Anhang 4-G:
Ergänzende Unterlagen

Axicabtagen-Ciloleucel (Yescarta®)

Gilead Sciences GmbH

Rezidiviertes oder refraktäres DLBCL und PMBCL nach zwei oder mehr systemischen Therapien

Stand: 30.06.2023

Anhang 4-G: Ergänzende Unterlagen

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Anhang 4-G1: ZUMA-1 - Patientenfluss und Folgetherapien

Anhang 4-G1.1: Patientenfluss

Kite Pharma, Inc. Confidential Protocol: KTE-C19-101

Table 14.1.2. Subject Disposition (Phase 1 and Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 119)

		Phase 2		
	Phase1 (N = 8)	Cohort1 (N = 81)	Cohort2 (N = 30)	Total (N = 111)
Subjects Enrolled n (%)	8 (100)	81 (100)	30 (100)	111 (100)
Subjects Leukapheresed n (%)	8 (100)	81 (100)	30 (100)	111 (100)
Subjects Treated with Conditioning Chemotherapy n (%)	7 (88)	77 (95)	26 (87)	103 (93)
Subjects Treated with Axicabtagene Ciloleucel n (%)	7 (88)	77 (95)	24 (80)	101 (91)
Primary reason for ending treatment n (%)				
Adverse Event	1 (13)	3 (4)	2 (7)	5 (5)
Death	0 (0)	1 (1)	2 (7)	3 (3)
Other	0 (0)	0 (0)	2 (7)	2 (2)
Primary reason for ending study for subjects treated with Axicabtagene Ciloleucel n (%)				
Death	5 (63)	49 (60)	10 (33)	59 (53)
Lost To Follow Up	0 (0)	1 (1)	0 (0)	1 (1)
Primary reason for ending study for subjects not treated with Axicabtagene Ciloleucel n (%)				
Death	1 (13)	4 (5)	4 (13)	8 (7)
Actual Follow-up Time from Axicabtagene Ciloleucel Dose (month)[a]				
N	7	77	24	101
Mean (STDEV)	30.2 (33.6)	30.9 (26.2)	43.5 (26.2)	33.9 (26.6)
Median (Q1, Q3)	9.0 (2.0, 71.8)	15.4 (6.9, 61.9)	60.3 (12.9, 62.9)	25.8 (7.4, 62.2)
Min, Max	0.6, 73.0	0.3, 67.9	0.5, 68.4	0.3, 68.4
Potential Follow-up Time from Axicabtagene Ciloleucel Dose (month)[b]				
N	7	77	24	101
Mean (STDEV)	73.7 (1.1)	63.6 (2.2)	62.8 (2.4)	63.4 (2.2)
Median (Q1, Q3)	73.8 (73.0, 74.7)	63.3 (61.8, 64.8)	62.2 (60.8, 64.7)	63.1 (61.7, 64.8)

Data cutoff date = 11AUG2021
Abbreviations: Q1, first quartile; Q3, third quartile ; STDEV, standard deviation.
Note: Percentages are based on number of subjects enrolled.
a. Actual follow-up time from axicabtagene ciloleucel dose as time from the first dose of axicabtagene ciloleucel to date of death or the last date known alive. (death date or last date known alive - axicabtagene ciloleucel treatment date + 1)/(365.25/12).
b. Potential follow-up time, calculated as the time from axicabtagene ciloleucel infusion to the data cutoff date. Percentages are based on number of subjects treated.

Data Source: ADSL Program Name: t_disp Output Generated: 20210923T14:04

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Table 14.1.2. Subject Disposition (Phase 1 and Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 119)

		Phase 2		
	Phase1 (N = 8)	Cohort1 (N = 81)	Cohort2 (N = 30)	Total (N = 111)
Min, Max	71.8, 74.8	59.9, 68.1	58.9, 68.4	58.9, 68.4
Subjects with ≥ 24 month Potential Follow-up[b] n (%)	7 (100)	77 (100)	24 (100)	101 (100)
Subjects with ≥ 30 month Potential Follow-up[b] n (%)	7 (100)	77 (100)	24 (100)	101 (100)
Subjects with ≥ 36 month Potential Follow-up[b] n (%)	7 (100)	77 (100)	24 (100)	101 (100)
Subjects with ≥ 42 month Potential Follow-up[b] n (%)	7 (100)	77 (100)	24 (100)	101 (100)
Subjects with ≥ 48 month Potential Follow-up[b] n (%)	7 (100)	77 (100)	24 (100)	101 (100)
Subjects with ≥ 54 month Potential Follow-up[b] n (%)	7 (100)	77 (100)	24 (100)	101 (100)
Subjects with ≥ 60 month Potential Follow-up[b] n (%)	7 (100)	76 (99)	23 (96)	99 (98)

Data cutoff date = 11AUG2021
Abbreviations: Q1, first quartile; Q3, third quartile ; STDEV, standard deviation.
Note: Percentages are based on number of subjects enrolled.
a. Actual follow-up time from axicabtagene ciloleucel dose as time from the first dose of axicabtagene ciloleucel to date of death or the last date known alive. (death date or last date known alive - axicabtagene ciloleucel treatment date + 1)/(365.25/12).
b. Potential follow-up time, calculated as the time from axicabtagene ciloleucel infusion to the data cutoff date. Percentages are based on number of subjects treated.

Data Source: ADSL Program Name: t_disp Output Generated: 20210923T14:04

Anhang 4-G1.2: Folgetherapien

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Table 14.2.17.2. Subsequent Anti-Cancer Therapy (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

WHO-DD Preferred Name n(%)	Cohort 1 (N = 81)	Cohort 2 (N = 30)	Total (N = 111)
Subjects with Conditioning Chemotherapy for SCT:	8 (10)	3 (10)	11 (10)
Fludarabine	5 (6)	1 (3)	6 (5)
Melphalan	6 (7)	0 (0)	6 (5)
Carmustine	2 (2)	1 (3)	3 (3)
Etoposide	2 (2)	1 (3)	3 (3)
Cyclophosphamide	1 (1)	1 (3)	2 (2)
Cytarabine	2 (2)	0 (0)	2 (2)
Dexamethasone	1 (1)	1 (3)	2 (2)
Radiotherapy	1 (1)	1 (3)	2 (2)
Vincristine	2 (2)	0 (0)	2 (2)
Antithymocyte Immunoglobulin	1 (1)	0 (0)	1 (1)
Busulfan	1 (1)	0 (0)	1 (1)
Doxorubicin	1 (1)	0 (0)	1 (1)
Hydrocortisone Sodium Succinate	1 (1)	0 (0)	1 (1)
Melphalan Hydrochloride	0 (0)	1 (3)	1 (1)
Methotrexate	1 (1)	0 (0)	1 (1)
Prednisone	1 (1)	0 (0)	1 (1)
Stem Cells Nos	1 (1)	0 (0)	1 (1)
Subjects with Other Therapy:	26 (32)	7 (23)	33 (30)
Rituximab	18 (22)	3 (10)	21 (19)
Lenalidomide	10 (12)	4 (13)	14 (13)
Pembrolizumab	6 (7)	1 (3)	7 (6)
Dexamethasone	6 (7)	0 (0)	6 (5)
Stem Cells Nos	4 (5)	2 (7)	6 (5)
Radiotherapy	5 (6)	0 (0)	5 (5)
Bendamustine	4 (5)	0 (0)	4 (4)
Gemcitabine	4 (5)	0 (0)	4 (4)
Oxaliplatin	4 (5)	0 (0)	4 (4)
Acalabrutinib	3 (4)	0 (0)	3 (3)
Carboplatin	3 (4)	0 (0)	3 (3)
Cyclophosphamide	2 (2)	1 (3)	3 (3)
Ifosfamide	3 (4)	0 (0)	3 (3)
Etoposide	2 (2)	0 (0)	2 (2)
Ibrutinib	2 (2)	0 (0)	2 (2)
Nivolumab	2 (2)	0 (0)	2 (2)

Data cutoff date = 11AUG2021
Abbreviations: SCT, stem cell transplant.
Notes: Percentages are based on number of subjects enrolled in each column; Subsequent anti-cancer therapies including SCT are coded using WHO-DD March 2021 version; Therapies taken during retreatment period are excluded.

Data Source: ADSL, ADCM Program Name: t_anticancer Output Generated: 20210923T14:04

Table 14.2.17.2. Subsequent Anti-Cancer Therapy (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

WHO-DD Preferred Name n(%)	Cohort 1 (N = 81)	Cohort 2 (N = 30)	Total (N = 111)
Avadomide	1 (1)	0 (0)	1 (1)
Bendamustine Hydrochloride	1 (1)	0 (0)	1 (1)
Brentuximab Vedotin	0 (0)	1 (3)	1 (1)
Cisplatin	1 (1)	0 (0)	1 (1)
Cytarabine	1 (1)	0 (0)	1 (1)
Donor Lymphocyte Infusion	0 (0)	1 (3)	1 (1)
Doxorubicin	1 (1)	0 (0)	1 (1)
Durvalumab	1 (1)	0 (0)	1 (1)
Hematopoietic Peripheral Blood Stem Cells	0 (0)	1 (3)	1 (1)
Investigational Antineoplastic Drugs	1 (1)	0 (0)	1 (1)
Loncastuximab Tesirine	1 (1)	0 (0)	1 (1)
Methotrexate	0 (0)	1 (3)	1 (1)
Monoclonal Antibodies	1 (1)	0 (0)	1 (1)
Obinutuzumab	1 (1)	0 (0)	1 (1)
Other Blood Products	1 (1)	0 (0)	1 (1)
Other Immunostimulants	0 (0)	1 (3)	1 (1)
Polatuzumab Vedotin	1 (1)	0 (0)	1 (1)
Romidepsin	1 (1)	0 (0)	1 (1)
Sirolimus	1 (1)	0 (0)	1 (1)
Tti 622	1 (1)	0 (0)	1 (1)
Vincristine	1 (1)	0 (0)	1 (1)
Vorinostat	1 (1)	0 (0)	1 (1)

Data cutoff date = 11AUG2021
Abbreviations: SCT, stem cell transplant.
Notes: Percentages are based on number of subjects enrolled in each column; Subsequent anti-cancer therapies including SCT are coded using WHO-DD March 2021 version; Therapies taken during retreatment period are excluded.

Data Source: ADSL, ADCM Program Name: t_anticancer Output Generated: 20210923T14:04

Anhang 4-G2: ZUMA-1 - 5-Jahres Daten zur Morbidität (Phase 1 und 2)

Anhang 4-G2.1: Progressionsfreies Überleben (PFS)

Table 2.6. Progression-free Survival (PFS) (Phase 2 Cohort 1 and Cohort 2) using Investigator Assessment per Cheson 2007 (mITT Analysis Set, N = 101)

	Phase 2 Cohort 1 and Cohort 2 (N = 101)				
	DLBCL (N = 77)	PMBCL (N = 8)	TFL (N = 16)	DLBCL+TFL (N = 93)	Total (N = 101)
Progression-free Survival (PFS)					
No. of subjects	77	8	16	93	101
Censored (%)	20 (26)	5 (63)	6 (38)	26 (28)	31 (31)
KM Median (95% CI) PFS time (in months)	5.1 (3.0, 8.8)	NR (0.7, NE)	32.3 (2.3, NE)	5.7 (3.1, 13.9)	5.9 (3.4, 15.0)
Min, max PFS (in months)	0.2, 62.0+	0.7, 60.0+	0.5, 63.4	0.2, 63.4	0.2, 63.4
Type of Events					
Disease Progression	51	3	6	57	60
Death	6	0	4	10	10
Censoring reason					
Response/SD Ongoing	20	5	6	26	31
PFS (95% CI) at					
3 Month	62.3 (50.5, 72.1)	87.5 (38.7, 98.1)	75.0 (46.3, 89.8)	64.5 (53.9, 73.3)	66.3 (56.2, 74.6)
6 Month	42.9 (31.7, 53.5)	75.0 (31.5, 93.1)	68.8 (40.5, 85.6)	47.3 (36.9, 57.0)	49.5 (39.4, 58.8)
9 Month	39.0 (28.1, 49.6)	75.0 (31.5, 93.1)	62.5 (34.9, 81.1)	43.0 (32.8, 52.8)	45.5 (35.6, 54.9)
12 Month	37.7 (27.0, 48.3)	75.0 (31.5, 93.1)	62.5 (34.9, 81.1)	41.9 (31.8, 51.7)	44.6 (34.7, 53.9)
15 Month	36.4 (25.8, 47.0)	62.5 (22.9, 86.1)	56.3 (29.5, 76.2)	39.8 (29.9, 49.5)	41.6 (31.9, 51.0)
18 Month	35.1 (24.6, 45.7)	62.5 (22.9, 86.1)	56.3 (29.5, 76.2)	38.7 (28.9, 48.4)	40.6 (31.0, 50.0)
24 Month	33.8 (23.5, 44.3)	62.5 (22.9, 86.1)	56.3 (29.5, 76.2)	37.6 (27.9, 47.3)	39.6 (30.1, 49.0)
30 Month	33.8 (23.5, 44.3)	62.5 (22.9, 86.1)	50.0 (24.5, 71.0)	36.6 (26.9, 46.2)	38.6 (29.2, 48.0)
36 Month	29.9 (20.1, 40.2)	62.5 (22.9, 86.1)	43.8 (19.8, 65.6)	32.3 (23.0, 41.8)	34.7 (25.6, 43.9)
42 Month	28.6 (19.0, 38.9)	62.5 (22.9, 86.1)	43.8 (19.8, 65.6)	31.2 (22.1, 40.7)	33.7 (24.7, 42.9)

Data cutoff date = 11AUG2021
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; NR, not reached; NE, not reached; PFS, progression-free survival; SCT, stem cell transplant; SD, stable disease.
Notes: Percentages are based on all enrolled subjects; PFS is defined as the time from the leukapheresis date to the date of disease progression or death; Disease assessment after initiation of new anti-cancer therapy (not including SCT) are not included in the PFS derivation; Disease status used are investigator assessment of disease status per Cheson 2007; Death after full withdrawal of consent or lost to follow-up is excluded from the derivation. "+" indicates censored record.

Data Source: ADSL, ADTTE, ADEFF Program Name: t_pfs Output Generated: 20230501T08:29

Table 2.6. Progression-free Survival (PFS) (Phase 2 Cohort 1 and Cohort 2) using Investigator Assessment per Cheson 2007 (mITT Analysis Set, N = 101)

	Phase 2 Cohort 1 and Cohort 2 (N = 101)				
	DLBCL (N = 77)	PMBCL (N = 8)	TFL (N = 16)	DLBCL+TFL (N = 93)	Total (N = 101)
48 Month	27.3 (17.9, 37.5)	62.5 (22.9, 86.1)	43.8 (19.8, 65.6)	30.1 (21.1, 39.6)	32.6 (23.7, 41.8)
54 Month	25.8 (16.6, 35.9)	62.5 (22.9, 86.1)	43.8 (19.8, 65.6)	28.9 (20.0, 38.3)	31.4 (22.6, 40.6)
60 Month	25.8 (16.6, 35.9)	NE (NE, NE)	43.8 (19.8, 65.6)	28.9 (20.0, 38.3)	31.4 (22.6, 40.6)

Data cutoff date = 11AUG2021
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; NR, not reached; NE, not reached; PFS, progression-free survival; SCT, stem cell transplant; SD, stable disease.
Notes: Percentages are based on all enrolled subjects; PFS is defined as the time from the leukapheresis date to the date of disease progression or death; Disease assessment after initiation of new anti-cancer therapy (not including SCT) are not included in the PFS derivation; Disease status used are investigator assessment of disease status per Cheson 2007; Death after full withdrawal of consent or lost to follow-up is excluded from the derivation. "+" indicates censored record.

Data Source: ADSL, ADTTE, ADEFF Program Name: t_pfs Output Generated: 20230501T08:29

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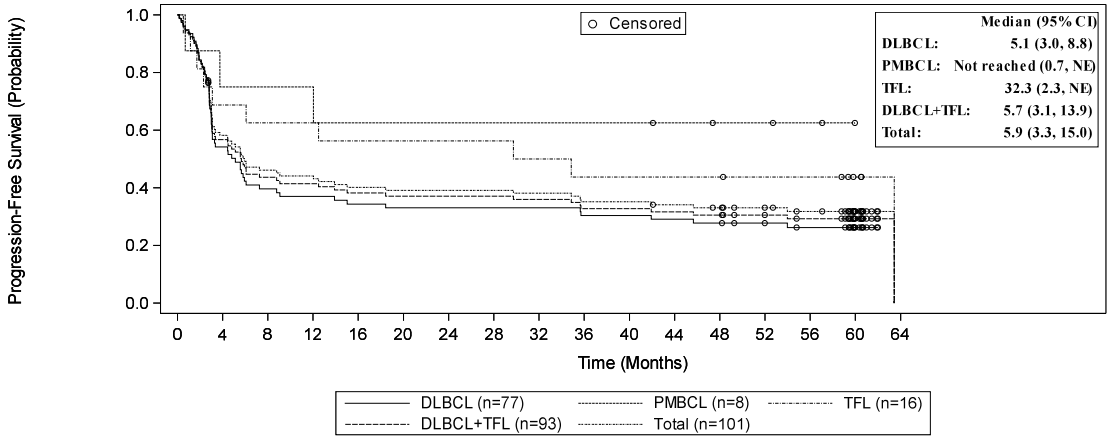
Figure 2.6. Progression-free Survival (PFS) (Phase 2 Cohort 1 and Cohort 2) using Investigator Assessment per Cheson 2007 (mITT Analysis Set, N = 101)



DLBCL at risk	77	41	30	28	26	25	25	25	25	23	23	22	21	18	16	8	0
(DLBCL censored)	(0)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(4)	(5)	(13)	(21)
PMBCL at risk	8	6	6	6	5	5	5	5	5	5	5	4	3	3	2	0	0
(PMBCL censored)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(2)	(2)	(3)	(5)	(5)
TFL at risk	16	11	10	10	9	9	9	9	8	7	7	7	7	6	6	3	0
(TFL censored)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(4)	(6)
DLBCL+TFL at risk	93	52	40	38	35	34	34	34	33	30	30	29	28	24	22	11	0
(DLBCL+TFL censored)	(0)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(5)	(6)	(17)	(27)
Total at risk	101	58	46	44	40	39	39	39	38	35	35	33	31	27	24	11	0
(Total censored)	(0)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(2)	(3)	(7)	(9)	(22)	(32)

Data cutoff date = 11AUG2021

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Data Source: ADSL, ADTTE Program Name: f_pfs_dis_p2c12 Output Generated: 20230428T03:34

Table 2.7. Progression-free Survival (PFS) (Phase 2 Cohort 1 and Cohort 2) using Investigator Assessment per Cheson 2007 (Full Analysis Set, N = 111)

	Phase 2 Cohort 1 and Cohort 2 (N = 111)				
	DLBCL (N = 81)	PMBCL (N = 9)	TFL (N = 21)	DLBCL+TFL (N = 102)	Total (N = 111)
Progression-free Survival (PFS)					
No. of subjects	81	9	21	102	111
Censored (%)	21 (26)	5 (56)	8 (38)	29 (28)	34 (31)
KM Median (95% CI) PFS time (in months)	6.0 (3.9, 8.1)	NR (2.6, NE)	32.0 (2.4, NE)	6.2 (3.9, 9.8)	6.3 (4.0, 12.7)
Min, max PFS (in months)	0.8, 63.0+	2.6, 60.7+	1.1, 68.4+	0.8, 68.4+	0.8, 68.4+
Type of Events					
Disease Progression	51	3	6	57	60
Death	9	1	7	16	17
Censoring reason					
Response/SD Ongoing	20	5	8	28	33
Started new anti-cancer therapy	1	0	0	1	1
PFS (95% CI) at					
3 Month	80.2 (69.8, 87.4)	77.8 (36.5, 93.9)	65.5 (40.9, 81.9)	77.3 (67.8, 84.3)	77.3 (68.3, 84.1)
6 Month	49.0 (37.7, 59.3)	66.7 (28.2, 87.8)	60.5 (36.3, 78.0)	51.2 (41.1, 60.5)	52.5 (42.8, 61.4)
9 Month	38.9 (28.3, 49.4)	66.7 (28.2, 87.8)	55.5 (31.8, 73.9)	42.2 (32.4, 51.6)	44.2 (34.8, 53.2)
12 Month	36.4 (26.0, 46.8)	66.7 (28.2, 87.8)	55.5 (31.8, 73.9)	40.2 (30.6, 49.6)	42.4 (33.0, 51.4)
15 Month	33.9 (23.8, 44.3)	55.6 (20.4, 80.5)	50.4 (27.5, 69.5)	37.2 (27.8, 46.5)	38.7 (29.6, 47.7)
18 Month	32.6 (22.7, 43.0)	55.6 (20.4, 80.5)	50.4 (27.5, 69.5)	36.2 (26.9, 45.5)	37.8 (28.7, 46.8)
24 Month	31.4 (21.6, 41.6)	55.6 (20.4, 80.5)	50.4 (27.5, 69.5)	35.2 (26.0, 44.5)	36.8 (27.9, 45.8)
30 Month	31.4 (21.6, 41.6)	55.6 (20.4, 80.5)	50.4 (27.5, 69.5)	35.2 (26.0, 44.5)	36.8 (27.9, 45.8)
36 Month	31.4 (21.6, 41.6)	55.6 (20.4, 80.5)	40.3 (19.5, 60.4)	33.2 (24.2, 42.4)	35.0 (26.2, 43.9)

Data cutoff date = 11AUG2021
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; NR, not reached; NE, not reached; PFS, progression-free survival; SCT, stem cell transplant; SD, stable disease.
Notes: Percentages are based on all enrolled subjects; PFS is defined as the time from the leukapheresis date to the date of disease progression or death; Disease assessment after initiation of new anti-cancer therapy (not including SCT) are not included in the PFS derivation; Disease status used are investigator assessment of disease status per Cheson 2007; Death after full withdrawal of consent or lost to follow-up is excluded from the derivation. "+" indicates censored record.

Data Source: ADSL, ADTTE, ADEFF Program Name: t_pfs Output Generated: 20230501T08:29

Table 2.7. Progression-free Survival (PFS) (Phase 2 Cohort 1 and Cohort 2) using Investigator Assessment per Cheson 2007 (Full Analysis Set, N = 111)

	Phase 2 Cohort 1 and Cohort 2 (N = 111)				
	DLBCL (N = 81)	PMBCL (N = 9)	TFL (N = 21)	DLBCL+TFL (N = 102)	Total (N = 111)
42 Month	28.9 (19.4, 39.0)	55.6 (20.4, 80.5)	40.3 (19.5, 60.4)	31.1 (22.4, 40.3)	33.2 (24.5, 42.0)
48 Month	26.4 (17.3, 36.3)	55.6 (20.4, 80.5)	40.3 (19.5, 60.4)	29.1 (20.6, 38.2)	31.3 (22.8, 40.1)
54 Month	26.4 (17.3, 36.3)	55.6 (20.4, 80.5)	40.3 (19.5, 60.4)	29.1 (20.6, 38.2)	31.3 (22.8, 40.1)
60 Month	24.9 (16.0, 34.8)	55.6 (20.4, 80.5)	40.3 (19.5, 60.4)	28.0 (19.5, 37.0)	30.1 (21.7, 38.9)

Data cutoff date = 11AUG2021
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; NR, not reached; NE, not reached; PFS, progression-free survival; SCT, stem cell transplant; SD, stable disease.
Notes: Percentages are based on all enrolled subjects; PFS is defined as the time from the leukapheresis date to the date of disease progression or death; Disease assessment after initiation of new anti-cancer therapy (not including SCT) are not included in the PFS derivation; Disease status used are investigator assessment of disease status per Cheson 2007; Death after full withdrawal of consent or lost to follow-up is excluded from the derivation. "+" indicates censored record.

Data Source: ADSL, ADTTE, ADEFF Program Name: t_pfs Output Generated: 20230501T08:29

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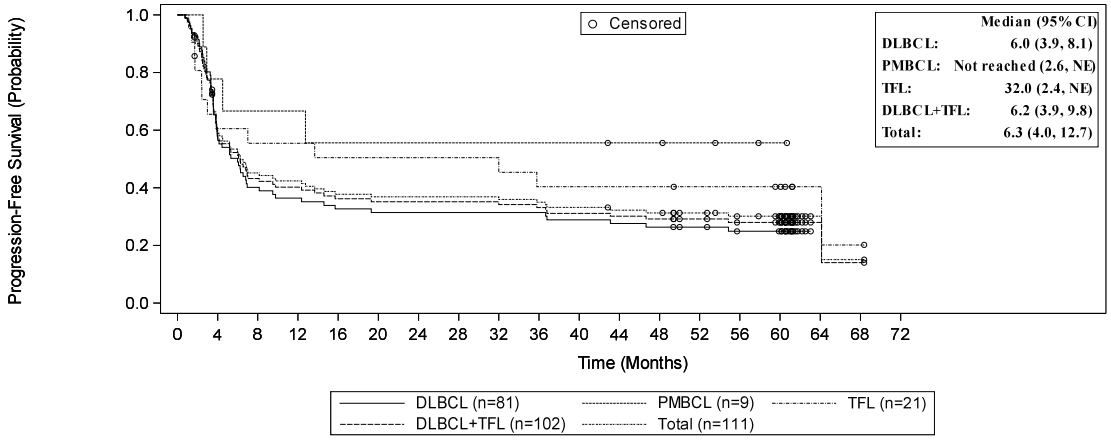
Figure 2.7. Progression-free Survival (PFS) (Phase 2 Cohort 1 and Cohort 2) using Investigator Assessment per Cheson 2007 (Full Analysis Set, N = 111)



DLBCL at risk	81	46	32	29	26	25	25	25	25	25	23	22	21	19	16	15	0	0	0
(DLBCL censored)	(0)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(3)	(5)	(6)	(21)	(21)	(21)
PMBCL at risk	9	7	6	6	5	5	5	5	5	5	5	4	4	3	2	1	0	0	0
(PMBCL censored)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(2)	(3)	(4)	(5)	(5)	(5)
TFL at risk	21	12	11	11	10	10	10	10	10	8	8	8	8	7	7	6	2	1	0
(TFL censored)	(0)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(2)	(2)	(3)	(7)	(7)	(8)
DLBCL+TFL at risk	102	58	43	40	36	35	35	35	35	33	31	30	29	26	23	21	2	1	0
(DLBCL+TFL censored)	(0)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(5)	(7)	(9)	(28)	(28)	(29)
Total at risk	111	65	49	46	41	40	40	40	40	38	36	34	33	29	25	22	2	1	0
(Total censored)	(0)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(3)	(3)	(7)	(10)	(13)	(33)	(33)	(34)

Data cutoff date = 11AUG2021

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Data Source: ADSL, ADTTE Program Name: f_pfs_dis_p2c12 Output Generated: 20230428T03:34

Table 2.1. Progression-free Survival (PFS) (Phase 1) using Investigator Assessment per Cheson 2007 (Full Analysis Set, N = 8)

	Phase 1 (N = 8)				
	DLBCL (N = 8)	PMBCL (N = 0)	TFL (N = 0)	DLBCL+TFL (N = 8)	Total (N = 8)
Progression-free Survival (PFS)					
No. of subjects	8	0	0	8	8
Censored (%)	2 (25)			2 (25)	2 (25)
KM Median (95% CI) PFS time (in months)	3.8 (0.3, NE)			3.8 (0.3, NE)	3.8 (0.3, NE)
Min, max PFS (in months)	0.3, 69.2+			0.3, 69.2+	0.3, 69.2+
Type of Events					
Disease Progression	4			4	4
Death	2			2	2
Censoring reason					
Response/SD Ongoing	2			2	2
PFS (95% CI) at					
3 Month	62.5 (22.9, 86.1)			62.5 (22.9, 86.1)	62.5 (22.9, 86.1)
6 Month	37.5 (8.7, 67.4)			37.5 (8.7, 67.4)	37.5 (8.7, 67.4)
9 Month	37.5 (8.7, 67.4)			37.5 (8.7, 67.4)	37.5 (8.7, 67.4)
12 Month	37.5 (8.7, 67.4)			37.5 (8.7, 67.4)	37.5 (8.7, 67.4)
15 Month	37.5 (8.7, 67.4)			37.5 (8.7, 67.4)	37.5 (8.7, 67.4)
18 Month	37.5 (8.7, 67.4)			37.5 (8.7, 67.4)	37.5 (8.7, 67.4)
24 Month	37.5 (8.7, 67.4)			37.5 (8.7, 67.4)	37.5 (8.7, 67.4)
30 Month	37.5 (8.7, 67.4)			37.5 (8.7, 67.4)	37.5 (8.7, 67.4)
36 Month	37.5 (8.7, 67.4)			37.5 (8.7, 67.4)	37.5 (8.7, 67.4)
42 Month	37.5 (8.7, 67.4)			37.5 (8.7, 67.4)	37.5 (8.7, 67.4)

Data cutoff date = 11AUG2021
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; NE, not estimable; PFS, progression-free survival; SCT, stem cell transplant; SD, stable disease.
Notes: Percentages are based on all enrolled subjects; PFS is defined as the time from the leukapheresis date to the date of disease progression or death; Disease assessment after initiation of new anti-cancer therapy (not including SCT) are not included in the PFS derivation; Disease status used are investigator assessment of disease status per Cheson 2007; Death after full withdrawal of consent or lost to follow-up is excluded from the derivation. "+" indicates censored record.

Data Source: ADSL, ADTTE, ADEFF Program Name: t_pfs Output Generated: 20230501T08:28

Table 2.1. Progression-free Survival (PFS) (Phase 1) using Investigator Assessment per Cheson 2007 (Full Analysis Set, N = 8)

	Phase 1 (N = 8)				
	DLBCL (N = 8)	PMBCL (N = 0)	TFL (N = 0)	DLBCL+TFL (N = 8)	Total (N = 8)
48 Month	37.5 (8.7, 67.4)			37.5 (8.7, 67.4)	37.5 (8.7, 67.4)
54 Month	25.0 (3.7, 55.8)			25.0 (3.7, 55.8)	25.0 (3.7, 55.8)
60 Month	25.0 (3.7, 55.8)			25.0 (3.7, 55.8)	25.0 (3.7, 55.8)

Data cutoff date = 11AUG2021
Abbreviations: CI, confidence interval; KM, Kaplan-Meier; NE, not estimable; PFS, progression-free survival; SCT, stem cell transplant; SD, stable disease.
Notes: Percentages are based on all enrolled subjects; PFS is defined as the time from the leukapheresis date to the date of disease progression or death; Disease assessment after initiation of new anti-cancer therapy (not including SCT) are not included in the PFS derivation; Disease status used are investigator assessment of disease status per Cheson 2007; Death after full withdrawal of consent or lost to follow-up is excluded from the derivation. "+" indicates censored record.

Data Source: ADSL, ADTTE, ADEFF Program Name: t_pfs Output Generated: 20230501T08:28

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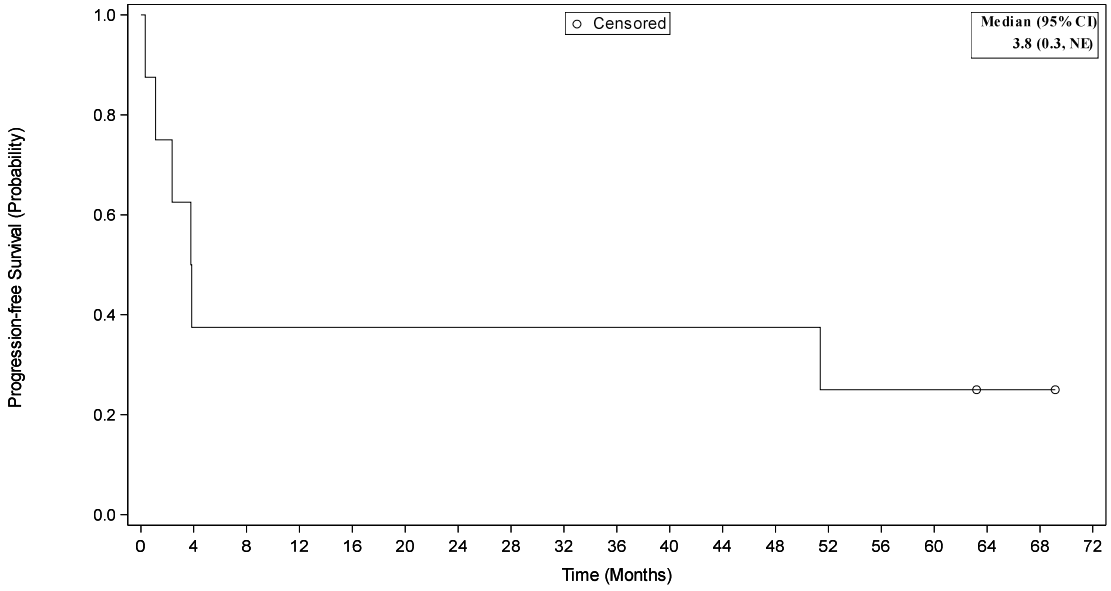
Figure 2.1. Progression-free Survival (PFS) (Phase 1) using Investigator Assessment per Cheson 2007 (Full Analysis Set, N = 8)



Data cutoff date = 11AUG2021

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Data Source: ADSL, ADTTE Program Name: f_pfs Output Generated: 20230428T04:05

Anhang 4-G2.2: Objektive Ansprechrate und bestes Ansprechen

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Table 3.6. Summary of Best Overall Response (Phase 2 Cohort 1 and Cohort 2) using Investigator Assessment per Cheson 2007 (mITT Analysis Set, N = 101)

	Phase 2 Cohort 1 and Cohort 2 (N = 101)				
	DLBCL (N = 77)	PMBCL (N = 8)	TFL (N = 16)	DLBCL+TFL (N = 93)	Total (N = 101)
Number of Objective Responders (CR + PR) n(%)	64 (83)	6 (75)	14 (88)	78 (84)	84 (83)
95% Confidence Interval (Clopper-Pearson method)	73, 91	35, 97	62, 98	75, 91	74, 90
95% Confidence Interval (Wilson's method)	73, 90	41, 93	64, 97	75, 90	75, 89
P-value of Exact Test of ORR =< 20%	<.0001	0.0012	<.0001	<.0001	<.0001
Time to first objective response (months)					
N	64	6	14	78	84
Mean (STDEV)	1.6 (1.7)	0.9 (0.0)	1.4 (0.8)	1.5 (1.6)	1.5 (1.5)
Median	1.0	1.0	1.0	1.0	1.0
Min, Max	0.9 ,12.0	0.9 ,1.0	0.8 ,2.9	0.8 ,12.0	0.8 ,12.0
Complete Response (CR) n(%)	41 (53)	6 (75)	12 (75)	53 (57)	59 (58)
95% Confidence Interval (Clopper-Pearson method)	42, 65	35, 97	48, 93	46, 67	48, 68
Partial Response (PR) n(%)	23 (30)	0 (0)	2 (13)	25 (27)	25 (25)
95% Confidence Interval (Clopper-Pearson method)	20, 41	0, 37	2, 38	18, 37	17, 34
Stable Disease n(%)	8 (10)	1 (13)	1 (6)	9 (10)	10 (10)
95% Confidence Interval (Clopper-Pearson method)	5, 19	0, 53	0, 30	5, 18	5, 17
Progressive Disease n(%)	4 (5)	1 (13)	0 (0)	4 (4)	5 (5)
95% Confidence Interval (Clopper-Pearson method)	1, 13	0, 53	0, 21	1, 11	2, 11

Data cutoff date = 11AUG2021
Abbreviations: STDEV, standard deviation.
Notes: Percentages are based on number of subjects in the mITT analysis set; Disease status used are Investigator assessment of disease status per Cheson 2007. Time to first objective response was calculated as (Date of first observed PR or CR - axicabtagene ciloleucel infusion date + 1)/ (365.25/12).

Data Source: ADSL, ADTTE, ADEFF Program Name: t_orr_inv Output Generated: 20230412T06:25

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Table 3.6. Summary of Best Overall Response (Phase 2 Cohort 1 and Cohort 2) using Investigator Assessment per Cheson 2007 (mITT Analysis Set, N = 101)

	Phase 2 Cohort 1 and Cohort 2 (N = 101)				
	DLBCL (N = 77)	PMBCL (N = 8)	TFL (N = 16)	DLBCL+TFL (N = 93)	Total (N = 101)
Not Evaluable n(%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
95% Confidence Interval (Clopper-Pearson method)	0, 5	0, 37	0, 21	0, 4	0, 4
Not Done (ND) n(%)	1 (1)	0 (0)	1 (6)	2 (2)	2 (2)
95% Confidence Interval (Clopper-Pearson method)	0, 7	0, 37	0, 30	0, 8	0, 7

Data cutoff date = 11AUG2021
Abbreviations: STDEV, standard deviation.
Notes: Percentages are based on number of subjects in the mITT analysis set; Disease status used are Investigator assessment of disease status per Cheson 2007. Time to first objective response was calculated as (Date of first observed PR or CR - axicabtagene ciloleucel infusion date + 1)/ (365.25/12).

Data Source: ADSL, ADTTE, ADEFF Program Name: t_orr_inv Output Generated: 20230412T06:25

Table 3.7. Summary of Best Overall Response (Phase 2 Cohort 1 and Cohort 2) using Investigator Assessment per Cheson 2007 (Full Analysis Set, N = 111)

	Phase 2 Cohort 1 and Cohort 2 (N = 111)				
	DLBCL (N = 81)	PMBCL (N = 9)	TFL (N = 21)	DLBCL+TFL (N = 102)	Total (N = 111)
Number of Objective Responders (CR + PR) n(%)	64 (79)	6 (67)	16 (76)	80 (78)	86 (77)
95% Confidence Interval (Clopper-Pearson method)	69, 87	30, 93	53, 92	69, 86	69, 85
95% Confidence Interval (Wilson's method)	69, 86	35, 88	55, 89	69, 85	69, 84
P-value of Exact Test of ORR =< 20%	<.0001	0.0031	<.0001	<.0001	<.0001
Time to first objective response (months)					
N	64	6	16	80	86
Mean (STDEV)	2.4 (1.7)	1.7 (0.1)	2.2 (1.1)	2.3 (1.6)	2.3 (1.6)
Median	1.8	1.7	1.7	1.8	1.7
Min, Max	1.4 ,12.9	1.6 ,1.8	0.7 ,5.1	0.7 ,12.9	0.7 ,12.9
Complete Response (CR) n(%)	41 (51)	6 (67)	14 (67)	55 (54)	61 (55)
95% Confidence Interval (Clopper-Pearson method)	39, 62	30, 93	43, 85	44, 64	45, 64
Partial Response (PR) n(%)	23 (28)	0 (0)	2 (10)	25 (25)	25 (23)
95% Confidence Interval (Clopper-Pearson method)	19, 40	0, 34	1, 30	17, 34	15, 31
Stable Disease n(%)	8 (10)	1 (11)	1 (5)	9 (9)	10 (9)
95% Confidence Interval (Clopper-Pearson method)	4, 19	0, 48	0, 24	4, 16	4, 16
Progressive Disease n(%)	4 (5)	1 (11)	0 (0)	4 (4)	5 (5)
95% Confidence Interval (Clopper-Pearson method)	1, 12	0, 48	0, 16	1, 10	1, 10

Data cutoff date = 11AUG2021
Abbreviations: STDEV, standard deviation.
Notes: Percentages are based on number of subjects enrolled; Disease status used are Investigator assessment of disease status per Cheson 2007. Time to first objective response was calculated as (Date of first observed PR or CR - Leukapheresis date + 1)/ (365.25/12).

Data Source: ADSL, ADTTE, ADEFF Program Name: t_orr_inv Output Generated: 20230412T06:25

Table 3.7. Summary of Best Overall Response (Phase 2 Cohort 1 and Cohort 2) using Investigator Assessment per Cheson 2007 (Full Analysis Set, N = 111)

	Phase 2 Cohort 1 and Cohort 2 (N = 111)				
	DLBCL (N = 81)	PMBCL (N = 9)	TFL (N = 21)	DLBCL+TFL (N = 102)	Total (N = 111)
Not Evaluable n(%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
95% Confidence Interval (Clopper-Pearson method)	0, 4	0, 34	0, 16	0, 4	0, 3
Not Done (ND) n(%)	5 (6)	1 (11)	4 (19)	9 (9)	10 (9)
95% Confidence Interval (Clopper-Pearson method)	2, 14	0, 48	5, 42	4, 16	4, 16

Data cutoff date = 11AUG2021
Abbreviations: STDEV, standard deviation.
Notes: Percentages are based on number of subjects enrolled; Disease status used are Investigator assessment of disease status per Cheson 2007. Time to first objective response was calculated as (Date of first observed PR or CR - Leukapheresis date + 1)/ (365.25/12).

Data Source: ADSL, ADTTE, ADEFF Program Name: t_orr_inv Output Generated: 20230412T06:25

Table 3.1. Summary of Best Overall Response (Phase 1) using Investigator Assessment per Cheson 2007 (Full Analysis Set, N = 8)

	Phase 1 (N = 8)				
	DLBCL (N = 8)	PMBCL (N = 0)	TFL (N = 0)	DLBCL+TFL (N = 8)	Total (N = 8)
Number of Objective Responders (CR + PR) n(%)	5 (63)	0 (0)	0 (0)	5 (63)	5 (63)
95% Confidence Interval (Clopper-Pearson method)	24, 91			24, 91	24, 91
95% Confidence Interval (Wilson's method)	31, 86			31, 86	31, 86
P-value of Exact Test of ORR =< 20%	0.0104			0.0104	0.0104
Time to first objective response (months)					
N	5	0	0	5	5
Mean (STDEV)	1.8 (0.3)			1.8 (0.3)	1.8 (0.3)
Median	1.6			1.6	1.6
Min, Max	1.6 ,2.4			1.6 ,2.4	1.6 ,2.4
Complete Response (CR) n(%)	4 (50)	0 (0)	0 (0)	4 (50)	4 (50)
95% Confidence Interval (Clopper-Pearson method)	16, 84			16, 84	16, 84
Partial Response (PR) n(%)	1 (13)	0 (0)	0 (0)	1 (13)	1 (13)
95% Confidence Interval (Clopper-Pearson method)	0, 53			0, 53	0, 53
Stable Disease n(%)	1 (13)	0 (0)	0 (0)	1 (13)	1 (13)
95% Confidence Interval (Clopper-Pearson method)	0, 53			0, 53	0, 53
Progressive Disease n(%)	1 (13)	0 (0)	0 (0)	1 (13)	1 (13)
95% Confidence Interval (Clopper-Pearson method)	0, 53			0, 53	0, 53

Data cutoff date = 11AUG2021
Abbreviations: STDEV, standard deviation.
Notes: Percentages are based on number of subjects enrolled; Disease status used are Investigator assessment of disease status per Cheson 2007. Time to first objective response was calculated as (Date of first observed PR or CR - Leukapheresis date + 1)/ (365.25/12).

Data Source: ADSL, ADTTE, ADEFF Program Name: t_orr_inv Output Generated: 20230412T06:25

Table 3.1. Summary of Best Overall Response (Phase 1) using Investigator Assessment per Cheson 2007 (Full Analysis Set, N = 8)

	Phase 1 (N = 8)				
	DLBCL (N = 8)	PMBCL (N = 0)	TFL (N = 0)	DLBCL+TFL (N = 8)	Total (N = 8)
Not Evaluable n(%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
95% Confidence Interval (Clopper-Pearson method)	0, 37			0, 37	0, 37
Not Done (ND) n(%)	1 (13)	0 (0)	0 (0)	1 (13)	1 (13)
95% Confidence Interval (Clopper-Pearson method)	0, 53			0, 53	0, 53

Data cutoff date = 11AUG2021
Abbreviations: STDEV, standard deviation.
Notes: Percentages are based on number of subjects enrolled; Disease status used are Investigator assessment of disease status per Cheson 2007. Time to first objective response was calculated as (Date of first observed PR or CR - Leukapheresis date + 1)/ (365.25/12).

Data Source: ADSL, ADTTE, ADEFF Program Name: t_orr_inv Output Generated: 20230412T06:25

Anhang 4-G2.3: Dauer des Ansprechens (DOR)

Table 4.6. Duration of Response (DOR) (Phase 2 Cohort 1 and Cohort 2) using Investigator Assessment per Cheson 2007 (mITT Analysis Set: Subjects with Objective Response, N = 84)

	Phase 2 Cohort 1 and Cohort 2 (N = 84)				
	DLBCL (N = 64)	PMBCL (N = 6)	TFL (N = 14)	DLBCL+TFL (N = 78)	Total (N = 84)
Duration of Response					
No. of subjects	64	6	14	78	84
Censored (%)	21 (33)	5 (83)	6 (43)	27 (35)	32 (38)
KM Median (95% CI) DOR time (in months)	5.0 (2.1, 34.7)	NR (11.1, NE)	48.0 (2.2, NE)	7.8 (3.3, 34.8)	11.1 (4.2, 51.3)
Min, max DOR (in months)	0.4, 61.1+	11.1, 59.1+	0.7, 62.2	0.4, 62.2	0.4, 62.2
Type of Events					
Disease Progression	40	1	6	46	47
Disease/treatment related Death	3	0	2	5	5
Censoring reason					
Response ongoing	20	5	6	26	31
Started new anti-cancer therapy	1	0	0	1	1
Event-free rate % (95% CI) by KM Estimation at					
3 Month	58.9 (45.8, 69.9)	100.0 (100.0, 100.0)	78.6 (47.2, 92.5)	62.5 (50.7, 72.2)	65.2 (53.9, 74.3)
6 Month	47.8 (35.1, 59.4)	100.0 (100.0, 100.0)	71.4 (40.6, 88.2)	52.1 (40.4, 62.5)	55.5 (44.2, 65.4)
9 Month	43.0 (30.6, 54.7)	100.0 (100.0, 100.0)	71.4 (40.6, 88.2)	48.2 (36.7, 58.7)	51.9 (40.7, 62.0)
12 Month	41.4 (29.2, 53.1)	83.3 (27.3, 97.5)	64.3 (34.3, 83.3)	45.6 (34.2, 56.2)	48.3 (37.2, 58.5)
15 Month	39.8 (27.8, 51.6)	83.3 (27.3, 97.5)	64.3 (34.3, 83.3)	44.3 (33.0, 54.9)	47.1 (36.1, 57.3)
18 Month	39.8 (27.8, 51.6)	83.3 (27.3, 97.5)	64.3 (34.3, 83.3)	44.3 (33.0, 54.9)	47.1 (36.1, 57.3)
24 Month	39.8 (27.8, 51.6)	83.3 (27.3, 97.5)	64.3 (34.3, 83.3)	44.3 (33.0, 54.9)	47.1 (36.1, 57.3)
30 Month	39.8 (27.8, 51.6)	83.3 (27.3, 97.5)	57.1 (28.4, 78.0)	43.0 (31.8, 53.6)	45.9 (34.9, 56.1)
36 Month	36.6 (24.9, 48.3)	83.3 (27.3, 97.5)	50.0 (22.9, 72.2)	39.1 (28.2, 49.7)	42.3 (31.5, 52.6)

Data cutoff date = 11AUG2021
Abbreviations: CI, confidence interval; DOR, duration of response; KM, Kaplan-Meier; NR, not reached; NE, not reached; SCT, stem cell transplant.
Notes: Percentages are based on number of all enrolled subjects with objective response; DOR is defined as the time from the first objective response to disease progression or to death due to disease relapse; Disease status used are investigator assessment of disease status per Cheson 2007; Disease assessment after initiation of new anti-cancer therapy (not including SCT) are not included in the DOR derivation; Death after full withdrawal of consent or lost to follow-up is excluded from the derivation. "+" indicates censored record.

Data Source: ADSL, ADTTE, ADEFF Program Name: t_dor Output Generated: 20230501T08:08

Table 4.6. Duration of Response (DOR) (Phase 2 Cohort 1 and Cohort 2) using Investigator Assessment per Cheson 2007 (mITT Analysis Set: Subjects with Objective Response, N = 84)

	Phase 2 Cohort 1 and Cohort 2 (N = 84)				
	DLBCL (N = 64)	PMBCL (N = 6)	TFL (N = 14)	DLBCL+TFL (N = 78)	Total (N = 84)
42 Month	35.0 (23.6, 46.7)	83.3 (27.3, 97.5)	50.0 (22.9, 72.2)	37.8 (27.0, 48.4)	41.0 (30.4, 51.3)
48 Month	33.4 (22.2, 45.1)	83.3 (27.3, 97.5)	50.0 (22.9, 72.2)	36.4 (25.9, 47.1)	39.8 (29.3, 50.1)
54 Month	31.6 (20.5, 43.2)	83.3 (27.3, 97.5)	50.0 (22.9, 72.2)	34.9 (24.5, 45.6)	38.3 (27.9, 48.7)
60 Month	31.6 (20.5, 43.2)	NE (NE, NE)	50.0 (22.9, 72.2)	34.9 (24.5, 45.6)	38.3 (27.9, 48.7)
Median Follow-up Time (in months) for DOR (reverse KM approach)	58.9 (56.3, 59.0)	51.7 (41.2, NE)	58.9 (45.4, 59.7)	58.9 (56.8, 59.3)	58.4 (56.1, 59.0)

Data cutoff date = 11AUG2021
Abbreviations: CI, confidence interval; DOR, duration of response; KM, Kaplan-Meier; NR, not reached; NE, not reached; SCT, stem cell transplant.
Notes: Percentages are based on number of all enrolled subjects with objective response; DOR is defined as the time from the first objective response to disease progression or to death due to disease relapse; Disease status used are investigator assessment of disease status per Cheson 2007; Disease assessment after initiation of new anti-cancer therapy (not including SCT) are not included in the DOR derivation; Death after full withdrawal of consent or lost to follow-up is excluded from the derivation. "+" indicates censored record.

Data Source: ADSL, ADTTE, ADEFF Program Name: t_dor Output Generated: 20230501T08:08

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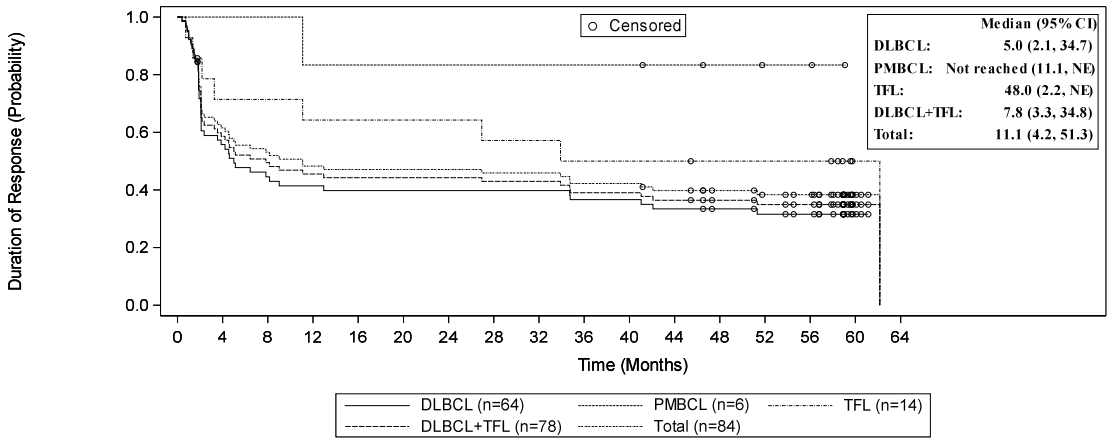
Figure 4.6. Duration of Response (DOR) (Phase 2 Cohort 1 and Cohort 2) using Investigator Assessment per Cheson 2007 (mITT Analysis Set: Subjects with Objective Response, N = 84)



DLBCL at risk	64	35	28	26	25	25	25	25	25	23	23	21	19	17	15	3	0
(DLBCL censored)	(0)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(3)	(4)	(6)	(18)	(21)
PMBCL at risk	6	6	6	5	5	5	5	5	5	5	5	4	3	2	2	0	0
(PMBCL censored)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(2)	(3)	(3)	(5)	(5)
TFL at risk	14	10	10	9	9	9	9	8	8	7	7	7	6	6	6	1	0
(TFL censored)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(1)	(1)	(6)	(6)
DLBCL+TFL at risk	78	45	38	35	34	34	34	33	33	30	30	28	25	23	21	4	0
(DLBCL+TFL censored)	(0)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(4)	(5)	(7)	(24)	(27)
Total at risk	84	51	44	40	39	39	39	38	38	35	35	32	28	25	23	4	0
(Total censored)	(0)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(2)	(6)	(8)	(10)	(29)	(32)

Data cutoff date = 11AUG2021

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Data Source: ADSL, ADTTE, ADEFF Program Name: f_dor_dis_p2c12 Output Generated: 20230428T04:40

Table 4.7. Duration of Response (DOR) (Phase 2 Cohort 1 and Cohort 2) using Investigator Assessment per Cheson 2007 (Full Analysis Set: Subjects with Objective Response, N = 86)

	Phase 2 Cohort1 and Cohort 2 (N = 86)				
	DLBCL (N = 64)	PMBCL (N = 6)	TFL (N = 16)	DLBCL+TFL (N = 80)	Total (N = 86)
Duration of Response					
No. of subjects	64	6	16	80	86
Censored (%)	21 (33)	5 (83)	8 (50)	29 (36)	34 (40)
KM Median (95% CI) DOR time (in months)	5.0 (2.1, 34.7)	NR (11.1, NE)	62.2 (2.2, NE)	8.1 (3.3, 41.0)	11.1 (4.2, 51.3)
Min, max DOR (in months)	0.4, 61.1+	11.1, 59.1+	0.0+, 67.7+	0.0+, 67.7+	0.0+, 67.7+
Type of Events					
Disease Progression	40	1	6	46	47
Disease/treatment related Death	3	0	2	5	5
Censoring reason					
Response ongoing	20	5	8	28	33
Started new anti-cancer therapy	1	0	0	1	1
Event-free rate % (95% CI) by KM Estimation at					
3 Month	58.9 (45.8, 69.9)	100.0 (100.0, 100.0)	80.0 (50.0, 93.1)	63.0 (51.3, 72.6)	65.6 (54.4, 74.7)
6 Month	47.8 (35.1, 59.4)	100.0 (100.0, 100.0)	73.3 (43.6, 89.1)	52.7 (41.1, 63.0)	56.1 (44.8, 65.9)
9 Month	43.0 (30.6, 54.7)	100.0 (100.0, 100.0)	73.3 (43.6, 89.1)	48.8 (37.4, 59.3)	52.5 (41.3, 62.5)
12 Month	41.4 (29.2, 53.1)	83.3 (27.3, 97.5)	66.7 (37.5, 84.6)	46.3 (34.9, 56.8)	48.9 (37.9, 59.0)
15 Month	39.8 (27.8, 51.6)	83.3 (27.3, 97.5)	66.7 (37.5, 84.6)	45.0 (33.7, 55.6)	47.7 (36.7, 57.9)
18 Month	39.8 (27.8, 51.6)	83.3 (27.3, 97.5)	66.7 (37.5, 84.6)	45.0 (33.7, 55.6)	47.7 (36.7, 57.9)
24 Month	39.8 (27.8, 51.6)	83.3 (27.3, 97.5)	66.7 (37.5, 84.6)	45.0 (33.7, 55.6)	47.7 (36.7, 57.9)
30 Month	39.8 (27.8, 51.6)	83.3 (27.3, 97.5)	60.0 (31.8, 79.7)	43.7 (32.5, 54.3)	46.5 (35.6, 56.7)
36 Month	36.6 (24.9, 48.3)	83.3 (27.3, 97.5)	53.3 (26.3, 74.4)	39.8 (29.0, 50.4)	42.9 (32.3, 53.2)

Data cutoff date = 11AUG2021
Abbreviations: CI, confidence interval; DOR, duration of response; KM, Kaplan-Meier; NR, not reached; NE, not reached; SCT, stem cell transplant.
Notes: Percentages are based on number of all enrolled subjects with objective response; DOR is defined as the time from the first objective response to disease progression or to death due to disease relapse; Disease status used are investigator assessment of disease status per Cheson 2007; Disease assessment after initiation of new anti-cancer therapy (not including SCT) are not included in the DOR derivation; Death after full withdrawal of consent or lost to follow-up is excluded from the derivation. "+" indicates censored record.

Data Source: ADSL, ADTTE, ADEFF Program Name: t_dor Output Generated: 20230501T08:08

Table 4.7. Duration of Response (DOR) (Phase 2 Cohort 1 and Cohort 2) using Investigator Assessment per Cheson 2007 (Full Analysis Set: Subjects with Objective Response, N = 86)

	Phase 2 Cohort1 and Cohort 2 (N = 86)				
	DLBCL (N = 64)	PMBCL (N = 6)	TFL (N = 16)	DLBCL+TFL (N = 80)	Total (N = 86)
42 Month	35.0 (23.6, 46.7)	83.3 (27.3, 97.5)	53.3 (26.3, 74.4)	38.6 (27.8, 49.1)	41.7 (31.1, 52.0)
48 Month	33.4 (22.2, 45.1)	83.3 (27.3, 97.5)	53.3 (26.3, 74.4)	37.3 (26.7, 47.8)	40.5 (30.0, 50.8)
54 Month	31.6 (20.5, 43.2)	83.3 (27.3, 97.5)	53.3 (26.3, 74.4)	35.8 (25.3, 46.4)	39.1 (28.6, 49.4)
60 Month	31.6 (20.5, 43.2)	NE (NE, NE)	53.3 (26.3, 74.4)	35.8 (25.3, 46.4)	39.1 (28.6, 49.4)
Median Follow-up Time (in months) for DOR (reverse KM approach)	58.9 (56.3, 59.0)	51.7 (41.2, NE)	58.9 (45.4, NE)	58.9 (56.8, 59.3)	58.9 (56.3, 59.0)

Data cutoff date = 11AUG2021
Abbreviations: CI, confidence interval; DOR, duration of response; KM, Kaplan-Meier; NR, not reached; NE, not reached; SCT, stem cell transplant.
Notes: Percentages are based on number of all enrolled subjects with objective response; DOR is defined as the time from the first objective response to disease progression or to death due to disease relapse; Disease status used are investigator assessment of disease status per Cheson 2007; Disease assessment after initiation of new anti-cancer therapy (not including SCT) are not included in the DOR derivation; Death after full withdrawal of consent or lost to follow-up is excluded from the derivation. "+" indicates censored record.

Data Source: ADSL, ADTTE, ADEFF Program Name: t_dor Output Generated: 20230501T08:08

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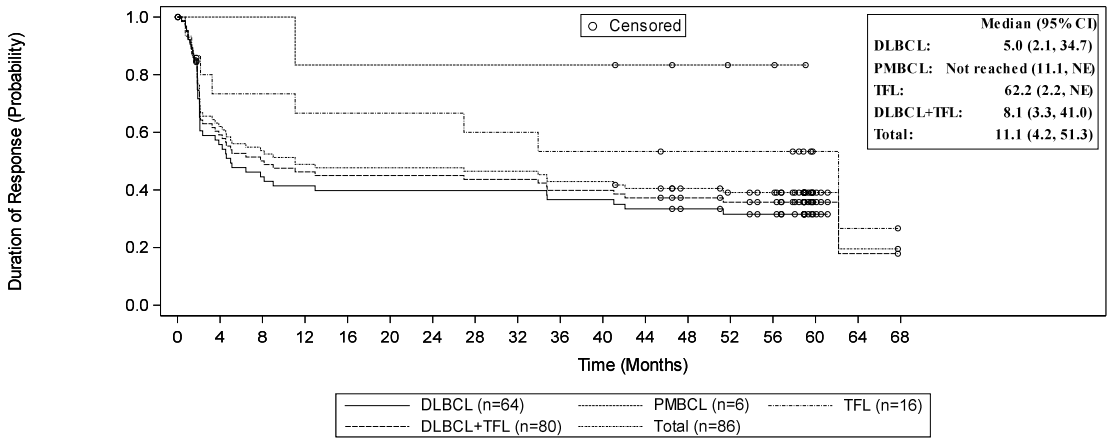
Figure 4.7. Duration of Response (DOR) (Phase 2 Cohort 1 and Cohort 2) using Investigator Assessment per Cheson 2007 (Full Analysis Set: Subjects with Objective Response, N = 86)



DLBCL at risk	64	35	28	26	25	25	25	25	25	23	23	21	19	17	15	3	0	0
(DLBCL censored)	(0)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(3)	(4)	(6)	(18)	(21)	(21)
PMBCL at risk	6	6	6	5	5	5	5	5	5	5	5	4	3	2	2	0	0	0
(PMBCL censored)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(1)	(2)	(3)	(3)	(5)	(5)	(5)
TFL at risk	16	11	11	10	10	10	10	9	9	8	8	8	7	7	7	2	1	0
(TFL censored)	(0)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(1)	(2)	(2)	(2)	(7)	(7)	(8)
DLBCL+TFL at risk	80	46	39	36	35	35	35	34	34	31	31	29	26	24	22	5	1	0
(DLBCL+TFL censored)	(0)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(5)	(6)	(8)	(25)	(28)	(29)
Total at risk	86	52	45	41	40	40	40	39	39	36	36	33	29	26	24	5	1	0
(Total censored)	(0)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(2)	(3)	(7)	(9)	(11)	(30)	(33)	(34)

Data cutoff date = 11AUG2021

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Data Source: ADSL, ADTTE, ADEFF Program Name: f_dor_dis_p2c12 Output Generated: 20230428T04:40

Table 4.1. Duration of Response (DOR) (Phase 1) using Investigator Assessment per Cheson 2007 (Full Analysis Set: Subjects with Objective Response, N = 5)

	Phase 1 (N = 5)				
	DLBCL (N = 5)	PMBCL (N = 0)	TFL (N = 0)	DLBCL+TFL (N = 5)	Total (N = 5)
Duration of Response					
No. of subjects	5	0	0	5	5
Censored (%)	2 (40)			2 (40)	2 (40)
KM Median (95% CI) DOR time (in months)	49.8 (2.2, NE)			49.8 (2.2, NE)	49.8 (2.2, NE)
Min, max DOR (in months)	2.2, 66.8+			2.2, 66.8+	2.2, 66.8+
Type of Events					
Disease Progression	2			2	2
Disease/treatment related Death	1			1	1
Censoring reason					
Response ongoing	2			2	2
Event-free rate % (95% CI) by KM Estimation at					
3 Month	60.0 (12.6, 88.2)			60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
6 Month	60.0 (12.6, 88.2)			60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
9 Month	60.0 (12.6, 88.2)			60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
12 Month	60.0 (12.6, 88.2)			60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
15 Month	60.0 (12.6, 88.2)			60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
18 Month	60.0 (12.6, 88.2)			60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
24 Month	60.0 (12.6, 88.2)			60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
30 Month	60.0 (12.6, 88.2)			60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
36 Month	60.0 (12.6, 88.2)			60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
42 Month	60.0 (12.6, 88.2)			60.0 (12.6, 88.2)	60.0 (12.6, 88.2)

Data cutoff date = 11AUG2021
Abbreviations: CI, confidence interval; DOR, duration of response; KM, Kaplan-Meier; NE, not estimable; SCT, stem cell transplant.
Notes: Percentages are based on number of all enrolled subjects with objective response; DOR is defined as the time from the first objective response to disease progression or to death due to disease relapse; Disease status used are investigator assessment of disease status per Cheson 2007; Disease assessment after initiation of new anti-cancer therapy (not including SCT) are not included in the DOR derivation; Death after full withdrawal of consent or lost to follow-up is excluded from the derivation. "+" indicates censored record.

Data Source: ADSL, ADTTE, ADEFF Program Name: t_dor Output Generated: 20230501T08:08

Table 4.1. Duration of Response (DOR) (Phase 1) using Investigator Assessment per Cheson 2007 (Full Analysis Set: Subjects with Objective Response, N = 5)

	Phase 1 (N = 5)				
	DLBCL (N = 5)	PMBCL (N = 0)	TFL (N = 0)	DLBCL+TFL (N = 5)	Total (N = 5)
48 Month	60.0 (12.6, 88.2)			60.0 (12.6, 88.2)	60.0 (12.6, 88.2)
54 Month	40.0 (5.2, 75.3)			40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
60 Month	40.0 (5.2, 75.3)			40.0 (5.2, 75.3)	40.0 (5.2, 75.3)
Median Follow-up Time (in months) for DOR (reverse KM approach)	64.2 (61.6, NE)			64.2 (61.6, NE)	64.2 (61.6, NE)

Data cutoff date = 11AUG2021
Abbreviations: CI, confidence interval; DOR, duration of response; KM, Kaplan-Meier; NE, not estimable; SCT, stem cell transplant.
Notes: Percentages are based on number of all enrolled subjects with objective response; DOR is defined as the time from the first objective response to disease progression or to death due to disease relapse; Disease status used are investigator assessment of disease status per Cheson 2007; Disease assessment after initiation of new anti-cancer therapy (not including SCT) are not included in the DOR derivation; Death after full withdrawal of consent or lost to follow-up is excluded from the derivation. "+" indicates censored record.

Data Source: ADSL, ADTTE, ADEFF Program Name: t_dor Output Generated: 20230501T08:08

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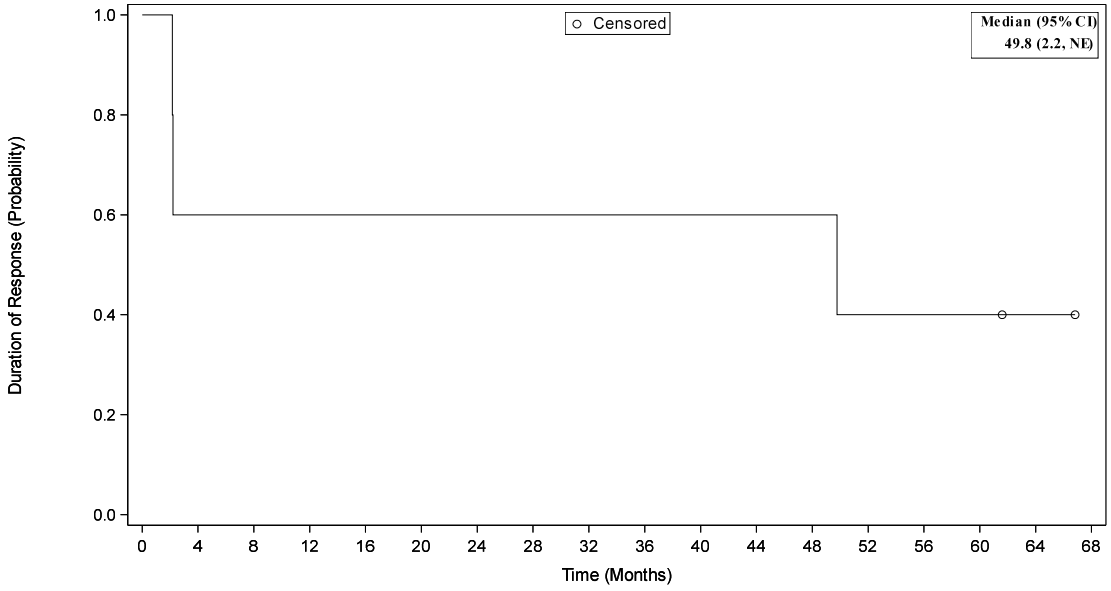
Figure 4.1. Duration of Response (DOR) (Phase 1) using Investigator Assessment per Cheson 2007 (Full Analysis Set: Subjects with Objective Response, N = 5)



Data cutoff date = 11AUG2021

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Data Source: ADSL, ADTTE, ADEFF Program Name: f_dor Output Generated: 20230428T04:19

Anhang 4-G3: ZUMA-1 - Ergänzende Analysen zu UE

Anhang 4-G3.1: UE nach SOC und PT (Full Analysis Set)

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Table 14.3.1.4.0.2.1. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects with Any TE Adverse Event	77 (95)	0 (0)	1 (1)	23 (28)	48 (59)	5 (6)
Blood and lymphatic system disorders	70 (86)	2 (2)	8 (10)	28 (35)	31 (38)	1 (1)
Anaemia	56 (69)	4 (5)	16 (20)	34 (42)	2 (2)	0 (0)
Neutropenia	33 (41)	0 (0)	4 (5)	9 (11)	20 (25)	0 (0)
Thrombocytopenia	29 (36)	4 (5)	5 (6)	9 (11)	11 (14)	0 (0)
Febrile neutropenia	27 (33)	0 (0)	3 (4)	23 (28)	1 (1)	0 (0)
Leukopenia	17 (21)	0 (0)	2 (2)	3 (4)	12 (15)	0 (0)
Lymphopenia	8 (10)	0 (0)	1 (1)	1 (1)	6 (7)	0 (0)
Pancytopenia	2 (2)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)
Bone marrow failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Coagulopathy	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Disseminated intravascular coagulation	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Histiocytosis haematophagic	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Increased tendency to bruise	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Splenic infarction	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Splenic vein thrombosis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Thrombocytosis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Cardiac disorders	54 (67)	37 (46)	10 (12)	4 (5)	3 (4)	0 (0)
Tachycardia	31 (38)	29 (36)	1 (1)	1 (1)	0 (0)	0 (0)
Sinus tachycardia	19 (23)	15 (19)	4 (5)	0 (0)	0 (0)	0 (0)
Atrial fibrillation	7 (9)	1 (1)	4 (5)	2 (2)	0 (0)	0 (0)
Atrial flutter	6 (7)	4 (5)	1 (1)	0 (0)	1 (1)	0 (0)
Sinus bradycardia	5 (6)	5 (6)	0 (0)	0 (0)	0 (0)	0 (0)
Ventricular arrhythmia	3 (4)	3 (4)	0 (0)	0 (0)	0 (0)	0 (0)
Ventricular tachycardia	3 (4)	0 (0)	3 (4)	0 (0)	0 (0)	0 (0)
Arrhythmia	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Cardiac arrest	2 (2)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
Supraventricular tachycardia	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
Acute left ventricular failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Atrioventricular block	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Bradycardia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.1. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Bundle branch block right	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cardiomegaly	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Palpitations	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Supraventricular extrasystoles	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Ear and labyrinth disorders	3 (4)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)
Ear discomfort	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Ear pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Excessive cerumen production	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Endocrine disorders	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Inappropriate antidiuretic hormone secretion	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	6 (7)	5 (6)	1 (1)	0 (0)	0 (0)	0 (0)
Vision blurred	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Dry eye	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Eye pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Periorbital oedema	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Pupils unequal	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Scleral haemorrhage	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Vitreous floaters	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Gastrointestinal disorders	65 (80)	35 (43)	23 (28)	7 (9)	0 (0)	0 (0)
Nausea	44 (54)	29 (36)	15 (19)	0 (0)	0 (0)	0 (0)
Diarrhoea	34 (42)	23 (28)	8 (10)	3 (4)	0 (0)	0 (0)
Constipation	22 (27)	15 (19)	7 (9)	0 (0)	0 (0)	0 (0)
Vomiting	22 (27)	19 (23)	2 (2)	1 (1)	0 (0)	0 (0)
Abdominal pain	12 (15)	6 (7)	4 (5)	2 (2)	0 (0)	0 (0)
Dry mouth	8 (10)	8 (10)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal distension	5 (6)	5 (6)	0 (0)	0 (0)	0 (0)	0 (0)
Dysphagia	4 (5)	1 (1)	3 (4)	0 (0)	0 (0)	0 (0)
Flatulence	3 (4)	1 (1)	2 (2)	0 (0)	0 (0)	0 (0)
Abdominal discomfort	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal pain upper	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.1. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Ascites	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
Dyspepsia	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Gastritis	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Gastrooesophageal reflux disease	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Haemorrhoids	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal hernia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal pain lower	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Anal incontinence	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Chapped lips	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Enteritis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Ileus	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Lip dry	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Lip swelling	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Neurogenic bowel	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Oral discomfort	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Rectal haemorrhage	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Toothache	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
General disorders and administration site conditions	73 (90)	12 (15)	47 (58)	14 (17)	0 (0)	0 (0)
Pyrexia	66 (81)	14 (17)	43 (53)	9 (11)	0 (0)	0 (0)
Fatigue	40 (49)	23 (28)	16 (20)	1 (1)	0 (0)	0 (0)
Chills	32 (40)	25 (31)	7 (9)	0 (0)	0 (0)	0 (0)
Oedema peripheral	17 (21)	12 (15)	5 (6)	0 (0)	0 (0)	0 (0)
Asthenia	7 (9)	0 (0)	5 (6)	2 (2)	0 (0)	0 (0)
Pain	7 (9)	5 (6)	0 (0)	2 (2)	0 (0)	0 (0)
Non-cardiac chest pain	6 (7)	5 (6)	1 (1)	0 (0)	0 (0)	0 (0)
Peripheral swelling	5 (6)	3 (4)	2 (2)	0 (0)	0 (0)	0 (0)
Malaise	4 (5)	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)
Chest discomfort	3 (4)	3 (4)	0 (0)	0 (0)	0 (0)	0 (0)
Gait disturbance	3 (4)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)
Generalised oedema	3 (4)	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.1. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Localised oedema	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Mucosal inflammation	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Catheter site swelling	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Face oedema	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypothermia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Oedema	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Swelling	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hepatobiliary disorders	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Hyperbilirubinaemia	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Immune system disorders	11 (14)	5 (6)	6 (7)	0 (0)	0 (0)	0 (0)
Hypogammaglobulinaemia	10 (12)	4 (5)	6 (7)	0 (0)	0 (0)	0 (0)
Graft versus host disease in skin	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypersensitivity	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Infections and infestations	31 (38)	1 (1)	10 (12)	20 (25)	0 (0)	0 (0)
Pneumonia	7 (9)	0 (0)	2 (2)	5 (6)	0 (0)	0 (0)
Lung infection	6 (7)	0 (0)	1 (1)	5 (6)	0 (0)	0 (0)
Upper respiratory tract infection	6 (7)	0 (0)	6 (7)	0 (0)	0 (0)	0 (0)
Urinary tract infection	6 (7)	1 (1)	2 (2)	3 (4)	0 (0)	0 (0)
Clostridium difficile infection	5 (6)	0 (0)	3 (4)	2 (2)	0 (0)	0 (0)
Clostridium difficile colitis	3 (4)	1 (1)	0 (0)	2 (2)	0 (0)	0 (0)
Herpes zoster	3 (4)	0 (0)	2 (2)	1 (1)	0 (0)	0 (0)
Sinusitis	3 (4)	1 (1)	2 (2)	0 (0)	0 (0)	0 (0)
Bacteraemia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Escherichia bacteraemia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Influenza	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
Oral herpes	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Rhinitis	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Bronchitis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Bronchopulmonary aspergillosis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Candida infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.1. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Cellulitis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cytomegalovirus enteritis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Cytomegalovirus infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cytomegalovirus viraemia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Device related infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Hepatitis B reactivation	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Herpes simplex	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Herpes zoster oticus	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Human herpesvirus 6 infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Infusion site infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Klebsiella infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Localised infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Oral candidiasis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Osteomyelitis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Parainfluenzae virus infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Parvovirus infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pneumonia klebsiella	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pneumonia staphylococcal	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Respiratory tract infection viral	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Rhinovirus infection	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Salmonellosis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Urinary tract infection bacterial	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Vulvovaginal candidiasis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Wound infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Injury, poisoning and procedural complications	11 (14)	8 (10)	3 (4)	0 (0)	0 (0)	0 (0)
Fall	5 (6)	3 (4)	2 (2)	0 (0)	0 (0)	0 (0)
Skin abrasion	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Contusion	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Face injury	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Infusion related reaction	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.1. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Procedural pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Sternal fracture	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Investigations	49 (60)	4 (5)	9 (11)	13 (16)	23 (28)	0 (0)
Neutrophil count decreased	27 (33)	0 (0)	1 (1)	6 (7)	20 (25)	0 (0)
Platelet count decreased	25 (31)	7 (9)	5 (6)	7 (9)	6 (7)	0 (0)
White blood cell count decreased	23 (28)	1 (1)	0 (0)	3 (4)	19 (23)	0 (0)
Alanine aminotransferase increased	14 (17)	9 (11)	2 (2)	3 (4)	0 (0)	0 (0)
Lymphocyte count decreased	14 (17)	0 (0)	0 (0)	1 (1)	13 (16)	0 (0)
Weight decreased	12 (15)	5 (6)	7 (9)	0 (0)	0 (0)	0 (0)
Aspartate aminotransferase increased	11 (14)	7 (9)	0 (0)	4 (5)	0 (0)	0 (0)
Weight increased	5 (6)	2 (2)	3 (4)	0 (0)	0 (0)	0 (0)
Blood bilirubin increased	4 (5)	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)
Blood creatinine increased	4 (5)	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)
Ejection fraction decreased	4 (5)	0 (0)	2 (2)	2 (2)	0 (0)	0 (0)
Blood alkaline phosphatase increased	3 (4)	2 (2)	0 (0)	1 (1)	0 (0)	0 (0)
Abdominal X-ray	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Blood immunoglobulin G decreased	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Blood urea increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Blood uric acid increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Breath sounds abnormal	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Electrocardiogram QT prolonged	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Heart rate irregular	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Liver function test abnormal	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Liver function test increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Nasogastric output abnormal	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Oxygen saturation decreased	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Prothrombin time prolonged	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Respiratory rate increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Serum ferritin increased	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Transaminases increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.1. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Troponin I increased	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Troponin T increased	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Troponin increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Metabolism and nutrition disorders	66 (81)	14 (17)	22 (27)	27 (33)	3 (4)	0 (0)
Decreased appetite	37 (46)	22 (27)	13 (16)	2 (2)	0 (0)	0 (0)
Hypoalbuminaemia	31 (38)	13 (16)	17 (21)	1 (1)	0 (0)	0 (0)
Hypocalcaemia	29 (36)	12 (15)	12 (15)	5 (6)	0 (0)	0 (0)
Hypokalaemia	26 (32)	18 (22)	7 (9)	1 (1)	0 (0)	0 (0)
Hyponatraemia	23 (28)	12 (15)	1 (1)	10 (12)	0 (0)	0 (0)
Hypophosphataemia	22 (27)	3 (4)	5 (6)	12 (15)	2 (2)	0 (0)
Hyperglycaemia	14 (17)	3 (4)	7 (9)	4 (5)	0 (0)	0 (0)
Hypomagnesaemia	13 (16)	12 (15)	1 (1)	0 (0)	0 (0)	0 (0)
Dehydration	6 (7)	2 (2)	3 (4)	1 (1)	0 (0)	0 (0)
Hyperkalaemia	6 (7)	4 (5)	2 (2)	0 (0)	0 (0)	0 (0)
Malnutrition	4 (5)	0 (0)	4 (5)	0 (0)	0 (0)	0 (0)
Metabolic acidosis	4 (5)	3 (4)	0 (0)	1 (1)	0 (0)	0 (0)
Fluid overload	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Hypercalcaemia	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Hyperuricaemia	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
Hypoglycaemia	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Hypermagnesaemia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypertriglyceridaemia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypervolaemia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Hypouricaemia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Lactic acidosis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Metabolic alkalosis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Tumour lysis syndrome	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	45 (56)	25 (31)	18 (22)	2 (2)	0 (0)	0 (0)
Back pain	12 (15)	8 (10)	4 (5)	0 (0)	0 (0)	0 (0)
Muscular weakness	11 (14)	5 (6)	5 (6)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.1. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Arthralgia	10 (12)	6 (7)	4 (5)	0 (0)	0 (0)	0 (0)
Myalgia	10 (12)	9 (11)	1 (1)	0 (0)	0 (0)	0 (0)
Pain in extremity	8 (10)	4 (5)	4 (5)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	4 (5)	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)
Neck pain	4 (5)	3 (4)	1 (1)	0 (0)	0 (0)	0 (0)
Bone pain	3 (4)	2 (2)	0 (0)	1 (1)	0 (0)	0 (0)
Flank pain	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Muscle spasms	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Groin pain	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Limb discomfort	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal chest pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Neck mass	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Torticollis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7 (9)	0 (0)	1 (1)	1 (1)	1 (1)	4 (5)
B-cell lymphoma	4 (5)	0 (0)	0 (0)	0 (0)	0 (0)	4 (5)
Tumour pain	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Carcinoma in situ	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Myelodysplastic syndrome	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Squamous cell carcinoma	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Nervous system disorders	62 (77)	31 (38)	11 (14)	18 (22)	2 (2)	0 (0)
Headache	35 (43)	30 (37)	5 (6)	0 (0)	0 (0)	0 (0)
Encephalopathy	28 (35)	8 (10)	3 (4)	16 (20)	1 (1)	0 (0)
Tremor	23 (28)	20 (25)	3 (4)	0 (0)	0 (0)	0 (0)
Aphasia	14 (17)	4 (5)	4 (5)	6 (7)	0 (0)	0 (0)
Dizziness	12 (15)	11 (14)	1 (1)	0 (0)	0 (0)	0 (0)
Somnolence	11 (14)	2 (2)	3 (4)	5 (6)	1 (1)	0 (0)
Memory impairment	6 (7)	5 (6)	1 (1)	0 (0)	0 (0)	0 (0)
Dysgeusia	5 (6)	5 (6)	0 (0)	0 (0)	0 (0)	0 (0)
Seizure	4 (5)	0 (0)	3 (4)	0 (0)	1 (1)	0 (0)
Ataxia	3 (4)	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.1. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Dysarthria	3 (4)	1 (1)	0 (0)	2 (2)	0 (0)	0 (0)
Lethargy	3 (4)	1 (1)	2 (2)	0 (0)	0 (0)	0 (0)
Speech disorder	3 (4)	1 (1)	0 (0)	2 (2)	0 (0)	0 (0)
Depressed level of consciousness	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Dyscalculia	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Myoclonus	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Neuropathy peripheral	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Amnesia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Cerebellar infarction	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cognitive disorder	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Coordination abnormal	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Disturbance in attention	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Facial paralysis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Facial paresis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Head discomfort	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hemiparesis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Hyperaesthesia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Leukoencephalopathy	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Paraesthesia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Post herpetic neuralgia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Presyncope	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Syncope	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Product issues	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Thrombosis in device	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Psychiatric disorders	39 (48)	18 (22)	11 (14)	10 (12)	0 (0)	0 (0)
Confusional state	20 (25)	7 (9)	6 (7)	7 (9)	0 (0)	0 (0)
Anxiety	11 (14)	8 (10)	2 (2)	1 (1)	0 (0)	0 (0)
Insomnia	9 (11)	5 (6)	4 (5)	0 (0)	0 (0)	0 (0)
Agitation	6 (7)	3 (4)	1 (1)	2 (2)	0 (0)	0 (0)
Mental status changes	6 (7)	1 (1)	2 (2)	3 (4)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.1. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Hallucination	4 (5)	3 (4)	1 (1)	0 (0)	0 (0)	0 (0)
Restlessness	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Abnormal dreams	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Adjustment disorder	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Bradyphrenia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Delirium	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Delusion	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Depression	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Disorientation	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Paranoia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	26 (32)	15 (19)	6 (7)	4 (5)	1 (1)	0 (0)
Acute kidney injury	7 (9)	2 (2)	1 (1)	3 (4)	1 (1)	0 (0)
Urinary incontinence	7 (9)	3 (4)	4 (5)	0 (0)	0 (0)	0 (0)
Dysuria	4 (5)	3 (4)	1 (1)	0 (0)	0 (0)	0 (0)
Haematuria	4 (5)	3 (4)	1 (1)	0 (0)	0 (0)	0 (0)
Urinary retention	4 (5)	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)
Micturition urgency	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Oliguria	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Polyuria	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Renal impairment	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Urinary tract obstruction	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Reproductive system and breast disorders	6 (7)	2 (2)	4 (5)	0 (0)	0 (0)	0 (0)
Oedema genital	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
Dyspareunia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Pelvic pain	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Scrotal oedema	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Vaginal discharge	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Vaginal haemorrhage	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	54 (67)	17 (21)	24 (30)	11 (14)	2 (2)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.1. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Hypoxia	25 (31)	1 (1)	15 (19)	8 (10)	1 (1)	0 (0)
Cough	22 (27)	18 (22)	4 (5)	0 (0)	0 (0)	0 (0)
Dyspnoea	14 (17)	10 (12)	4 (5)	0 (0)	0 (0)	0 (0)
Pleural effusion	12 (15)	6 (7)	4 (5)	2 (2)	0 (0)	0 (0)
Hiccups	6 (7)	4 (5)	2 (2)	0 (0)	0 (0)	0 (0)
Pulmonary oedema	6 (7)	0 (0)	4 (5)	2 (2)	0 (0)	0 (0)
Upper-airway cough syndrome	5 (6)	4 (5)	1 (1)	0 (0)	0 (0)	0 (0)
Nasal congestion	4 (5)	3 (4)	1 (1)	0 (0)	0 (0)	0 (0)
Oropharyngeal pain	4 (5)	4 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Wheezing	4 (5)	3 (4)	1 (1)	0 (0)	0 (0)	0 (0)
Productive cough	3 (4)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)
Atelectasis	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Rhinorrhoea	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Sinus congestion	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Tachypnoea	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Acute respiratory failure	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Aspiration	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Dysphonia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Haemoptysis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Orthopnoea	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Pneumothorax	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Pulmonary congestion	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Pulmonary hypertension	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Rales	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Reexpansion pulmonary oedema	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Rhinitis allergic	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Sinus pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Tonsillar hypertrophy	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	26 (32)	18 (22)	8 (10)	0 (0)	0 (0)	0 (0)
Pruritus	5 (6)	3 (4)	2 (2)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.1. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Rash maculo-papular	4 (5)	3 (4)	1 (1)	0 (0)	0 (0)	0 (0)
Rash	3 (4)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)
Alopecia	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Dry skin	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Pain of skin	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Erythema	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Hyperhidrosis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Livedo reticularis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Papule	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus generalised	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Rash erythematous	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Skin lesion	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Skin ulcer	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Vascular disorders	55 (68)	12 (15)	29 (36)	13 (16)	1 (1)	0 (0)
Hypotension	46 (57)	13 (16)	22 (27)	10 (12)	1 (1)	0 (0)
Hypertension	11 (14)	1 (1)	5 (6)	5 (6)	0 (0)	0 (0)
Deep vein thrombosis	3 (4)	0 (0)	3 (4)	0 (0)	0 (0)	0 (0)
Thrombosis	3 (4)	1 (1)	2 (2)	0 (0)	0 (0)	0 (0)
Capillary leak syndrome	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
Orthostatic hypotension	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
Diastolic hypotension	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Embolism venous	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Flushing	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Haematoma	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Shock	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.2. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 21)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects with Any TE Adverse Event	18 (86)	0 (0)	1 (5)	2 (10)	12 (57)	3 (14)
Blood and lymphatic system disorders	16 (76)	0 (0)	2 (10)	5 (24)	9 (43)	0 (0)
Anaemia	11 (52)	0 (0)	3 (14)	7 (33)	1 (5)	0 (0)
Neutropenia	9 (43)	1 (5)	1 (5)	0 (0)	7 (33)	0 (0)
Thrombocytopenia	5 (24)	1 (5)	1 (5)	1 (5)	2 (10)	0 (0)
Febrile neutropenia	4 (19)	0 (0)	1 (5)	3 (14)	0 (0)	0 (0)
Leukopenia	2 (10)	0 (0)	0 (0)	1 (5)	1 (5)	0 (0)
Lymphopenia	2 (10)	0 (0)	1 (5)	0 (0)	1 (5)	0 (0)
Pancytopenia	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Cardiac disorders	12 (57)	6 (29)	3 (14)	1 (5)	2 (10)	0 (0)
Tachycardia	8 (38)	6 (29)	1 (5)	1 (5)	0 (0)	0 (0)
Sinus bradycardia	3 (14)	3 (14)	0 (0)	0 (0)	0 (0)	0 (0)
Atrial fibrillation	2 (10)	0 (0)	0 (0)	2 (10)	0 (0)	0 (0)
Cardiac arrest	2 (10)	0 (0)	0 (0)	0 (0)	2 (10)	0 (0)
Sinus tachycardia	2 (10)	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)
Supraventricular tachycardia	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Ventricular arrhythmia	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	3 (14)	2 (10)	1 (5)	0 (0)	0 (0)	0 (0)
Blepharospasm	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Dry eye	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Papilloedema	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Photophobia	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Photopsia	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Retinal tear	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Vision blurred	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Gastrointestinal disorders	17 (81)	9 (43)	4 (19)	3 (14)	1 (5)	0 (0)
Diarrhoea	9 (43)	7 (33)	1 (5)	1 (5)	0 (0)	0 (0)
Nausea	9 (43)	6 (29)	3 (14)	0 (0)	0 (0)	0 (0)
Vomiting	8 (38)	6 (29)	2 (10)	0 (0)	0 (0)	0 (0)
Constipation	4 (19)	4 (19)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal pain	3 (14)	3 (14)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.2. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 21)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Dry mouth	2 (10)	2 (10)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal compartment syndrome	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Abdominal pain upper	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Anal incontinence	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Colitis	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Dyspepsia	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Dysphagia	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Flatulence	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Gastrointestinal haemorrhage	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Gastrointestinal perforation	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Haemorrhoids	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Mesenteric vein thrombosis	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Mouth ulceration	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Oesophageal fistula	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Proctalgia	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Rectal haemorrhage	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
General disorders and administration site conditions	15 (71)	0 (0)	10 (48)	4 (19)	1 (5)	0 (0)
Pyrexia	14 (67)	0 (0)	10 (48)	3 (14)	1 (5)	0 (0)
Fatigue	8 (38)	3 (14)	4 (19)	1 (5)	0 (0)	0 (0)
Chills	4 (19)	4 (19)	0 (0)	0 (0)	0 (0)	0 (0)
Oedema peripheral	2 (10)	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)
Asthenia	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Chest pain	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Non-cardiac chest pain	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Pain	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Hepatobiliary disorders	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Acute hepatic failure	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Immune system disorders	2 (10)	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)
Hypogammaglobulinaemia	2 (10)	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)
Infections and infestations	7 (33)	0 (0)	1 (5)	4 (19)	2 (10)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.2. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 21)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Herpes zoster	2 (10)	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)
Urinary tract infection	2 (10)	0 (0)	1 (5)	1 (5)	0 (0)	0 (0)
Candida infection	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Clostridium difficile colitis	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Device related infection	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Device related sepsis	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Ecthyma	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Fungal skin infection	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Lung infection	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Nasopharyngitis	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Pneumonia	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Sepsis	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Skin infection	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Tongue fungal infection	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Upper respiratory tract infection	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Wound infection	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Injury, poisoning and procedural complications	3 (14)	2 (10)	1 (5)	0 (0)	0 (0)	0 (0)
Fall	2 (10)	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)
Wound	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Investigations	9 (43)	1 (5)	2 (10)	0 (0)	6 (29)	0 (0)
Neutrophil count decreased	6 (29)	0 (0)	0 (0)	1 (5)	5 (24)	0 (0)
White blood cell count decreased	6 (29)	0 (0)	1 (5)	0 (0)	5 (24)	0 (0)
Lymphocyte count decreased	4 (19)	0 (0)	0 (0)	0 (0)	4 (19)	0 (0)
Platelet count decreased	4 (19)	1 (5)	0 (0)	1 (5)	2 (10)	0 (0)
Weight decreased	4 (19)	3 (14)	1 (5)	0 (0)	0 (0)	0 (0)
Alanine aminotransferase increased	3 (14)	1 (5)	1 (5)	1 (5)	0 (0)	0 (0)
Aspartate aminotransferase increased	3 (14)	1 (5)	1 (5)	1 (5)	0 (0)	0 (0)
Blood creatinine increased	2 (10)	2 (10)	0 (0)	0 (0)	0 (0)	0 (0)
Blood alkaline phosphatase increased	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Blood bilirubin increased	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.2. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 21)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Chest X-ray abnormal	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Metabolism and nutrition disorders	16 (76)	3 (14)	5 (24)	6 (29)	1 (5)	1 (5)
Hypoalbuminaemia	9 (43)	2 (10)	7 (33)	0 (0)	0 (0)	0 (0)
Hypocalcaemia	9 (43)	5 (24)	3 (14)	1 (5)	0 (0)	0 (0)
Hyponatraemia	8 (38)	8 (38)	0 (0)	0 (0)	0 (0)	0 (0)
Decreased appetite	7 (33)	7 (33)	0 (0)	0 (0)	0 (0)	0 (0)
Hypokalaemia	6 (29)	4 (19)	0 (0)	2 (10)	0 (0)	0 (0)
Hypophosphataemia	6 (29)	2 (10)	1 (5)	3 (14)	0 (0)	0 (0)
Hyperglycaemia	5 (24)	0 (0)	4 (19)	1 (5)	0 (0)	0 (0)
Dehydration	3 (14)	1 (5)	0 (0)	2 (10)	0 (0)	0 (0)
Hypomagnesaemia	3 (14)	3 (14)	0 (0)	0 (0)	0 (0)	0 (0)
Hyperkalaemia	2 (10)	2 (10)	0 (0)	0 (0)	0 (0)	0 (0)
Hypoglycaemia	2 (10)	2 (10)	0 (0)	0 (0)	0 (0)	0 (0)
Acidosis	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Hyperalbuminaemia	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Hypercalcaemia	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Hypermagnesaemia	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Hypernatraemia	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Lactic acidosis	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Tumour lysis syndrome	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)
Musculoskeletal and connective tissue disorders	7 (33)	5 (24)	2 (10)	0 (0)	0 (0)	0 (0)
Muscular weakness	4 (19)	3 (14)	1 (5)	0 (0)	0 (0)	0 (0)
Pain in extremity	3 (14)	2 (10)	1 (5)	0 (0)	0 (0)	0 (0)
Myalgia	2 (10)	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)
Arthralgia	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Back pain	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Neck pain	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (10)	0 (0)	1 (5)	0 (0)	1 (5)	0 (0)
Myelodysplastic syndrome	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Tumour pain	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.2. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 21)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Nervous system disorders	16 (76)	5 (24)	3 (14)	6 (29)	1 (5)	1 (5)
Dizziness	7 (33)	6 (29)	1 (5)	0 (0)	0 (0)	0 (0)
Headache	7 (33)	5 (24)	1 (5)	1 (5)	0 (0)	0 (0)
Encephalopathy	6 (29)	2 (10)	0 (0)	4 (19)	0 (0)	0 (0)
Tremor	5 (24)	4 (19)	1 (5)	0 (0)	0 (0)	0 (0)
Aphasia	3 (14)	0 (0)	2 (10)	1 (5)	0 (0)	0 (0)
Somnolence	3 (14)	0 (0)	2 (10)	1 (5)	0 (0)	0 (0)
Disturbance in attention	2 (10)	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)
Memory impairment	2 (10)	2 (10)	0 (0)	0 (0)	0 (0)	0 (0)
Peripheral sensory neuropathy	2 (10)	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)
Ataxia	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Brain injury	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)
Coma hepatic	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Dysgeusia	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Hypoaesthesia	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Loss of consciousness	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Meningism	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Muscle spasticity	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Presyncope	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Psychomotor hyperactivity	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Stupor	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Psychiatric disorders	8 (38)	1 (5)	4 (19)	3 (14)	0 (0)	0 (0)
Confusional state	7 (33)	1 (5)	4 (19)	2 (10)	0 (0)	0 (0)
Anxiety	3 (14)	2 (10)	1 (5)	0 (0)	0 (0)	0 (0)
Agitation	2 (10)	0 (0)	0 (0)	2 (10)	0 (0)	0 (0)
Insomnia	2 (10)	2 (10)	0 (0)	0 (0)	0 (0)	0 (0)
Delirium	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Depression	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Disorientation	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Mental status changes	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.2. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 21)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Restlessness	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	4 (19)	1 (5)	1 (5)	2 (10)	0 (0)	0 (0)
Acute kidney injury	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Dysuria	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Nocturia	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Oliguria	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Urinary incontinence	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	13 (62)	4 (19)	7 (33)	0 (0)	1 (5)	1 (5)
Cough	5 (24)	3 (14)	2 (10)	0 (0)	0 (0)	0 (0)
Hypoxia	4 (19)	0 (0)	4 (19)	0 (0)	0 (0)	0 (0)
Dyspnoea	3 (14)	2 (10)	1 (5)	0 (0)	0 (0)	0 (0)
Pleural effusion	2 (10)	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)
Atelectasis	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Hiccups	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Nasal congestion	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Oropharyngeal pain	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Pneumonia aspiration	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Pulmonary embolism	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)
Respiratory distress	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Rhinitis allergic	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Tachypnoea	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Upper-airway cough syndrome	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	3 (14)	2 (10)	1 (5)	0 (0)	0 (0)	0 (0)
Rash	2 (10)	2 (10)	0 (0)	0 (0)	0 (0)	0 (0)
Ecchymosis	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Hyperhidrosis	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Vascular disorders	11 (52)	3 (14)	3 (14)	4 (19)	1 (5)	0 (0)
Hypotension	10 (48)	5 (24)	2 (10)	3 (14)	0 (0)	0 (0)
Hypertension	5 (24)	2 (10)	1 (5)	2 (10)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.2. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 21)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Flushing	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Orthostatic hypotension	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Shock	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.3. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: PMBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 9)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects with Any TE Adverse Event	8 (89)	0 (0)	0 (0)	3 (33)	5 (56)	0 (0)
Blood and lymphatic system disorders	7 (78)	0 (0)	1 (11)	4 (44)	2 (22)	0 (0)
Febrile neutropenia	5 (56)	0 (0)	0 (0)	5 (56)	0 (0)	0 (0)
Anaemia	3 (33)	0 (0)	1 (11)	2 (22)	0 (0)	0 (0)
Neutropenia	3 (33)	0 (0)	0 (0)	1 (11)	2 (22)	0 (0)
Thrombocytopenia	2 (22)	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)
Leukopenia	1 (11)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)
Cardiac disorders	4 (44)	4 (44)	0 (0)	0 (0)	0 (0)	0 (0)
Extrasystoles	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Sinus tachycardia	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Tachycardia	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Ventricular arrhythmia	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Ear and labyrinth disorders	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Hypoacusis	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	3 (33)	1 (11)	2 (22)	0 (0)	0 (0)	0 (0)
Eye disorder	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Keratitis	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Photophobia	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Vision blurred	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Gastrointestinal disorders	7 (78)	4 (44)	3 (33)	0 (0)	0 (0)	0 (0)
Nausea	7 (78)	5 (56)	2 (22)	0 (0)	0 (0)	0 (0)
Constipation	5 (56)	4 (44)	1 (11)	0 (0)	0 (0)	0 (0)
Vomiting	5 (56)	4 (44)	1 (11)	0 (0)	0 (0)	0 (0)
Abdominal distension	2 (22)	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)
Abdominal discomfort	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal pain	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Diarrhoea	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Dry mouth	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Dyspepsia	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Rectal haemorrhage	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Tongue disorder	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: PMBCL, primary mediastinal B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.3. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: PMBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 9)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
General disorders and administration site conditions	8 (89)	1 (11)	6 (67)	1 (11)	0 (0)	0 (0)
Pyrexia	8 (89)	2 (22)	5 (56)	1 (11)	0 (0)	0 (0)
Fatigue	5 (56)	3 (33)	2 (22)	0 (0)	0 (0)	0 (0)
Chills	3 (33)	3 (33)	0 (0)	0 (0)	0 (0)	0 (0)
Asthenia	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Catheter site haematoma	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Catheter site pain	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Oedema peripheral	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Pain	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Swelling	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Immune system disorders	2 (22)	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)
Hypersensitivity	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Hypogammaglobulinaemia	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Infections and infestations	4 (44)	0 (0)	3 (33)	1 (11)	0 (0)	0 (0)
Sinusitis	2 (22)	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)
Conjunctivitis	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Herpes simplex	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Herpes zoster	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Pneumonia	1 (11)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)
Upper respiratory tract infection	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Injury, poisoning and procedural complications	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Infusion related reaction	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Procedural headache	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Procedural pain	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Investigations	4 (44)	0 (0)	1 (11)	0 (0)	3 (33)	0 (0)
Alanine aminotransferase increased	3 (33)	0 (0)	2 (22)	1 (11)	0 (0)	0 (0)
Aspartate aminotransferase increased	3 (33)	2 (22)	1 (11)	0 (0)	0 (0)	0 (0)
Lymphocyte count decreased	3 (33)	0 (0)	0 (0)	1 (11)	2 (22)	0 (0)
White blood cell count decreased	3 (33)	0 (0)	0 (0)	0 (0)	3 (33)	0 (0)
Neutrophil count decreased	2 (22)	0 (0)	0 (0)	0 (0)	2 (22)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: PMBCL, primary mediastinal B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.3. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: PMBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 9)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Platelet count decreased	2 (22)	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)
Blood creatinine increased	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
C-reactive protein increased	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Hepatic enzyme increased	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Serum ferritin increased	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Urine output decreased	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Weight decreased	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Metabolism and nutrition disorders	6 (67)	3 (33)	2 (22)	1 (11)	0 (0)	0 (0)
Decreased appetite	6 (67)	4 (44)	2 (22)	0 (0)	0 (0)	0 (0)
Hypocalcaemia	3 (33)	3 (33)	0 (0)	0 (0)	0 (0)	0 (0)
Hyponatraemia	3 (33)	3 (33)	0 (0)	0 (0)	0 (0)	0 (0)
Hyperglycaemia	2 (22)	2 (22)	0 (0)	0 (0)	0 (0)	0 (0)
Hypermagnesaemia	2 (22)	2 (22)	0 (0)	0 (0)	0 (0)	0 (0)
Hypoalbuminaemia	2 (22)	2 (22)	0 (0)	0 (0)	0 (0)	0 (0)
Hypokalaemia	2 (22)	2 (22)	0 (0)	0 (0)	0 (0)	0 (0)
Hypomagnesaemia	2 (22)	2 (22)	0 (0)	0 (0)	0 (0)	0 (0)
Dehydration	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Hypophosphataemia	1 (11)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	5 (56)	4 (44)	0 (0)	1 (11)	0 (0)	0 (0)
Pain in extremity	2 (22)	2 (22)	0 (0)	0 (0)	0 (0)	0 (0)
Back pain	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Flank pain	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	1 (11)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Basal cell carcinoma	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Nervous system disorders	8 (89)	4 (44)	2 (22)	2 (22)	0 (0)	0 (0)
Headache	5 (56)	2 (22)	3 (33)	0 (0)	0 (0)	0 (0)
Dizziness	3 (33)	3 (33)	0 (0)	0 (0)	0 (0)	0 (0)
Dysarthria	2 (22)	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: PMBCL, primary mediastinal B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.3. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: PMBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 9)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Aphasia	1 (11)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)
Dysgeusia	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Encephalopathy	1 (11)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)
Head titubation	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Hemiparesis	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Hyperaesthesia	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Hypersomnia	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Somnolence	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Tremor	1 (11)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)
Vagus nerve disorder	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Psychiatric disorders	3 (33)	1 (11)	1 (11)	1 (11)	0 (0)	0 (0)
Confusional state	2 (22)	0 (0)	1 (11)	1 (11)	0 (0)	0 (0)
Insomnia	2 (22)	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)
Agitation	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Anxiety	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Depression	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Mood altered	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	2 (22)	2 (22)	0 (0)	0 (0)	0 (0)	0 (0)
Dysuria	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Pollakiuria	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Reproductive system and breast disorders	3 (33)	2 (22)	1 (11)	0 (0)	0 (0)	0 (0)
Amenorrhoea	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Erectile dysfunction	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Vaginal haemorrhage	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	7 (78)	4 (44)	1 (11)	2 (22)	0 (0)	0 (0)
Dyspnoea	3 (33)	1 (11)	0 (0)	2 (22)	0 (0)	0 (0)
Cough	2 (22)	2 (22)	0 (0)	0 (0)	0 (0)	0 (0)
Dysphonia	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Hypoxia	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Obstructive airways disorder	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: PMBCL, primary mediastinal B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.3. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: PMBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 9)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Oropharyngeal pain	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Pleural effusion	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Pulmonary haemorrhage	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	3 (33)	3 (33)	0 (0)	0 (0)	0 (0)	0 (0)
Night sweats	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus generalised	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Vascular disorders	5 (56)	2 (22)	2 (22)	1 (11)	0 (0)	0 (0)
Hypotension	5 (56)	2 (22)	3 (33)	0 (0)	0 (0)	0 (0)
Hypertension	1 (11)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: PMBCL, primary mediastinal B-cell lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.4. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects with Any TE Adverse Event	95 (93)	0 (0)	2 (2)	25 (25)	60 (59)	8 (8)
Blood and lymphatic system disorders	86 (84)	2 (2)	10 (10)	33 (32)	40 (39)	1 (1)
Anaemia	67 (66)	4 (4)	19 (19)	41 (40)	3 (3)	0 (0)
Neutropenia	42 (41)	1 (1)	5 (5)	9 (9)	27 (26)	0 (0)
Thrombocytopenia	34 (33)	5 (5)	6 (6)	10 (10)	13 (13)	0 (0)
Febrile neutropenia	31 (30)	0 (0)	4 (4)	26 (25)	1 (1)	0 (0)
Leukopenia	19 (19)	0 (0)	2 (2)	4 (4)	13 (13)	0 (0)
Lymphopenia	10 (10)	0 (0)	2 (2)	1 (1)	7 (7)	0 (0)
Pancytopenia	3 (3)	0 (0)	1 (1)	1 (1)	1 (1)	0 (0)
Bone marrow failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Coagulopathy	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Disseminated intravascular coagulation	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Histiocytosis haematophagic	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Increased tendency to bruise	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Splenic infarction	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Splenic vein thrombosis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Thrombocytosis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Cardiac disorders	66 (65)	43 (42)	13 (13)	5 (5)	5 (5)	0 (0)
Tachycardia	39 (38)	35 (34)	2 (2)	2 (2)	0 (0)	0 (0)
Sinus tachycardia	21 (21)	16 (16)	5 (5)	0 (0)	0 (0)	0 (0)
Atrial fibrillation	9 (9)	1 (1)	4 (4)	4 (4)	0 (0)	0 (0)
Sinus bradycardia	8 (8)	8 (8)	0 (0)	0 (0)	0 (0)	0 (0)
Atrial flutter	6 (6)	4 (4)	1 (1)	0 (0)	1 (1)	0 (0)
Cardiac arrest	4 (4)	0 (0)	0 (0)	0 (0)	4 (4)	0 (0)
Ventricular arrhythmia	4 (4)	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)
Supraventricular tachycardia	3 (3)	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)
Ventricular tachycardia	3 (3)	0 (0)	3 (3)	0 (0)	0 (0)	0 (0)
Arrhythmia	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Acute left ventricular failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Atrioventricular block	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Bradycardia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.4. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Bundle branch block right	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cardiomegaly	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Palpitations	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Supraventricular extrasystoles	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Ear and labyrinth disorders	3 (3)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)
Ear discomfort	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Ear pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Excessive cerumen production	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Endocrine disorders	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Inappropriate antidiuretic hormone secretion	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	9 (9)	7 (7)	2 (2)	0 (0)	0 (0)	0 (0)
Vision blurred	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Dry eye	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Blepharospasm	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Eye pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Papilloedema	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Periorbital oedema	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Photophobia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Photopsia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Pupils unequal	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Retinal tear	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Scleral haemorrhage	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Vitreous floaters	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Gastrointestinal disorders	82 (80)	44 (43)	27 (26)	10 (10)	1 (1)	0 (0)
Nausea	53 (52)	35 (34)	18 (18)	0 (0)	0 (0)	0 (0)
Diarrhoea	43 (42)	30 (29)	9 (9)	4 (4)	0 (0)	0 (0)
Vomiting	30 (29)	25 (25)	4 (4)	1 (1)	0 (0)	0 (0)
Constipation	26 (25)	19 (19)	7 (7)	0 (0)	0 (0)	0 (0)
Abdominal pain	15 (15)	9 (9)	4 (4)	2 (2)	0 (0)	0 (0)
Dry mouth	10 (10)	10 (10)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.4. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Abdominal distension	5 (5)	5 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Dysphagia	5 (5)	2 (2)	3 (3)	0 (0)	0 (0)	0 (0)
Flatulence	4 (4)	1 (1)	3 (3)	0 (0)	0 (0)	0 (0)
Abdominal pain upper	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Dyspepsia	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Haemorrhoids	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal discomfort	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Anal incontinence	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
Ascites	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
Gastritis	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Gastrooesophageal reflux disease	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Rectal haemorrhage	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal compartment syndrome	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Abdominal hernia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal pain lower	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Chapped lips	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Colitis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Enteritis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Gastrointestinal haemorrhage	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Gastrointestinal perforation	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Ileus	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Lip dry	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Lip swelling	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Mesenteric vein thrombosis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Mouth ulceration	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Neurogenic bowel	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Oesophageal fistula	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Oral discomfort	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Proctalgia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Toothache	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.4. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
General disorders and administration site conditions	88 (86)	12 (12)	57 (56)	18 (18)	1 (1)	0 (0)
Pyrexia	80 (78)	14 (14)	53 (52)	12 (12)	1 (1)	0 (0)
Fatigue	48 (47)	26 (25)	20 (20)	2 (2)	0 (0)	0 (0)
Chills	36 (35)	29 (28)	7 (7)	0 (0)	0 (0)	0 (0)
Oedema peripheral	19 (19)	13 (13)	5 (5)	1 (1)	0 (0)	0 (0)
Asthenia	8 (8)	1 (1)	5 (5)	2 (2)	0 (0)	0 (0)
Pain	8 (8)	6 (6)	0 (0)	2 (2)	0 (0)	0 (0)
Non-cardiac chest pain	7 (7)	6 (6)	1 (1)	0 (0)	0 (0)	0 (0)
Peripheral swelling	5 (5)	3 (3)	2 (2)	0 (0)	0 (0)	0 (0)
Malaise	4 (4)	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)
Chest discomfort	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Gait disturbance	3 (3)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)
Generalised oedema	3 (3)	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)
Localised oedema	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Mucosal inflammation	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Catheter site swelling	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Chest pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Face oedema	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypothermia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Oedema	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Swelling	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hepatobiliary disorders	2 (2)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
Acute hepatic failure	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Hyperbilirubinaemia	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Immune system disorders	13 (13)	6 (6)	7 (7)	0 (0)	0 (0)	0 (0)
Hypogammaglobulinaemia	12 (12)	5 (5)	7 (7)	0 (0)	0 (0)	0 (0)
Graft versus host disease in skin	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypersensitivity	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Infections and infestations	38 (37)	1 (1)	11 (11)	24 (24)	2 (2)	0 (0)
Pneumonia	8 (8)	0 (0)	2 (2)	6 (6)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.4. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Urinary tract infection	8 (8)	1 (1)	3 (3)	4 (4)	0 (0)	0 (0)
Lung infection	7 (7)	0 (0)	1 (1)	6 (6)	0 (0)	0 (0)
Upper respiratory tract infection	7 (7)	0 (0)	7 (7)	0 (0)	0 (0)	0 (0)
Clostridium difficile infection	5 (5)	0 (0)	3 (3)	2 (2)	0 (0)	0 (0)
Herpes zoster	5 (5)	1 (1)	3 (3)	1 (1)	0 (0)	0 (0)
Clostridium difficile colitis	4 (4)	1 (1)	0 (0)	3 (3)	0 (0)	0 (0)
Sinusitis	3 (3)	1 (1)	2 (2)	0 (0)	0 (0)	0 (0)
Bacteraemia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Candida infection	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
Device related infection	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Escherichia bacteraemia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Influenza	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
Oral herpes	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Rhinitis	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Wound infection	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Bronchitis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Bronchopulmonary aspergillosis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cellulitis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cytomegalovirus enteritis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Cytomegalovirus infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cytomegalovirus viraemia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Device related sepsis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Ecthyma	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Fungal skin infection	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hepatitis B reactivation	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Herpes simplex	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Herpes zoster oticus	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Human herpesvirus 6 infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Infusion site infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Klebsiella infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.4. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Localised infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Nasopharyngitis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Oral candidiasis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Osteomyelitis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Parainfluenzae virus infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Parvovirus infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pneumonia klebsiella	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pneumonia staphylococcal	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Respiratory tract infection viral	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Rhinovirus infection	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Salmonellosis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Sepsis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Skin infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Tongue fungal infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Urinary tract infection bacterial	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Vulvovaginal candidiasis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Injury, poisoning and procedural complications	14 (14)	10 (10)	4 (4)	0 (0)	0 (0)	0 (0)
Fall	7 (7)	4 (4)	3 (3)	0 (0)	0 (0)	0 (0)
Skin abrasion	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Contusion	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Face injury	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Infusion related reaction	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Procedural pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Sternal fracture	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Wound	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Investigations	58 (57)	5 (5)	11 (11)	13 (13)	29 (28)	0 (0)
Neutrophil count decreased	33 (32)	0 (0)	1 (1)	7 (7)	25 (25)	0 (0)
Platelet count decreased	29 (28)	8 (8)	5 (5)	8 (8)	8 (8)	0 (0)
White blood cell count decreased	29 (28)	1 (1)	1 (1)	3 (3)	24 (24)	0 (0)
Lymphocyte count decreased	18 (18)	0 (0)	0 (0)	1 (1)	17 (17)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.4. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Alanine aminotransferase increased	17 (17)	10 (10)	3 (3)	4 (4)	0 (0)	0 (0)
Weight decreased	16 (16)	8 (8)	8 (8)	0 (0)	0 (0)	0 (0)
Aspartate aminotransferase increased	14 (14)	8 (8)	1 (1)	5 (5)	0 (0)	0 (0)
Blood creatinine increased	6 (6)	4 (4)	1 (1)	1 (1)	0 (0)	0 (0)
Blood bilirubin increased	5 (5)	3 (3)	1 (1)	1 (1)	0 (0)	0 (0)
Weight increased	5 (5)	2 (2)	3 (3)	0 (0)	0 (0)	0 (0)
Blood alkaline phosphatase increased	4 (4)	3 (3)	0 (0)	1 (1)	0 (0)	0 (0)
Ejection fraction decreased	4 (4)	0 (0)	2 (2)	2 (2)	0 (0)	0 (0)
Abdominal X-ray	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Blood immunoglobulin G decreased	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Blood urea increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Blood uric acid increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Breath sounds abnormal	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Chest X-ray abnormal	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Electrocardiogram QT prolonged	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Heart rate irregular	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Liver function test abnormal	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Liver function test increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Nasogastric output abnormal	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Oxygen saturation decreased	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Prothrombin time prolonged	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Respiratory rate increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Serum ferritin increased	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Transaminases increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Troponin I increased	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Troponin T increased	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Troponin increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Metabolism and nutrition disorders	82 (80)	17 (17)	27 (26)	33 (32)	4 (4)	1 (1)
Decreased appetite	44 (43)	29 (28)	13 (13)	2 (2)	0 (0)	0 (0)
Hypoalbuminaemia	40 (39)	15 (15)	24 (24)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.4. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Hypocalcaemia	38 (37)	17 (17)	15 (15)	6 (6)	0 (0)	0 (0)
Hypokalaemia	32 (31)	22 (22)	7 (7)	3 (3)	0 (0)	0 (0)
Hyponatraemia	31 (30)	20 (20)	1 (1)	10 (10)	0 (0)	0 (0)
Hypophosphataemia	28 (27)	5 (5)	6 (6)	15 (15)	2 (2)	0 (0)
Hyperglycaemia	19 (19)	3 (3)	11 (11)	5 (5)	0 (0)	0 (0)
Hypomagnesaemia	16 (16)	15 (15)	1 (1)	0 (0)	0 (0)	0 (0)
Dehydration	9 (9)	3 (3)	3 (3)	3 (3)	0 (0)	0 (0)
Hyperkalaemia	8 (8)	6 (6)	2 (2)	0 (0)	0 (0)	0 (0)
Hypoglycaemia	4 (4)	3 (3)	1 (1)	0 (0)	0 (0)	0 (0)
Malnutrition	4 (4)	0 (0)	4 (4)	0 (0)	0 (0)	0 (0)
Metabolic acidosis	4 (4)	3 (3)	0 (0)	1 (1)	0 (0)	0 (0)
Hypercalcaemia	3 (3)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)
Fluid overload	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Hypermagnesaemia	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Hyperuricaemia	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
Lactic acidosis	2 (2)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
Tumour lysis syndrome	2 (2)	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)
Acidosis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Hyperalbuminaemia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypernatraemia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypertriglyceridaemia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypervolaemia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Hypouricaemia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Metabolic alkalosis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	52 (51)	30 (29)	20 (20)	2 (2)	0 (0)	0 (0)
Muscular weakness	15 (15)	8 (8)	6 (6)	1 (1)	0 (0)	0 (0)
Back pain	13 (13)	8 (8)	5 (5)	0 (0)	0 (0)	0 (0)
Myalgia	12 (12)	10 (10)	2 (2)	0 (0)	0 (0)	0 (0)
Arthralgia	11 (11)	7 (7)	4 (4)	0 (0)	0 (0)	0 (0)
Pain in extremity	11 (11)	6 (6)	5 (5)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.4. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Neck pain	5 (5)	4 (4)	1 (1)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	4 (4)	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)
Bone pain	3 (3)	2 (2)	0 (0)	1 (1)	0 (0)	0 (0)
Flank pain	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Muscle spasms	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Groin pain	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Limb discomfort	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal chest pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Neck mass	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Torticollis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9 (9)	0 (0)	2 (2)	1 (1)	2 (2)	4 (4)
B-cell lymphoma	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Tumour pain	3 (3)	0 (0)	2 (2)	1 (1)	0 (0)	0 (0)
Myelodysplastic syndrome	2 (2)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
Carcinoma in situ	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Squamous cell carcinoma	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Nervous system disorders	78 (76)	36 (35)	14 (14)	24 (24)	3 (3)	1 (1)
Headache	42 (41)	35 (34)	6 (6)	1 (1)	0 (0)	0 (0)
Encephalopathy	34 (33)	10 (10)	3 (3)	20 (20)	1 (1)	0 (0)
Tremor	28 (27)	24 (24)	4 (4)	0 (0)	0 (0)	0 (0)
Dizziness	19 (19)	17 (17)	2 (2)	0 (0)	0 (0)	0 (0)
Aphasia	17 (17)	4 (4)	6 (6)	7 (7)	0 (0)	0 (0)
Somnolence	14 (14)	2 (2)	5 (5)	6 (6)	1 (1)	0 (0)
Memory impairment	8 (8)	7 (7)	1 (1)	0 (0)	0 (0)	0 (0)
Dysgeusia	6 (6)	5 (5)	1 (1)	0 (0)	0 (0)	0 (0)
Ataxia	4 (4)	1 (1)	2 (2)	1 (1)	0 (0)	0 (0)
Seizure	4 (4)	0 (0)	3 (3)	0 (0)	1 (1)	0 (0)
Disturbance in attention	3 (3)	1 (1)	0 (0)	2 (2)	0 (0)	0 (0)
Dysarthria	3 (3)	1 (1)	0 (0)	2 (2)	0 (0)	0 (0)
Lethargy	3 (3)	1 (1)	2 (2)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.4. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Speech disorder	3 (3)	1 (1)	0 (0)	2 (2)	0 (0)	0 (0)
Depressed level of consciousness	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Dyscalculia	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Myoclonus	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Neuropathy peripheral	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Peripheral sensory neuropathy	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Presyncope	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
Amnesia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Brain injury	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cerebellar infarction	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cognitive disorder	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Coma hepatic	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Coordination abnormal	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Facial paralysis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Facial paresis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Head discomfort	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hemiparesis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Hyperaesthesia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypoaesthesia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Leukoencephalopathy	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Loss of consciousness	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Meningism	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Muscle spasticity	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Paraesthesia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Post herpetic neuralgia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Psychomotor hyperactivity	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Stupor	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Syncope	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Product issues	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Thrombosis in device	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
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Table 14.3.1.4.0.2.4. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Psychiatric disorders	47 (46)	19 (19)	15 (15)	13 (13)	0 (0)	0 (0)
Confusional state	27 (26)	8 (8)	10 (10)	9 (9)	0 (0)	0 (0)
Anxiety	14 (14)	10 (10)	3 (3)	1 (1)	0 (0)	0 (0)
Insomnia	11 (11)	7 (7)	4 (4)	0 (0)	0 (0)	0 (0)
Agitation	8 (8)	3 (3)	1 (1)	4 (4)	0 (0)	0 (0)
Mental status changes	7 (7)	1 (1)	3 (3)	3 (3)	0 (0)	0 (0)
Hallucination	4 (4)	3 (3)	1 (1)	0 (0)	0 (0)	0 (0)
Restlessness	3 (3)	0 (0)	2 (2)	1 (1)	0 (0)	0 (0)
Delirium	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Depression	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Disorientation	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Abnormal dreams	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Adjustment disorder	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Bradyphrenia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Delusion	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Paranoia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	30 (29)	16 (16)	7 (7)	6 (6)	1 (1)	0 (0)
Acute kidney injury	8 (8)	2 (2)	2 (2)	3 (3)	1 (1)	0 (0)
Urinary incontinence	8 (8)	3 (3)	4 (4)	1 (1)	0 (0)	0 (0)
Dysuria	5 (5)	4 (4)	1 (1)	0 (0)	0 (0)	0 (0)
Haematuria	4 (4)	3 (3)	1 (1)	0 (0)	0 (0)	0 (0)
Urinary retention	4 (4)	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)
Micturition urgency	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Oliguria	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Pollakiuria	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Nocturia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Polyuria	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Renal impairment	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Urinary tract obstruction	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Reproductive system and breast disorders	6 (6)	2 (2)	4 (4)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

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Table 14.3.1.4.0.2.4. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Oedema genital	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
Dyspareunia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Pelvic pain	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Scrotal oedema	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Vaginal discharge	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Vaginal haemorrhage	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	67 (66)	21 (21)	31 (30)	11 (11)	3 (3)	1 (1)
Hypoxia	29 (28)	1 (1)	19 (19)	8 (8)	1 (1)	0 (0)
Cough	27 (26)	21 (21)	6 (6)	0 (0)	0 (0)	0 (0)
Dyspnoea	17 (17)	12 (12)	5 (5)	0 (0)	0 (0)	0 (0)
Pleural effusion	14 (14)	7 (7)	5 (5)	2 (2)	0 (0)	0 (0)
Hiccups	7 (7)	4 (4)	3 (3)	0 (0)	0 (0)	0 (0)
Pulmonary oedema	6 (6)	0 (0)	4 (4)	2 (2)	0 (0)	0 (0)
Upper-airway cough syndrome	6 (6)	5 (5)	1 (1)	0 (0)	0 (0)	0 (0)
Nasal congestion	5 (5)	4 (4)	1 (1)	0 (0)	0 (0)	0 (0)
Oropharyngeal pain	5 (5)	4 (4)	1 (1)	0 (0)	0 (0)	0 (0)
Wheezing	4 (4)	3 (3)	1 (1)	0 (0)	0 (0)	0 (0)
Atelectasis	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Productive cough	3 (3)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)
Tachypnoea	3 (3)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)
Rhinitis allergic	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Rhinorrhoea	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Sinus congestion	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Acute respiratory failure	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Aspiration	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Dysphonia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Haemoptysis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Orthopnoea	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Pneumonia aspiration	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Pneumothorax	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.4. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Pulmonary congestion	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Pulmonary embolism	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pulmonary hypertension	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Rales	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Reexpansion pulmonary oedema	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Respiratory distress	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Sinus pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Tonsillar hypertrophy	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	29 (28)	20 (20)	9 (9)	0 (0)	0 (0)	0 (0)
Pruritus	6 (6)	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)
Rash	5 (5)	4 (4)	1 (1)	0 (0)	0 (0)	0 (0)
Rash maculo-papular	4 (4)	3 (3)	1 (1)	0 (0)	0 (0)	0 (0)
Alopecia	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Dry skin	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Hyperhidrosis	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Pain of skin	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Ecchymosis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Erythema	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Livedo reticularis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Papule	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus generalised	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Rash erythematous	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Skin lesion	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Skin ulcer	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Vascular disorders	66 (65)	15 (15)	32 (31)	17 (17)	2 (2)	0 (0)
Hypotension	56 (55)	18 (18)	24 (24)	13 (13)	1 (1)	0 (0)
Hypertension	16 (16)	3 (3)	6 (6)	7 (7)	0 (0)	0 (0)
Deep vein thrombosis	3 (3)	0 (0)	3 (3)	0 (0)	0 (0)	0 (0)
Orthostatic hypotension	3 (3)	0 (0)	2 (2)	1 (1)	0 (0)	0 (0)
Thrombosis	3 (3)	1 (1)	2 (2)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.4. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Capillary leak syndrome	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
Flushing	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Shock	2 (2)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
Diastolic hypotension	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Embolism venous	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Haematoma	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.5. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects with Any TE Adverse Event	103 (93)	0 (0)	2 (2)	28 (25)	65 (59)	8 (7)
Blood and lymphatic system disorders	93 (84)	2 (2)	11 (10)	37 (33)	42 (38)	1 (1)
Anaemia	70 (63)	4 (4)	20 (18)	43 (39)	3 (3)	0 (0)
Neutropenia	45 (41)	1 (1)	5 (5)	10 (9)	29 (26)	0 (0)
Febrile neutropenia	36 (32)	0 (0)	4 (4)	31 (28)	1 (1)	0 (0)
Thrombocytopenia	36 (32)	6 (5)	6 (5)	11 (10)	13 (12)	0 (0)
Leukopenia	20 (18)	0 (0)	2 (2)	5 (5)	13 (12)	0 (0)
Lymphopenia	10 (9)	0 (0)	2 (2)	1 (1)	7 (6)	0 (0)
Pancytopenia	3 (3)	0 (0)	1 (1)	1 (1)	1 (1)	0 (0)
Bone marrow failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Coagulopathy	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Disseminated intravascular coagulation	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Histiocytosis haematophagic	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Increased tendency to bruise	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Splenic infarction	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Splenic vein thrombosis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Thrombocytosis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Cardiac disorders	70 (63)	47 (42)	13 (12)	5 (5)	5 (5)	0 (0)
Tachycardia	40 (36)	36 (32)	2 (2)	2 (2)	0 (0)	0 (0)
Sinus tachycardia	22 (20)	17 (15)	5 (5)	0 (0)	0 (0)	0 (0)
Atrial fibrillation	9 (8)	1 (1)	4 (4)	4 (4)	0 (0)	0 (0)
Sinus bradycardia	8 (7)	8 (7)	0 (0)	0 (0)	0 (0)	0 (0)
Atrial flutter	6 (5)	4 (4)	1 (1)	0 (0)	1 (1)	0 (0)
Ventricular arrhythmia	5 (5)	5 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Cardiac arrest	4 (4)	0 (0)	0 (0)	0 (0)	4 (4)	0 (0)
Supraventricular tachycardia	3 (3)	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)
Ventricular tachycardia	3 (3)	0 (0)	3 (3)	0 (0)	0 (0)	0 (0)
Arrhythmia	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Acute left ventricular failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Atrioventricular block	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Bradycardia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.5. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Bundle branch block right	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cardiomegaly	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Extrasystoles	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Palpitations	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Supraventricular extrasystoles	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Ear and labyrinth disorders	4 (4)	3 (3)	1 (1)	0 (0)	0 (0)	0 (0)
Ear discomfort	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Ear pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Excessive cerumen production	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Hypoacusis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Endocrine disorders	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Inappropriate antidiuretic hormone secretion	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorders	12 (11)	8 (7)	4 (4)	0 (0)	0 (0)	0 (0)
Vision blurred	4 (4)	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)
Dry eye	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Photophobia	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Blepharospasm	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Eye disorder	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Eye pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Keratitis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Papilloedema	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Periorbital oedema	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Photopsia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Pupils unequal	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Retinal tear	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Scleral haemorrhage	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Vitreous floaters	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Gastrointestinal disorders	89 (80)	48 (43)	30 (27)	10 (9)	1 (1)	0 (0)
Nausea	60 (54)	40 (36)	20 (18)	0 (0)	0 (0)	0 (0)
Diarrhoea	44 (40)	31 (28)	9 (8)	4 (4)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.5. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Vomiting	35 (32)	29 (26)	5 (5)	1 (1)	0 (0)	0 (0)
Constipation	31 (28)	23 (21)	8 (7)	0 (0)	0 (0)	0 (0)
Abdominal pain	16 (14)	10 (9)	4 (4)	2 (2)	0 (0)	0 (0)
Dry mouth	11 (10)	11 (10)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal distension	7 (6)	6 (5)	1 (1)	0 (0)	0 (0)	0 (0)
Dysphagia	5 (5)	2 (2)	3 (3)	0 (0)	0 (0)	0 (0)
Dyspepsia	4 (4)	3 (3)	1 (1)	0 (0)	0 (0)	0 (0)
Flatulence	4 (4)	1 (1)	3 (3)	0 (0)	0 (0)	0 (0)
Abdominal discomfort	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal pain upper	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Haemorrhoids	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Rectal haemorrhage	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Anal incontinence	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
Ascites	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
Gastritis	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Gastrooesophageal reflux disease	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Abdominal compartment syndrome	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Abdominal hernia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Abdominal pain lower	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Chapped lips	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Colitis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Enteritis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Gastrointestinal haemorrhage	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Gastrointestinal perforation	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Ileus	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Lip dry	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Lip swelling	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Mesenteric vein thrombosis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Mouth ulceration	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Neurogenic bowel	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.5. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Oesophageal fistula	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Oral discomfort	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Proctalgia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Tongue disorder	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Toothache	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
General disorders and administration site conditions	96 (86)	13 (12)	63 (57)	19 (17)	1 (1)	0 (0)
Pyrexia	88 (79)	16 (14)	58 (52)	13 (12)	1 (1)	0 (0)
Fatigue	53 (48)	29 (26)	22 (20)	2 (2)	0 (0)	0 (0)
Chills	39 (35)	32 (29)	7 (6)	0 (0)	0 (0)	0 (0)
Oedema peripheral	20 (18)	14 (13)	5 (5)	1 (1)	0 (0)	0 (0)
Asthenia	9 (8)	2 (2)	5 (5)	2 (2)	0 (0)	0 (0)
Pain	9 (8)	7 (6)	0 (0)	2 (2)	0 (0)	0 (0)
Non-cardiac chest pain	7 (6)	6 (5)	1 (1)	0 (0)	0 (0)	0 (0)
Peripheral swelling	5 (5)	3 (3)	2 (2)	0 (0)	0 (0)	0 (0)
Malaise	4 (4)	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)
Chest discomfort	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Gait disturbance	3 (3)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)
Generalised oedema	3 (3)	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)
Localised oedema	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Mucosal inflammation	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Swelling	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Catheter site haematoma	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Catheter site pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Catheter site swelling	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Chest pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Face oedema	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypothermia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Oedema	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Hepatobiliary disorders	2 (2)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
Acute hepatic failure	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.5. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Hyperbilirubinaemia	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Immune system disorders	15 (14)	7 (6)	8 (7)	0 (0)	0 (0)	0 (0)
Hypogammaglobulinaemia	13 (12)	6 (5)	7 (6)	0 (0)	0 (0)	0 (0)
Hypersensitivity	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Graft versus host disease in skin	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Infections and infestations	42 (38)	1 (1)	14 (13)	25 (23)	2 (2)	0 (0)
Pneumonia	9 (8)	0 (0)	2 (2)	7 (6)	0 (0)	0 (0)
Upper respiratory tract infection	8 (7)	0 (0)	8 (7)	0 (0)	0 (0)	0 (0)
Urinary tract infection	8 (7)	1 (1)	3 (3)	4 (4)	0 (0)	0 (0)
Lung infection	7 (6)	0 (0)	1 (1)	6 (5)	0 (0)	0 (0)
Herpes zoster	6 (5)	1 (1)	4 (4)	1 (1)	0 (0)	0 (0)
Clostridium difficile infection	5 (5)	0 (0)	3 (3)	2 (2)	0 (0)	0 (0)
Sinusitis	5 (5)	2 (2)	3 (3)	0 (0)	0 (0)	0 (0)
Clostridium difficile colitis	4 (4)	1 (1)	0 (0)	3 (3)	0 (0)	0 (0)
Bacteraemia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Candida infection	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
Device related infection	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Escherichia bacteraemia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Herpes simplex	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Influenza	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
Oral herpes	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Rhinitis	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Wound infection	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Bronchitis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Bronchopulmonary aspergillosis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cellulitis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Conjunctivitis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cytomegalovirus enteritis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Cytomegalovirus infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cytomegalovirus viraemia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.5. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Device related sepsis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Ecthyma	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Fungal skin infection	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hepatitis B reactivation	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Herpes zoster oticus	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Human herpesvirus 6 infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Infusion site infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Klebsiella infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Localised infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Nasopharyngitis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Oral candidiasis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Osteomyelitis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Parainfluenzae virus infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Parvovirus infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pneumonia klebsiella	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pneumonia staphylococcal	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Respiratory tract infection viral	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Rhinovirus infection	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Salmonellosis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Sepsis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Skin infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Tongue fungal infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Urinary tract infection bacterial	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Vulvovaginal candidiasis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Injury, poisoning and procedural complications	15 (14)	10 (9)	5 (5)	0 (0)	0 (0)	0 (0)
Fall	7 (6)	4 (4)	3 (3)	0 (0)	0 (0)	0 (0)
Infusion related reaction	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Procedural pain	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Skin abrasion	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Contusion	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.5. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Face injury	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Procedural headache	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Sternal fracture	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Wound	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Investigations	62 (56)	5 (5)	12 (11)	13 (12)	32 (29)	0 (0)
Neutrophil count decreased	35 (32)	0 (0)	1 (1)	7 (6)	27 (24)	0 (0)
White blood cell count decreased	32 (29)	1 (1)	1 (1)	3 (3)	27 (24)	0 (0)
Platelet count decreased	31 (28)	9 (8)	6 (5)	8 (7)	8 (7)	0 (0)
Lymphocyte count decreased	21 (19)	0 (0)	0 (0)	2 (2)	19 (17)	0 (0)
Alanine aminotransferase increased	20 (18)	10 (9)	5 (5)	5 (5)	0 (0)	0 (0)
Aspartate aminotransferase increased	17 (15)	10 (9)	2 (2)	5 (5)	0 (0)	0 (0)
Weight decreased	17 (15)	8 (7)	9 (8)	0 (0)	0 (0)	0 (0)
Blood creatinine increased	7 (6)	5 (5)	1 (1)	1 (1)	0 (0)	0 (0)
Blood bilirubin increased	5 (5)	3 (3)	1 (1)	1 (1)	0 (0)	0 (0)
Weight increased	5 (5)	2 (2)	3 (3)	0 (0)	0 (0)	0 (0)
Blood alkaline phosphatase increased	4 (4)	3 (3)	0 (0)	1 (1)	0 (0)	0 (0)
Ejection fraction decreased	4 (4)	0 (0)	2 (2)	2 (2)	0 (0)	0 (0)
Serum ferritin increased	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Abdominal X-ray	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Blood immunoglobulin G decreased	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Blood urea increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Blood uric acid increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Breath sounds abnormal	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
C-reactive protein increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Chest X-ray abnormal	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Electrocardiogram QT prolonged	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Heart rate irregular	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hepatic enzyme increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Liver function test abnormal	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Liver function test increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.5. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Nasogastric output abnormal	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Oxygen saturation decreased	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Prothrombin time prolonged	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Respiratory rate increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Transaminases increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Troponin I increased	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Troponin T increased	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Troponin increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Urine output decreased	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Metabolism and nutrition disorders	88 (79)	20 (18)	29 (26)	34 (31)	4 (4)	1 (1)
Decreased appetite	50 (45)	33 (30)	15 (14)	2 (2)	0 (0)	0 (0)
Hypoalbuminaemia	42 (38)	17 (15)	24 (22)	1 (1)	0 (0)	0 (0)
Hypocalcaemia	41 (37)	20 (18)	15 (14)	6 (5)	0 (0)	0 (0)
Hypokalaemia	34 (31)	24 (22)	7 (6)	3 (3)	0 (0)	0 (0)
Hyponatraemia	34 (31)	23 (21)	1 (1)	10 (9)	0 (0)	0 (0)
Hypophosphataemia	29 (26)	5 (5)	6 (5)	16 (14)	2 (2)	0 (0)
Hyperglycaemia	21 (19)	5 (5)	11 (10)	5 (5)	0 (0)	0 (0)
Hypomagnesaemia	18 (16)	17 (15)	1 (1)	0 (0)	0 (0)	0 (0)
Dehydration	10 (9)	3 (3)	4 (4)	3 (3)	0 (0)	0 (0)
Hyperkalaemia	8 (7)	6 (5)	2 (2)	0 (0)	0 (0)	0 (0)
Hypermagnesaemia	4 (4)	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)
Hypoglycaemia	4 (4)	3 (3)	1 (1)	0 (0)	0 (0)	0 (0)
Malnutrition	4 (4)	0 (0)	4 (4)	0 (0)	0 (0)	0 (0)
Metabolic acidosis	4 (4)	3 (3)	0 (0)	1 (1)	0 (0)	0 (0)
Hypercalcaemia	3 (3)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)
Fluid overload	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Hyperuricaemia	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
Lactic acidosis	2 (2)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
Tumour lysis syndrome	2 (2)	0 (0)	0 (0)	1 (1)	0 (0)	1 (1)
Acidosis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.5. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Hyperalbuminaemia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypernatraemia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypertriglyceridaemia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypervolaemia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Hypouricaemia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Metabolic alkalosis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Musculoskeletal and connective tissue disorders	57 (51)	34 (31)	20 (18)	3 (3)	0 (0)	0 (0)
Muscular weakness	15 (14)	8 (7)	6 (5)	1 (1)	0 (0)	0 (0)
Back pain	14 (13)	9 (8)	5 (5)	0 (0)	0 (0)	0 (0)
Myalgia	13 (12)	10 (9)	2 (2)	1 (1)	0 (0)	0 (0)
Pain in extremity	13 (12)	8 (7)	5 (5)	0 (0)	0 (0)	0 (0)
Arthralgia	11 (10)	7 (6)	4 (4)	0 (0)	0 (0)	0 (0)
Musculoskeletal pain	5 (5)	3 (3)	2 (2)	0 (0)	0 (0)	0 (0)
Neck pain	5 (5)	4 (4)	1 (1)	0 (0)	0 (0)	0 (0)
Bone pain	3 (3)	2 (2)	0 (0)	1 (1)	0 (0)	0 (0)
Flank pain	3 (3)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)
Muscle spasms	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Groin pain	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Limb discomfort	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Musculoskeletal chest pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Neck mass	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Torticollis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10 (9)	0 (0)	3 (3)	1 (1)	2 (2)	4 (4)
B-cell lymphoma	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Tumour pain	3 (3)	0 (0)	2 (2)	1 (1)	0 (0)	0 (0)
Myelodysplastic syndrome	2 (2)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
Basal cell carcinoma	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Carcinoma in situ	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Squamous cell carcinoma	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Nervous system disorders	86 (77)	40 (36)	16 (14)	26 (23)	3 (3)	1 (1)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.5. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Headache	47 (42)	37 (33)	9 (8)	1 (1)	0 (0)	0 (0)
Encephalopathy	35 (32)	10 (9)	3 (3)	21 (19)	1 (1)	0 (0)
Tremor	29 (26)	24 (22)	4 (4)	1 (1)	0 (0)	0 (0)
Dizziness	22 (20)	20 (18)	2 (2)	0 (0)	0 (0)	0 (0)
Aphasia	18 (16)	4 (4)	6 (5)	8 (7)	0 (0)	0 (0)
Somnolence	15 (14)	2 (2)	6 (5)	6 (5)	1 (1)	0 (0)
Memory impairment	8 (7)	7 (6)	1 (1)	0 (0)	0 (0)	0 (0)
Dysgeusia	7 (6)	6 (5)	1 (1)	0 (0)	0 (0)	0 (0)
Dysarthria	5 (5)	2 (2)	1 (1)	2 (2)	0 (0)	0 (0)
Ataxia	4 (4)	1 (1)	2 (2)	1 (1)	0 (0)	0 (0)
Seizure	4 (4)	0 (0)	3 (3)	0 (0)	1 (1)	0 (0)
Disturbance in attention	3 (3)	1 (1)	0 (0)	2 (2)	0 (0)	0 (0)
Lethargy	3 (3)	1 (1)	2 (2)	0 (0)	0 (0)	0 (0)
Speech disorder	3 (3)	1 (1)	0 (0)	2 (2)	0 (0)	0 (0)
Depressed level of consciousness	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Dyscalculia	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Hemiparesis	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Hyperaesthesia	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Myoclonus	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Neuropathy peripheral	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Peripheral sensory neuropathy	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Presyncope	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
Amnesia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Brain injury	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Cerebellar infarction	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cognitive disorder	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Coma hepatic	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Coordination abnormal	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Facial paralysis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Facial paresis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.5. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Head discomfort	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Head titubation	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypersomnia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Hypoaesthesia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Leukoencephalopathy	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Loss of consciousness	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Meningism	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Muscle spasticity	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Paraesthesia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Post herpetic neuralgia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Psychomotor hyperactivity	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Stupor	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Syncope	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Vagus nerve disorder	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Product issues	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Thrombosis in device	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Psychiatric disorders	50 (45)	20 (18)	16 (14)	14 (13)	0 (0)	0 (0)
Confusional state	29 (26)	8 (7)	11 (10)	10 (9)	0 (0)	0 (0)
Anxiety	15 (14)	10 (9)	4 (4)	1 (1)	0 (0)	0 (0)
Insomnia	13 (12)	8 (7)	5 (5)	0 (0)	0 (0)	0 (0)
Agitation	9 (8)	3 (3)	2 (2)	4 (4)	0 (0)	0 (0)
Mental status changes	7 (6)	1 (1)	3 (3)	3 (3)	0 (0)	0 (0)
Hallucination	4 (4)	3 (3)	1 (1)	0 (0)	0 (0)	0 (0)
Depression	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Restlessness	3 (3)	0 (0)	2 (2)	1 (1)	0 (0)	0 (0)
Delirium	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Disorientation	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Abnormal dreams	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Adjustment disorder	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Bradyphrenia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.5. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Delusion	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Mood altered	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Paranoia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Renal and urinary disorders	32 (29)	18 (16)	7 (6)	6 (5)	1 (1)	0 (0)
Acute kidney injury	8 (7)	2 (2)	2 (2)	3 (3)	1 (1)	0 (0)
Urinary incontinence	8 (7)	3 (3)	4 (4)	1 (1)	0 (0)	0 (0)
Dysuria	6 (5)	5 (5)	1 (1)	0 (0)	0 (0)	0 (0)
Haematuria	4 (4)	3 (3)	1 (1)	0 (0)	0 (0)	0 (0)
Urinary retention	4 (4)	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)
Pollakiuria	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Micturition urgency	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Oliguria	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Nocturia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Polyuria	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Renal impairment	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Urinary tract obstruction	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Reproductive system and breast disorders	9 (8)	4 (4)	5 (5)	0 (0)	0 (0)	0 (0)
Oedema genital	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
Vaginal haemorrhage	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Amenorrhoea	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Dyspareunia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Erectile dysfunction	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Pelvic pain	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Scrotal oedema	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Vaginal discharge	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory, thoracic and mediastinal disorders	74 (67)	25 (23)	32 (29)	13 (12)	3 (3)	1 (1)
Hypoxia	30 (27)	1 (1)	20 (18)	8 (7)	1 (1)	0 (0)
Cough	29 (26)	23 (21)	6 (5)	0 (0)	0 (0)	0 (0)
Dyspnoea	20 (18)	13 (12)	5 (5)	2 (2)	0 (0)	0 (0)
Pleural effusion	15 (14)	8 (7)	5 (5)	2 (2)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.5. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Hiccups	7 (6)	4 (4)	3 (3)	0 (0)	0 (0)	0 (0)
Oropharyngeal pain	6 (5)	5 (5)	1 (1)	0 (0)	0 (0)	0 (0)
Pulmonary oedema	6 (5)	0 (0)	4 (4)	2 (2)	0 (0)	0 (0)
Upper-airway cough syndrome	6 (5)	5 (5)	1 (1)	0 (0)	0 (0)	0 (0)
Nasal congestion	5 (5)	4 (4)	1 (1)	0 (0)	0 (0)	0 (0)
Wheezing	4 (4)	3 (3)	1 (1)	0 (0)	0 (0)	0 (0)
Atelectasis	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Productive cough	3 (3)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)
Tachypnoea	3 (3)	2 (2)	1 (1)	0 (0)	0 (0)	0 (0)
Dysphonia	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Rhinitis allergic	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Rhinorrhoea	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Sinus congestion	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Acute respiratory failure	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Aspiration	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Haemoptysis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Obstructive airways disorder	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Orthopnoea	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Pneumonia aspiration	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Pneumothorax	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Pulmonary congestion	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Pulmonary embolism	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pulmonary haemorrhage	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Pulmonary hypertension	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Rales	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Reexpansion pulmonary oedema	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Respiratory distress	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Sinus pain	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Tonsillar hypertrophy	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Skin and subcutaneous tissue disorders	32 (29)	23 (21)	9 (8)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Table 14.3.1.4.0.2.5. Subject Incidence of Treatment Emergent Adverse Events by System Organ Class and Preferred Term and Worst Grade by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA SOC Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Pruritus	7 (6)	4 (4)	3 (3)	0 (0)	0 (0)	0 (0)
Rash	5 (5)	4 (4)	1 (1)	0 (0)	0 (0)	0 (0)
Rash maculo-papular	4 (4)	3 (3)	1 (1)	0 (0)	0 (0)	0 (0)
Alopecia	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Dry skin	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Hyperhidrosis	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Pain of skin	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Pruritus generalised	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Ecchymosis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Erythema	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Livedo reticularis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Night sweats	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Papule	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Rash erythematous	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Skin lesion	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Skin ulcer	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Vascular disorders	71 (64)	17 (15)	34 (31)	18 (16)	2 (2)	0 (0)
Hypotension	61 (55)	20 (18)	27 (24)	13 (12)	1 (1)	0 (0)
Hypertension	17 (15)	3 (3)	6 (5)	8 (7)	0 (0)	0 (0)
Deep vein thrombosis	3 (3)	0 (0)	3 (3)	0 (0)	0 (0)	0 (0)
Orthostatic hypotension	3 (3)	0 (0)	2 (2)	1 (1)	0 (0)	0 (0)
Thrombosis	3 (3)	1 (1)	2 (2)	0 (0)	0 (0)	0 (0)
Capillary leak syndrome	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
Flushing	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Shock	2 (2)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
Diastolic hypotension	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Embolism venous	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Haematoma	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Notes: Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae_socpt Output Generated: 20211203T12:05

Anhang 4-G3.2: SUE nach SOC und PT (Full Analysis Set)

Table 14.3.2.4.0.1. Subject Incidence of Serious Treatment Emergent Adverse Events by Preferred Term and Worst Grade and by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

MedDRA Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects with any Serious TE Adverse Event	42 (52)	3 (4)	4 (5)	23 (28)	7 (9)	5 (6)
Encephalopathy	16 (20)	0 (0)	0 (0)	15 (19)	1 (1)	0 (0)
Pyrexia	7 (9)	4 (5)	3 (4)	0 (0)	0 (0)	0 (0)
Febrile neutropenia	5 (6)	0 (0)	1 (1)	4 (5)	0 (0)	0 (0)
Lung infection	5 (6)	0 (0)	0 (0)	5 (6)	0 (0)	0 (0)
B-cell lymphoma	4 (5)	0 (0)	0 (0)	0 (0)	0 (0)	4 (5)
Pneumonia	4 (5)	0 (0)	0 (0)	4 (5)	0 (0)	0 (0)
Acute kidney injury	3 (4)	0 (0)	0 (0)	2 (2)	1 (1)	0 (0)
Aphasia	3 (4)	0 (0)	0 (0)	3 (4)	0 (0)	0 (0)
Atrial fibrillation	3 (4)	0 (0)	1 (1)	2 (2)	0 (0)	0 (0)
Confusional state	3 (4)	0 (0)	0 (0)	3 (4)	0 (0)	0 (0)
Ejection fraction decreased	3 (4)	0 (0)	1 (1)	2 (2)	0 (0)	0 (0)
Hypoxia	3 (4)	0 (0)	0 (0)	2 (2)	1 (1)	0 (0)
Somnolence	3 (4)	0 (0)	0 (0)	2 (2)	1 (1)	0 (0)
Urinary tract infection	3 (4)	0 (0)	0 (0)	3 (4)	0 (0)	0 (0)
Atrial flutter	2 (2)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)
Bacteraemia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Cardiac arrest	2 (2)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
Escherichia bacteraemia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Hypotension	2 (2)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
Mental status changes	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Neutropenia	2 (2)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
Acute left ventricular failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Acute respiratory failure	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Agitation	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Aspiration	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Bone marrow failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Bone pain	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Carcinoma in situ	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Clostridium difficile colitis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Clostridium difficile infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Cytomegalovirus enteritis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Dehydration	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Delirium	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Depressed level of consciousness	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Herpes zoster	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count; Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled as the denominator; Treatment-Emergent Adverse Events are events onset on or after conditioning chemotherapy start date.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae Output Generated: 20211130T23:13

Table 14.3.2.4.0.1. Subject Incidence of Serious Treatment Emergent Adverse Events by Preferred Term and Worst Grade and by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

MedDRA Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Histiocytosis haematophagic	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Influenza	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Klebsiella infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Lactic acidosis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Lethargy	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Leukoencephalopathy	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Muscular weakness	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Myelodysplastic syndrome	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Oedema peripheral	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Oral herpes	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pancytopenia	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Pleural effusion	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pneumonia staphylococcal	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pulmonary oedema	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Reexpansion pulmonary oedema	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Seizure	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Shock	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Squamous cell carcinoma	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Supraventricular tachycardia	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Thrombocytopenia	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Troponin T increased	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Tumour pain	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count; Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled as the denominator; Treatment-Emergent Adverse Events are events onset on or after conditioning chemotherapy start date.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae Output Generated: 20211130T23:13

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Table 14.3.2.4.0.2. Subject Incidence of Serious Treatment Emergent Adverse Events by Preferred Term and Worst Grade and by Disease Type: TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 21)

MedDRA Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects with any Serious TE Adverse Event	10 (48)	0 (0)	0 (0)	5 (24)	2 (10)	3 (14)
Agitation	2 (10)	0 (0)	0 (0)	2 (10)	0 (0)	0 (0)
Cardiac arrest	2 (10)	0 (0)	0 (0)	0 (0)	2 (10)	0 (0)
Encephalopathy	2 (10)	0 (0)	0 (0)	2 (10)	0 (0)	0 (0)
Acidosis	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Aphasia	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Atrial fibrillation	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Brain injury	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)
Confusional state	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Delirium	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Device related sepsis	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Gastrointestinal haemorrhage	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Headache	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Hypertension	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Hypotension	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Lung infection	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Myelodysplastic syndrome	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Pneumonia	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Pneumonia aspiration	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Pulmonary embolism	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)
Pyrexia	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Respiratory distress	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Sepsis	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Shock	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Tumour lysis syndrome	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)	1 (5)
Urinary tract infection	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TFL, transformed follicular lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count; Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled as the denominator; Treatment-Emergent Adverse Events are events onset on or after conditioning chemotherapy start date.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae Output Generated: 20211130T23:13

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Table 14.3.2.4.0.3. Subject Incidence of Serious Treatment Emergent Adverse Events by Preferred Term and Worst Grade and by Disease Type: PMBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 9)

MedDRA Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects with any Serious TE Adverse Event	4 (44)	0 (0)	1 (11)	3 (33)	0 (0)	0 (0)
Confusional state	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Dysarthria	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Dyspnoea	1 (11)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)
Encephalopathy	1 (11)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)
Hemiparesis	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)	0 (0)
Pneumonia	1 (11)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: PMBCL, primary mediastinal B-cell lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count; Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled as the denominator; Treatment-Emergent Adverse Events are events onset on or after conditioning chemotherapy start date.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae Output Generated: 20211130T23:13

Table 14.3.2.4.0.4. Subject Incidence of Serious Treatment Emergent Adverse Events by Preferred Term and Worst Grade and by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects with any Serious TE Adverse Event	52 (51)	3 (3)	4 (4)	28 (27)	9 (9)	8 (8)
Encephalopathy	18 (18)	0 (0)	0 (0)	17 (17)	1 (1)	0 (0)
Pyrexia	8 (8)	4 (4)	3 (3)	1 (1)	0 (0)	0 (0)
Lung infection	6 (6)	0 (0)	0 (0)	6 (6)	0 (0)	0 (0)
Febrile neutropenia	5 (5)	0 (0)	1 (1)	4 (4)	0 (0)	0 (0)
Pneumonia	5 (5)	0 (0)	0 (0)	5 (5)	0 (0)	0 (0)
Aphasia	4 (4)	0 (0)	0 (0)	4 (4)	0 (0)	0 (0)
Atrial fibrillation	4 (4)	0 (0)	1 (1)	3 (3)	0 (0)	0 (0)
B-cell lymphoma	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Cardiac arrest	4 (4)	0 (0)	0 (0)	0 (0)	4 (4)	0 (0)
Confusional state	4 (4)	0 (0)	0 (0)	4 (4)	0 (0)	0 (0)
Urinary tract infection	4 (4)	0 (0)	0 (0)	4 (4)	0 (0)	0 (0)
Acute kidney injury	3 (3)	0 (0)	0 (0)	2 (2)	1 (1)	0 (0)
Agitation	3 (3)	0 (0)	0 (0)	3 (3)	0 (0)	0 (0)
Ejection fraction decreased	3 (3)	0 (0)	1 (1)	2 (2)	0 (0)	0 (0)
Hypotension	3 (3)	0 (0)	0 (0)	2 (2)	1 (1)	0 (0)
Hypoxia	3 (3)	0 (0)	0 (0)	2 (2)	1 (1)	0 (0)
Somnolence	3 (3)	0 (0)	0 (0)	2 (2)	1 (1)	0 (0)
Atrial flutter	2 (2)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)
Bacteraemia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Delirium	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Escherichia bacteraemia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Mental status changes	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Myelodysplastic syndrome	2 (2)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
Neutropenia	2 (2)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
Shock	2 (2)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
Acidosis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Acute left ventricular failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Acute respiratory failure	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Aspiration	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Bone marrow failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Bone pain	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Brain injury	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Carcinoma in situ	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Clostridium difficile colitis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Clostridium difficile infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count; Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled as the denominator; Treatment-Emergent Adverse Events are events onset on or after conditioning chemotherapy start date.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae Output Generated: 20211130T23:13

Kite Pharma, Inc. Confidential Protocol: KTE-C19-101

Table 14.3.2.4.0.4. Subject Incidence of Serious Treatment Emergent Adverse Events by Preferred Term and Worst Grade and by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Cytomegalovirus enteritis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Dehydration	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Depressed level of consciousness	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Device related sepsis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Gastrointestinal haemorrhage	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Headache	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Herpes zoster	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Histiocytosis haematophagic	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hypertension	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Influenza	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Klebsiella infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Lactic acidosis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Lethargy	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Leukoencephalopathy	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Muscular weakness	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Oedema peripheral	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Oral herpes	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pancytopenia	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Pleural effusion	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pneumonia aspiration	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Pneumonia staphylococcal	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pulmonary embolism	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pulmonary oedema	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Reexpansion pulmonary oedema	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Respiratory distress	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Seizure	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Sepsis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Squamous cell carcinoma	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Supraventricular tachycardia	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Thrombocytopenia	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Troponin T increased	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Tumour lysis syndrome	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Tumour pain	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count; Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled as the denominator; Treatment-Emergent Adverse Events are events onset on or after conditioning chemotherapy start date.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae Output Generated: 20211130T23:13

Table 14.3.2.4.0.5. Subject Incidence of Serious Treatment Emergent Adverse Events by Preferred Term and Worst Grade and by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects with any Serious TE Adverse Event	56 (50)	3 (3)	5 (5)	31 (28)	9 (8)	8 (7)
Encephalopathy	19 (17)	0 (0)	0 (0)	18 (16)	1 (1)	0 (0)
Pyrexia	8 (7)	4 (4)	3 (3)	1 (1)	0 (0)	0 (0)
Lung infection	6 (5)	0 (0)	0 (0)	6 (5)	0 (0)	0 (0)
Pneumonia	6 (5)	0 (0)	0 (0)	6 (5)	0 (0)	0 (0)
Confusional state	5 (5)	1 (1)	0 (0)	4 (4)	0 (0)	0 (0)
Febrile neutropenia	5 (5)	0 (0)	1 (1)	4 (4)	0 (0)	0 (0)
Aphasia	4 (4)	0 (0)	0 (0)	4 (4)	0 (0)	0 (0)
Atrial fibrillation	4 (4)	0 (0)	1 (1)	3 (3)	0 (0)	0 (0)
B-cell lymphoma	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)	4 (4)
Cardiac arrest	4 (4)	0 (0)	0 (0)	0 (0)	4 (4)	0 (0)
Urinary tract infection	4 (4)	0 (0)	0 (0)	4 (4)	0 (0)	0 (0)
Acute kidney injury	3 (3)	0 (0)	0 (0)	2 (2)	1 (1)	0 (0)
Agitation	3 (3)	0 (0)	0 (0)	3 (3)	0 (0)	0 (0)
Ejection fraction decreased	3 (3)	0 (0)	1 (1)	2 (2)	0 (0)	0 (0)
Hypotension	3 (3)	0 (0)	0 (0)	2 (2)	1 (1)	0 (0)
Hypoxia	3 (3)	0 (0)	0 (0)	2 (2)	1 (1)	0 (0)
Somnolence	3 (3)	0 (0)	0 (0)	2 (2)	1 (1)	0 (0)
Atrial flutter	2 (2)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)
Bacteraemia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Delirium	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Escherichia bacteraemia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Mental status changes	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Myelodysplastic syndrome	2 (2)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
Neutropenia	2 (2)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)
Shock	2 (2)	0 (0)	0 (0)	0 (0)	2 (2)	0 (0)
Acidosis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Acute left ventricular failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Acute respiratory failure	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Aspiration	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Bone marrow failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Bone pain	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Brain injury	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Carcinoma in situ	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Clostridium difficile colitis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Clostridium difficile infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count; Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled as the denominator; Treatment-Emergent Adverse Events are events onset on or after conditioning chemotherapy start date.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae Output Generated: 20211130T23:13

Table 14.3.2.4.0.5. Subject Incidence of Serious Treatment Emergent Adverse Events by Preferred Term and Worst Grade and by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Cytomegalovirus enteritis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Dehydration	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Depressed level of consciousness	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Device related sepsis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Dysarthria	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Dyspnoea	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Gastrointestinal haemorrhage	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Headache	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Hemiparesis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Herpes zoster	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Histiocytosis haematophagic	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hypertension	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Influenza	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Klebsiella infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Lactic acidosis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Lethargy	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Leukoencephalopathy	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Muscular weakness	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Oedema peripheral	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Oral herpes	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pancytopenia	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Pleural effusion	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pneumonia aspiration	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Pneumonia staphylococcal	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pulmonary embolism	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Pulmonary oedema	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Reexpansion pulmonary oedema	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Respiratory distress	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Seizure	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Sepsis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Squamous cell carcinoma	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Supraventricular tachycardia	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Thrombocytopenia	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Troponin T increased	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Tumour lysis syndrome	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count; Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled as the denominator; Treatment-Emergent Adverse Events are events onset on or after conditioning chemotherapy start date.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae Output Generated: 20211130T23:13

Table 14.3.2.4.0.5. Subject Incidence of Serious Treatment Emergent Adverse Events by Preferred Term and Worst Grade and by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA Preferred Term n(%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Tumour pain	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count; Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled as the denominator; Treatment-Emergent Adverse Events are events onset on or after conditioning chemotherapy start date.

Data Source: ADSL, ADBASE, ADAE Program Name: t_teae Output Generated: 20211130T23:13

Anhang 4-G3.3: UE von speziellem Interesse (Full Analysis Set)

Table 14.3.12.4.0.1.1. Subject Incidence of Treatment Emergent Cytokine Release Syndrome (CRS) by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

MedDRA Preferred Term n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
CRS – Any[a]	73 (90)	27 (33)	36 (44)	7 (9)	2 (2)	1 (1)
CRS by Preferred Term[b]						
Pyrexia	58 (79)	12 (16)	38 (52)	8 (11)	0 (0)	0 (0)
Hypotension	35 (48)	8 (11)	18 (25)	9 (12)	0 (0)	0 (0)
Hypoxia	18 (25)	1 (1)	9 (12)	7 (10)	1 (1)	0 (0)
Tachycardia	17 (23)	16 (22)	0 (0)	1 (1)	0 (0)	0 (0)
Chills	16 (22)	12 (16)	4 (5)	0 (0)	0 (0)	0 (0)
Sinus tachycardia	7 (10)	5 (7)	2 (3)	0 (0)	0 (0)	0 (0)
Headache	4 (5)	3 (4)	1 (1)	0 (0)	0 (0)	0 (0)
Myalgia	4 (5)	4 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Acute kidney injury	3 (4)	0 (0)	1 (1)	1 (1)	1 (1)	0 (0)
Atrial fibrillation	3 (4)	0 (0)	1 (1)	2 (3)	0 (0)	0 (0)
Diarrhoea	3 (4)	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)
Ejection fraction decreased	3 (4)	0 (0)	2 (3)	1 (1)	0 (0)	0 (0)
Fatigue	3 (4)	3 (4)	0 (0)	0 (0)	0 (0)	0 (0)
Pulmonary oedema	3 (4)	0 (0)	3 (4)	0 (0)	0 (0)	0 (0)
Vomiting	3 (4)	3 (4)	0 (0)	0 (0)	0 (0)	0 (0)
Atrial flutter	2 (3)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)
Capillary leak syndrome	2 (3)	0 (0)	2 (3)	0 (0)	0 (0)	0 (0)
Decreased appetite	2 (3)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Dyspnoea	2 (3)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Febrile neutropenia	2 (3)	0 (0)	0 (0)	2 (3)	0 (0)	0 (0)
Malaise	2 (3)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Acute left ventricular failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Alanine aminotransferase increased	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Anal incontinence	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Blood creatinine increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Cough	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Histiocytosis haematophagic	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Localised oedema	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Metabolic acidosis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Nasal congestion	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Nausea	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Oedema genital	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Oedema peripheral	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Oliguria	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Periorbital oedema	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory rate increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; CRS, cytokine release syndrome.
Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03.
a. Overall CRS is graded per the revised grading system proposed by Lee et al 2014. Percentages are calculated using the total number of subjects enrolled and with a disease subtype of DLBCL as denominator.
b. Individual CRS symptoms are graded per CTCAE 4.03. Percentages are calculated using the number of subjects with any CRS of any grade.

Data Source: ADSL, ADBASE, ADAE Program Name: t_kcrs Output Generated: 20211206T13:56

Table 14.3.12.4.0.1.1. Subject Incidence of Treatment Emergent Cytokine Release Syndrome (CRS) by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

MedDRA Preferred Term n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Syncope	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Tachypnoea	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Transaminases increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Troponin T increased	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; CRS, cytokine release syndrome.
Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03.
a. Overall CRS is graded per the revised grading system proposed by Lee et al 2014. Percentages are calculated using the total number of subjects enrolled and with a disease subtype of DLBCL as denominator.
b. Individual CRS symptoms are graded per CTCAE 4.03. Percentages are calculated using the number of subjects with any CRS of any grade.

Data Source: ADSL, ADBASE, ADAE Program Name: t_kcrs Output Generated: 20211206T13:56

Table 14.3.12.4.0.1.2. Subject Incidence of Treatment Emergent Cytokine Release Syndrome (CRS) by Disease Type: TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 21)

MedDRA Preferred Term n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
CRS – Any[a]	13 (62)	6 (29)	6 (29)	0 (0)	1 (5)	0 (0)
CRS by Preferred Term[b]						
Pyrexia	12 (92)	0 (0)	10 (77)	2 (15)	0 (0)	0 (0)
Tachycardia	4 (31)	3 (23)	1 (8)	0 (0)	0 (0)	0 (0)
Hypotension	3 (23)	2 (15)	1 (8)	0 (0)	0 (0)	0 (0)
Hypoxia	3 (23)	0 (0)	3 (23)	0 (0)	0 (0)	0 (0)
Chills	2 (15)	2 (15)	0 (0)	0 (0)	0 (0)	0 (0)
Acidosis	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)
Blood creatinine increased	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)
Cardiac arrest	1 (8)	0 (0)	0 (0)	0 (0)	1 (8)	0 (0)
Dyspnoea	1 (8)	0 (0)	1 (8)	0 (0)	0 (0)	0 (0)
Fatigue	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)
Hyperhidrosis	1 (8)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TFL, transformed follicular lymphoma; CRS, cytokine release syndrome.
Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03.
a. Overall CRS is graded per the revised grading system proposed by Lee et al 2014. Percentages are calculated using the total number of subjects enrolled and with a disease subtype of TFL as denominator.
b. Individual CRS symptoms are graded per CTCAE 4.03. Percentages are calculated using the number of subjects with any CRS of any grade.

Data Source: ADSL, ADBASE, ADAE Program Name: t_kcrs Output Generated: 20211206T13:56

Kite Pharma, Inc. Confidential Protocol: KTE-C19-101

Table 14.3.12.4.0.1.3. Subject Incidence of Treatment Emergent Cytokine Release Syndrome (CRS) by Disease Type: PMBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 9)

MedDRA Preferred Term n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
CRS – Any[a]	8 (89)	4 (44)	4 (44)	0 (0)	0 (0)	0 (0)
CRS by Preferred Term[b]						
Pyrexia	8 (100)	2 (25)	5 (63)	1 (13)	0 (0)	0 (0)
Hypotension	3 (38)	0 (0)	3 (38)	0 (0)	0 (0)	0 (0)
Chills	2 (25)	2 (25)	0 (0)	0 (0)	0 (0)	0 (0)
Asthenia	1 (13)	1 (13)	0 (0)	0 (0)	0 (0)	0 (0)
Extrasystoles	1 (13)	1 (13)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	1 (13)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
Hypoxia	1 (13)	0 (0)	1 (13)	0 (0)	0 (0)	0 (0)
Sinus tachycardia	1 (13)	1 (13)	0 (0)	0 (0)	0 (0)	0 (0)
Tachycardia	1 (13)	1 (13)	0 (0)	0 (0)	0 (0)	0 (0)
Vomiting	1 (13)	1 (13)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: PMBCL, primary mediastinal B-cell lymphoma; CRS, cytokine release syndrome.
Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03.
a. Overall CRS is graded per the revised grading system proposed by Lee et al 2014. Percentages are calculated using the total number of subjects enrolled and with a disease subtype of PMBCL as denominator.
b. Individual CRS symptoms are graded per CTCAE 4.03. Percentages are calculated using the number of subjects with any CRS of any grade.

Data Source: ADSL, ADBASE, ADAE Program Name: t_kcrs Output Generated: 20211206T13:56

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Table 14.3.12.4.0.1.4. Subject Incidence of Treatment Emergent Cytokine Release Syndrome (CRS) by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA Preferred Term n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
CRS – Any[a]	86 (84)	33 (32)	42 (41)	7 (7)	3 (3)	1 (1)
CRS by Preferred Term[b]						
Pyrexia	70 (81)	12 (14)	48 (56)	10 (12)	0 (0)	0 (0)
Hypotension	38 (44)	10 (12)	19 (22)	9 (10)	0 (0)	0 (0)
Hypoxia	21 (24)	1 (1)	12 (14)	7 (8)	1 (1)	0 (0)
Tachycardia	21 (24)	19 (22)	1 (1)	1 (1)	0 (0)	0 (0)
Chills	18 (21)	14 (16)	4 (5)	0 (0)	0 (0)	0 (0)
Sinus tachycardia	7 (8)	5 (6)	2 (2)	0 (0)	0 (0)	0 (0)
Fatigue	4 (5)	4 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Headache	4 (5)	3 (3)	1 (1)	0 (0)	0 (0)	0 (0)
Myalgia	4 (5)	4 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Acute kidney injury	3 (3)	0 (0)	1 (1)	1 (1)	1 (1)	0 (0)
Atrial fibrillation	3 (3)	0 (0)	1 (1)	2 (2)	0 (0)	0 (0)
Diarrhoea	3 (3)	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)
Dyspnoea	3 (3)	1 (1)	2 (2)	0 (0)	0 (0)	0 (0)
Ejection fraction decreased	3 (3)	0 (0)	2 (2)	1 (1)	0 (0)	0 (0)
Pulmonary oedema	3 (3)	0 (0)	3 (3)	0 (0)	0 (0)	0 (0)
Vomiting	3 (3)	3 (3)	0 (0)	0 (0)	0 (0)	0 (0)
Atrial flutter	2 (2)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)
Blood creatinine increased	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Capillary leak syndrome	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
Decreased appetite	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Febrile neutropenia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Malaise	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Acidosis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Acute left ventricular failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Alanine aminotransferase increased	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Anal incontinence	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Cardiac arrest	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Cough	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Histiocytosis haematophagic	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hyperhidrosis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Localised oedema	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Metabolic acidosis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Nasal congestion	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Nausea	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Oedema genital	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Oedema peripheral	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; CRS, cytokine release syndrome.
Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03.
a. Overall CRS is graded per the revised grading system proposed by Lee et al 2014. Percentages are calculated using the total number of subjects enrolled and with a disease subtype of DLBCL and TFL as denominator.
b. Individual CRS symptoms are graded per CTCAE 4.03. Percentages are calculated using the number of subjects with any CRS of any grade.

Data Source: ADSL, ADBASE, ADAE Program Name: t_kcrs Output Generated: 20211206T13:56

Table 14.3.12.4.0.1.4. Subject Incidence of Treatment Emergent Cytokine Release Syndrome (CRS) by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

MedDRA Preferred Term n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Oliguria	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Periorbital oedema	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory rate increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Syncope	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Tachypnoea	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Transaminases increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Troponin T increased	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; CRS, cytokine release syndrome.
Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03.
a. Overall CRS is graded per the revised grading system proposed by Lee et al 2014. Percentages are calculated using the total number of subjects enrolled and with a disease subtype of DLBCL and TFL as denominator.
b. Individual CRS symptoms are graded per CTCAE 4.03. Percentages are calculated using the number of subjects with any CRS of any grade.

Data Source: ADSL, ADBASE, ADAE Program Name: t_kcrs Output Generated: 20211206T13:56

Kite Pharma, Inc. Confidential Protocol: KTE-C19-101

Table 14.3.12.4.0.1.5. Subject Incidence of Treatment Emergent Cytokine Release Syndrome (CRS) by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA Preferred Term n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
CRS – Any[a]	94 (85)	37 (33)	46 (41)	7 (6)	3 (3)	1 (1)
CRS by Preferred Term[b]						
Pyrexia	78 (83)	14 (15)	53 (56)	11 (12)	0 (0)	0 (0)
Hypotension	41 (44)	10 (11)	22 (23)	9 (10)	0 (0)	0 (0)
Hypoxia	22 (23)	1 (1)	13 (14)	7 (7)	1 (1)	0 (0)
Tachycardia	22 (23)	20 (21)	1 (1)	1 (1)	0 (0)	0 (0)
Chills	20 (21)	16 (17)	4 (4)	0 (0)	0 (0)	0 (0)
Sinus tachycardia	8 (9)	6 (6)	2 (2)	0 (0)	0 (0)	0 (0)
Headache	5 (5)	3 (3)	2 (2)	0 (0)	0 (0)	0 (0)
Fatigue	4 (4)	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)
Myalgia	4 (4)	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)
Vomiting	4 (4)	4 (4)	0 (0)	0 (0)	0 (0)	0 (0)
Acute kidney injury	3 (3)	0 (0)	1 (1)	1 (1)	1 (1)	0 (0)
Atrial fibrillation	3 (3)	0 (0)	1 (1)	2 (2)	0 (0)	0 (0)
Diarrhoea	3 (3)	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)
Dyspnoea	3 (3)	1 (1)	2 (2)	0 (0)	0 (0)	0 (0)
Ejection fraction decreased	3 (3)	0 (0)	2 (2)	1 (1)	0 (0)	0 (0)
Pulmonary oedema	3 (3)	0 (0)	3 (3)	0 (0)	0 (0)	0 (0)
Atrial flutter	2 (2)	0 (0)	1 (1)	0 (0)	1 (1)	0 (0)
Blood creatinine increased	2 (2)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)
Capillary leak syndrome	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
Decreased appetite	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Febrile neutropenia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Malaise	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Acidosis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Acute left ventricular failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Alanine aminotransferase increased	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Anal incontinence	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Asthenia	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Cardiac arrest	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Cough	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Extrasystoles	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Histiocytosis haematophagic	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)
Hyperhidrosis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Localised oedema	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Metabolic acidosis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Nasal congestion	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Nausea	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: CRS, cytokine release syndrome.
Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03.
a. Overall CRS is graded per the revised grading system proposed by Lee et al 2014. Percentages are calculated using the number of subjects enrolled as denominator.
b. Individual CRS symptoms are graded per CTCAE 4.03. Percentages are calculated using the number of subjects with any CRS of any grade.

Data Source: ADSL, ADBASE, ADAE Program Name: t_kcrs Output Generated: 20211206T13:56

Table 14.3.12.4.0.1.5. Subject Incidence of Treatment Emergent Cytokine Release Syndrome (CRS) by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

MedDRA Preferred Term n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Oedema genital	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Oedema peripheral	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Oliguria	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Periorbital oedema	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Respiratory rate increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Syncope	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Tachypnoea	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Transaminases increased	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Troponin T increased	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: CRS, cytokine release syndrome.
Adverse events are coded using MedDRA Version 21.0 and graded per CTCAE 4.03.
a. Overall CRS is graded per the revised grading system proposed by Lee et al 2014. Percentages are calculated using the number of subjects enrolled as denominator.
b. Individual CRS symptoms are graded per CTCAE 4.03. Percentages are calculated using the number of subjects with any CRS of any grade.

Data Source: ADSL, ADBASE, ADAE Program Name: t_kcrs Output Generated: 20211206T13:56

Kite Pharma, Inc. Confidential Protocol: KTE-C19-101

Table 14.31.1.1. Subject Incidence of Treatment Emergent Prolonged Thrombocytopenia, Neutropenia, and Anaemia by Disease Type (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

	DLBCL (N = 81)		TFL (N = 21)		PMBCL (N = 9)		DLBCL+TFL (N = 102)		Cohort 1 and Cohort 2 Overall (N = 111)	
Preferred Term n (%)	Any	≥ Worst Gr 3	Any	≥ Worst Gr 3	Any	≥ Worst Gr 3	Any	≥ Worst Gr 3	Any	≥ Worst Gr 3
Subjects with Any Events	44 (54)	31 (38)	7 (33)	6 (29)	2 (22)	1 (11)	51 (50)	37 (36)	53 (48)	38 (34)
Subjects with Prolonged Thrombocytopenia	33 (41)	20 (25)	4 (19)	3 (14)	2 (22)	0 (0)	37 (36)	23 (23)	39 (35)	23 (21)
Platelet count decreased	17 (21)	8 (10)	1 (5)	1 (5)	2 (22)	0 (0)	18 (18)	9 (9)	20 (18)	9 (8)
Thrombocytopenia	17 (21)	12 (15)	3 (14)	2 (10)	0 (0)	0 (0)	20 (20)	14 (14)	20 (18)	14 (13)
Subjects with Prolonged Neutropenia	28 (35)	21 (26)	6 (29)	4 (19)	1 (11)	0 (0)	34 (33)	25 (25)	35 (32)	25 (23)
Neutropenia	14 (17)	11 (14)	4 (19)	3 (14)	0 (0)	0 (0)	18 (18)	14 (14)	18 (16)	14 (13)
Neutrophil count decreased	14 (17)	9 (11)	2 (10)	1 (5)	1 (11)	0 (0)	16 (16)	10 (10)	17 (15)	10 (9)
Febrile neutropenia	3 (4)	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)	2 (2)	3 (3)	2 (2)
Subjects with Prolonged Anaemia	25 (31)	9 (11)	2 (10)	0 (0)	1 (11)	1 (11)	27 (26)	9 (9)	28 (25)	10 (9)
Anaemia	25 (31)	9 (11)	2 (10)	0 (0)	1 (11)	1 (11)	27 (26)	9 (9)	28 (25)	10 (9)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; PMBCL, primary mediastinal B-cell lymphoma; TFL, transformed follicular lymphoma.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Prolonged Thrombocytopenia/Neutropenia/Anaemia are defined as Thrombocytopenia/Neutropenia/Anaemia present on or after Day 30; Thrombocytopenia is identified using the SMQ for haematopoietic thrombocytopenia (narrow search); Neutropenia is identified using MedDRA search terms (MST); Anemia (including aplastic anemia) is identified using the SMQ haematopoietic erythropenia (broad search).

Data Source: ADSL, ADBASE, ADAE Program Name: t_plngae30 Output Generated: 20211203T06:16

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Table 14.7.5.3.1.5. Subject Incidence of Treatment Emergent Cerebral Edema by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

No Data to Report

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled as denominator.

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:33

Table 14.7.6.3.1.1. Subject Incidence of Treatment Emergent Cardiac Failure by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Cardiac Failure	9 (11)	0 (0)	4 (5)	5 (6)	0 (0)	0 (0)
Pulmonary oedema	6 (7)	0 (0)	4 (5)	2 (2)	0 (0)	0 (0)
Ejection fraction decreased	4 (5)	0 (0)	2 (2)	2 (2)	0 (0)	0 (0)
Acute left ventricular failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of DLBCL as denominator.

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:33

Table 14.7.6.3.1.2. Subject Incidence of Treatment Emergent Cardiac Failure by Disease Type: TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 21)

No Data to Report

Data cutoff date = 11AUG2018
Abbreviations: TFL, transformed follicular lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of TFL as denominator.

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:33

Kite Pharma, Inc. Confidential Protocol: KTE-C19-101

Table 14.7.6.3.1.3. Subject Incidence of Treatment Emergent Cardiac Failure by Disease Type: PMBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 9)

No Data to Report

Data cutoff date = 11AUG2018
Abbreviations: PMBCL, primary mediastinal B-cell lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of PMBCL as denominator.

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:33

Table 14.7.6.3.1.4. Subject Incidence of Treatment Emergent Cardiac Failure by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Cardiac Failure	9 (9)	0 (0)	4 (4)	5 (5)	0 (0)	0 (0)
Pulmonary oedema	6 (6)	0 (0)	4 (4)	2 (2)	0 (0)	0 (0)
Ejection fraction decreased	4 (4)	0 (0)	2 (2)	2 (2)	0 (0)	0 (0)
Acute left ventricular failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of DLBCL and TFL as denominator.

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:33

Table 14.7.6.3.1.5. Subject Incidence of Treatment Emergent Cardiac Failure by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Cardiac Failure	9 (8)	0 (0)	4 (4)	5 (5)	0 (0)	0 (0)
Pulmonary oedema	6 (5)	0 (0)	4 (4)	2 (2)	0 (0)	0 (0)
Ejection fraction decreased	4 (4)	0 (0)	2 (2)	2 (2)	0 (0)	0 (0)
Acute left ventricular failure	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled as denominator.

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:33

Kite Pharma, Inc. Confidential Protocol: KTE-C19-101

Table 14.71.1. Subject Incidence of Treatment Emergent Bacterial Infections by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Bacterial Infection	14 (17)	1 (1)	5 (6)	8 (10)	0 (0)	0 (0)
Clostridium difficile infection	5 (6)	0 (0)	3 (4)	2 (2)	0 (0)	0 (0)
Clostridium difficile colitis	3 (4)	1 (1)	0 (0)	2 (2)	0 (0)	0 (0)
Escherichia bacteraemia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Cellulitis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Klebsiella infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pneumonia klebsiella	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pneumonia staphylococcal	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Salmonellosis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Urinary tract infection bacterial	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of DLBCL as denominator; Search strategy of bacterial infection: using bacterial infectious disorders (HLGT) and Chlamydial infectious disorders (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:33

Table 14.71.2. Subject Incidence of Treatment Emergent Bacterial Infections by Disease Type: TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 21)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Bacterial Infection	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Clostridium difficile colitis	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TFL, transformed follicular lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of TFL as denominator; Search strategy of bacterial infection: using bacterial infectious disorders (HLGT) and Chlamydial infectious disorders (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:33

Kite Pharma, Inc. Confidential Protocol: KTE-C19-101

Table 14.71.3. Subject Incidence of Treatment Emergent Bacterial Infections by Disease Type: PMBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 9)

No Data to Report

Data cutoff date = 11AUG2018
Abbreviations: PMBCL, primary mediastinal B-cell lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of PMBCL as denominator; Search strategy of bacterial infection: using bacterial infectious disorders (HLGT) and Chlamydial infectious disorders (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:34

Table 14.71.4. Subject Incidence of Treatment Emergent Bacterial Infections by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Bacterial Infection	15 (15)	1 (1)	5 (5)	9 (9)	0 (0)	0 (0)
Clostridium difficile infection	5 (5)	0 (0)	3 (3)	2 (2)	0 (0)	0 (0)
Clostridium difficile colitis	4 (4)	1 (1)	0 (0)	3 (3)	0 (0)	0 (0)
Escherichia bacteraemia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Cellulitis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Klebsiella infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pneumonia klebsiella	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pneumonia staphylococcal	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Salmonellosis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Urinary tract infection bacterial	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of DLBCL and TFL as denominator; Search strategy of bacterial infection: using bacterial infectious disorders (HLGT) and Chlamydial infectious disorders (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:34

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Table 14.71.5. Subject Incidence of Treatment Emergent Bacterial Infections by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Bacterial Infection	15 (14)	1 (1)	5 (5)	9 (8)	0 (0)	0 (0)
Clostridium difficile infection	5 (5)	0 (0)	3 (3)	2 (2)	0 (0)	0 (0)
Clostridium difficile colitis	4 (4)	1 (1)	0 (0)	3 (3)	0 (0)	0 (0)
Escherichia bacteraemia	2 (2)	0 (0)	0 (0)	2 (2)	0 (0)	0 (0)
Cellulitis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Klebsiella infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pneumonia klebsiella	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Pneumonia staphylococcal	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Salmonellosis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Urinary tract infection bacterial	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled as denominator; Search strategy of bacterial infection: using bacterial infectious disorders (HLGT) and Chlamydial infectious disorders (HLGT).

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Table 14.77.1. Subject Incidence of Treatment Emergent Viral Infection by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Viral Infection	15 (19)	4 (5)	6 (7)	5 (6)	0 (0)	0 (0)
Herpes zoster	3 (4)	0 (0)	2 (2)	1 (1)	0 (0)	0 (0)
Influenza	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
Oral herpes	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Cytomegalovirus enteritis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Cytomegalovirus infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cytomegalovirus viraemia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Hepatitis B reactivation	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Herpes simplex	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Herpes zoster oticus	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Human herpesvirus 6 infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Parainfluenzae virus infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Parvovirus infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Respiratory tract infection viral	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Rhinovirus infection	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of DLBCL as denominator; Search strategy of viral infection: using viral infectious disorders (HLGT).

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Table 14.77.2. Subject Incidence of Treatment Emergent Viral Infection by Disease Type: TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 21)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Viral Infection	2 (10)	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)
Herpes zoster	2 (10)	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TFL, transformed follicular lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of TFL as denominator; Search strategy of viral infection: using viral infectious disorders (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:34

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Table 14.77.3. Subject Incidence of Treatment Emergent Viral Infection by Disease Type: PMBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 9)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Viral Infection	2 (22)	0 (0)	2 (22)	0 (0)	0 (0)	0 (0)
Herpes simplex	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Herpes zoster	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: PMBCL, primary mediastinal B-cell lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of PMBCL as denominator; Search strategy of viral infection: using viral infectious disorders (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:34

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Table 14.77.4. Subject Incidence of Treatment Emergent Viral Infection by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Viral Infection	17 (17)	5 (5)	7 (7)	5 (5)	0 (0)	0 (0)
Herpes zoster	5 (5)	1 (1)	3 (3)	1 (1)	0 (0)	0 (0)
Influenza	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
Oral herpes	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Cytomegalovirus enteritis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Cytomegalovirus infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cytomegalovirus viraemia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Hepatitis B reactivation	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Herpes simplex	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Herpes zoster oticus	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Human herpesvirus 6 infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Parainfluenzae virus infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Parvovirus infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Respiratory tract infection viral	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Rhinovirus infection	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of DLBCL and TFL as denominator; Search strategy of viral infection: using viral infectious disorders (HLGT).

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Table 14.77.5. Subject Incidence of Treatment Emergent Viral Infection by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Viral Infection	19 (17)	5 (5)	9 (8)	5 (5)	0 (0)	0 (0)
Herpes zoster	6 (5)	1 (1)	4 (4)	1 (1)	0 (0)	0 (0)
Herpes simplex	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Influenza	2 (2)	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)
Oral herpes	2 (2)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)
Cytomegalovirus enteritis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Cytomegalovirus infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Cytomegalovirus viraemia	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Hepatitis B reactivation	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Herpes zoster oticus	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Human herpesvirus 6 infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Parainfluenzae virus infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Parvovirus infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Respiratory tract infection viral	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Rhinovirus infection	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled as denominator; Search strategy of viral infection: using viral infectious disorders (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:34

Table 14.83.1. Subject Incidence of Treatment Emergent Opportunistic Infection by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Opportunistic Infection	3 (4)	0 (0)	3 (4)	0 (0)	0 (0)	0 (0)
Bronchopulmonary aspergillosis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Candida infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Oral candidiasis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of DLBCL as denominator; Search strategy of opportunistic infection: using Fungal infectious disorders (HLGT) and Mycobacterial infectious disorders (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:34

Table 14.83.2. Subject Incidence of Treatment Emergent Opportunistic Infection by Disease Type: TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 21)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Opportunistic Infection	2 (10)	0 (0)	2 (10)	0 (0)	0 (0)	0 (0)
Candida infection	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Fungal skin infection	1 (5)	1 (5)	0 (0)	0 (0)	0 (0)	0 (0)
Tongue fungal infection	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TFL, transformed follicular lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of TFL as denominator; Search strategy of opportunistic infection: using Fungal infectious disorders (HLGT) and Mycobacterial infectious disorders (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:34

Table 14.83.3. Subject Incidence of Treatment Emergent Opportunistic Infection by Disease Type: PMBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 9)

No Data to Report

Data cutoff date = 11AUG2018
Abbreviations: PMBCL, primary mediastinal B-cell lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of PMBCL as denominator; Search strategy of opportunistic infection: using Fungal infectious disorders (HLGT) and Mycobacterial infectious disorders (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:34

Table 14.83.4. Subject Incidence of Treatment Emergent Opportunistic Infection by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Opportunistic Infection	5 (5)	0 (0)	5 (5)	0 (0)	0 (0)	0 (0)
Candida infection	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
Bronchopulmonary aspergillosis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Fungal skin infection	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Oral candidiasis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Tongue fungal infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of DLBCL and TFL as denominator; Search strategy of opportunistic infection: using Fungal infectious disorders (HLGT) and Mycobacterial infectious disorders (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:34

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Table 14.83.5. Subject Incidence of Treatment Emergent Opportunistic Infection by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Opportunistic Infection	5 (5)	0 (0)	5 (5)	0 (0)	0 (0)	0 (0)
Candida infection	2 (2)	0 (0)	2 (2)	0 (0)	0 (0)	0 (0)
Bronchopulmonary aspergillosis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Fungal skin infection	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Oral candidiasis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Tongue fungal infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled as denominator; Search strategy of opportunistic infection: using Fungal infectious disorders (HLGT) and Mycobacterial infectious disorders (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:34

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Table 14.89.1. Subject Incidence of Treatment Emergent Other Infection by Disease Type: DLBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 81)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Other Infection	19 (23)	0 (0)	6 (7)	13 (16)	0 (0)	0 (0)
Pneumonia	6 (7)	0 (0)	2 (2)	4 (5)	0 (0)	0 (0)
Lung infection	5 (6)	0 (0)	1 (1)	4 (5)	0 (0)	0 (0)
Upper respiratory tract infection	5 (6)	0 (0)	5 (6)	0 (0)	0 (0)	0 (0)
Urinary tract infection	5 (6)	1 (1)	1 (1)	3 (4)	0 (0)	0 (0)
Sinusitis	3 (4)	1 (1)	2 (2)	0 (0)	0 (0)	0 (0)
Rhinitis	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Bacteraemia	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Bronchitis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Device related infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Infusion site infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Localised infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Osteomyelitis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of DLBCL as denominator; Search strategy of other infection: using Infections-pathogen unspecified (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:34

Table 14.89.2. Subject Incidence of Treatment Emergent Other Infection by Disease Type: TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 21)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Other Infection	5 (24)	0 (0)	1 (5)	2 (10)	2 (10)	0 (0)
Urinary tract infection	2 (10)	0 (0)	1 (5)	1 (5)	0 (0)	0 (0)
Device related sepsis	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Lung infection	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Nasopharyngitis	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)
Pneumonia	1 (5)	0 (0)	0 (0)	1 (5)	0 (0)	0 (0)
Sepsis	1 (5)	0 (0)	0 (0)	0 (0)	1 (5)	0 (0)
Upper respiratory tract infection	1 (5)	0 (0)	1 (5)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TFL, transformed follicular lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolledand with a disease subtype of TFL as denominator; Search strategy of other infection: using Infections-pathogen unspecified (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:34

Table 14.89.3. Subject Incidence of Treatment Emergent Other Infection by Disease Type: PMBCL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 9)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Other Infection	3 (33)	0 (0)	2 (22)	1 (11)	0 (0)	0 (0)
Sinusitis	2 (22)	1 (11)	1 (11)	0 (0)	0 (0)	0 (0)
Conjunctivitis	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)
Pneumonia	1 (11)	0 (0)	0 (0)	1 (11)	0 (0)	0 (0)
Upper respiratory tract infection	1 (11)	0 (0)	1 (11)	0 (0)	0 (0)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: PMBCL, primary mediastinal B-cell lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of PMBCL as denominator; Search strategy of other infection: using Infections-pathogen unspecified (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:34

Table 14.89.4. Subject Incidence of Treatment Emergent Other Infection by Disease Type: DLBCL+TFL (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 102)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Other Infection	24 (24)	0 (0)	7 (7)	15 (15)	2 (2)	0 (0)
Pneumonia	7 (7)	0 (0)	2 (2)	5 (5)	0 (0)	0 (0)
Urinary tract infection	7 (7)	1 (1)	2 (2)	4 (4)	0 (0)	0 (0)
Lung infection	6 (6)	0 (0)	1 (1)	5 (5)	0 (0)	0 (0)
Upper respiratory tract infection	6 (6)	0 (0)	6 (6)	0 (0)	0 (0)	0 (0)
Sinusitis	3 (3)	1 (1)	2 (2)	0 (0)	0 (0)	0 (0)
Rhinitis	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Bacteraemia	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Bronchitis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Device related infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Device related sepsis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Infusion site infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Localised infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Nasopharyngitis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Osteomyelitis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Sepsis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: DLBCL, diffuse large B-cell lymphoma; TFL, transformed follicular lymphoma; TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled and with a disease subtype of DLBCL and TFL as denominator; Search strategy of other infection: using Infections-pathogen unspecified (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:34

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Table 14.89.5. Subject Incidence of Treatment Emergent Other Infection by Disease Type: Overall (Phase 2 Cohort 1 and Cohort 2) (Full Analysis Set, N = 111)

Event n (%)	Any	Worst Grade 1	Worst Grade 2	Worst Grade 3	Worst Grade 4	Worst Grade 5
Subjects who had TE Other Infection	27 (24)	0 (0)	9 (8)	16 (14)	2 (2)	0 (0)
Pneumonia	8 (7)	0 (0)	2 (2)	6 (5)	0 (0)	0 (0)
Upper respiratory tract infection	7 (6)	0 (0)	7 (6)	0 (0)	0 (0)	0 (0)
Urinary tract infection	7 (6)	1 (1)	2 (2)	4 (4)	0 (0)	0 (0)
Lung infection	6 (5)	0 (0)	1 (1)	5 (5)	0 (0)	0 (0)
Sinusitis	5 (5)	2 (2)	3 (3)	0 (0)	0 (0)	0 (0)
Rhinitis	2 (2)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)
Bacteraemia	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Bronchitis	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Conjunctivitis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Device related infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Device related sepsis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)
Infusion site infection	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Localised infection	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Nasopharyngitis	1 (1)	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)
Osteomyelitis	1 (1)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)
Sepsis	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)

Data cutoff date = 11AUG2018
Abbreviations: TE, treatment emergent.
Note: Preferred terms are sorted in descending order of total frequency count in the Overall Any grade column; Adverse events are coded using MedDRA version 21.0 and graded per CTCAE 4.03; Percentages are calculated using the total number of subjects enrolled as denominator; Search strategy of other infection: using Infections-pathogen unspecified (HLGT).

Data Source: ADSL, ADBASE, ADAE Program Name: t_prisk Output Generated: 20211203T11:34

Anhang 4-G3.4: UE von Patienten mit Leukapherese aber ohne Infusion mit Axi-Cel

Table 3. Summary of Treatment Emergent Adverse Events (Phase 2 Cohort 1 and Cohort 2) (Patients with Leukapheresis but not Treated with Axicabtagene Ciloleucel, N = 10)

	Patients with Leukapheresis but not Treated with Axicabtagene Ciloleucel (N = 10)
Any TEAE	2 (20)
Worst Grade 1	0 (0)
Worst Grade 2	0 (0)
Worst Grade 3	0 (0)
Worst Grade 4	1 (10)
Worst Grade 5	1 (10)
due to disease progression	0 (0)
Worst Grade ≥ 3	2 (20)
Any Serious TEAE	1 (10)
Worst Grade 1	0 (0)
Worst Grade 2	0 (0)
Worst Grade 3	0 (0)
Worst Grade 4	0 (0)
Worst Grade 5	1 (10)
due to disease progression	0 (0)
Worst Grade ≥ 3	1 (10)
Any Conditioning Chemotherapy Related TEAE	2 (20)
Worst Grade 1	0 (0)
Worst Grade 2	0 (0)
Worst Grade 3	0 (0)
Worst Grade 4	1 (10)
Worst Grade 5	1 (10)
due to disease progression	0 (0)
Worst Grade ≥ 3	2 (20)
Any Serious Conditioning Chemotherapy Related TEAE	1 (10)
Worst Grade 1	0 (0)
Worst Grade 2	0 (0)
Worst Grade 3	0 (0)
Worst Grade 4	0 (0)
Worst Grade 5	1 (10)
due to disease progression	0 (0)
Worst Grade ≥ 3	1 (10)

Data cutoff date = 11AUG2021
Abbreviations: NA, not applicable; TEAE, treatment emergent adverse event; TE, treatmenr emergent; CRS, cytokine release syndrome.
Notes: For enrolled but not dosed subjects, the treatment emergent adverse event is defined as an AE from the first dose of conditioning chemotherapy to 30 days after the last study-specific procedure; CRS events were graded per the revised grading system proposed by Lee et al 2014; All other events were graded by CTCAE version 4.03; Adverse events are coded using MedDRA Version 24.0; Percentages are calculated using the number of subjects with leukapheresis but not treated with Axicabtagene Ciloleucel as the denominator.

Data Source: ADSL, ADAE Program Name: t_ae_sumry Output Generated: 20220826T06:40

Table 3. Summary of Treatment Emergent Adverse Events (Phase 2 Cohort 1 and Cohort 2) (Patients with Leukapheresis but not Treated with Axicabtagene Ciloleucel, N = 10)

	Patients with Leukapheresis but not Treated with Axicabtagene Ciloleucel (N = 10)
Any KTE-C19 Related TEAE	NA
Worst Grade 1	NA
Worst Grade 2	NA
Worst Grade 3	NA
Worst Grade 4	NA
Worst Grade 5	NA
Worst Grade ≥ 3	NA
Any Serious KTE-C19 Related TEAE	NA
Worst Grade 1	NA
Worst Grade 2	NA
Worst Grade 3	NA
Worst Grade 4	NA
Worst Grade 5	NA
Worst Grade ≥ 3	NA
Any TE CRS or Neurologic event	1 (10)
Worst Grade 1	1 (10)
Worst Grade 2	0 (0)
Worst Grade 3	0 (0)
Worst Grade 4	0 (0)
Worst Grade 5	0 (0)
Worst Grade ≥ 3	0 (0)
Any TE Neurologic Event	1 (10)
Worst Grade 1	1 (10)
Worst Grade 2	0 (0)
Worst Grade 3	0 (0)
Worst Grade 4	0 (0)
Worst Grade 5	0 (0)
Worst Grade ≥ 3	0 (0)

Data cutoff date = 11AUG2021
Abbreviations: NA, not applicable; TEAE, treatment emergent adverse event; TE, treatmenr emergent; CRS, cytokine release syndrome.
Notes: For enrolled but not dosed subjects, the treatment emergent adverse event is defined as an AE from the first dose of conditioning chemotherapy to 30 days after the last study-specific procedure; CRS events were graded per the revised grading system proposed by Lee et al 2014; All other events were graded by CTCAE version 4.03; Adverse events are coded using MedDRA Version 24.0; Percentages are calculated using the number of subjects with leukapheresis but not treated with Axicabtagene Ciloleucel as the denominator.

Data Source: ADSL, ADAE Program Name: t_ae_sumry Output Generated: 20220826T06:40

Table 3. Summary of Treatment Emergent Adverse Events (Phase 2 Cohort 1 and Cohort 2) (Patients with Leukapheresis but not Treated with Axicabtagene Ciloleucel, N = 10)

	Patients with Leukapheresis but not Treated with Axicabtagene Ciloleucel (N = 10)
Any Serious TE Neurologic event	0 (0)
Worst Grade 1	0 (0)
Worst Grade 2	0 (0)
Worst Grade 3	0 (0)
Worst Grade 4	0 (0)
Worst Grade 5	0 (0)
Worst Grade ≥ 3	0 (0)
Any TE CRS	0 (0)
Worst Grade 1	0 (0)
Worst Grade 2	0 (0)
Worst Grade 3	0 (0)
Worst Grade 4	0 (0)
Worst Grade 5	0 (0)
Worst Grade ≥ 3	0 (0)
Any TE Thrombocytopenia	1 (10)
Worst Grade 1	0 (0)
Worst Grade 2	0 (0)
Worst Grade 3	0 (0)
Worst Grade 4	1 (10)
Worst Grade 5	0 (0)
Worst Grade ≥ 3	1 (10)
Any TE Neutropenia	1 (10)
Worst Grade 1	0 (0)
Worst Grade 2	0 (0)
Worst Grade 3	0 (0)
Worst Grade 4	1 (10)
Worst Grade 5	0 (0)
Worst Grade ≥ 3	1 (10)

Data cutoff date = 11AUG2021
Abbreviations: NA, not applicable; TEAE, treatment emergent adverse event; TE, treatmenr emergent; CRS, cytokine release syndrome.
Notes: For enrolled but not dosed subjects, the treatment emergent adverse event is defined as an AE from the first dose of conditioning chemotherapy to 30 days after the last study-specific procedure; CRS events were graded per the revised grading system proposed by Lee et al 2014; All other events were graded by CTCAE version 4.03; Adverse events are coded using MedDRA Version 24.0; Percentages are calculated using the number of subjects with leukapheresis but not treated with Axicabtagene Ciloleucel as the denominator.

Data Source: ADSL, ADAE Program Name: t_ae_sumry Output Generated: 20220826T06:40

Table 3. Summary of Treatment Emergent Adverse Events (Phase 2 Cohort 1 and Cohort 2) (Patients with Leukapheresis but not Treated with Axicabtagene Ciloleucel, N = 10)

	Patients with Leukapheresis but not Treated with Axicabtagene Ciloleucel (N = 10)
Any TE Anaemia	1 (10)
Worst Grade 1	0 (0)
Worst Grade 2	0 (0)
Worst Grade 3	1 (10)
Worst Grade 4	0 (0)
Worst Grade 5	0 (0)
Worst Grade ≥ 3	1 (10)

Data cutoff date = 11AUG2021
Abbreviations: NA, not applicable; TEAE, treatment emergent adverse event; TE, treatmenr emergent; CRS, cytokine release syndrome.
Notes: For enrolled but not dosed subjects, the treatment emergent adverse event is defined as an AE from the first dose of conditioning chemotherapy to 30 days after the last study-specific procedure; CRS events were graded per the revised grading system proposed by Lee et al 2014; All other events were graded by CTCAE version 4.03; Adverse events are coded using MedDRA Version 24.0; Percentages are calculated using the number of subjects with leukapheresis but not treated with Axicabtagene Ciloleucel as the denominator.

Data Source: ADSL, ADAE Program Name: t_ae_sumry Output Generated: 20220826T06:40