disorders			
-Total	10 (43.5)	7 (30.4)	3 (13.0)
Hypokalaemia	5 (21.7)	3 (13.0)	2 (8.7)
Decreased appetite	4 (17.4)	4 (17.4)	0
Hyperglycaemia	2 (8.7)	2 (8.7)	0
Hypophosphataemia	2 (8.7)	2 (8.7)	0
Dehydration	1 (4.3)	1 (4.3)	0
Hypernatraemia	1 (4.3)	0	1 (4.3)

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Tumour lysis syndrome	1 (4.3)	1 (4.3)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (8.7)	2 (8.7)	0
Back pain	2 (8.7)	2 (8.7)	0
Arthralgia	1 (4.3)	1 (4.3)	0
Pain in extremity	1 (4.3)	1 (4.3)	0
Nervous system disorders			
-Total	3 (13.0)	2 (8.7)	1 (4.3)
Headache	2 (8.7)	2 (8.7)	0
Seizure	2 (8.7)	1 (4.3)	1 (4.3)
Renal and urinary disorders			
-Total	4 (17.4)	4 (17.4)	0
Acute kidney injury	3 (13.0)	3 (13.0)	0
Haematuria	1 (4.3)	1 (4.3)	0
Oliguria	1 (4.3)	1 (4.3)	0
Respiratory, thoracic and mediastinal disorders			
-Total	7 (30.4)	4 (17.4)	3 (13.0)

Number of previous relapses: 1

	All patients N=23		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypoxia	4 (17.4)	4 (17.4)	0
Pulmonary oedema	4 (17.4)	2 (8.7)	2 (8.7)
Epistaxis	2 (8.7)	2 (8.7)	0
Respiratory distress	2 (8.7)	0	2 (8.7)
Tachypnoea	2 (8.7)	2 (8.7)	0
Dyspnoea	1 (4.3)	1 (4.3)	0
Haemoptysis	1 (4.3)	1 (4.3)	0
Pleural effusion	1 (4.3)	1 (4.3)	0
Respiratory failure	1 (4.3)	0	1 (4.3)
Vascular disorders			
-Total	6 (26.1)	2 (8.7)	4 (17.4)
Hypotension	6 (26.1)	2 (8.7)	4 (17.4)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193r
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	21 (87.5)	5 (20.8)	16 (66.7)
Blood and lymphatic system disorders			
-Total	18 (75.0)	10 (41.7)	8 (33.3)
Febrile neutropenia	11 (45.8)	10 (41.7)	1 (4.2)
Anaemia	6 (25.0)	6 (25.0)	0
Neutropenia	6 (25.0)	2 (8.3)	4 (16.7)
Thrombocytopenia	4 (16.7)	0	4 (16.7)
Pancytopenia	2 (8.3)	1 (4.2)	1 (4.2)
Lymphopenia	1 (4.2)	1 (4.2)	0
Cardiac disorders			

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	1 (4.2)	1 (4.2)	0
Left ventricular dysfunction	1 (4.2)	1 (4.2)	0
Gastrointestinal disorders			
-Total	4 (16.7)	4 (16.7)	0
Nausea	2 (8.3)	2 (8.3)	0
Vomiting	2 (8.3)	2 (8.3)	0
Abdominal pain	1 (4.2)	1 (4.2)	0
Ascites	1 (4.2)	1 (4.2)	0
Immune system disorders			
-Total	7 (29.2)	6 (25.0)	1 (4.2)
Cytokine release syndrome	5 (20.8)	4 (16.7)	1 (4.2)
Hypogammaglobulinaemia	3 (12.5)	3 (12.5)	0
Investigations			
-Total	20 (83.3)	7 (29.2)	13 (54.2)
White blood cell count decreased	15 (62.5)	4 (16.7)	11 (45.8)
Alanine aminotransferase increased	10 (41.7)	10 (41.7)	0
Neutrophil count decreased	8 (33.3)	1 (4.2)	7 (29.2)

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Aspartate aminotransferase increased	5 (20.8)	5 (20.8)	0
Lymphocyte count decreased	5 (20.8)	3 (12.5)	2 (8.3)
Platelet count decreased	4 (16.7)	2 (8.3)	2 (8.3)
Blood fibrinogen decreased	2 (8.3)	2 (8.3)	0
Blood bilirubin increased	1 (4.2)	1 (4.2)	0
Lipase increased	1 (4.2)	0	1 (4.2)
Metabolism and nutrition disorders			
-Total	11 (45.8)	9 (37.5)	2 (8.3)
Decreased appetite	6 (25.0)	6 (25.0)	0
Hypophosphataemia	5 (20.8)	4 (16.7)	1 (4.2)
Hypokalaemia	4 (16.7)	3 (12.5)	1 (4.2)
Hyponatraemia	2 (8.3)	2 (8.3)	0
Tumour lysis syndrome	2 (8.3)	2 (8.3)	0
Dehydration	1 (4.2)	1 (4.2)	0
Hyperglycaemia	1 (4.2)	1 (4.2)	0
Hypernatraemia	1 (4.2)	0	1 (4.2)
Hypocalcaemia	1 (4.2)	0	1 (4.2)

Number of previous relapses: 2

	All patients N=24		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Nervous system disorders			
-Total	2 (8.3)	2 (8.3)	0
Headache	2 (8.3)	2 (8.3)	0
Renal and urinary disorders			
-Total	4 (16.7)	2 (8.3)	2 (8.3)
Acute kidney injury	4 (16.7)	2 (8.3)	2 (8.3)
Respiratory, thoracic and mediastinal disorders			
-Total	4 (16.7)	1 (4.2)	3 (12.5)
Hypoxia	2 (8.3)	1 (4.2)	1 (4.2)
Pulmonary oedema	2 (8.3)	1 (4.2)	1 (4.2)
Respiratory failure	2 (8.3)	0	2 (8.3)
Pleural effusion	1 (4.2)	1 (4.2)	0
Vascular disorders			
-Total	5 (20.8)	3 (12.5)	2 (8.3)
Hypotension	5 (20.8)	3 (12.5)	2 (8.3)

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.

- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.

Table 193r
Severe adverse events (AE CTCAE Grade 3/4) that occurred in at least 5% of the patients OR (in at least 10 patients AND in at least 1% of the patients) at anytime post-enrollment by primary system organ class, preferred term, maximum CTC grade and Number of previous relapses
Enrolled set

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Number of patients with at least one AE	20 (100)	5 (25.0)	15 (75.0)
Blood and lymphatic system disorders			
-Total	15 (75.0)	10 (50.0)	5 (25.0)
Anaemia	8 (40.0)	8 (40.0)	0
Febrile neutropenia	8 (40.0)	8 (40.0)	0
Thrombocytopenia	5 (25.0)	3 (15.0)	2 (10.0)
Neutropenia	4 (20.0)	1 (5.0)	3 (15.0)
Disseminated intravascular coagulation	1 (5.0)	0	1 (5.0)
Eosinophilia	1 (5.0)	1 (5.0)	0
Cardiac disorders			

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	3 (15.0)	2 (10.0)	1 (5.0)
Cardiovascular insufficiency	1 (5.0)	0	1 (5.0)
Sinus tachycardia	1 (5.0)	1 (5.0)	0
Tachycardia	1 (5.0)	1 (5.0)	0
Gastrointestinal disorders			
-Total	5 (25.0)	5 (25.0)	0
Colitis	3 (15.0)	3 (15.0)	0
Abdominal pain	1 (5.0)	1 (5.0)	0
Ascites	1 (5.0)	1 (5.0)	0
Mouth haemorrhage	1 (5.0)	1 (5.0)	0
Stomatitis	1 (5.0)	1 (5.0)	0
General disorders and administration site conditions			
-Total	6 (30.0)	3 (15.0)	3 (15.0)
Multiple organ dysfunction syndrome	3 (15.0)	0	3 (15.0)
Cyst	1 (5.0)	1 (5.0)	0
Fatigue	1 (5.0)	1 (5.0)	0
Pain	1 (5.0)	1 (5.0)	0

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Pyrexia	1 (5.0)	1 (5.0)	0
Hepatobiliary disorders			
-Total	3 (15.0)	2 (10.0)	1 (5.0)
Cholecystitis	1 (5.0)	1 (5.0)	0
Hepatic failure	1 (5.0)	0	1 (5.0)
Hyperbilirubinaemia	1 (5.0)	1 (5.0)	0
Immune system disorders			
-Total	4 (20.0)	2 (10.0)	2 (10.0)
Cytokine release syndrome	4 (20.0)	2 (10.0)	2 (10.0)
Infections and infestations			
-Total	10 (50.0)	7 (35.0)	3 (15.0)
Bacteraemia	1 (5.0)	1 (5.0)	0
Campylobacter infection	1 (5.0)	1 (5.0)	0
Cellulitis of male external genital organ	1 (5.0)	1 (5.0)	0
Clostridium difficile infection	1 (5.0)	1 (5.0)	0
Croup infectious	1 (5.0)	1 (5.0)	0
Device related infection	1 (5.0)	1 (5.0)	0

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Enterovirus infection	1 (5.0)	1 (5.0)	0
Klebsiella sepsis	1 (5.0)	0	1 (5.0)
Necrotising fasciitis	1 (5.0)	1 (5.0)	0
Respiratory tract infection viral	1 (5.0)	1 (5.0)	0
Rotavirus infection	1 (5.0)	1 (5.0)	0
Sepsis	1 (5.0)	0	1 (5.0)
Staphylococcal bacteraemia	1 (5.0)	1 (5.0)	0
Staphylococcal infection	1 (5.0)	0	1 (5.0)
Streptococcal bacteraemia	1 (5.0)	1 (5.0)	0
Upper respiratory tract infection	1 (5.0)	1 (5.0)	0
Urinary tract infection	1 (5.0)	1 (5.0)	0
Vascular device infection	1 (5.0)	1 (5.0)	0
Injury, poisoning and procedural complications			
-Total	1 (5.0)	1 (5.0)	0
Extradural haematoma	1 (5.0)	1 (5.0)	0
Subdural haematoma	1 (5.0)	1 (5.0)	0
Investigations			

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
-Total	10 (50.0)	0	10 (50.0)
Neutrophil count decreased	8 (40.0)	0	8 (40.0)
White blood cell count decreased	7 (35.0)	1 (5.0)	6 (30.0)
Alanine aminotransferase increased	5 (25.0)	4 (20.0)	1 (5.0)
Platelet count decreased	5 (25.0)	0	5 (25.0)
Aspartate aminotransferase increased	4 (20.0)	1 (5.0)	3 (15.0)
Lymphocyte count decreased	4 (20.0)	1 (5.0)	3 (15.0)
Blood bilirubin increased	2 (10.0)	1 (5.0)	1 (5.0)
Blood creatinine increased	1 (5.0)	1 (5.0)	0
Blood lactic acid increased	1 (5.0)	0	1 (5.0)
Electrocardiogram qt prolonged	1 (5.0)	1 (5.0)	0
Metabolism and nutrition disorders			
-Total	8 (40.0)	7 (35.0)	1 (5.0)
Hypokalaemia	4 (20.0)	3 (15.0)	1 (5.0)
Decreased appetite	2 (10.0)	2 (10.0)	0
Dehydration	1 (5.0)	1 (5.0)	0
Hyperglycaemia	1 (5.0)	1 (5.0)	0

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Hypernatraemia	1 (5.0)	0	1 (5.0)
Hypocalcaemia	1 (5.0)	1 (5.0)	0
Hypoglycaemia	1 (5.0)	1 (5.0)	0
Hypophosphataemia	1 (5.0)	1 (5.0)	0
Musculoskeletal and connective tissue disorders			
-Total	2 (10.0)	2 (10.0)	0
Musculoskeletal pain	1 (5.0)	1 (5.0)	0
Myalgia	1 (5.0)	1 (5.0)	0
Pain in extremity	1 (5.0)	1 (5.0)	0
Nervous system disorders			
-Total	2 (10.0)	2 (10.0)	0
Headache	1 (5.0)	1 (5.0)	0
Seizure	1 (5.0)	1 (5.0)	0
Psychiatric disorders			
-Total	3 (15.0)	3 (15.0)	0
Anxiety	1 (5.0)	1 (5.0)	0
Delirium	1 (5.0)	1 (5.0)	0

Number of previous relapses: >=3

	All patients N=20		
Group term Preferred term	**All grades n (%)**	**Grade 3 n (%)**	**Grade 4 n (%)**
Mental status changes	1 (5.0)	1 (5.0)	0
Renal and urinary disorders			
-Total	1 (5.0)	0	1 (5.0)
Acute kidney injury	1 (5.0)	0	1 (5.0)
Oliguria	1 (5.0)	1 (5.0)	0
Respiratory, thoracic and mediastinal disorders			
-Total	6 (30.0)	4 (20.0)	2 (10.0)
Hypoxia	3 (15.0)	2 (10.0)	1 (5.0)
Epistaxis	2 (10.0)	2 (10.0)	0
Dyspnoea	1 (5.0)	1 (5.0)	0
Idiopathic pneumonia syndrome	1 (5.0)	0	1 (5.0)
Pleural effusion	1 (5.0)	1 (5.0)	0
Pulmonary oedema	1 (5.0)	1 (5.0)	0
Tachypnoea	1 (5.0)	1 (5.0)	0
Skin and subcutaneous tissue disorders			
-Total	1 (5.0)	1 (5.0)	0
Rash macular	1 (5.0)	1 (5.0)	0

Number of previous relapses: >=3

Group term Preferred term	All patients N=20 All grades n (%)	Grade 3 n (%)	Grade 4 n (%)
Vascular disorders			
-Total	9 (45.0)	7 (35.0)	2 (10.0)
Hypotension	7 (35.0)	5 (25.0)	2 (10.0)
Hypertension	2 (10.0)	2 (10.0)	0
Embolism	1 (5.0)	1 (5.0)	0

- Enrolled set = All patients who meet all inclusion/exclusion criteria, and whose apheresis product is received and accepted by the manufacturing facility.
- A patient with multiple adverse events within a primary system organ class is counted only once in the total row.
- A patient with multiple occurrences of an AE is counted only once in the AE category at the maximum toxicity grade.
- System organ classes are presented in alphabetical order; preferred terms are presented in descending frequency of all grades column, as reported in the All patients column.
- MedDRA version 22.0 and CTCAE version 4.03 have been used for the reporting of adverse events.