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POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Intent-to-Treat Patients
 ENDPOINT: All patients
 MODEL: --
 STUDY: NP30179
 Number of centers/countries/geographical regions with <10, >=10 patients per arm

Category	Center				Country				Geographical region (3)			
	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)
Overall	31	100	115	100	13	100	115	100	4	100	115	100
with <10 patients per arm (1)	29	93.5	85	73.9	10	76.9	44	38.3	3	75	21	18.3
with >=10 patients per arm (2)	2	6.5	30	26.1	3	23.1	71	61.7	1	25	94	81.7

(1) "<10 patients category" if at least one treatment arm has <10 patients. (2) ">=10 patients" category if all treatment arms have >=10 patients.
 (3) Geographical regions: North America (Canada and USA), Australia/New Zealand, Asia (Taiwan), Europe (all other countries). (4) Number of centers/countries/geographical regions.
 (5) % of centers/countries/geographical regions compared to overall number of centers/countries/geographical regions.
 (6) Number of patients randomized in the corresponding category (e.g. Number of patients randomized in centers with <10 pts per arm).
 (7) % of randomized patients compared to overall number of randomized patients (e.g. % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients).
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_center.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_center_JUN22_ITT_D23.xls
 01MAR2023 9:52

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Summary of Previous Cancer Therapies

	Glofitamab Cohorts D2 (Sub 2) and D3 (N=115)
Prior Cancer-related Surgery	40 (34.8%)
Prior Radiotherapy	36 (31.3%)
Prior Cancer Therapy	115 (100%)
Chemotherapy	115 (100%)
Anti-CD20 Monoclonal Antibody	115 (100%)
Non Anti-CD20 Monoclonal Antibody	18 (15.7%)
Conditioning Regimen For Stem Cell Transplant	25 (21.7%)
Signaling Pathway Inhibitor	14 (12.2%)
Immunotherapy Non Stem Cell Transplant	10 (8.7%)
PI3K Inhibitor	3 (2.6%)
Car-T Therapy	39 (33.9%)
Anthracycline	113 (98.3%)
Alkylator	115 (100%)
Immunomodulatory Imide	17 (14.8%)
Autologous Stem Cell Transplant	22 (19.1%)
Other	27 (23.5%)
Number of Prior Lines of Cancer Therapy per Subject	
n	115
Mean (SD)	3.1 (1.2)
Median	3
Min - Max	2 - 7
Prior Lines of Cancer Therapy per Subject (Cat)	

2	44 (38.3%)
3	37 (32.2%)
>3	34 (29.6%)
Numbers of Prior Lines of Cancer Therapy (N)	
2	44 (38.3%)
3	37 (32.2%)
4	19 (16.5%)
5	8 (7.0%)
6	5 (4.3%)
7	2 (1.7%)
Category Time from Last Prior Therapy to First Study Treatment (0-3 vs. 3+) (Months)	
<3	60 (52.2%)
>=3	52 (45.2%)
Category Time from Last Prior CD20 Therapy to First Study Treatment (0-3 vs. 3+) (Months)	
<3	39 (33.9%)
>=3	71 (61.7%)
Time from Last Prior Therapy to First Study Treatment (Months)	
n	112
Mean (SD)	7.38 (17.29)
Median	2.6
Min - Max	0.3 - 147.3
Time from Last Anti-CD20 Therapy to First Study Treatment (Months)	
n	110
Mean (SD)	13.01 (26.43)
Median	4.75
Min - Max	0.9 - 198.9

Category Time from Last Prior Therapy, or Last Prior CD20 Therapy, is not available where Medication End date is missing the month or First Study Treatment is missing.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/R07082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_cm_prior.sas

Output: root/clinical_studies/R07082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_cm_prior_JUN22_ITT_D23.xls

01MAR2023 9:59

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Summary of Previous Cancer Therapies

	Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)
Prior Cancer-related Surgery	40 (35.1%)
Prior Radiotherapy	36 (31.6%)
Prior Cancer Therapy	114 (100%)
Chemotherapy	114 (100%)
Anti-CD20 Monoclonal Antibody	114 (100%)
Non Anti-CD20 Monoclonal Antibody	18 (15.8%)
Conditioning Regimen For Stem Cell Transplant	25 (21.9%)
Signaling Pathway Inhibitor	14 (12.3%)
Immunotherapy Non Stem Cell Transplant	10 (8.8%)
PI3K Inhibitor	3 (2.6%)
Car-T Therapy	38 (33.3%)
Anthracycline	112 (98.2%)
Alkylator	114 (100%)
Immunomodulatory Imide	17 (14.9%)
Autologous Stem Cell Transplant	22 (19.3%)
Other	26 (22.8%)
Number of Prior Lines of Cancer Therapy per Subject	
n	114
Mean (SD)	3.1 (1.2)
Median	3
Min - Max	2 - 7

Prior Lines of Cancer Therapy per Subject (Cat)	
2	44 (38.6%)
3	36 (31.6%)
>3	34 (29.8%)
Numbers of Prior Lines of Cancer Therapy (N)	
2	44 (38.6%)
3	36 (31.6%)
4	19 (16.7%)
5	8 (7.0%)
6	5 (4.4%)
7	2 (1.8%)
Category Time from Last Prior Therapy to First Study Treatment (0-3 vs. 3+) (Months)	
<3	60 (52.6%)
>=3	52 (45.6%)
Category Time from Last Prior CD20 Therapy to First Study Treatment (0-3 vs. 3+) (Months)	
<3	39 (34.2%)
>=3	71 (62.3%)
Time from Last Prior Therapy to First Study Treatment (Months)	
n	112
Mean (SD)	7.38 (17.29)
Median	2.6
Min - Max	0.3 - 147.3
Time from Last Anti-CD20 Therapy to First Study Treatment (Months)	
n	110
Mean (SD)	13.01 (26.43)
Median	4.75
Min - Max	0.9 - 198.9

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Category Time from Last Prior Therapy, or Last Prior CD20 Therapy, is not available where Medication End date is missing the month or First Study Treatment is missing.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_cm_prior.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_cm_prior_JUN22_SE_D23.xls

01MAR2023 10:02

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Summary of Refractory and Relapse Status to Prior Lines of Therapy

	Glofitamab Cohorts D2 (Sub 2) and D3 (N=115)
Relapse or Refractory to Any Prior Therapy	
n	115
Refractory	103 (89.6%)
Relapse (No Refractory)	12 (10.4%)
Relapse or Refractory to Last Line of Prior Therapy	
n	115
Refractory	96 (83.5%)
Relapse	19 (16.5%)
Relapse or Refractory to First Line of Prior Therapy	
n	115
Refractory	69 (60.0%)
Relapse	46 (40.0%)
Relapse or Refractory to Any Prior Anti-CD20 Therapy	
n	115
Refractory	97 (84.3%)
Relapse (No Refractory)	18 (15.7%)
Relapse or Refractory to Any Prior Alkylator Therapy	
n	115
Refractory	95 (82.6%)

Relapse (No Refractory)	20 (17.4%)
Relapse or Refractory to Any Prior CAR-T Therapy	
n	115
Refractory	35 (30.4%)
Relapse (No Refractory)	4 (3.5%)
Unknown	76 (66.1%)
Relapse or Refractory to Any Prior Pi3K Therapy	
n	115
Refractory	2 (1.7%)
Relapse (No Refractory)	1 (0.9%)
Unknown	112 (97.4%)
Relapse or Refractory to Any Prior Autologous Stem Cell Transplant Therapy	
n	115
Refractory	5 (4.3%)
Relapse (No Refractory)	17 (14.8%)
Unknown	93 (80.9%)
Relapse or Refractory to Any Prior Conditioning Regimen to Stem Cell Transplant Therapy	
n	115
Refractory	7 (6.1%)
Relapse (No Refractory)	18 (15.7%)
Unknown	90 (78.3%)
Progress or Relapse within 24 months after 1L Treatment Start	
n	115
No	23 (20.0%)
Yes	92 (80.0%)
Double Refractory to Both Anti-CD20 and Alkylating Agent Prior Therapies	
n	115

No	21 (18.3%)
Yes	94 (81.7%)
Primary Refractory	
n	115
No	87 (75.7%)
Yes	28 (24.3%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_cm_rrstat.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_cm_rrstat_JUN22_ITT_D23.xls

08JUN2023 9:39

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Summary of Refractory and Relapse Status to Prior Lines of Therapy

	Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)
Relapse or Refractory to Any Prior Therapy	
n	114
Refractory	102 (89.5%)
Relapse (No Refractory)	12 (10.5%)
Relapse or Refractory to Last Line of Prior Therapy	
n	114
Refractory	96 (84.2%)
Relapse	18 (15.8%)
Relapse or Refractory to First Line of Prior Therapy	
n	114
Refractory	68 (59.6%)
Relapse	46 (40.4%)
Relapse or Refractory to Any Prior Anti-CD20 Therapy	
n	114
Refractory	96 (84.2%)
Relapse (No Refractory)	18 (15.8%)
Relapse or Refractory to Any Prior Alkylator Therapy	
n	114
Refractory	94 (82.5%)

Relapse (No Refractory)	20 (17.5%)
Relapse or Refractory to Any Prior CAR-T Therapy	
n	114
Refractory	35 (30.7%)
Relapse (No Refractory)	3 (2.6%)
Unknown	76 (66.7%)
Relapse or Refractory to Any Prior Pi3K Therapy	
n	114
Refractory	2 (1.8%)
Relapse (No Refractory)	1 (0.9%)
Unknown	111 (97.4%)
Relapse or Refractory to Any Prior Autologous Stem Cell Transplant Therapy	
n	114
Refractory	5 (4.4%)
Relapse (No Refractory)	17 (14.9%)
Unknown	92 (80.7%)
Relapse or Refractory to Any Prior Conditioning Regimen to Stem Cell Transplant Therapy	
n	114
Refractory	7 (6.1%)
Relapse (No Refractory)	18 (15.8%)
Unknown	89 (78.1%)
Progress or Relapse within 24 months after 1L Treatment Start	
n	114
No	23 (20.2%)
Yes	91 (79.8%)
Double Refractory to Both Anti-CD20 and Alkylating Agent Prior Therapies	
n	114

No	21 (18.4%)
Yes	93 (81.6%)
Primary Refractory	
n	114
No	86 (75.4%)
Yes	28 (24.6%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_cm_rrstat.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_cm_rrstat_JUN22_EE_D23.xls

08JUN2023 9:40

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Number of patients who died including primary reason

	Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)
Total number of deaths	65 (57.0%)
Primary cause of death	
n	65
Adverse event	7 (10.8%)
Progressive disease	47 (72.3%)
Other	10 (15.4%)
Missing	1 (1.5%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_dd.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_dd_JUN22_SE_D23.xls

01MAR2023 10:10

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Demographic and Baseline Characteristics

	Glofitamab Cohorts D2 (Sub 2) and D3 (N=115)
Age (yr)	
n	115
Mean (SD)	62.0 (14.7)
Median	66
Min - Max	21 - 90
Age group (yr)	
n	115
<65	55 (47.8%)
>=65	60 (52.2%)
Sex	
n	115
Male	78 (67.8%)
Female	37 (32.2%)
Ethnicity	
n	115
Hispanic or Latino	6 (5.2%)
Not Hispanic or Latino	87 (75.7%)
Not Stated	18 (15.7%)
Unknown	4 (3.5%)
Country	
n	115
Australia	6 (5.2%)
Belgium	3 (2.6%)
Canada	1 (0.9%)

Czech Republic	4 (3.5%)
Denmark	8 (7.0%)
Spain	16 (13.9%)
Finland	2 (1.7%)
France	25 (21.7%)
Italy	30 (26.1%)
New Zealand	1 (0.9%)
Poland	6 (5.2%)
Taiwan	5 (4.3%)
United States	8 (7.0%)
Race	
n	115
Asian	6 (5.2%)
Black or African American	1 (0.9%)
White	85 (73.9%)
Unknown	23 (20.0%)
Weight (kg)	
n	113
Mean (SD)	75.13 (15.55)
Median	73.7
Min - Max	45.0 - 151.1
Height (cm)	
n	113
Mean (SD)	171.39 (9.94)
Median	173
Min - Max	144.0 - 193.0
Body Mass Index (kg/m2) at Baseline	
n	113
Mean (SD)	25.56 (4.78)
Median	24.76
Min - Max	17.6 - 45.1
ECOG Status at Baseline	
0	55 (47.8%)
1	59 (51.3%)
Missing/Unknown	1 (0.9%)

Cancer Hist. Subtype II at Study Entry	
Diffuse Large B-Cell Lymphoma	81 (70.4%)
High Grade B Cell Lymphoma	8 (7.0%)
Primary Mediastinal B Cell Lymphoma	6 (5.2%)
Transformed Follicular Lymphoma	20 (17.4%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_dm.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_dm_JUN22_ITT_D23.xls

01MAR2023 9:53

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Demographic and Baseline Characteristics

	Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)
Age (yr)	
n	114
Mean (SD)	62.1 (14.7)
Median	66
Min - Max	21 - 90
Age group (yr)	
n	114
<65	54 (47.4%)
>=65	60 (52.6%)
Sex	
n	114
Male	77 (67.5%)
Female	37 (32.5%)
Ethnicity	
n	114
Hispanic or Latino	6 (5.3%)
Not Hispanic or Latino	86 (75.4%)
Not Stated	18 (15.8%)
Unknown	4 (3.5%)
Country	
n	114
Australia	6 (5.3%)
Belgium	3 (2.6%)
Canada	1 (0.9%)

Czech Republic	4 (3.5%)
Denmark	8 (7.0%)
Spain	15 (13.2%)
Finland	2 (1.8%)
France	25 (21.9%)
Italy	30 (26.3%)
New Zealand	1 (0.9%)
Poland	6 (5.3%)
Taiwan	5 (4.4%)
United States	8 (7.0%)
Race	
n	114
Asian	6 (5.3%)
Black or African American	1 (0.9%)
White	84 (73.7%)
Unknown	23 (20.2%)
Weight (kg)	
n	113
Mean (SD)	75.13 (15.55)
Median	73.7
Min - Max	45.0 - 151.1
Height (cm)	
n	113
Mean (SD)	171.39 (9.94)
Median	173
Min - Max	144.0 - 193.0
Body Mass Index (kg/m2) at Baseline	
n	113
Mean (SD)	25.56 (4.78)
Median	24.76
Min - Max	17.6 - 45.1
ECOG Status at Baseline	
0	55 (48.2%)
1	59 (51.8%)
Cancer Hist. Subtype II at Study Entry	

Diffuse Large B-Cell Lymphoma	81 (71.1%)
High Grade B Cell Lymphoma	8 (7.0%)
Primary Mediastinal B Cell Lymphoma	6 (5.3%)
Transformed Follicular Lymphoma	19 (16.7%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_dm.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_dm_JUN22_SE_D23.xls

01MAR2023 9:54

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Disposition of Patients

	Glofitamab Cohorts D2 (Sub 2) and D3 (N=115)
Ongoing Study	41 (35.7%)
Discontinued Study	74 (64.3%)
Reason for Study Discontinuation	
Death	65 (56.5%)
Lost To Follow-Up	2 (1.7%)
Protocol Deviation	1 (0.9%)
Withdrawal By Subject	6 (5.2%)
Not Started Treatment	1 (0.9%)
Active on Treatment	0
Completed Treatment	28 (24.3%)
Discontinued Treatment	83 (72.2%)
Reason for Treatment Discontinuation	
Adverse Event	7 (6.1%)
Death	8 (7.0%)
Lack Of Efficacy	2 (1.7%)
Other	2 (1.7%)
Physician Decision	6 (5.2%)
Progressive Disease	50 (43.5%)
Protocol Deviation	1 (0.9%)
Symptomatic Deterioration	2 (1.7%)
Withdrawal By Subject	5 (4.3%)

Not Started Initial Treatment	1 (0.9%)
Active on Initial Treatment	0
Completed Initial Treatment	31 (27.0%)
Discontinued Initial Treatment	83 (72.2%)
Reason for Initial Treatment Discontinuation	
Adverse Event	7 (6.1%)
Death	8 (7.0%)
Lack Of Efficacy	2 (1.7%)
Other	2 (1.7%)
Physician Decision	6 (5.2%)
Progressive Disease	50 (43.5%)
Protocol Deviation	1 (0.9%)
Symptomatic Deterioration	2 (1.7%)
Withdrawal By Subject	5 (4.3%)
Active on Retreatment	0
Completed Retreatment	0
Discontinued Retreatment	3 (2.6%)
Reason for Retreatment Discontinuation	
Adverse Event	1 (0.9%)
Progressive Disease	2 (1.7%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_ds.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_ds_JUN22_ITT_D23.xls
01MAR2023 10:06

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Disposition of Patients

	Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)
Ongoing Study	40 (35.1%)
Discontinued Study	74 (64.9%)
Reason for Study Discontinuation	
Death	65 (57.0%)
Lost To Follow-Up	2 (1.8%)
Protocol Deviation	1 (0.9%)
Withdrawal By Subject	6 (5.3%)
Active on Treatment	0
Completed Treatment	28 (24.6%)
Discontinued Treatment	83 (72.8%)
Reason for Treatment Discontinuation	
Adverse Event	7 (6.1%)
Death	8 (7.0%)
Lack Of Efficacy	2 (1.8%)
Other	2 (1.8%)
Physician Decision	6 (5.3%)
Progressive Disease	50 (43.9%)
Protocol Deviation	1 (0.9%)
Symptomatic Deterioration	2 (1.8%)
Withdrawal By Subject	5 (4.4%)
Active on Initial Treatment	0

Completed Initial Treatment	31 (27.2%)
Discontinued Initial Treatment	83 (72.8%)
Reason for Initial Treatment Discontinuation	
Adverse Event	7 (6.1%)
Death	8 (7.0%)
Lack Of Efficacy	2 (1.8%)
Other	2 (1.8%)
Physician Decision	6 (5.3%)
Progressive Disease	50 (43.9%)
Protocol Deviation	1 (0.9%)
Symptomatic Deterioration	2 (1.8%)
Withdrawal By Subject	5 (4.4%)
Active on Retreatment	0
Completed Retreatment	0
Discontinued Retreatment	3 (2.6%)
Reason for Retreatment Discontinuation	
Adverse Event	1 (0.9%)
Progressive Disease	2 (1.8%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_ds.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_ds_JUN22_SE_D23.xls

01MAR2023 10:08

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Duration of follow-up

	Glofitamab Cohorts D2 (Sub 2) and D3 (N=115)
Median follow-up time (months)	
n	115
Mean	11.74
Median	7.98
Min - Max	0.1 - 29.2

Median follow-up time is time from patient randomization to study discontinuation date, death date or CCOD, whichever is the earliest.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_fut.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_fut_JUN22_ITT_D23.xls

01MAR2023 10:10

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: All patients
MODEL: --
STUDY: NP30179
Duration of follow-up

	Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)
Median follow-up time (months)	
n	114
Mean	6.4
Median	5.68
Min - Max	0.0 - 27.8

Median follow-up time is time from first dose to end of 90 day safety follow up period or earliest of CCOD, NALT, study discontinuation or start of a re-treatment.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_fut.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_fut_JUN22_SE_D23.xls
01MAR2023 10:11

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Summary of Baseline Disease Characteristics

	Glofitamab Cohorts D2 (Sub 2) and D3 (N=115)
Ann Arbor Staging at Study Entry	
n	115
STAGE I	10 (8.7%)
STAGE II	16 (13.9%)
STAGE III	21 (18.3%)
STAGE IV	65 (56.5%)
UNKNOWN	3 (2.6%)
Risk factors for IPI (non-FL patients only)	
n	115
0	5 (4.3%)
1	17 (14.8%)
2	33 (28.7%)
3	39 (33.9%)
4	21 (18.3%)
Extranodal Disease	
n	115
No	39 (33.9%)
Yes	76 (66.1%)
Bulky Disease > 6cm	
n	114
No	67 (58.3%)
Yes	47 (40.9%)
Bulky Disease > 10cm	
n	114

No	99 (86.1%)
Yes	15 (13.0%)
Baseline Sum of Products of Diameters Value (mm2) - Investigator	
n	113
Mean (SD)	5776.71 (6864.29)
Median	3575
Min - Max	48.7 - 40152.0
Category Sum of Products of Diameters Value >=3000 (mm2) - Investigator	
n	113
Baseline SPD < 3000	52 (45.2%)
Baseline SPD >= 3000	61 (53.0%)
Category Sum of Products of Diameters Value >=10000 (mm2) - Investigator	
n	113
Baseline SPD < 10000	96 (83.5%)
Baseline SPD >= 10000	17 (14.8%)
Absence of circulating malignant cells	
n	29
No	5 (4.3%)
Yes	24 (20.9%)
Cancer Histological Subtype	
n	115
DLBCL	81 (70.4%)
HGBCL	8 (7.0%)
PMBCL	6 (5.2%)
trFL	20 (17.4%)
Cancer Grouped Histology	
n	115
aNHL	115 (100%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_mh_char.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_mh_char_JUN22_ITT_D23.xls

01MAR2023 9:56

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Summary of Baseline Disease Characteristics

	Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)
Ann Arbor Staging at Study Entry	
n	114
STAGE I	10 (8.8%)
STAGE II	16 (14.0%)
STAGE III	21 (18.4%)
STAGE IV	65 (57.0%)
UNKNOWN	2 (1.8%)
Risk factors for IPI (non-FL patients only)	
n	114
0	4 (3.5%)
1	17 (14.9%)
2	33 (28.9%)
3	39 (34.2%)
4	21 (18.4%)
Extranodal Disease	
n	114
No	38 (33.3%)
Yes	76 (66.7%)
Bulky Disease > 6cm	
n	114
No	67 (58.8%)
Yes	47 (41.2%)
Bulky Disease > 10cm	
n	114

No	99 (86.8%)
Yes	15 (13.2%)
Baseline Sum of Products of Diameters Value (mm2) - Investigator	
n	113
Mean (SD)	5776.71 (6864.29)
Median	3575
Min - Max	48.7 - 40152.0
Category Sum of Products of Diameters Value >=3000 (mm2) - Investigator	
n	113
Baseline SPD < 3000	52 (45.6%)
Baseline SPD >= 3000	61 (53.5%)
Category Sum of Products of Diameters Value >=10000 (mm2) - Investigator	
n	113
Baseline SPD < 10000	96 (84.2%)
Baseline SPD >= 10000	17 (14.9%)
Absence of circulating malignant cells	
n	29
No	5 (4.4%)
Yes	24 (21.1%)
Cancer Histological Subtype	
n	114
DLBCL	81 (71.1%)
HGBCL	8 (7.0%)
PMBCL	6 (5.3%)
trFL	19 (16.7%)
Cancer Grouped Histology	
n	114
aNHL	114 (100%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_mh_char.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_mh_char_JUN22_SE_D23.xls

01MAR2023 9:57

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Intent-to-Treat Patients
 ENDPOINT: Overall Survival
 MODEL: --
 STUDY: NP30179
 Time to event analysis (efficacy)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=115)											
		Patients		Patients with Event		Censored		Time To Event					
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	115	100.0	65	56.5	50	43.5	4.7	3.2	6.7	10.2	7.5	15.7

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_tte.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_tte_JUN22_ITT_D23_OS.xls
 27FEB2023 9:47

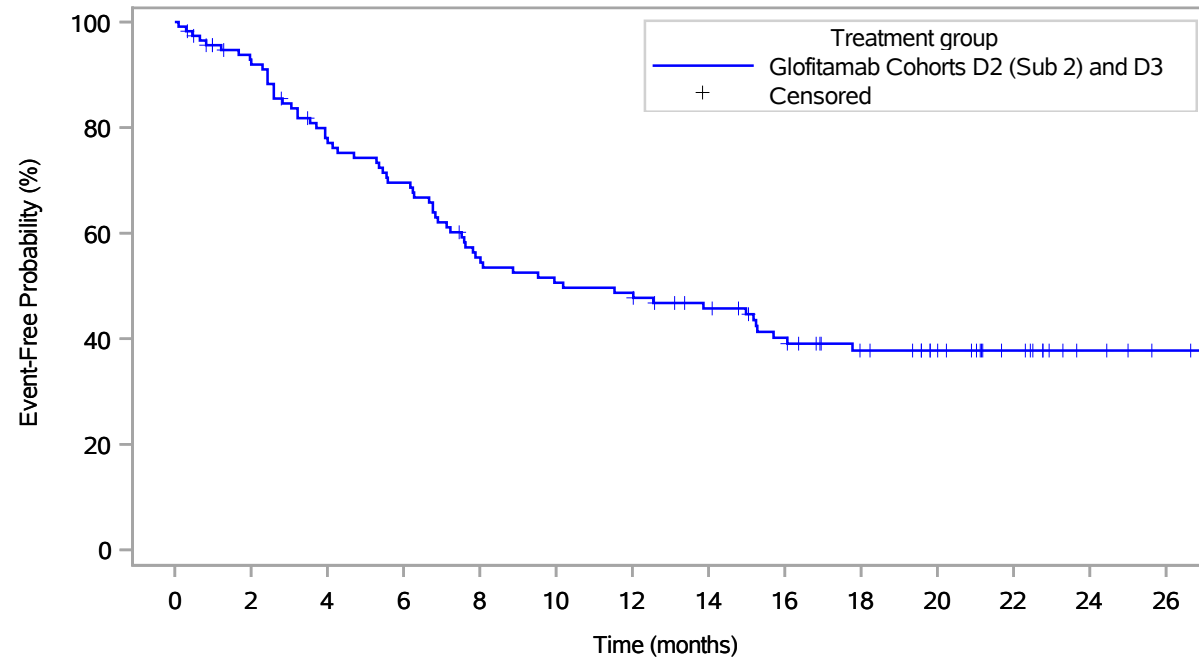
POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: Overall Survival

MODEL: --

STUDY: NP30179

Kaplan-Meier plot of time to first event (months)



Patients at risk	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Glofitamab Cohorts D2 (Sub 2) and D3	115	101	83	74	58	53	51	44	36	28	22	14	6	3
Patients censored														
Glofitamab Cohorts D2 (Sub 2) and D3	0	6	8	8	9	9	9	13	16	22	28	36	44	47

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_tte.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_tte_JUN22_ITT_D23_OS.pdf
 27FEB2023 9:52

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: Overall Survival

MODEL: --

STUDY: NP30179

Time to event landmark analysis

	Glofitamab Cohorts D2 (Sub 2) and D3 (N=115)
Patients included in analysis (%)	115 (100%)
Patients with event (%)	65 (56.5%)
Patients without event (%)	50 (43.5%)
Time to event (months)	
Median	10.2
95% CI	(7.5, 15.7)
25% and 75%-ile	4.7 - NE
Range	0.1 - 28.6*
Time point analysis (Unstratified)	
3 Months	
Patients remaining at risk	91
Event free proportion (%)	84.58
95% CI	(77.83, 91.33)
6 Months	
Patients remaining at risk	74
Event free proportion (%)	69.57
95% CI	(60.89, 78.25)
9 Months	
Patients remaining at risk	55

Event free proportion (%)	52.53
95% CI	(43.05, 62.00)
12 Months	
Patients remaining at risk	51
Event free proportion (%)	48.71
95% CI	(39.21, 58.20)
15 Months	
Patients remaining at risk	41
Event free proportion (%)	44.65
95% CI	(35.14, 54.16)
18 Months	
Patients remaining at risk	28
Event free proportion (%)	37.77
95% CI	(28.25, 47.28)
21 Months	
Patients remaining at risk	19
Event free proportion (%)	37.77
95% CI	(28.25, 47.28)
24 Months	
Patients remaining at risk	6
Event free proportion (%)	37.77
95% CI	(28.25, 47.28)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_lma.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_lma_JUN22_ITT_D23_OS.xls

27FEB2023 9:42

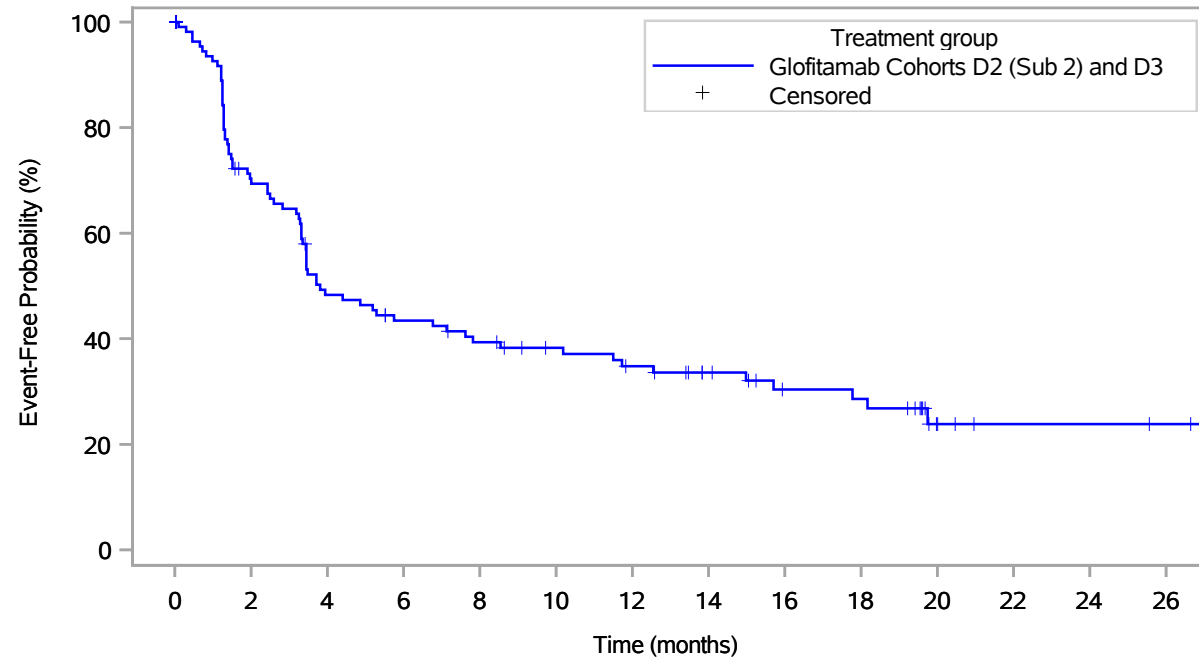
POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Intent-to-Treat Patients
 ENDPOINT: IRC Assessed Progression Free Survival
 MODEL: --
 STUDY: NP30179
 Time to event analysis (efficacy)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=115)											
		Patients		Patients with Event		Censored		Time To Event					
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	115	100.0	74	64.3	41	35.7	1.4	1.3	2.6	3.8	3.3	7.6

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_tte.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_tte_JUN22_ITT_D23_IRCPFS.xls
 27FEB2023 9:46

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Intent-to-Treat Patients
ENDPOINT: IRC Assessed Progression Free Survival
MODEL: --
STUDY: NP30179
Kaplan-Meier plot of time to first event (months)



Patients at risk	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Glofitamab Cohorts D2 (Sub 2) and D3	115	74	50	43	38	33	29	23	17	16	6	3	3	2
Patients censored														
Glofitamab Cohorts D2 (Sub 2) and D3	0	9	10	12	13	17	18	23	27	27	35	38	38	39

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_tte.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_tte_JUN22_ITT_D23_IRCPFS.pdf
 27FEB2023 9:51

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: IRC Assessed Progression Free Survival

MODEL: --

STUDY: NP30179

Time to event landmark analysis

	Glofitamab Cohorts D2 (Sub 2) and D3 (N=115)
Patients included in analysis (%)	115 (100%)
Patients with event (%)	74 (64.3%)
Patients without event (%)	41 (35.7%)
Time to event (months)	
Median	3.8
95% CI	(3.3, 7.6)
25% and 75%-ile	1.4 - 19.7
Range	0.0* - 28.3*
Time point analysis (Unstratified)	
3 Months	
Patients remaining at risk	68
Event free proportion (%)	64.62
95% CI	(55.57, 73.67)
6 Months	
Patients remaining at risk	43
Event free proportion (%)	43.43
95% CI	(33.95, 52.91)
9 Months	
Patients remaining at risk	35

Event free proportion (%)	38.28
95% CI	(28.91, 47.65)
12 Months	
Patients remaining at risk	29
Event free proportion (%)	34.8
95% CI	(25.49, 44.11)
15 Months	
Patients remaining at risk	21
Event free proportion (%)	32.07
95% CI	(22.74, 41.40)
18 Months	
Patients remaining at risk	16
Event free proportion (%)	28.6
95% CI	(19.11, 38.08)
21 Months	
Patients remaining at risk	3
Event free proportion (%)	23.83
95% CI	(13.74, 33.92)
24 Months	
Patients remaining at risk	3
Event free proportion (%)	23.83
95% CI	(13.74, 33.92)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_lma.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_lma_JUN22_ITT_D23_IRCPFS.xls

27FEB2023 9:41

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: Duration of IRC Assessed Complete Response

MODEL: --

STUDY: NP30179

Time to event analysis (efficacy)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)											
		Patients		Patients with Event		Censored		Time To Event					
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	43	37.7	12	27.9	31	72.1	14.4	6.5	NE	NE	16.8	NE

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_tte.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_tte_JUN22_EE_D23_IRCCR.xls

27FEB2023 9:42

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: Time to First IRC Assessed Complete Response

MODEL: --

STUDY: NP30179

Time to event analysis (efficacy)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)											
		Patients		Patients with Event		Censored		Time To Event					
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	114	100.0	43	37.7	71	62.3	1.3	1.2	1.3	1.4	1.4	1.9

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_tte.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_tte_JUN22_EE_D23_IRCFCRSP.xls
14APR2023 14:41

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: Time to First IRC Assessed Response

MODEL: --

STUDY: NP30179

Time to event analysis (efficacy)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)											
		Patients		Patients with Event		Censored		Time To Event					
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	114	100.0	59	51.8	55	48.2	1.2	1.2	1.3	1.4	1.3	1.4

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_tte.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_tte_JUN22_EE_D23_IRCFRSP.xls

14APR2023 14:47

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: Duration of IRC Assessed Any Response

MODEL: --

STUDY: NP30179

Time to event analysis (efficacy)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)											
		Patients		Patients with Event		Censored		Time To Event					
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	59	51.8	26	44.1	33	55.9	3.5	2.1	10.4	16.8	9.3	NE

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_tte.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_tte_JUN22_EE_D23_IRCOVR.xls

27FEB2023 9:43

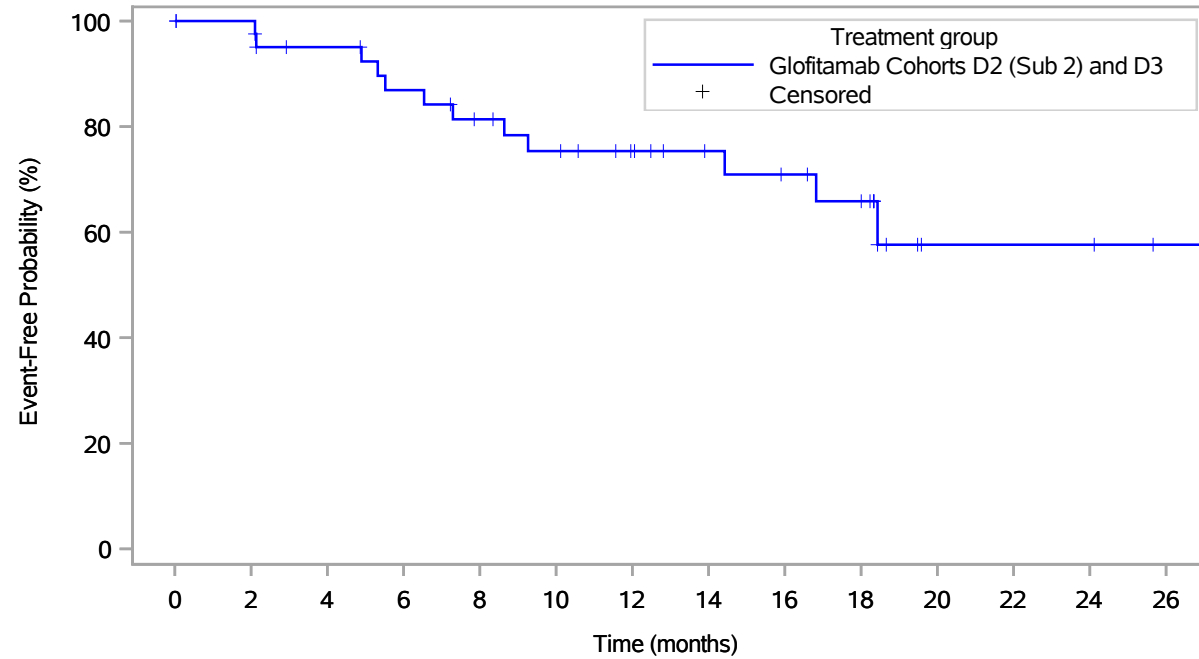
POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: Duration of IRC Assessed Complete Response

MODEL: --

STUDY: NP30179

Kaplan-Meier plot of time to first event (months)



Patients at risk														
Glofitamab Cohorts D2 (Sub 2) and D3	43	41	36	32	28	25	21	17	15	13	3	3	3	1
Patients censored														
Glofitamab Cohorts D2 (Sub 2) and D3	0	2	5	6	8	9	13	17	18	19	28	28	28	30

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_tte.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_tte_JUN22_EE_D23_IRCCR.pdf
 27FEB2023 9:48

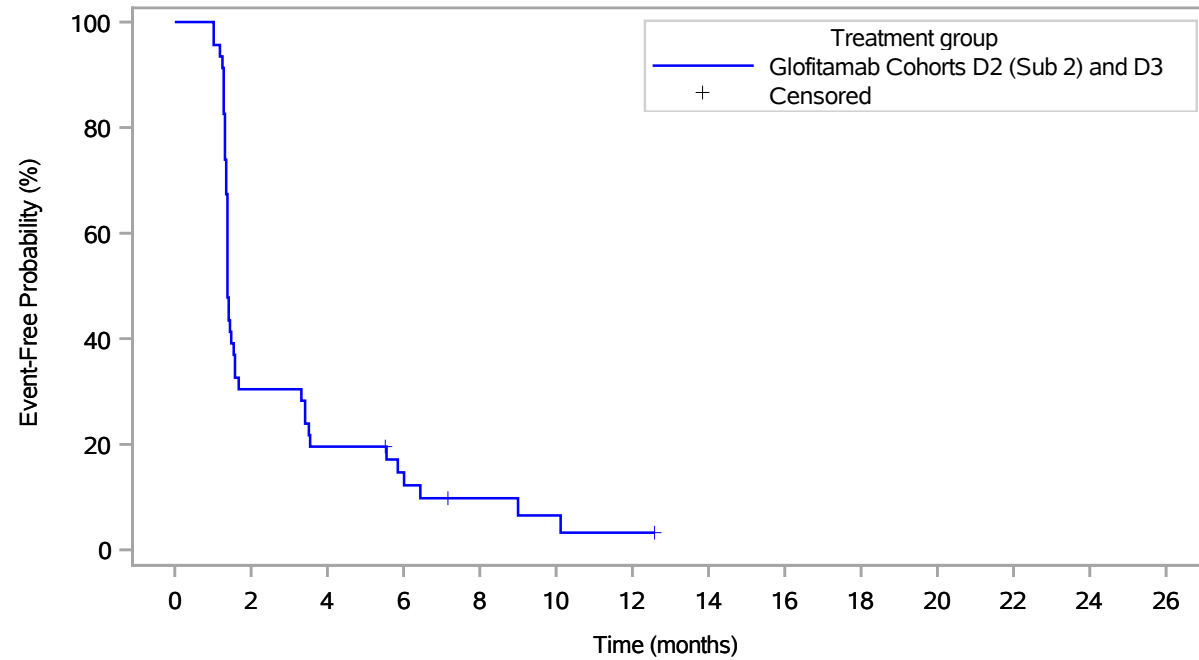
POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: Time to First IRC Assessed Complete Response

MODEL: --

STUDY: NP30179

Kaplan-Meier plot of time to first event (months)



Patients at risk															
Glofitamab Cohorts D2 (Sub 2) and D3	46	14	9	6	3	2	1	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Glofitamab Cohorts D2 (Sub 2) and D3	0	0	0	1	2	2	2	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_tte.sas
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 27FEB2023 9:49

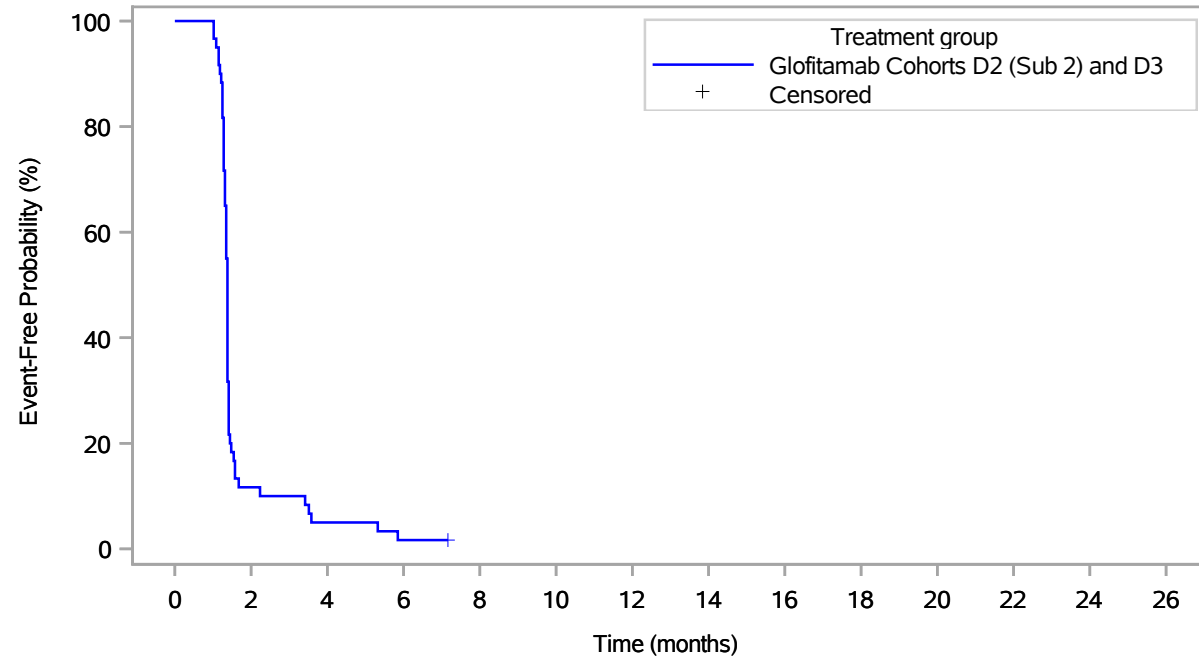
POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: Time to First IRC Assessed Response

MODEL: --

STUDY: NP30179

Kaplan-Meier plot of time to first event (months)



Patients at risk															
Glofitamab Cohorts D2 (Sub 2) and D3	60	7	3	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Glofitamab Cohorts D2 (Sub 2) and D3	0	0	0	0	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_tte.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_tte_JUN22_EE_D23_IRCFRSP.pdf
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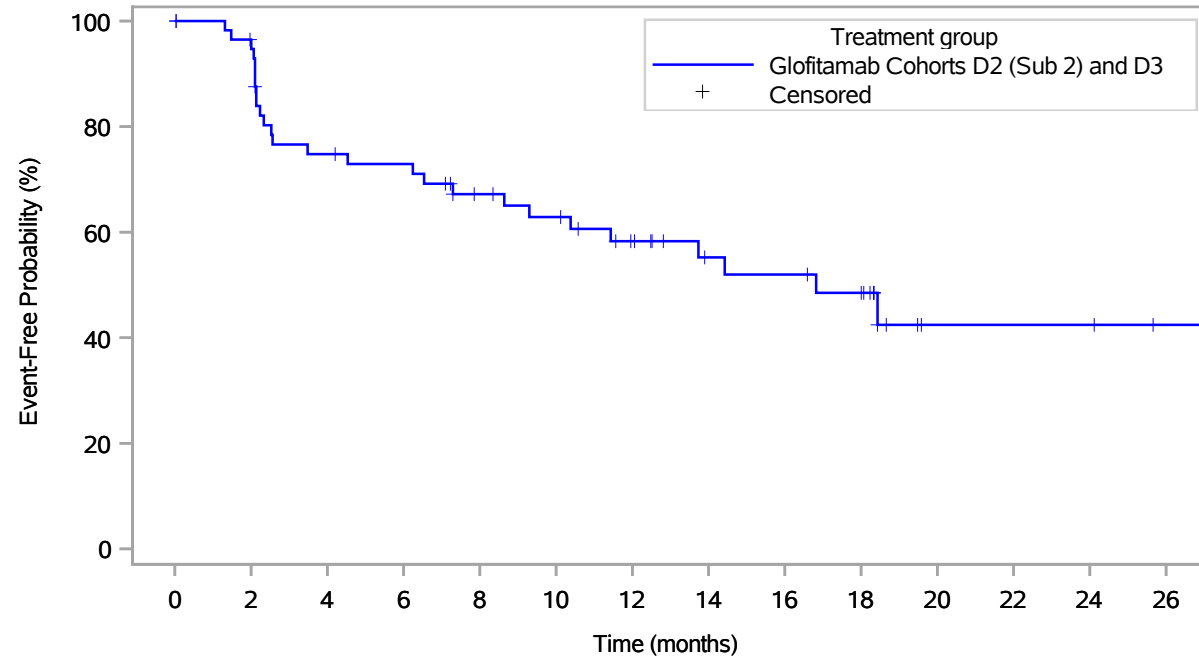
POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: Duration of IRC Assessed Any Response

MODEL: --

STUDY: NP30179

Kaplan-Meier plot of time to first event (months)



Patients at risk	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Glofitamab Cohorts D2 (Sub 2) and D3	59	54	41	39	32	29	23	17	16	14	3	3	3	1
Patients censored	0	3	4	5	9	10	14	19	19	20	30	30	30	32

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_tte.sas
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 27FEB2023 9:49

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: IRC Assessed Objective Response Rate

MODEL: --

STUDY: NP30179

Dichotomous analysis (efficacy)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	59	51.8	42.7	60.7

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_EE_D23_IRCORR.xls

27FEB2023 9:38

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
 ENDPOINT: Investigator Assessed BOR
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

			Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	CR	n/a	114	100.0	41	36.0	27.7	45.1
	PR	n/a	114	100.0	26	22.8	16.1	31.3
	SD	n/a	114	100.0	6	5.3	2.4	11.0
	PD	n/a	114	100.0	31	27.2	19.9	36.0
	NE	n/a	114	100.0	0	0.0	0.0	3.3
	Missing or No Data	n/a	114	100.0	10	8.8	4.8	15.4

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp_new.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_new_JUN22_EE_D23_INV.xls
 27FEB2023 9:40

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
 ENDPOINT: IRC Assessed BOR
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

			Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	CR	n/a	114	100.0	43	37.7	29.4	46.9
	PR	n/a	114	100.0	16	14.0	8.8	21.6
	SD	n/a	114	100.0	13	11.4	6.8	18.5
	PD	n/a	114	100.0	32	28.1	20.6	36.9
	NE	n/a	114	100.0	0	0.0	0.0	3.3
	Missing or No Data	n/a	114	100.0	10	8.8	4.8	15.4

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp_new.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_new_JUN22_EE_D23_IRC.xls
 27FEB2023 9:39

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Appetite Loss

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab 2.5/10/30 mg Cohort D3 (N=107)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	107	100.0	97	90.7	19.93	28.33
Cycle 1 Day 8	n/a	101	94.4	97	96.0	16.84	25.51
Cycle 2 Day 1	n/a	90	84.1	84	93.3	19.44	30.26
Cycle 3 Day 1	n/a	75	70.1	67	89.3	14.93	24.12
Cycle 5 Day 1	n/a	57	53.3	50	87.7	8.00	15.88
Cycle 7 Day 1	n/a	41	38.3	39	95.1	10.26	23.14
Cycle 9 Day 1	n/a	28	26.2	6	21.4	11.11	17.21
Cycle 12 Day 1	n/a	27	25.2	9	33.3	14.81	17.57

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

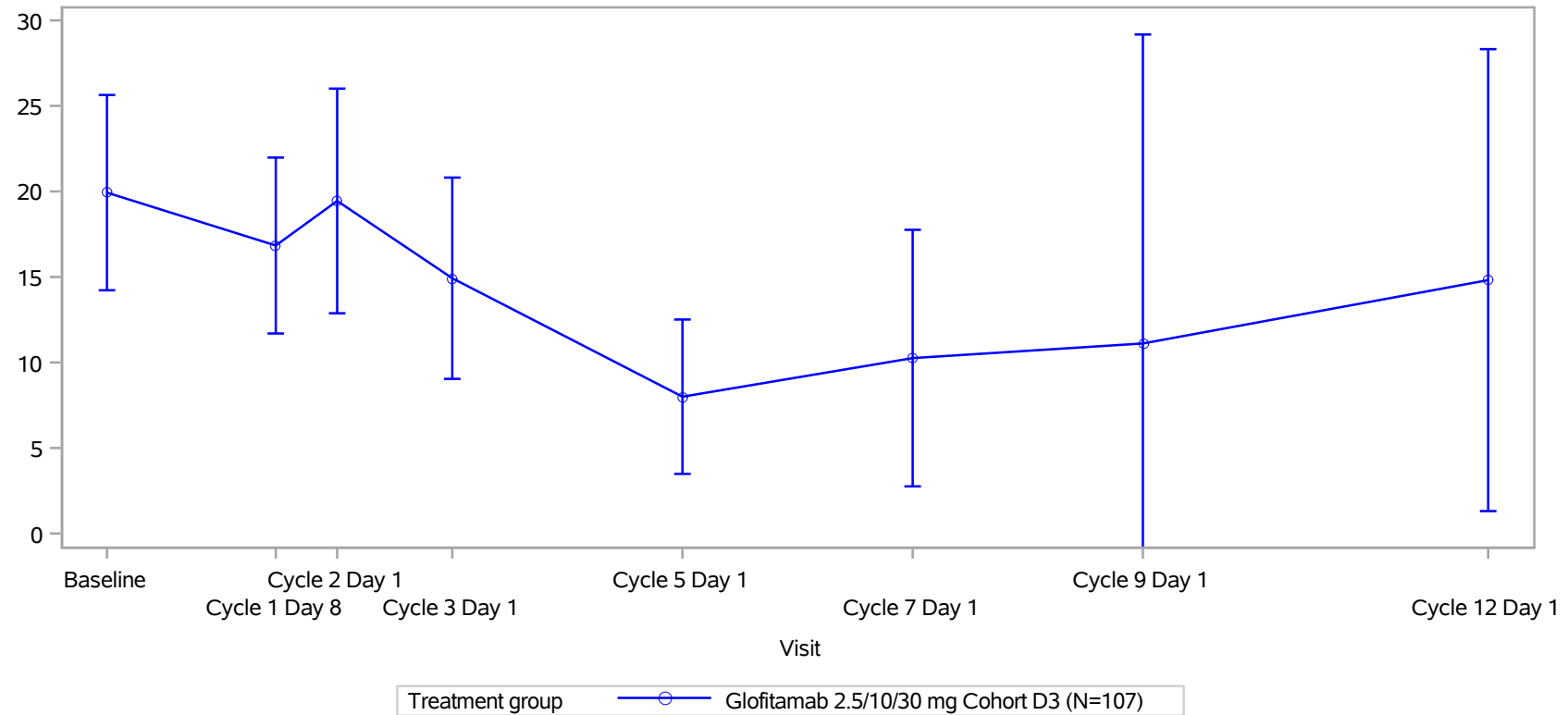
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D3_C30AP.xls

27FEB2023 9:58

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Appetite Loss
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D3_C30AP.pdf
27FEB2023 10:10

POPULATION: Cohort D3 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Appetite Loss (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab 2.5/10/30 mg Cohort D3 (N=92)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	92	100.0	27	29.3	21.0	39.3

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D3_M10C30AP.xls
 27FEB2023 10:20

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Constipation

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab 2.5/10/30 mg Cohort D3 (N=107)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	107	100.0	97	90.7	15.46	25.94
Cycle 1 Day 8	n/a	101	94.4	97	96.0	19.24	27.15
Cycle 2 Day 1	n/a	90	84.1	84	93.3	19.84	28.40
Cycle 3 Day 1	n/a	75	70.1	67	89.3	15.92	24.86
Cycle 5 Day 1	n/a	57	53.3	51	89.5	15.03	26.09
Cycle 7 Day 1	n/a	41	38.3	40	97.6	12.50	22.25
Cycle 9 Day 1	n/a	28	26.2	6	21.4	5.56	13.61
Cycle 12 Day 1	n/a	27	25.2	9	33.3	11.11	16.67

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

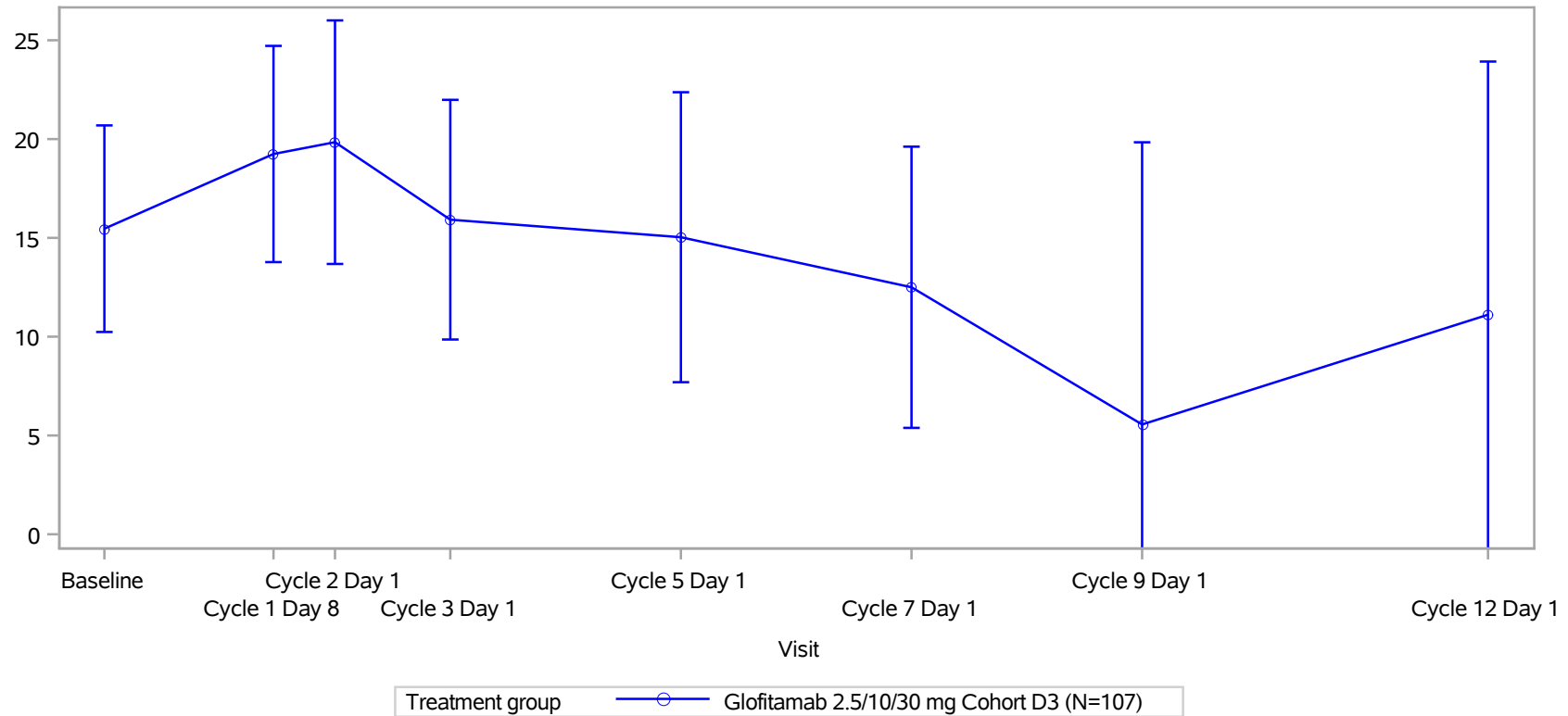
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D3_C30CO.xls

27FEB2023 9:57

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Constipation
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D3_C30CO.pdf
27FEB2023 10:08

POPULATION: Cohort D3 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Constipation (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab 2.5/10/30 mg Cohort D3 (N=92)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	92	100.0	33	35.9	26.8	46.1

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D3_M10C30CO.xls
 27FEB2023 10:19

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Diarrhoea

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab 2.5/10/30 mg Cohort D3 (N=107)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	107	100.0	97	90.7	7.90	16.51
Cycle 1 Day 8	n/a	101	94.4	97	96.0	9.62	20.39
Cycle 2 Day 1	n/a	90	84.1	84	93.3	4.37	13.47
Cycle 3 Day 1	n/a	75	70.1	67	89.3	6.97	17.92
Cycle 5 Day 1	n/a	57	53.3	51	89.5	10.46	24.49
Cycle 7 Day 1	n/a	41	38.3	40	97.6	8.33	18.10
Cycle 9 Day 1	n/a	28	26.2	6	21.4	5.56	13.61
Cycle 12 Day 1	n/a	27	25.2	9	33.3	7.41	14.70

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

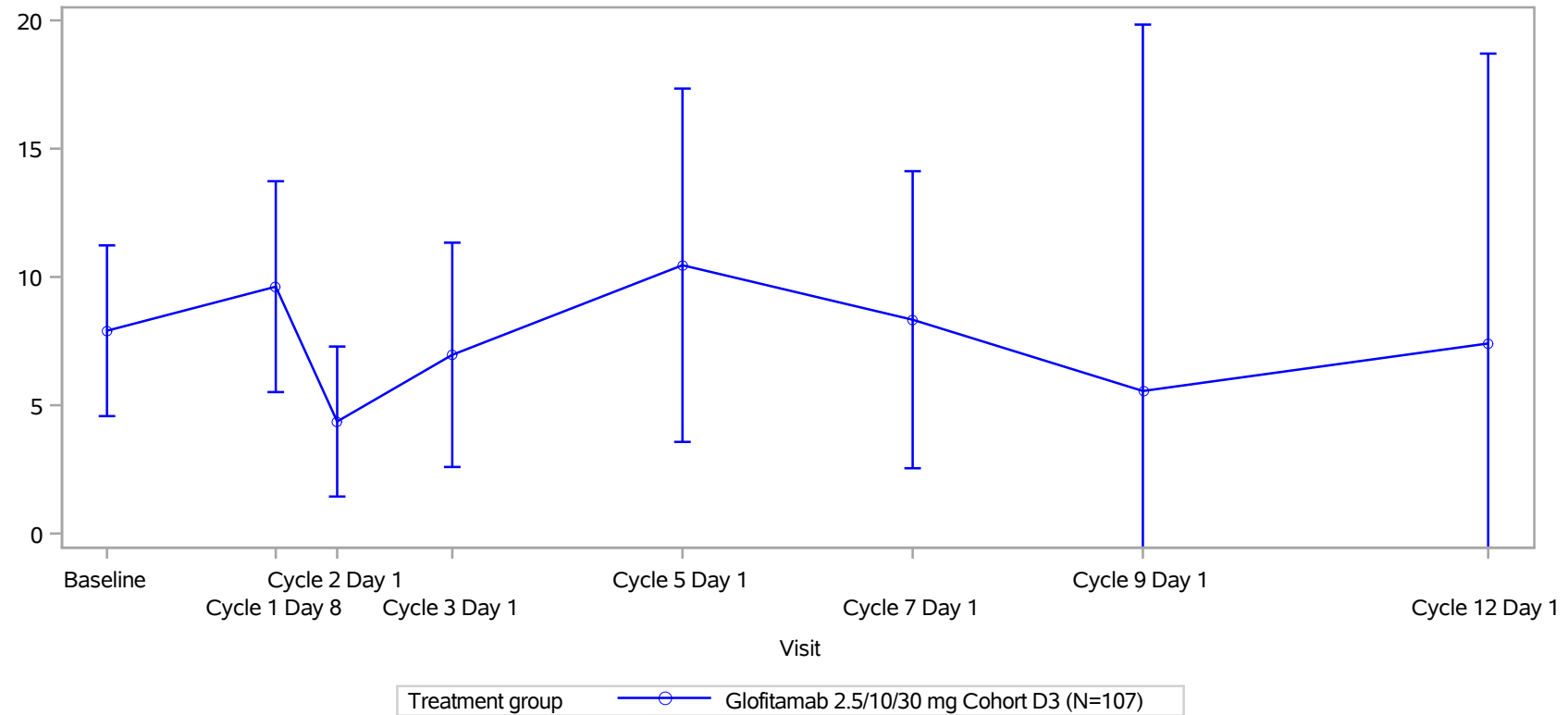
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D3_C30DI.xls

27FEB2023 9:57

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Diarrhoea
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D3_C30DI.pdf
27FEB2023 10:07

POPULATION: Cohort D3 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Diarrhoea (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab 2.5/10/30 mg Cohort D3 (N=92)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	92	100.0	16	17.4	11.0	26.4

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D3_M10C30DI.xls
 27FEB2023 10:18

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Dyspnoea

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab 2.5/10/30 mg Cohort D3 (N=107)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	107	100.0	97	90.7	19.93	25.76
Cycle 1 Day 8	n/a	101	94.4	97	96.0	17.18	25.51
Cycle 2 Day 1	n/a	90	84.1	84	93.3	17.86	24.51
Cycle 3 Day 1	n/a	75	70.1	67	89.3	14.93	23.42
Cycle 5 Day 1	n/a	57	53.3	51	89.5	14.38	21.35
Cycle 7 Day 1	n/a	41	38.3	40	97.6	13.33	18.18
Cycle 9 Day 1	n/a	28	26.2	6	21.4	11.11	17.21
Cycle 12 Day 1	n/a	27	25.2	9	33.3	11.11	16.67

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

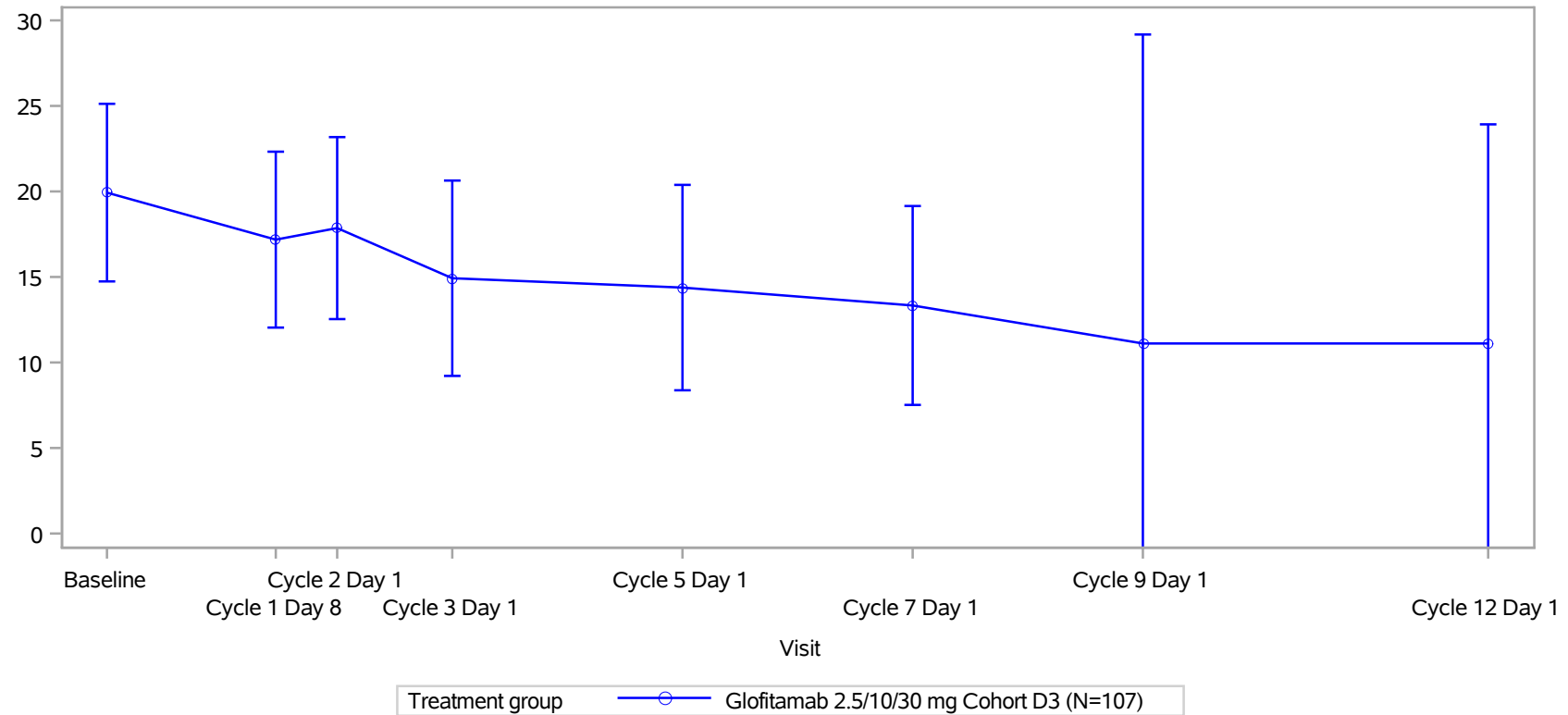
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D3_C30DY.xls

27FEB2023 9:56

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Dyspnoea
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D3_C30DY.pdf
27FEB2023 10:06

POPULATION: Cohort D3 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Dyspnoea (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab 2.5/10/30 mg Cohort D3 (N=92)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	92	100.0	21	22.8	15.4	32.4

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D3_M10C30DY.xls
 27FEB2023 10:17

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Fatigue

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab 2.5/10/30 mg Cohort D3 (N=107)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	107	100.0	97	90.7	37.11	25.82
Cycle 1 Day 8	n/a	101	94.4	98	97.0	36.68	27.18
Cycle 2 Day 1	n/a	90	84.1	84	93.3	36.77	23.52
Cycle 3 Day 1	n/a	75	70.1	67	89.3	33.25	21.76
Cycle 5 Day 1	n/a	57	53.3	51	89.5	29.85	19.69
Cycle 7 Day 1	n/a	41	38.3	39	95.1	25.64	21.35
Cycle 9 Day 1	n/a	28	26.2	6	21.4	20.37	16.36
Cycle 12 Day 1	n/a	27	25.2	9	33.3	32.10	31.15

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

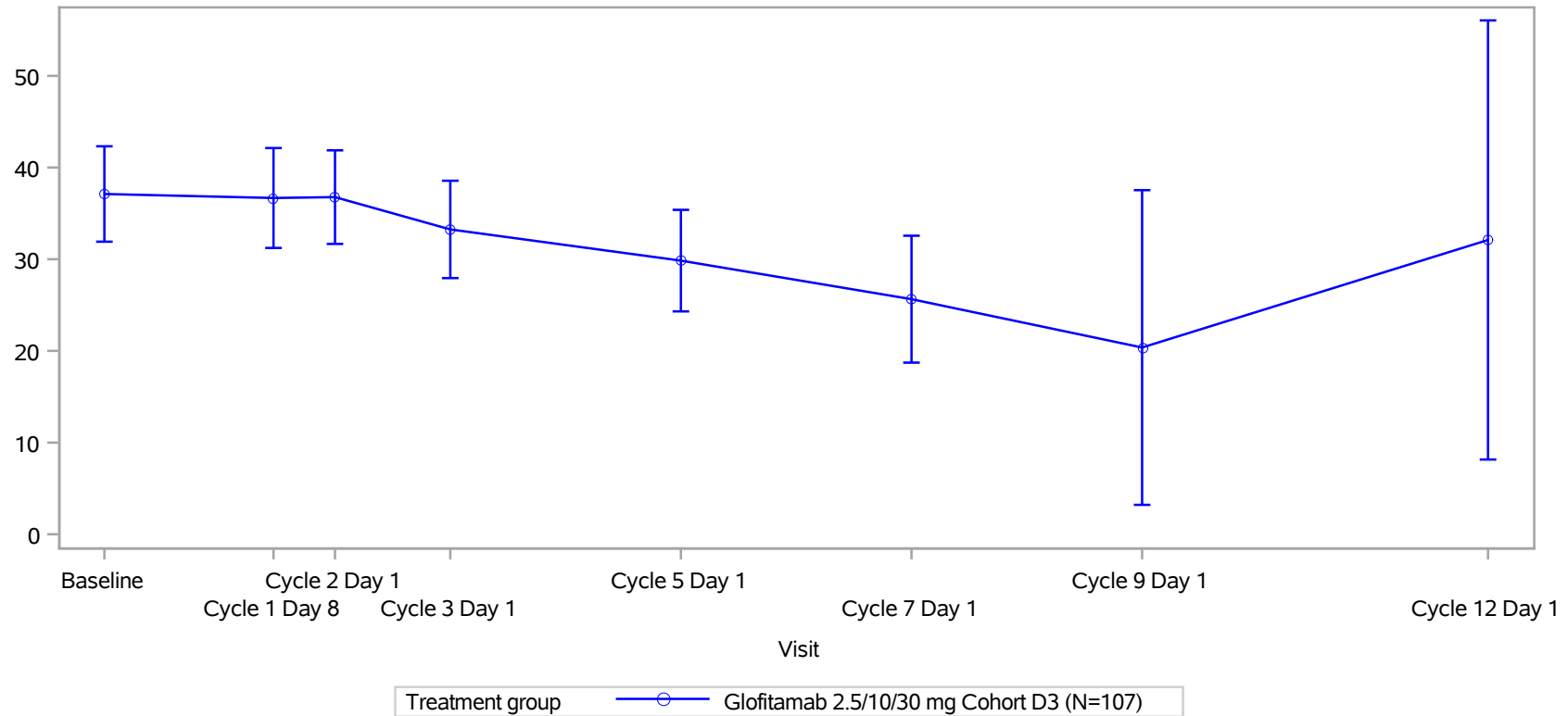
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D3_C30FA.xls

27FEB2023 10:05

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Fatigue
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D3_C30FA.pdf
27FEB2023 10:16

POPULATION: Cohort D3 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Fatigue (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab 2.5/10/30 mg Cohort D3 (N=92)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	92	100.0	48	52.2	42.1	62.1

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D3_M10C30FA.xls
 27FEB2023 10:27

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Nausea/Vomiting

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab 2.5/10/30 mg Cohort D3 (N=107)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	107	100.0	97	90.7	3.09	9.72
Cycle 1 Day 8	n/a	101	94.4	98	97.0	5.61	16.22
Cycle 2 Day 1	n/a	90	84.1	84	93.3	4.37	10.06
Cycle 3 Day 1	n/a	75	70.1	67	89.3	4.23	10.60
Cycle 5 Day 1	n/a	57	53.3	51	89.5	3.27	10.55
Cycle 7 Day 1	n/a	41	38.3	40	97.6	0.42	2.64
Cycle 9 Day 1	n/a	28	26.2	6	21.4	0.00	0.00
Cycle 12 Day 1	n/a	27	25.2	9	33.3	1.85	5.56

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

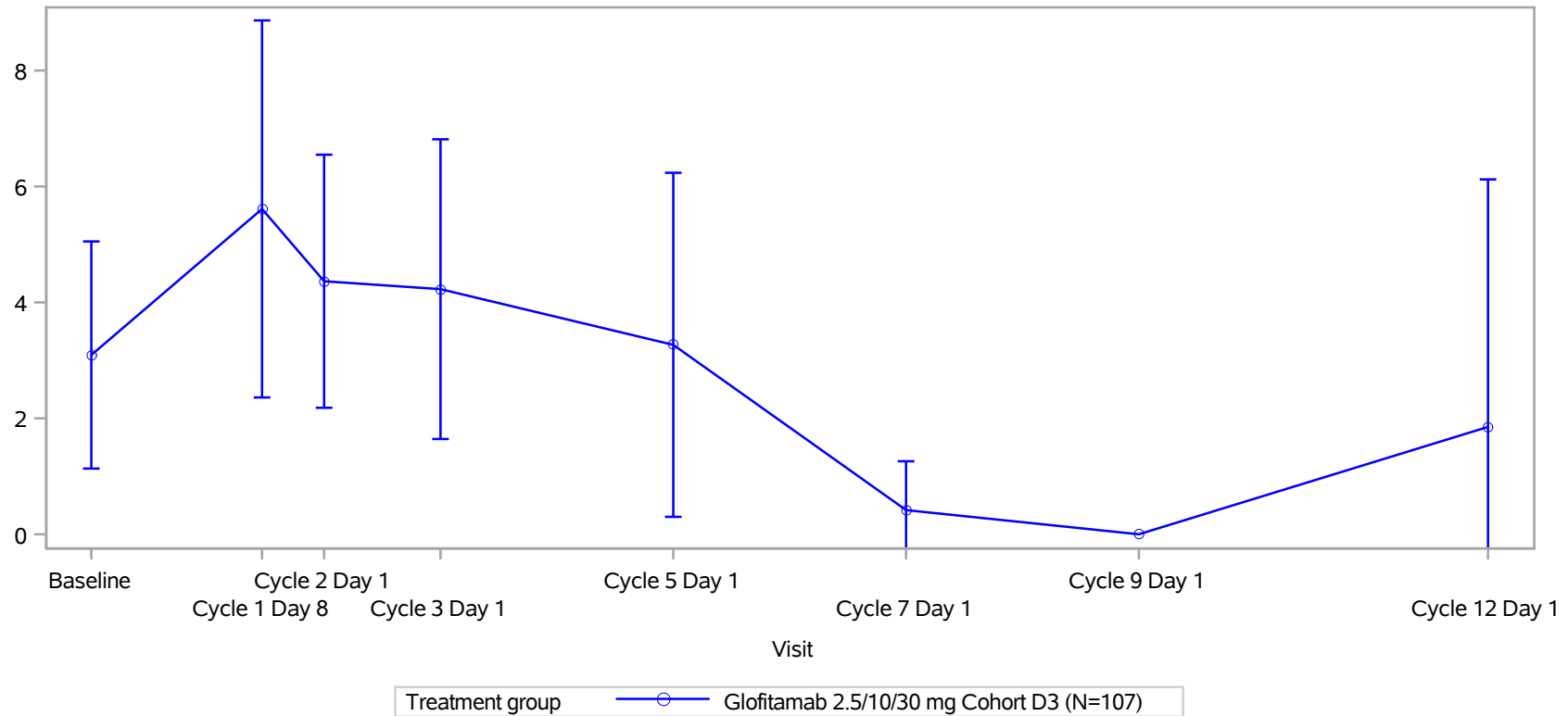
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D3_C30NV.xls

27FEB2023 9:55

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Nausea/Vomiting
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D3_C30NV.pdf
27FEB2023 10:06

POPULATION: Cohort D3 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Nausea/Vomiting (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab 2.5/10/30 mg Cohort D3 (N=92)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	92	100.0	27	29.3	21.0	39.3

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D3_M10C30NV.xls
 27FEB2023 10:17

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Pain

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab 2.5/10/30 mg Cohort D3 (N=107)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	107	100.0	97	90.7	30.41	27.64
Cycle 1 Day 8	n/a	101	94.4	98	97.0	26.87	26.07
Cycle 2 Day 1	n/a	90	84.1	84	93.3	23.41	28.71
Cycle 3 Day 1	n/a	75	70.1	67	89.3	19.65	25.28
Cycle 5 Day 1	n/a	57	53.3	51	89.5	18.30	20.62
Cycle 7 Day 1	n/a	41	38.3	38	92.7	16.23	19.56
Cycle 9 Day 1	n/a	28	26.2	6	21.4	8.33	13.94
Cycle 12 Day 1	n/a	27	25.2	9	33.3	18.52	32.75

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

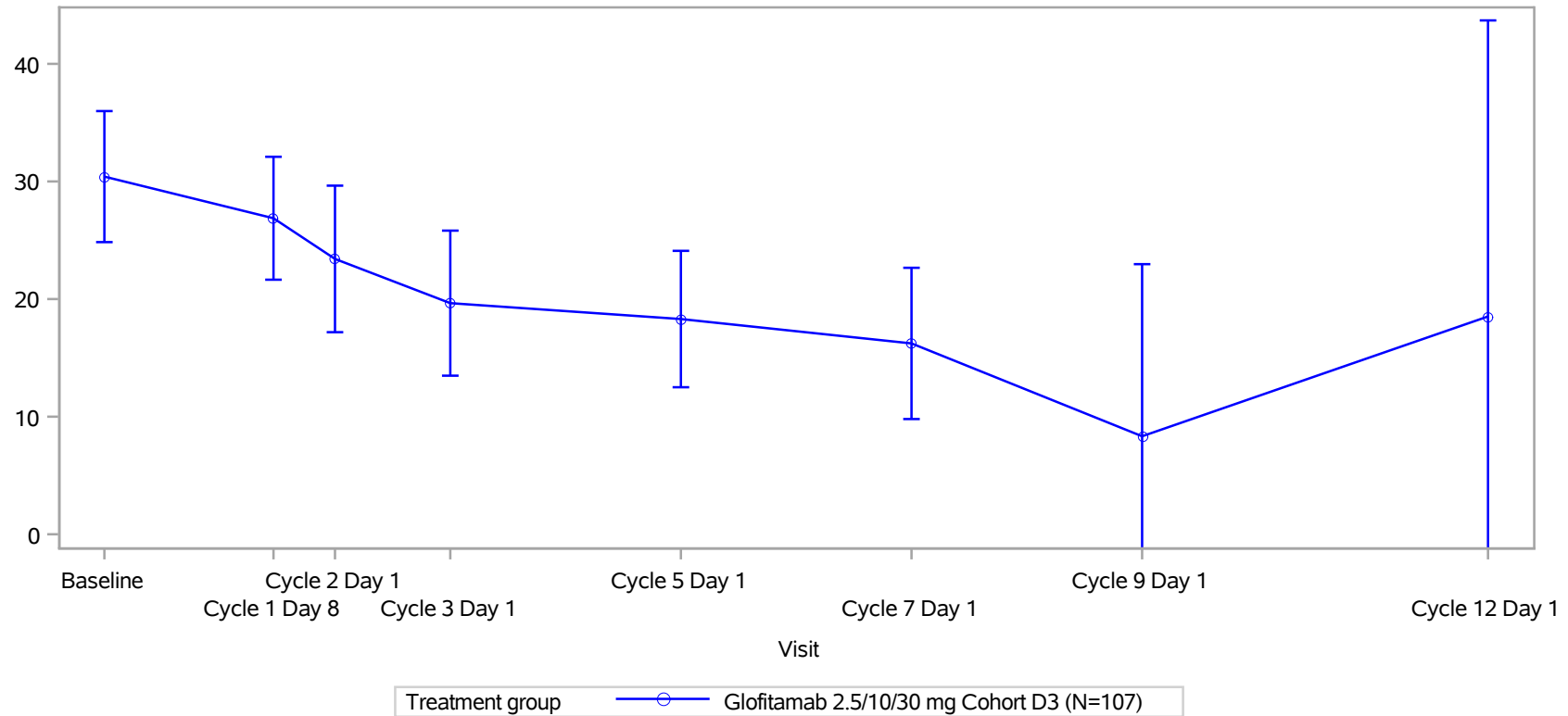
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D3_C30PA.xls

27FEB2023 9:59

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Pain
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D3_C30PA.pdf
27FEB2023 10:11

POPULATION: Cohort D3 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Pain (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab 2.5/10/30 mg Cohort D3 (N=92)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	92	100.0	43	46.7	36.9	56.9

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D3_M10C30PA.xls
 27FEB2023 10:22

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Insomnia

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab 2.5/10/30 mg Cohort D3 (N=107)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	107	100.0	96	89.7	30.21	31.37
Cycle 1 Day 8	n/a	101	94.4	98	97.0	28.57	27.91
Cycle 2 Day 1	n/a	90	84.1	83	92.2	29.32	29.63
Cycle 3 Day 1	n/a	75	70.1	66	88.0	24.24	30.69
Cycle 5 Day 1	n/a	57	53.3	51	89.5	28.10	30.09
Cycle 7 Day 1	n/a	41	38.3	39	95.1	24.79	26.18
Cycle 9 Day 1	n/a	28	26.2	6	21.4	11.11	17.21
Cycle 12 Day 1	n/a	27	25.2	9	33.3	18.52	24.22

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

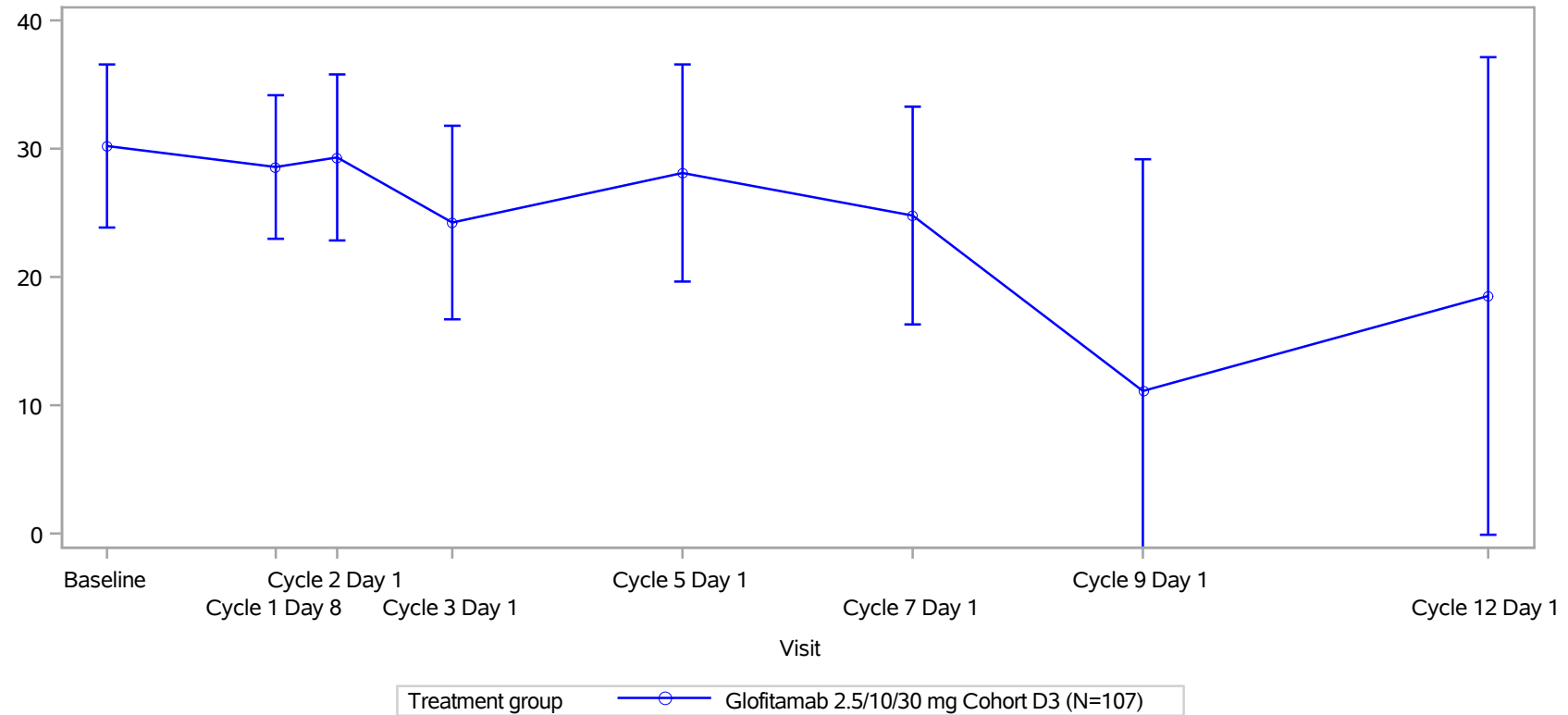
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D3_C30SL.xls

27FEB2023 10:04

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Insomnia
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D3_C30SL.pdf
27FEB2023 10:15

POPULATION: Cohort D3 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Insomnia (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab 2.5/10/30 mg Cohort D3 (N=92)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	91	98.9	31	33.7	24.9	43.8

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D3_M10C30SL.xls
 27FEB2023 10:26

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Cognitive Functioning

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab 2.5/10/30 mg Cohort D3 (N=107)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	107	100.0	97	90.7	85.74	21.65
Cycle 1 Day 8	n/a	101	94.4	98	97.0	89.63	17.01
Cycle 2 Day 1	n/a	90	84.1	84	93.3	88.10	18.76
Cycle 3 Day 1	n/a	75	70.1	67	89.3	88.06	16.10
Cycle 5 Day 1	n/a	57	53.3	51	89.5	88.24	15.74
Cycle 7 Day 1	n/a	41	38.3	40	97.6	86.67	16.54
Cycle 9 Day 1	n/a	28	26.2	6	21.4	88.89	17.21
Cycle 12 Day 1	n/a	27	25.2	9	33.3	83.33	26.35

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

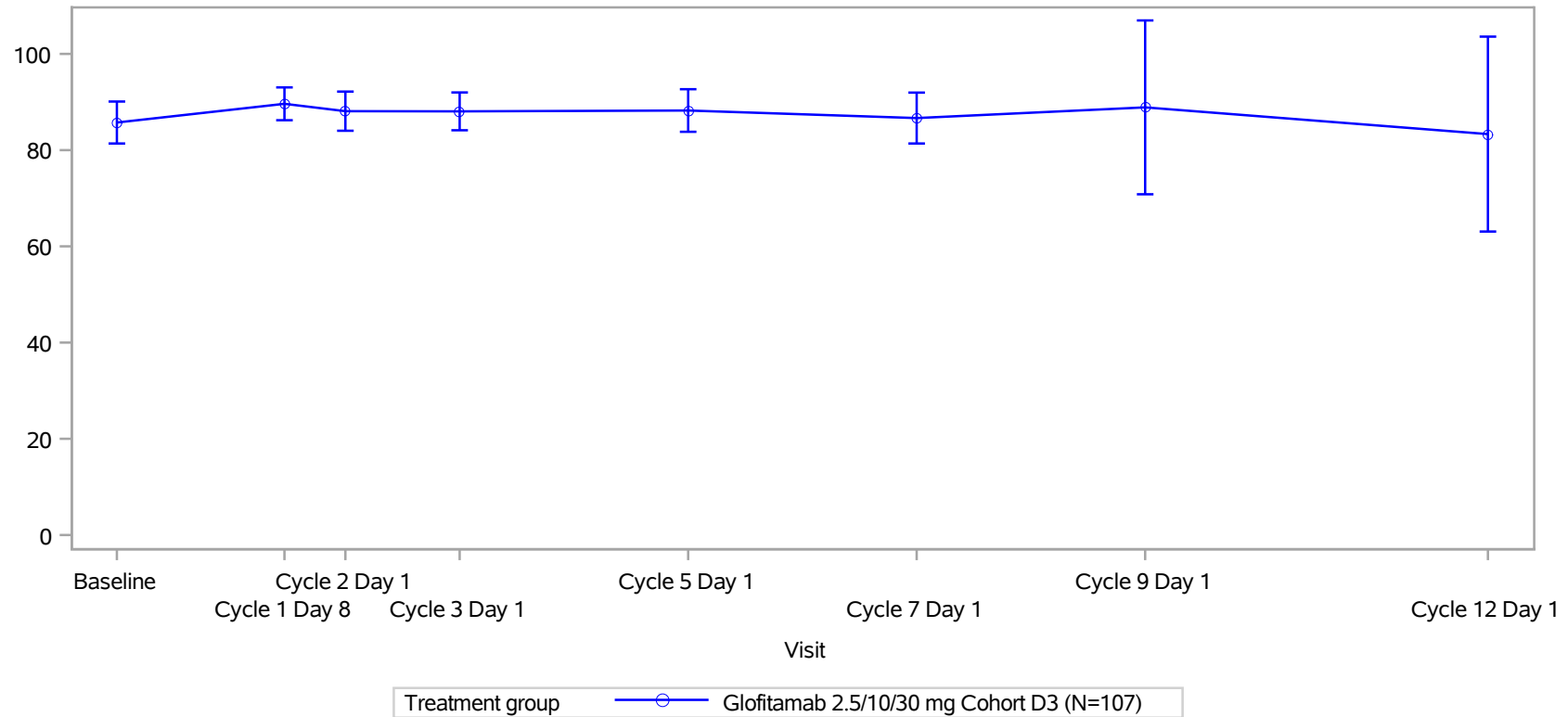
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D3_C30CF.xls

27FEB2023 10:02

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Cognitive Functioning
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D3_C30CF.pdf
27FEB2023 10:13

POPULATION: Cohort D3 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Cognitive Functioning (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab 2.5/10/30 mg Cohort D3 (N=92)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	92	100.0	32	34.8	25.8	44.9

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D3_M10C30CF.xls
 27FEB2023 10:25

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Emotional Functioning

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab 2.5/10/30 mg Cohort D3 (N=107)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	107	100.0	97	90.7	75.26	21.95
Cycle 1 Day 8	n/a	101	94.4	98	97.0	78.54	20.78
Cycle 2 Day 1	n/a	90	84.1	84	93.3	78.77	22.29
Cycle 3 Day 1	n/a	75	70.1	66	88.0	79.29	20.32
Cycle 5 Day 1	n/a	57	53.3	51	89.5	81.37	16.96
Cycle 7 Day 1	n/a	41	38.3	40	97.6	77.71	22.75
Cycle 9 Day 1	n/a	28	26.2	6	21.4	86.11	15.52
Cycle 12 Day 1	n/a	27	25.2	9	33.3	75.93	30.74

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

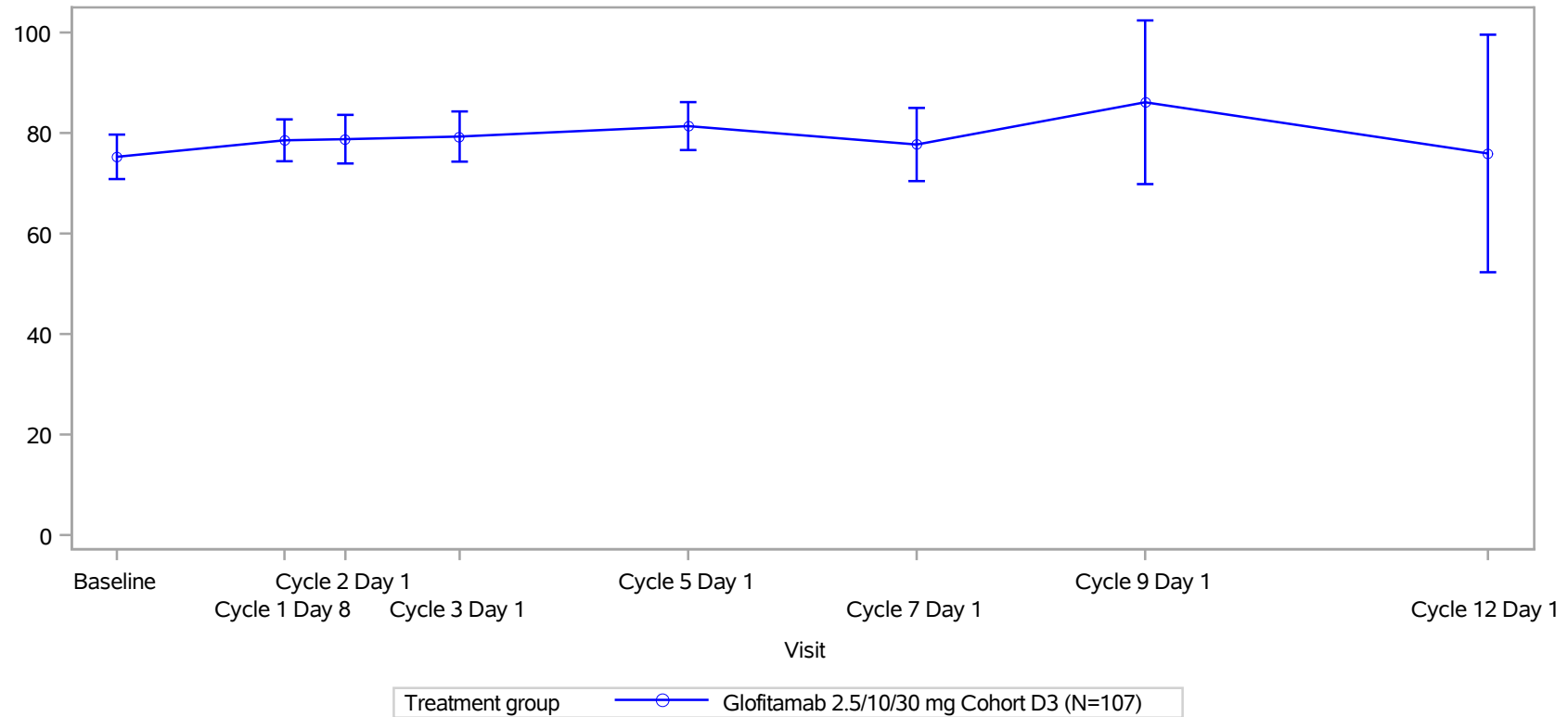
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D3_C30EF.xls

27FEB2023 10:02

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Emotional Functioning
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D3_C30EF.pdf
27FEB2023 10:13

POPULATION: Cohort D3 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Emotional Functioning (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab 2.5/10/30 mg Cohort D3 (N=92)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	92	100.0	21	22.8	15.4	32.4

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D3_M10C30EF.xls
 27FEB2023 10:24

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Physical Functioning

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab 2.5/10/30 mg Cohort D3 (N=107)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	107	100.0	97	90.7	77.11	21.56
Cycle 1 Day 8	n/a	101	94.4	98	97.0	76.77	21.13
Cycle 2 Day 1	n/a	90	84.1	84	93.3	78.19	19.03
Cycle 3 Day 1	n/a	75	70.1	67	89.3	79.28	20.88
Cycle 5 Day 1	n/a	57	53.3	51	89.5	84.05	17.03
Cycle 7 Day 1	n/a	41	38.3	40	97.6	86.12	16.08
Cycle 9 Day 1	n/a	28	26.2	6	21.4	91.11	8.07
Cycle 12 Day 1	n/a	27	25.2	9	33.3	83.70	21.63

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

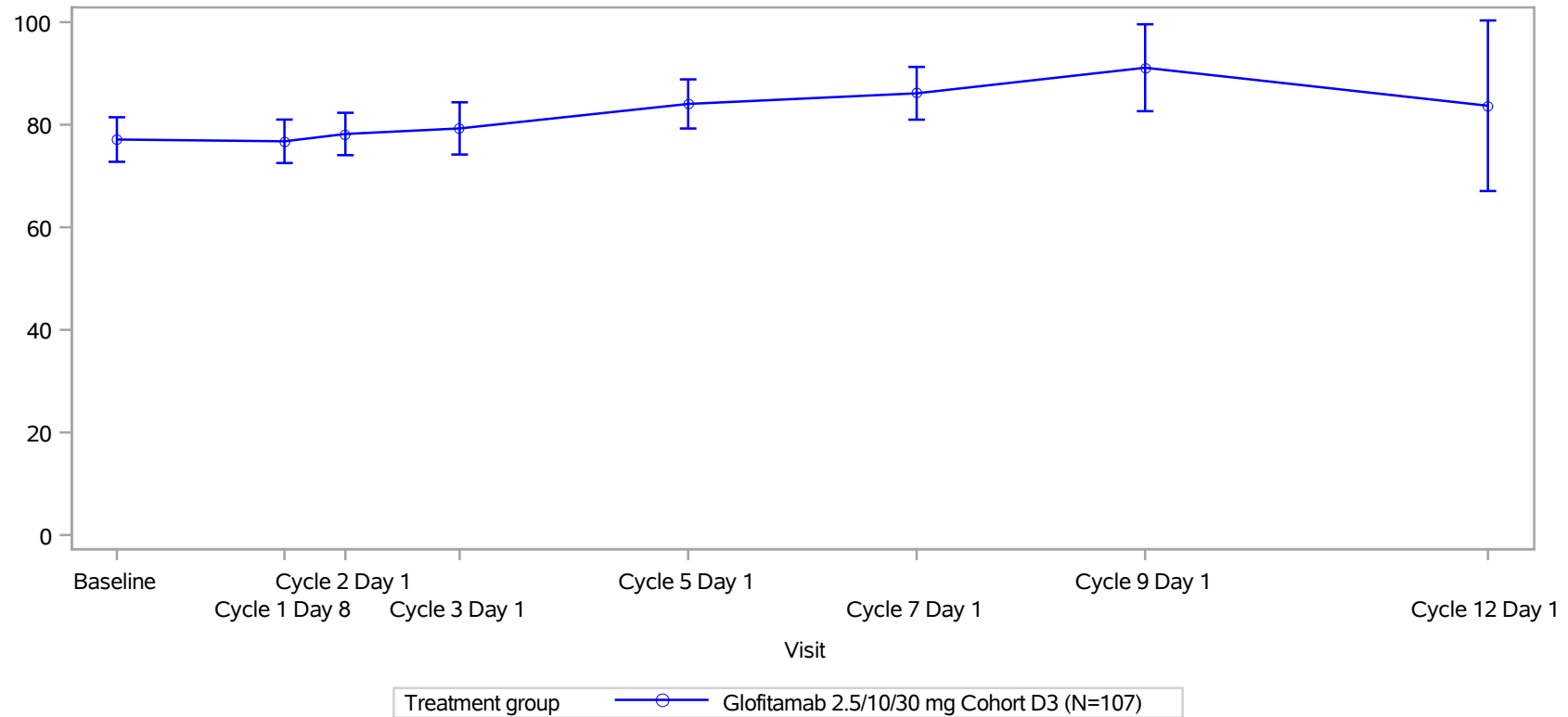
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D3_C30PF.xls

27FEB2023 9:59

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Physical Functioning
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D3_C30PF.pdf
27FEB2023 10:10

POPULATION: Cohort D3 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Physical Functioning (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab 2.5/10/30 mg Cohort D3 (N=92)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	92	100.0	32	34.8	25.8	44.9

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D3_M10C30PF.xls
 27FEB2023 10:21

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Global Health Status

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab 2.5/10/30 mg Cohort D3 (N=107)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	107	100.0	97	90.7	57.73	23.39
Cycle 1 Day 8	n/a	101	94.4	98	97.0	59.01	21.26
Cycle 2 Day 1	n/a	90	84.1	84	93.3	61.61	19.58
Cycle 3 Day 1	n/a	75	70.1	66	88.0	62.63	19.84
Cycle 5 Day 1	n/a	57	53.3	51	89.5	65.36	17.19
Cycle 7 Day 1	n/a	41	38.3	39	95.1	66.03	22.00
Cycle 9 Day 1	n/a	28	26.2	6	21.4	70.83	24.58
Cycle 12 Day 1	n/a	27	25.2	9	33.3	62.96	25.72

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

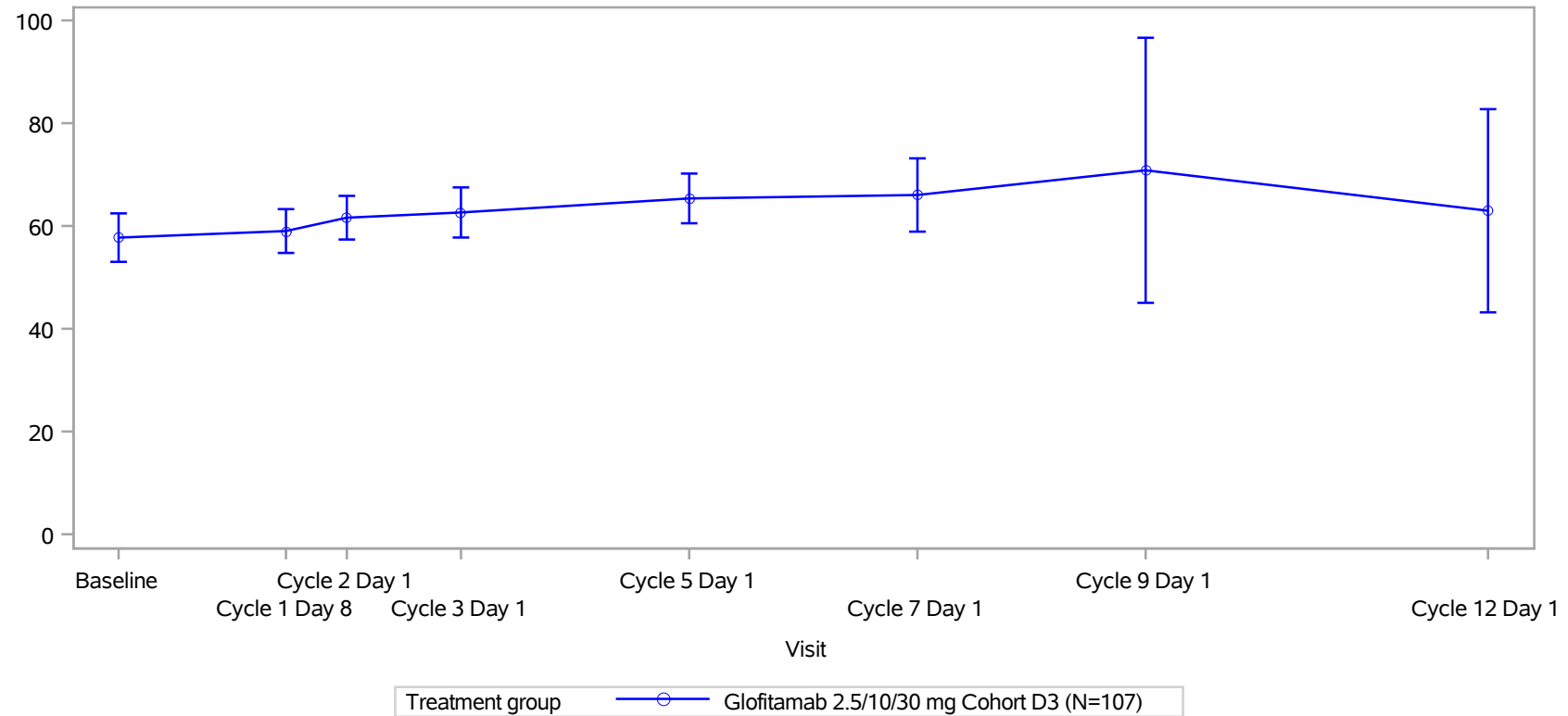
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D3_C30QL.xls

27FEB2023 9:58

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Global Health Status
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D3_C30QL.pdf
27FEB2023 10:09

POPULATION: Cohort D3 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Global Health Status (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab 2.5/10/30 mg Cohort D3 (N=92)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	92	100.0	34	37.0	27.8	47.2

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D3_M10C30QL.xls
 27FEB2023 10:20

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Role Functioning

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab 2.5/10/30 mg Cohort D3 (N=107)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	107	100.0	97	90.7	74.23	28.36
Cycle 1 Day 8	n/a	101	94.4	98	97.0	71.77	28.16
Cycle 2 Day 1	n/a	90	84.1	84	93.3	74.01	28.26
Cycle 3 Day 1	n/a	75	70.1	67	89.3	78.11	26.62
Cycle 5 Day 1	n/a	57	53.3	50	87.7	85.00	19.12
Cycle 7 Day 1	n/a	41	38.3	40	97.6	82.50	25.02
Cycle 9 Day 1	n/a	28	26.2	6	21.4	88.89	17.21
Cycle 12 Day 1	n/a	27	25.2	9	33.3	87.04	28.60

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

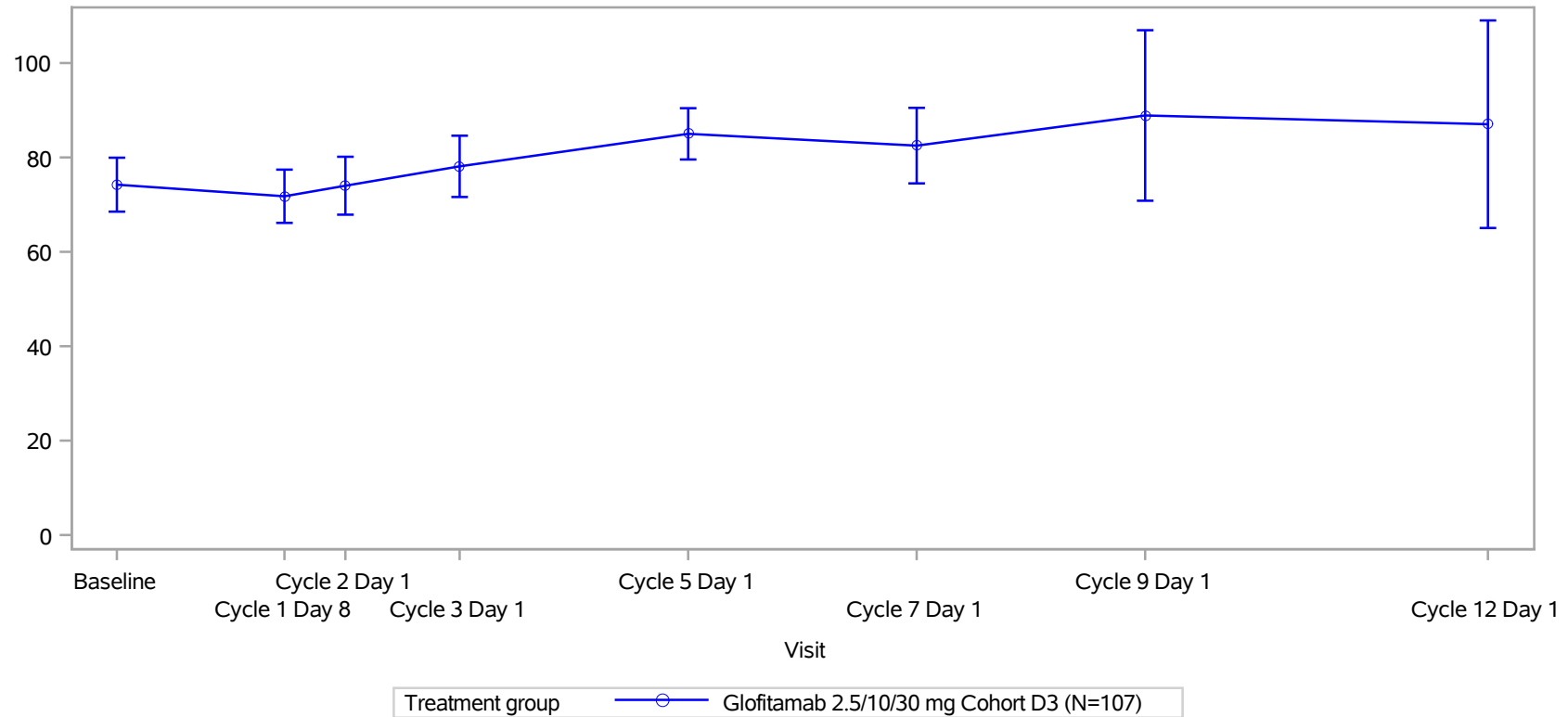
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D3_C30RF.xls

27FEB2023 10:01

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Role Functioning
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D3_C30RF.pdf
27FEB2023 10:12

POPULATION: Cohort D3 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Role Functioning (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab 2.5/10/30 mg Cohort D3 (N=92)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	92	100.0	44	47.8	37.9	57.9

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D3_M10C30RF.xls
 27FEB2023 10:23

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Social Functioning

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab 2.5/10/30 mg Cohort D3 (N=107)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	107	100.0	97	90.7	78.01	27.59
Cycle 1 Day 8	n/a	101	94.4	98	97.0	78.06	26.17
Cycle 2 Day 1	n/a	90	84.1	84	93.3	79.17	27.61
Cycle 3 Day 1	n/a	75	70.1	67	89.3	79.85	25.71
Cycle 5 Day 1	n/a	57	53.3	51	89.5	85.62	20.28
Cycle 7 Day 1	n/a	41	38.3	40	97.6	82.50	26.94
Cycle 9 Day 1	n/a	28	26.2	6	21.4	97.22	6.80
Cycle 12 Day 1	n/a	27	25.2	9	33.3	83.33	33.33

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

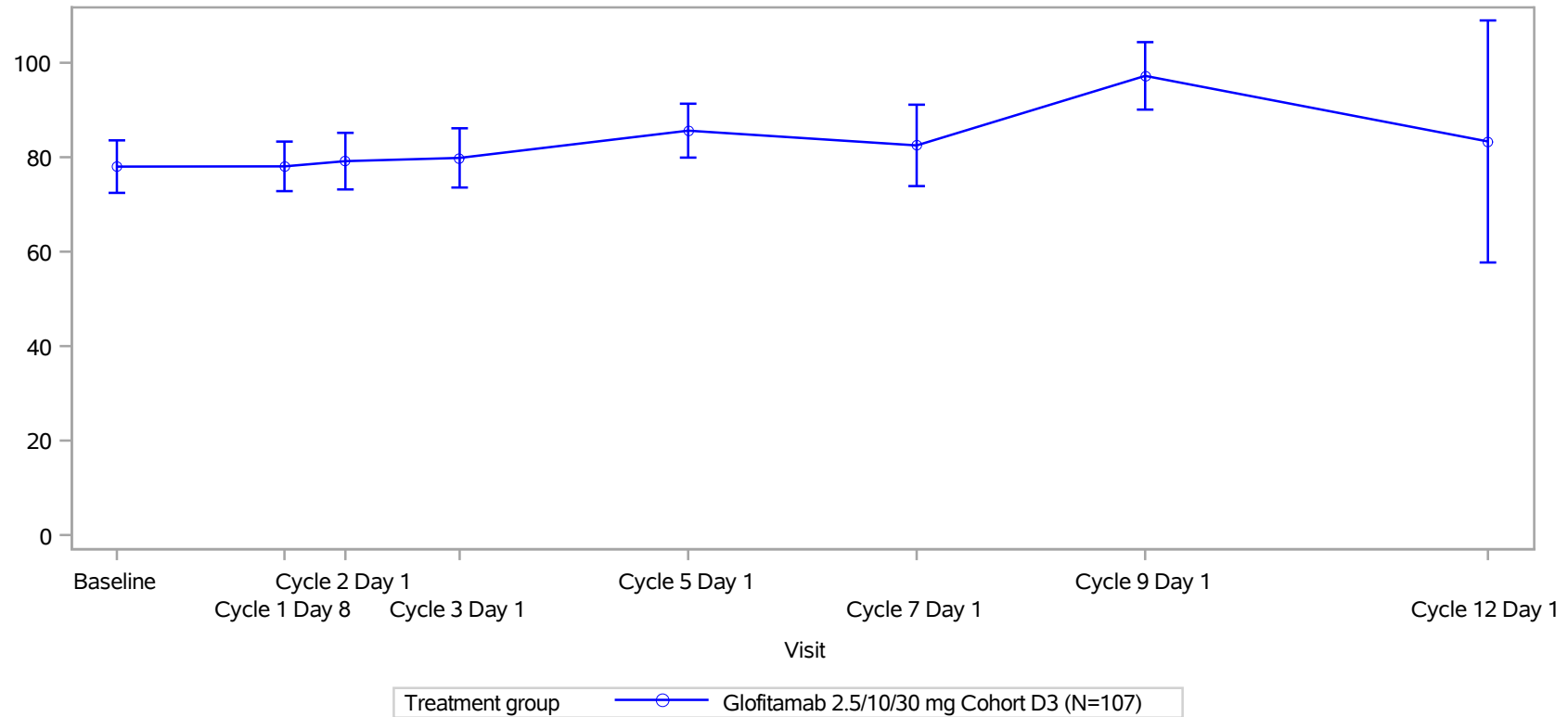
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D3_C30SF.xls

27FEB2023 10:03

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Social Functioning
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D3_C30SF.pdf
27FEB2023 10:14

POPULATION: Cohort D3 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Social Functioning (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab 2.5/10/30 mg Cohort D3 (N=92)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	92	100.0	37	40.2	30.8	50.4

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D3_M10C30SF.xls
 27FEB2023 10:26

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: FACT-Lym Subscale Score

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab 2.5/10/30 mg Cohort D3 (N=107)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	107	100.0	96	89.7	12.41	9.35
Cycle 1 Day 8	n/a	101	94.4	98	97.0	13.39	8.93
Cycle 2 Day 1	n/a	90	84.1	82	91.1	12.36	9.01
Cycle 3 Day 1	n/a	75	70.1	67	89.3	10.89	8.01
Cycle 5 Day 1	n/a	57	53.3	51	89.5	10.24	7.59
Cycle 7 Day 1	n/a	41	38.3	38	92.7	10.53	8.20
Cycle 9 Day 1	n/a	28	26.2	6	21.4	5.50	4.32
Cycle 12 Day 1	n/a	27	25.2	9	33.3	10.97	13.28

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

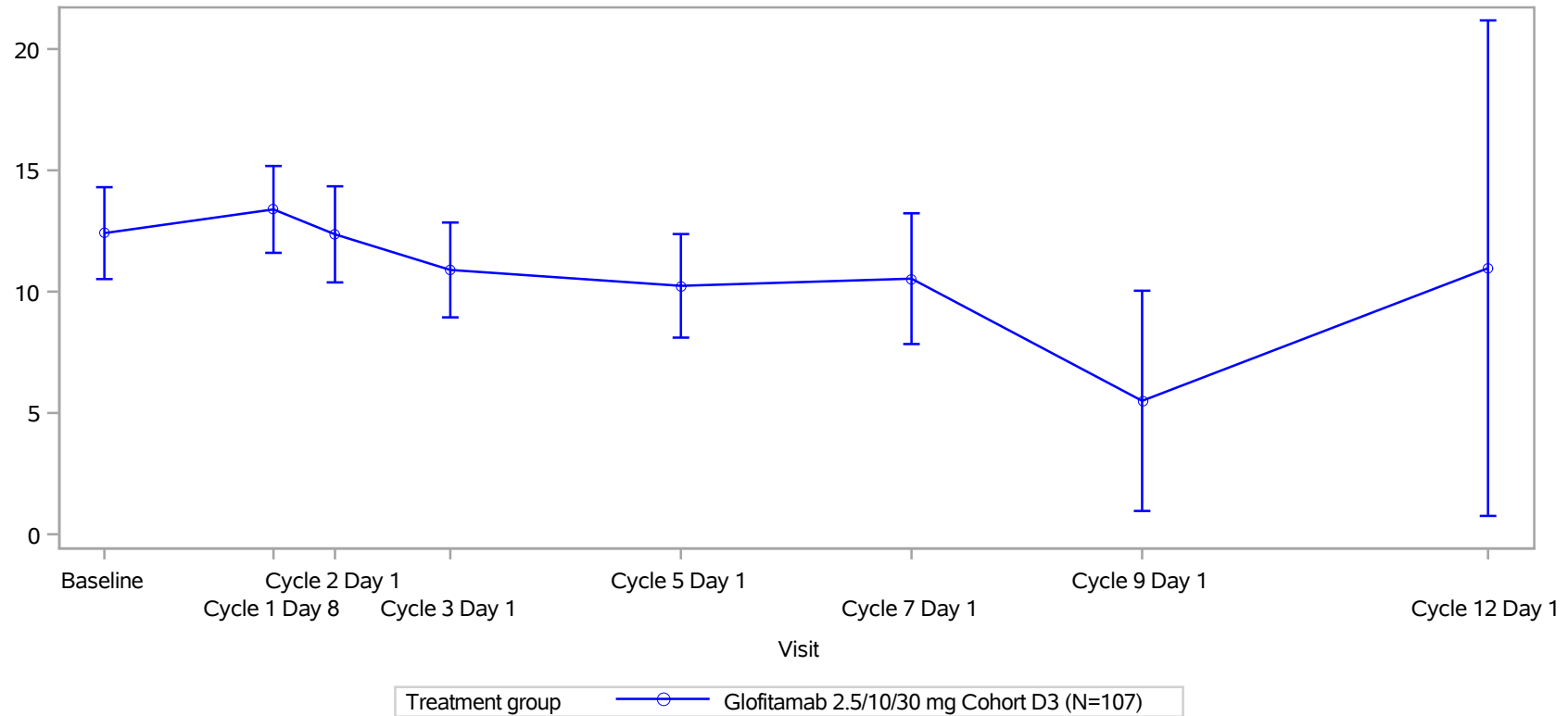
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D3_FLYM.xls

27FEB2023 10:04

POPULATION: Cohort D3 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: FACT-Lym Subscale Score
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D3_FLYM.pdf
27FEB2023 10:15

POPULATION: Cohort D3 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: FACT-Lym Subscale Score (MID 3, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab 2.5/10/30 mg Cohort D3 (N=92)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	90	97.8	52	56.5	46.3	66.2

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D3_M3FLYM.xls

27FEB2023 10:28

POPULATION: Cohort D3 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: FACT-Lym Subscale Score (MID 9, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab 2.5/10/30 mg Cohort D3 (N=92)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	90	97.8	16	17.4	11.0	26.4

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D3_M9FLYM.xls

27FEB2023 10:28

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: Any AEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	113	99.1	95.2	99.8

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_AEANY.xls

01MAR2023 8:25

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: Any AEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
Name	SOC	PT	Level	Patients		Patients with Event			
				n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	114	100.0	61	53.5	44.4	62.4
		Anaemia	n/a	114	100.0	35	30.7	23.0	39.7
		Anaemia of malignant disease	n/a	114	100.0	1	0.9	0.2	4.8
		Febrile neutropenia	n/a	114	100.0	4	3.5	1.4	8.7
		Iron deficiency anaemia	n/a	114	100.0	1	0.9	0.2	4.8
		Leukocytosis	n/a	114	100.0	1	0.9	0.2	4.8
		Lymphopenia	n/a	114	100.0	4	3.5	1.4	8.7
		Monocytosis	n/a	114	100.0	1	0.9	0.2	4.8
		Neutropenia	n/a	114	100.0	43	37.7	29.4	46.9
		Polycythaemia	n/a	114	100.0	1	0.9	0.2	4.8
		Thrombocytopenia	n/a	114	100.0	25	21.9	15.3	30.4
	Cardiac disorders	-Total	n/a	114	100.0	11	9.6	5.5	16.5
		Atrial fibrillation	n/a	114	100.0	3	2.6	0.9	7.5
		Cardiac failure	n/a	114	100.0	1	0.9	0.2	4.8
		Sinus bradycardia	n/a	114	100.0	1	0.9	0.2	4.8
		Sinus node dysfunction	n/a	114	100.0	1	0.9	0.2	4.8
		Sinus tachycardia	n/a	114	100.0	1	0.9	0.2	4.8

		Tachycardia	n/a	114	100.0	4	3.5	1.4	8.7
		Ventricular extrasystoles	n/a	114	100.0	1	0.9	0.2	4.8
	Ear and labyrinth disorders	-Total	n/a	114	100.0	2	1.8	0.5	6.2
		Ear congestion	n/a	114	100.0	1	0.9	0.2	4.8
		Ear pain	n/a	114	100.0	1	0.9	0.2	4.8
		Vertigo	n/a	114	100.0	1	0.9	0.2	4.8
	Endocrine disorders	-Total	n/a	114	100.0	1	0.9	0.2	4.8
		Hypothyroidism	n/a	114	100.0	1	0.9	0.2	4.8
	Eye disorders	-Total	n/a	114	100.0	4	3.5	1.4	8.7
		Conjunctival haemorrhage	n/a	114	100.0	1	0.9	0.2	4.8
		Conjunctivitis allergic	n/a	114	100.0	1	0.9	0.2	4.8
		Eye pain	n/a	114	100.0	1	0.9	0.2	4.8
		Periorbital pain	n/a	114	100.0	1	0.9	0.2	4.8
		Periorbital swelling	n/a	114	100.0	1	0.9	0.2	4.8
	Gastrointestinal disorders	-Total	n/a	114	100.0	54	47.4	38.4	56.5
		Abdominal discomfort	n/a	114	100.0	2	1.8	0.5	6.2
		Abdominal distension	n/a	114	100.0	1	0.9	0.2	4.8
		Abdominal pain	n/a	114	100.0	10	8.8	4.8	15.4
		Abdominal pain upper	n/a	114	100.0	1	0.9	0.2	4.8
		Anorectal discomfort	n/a	114	100.0	1	0.9	0.2	4.8
		Ascites	n/a	114	100.0	1	0.9	0.2	4.8
		Colitis	n/a	114	100.0	1	0.9	0.2	4.8
		Constipation	n/a	114	100.0	13	11.4	6.8	18.5
		Dental caries	n/a	114	100.0	1	0.9	0.2	4.8

		Diarrhoea	n/a	114	100.0	14	12.3	7.5	19.6
		Dry mouth	n/a	114	100.0	1	0.9	0.2	4.8
		Dyspepsia	n/a	114	100.0	1	0.9	0.2	4.8
		Dysphagia	n/a	114	100.0	1	0.9	0.2	4.8
		Faeces discoloured	n/a	114	100.0	1	0.9	0.2	4.8
		Gastric haemorrhage	n/a	114	100.0	1	0.9	0.2	4.8
		Gastritis	n/a	114	100.0	1	0.9	0.2	4.8
		Gastrointestinal haemorrhage	n/a	114	100.0	2	1.8	0.5	6.2
		Haemorrhoids	n/a	114	100.0	1	0.9	0.2	4.8
		Intestinal perforation	n/a	114	100.0	1	0.9	0.2	4.8
		Large intestinal haemorrhage	n/a	114	100.0	1	0.9	0.2	4.8
		Nausea	n/a	114	100.0	12	10.5	6.1	17.5
		Stomatitis	n/a	114	100.0	1	0.9	0.2	4.8
		Toothache	n/a	114	100.0	3	2.6	0.9	7.5
		Umbilical hernia	n/a	114	100.0	1	0.9	0.2	4.8
		Vomiting	n/a	114	100.0	5	4.4	1.9	9.9
	General disorders and administration site conditions	-Total	n/a	114	100.0	50	43.9	35.1	53.0
		Asthenia	n/a	114	100.0	8	7.0	3.6	13.2
		Catheter site pain	n/a	114	100.0	1	0.9	0.2	4.8
		Catheter site pruritus	n/a	114	100.0	1	0.9	0.2	4.8
		Chest discomfort	n/a	114	100.0	1	0.9	0.2	4.8
		Chills	n/a	114	100.0	1	0.9	0.2	4.8
		Facial pain	n/a	114	100.0	1	0.9	0.2	4.8

		Appendicitis	n/a	114	100.0	1	0.9	0.2	4.8
		Bacterial infection	n/a	114	100.0	1	0.9	0.2	4.8
		Biliary tract infection bacterial	n/a	114	100.0	1	0.9	0.2	4.8
		Bronchitis	n/a	114	100.0	3	2.6	0.9	7.5
		COVID-19	n/a	114	100.0	8	7.0	3.6	13.2
		COVID-19 pneumonia	n/a	114	100.0	5	4.4	1.9	9.9
		Campylobacter infection	n/a	114	100.0	1	0.9	0.2	4.8
		Chronic sinusitis	n/a	114	100.0	1	0.9	0.2	4.8
		Clostridium difficile infection	n/a	114	100.0	2	1.8	0.5	6.2
		Escherichia infection	n/a	114	100.0	2	1.8	0.5	6.2
		Gastroenteritis	n/a	114	100.0	1	0.9	0.2	4.8
		Herpes zoster	n/a	114	100.0	2	1.8	0.5	6.2
		Infection	n/a	114	100.0	1	0.9	0.2	4.8
		Localised infection	n/a	114	100.0	1	0.9	0.2	4.8
		Myelitis	n/a	114	100.0	1	0.9	0.2	4.8
		Nasopharyngitis	n/a	114	100.0	2	1.8	0.5	6.2
		Neutropenic infection	n/a	114	100.0	1	0.9	0.2	4.8
		Oesophageal candidiasis	n/a	114	100.0	1	0.9	0.2	4.8
		Ophthalmic herpes zoster	n/a	114	100.0	1	0.9	0.2	4.8
		Paronychia	n/a	114	100.0	1	0.9	0.2	4.8
		Periodontitis	n/a	114	100.0	1	0.9	0.2	4.8
		Peritonitis	n/a	114	100.0	1	0.9	0.2	4.8

		Pneumococcal infection	n/a	114	100.0	1	0.9	0.2	4.8
		Pneumonia	n/a	114	100.0	6	5.3	2.4	11.0
		Respiratory tract infection	n/a	114	100.0	2	1.8	0.5	6.2
		Rhinitis	n/a	114	100.0	2	1.8	0.5	6.2
		Sepsis	n/a	114	100.0	6	5.3	2.4	11.0
		Sinusitis	n/a	114	100.0	3	2.6	0.9	7.5
		Tooth infection	n/a	114	100.0	2	1.8	0.5	6.2
		Upper respiratory tract infection	n/a	114	100.0	2	1.8	0.5	6.2
		Urinary tract infection	n/a	114	100.0	2	1.8	0.5	6.2
		Urinary tract infection bacterial	n/a	114	100.0	1	0.9	0.2	4.8
		Vascular device infection	n/a	114	100.0	3	2.6	0.9	7.5
		Viral upper respiratory tract infection	n/a	114	100.0	1	0.9	0.2	4.8
	Injury, poisoning and procedural complications	-Total	n/a	114	100.0	12	10.5	6.1	17.5
		Fall	n/a	114	100.0	1	0.9	0.2	4.8
		Infusion related reaction	n/a	114	100.0	7	6.1	3.0	12.1
		Joint dislocation	n/a	114	100.0	1	0.9	0.2	4.8
		Thermal burn	n/a	114	100.0	1	0.9	0.2	4.8
		Toxicity to various agents	n/a	114	100.0	1	0.9	0.2	4.8
		Wound complication	n/a	114	100.0	1	0.9	0.2	4.8
	Investigations	-Total	n/a	114	100.0	35	30.7	23.0	39.7

		Alanine aminotransferase increased	n/a	114	100.0	7	6.1	3.0	12.1
		Aspartate aminotransferase increased	n/a	114	100.0	8	7.0	3.6	13.2
		Blood alkaline phosphatase increased	n/a	114	100.0	7	6.1	3.0	12.1
		Blood bilirubin increased	n/a	114	100.0	3	2.6	0.9	7.5
		Blood creatinine increased	n/a	114	100.0	7	6.1	3.0	12.1
		Blood fibrinogen decreased	n/a	114	100.0	1	0.9	0.2	4.8
		Blood lactate dehydrogenase increased	n/a	114	100.0	3	2.6	0.9	7.5
		Blood urea increased	n/a	114	100.0	1	0.9	0.2	4.8
		Blood uric acid increased	n/a	114	100.0	1	0.9	0.2	4.8
		C-reactive protein increased	n/a	114	100.0	5	4.4	1.9	9.9
		Cardiac murmur	n/a	114	100.0	1	0.9	0.2	4.8
		Ejection fraction decreased	n/a	114	100.0	1	0.9	0.2	4.8
		Fibrin D dimer increased	n/a	114	100.0	1	0.9	0.2	4.8
		Gamma-glutamyltransferase increased	n/a	114	100.0	8	7.0	3.6	13.2
		Hepatic enzyme increased	n/a	114	100.0	2	1.8	0.5	6.2
		Lymphocyte count decreased	n/a	114	100.0	1	0.9	0.2	4.8
		Neutrophil count decreased	n/a	114	100.0	2	1.8	0.5	6.2

		Neutrophil count increased	n/a	114	100.0	1	0.9	0.2	4.8
		Platelet count decreased	n/a	114	100.0	3	2.6	0.9	7.5
		Platelet count increased	n/a	114	100.0	1	0.9	0.2	4.8
		Polymerase chain reaction positive	n/a	114	100.0	2	1.8	0.5	6.2
		Serum ferritin decreased	n/a	114	100.0	1	0.9	0.2	4.8
		Serum ferritin increased	n/a	114	100.0	1	0.9	0.2	4.8
		Weight decreased	n/a	114	100.0	2	1.8	0.5	6.2
		White blood cell count decreased	n/a	114	100.0	2	1.8	0.5	6.2
	Metabolism and nutrition disorders	-Total	n/a	114	100.0	50	43.9	35.1	53.0
		Decreased appetite	n/a	114	100.0	4	3.5	1.4	8.7
		Dehydration	n/a	114	100.0	2	1.8	0.5	6.2
		Fluid retention	n/a	114	100.0	1	0.9	0.2	4.8
		Hypercalcaemia	n/a	114	100.0	3	2.6	0.9	7.5
		Hyperglycaemia	n/a	114	100.0	1	0.9	0.2	4.8
		Hyperkalaemia	n/a	114	100.0	1	0.9	0.2	4.8
		Hypermagnesaemia	n/a	114	100.0	2	1.8	0.5	6.2
		Hyperphosphataemia	n/a	114	100.0	3	2.6	0.9	7.5
		Hyperuricaemia	n/a	114	100.0	5	4.4	1.9	9.9
		Hypoalbuminaemia	n/a	114	100.0	1	0.9	0.2	4.8
		Hypocalcaemia	n/a	114	100.0	13	11.4	6.8	18.5
		Hypochloraemia	n/a	114	100.0	6	5.3	2.4	11.0
		Hypoglycaemia	n/a	114	100.0	1	0.9	0.2	4.8

		Hypokalaemia	n/a	114	100.0	12	10.5	6.1	17.5
		Hypomagnesaemia	n/a	114	100.0	19	16.7	10.9	24.6
		Hyponatraemia	n/a	114	100.0	9	7.9	4.2	14.3
		Hypophosphataemia	n/a	114	100.0	20	17.5	11.7	25.6
		Tumour lysis syndrome	n/a	114	100.0	2	1.8	0.5	6.2
	Musculoskeletal and connective tissue disorders	-Total	n/a	114	100.0	30	26.3	19.1	35.1
		Arthralgia	n/a	114	100.0	7	6.1	3.0	12.1
		Back pain	n/a	114	100.0	11	9.6	5.5	16.5
		Bone pain	n/a	114	100.0	3	2.6	0.9	7.5
		Flank pain	n/a	114	100.0	1	0.9	0.2	4.8
		Joint swelling	n/a	114	100.0	1	0.9	0.2	4.8
		Limb mass	n/a	114	100.0	1	0.9	0.2	4.8
		Muscle spasms	n/a	114	100.0	1	0.9	0.2	4.8
		Muscular weakness	n/a	114	100.0	1	0.9	0.2	4.8
		Musculoskeletal pain	n/a	114	100.0	1	0.9	0.2	4.8
		Myalgia	n/a	114	100.0	3	2.6	0.9	7.5
		Neck pain	n/a	114	100.0	1	0.9	0.2	4.8
		Pain in extremity	n/a	114	100.0	2	1.8	0.5	6.2
		Pain in jaw	n/a	114	100.0	3	2.6	0.9	7.5
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	114	100.0	19	16.7	10.9	24.6
		Benign neoplasm of thyroid gland	n/a	114	100.0	1	0.9	0.2	4.8
		Tumour associated fever	n/a	114	100.0	1	0.9	0.2	4.8
		Tumour flare	n/a	114	100.0	14	12.3	7.5	19.6

Renal and urinary disorders	-Total	n/a	114	100.0	6	5.3	2.4	11.0
	Acute kidney injury	n/a	114	100.0	1	0.9	0.2	4.8
	Cystitis noninfective	n/a	114	100.0	1	0.9	0.2	4.8
	Dysuria	n/a	114	100.0	1	0.9	0.2	4.8
	Hydronephrosis	n/a	114	100.0	1	0.9	0.2	4.8
	Oliguria	n/a	114	100.0	1	0.9	0.2	4.8
	Renal impairment	n/a	114	100.0	1	0.9	0.2	4.8
Reproductive system and breast disorders	-Total	n/a	114	100.0	4	3.5	1.4	8.7
	Erectile dysfunction	n/a	114	100.0	1	0.9	0.2	4.8
	Orchitis noninfective	n/a	114	100.0	1	0.9	0.2	4.8
	Prostatitis	n/a	114	100.0	2	1.8	0.5	6.2
Respiratory, thoracic and mediastinal disorders	-Total	n/a	114	100.0	21	18.4	12.4	26.5
	Bronchopneumopathy	n/a	114	100.0	1	0.9	0.2	4.8
	Cough	n/a	114	100.0	3	2.6	0.9	7.5
	Cough variant asthma	n/a	114	100.0	1	0.9	0.2	4.8
	Dysphonia	n/a	114	100.0	2	1.8	0.5	6.2
	Dyspnoea	n/a	114	100.0	3	2.6	0.9	7.5
	Hyperventilation	n/a	114	100.0	1	0.9	0.2	4.8
	Hypoxia	n/a	114	100.0	1	0.9	0.2	4.8
	Lung disorder	n/a	114	100.0	1	0.9	0.2	4.8
	Oropharyngeal pain	n/a	114	100.0	2	1.8	0.5	6.2
	Pleural effusion	n/a	114	100.0	3	2.6	0.9	7.5
	Rales	n/a	114	100.0	1	0.9	0.2	4.8
	Rhinitis allergic	n/a	114	100.0	1	0.9	0.2	4.8
	Rhinorrhoea	n/a	114	100.0	2	1.8	0.5	6.2

		Jugular vein thrombosis	n/a	114	100.0	1	0.9	0.2	4.8
		Phlebitis	n/a	114	100.0	2	1.8	0.5	6.2
		Phlebitis superficial	n/a	114	100.0	1	0.9	0.2	4.8

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_soc_JUN22_SE_D23_AEANY.xls

01MAR2023 9:03

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	45	39.5	31.0	48.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_AEGR3.xls

01MAR2023 8:26

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
Name	SOC	PT	Level	Patients		Patients with Event			
				n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	114	100.0	33	28.9	21.4	37.9
		Anaemia	n/a	114	100.0	10	8.8	4.8	15.4
		Anaemia of malignant disease	n/a	114	100.0	1	0.9	0.2	4.8
		Febrile neutropenia	n/a	114	100.0	2	1.8	0.5	6.2
		Lymphopenia	n/a	114	100.0	1	0.9	0.2	4.8
		Neutropenia	n/a	114	100.0	21	18.4	12.4	26.5
		Thrombocytopenia	n/a	114	100.0	5	4.4	1.9	9.9
	Cardiac disorders	-Total	n/a	114	100.0	1	0.9	0.2	4.8
		Cardiac failure	n/a	114	100.0	1	0.9	0.2	4.8
	Eye disorders	-Total	n/a	114	100.0	1	0.9	0.2	4.8
		Periorbital swelling	n/a	114	100.0	1	0.9	0.2	4.8
	Gastrointestinal disorders	-Total	n/a	114	100.0	3	2.6	0.9	7.5
		Ascites	n/a	114	100.0	1	0.9	0.2	4.8
		Gastric haemorrhage	n/a	114	100.0	1	0.9	0.2	4.8
		Gastrointestinal haemorrhage	n/a	114	100.0	1	0.9	0.2	4.8
	General disorders and administration site conditions	-Total	n/a	114	100.0	4	3.5	1.4	8.7
		Asthenia	n/a	114	100.0	1	0.9	0.2	4.8
		Fatigue	n/a	114	100.0	1	0.9	0.2	4.8

		General physical health deterioration	n/a	114	100.0	1	0.9	0.2	4.8
		Pain	n/a	114	100.0	1	0.9	0.2	4.8
		Swelling	n/a	114	100.0	1	0.9	0.2	4.8
	Immune system disorders	-Total	n/a	114	100.0	3	2.6	0.9	7.5
		Cytokine release syndrome by ASTCT grade	n/a	114	100.0	3	2.6	0.9	7.5
		Cytokine release syndrome by Lee grade	n/a	114	100.0	2	1.8	0.5	6.2
	Infections and infestations	-Total	n/a	114	100.0	10	8.8	4.8	15.4
		Appendicitis	n/a	114	100.0	1	0.9	0.2	4.8
		Biliary tract infection bacterial	n/a	114	100.0	1	0.9	0.2	4.8
		COVID-19	n/a	114	100.0	2	1.8	0.5	6.2
		COVID-19 pneumonia	n/a	114	100.0	2	1.8	0.5	6.2
		Clostridium difficile infection	n/a	114	100.0	1	0.9	0.2	4.8
		Gastroenteritis	n/a	114	100.0	1	0.9	0.2	4.8
		Neutropenic infection	n/a	114	100.0	1	0.9	0.2	4.8
		Peritonitis	n/a	114	100.0	1	0.9	0.2	4.8
		Pneumococcal infection	n/a	114	100.0	1	0.9	0.2	4.8
		Pneumonia	n/a	114	100.0	1	0.9	0.2	4.8
		Sepsis	n/a	114	100.0	1	0.9	0.2	4.8
		Vascular device infection	n/a	114	100.0	2	1.8	0.5	6.2
	Injury, poisoning and procedural complications	-Total	n/a	114	100.0	1	0.9	0.2	4.8
		Toxicity to various agents	n/a	114	100.0	1	0.9	0.2	4.8

	Investigations	-Total	n/a	114	100.0	11	9.6	5.5	16.5
		Alanine aminotransferase increased	n/a	114	100.0	2	1.8	0.5	6.2
		Aspartate aminotransferase increased	n/a	114	100.0	2	1.8	0.5	6.2
		Blood alkaline phosphatase increased	n/a	114	100.0	1	0.9	0.2	4.8
		C-reactive protein increased	n/a	114	100.0	1	0.9	0.2	4.8
		Ejection fraction decreased	n/a	114	100.0	1	0.9	0.2	4.8
		Gamma-glutamyltransferase increased	n/a	114	100.0	3	2.6	0.9	7.5
		Hepatic enzyme increased	n/a	114	100.0	2	1.8	0.5	6.2
		Lymphocyte count decreased	n/a	114	100.0	1	0.9	0.2	4.8
		Neutrophil count decreased	n/a	114	100.0	1	0.9	0.2	4.8
		Weight decreased	n/a	114	100.0	1	0.9	0.2	4.8
		White blood cell count decreased	n/a	114	100.0	1	0.9	0.2	4.8
	Metabolism and nutrition disorders	-Total	n/a	114	100.0	11	9.6	5.5	16.5
		Hypercalcaemia	n/a	114	100.0	3	2.6	0.9	7.5
		Hypokalaemia	n/a	114	100.0	1	0.9	0.2	4.8
		Hyponatraemia	n/a	114	100.0	2	1.8	0.5	6.2
		Hypophosphataemia	n/a	114	100.0	4	3.5	1.4	8.7
		Tumour lysis syndrome	n/a	114	100.0	2	1.8	0.5	6.2
	Musculoskeletal and connective tissue disorders	-Total	n/a	114	100.0	3	2.6	0.9	7.5

		Back pain	n/a	114	100.0	2	1.8	0.5	6.2
		Pain in jaw	n/a	114	100.0	1	0.9	0.2	4.8
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	114	100.0	4	3.5	1.4	8.7
		Tumour flare	n/a	114	100.0	2	1.8	0.5	6.2
		Tumour pain	n/a	114	100.0	2	1.8	0.5	6.2
	Nervous system disorders	-Total	n/a	114	100.0	1	0.9	0.2	4.8
		Somnolence	n/a	114	100.0	1	0.9	0.2	4.8
	Respiratory, thoracic and mediastinal disorders	-Total	n/a	114	100.0	4	3.5	1.4	8.7
		Pleural effusion	n/a	114	100.0	3	2.6	0.9	7.5
		Wheezing	n/a	114	100.0	1	0.9	0.2	4.8
	Skin and subcutaneous tissue disorders	-Total	n/a	114	100.0	2	1.8	0.5	6.2
		Rash	n/a	114	100.0	1	0.9	0.2	4.8
		Rash pruritic	n/a	114	100.0	1	0.9	0.2	4.8
	Vascular disorders	-Total	n/a	114	100.0	1	0.9	0.2	4.8
		Hypertension	n/a	114	100.0	1	0.9	0.2	4.8

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_soc_JUN22_SE_D23_AEGR3.xls

01MAR2023 9:04

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 4

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	23	20.2	13.8	28.5

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_AEGR4.xls

01MAR2023 8:27

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 4

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
				Patients		Patients with Event			
Name	SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	114	100,0	16	14,0	8,8	21,6
		Febrile neutropenia	n/a	114	100,0	2	1,8	0,5	6,2
		Lymphopenia	n/a	114	100,0	3	2,6	0,9	7,5
		Neutropenia	n/a	114	100,0	10	8,8	4,8	15,4
		Thrombocytopenia	n/a	114	100,0	2	1,8	0,5	6,2
	Gastrointestinal disorders	-Total	n/a	114	100,0	2	1,8	0,5	6,2
		Colitis	n/a	114	100,0	1	0,9	0,2	4,8
		Gastrointestinal haemorrhage	n/a	114	100,0	1	0,9	0,2	4,8
		Large intestinal haemorrhage	n/a	114	100,0	1	0,9	0,2	4,8
	Immune system disorders	-Total	n/a	114	100,0	2	1,8	0,5	6,2
		Cytokine release syndrome by ASTCT grade	n/a	114	100,0	2	1,8	0,5	6,2
		Cytokine release syndrome by Lee grade	n/a	114	100,0	2	1,8	0,5	6,2
	Infections and infestations	-Total	n/a	114	100,0	6	5,3	2,4	11,0
		COVID-19	n/a	114	100,0	1	0,9	0,2	4,8
		Myelitis	n/a	114	100,0	1	0,9	0,2	4,8

		Pneumonia	n/a	114	100,0	1	0,9	0,2	4,8
		Sepsis	n/a	114	100,0	3	2,6	0,9	7,5
	Investigations	-Total	n/a	114	100,0	3	2,6	0,9	7,5
		Neutrophil count decreased	n/a	114	100,0	1	0,9	0,2	4,8
		Platelet count decreased	n/a	114	100,0	1	0,9	0,2	4,8
		White blood cell count decreased	n/a	114	100,0	1	0,9	0,2	4,8
	Metabolism and nutrition disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Hypophosphataemia	n/a	114	100,0	1	0,9	0,2	4,8

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_soc_JUN22_SE_D23_AEGR4.xls

01MAR2023 9:05

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 5 (AEs leading to death)

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	7	6.1	3.0	12.1

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_AEGR5.xls

01MAR2023 8:28

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 5 (AEs leading to death)

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
				Patients		Patients with Event			
Name	SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	Infections and infestations	-Total	n/a	114	100,0	6	5,3	2,4	11,0
		COVID-19	n/a	114	100,0	1	0,9	0,2	4,8
		COVID-19 pneumonia	n/a	114	100,0	3	2,6	0,9	7,5
		Sepsis	n/a	114	100,0	2	1,8	0,5	6,2
	Psychiatric disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Delirium	n/a	114	100,0	1	0,9	0,2	4,8

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_soc_JUN22_SE_D23_AEGR5.xls

01MAR2023 9:06

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade >=3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	75	65.8	56.7	73.9

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_AEGR345.xls

01MAR2023 8:29

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade >=3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
Name	SOC	PT	Level	Patients		Patients with Event			
				n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	114	100.0	40	35.1	26.9	44.2
		Anaemia	n/a	114	100.0	10	8.8	4.8	15.4
		Anaemia of malignant disease	n/a	114	100.0	1	0.9	0.2	4.8
		Febrile neutropenia	n/a	114	100.0	4	3.5	1.4	8.7
		Lymphopenia	n/a	114	100.0	4	3.5	1.4	8.7
		Neutropenia	n/a	114	100.0	31	27.2	19.9	36.0
		Thrombocytopenia	n/a	114	100.0	7	6.1	3.0	12.1
	Cardiac disorders	-Total	n/a	114	100.0	1	0.9	0.2	4.8
		Cardiac failure	n/a	114	100.0	1	0.9	0.2	4.8
	Eye disorders	-Total	n/a	114	100.0	1	0.9	0.2	4.8
		Periorbital swelling	n/a	114	100.0	1	0.9	0.2	4.8
	Gastrointestinal disorders	-Total	n/a	114	100.0	4	3.5	1.4	8.7
		Ascites	n/a	114	100.0	1	0.9	0.2	4.8
		Colitis	n/a	114	100.0	1	0.9	0.2	4.8
		Gastric haemorrhage	n/a	114	100.0	1	0.9	0.2	4.8
		Gastrointestinal haemorrhage	n/a	114	100.0	2	1.8	0.5	6.2
		Large intestinal haemorrhage	n/a	114	100.0	1	0.9	0.2	4.8

	General disorders and administration site conditions	-Total	n/a	114	100.0	4	3.5	1.4	8.7
		Asthenia	n/a	114	100.0	1	0.9	0.2	4.8
		Fatigue	n/a	114	100.0	1	0.9	0.2	4.8
		General physical health deterioration	n/a	114	100.0	1	0.9	0.2	4.8
		Pain	n/a	114	100.0	1	0.9	0.2	4.8
		Swelling	n/a	114	100.0	1	0.9	0.2	4.8
	Immune system disorders	-Total	n/a	114	100.0	5	4.4	1.9	9.9
		Cytokine release syndrome by ASTCT grade	n/a	114	100.0	5	4.4	1.9	9.9
		Cytokine release syndrome by Lee grade	n/a	114	100.0	4	3.5	1.4	8.7
	Infections and infestations	-Total	n/a	114	100.0	21	18.4	12.4	26.5
		Appendicitis	n/a	114	100.0	1	0.9	0.2	4.8
		Biliary tract infection bacterial	n/a	114	100.0	1	0.9	0.2	4.8
		COVID-19	n/a	114	100.0	4	3.5	1.4	8.7
		COVID-19 pneumonia	n/a	114	100.0	5	4.4	1.9	9.9
		Clostridium difficile infection	n/a	114	100.0	1	0.9	0.2	4.8
		Gastroenteritis	n/a	114	100.0	1	0.9	0.2	4.8
		Myelitis	n/a	114	100.0	1	0.9	0.2	4.8
		Neutropenic infection	n/a	114	100.0	1	0.9	0.2	4.8
		Peritonitis	n/a	114	100.0	1	0.9	0.2	4.8
		Pneumococcal infection	n/a	114	100.0	1	0.9	0.2	4.8
		Pneumonia	n/a	114	100.0	2	1.8	0.5	6.2
		Sepsis	n/a	114	100.0	6	5.3	2.4	11.0

		Vascular device infection	n/a	114	100.0	2	1.8	0.5	6.2
	Injury, poisoning and procedural complications	-Total	n/a	114	100.0	1	0.9	0.2	4.8
		Toxicity to various agents	n/a	114	100.0	1	0.9	0.2	4.8
	Investigations	-Total	n/a	114	100.0	13	11.4	6.8	18.5
		Alanine aminotransferase increased	n/a	114	100.0	2	1.8	0.5	6.2
		Aspartate aminotransferase increased	n/a	114	100.0	2	1.8	0.5	6.2
		Blood alkaline phosphatase increased	n/a	114	100.0	1	0.9	0.2	4.8
		C-reactive protein increased	n/a	114	100.0	1	0.9	0.2	4.8
		Ejection fraction decreased	n/a	114	100.0	1	0.9	0.2	4.8
		Gamma-glutamyltransferase increased	n/a	114	100.0	3	2.6	0.9	7.5
		Hepatic enzyme increased	n/a	114	100.0	2	1.8	0.5	6.2
		Lymphocyte count decreased	n/a	114	100.0	1	0.9	0.2	4.8
		Neutrophil count decreased	n/a	114	100.0	2	1.8	0.5	6.2
		Platelet count decreased	n/a	114	100.0	1	0.9	0.2	4.8
		Weight decreased	n/a	114	100.0	1	0.9	0.2	4.8
		White blood cell count decreased	n/a	114	100.0	2	1.8	0.5	6.2
	Metabolism and nutrition disorders	-Total	n/a	114	100.0	12	10.5	6.1	17.5
		Hypercalcaemia	n/a	114	100.0	3	2.6	0.9	7.5

		Hypokalaemia	n/a	114	100.0	1	0.9	0.2	4.8
		Hyponatraemia	n/a	114	100.0	2	1.8	0.5	6.2
		Hypophosphataemia	n/a	114	100.0	5	4.4	1.9	9.9
		Tumour lysis syndrome	n/a	114	100.0	2	1.8	0.5	6.2
	Musculoskeletal and connective tissue disorders	-Total	n/a	114	100.0	3	2.6	0.9	7.5
		Back pain	n/a	114	100.0	2	1.8	0.5	6.2
		Pain in jaw	n/a	114	100.0	1	0.9	0.2	4.8
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	114	100.0	4	3.5	1.4	8.7
		Tumour flare	n/a	114	100.0	2	1.8	0.5	6.2
		Tumour pain	n/a	114	100.0	2	1.8	0.5	6.2
	Nervous system disorders	-Total	n/a	114	100.0	1	0.9	0.2	4.8
		Somnolence	n/a	114	100.0	1	0.9	0.2	4.8
	Psychiatric disorders	-Total	n/a	114	100.0	1	0.9	0.2	4.8
		Delirium	n/a	114	100.0	1	0.9	0.2	4.8
	Respiratory, thoracic and mediastinal disorders	-Total	n/a	114	100.0	4	3.5	1.4	8.7
		Pleural effusion	n/a	114	100.0	3	2.6	0.9	7.5
		Wheezing	n/a	114	100.0	1	0.9	0.2	4.8
	Skin and subcutaneous tissue disorders	-Total	n/a	114	100.0	2	1.8	0.5	6.2
		Rash	n/a	114	100.0	1	0.9	0.2	4.8
		Rash pruritic	n/a	114	100.0	1	0.9	0.2	4.8
	Vascular disorders	-Total	n/a	114	100.0	1	0.9	0.2	4.8
		Hypertension	n/a	114	100.0	1	0.9	0.2	4.8

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_soc_JUN22_SE_D23_AEGR345.xls

01MAR2023 9:07

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: Any SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	60	52.6	43.5	61.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_AESAE.xls

01MAR2023 8:35

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: Any SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)							
Name	SOC	PT	Level	Patients		Patients with Event					
				n	%	n	%	95% CI (LL)	95% CI (UL)		
All	Blood and lymphatic system disorders	-Total	n/a	114	100.0	8	7.0	3.6	13.2		
		Anaemia	n/a	114	100.0	2	1.8	0.5	6.2		
		Febrile neutropenia	n/a	114	100.0	3	2.6	0.9	7.5		
		Lymphopenia	n/a	114	100.0	1	0.9	0.2	4.8		
		Neutropenia	n/a	114	100.0	2	1.8	0.5	6.2		
		Thrombocytopenia	n/a	114	100.0	1	0.9	0.2	4.8		
	Cardiac disorders	-Total	n/a	114	100.0	2	1.8	0.5	6.2		
		Cardiac failure	n/a	114	100.0	1	0.9	0.2	4.8		
		Sinus node dysfunction	n/a	114	100.0	1	0.9	0.2	4.8		
	Gastrointestinal disorders	-Total	n/a	114	100.0	6	5.3	2.4	11.0		
		Colitis	n/a	114	100.0	1	0.9	0.2	4.8		
		Constipation	n/a	114	100.0	1	0.9	0.2	4.8		
		Gastric haemorrhage	n/a	114	100.0	1	0.9	0.2	4.8		
		Gastrointestinal haemorrhage	n/a	114	100.0	2	1.8	0.5	6.2		
		Intestinal perforation	n/a	114	100.0	1	0.9	0.2	4.8		
		Large intestinal haemorrhage	n/a	114	100.0	1	0.9	0.2	4.8		
		Nausea	n/a	114	100.0	1	0.9	0.2	4.8		

		Vomiting	n/a	114	100.0	1	0.9	0.2	4.8
	General disorders and administration site conditions	-Total	n/a	114	100.0	3	2.6	0.9	7.5
		General physical health deterioration	n/a	114	100.0	1	0.9	0.2	4.8
		Pyrexia	n/a	114	100.0	2	1.8	0.5	6.2
	Immune system disorders	-Total	n/a	114	100.0	28	24.6	17.6	33.2
		Cytokine release syndrome by ASTCT grade	n/a	114	100.0	14	12.3	7.5	19.6
		Cytokine release syndrome by Lee grade	n/a	114	100.0	28	24.6	17.6	33.2
	Infections and infestations	-Total	n/a	114	100.0	22	19.3	13.1	27.5
		Abscess	n/a	114	100.0	1	0.9	0.2	4.8
		Appendicitis	n/a	114	100.0	1	0.9	0.2	4.8
		Biliary tract infection bacterial	n/a	114	100.0	1	0.9	0.2	4.8
		COVID-19	n/a	114	100.0	3	2.6	0.9	7.5
		COVID-19 pneumonia	n/a	114	100.0	5	4.4	1.9	9.9
		Campylobacter infection	n/a	114	100.0	1	0.9	0.2	4.8
		Infection	n/a	114	100.0	1	0.9	0.2	4.8
		Myelitis	n/a	114	100.0	1	0.9	0.2	4.8
		Neutropenic infection	n/a	114	100.0	1	0.9	0.2	4.8
		Peritonitis	n/a	114	100.0	1	0.9	0.2	4.8
		Pneumococcal infection	n/a	114	100.0	1	0.9	0.2	4.8
		Pneumonia	n/a	114	100.0	2	1.8	0.5	6.2
		Sepsis	n/a	114	100.0	6	5.3	2.4	11.0

		Vascular device infection	n/a	114	100.0	2	1.8	0.5	6.2
	Injury, poisoning and procedural complications	-Total	n/a	114	100.0	3	2.6	0.9	7.5
		Infusion related reaction	n/a	114	100.0	1	0.9	0.2	4.8
		Joint dislocation	n/a	114	100.0	1	0.9	0.2	4.8
		Toxicity to various agents	n/a	114	100.0	1	0.9	0.2	4.8
	Investigations	-Total	n/a	114	100.0	2	1.8	0.5	6.2
		C-reactive protein increased	n/a	114	100.0	1	0.9	0.2	4.8
		Weight decreased	n/a	114	100.0	1	0.9	0.2	4.8
	Metabolism and nutrition disorders	-Total	n/a	114	100.0	1	0.9	0.2	4.8
		Hyponatraemia	n/a	114	100.0	1	0.9	0.2	4.8
	Musculoskeletal and connective tissue disorders	-Total	n/a	114	100.0	2	1.8	0.5	6.2
		Back pain	n/a	114	100.0	2	1.8	0.5	6.2
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	114	100.0	7	6.1	3.0	12.1
		Tumour associated fever	n/a	114	100.0	1	0.9	0.2	4.8
		Tumour flare	n/a	114	100.0	5	4.4	1.9	9.9
		Tumour pain	n/a	114	100.0	1	0.9	0.2	4.8
	Psychiatric disorders	-Total	n/a	114	100.0	1	0.9	0.2	4.8
		Delirium	n/a	114	100.0	1	0.9	0.2	4.8
	Renal and urinary disorders	-Total	n/a	114	100.0	1	0.9	0.2	4.8
		Acute kidney injury	n/a	114	100.0	1	0.9	0.2	4.8
	Respiratory, thoracic and mediastinal disorders	-Total	n/a	114	100.0	2	1.8	0.5	6.2
		Pleural effusion	n/a	114	100.0	2	1.8	0.5	6.2

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_soc_JUN22_SE_D23_AESAE.xls

01MAR2023 9:08

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs leading to treatment discontinuation

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	10	8.8	4.8	15.4

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_AEDISC.xls

01MAR2023 8:36

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs leading to treatment discontinuation

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
Name	SOC	PT	Level	Patients		Patients with Event			
				n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Neutropenia	n/a	114	100,0	1	0,9	0,2	4,8
	Gastrointestinal disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Gastrointestinal haemorrhage	n/a	114	100,0	1	0,9	0,2	4,8
	Immune system disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Cytokine release syndrome by ASTCT grade	n/a	114	100,0	1	0,9	0,2	4,8
		Cytokine release syndrome by Lee grade	n/a	114	100,0	1	0,9	0,2	4,8
	Infections and infestations	-Total	n/a	114	100,0	6	5,3	2,4	11,0
		Biliary tract infection bacterial	n/a	114	100,0	1	0,9	0,2	4,8
		COVID-19	n/a	114	100,0	2	1,8	0,5	6,2
		COVID-19 pneumonia	n/a	114	100,0	1	0,9	0,2	4,8
		Myelitis	n/a	114	100,0	1	0,9	0,2	4,8
		Sepsis	n/a	114	100,0	1	0,9	0,2	4,8
	Psychiatric disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Delirium	n/a	114	100,0	1	0,9	0,2	4,8

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_soc_JUN22_SE_D23_AEDISC.xls

01MAR2023 9:09

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: AST, ALT, or total bilirubin elevation - Grade \geq 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	5	4.4	1.9	9.9

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ABIL.xls

01MAR2023 8:49

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: AST, ALT, or total bilirubin elevation - Grade >= 3
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	3	2.6	0.9	7.5

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ABIL345.xls

01MAR2023 8:49

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: AST, ALT, or total bilirubin elevation - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ABILSAE.xls
01MAR2023 8:51

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Colitis

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	1	0.9	0.2	4.8

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ACOL.xls

01MAR2023 8:57

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Colitis - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	1	0.9	0.2	4.8

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ACOL345.xls

01MAR2023 8:58

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Colitis - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	1	0.9	0.2	4.8

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ACOLSAE.xls

01MAR2023 8:59

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: Cytokine release syndrome by ASTCT grade - Grade \geq 2
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	21	18.4	12.4	26.5

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ACRS.xls

01MAR2023 8:37

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by ASTCT grade - Grade 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	16	14.0	8.8	21.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ACRS2.xls

01MAR2023 8:37

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by ASTCT grade - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	5	4.4	1.9	9.9

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ACRS345.xls

01MAR2023 8:38

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by ASTCT grade - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	14	12.3	7.5	19.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ACRSSAE.xls

01MAR2023 8:39

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by Lee grade - Grade \geq 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	25	21.9	15.3	30.4

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ACRSL.xls

01MAR2023 8:39

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by Lee grade - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	4	3.5	1.4	8.7

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ACRSL345.xls

01MAR2023 8:40

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by Lee grade - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	16	14.0	8.8	21.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ACRSLSAE.xls

01MAR2023 8:41

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Disseminated Intravascular Coagulation - Grade \geq 2
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ADIC.xls
01MAR2023 8:51

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Disseminated Intravascular Coagulation - Grade \geq 3
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ADIC345.xls
01MAR2023 8:52

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Disseminated Intravascular Coagulation - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ADICSAE.xls
01MAR2023 8:52

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Febrile Neutropenia - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	4	3.5	1.4	8.7

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_AFEB.xls

01MAR2023 8:47

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Febrile Neutropenia - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	3	2.6	0.9	7.5

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_AFEBSAE.xls

01MAR2023 8:48

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Hemophagocytic lymphohistiocytosis
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_AHEMA.xls
01MAR2023 8:44

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Hemophagocytic lymphohistiocytosis - Grade \geq 3
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_AHEMA345.xls
01MAR2023 8:44

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Hemophagocytic lymphohistiocytosis - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_AHEMASAE.xls
01MAR2023 8:45

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Secondary malignancies
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_AMAL.xls
01MAR2023 8:59

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Secondary malignancies - Grade \geq 3
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_AMAL345.xls
01MAR2023 9:00

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Secondary malignancies - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_AMALSAE.xls
01MAR2023 9:00

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Neurologic AEs - Grade \geq 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	17	14.9	9.5	22.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ANAE.xls

01MAR2023 8:42

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Neurologic AEs - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	3	2.6	0.9	7.5

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ANAE345.xls

01MAR2023 8:42

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Neurologic AEs - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	2	1.8	0.5	6.2

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ANAESAE.xls

01MAR2023 8:43

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Pneumonitis or interstitial lung disease
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_APILD.xls
01MAR2023 8:56

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Pneumonitis or interstitial lung disease - Grade \geq 3
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_APILD345.xls
01MAR2023 8:56

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Pneumonitis or interstitial lung disease - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_APILDSAE.xls
01MAR2023 8:57

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Tumor flare - Grade \geq 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	8	7.0	3.6	13.2

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ATF.xls

01MAR2023 8:53

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Tumor flare - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	2	1.8	0.5	6.2

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ATF345.xls

01MAR2023 8:54

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Tumor flare - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	4	3.5	1.4	8.7

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ATFSAE.xls

01MAR2023 8:55

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Tumor lysis syndrome - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	2	1.8	0.5	6.2

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ATLS.xls

01MAR2023 8:45

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Tumor lysis syndrome - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ATLSSAE.xls
01MAR2023 8:46

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Obinutuzumab: Tumor lysis syndrome

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	2	1.8	0.5	6.2

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ATLSO.xls

01MAR2023 9:01

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Obinutuzumab: Tumor lysis syndrome - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100.0	2	1.8	0.5	6.2

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ATLSO345.xls

01MAR2023 9:02

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Obinutuzumab: Tumor lysis syndrome - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D23_ATLSOSAE.xls
01MAR2023 9:02

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLCL Patients), Safety-Evaluable Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Outcome of Adverse Events

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)															
		Total		RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs																	
	All	1069	100.0	846	79.1	5	0.5	204	19.1	8	0.7	6	0.6	0	0.0	0	0.0
	Grade 1	556	100.0	456	82.0	1	0.2	96	17.3	0	0.0	3	0.5	0	0.0	0	0.0
	Grade 2	313	100.0	237	75.7	4	1.3	71	22.7	0	0.0	1	0.3	0	0.0	0	0.0
	Grade 3	153	100.0	127	83.0	0	0.0	26	17.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	38	100.0	26	68.4	0	0.0	10	26.3	0	0.0	2	5.3	0	0.0	0	0.0
	Grade 5	8	100.0	0	0.0	0	0.0	0	0.0	8	100.0	0	0.0	0	0.0	0	0.0
	Missing	1	100.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Any SAEs																	
	All	140	100.0	115	82.1	0	0.0	15	10.7	8	5.7	2	1.4	0	0.0	0	0.0
	Grade 1	27	100.0	24	88.9	0	0.0	3	11.1	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 2	40	100.0	39	97.5	0	0.0	1	2.5	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	42	100.0	38	90.5	0	0.0	4	9.5	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	23	100.0	14	60.9	0	0.0	7	30.4	0	0.0	2	8.7	0	0.0	0	0.0
	Grade 5	8	100.0	0	0.0	0	0.0	0	0.0	8	100.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Any AESI																	
	All	75	100.0	61	81.3	1	1.3	11	14.7	1	1.3	1	1.3	0	0.0	0	0.0
	Grade 1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 2	49	100.0	40	81.6	1	2.0	8	16.3	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	19	100.0	18	94.7	0	0.0	1	5.3	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	6	100.0	3	50.0	0	0.0	2	33.3	0	0.0	1	16.7	0	0.0	0	0.0
	Grade 5	1	100.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_resolved.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_resolved_JUN22_SE_D23_SG.xls

11APR2023 16:02

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: All patients
 MODEL: --
 STUDY: NP30179
 Outcome of Adverse Events of Special Interest

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)															
Category of Adverse Events		Total		RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
AESI: Cytokine release syndrome by Lee grade, Grade >= 2																	
	All	58	100.0	54	93.1	0	0.0	4	6.9	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 2	49	100.0	47	95.9	0	0.0	2	4.1	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	5	100.0	5	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	4	100.0	2	50.0	0	0.0	2	50.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: Cytokine release syndrome by ASTCT grade, Grade >= 2																	
	All	23	100.0	22	95.7	0	0.0	1	4.3	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 2	18	100.0	18	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	3	100.0	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	2	100.0	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: Neurologic AEs, Grade >= 2																	
	All	36	100.0	18	50.0	2	5.6	14	38.9	2	5.6	0	0.0	0	0.0	0	0.0
	Grade 2	30	100.0	18	60.0	2	6.7	10	33.3	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	2	100.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	2	100.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	2	100.0	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: Tumor lysis syndrome, Grade >= 3																	
	All	4	100.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	4	100.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: Febrile Neutropenia, Grade >= 3																	
	All	12	100.0	12	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	8	100.0	8	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	4	100.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: AST, ALT, or total bilirubin elevation, Grade >= 2																	
	All	18	100.0	16	88.9	0	0.0	2	11.1	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 2	6	100.0	4	66.7	0	0.0	2	33.3	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	12	100.0	12	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: Tumour flare, Grade >= 2																	
	All	16	100.0	14	87.5	0	0.0	2	12.5	0	0.0	0	0.0	0	0.0	0	0.0

	Grade 2	12	100.0	10	83.3	0	0.0	2	16.7	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	4	100.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: Colitis																	
	All	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0
	Grade 1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: Obinutuzumab - TLS																	
	All	2	100.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	2	100.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_resolved_aesi.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_resolved_aesi_JUN22_SE_D23_SG.xls

11APR2023 16:02

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Number of centers/countries/geographical regions with <10, >=10 patients per arm

Category	Center				Country				Geographical region (3)			
	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)	n (4)	% (5)	n of patients randomized (6)	% randomized patients (7)
Overall	32	100	155	100	13	100	155	100	4	100	155	100
with <10 patients per arm (1)	30	93.8	114	73.5	9	69.2	47	30.3	1	25	6	3.9
with >=10 patients per arm (2)	2	6.3	41	26.5	4	30.8	108	69.7	3	75	149	96.1

(1) "<10 patients category" if at least one treatment arm has <10 patients. (2) ">=10 patients" category if all treatment arms have >=10 patients.

(3) Geographical regions: North America (Canada and USA), Australia/New Zealand, Asia (Taiwan), Europe (all other countries). (4) Number of centers/countries/geographical regions.

(5) % of centers/countries/geographical regions compared to overall number of centers/countries/geographical regions.

(6) Number of patients randomized in the corresponding category (e.g. Number of patients randomized in centers with <10 pts per arm).

(7) % of randomized patients compared to overall number of randomized patients (e.g. % of randomized patients in centers with <10 patients per arm compared to overall number of randomized patients).

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_center.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_center_JUN22_ITT_D235.xls

01MAR2023 9:34

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Summary of Previous Cancer Therapies

	Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=155)
Prior Cancer-related Surgery	55 (35.5%)
Prior Radiotherapy	49 (31.6%)
Prior Cancer Therapy	155 (100%)
Chemotherapy	155 (100%)
Anti-CD20 Monoclonal Antibody	155 (100%)
Non Anti-CD20 Monoclonal Antibody	25 (16.1%)
Conditioning Regimen For Stem Cell Transplant	31 (20.0%)
Signaling Pathway Inhibitor	17 (11.0%)
Immunotherapy Non Stem Cell Transplant	14 (9.0%)
PI3K Inhibitor	3 (1.9%)
Car-T Therapy	52 (33.5%)
Anthracycline	152 (98.1%)
Alkylator	155 (100%)
Immunomodulatory Imide	22 (14.2%)
Autologous Stem Cell Transplant	28 (18.1%)
Other	36 (23.2%)
Number of Prior Lines of Cancer Therapy per Subject	
n	155
Mean (SD)	3.1 (1.2)
Median	3
Min - Max	2 - 7

Prior Lines of Cancer Therapy per Subject (Cat)	
2	61 (39.4%)
3	49 (31.6%)
>3	45 (29.0%)
Numbers of Prior Lines of Cancer Therapy (N)	
2	61 (39.4%)
3	49 (31.6%)
4	27 (17.4%)
5	10 (6.5%)
6	5 (3.2%)
7	3 (1.9%)
Category Time from Last Prior Therapy to First Study Treatment (0-3 vs. 3+) (Months)	
<3	79 (51.0%)
>=3	71 (45.8%)
Category Time from Last Prior CD20 Therapy to First Study Treatment (0-3 vs. 3+) (Months)	
<3	49 (31.6%)
>=3	101 (65.2%)
Time from Last Prior Therapy to First Study Treatment (Months)	
n	150
Mean (SD)	6.71 (15.33)
Median	2.7
Min - Max	0.3 - 147.3
Time from Last Anti-CD20 Therapy to First Study Treatment (Months)	
n	150
Mean (SD)	12.21 (23.50)
Median	4.75
Min - Max	0.9 - 198.9

Category Time from Last Prior Therapy, or Last Prior CD20 Therapy, is not available where Medication End date is missing the month or First Study Treatment is missing.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_cm_prior.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_cm_prior_JUN22_ITT_D235.xls

01MAR2023 9:41

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Summary of Previous Cancer Therapies

	Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)
Prior Cancer-related Surgery	55 (35.7%)
Prior Radiotherapy	49 (31.8%)
Prior Cancer Therapy	154 (100%)
Chemotherapy	154 (100%)
Anti-CD20 Monoclonal Antibody	154 (100%)
Non Anti-CD20 Monoclonal Antibody	25 (16.2%)
Conditioning Regimen For Stem Cell Transplant	31 (20.1%)
Signaling Pathway Inhibitor	17 (11.0%)
Immunotherapy Non Stem Cell Transplant	14 (9.1%)
PI3K Inhibitor	3 (1.9%)
Car-T Therapy	51 (33.1%)
Anthracycline	151 (98.1%)
Alkylator	154 (100%)
Immunomodulatory Imide	22 (14.3%)
Autologous Stem Cell Transplant	28 (18.2%)
Other	35 (22.7%)
Number of Prior Lines of Cancer Therapy per Subject	
n	154
Mean (SD)	3.1 (1.2)
Median	3
Min - Max	2 - 7

Prior Lines of Cancer Therapy per Subject (Cat)	
2	61 (39.6%)
3	48 (31.2%)
>3	45 (29.2%)
Numbers of Prior Lines of Cancer Therapy (N)	
2	61 (39.6%)
3	48 (31.2%)
4	27 (17.5%)
5	10 (6.5%)
6	5 (3.2%)
7	3 (1.9%)
Category Time from Last Prior Therapy to First Study Treatment (0-3 vs. 3+) (Months)	
<3	79 (51.3%)
>=3	71 (46.1%)
Category Time from Last Prior CD20 Therapy to First Study Treatment (0-3 vs. 3+) (Months)	
<3	49 (31.8%)
>=3	101 (65.6%)
Time from Last Prior Therapy to First Study Treatment (Months)	
n	150
Mean (SD)	6.71 (15.33)
Median	2.7
Min - Max	0.3 - 147.3
Time from Last Anti-CD20 Therapy to First Study Treatment (Months)	
n	150
Mean (SD)	12.21 (23.50)
Median	4.75
Min - Max	0.9 - 198.9

Category Time from Last Prior Therapy, or Last Prior CD20 Therapy, is not available where Medication End date is missing the month or First Study Treatment is missing.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_cm_prior.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_cm_prior_JUN22_SE_D235.xls
01MAR2023 9:43

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Summary of Refractory and Relapse Status to Prior Lines of Therapy

	Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=155)
Relapse or Refractory to Any Prior Therapy	
n	155
Refractory	139 (89.7%)
Relapse (No Refractory)	16 (10.3%)
Relapse or Refractory to Last Line of Prior Therapy	
n	155
Refractory	131 (84.5%)
Relapse	24 (15.5%)
Relapse or Refractory to First Line of Prior Therapy	
n	155
Refractory	91 (58.7%)
Relapse	64 (41.3%)
Relapse or Refractory to Any Prior Anti-CD20 Therapy	
n	155
Refractory	129 (83.2%)
Relapse (No Refractory)	26 (16.8%)
Relapse or Refractory to Any Prior Alkylator Therapy	
n	155
Refractory	128 (82.6%)
Relapse (No Refractory)	27 (17.4%)

Relapse or Refractory to Any Prior CAR-T Therapy	
n	155
Refractory	46 (29.7%)
Relapse (No Refractory)	6 (3.9%)
Unknown	103 (66.5%)
Relapse or Refractory to Any Prior Pi3K Therapy	
n	155
Refractory	2 (1.3%)
Relapse (No Refractory)	1 (0.6%)
Unknown	152 (98.1%)
Relapse or Refractory to Any Prior Autologous Stem Cell Transplant Therapy	
n	155
Refractory	7 (4.5%)
Relapse (No Refractory)	21 (13.5%)
Unknown	127 (81.9%)
Relapse or Refractory to Any Prior Conditioning Regimen to Stem Cell Transplant Therapy	
n	155
Refractory	9 (5.8%)
Relapse (No Refractory)	22 (14.2%)
Unknown	124 (80.0%)
Progress or Relapse within 24 months after 1L Treatment Start	
n	155
No	32 (20.6%)
Yes	123 (79.4%)
Double Refractory to Both Anti-CD20 and Alkylating Agent Prior Therapies	
n	155
No	30 (19.4%)
Yes	125 (80.6%)

Primary Refractory	
n	155
No	119 (76.8%)
Yes	36 (23.2%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_cm_rrstat.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_cm_rrstat_JUN22_ITT_D235.xls

08JUN2023 9:36

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Summary of Refractory and Relapse Status to Prior Lines of Therapy

	Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)
Relapse or Refractory to Any Prior Therapy	
n	154
Refractory	138 (89.6%)
Relapse (No Refractory)	16 (10.4%)
Relapse or Refractory to Last Line of Prior Therapy	
n	154
Refractory	131 (85.1%)
Relapse	23 (14.9%)
Relapse or Refractory to First Line of Prior Therapy	
n	154
Refractory	90 (58.4%)
Relapse	64 (41.6%)
Relapse or Refractory to Any Prior Anti-CD20 Therapy	
n	154
Refractory	128 (83.1%)
Relapse (No Refractory)	26 (16.9%)
Relapse or Refractory to Any Prior Alkylator Therapy	
n	154
Refractory	127 (82.5%)
Relapse (No Refractory)	27 (17.5%)

Relapse or Refractory to Any Prior CAR-T Therapy	
n	154
Refractory	46 (29.9%)
Relapse (No Refractory)	5 (3.2%)
Unknown	103 (66.9%)
Relapse or Refractory to Any Prior Pi3K Therapy	
n	154
Refractory	2 (1.3%)
Relapse (No Refractory)	1 (0.6%)
Unknown	151 (98.1%)
Relapse or Refractory to Any Prior Autologous Stem Cell Transplant Therapy	
n	154
Refractory	7 (4.5%)
Relapse (No Refractory)	21 (13.6%)
Unknown	126 (81.8%)
Relapse or Refractory to Any Prior Conditioning Regimen to Stem Cell Transplant Therapy	
n	154
Refractory	9 (5.8%)
Relapse (No Refractory)	22 (14.3%)
Unknown	123 (79.9%)
Progress or Relapse within 24 months after 1L Treatment Start	
n	154
No	32 (20.8%)
Yes	122 (79.2%)
Double Refractory to Both Anti-CD20 and Alkylating Agent Prior Therapies	
n	154
No	30 (19.5%)
Yes	124 (80.5%)

Primary Refractory	
n	154
No	118 (76.6%)
Yes	36 (23.4%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_cm_rrstat.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_cm_rrstat_JUN22_EE_D235.xls

08JUN2023 9:44

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Number of patients who died including primary reason

	Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)
Total number of deaths	81 (52.6%)
Primary cause of death	
n	81
Adverse event	8 (9.9%)
Progressive disease	61 (75.3%)
Other	11 (13.6%)
Missing	1 (1.2%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_dd.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_dd_JUN22_SE_D235.xls

01MAR2023 9:50

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Demographic and Baseline Characteristics

	Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=155)
Age (yr)	
n	155
Mean (SD)	63.1 (14.7)
Median	66
Min - Max	21 - 90
Age group (yr)	
n	155
<65	71 (45.8%)
>=65	84 (54.2%)
Sex	
n	155
Male	101 (65.2%)
Female	54 (34.8%)
Ethnicity	
n	155
Hispanic or Latino	9 (5.8%)
Not Hispanic or Latino	121 (78.1%)
Not Stated	21 (13.5%)
Unknown	4 (2.6%)
Country	
n	155
Australia	8 (5.2%)
Belgium	4 (2.6%)
Canada	2 (1.3%)

Czech Republic	4 (2.6%)
Denmark	9 (5.8%)
Spain	20 (12.9%)
Finland	3 (1.9%)
France	29 (18.7%)
Italy	41 (26.5%)
New Zealand	3 (1.9%)
Poland	8 (5.2%)
Taiwan	6 (3.9%)
United States	18 (11.6%)
Race	
n	155
Asian	7 (4.5%)
Black or African American	3 (1.9%)
White	119 (76.8%)
Unknown	26 (16.8%)
Weight (kg)	
n	152
Mean (SD)	74.95 (16.38)
Median	73.65
Min - Max	44.4 - 151.1
Height (cm)	
n	152
Mean (SD)	170.52 (10.13)
Median	171
Min - Max	141.0 - 193.0
Body Mass Index (kg/m2) at Baseline	
n	152
Mean (SD)	25.73 (5.02)
Median	24.81
Min - Max	17.6 - 45.1
ECOG Status at Baseline	
0	69 (44.5%)
1	84 (54.2%)
2	1 (0.6%)
Missing/Unknown	1 (0.6%)

Cancer Hist. Subtype II at Study Entry	
Diffuse Large B-Cell Lymphoma	110 (71.0%)
High Grade B Cell Lymphoma	10 (6.5%)
Primary Mediastinal B Cell Lymphoma	6 (3.9%)
Transformed Follicular Lymphoma	29 (18.7%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_dm.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_dm_JUN22_ITT_D235.xls

01MAR2023 9:35

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluatable Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Demographic and Baseline Characteristics

	Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)
Age (yr)	
n	154
Mean (SD)	63.2 (14.6)
Median	66
Min - Max	21 - 90
Age group (yr)	
n	154
<65	70 (45.5%)
>=65	84 (54.5%)
Sex	
n	154
Male	100 (64.9%)
Female	54 (35.1%)
Ethnicity	
n	154
Hispanic or Latino	9 (5.8%)
Not Hispanic or Latino	120 (77.9%)
Not Stated	21 (13.6%)
Unknown	4 (2.6%)
Country	
n	154
Australia	8 (5.2%)
Belgium	4 (2.6%)
Canada	2 (1.3%)

Czech Republic	4 (2.6%)
Denmark	9 (5.8%)
Spain	19 (12.3%)
Finland	3 (1.9%)
France	29 (18.8%)
Italy	41 (26.6%)
New Zealand	3 (1.9%)
Poland	8 (5.2%)
Taiwan	6 (3.9%)
United States	18 (11.7%)
Race	
n	154
Asian	7 (4.5%)
Black or African American	3 (1.9%)
White	118 (76.6%)
Unknown	26 (16.9%)
Weight (kg)	
n	152
Mean (SD)	74.95 (16.38)
Median	73.65
Min - Max	44.4 - 151.1
Height (cm)	
n	152
Mean (SD)	170.52 (10.13)
Median	171
Min - Max	141.0 - 193.0
Body Mass Index (kg/m2) at Baseline	
n	152
Mean (SD)	25.73 (5.02)
Median	24.81
Min - Max	17.6 - 45.1
ECOG Status at Baseline	
0	69 (44.8%)
1	84 (54.5%)
2	1 (0.6%)

Cancer Hist. Subtype II at Study Entry	
Diffuse Large B-Cell Lymphoma	110 (71.4%)
High Grade B Cell Lymphoma	10 (6.5%)
Primary Mediastinal B Cell Lymphoma	6 (3.9%)
Transformed Follicular Lymphoma	28 (18.2%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_dm.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_dm_JUN22_SE_D235.xls

01MAR2023 9:36

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Disposition of Patients

	Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=155)
Ongoing Study	64 (41.3%)
Discontinued Study	91 (58.7%)
Reason for Study Discontinuation	
Adverse Event	1 (0.6%)
Death	81 (52.3%)
Lost To Follow-Up	2 (1.3%)
Protocol Deviation	1 (0.6%)
Withdrawal By Subject	6 (3.9%)
Not Started Treatment	1 (0.6%)
Active on Treatment	4 (2.6%)
Completed Treatment	38 (24.5%)
Discontinued Treatment	109 (70.3%)
Reason for Treatment Discontinuation	
Adverse Event	11 (7.1%)
Death	11 (7.1%)
Lack Of Efficacy	3 (1.9%)
Other	3 (1.9%)
Physician Decision	9 (5.8%)
Progressive Disease	63 (40.6%)
Protocol Deviation	1 (0.6%)
Symptomatic Deterioration	3 (1.9%)

Withdrawal By Subject	5 (3.2%)
Not Started Initial Treatment	1 (0.6%)
Active on Initial Treatment	4 (2.6%)
Completed Initial Treatment	41 (26.5%)
Discontinued Initial Treatment	109 (70.3%)
Reason for Initial Treatment Discontinuation	
Adverse Event	11 (7.1%)
Death	11 (7.1%)
Lack Of Efficacy	3 (1.9%)
Other	3 (1.9%)
Physician Decision	9 (5.8%)
Progressive Disease	63 (40.6%)
Protocol Deviation	1 (0.6%)
Symptomatic Deterioration	3 (1.9%)
Withdrawal By Subject	5 (3.2%)
Active on Retreatment	0
Completed Retreatment	0
Discontinued Retreatment	3 (1.9%)
Reason for Retreatment Discontinuation	
Adverse Event	1 (0.6%)
Progressive Disease	2 (1.3%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_ds.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_ds_JUN22_ITT_D235.xls

01MAR2023 9:48

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluatable Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Disposition of Patients

	Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)
Ongoing Study	63 (40.9%)
Discontinued Study	91 (59.1%)
Reason for Study Discontinuation	
Adverse Event	1 (0.6%)
Death	81 (52.6%)
Lost To Follow-Up	2 (1.3%)
Protocol Deviation	1 (0.6%)
Withdrawal By Subject	6 (3.9%)
Active on Treatment	4 (2.6%)
Completed Treatment	38 (24.7%)
Discontinued Treatment	109 (70.8%)
Reason for Treatment Discontinuation	
Adverse Event	11 (7.1%)
Death	11 (7.1%)
Lack Of Efficacy	3 (1.9%)
Other	3 (1.9%)
Physician Decision	9 (5.8%)
Progressive Disease	63 (40.9%)
Protocol Deviation	1 (0.6%)
Symptomatic Deterioration	3 (1.9%)
Withdrawal By Subject	5 (3.2%)

Active on Initial Treatment	4 (2.6%)
Completed Initial Treatment	41 (26.6%)
Discontinued Initial Treatment	109 (70.8%)
Reason for Initial Treatment Discontinuation	
Adverse Event	11 (7.1%)
Death	11 (7.1%)
Lack Of Efficacy	3 (1.9%)
Other	3 (1.9%)
Physician Decision	9 (5.8%)
Progressive Disease	63 (40.9%)
Protocol Deviation	1 (0.6%)
Symptomatic Deterioration	3 (1.9%)
Withdrawal By Subject	5 (3.2%)
Active on Retreatment	0
Completed Retreatment	0
Discontinued Retreatment	3 (1.9%)
Reason for Retreatment Discontinuation	
Adverse Event	1 (0.6%)
Progressive Disease	2 (1.3%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_ds.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_ds_JUN22_SE_D235.xls

01MAR2023 9:49

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Duration of follow-up

	Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=155)
Median follow-up time (months)	
n	155
Mean	10.77
Median	9.13
Min - Max	0.1 - 29.2

Median follow-up time is time from patient randomization to study discontinuation date, death date or CCOD, whichever is the earliest.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_fut.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_fut_JUN22_ITT_D235.xls

01MAR2023 9:51

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: All patients
MODEL: --
STUDY: NP30179
Duration of follow-up

	Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)
Median follow-up time (months)	
n	154
Mean	6.33
Median	5.68
Min - Max	0.0 - 27.8

Median follow-up time is time from first dose to end of 90 day safety follow up period or earliest of CCOD, NALT, study discontinuation or start of a re-treatment.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_fut.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_fut_JUN22_SE_D235.xls
01MAR2023 9:51

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Summary of Baseline Disease Characteristics

Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=155)	
Ann Arbor Staging at Study Entry	
n	155
STAGE I	10 (6.5%)
STAGE II	25 (16.1%)
STAGE III	31 (20.0%)
STAGE IV	85 (54.8%)
UNKNOWN	4 (2.6%)
Risk factors for IPI (non-FL patients only)	
n	155
0	5 (3.2%)
1	24 (15.5%)
2	45 (29.0%)
3	55 (35.5%)
4	26 (16.8%)
Extranodal Disease	
n	155
No	60 (38.7%)
Yes	95 (61.3%)
Bulky Disease > 6cm	
n	154
No	90 (58.1%)
Yes	64 (41.3%)
Bulky Disease > 10cm	
n	154

No	135 (87.1%)
Yes	19 (12.3%)
Baseline Sum of Products of Diameters Value (mm2) - Investigator	
n	153
Mean (SD)	5385.18 (6242.22)
Median	3415
Min - Max	48.7 - 40152.0
Category Sum of Products of Diameters Value >=3000 (mm2) - Investigator	
n	153
Baseline SPD < 3000	71 (45.8%)
Baseline SPD >= 3000	82 (52.9%)
Category Sum of Products of Diameters Value >=10000 (mm2) - Investigator	
n	153
Baseline SPD < 10000	133 (85.8%)
Baseline SPD >= 10000	20 (12.9%)
Absence of circulating malignant cells	
n	35
No	5 (3.2%)
Yes	30 (19.4%)
Cancer Histological Subtype	
n	155
DLBCL	110 (71.0%)
HGBCL	10 (6.5%)
PMBCL	6 (3.9%)
trFL	29 (18.7%)
Cancer Grouped Histology	
n	155
aNHL	155 (100%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_mh_char.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_mh_char_JUN22_ITT_D235.xls

01MAR2023 9:38

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluatable Patients

ENDPOINT: All patients

MODEL: --

STUDY: NP30179

Summary of Baseline Disease Characteristics

Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)	
Ann Arbor Staging at Study Entry	
n	154
STAGE I	10 (6.5%)
STAGE II	25 (16.2%)
STAGE III	31 (20.1%)
STAGE IV	85 (55.2%)
UNKNOWN	3 (1.9%)
Risk factors for IPI (non-FL patients only)	
n	154
0	4 (2.6%)
1	24 (15.6%)
2	45 (29.2%)
3	55 (35.7%)
4	26 (16.9%)
Extranodal Disease	
n	154
No	59 (38.3%)
Yes	95 (61.7%)
Bulky Disease > 6cm	
n	154
No	90 (58.4%)
Yes	64 (41.6%)
Bulky Disease > 10cm	
n	154

No	135 (87.7%)
Yes	19 (12.3%)
Baseline Sum of Products of Diameters Value (mm2) - Investigator	
n	153
Mean (SD)	5385.18 (6242.22)
Median	3415
Min - Max	48.7 - 40152.0
Category Sum of Products of Diameters Value >=3000 (mm2) - Investigator	
n	153
Baseline SPD < 3000	71 (46.1%)
Baseline SPD >= 3000	82 (53.2%)
Category Sum of Products of Diameters Value >=10000 (mm2) - Investigator	
n	153
Baseline SPD < 10000	133 (86.4%)
Baseline SPD >= 10000	20 (13.0%)
Absence of circulating malignant cells	
n	35
No	5 (3.2%)
Yes	30 (19.5%)
Cancer Histological Subtype	
n	154
DLBCL	110 (71.4%)
HGBCL	10 (6.5%)
PMBCL	6 (3.9%)
trFL	28 (18.2%)
Cancer Grouped Histology	
n	154
aNHL	154 (100%)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/oth_mh_char.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/oth_mh_char_JUN22_SE_D235.xls

01MAR2023 9:39

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Intent-to-Treat Patients
 ENDPOINT: Overall Survival
 MODEL: --
 STUDY: NP30179
 Time to event analysis (efficacy)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=155)											
		Patients		Patients with Event		Censored		Time To Event					
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	155	100.0	81	52.3	74	47.7	5.3	3.2	6.8	12.0	8.0	16.1

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_tte.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_tte_JUN22_ITT_D235_OS.xls
 27FEB2023 9:32

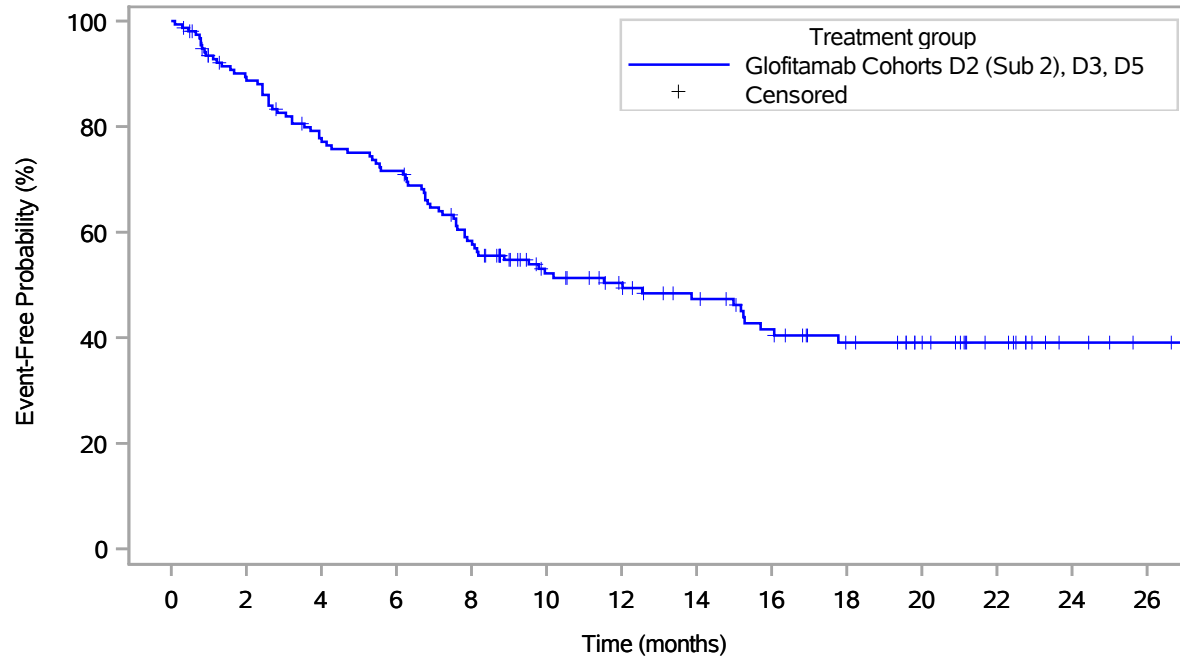
POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: Overall Survival

MODEL: --

STUDY: NP30179

Kaplan-Meier plot of time to first event (months)



Patients at risk														
Glofitamab Cohorts D2 (Sub 2), D3, D5	155	132	113	104	83	60	52	44	36	28	22	14	6	3
Patients censored														
Glofitamab Cohorts D2 (Sub 2), D3, D5	0	7	9	9	11	26	32	37	40	46	52	60	68	71

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_tte.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_tte_JUN22_ITT_D235_OS.pdf
 27FEB2023 9:37

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: Overall Survival

MODEL: --

STUDY: NP30179

Time to event landmark analysis

	Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=155)
Patients included in analysis (%)	155 (100%)
Patients with event (%)	81 (52.3%)
Patients without event (%)	74 (47.7%)
Time to event (months)	
Median	12
95% CI	(8.0, 16.1)
25% and 75%-ile	5.3 - NE
Range	0.1 - 28.6*
Time point analysis (Unstratified)	
3 Months	
Patients remaining at risk	121
Event free proportion (%)	82.61
95% CI	(76.53, 88.69)
6 Months	
Patients remaining at risk	104
Event free proportion (%)	71.61
95% CI	(64.34, 78.89)
9 Months	
Patients remaining at risk	70

Event free proportion (%)	54.76
95% CI	(46.65, 62.87)
12 Months	
Patients remaining at risk	52
Event free proportion (%)	50.39
95% CI	(42.06, 58.71)
15 Months	
Patients remaining at risk	41
Event free proportion (%)	46.21
95% CI	(37.62, 54.80)
18 Months	
Patients remaining at risk	28
Event free proportion (%)	39.08
95% CI	(30.11, 48.06)
21 Months	
Patients remaining at risk	19
Event free proportion (%)	39.08
95% CI	(30.11, 48.06)
24 Months	
Patients remaining at risk	6
Event free proportion (%)	39.08
95% CI	(30.11, 48.06)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_lma.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_lma_JUN22_ITT_D235_OS.xls

27FEB2023 9:26

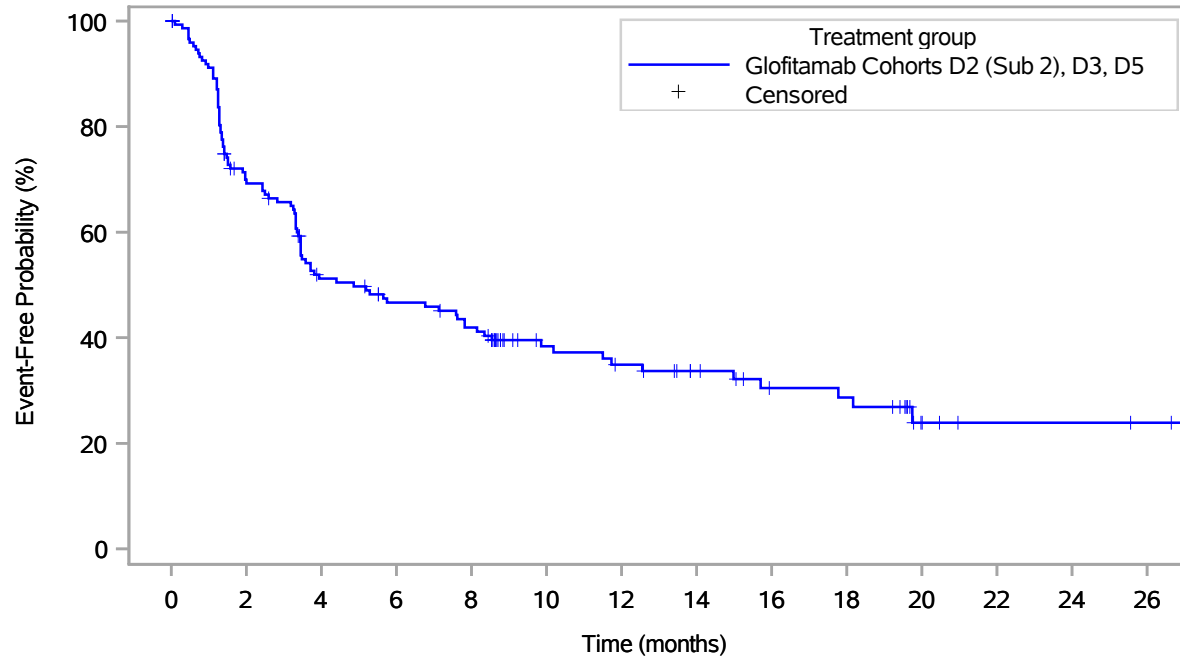
POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Intent-to-Treat Patients
 ENDPOINT: IRC Assessed Progression Free Survival
 MODEL: --
 STUDY: NP30179
 Time to event analysis (efficacy)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=155)											
		Patients		Patients with Event		Censored		Time To Event					
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	155	100.0	95	61.3	60	38.7	1.4	1.3	2.5	4.9	3.4	8.1

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_tte.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_tte_JUN22_ITT_D235_IRCPFS.xls
 27FEB2023 9:31

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Intent-to-Treat Patients
ENDPOINT: IRC Assessed Progression Free Survival
MODEL: --
STUDY: NP30179
Kaplan-Meier plot of time to first event (months)



Patients at risk														
Glofitamab Cohorts D2 (Sub 2), D3, D5	155	99	69	60	53	33	29	23	17	16	6	3	3	2
Patients censored														
Glofitamab Cohorts D2 (Sub 2), D3, D5	0	12	16	19	20	36	37	42	46	46	54	57	57	58

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_tte.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_tte_JUN22_ITT_D235_IRCPFS.pdf
 27FEB2023 9:36

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Intent-to-Treat Patients

ENDPOINT: IRC Assessed Progression Free Survival

MODEL: --

STUDY: NP30179

Time to event landmark analysis

	Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=155)
Patients included in analysis (%)	155 (100%)
Patients with event (%)	95 (61.3%)
Patients without event (%)	60 (38.7%)
Time to event (months)	
Median	4.9
95% CI	(3.4, 8.1)
25% and 75%-ile	1.4 - 19.7
Range	0.0* - 28.3*
Time point analysis (Unstratified)	
3 Months	
Patients remaining at risk	92
Event free proportion (%)	65.69
95% CI	(57.97, 73.41)
6 Months	
Patients remaining at risk	60
Event free proportion (%)	46.66
95% CI	(38.40, 54.92)
9 Months	
Patients remaining at risk	37

Event free proportion (%)	39.55
95% CI	(31.34, 47.76)
12 Months	
Patients remaining at risk	29
Event free proportion (%)	34.9
95% CI	(26.48, 43.31)
15 Months	
Patients remaining at risk	21
Event free proportion (%)	32.16
95% CI	(23.58, 40.74)
18 Months	
Patients remaining at risk	16
Event free proportion (%)	28.68
95% CI	(19.77, 37.59)
21 Months	
Patients remaining at risk	3
Event free proportion (%)	23.9
95% CI	(14.16, 33.63)
24 Months	
Patients remaining at risk	3
Event free proportion (%)	23.9
95% CI	(14.16, 33.63)

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_lma.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_lma_JUN22_ITT_D235_IRCPFS.xls
27FEB2023 9:26

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: Duration of IRC Assessed Complete Response

MODEL: --

STUDY: NP30179

Time to event analysis (efficacy)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)											
		Patients		Patients with Event		Censored		Time To Event					
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	62	40.3	15	24.2	47	75.8	9.3	6.7	NE	NE	16.8	NE

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_tte.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_tte_JUN22_EE_D235_IRCCR.xls

27FEB2023 9:27

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
 ENDPOINT: Time to First IRC Assessed Complete Response
 MODEL: --
 STUDY: NP30179
 Time to event analysis (efficacy)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)											
		Patients		Patients with Event		Censored		Time To Event					
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	154	100.0	62	40.3	92	59.7	1.3	1.2	1.3	1.4	1.4	1.6

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_tte.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_tte_JUN22_EE_D235_IRCFCRSP.xls
 14APR2023 14:48

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: Time to First IRC Assessed Response

MODEL: --

STUDY: NP30179

Time to event analysis (efficacy)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)											
		Patients		Patients with Event		Censored		Time To Event					
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	154	100.0	80	51.9	74	48.1	1.2	1.2	1.3	1.4	1.3	1.4

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_tte.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_tte_JUN22_EE_D235_IRCFRSP.xls

14APR2023 14:50

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: Duration of IRC Assessed Any Response

MODEL: --

STUDY: NP30179

Time to event analysis (efficacy)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)											
		Patients		Patients with Event		Censored		Time To Event					
Name	Level	n	%	n	%	n	%	Q1 (months)	95% Lower CL for Q1	95% Upper CL for Q1	Median (months)	95% Lower CL for Median	95% Upper CL for Median
All	n/a	80	51.9	30	37.5	50	62.5	6.5	2.3	10.4	16.8	10.4	NE

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_tte.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_tte_JUN22_EE_D235_IRCOVR.xls

27FEB2023 9:28

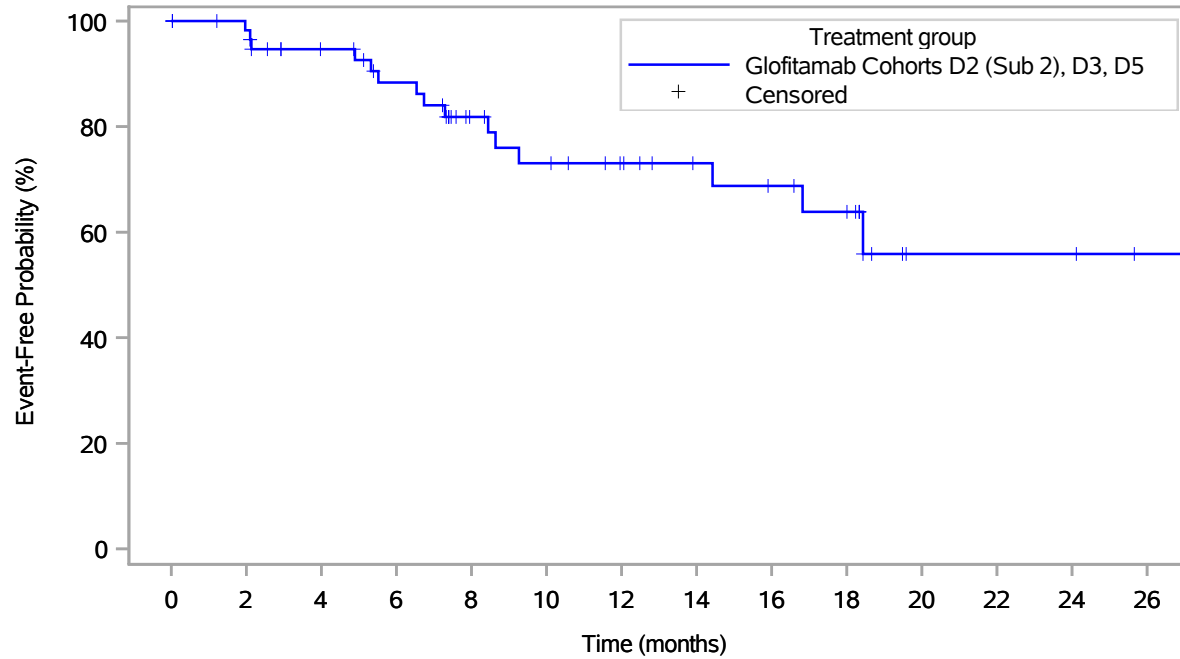
POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: Duration of IRC Assessed Complete Response

MODEL: --

STUDY: NP30179

Kaplan-Meier plot of time to first event (months)



Patients at risk	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Glofitamab Cohorts D2 (Sub 2), D3, D5	62	56	47	41	29	25	21	17	15	13	3	3	3	1
Patients censored														
Glofitamab Cohorts D2 (Sub 2), D3, D5	0	5	12	15	24	25	29	33	34	35	44	44	44	46

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_tte.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_tte_JUN22_EE_D235_IRCCR.pdf
 27FEB2023 9:33

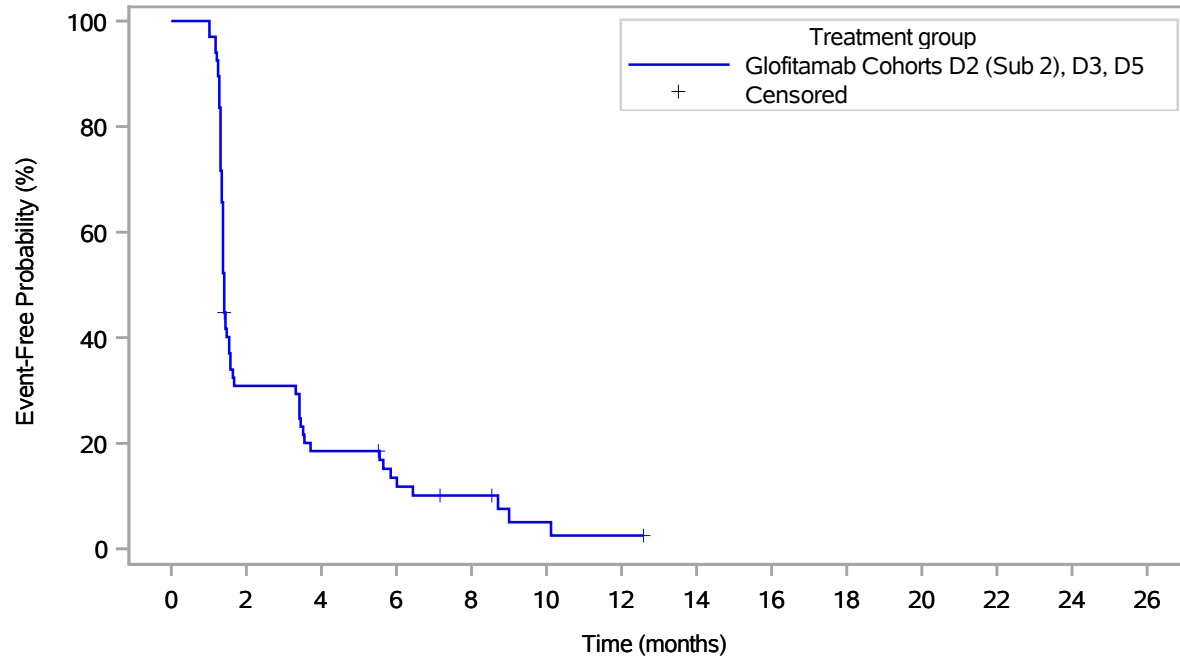
POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: Time to First IRC Assessed Complete Response

MODEL: --

STUDY: NP30179

Kaplan-Meier plot of time to first event (months)



Patients at risk															
Glofitamab Cohorts D2 (Sub 2), D3, D5	67	20	12	8	5	2	1	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Glofitamab Cohorts D2 (Sub 2), D3, D5	0	1	1	2	3	4	4	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_tte.sas
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 27FEB2023 9:35

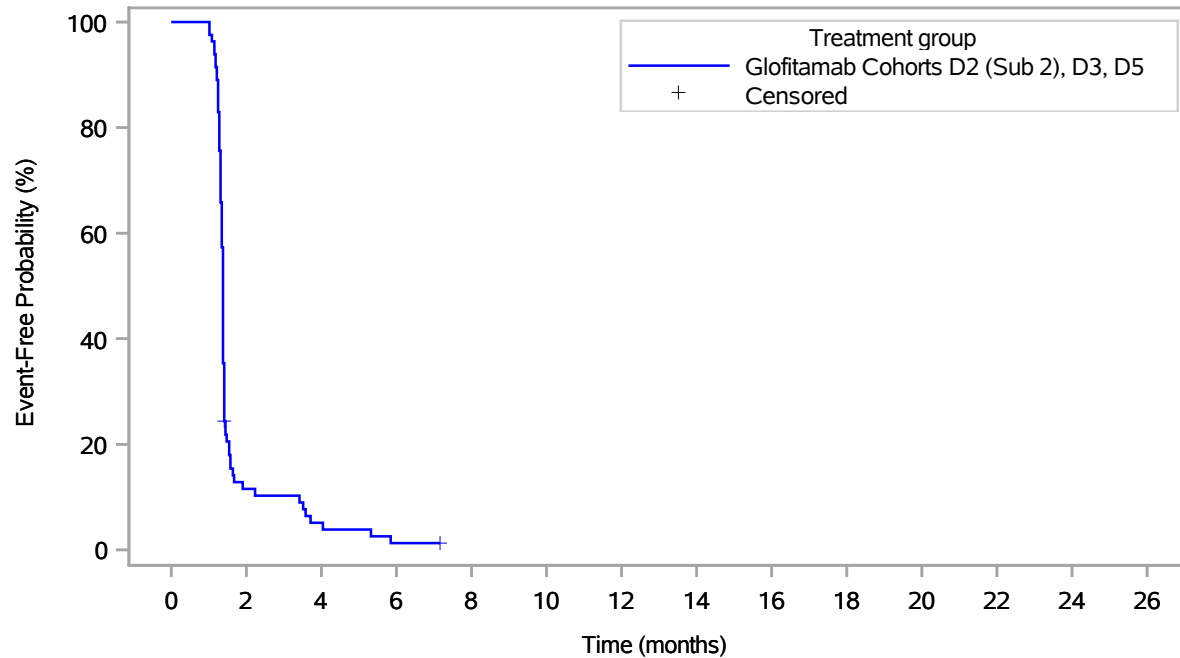
POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: Time to First IRC Assessed Response

MODEL: --

STUDY: NP30179

Kaplan-Meier plot of time to first event (months)



Patients at risk															
Glofitamab Cohorts D2 (Sub 2), D3, D5	82	9	4	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Patients censored															
Glofitamab Cohorts D2 (Sub 2), D3, D5	0	1	1	1	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_tte.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_tte_JUN22_EE_D235_IRCFRSP.pdf
 27FEB2023 9:36

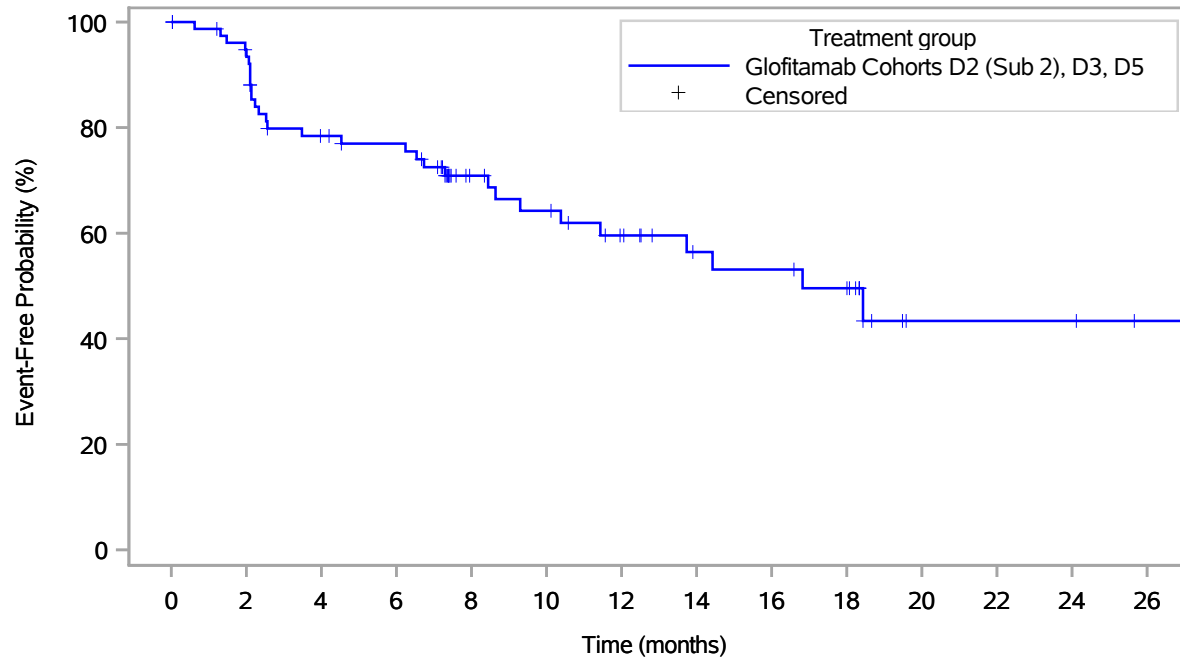
POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: Duration of IRC Assessed Any Response

MODEL: --

STUDY: NP30179

Kaplan-Meier plot of time to first event (months)



Time (months)	0	2	4	6	8	10	12	14	16	18	20	22	24	26
Patients at risk	80	71	55	52	33	29	23	17	16	14	3	3	3	1
Patients censored	0	5	9	11	26	27	31	36	36	37	47	47	47	49

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_tte.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_tte_JUN22_EE_D235_IRCOVR.pdf
 27FEB2023 9:34

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: IRC Assessed Objective Response Rate

MODEL: --

STUDY: NP30179

Dichotomous analysis (efficacy)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	80	51.9	44.1	59.7

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_EE_D235_IRCORR.xls

27FEB2023 9:23

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
 ENDPOINT: Investigator Assessed BOR
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

			Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	CR	n/a	154	100.0	59	38.3	31.0	46.2
	PR	n/a	154	100.0	32	20.8	15.1	27.9
	SD	n/a	154	100.0	8	5.2	2.7	9.9
	PD	n/a	154	100.0	44	28.6	22.0	36.2
	NE	n/a	154	100.0	0	0.0	0.0	2.4
	Missing or No Data	n/a	154	100.0	11	7.1	4.0	12.3

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp_new.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_new_JUN22_EE_D235_INV.xls

27FEB2023 9:25

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
 ENDPOINT: IRC Assessed BOR
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

			Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
			Patients		Patients with Event			
Name	Parameter	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	CR	n/a	154	100.0	62	40.3	32.8	48.2
	PR	n/a	154	100.0	18	11.7	7.5	17.7
	SD	n/a	154	100.0	21	13.6	9.1	19.9
	PD	n/a	154	100.0	42	27.3	20.9	34.8
	NE	n/a	154	100.0	0	0.0	0.0	2.4
	Missing or No Data	n/a	154	100.0	11	7.1	4.0	12.3

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp_new.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_new_JUN22_EE_D235_IRC.xls
 27FEB2023 9:24

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Appetite Loss

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab Cohorts D3 and D5 (N=147)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	147	100.0	136	92.5	19.12	29.15
Cycle 1 Day 8	n/a	139	94.6	131	94.2	17.05	27.54
Cycle 2 Day 1	n/a	122	83.0	113	92.6	17.40	28.90
Cycle 3 Day 1	n/a	104	70.7	94	90.4	12.77	22.46
Cycle 5 Day 1	n/a	80	54.4	73	91.3	8.22	16.46
Cycle 7 Day 1	n/a	57	38.8	53	93.0	8.81	20.83
Cycle 9 Day 1	n/a	43	29.3	21	48.8	7.94	14.55
Cycle 12 Day 1	n/a	41	27.9	23	56.1	8.70	14.97

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

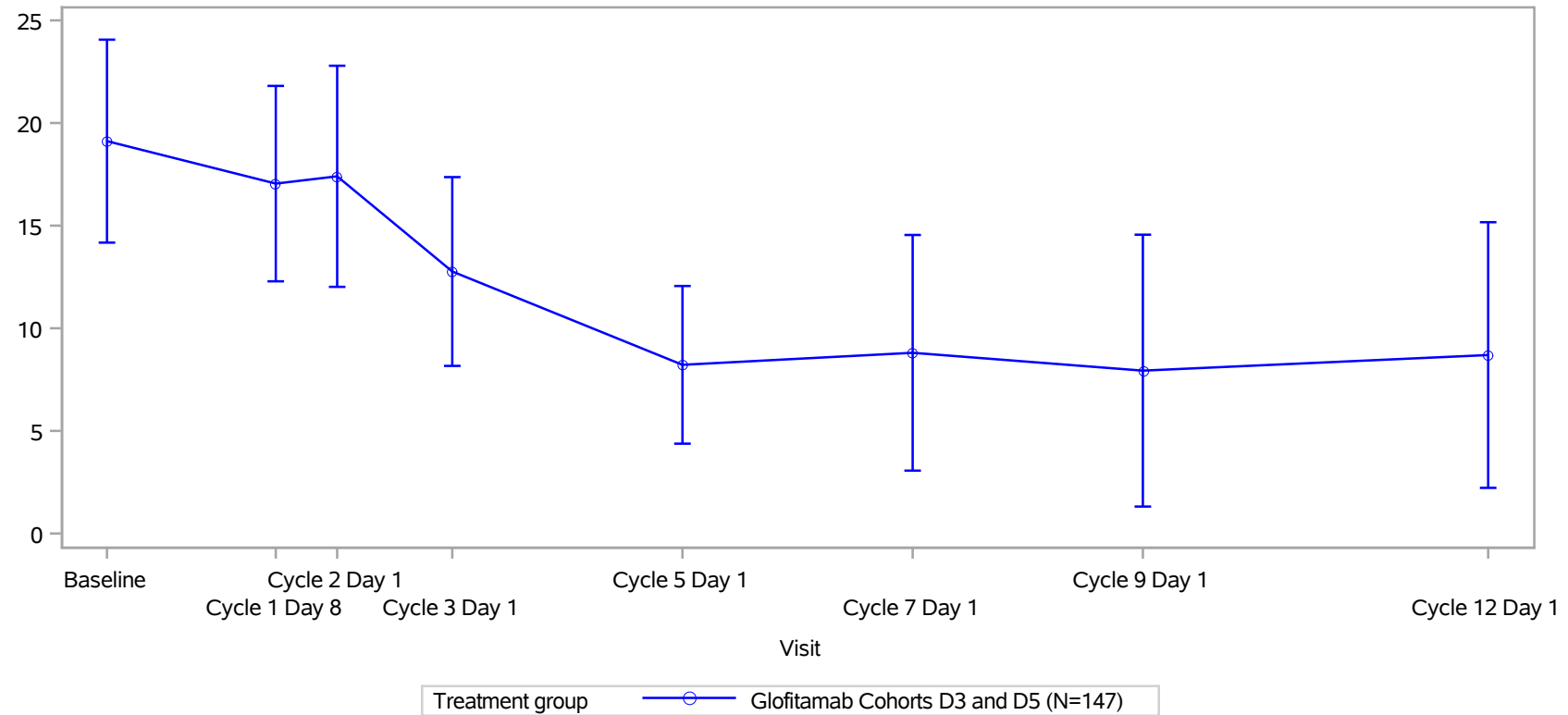
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D35_C30AP.xls

27FEB2023 10:32

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Appetite Loss
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D35_C30AP.pdf
27FEB2023 10:40

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Appetite Loss (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab Cohorts D3 and D5 (N=127)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	127	100.0	33	26.0	19.1	34.2

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D35_M10C30AP.xls
 27FEB2023 10:51

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Constipation

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab Cohorts D3 and D5 (N=147)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	147	100.0	136	92.5	18.14	27.78
Cycle 1 Day 8	n/a	139	94.6	130	93.5	19.74	27.75
Cycle 2 Day 1	n/a	122	83.0	113	92.6	18.88	28.13
Cycle 3 Day 1	n/a	104	70.7	94	90.4	15.60	24.78
Cycle 5 Day 1	n/a	80	54.4	74	92.5	17.12	28.80
Cycle 7 Day 1	n/a	57	38.8	54	94.7	12.35	22.71
Cycle 9 Day 1	n/a	43	29.3	21	48.8	9.52	21.46
Cycle 12 Day 1	n/a	41	27.9	23	56.1	14.49	26.26

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

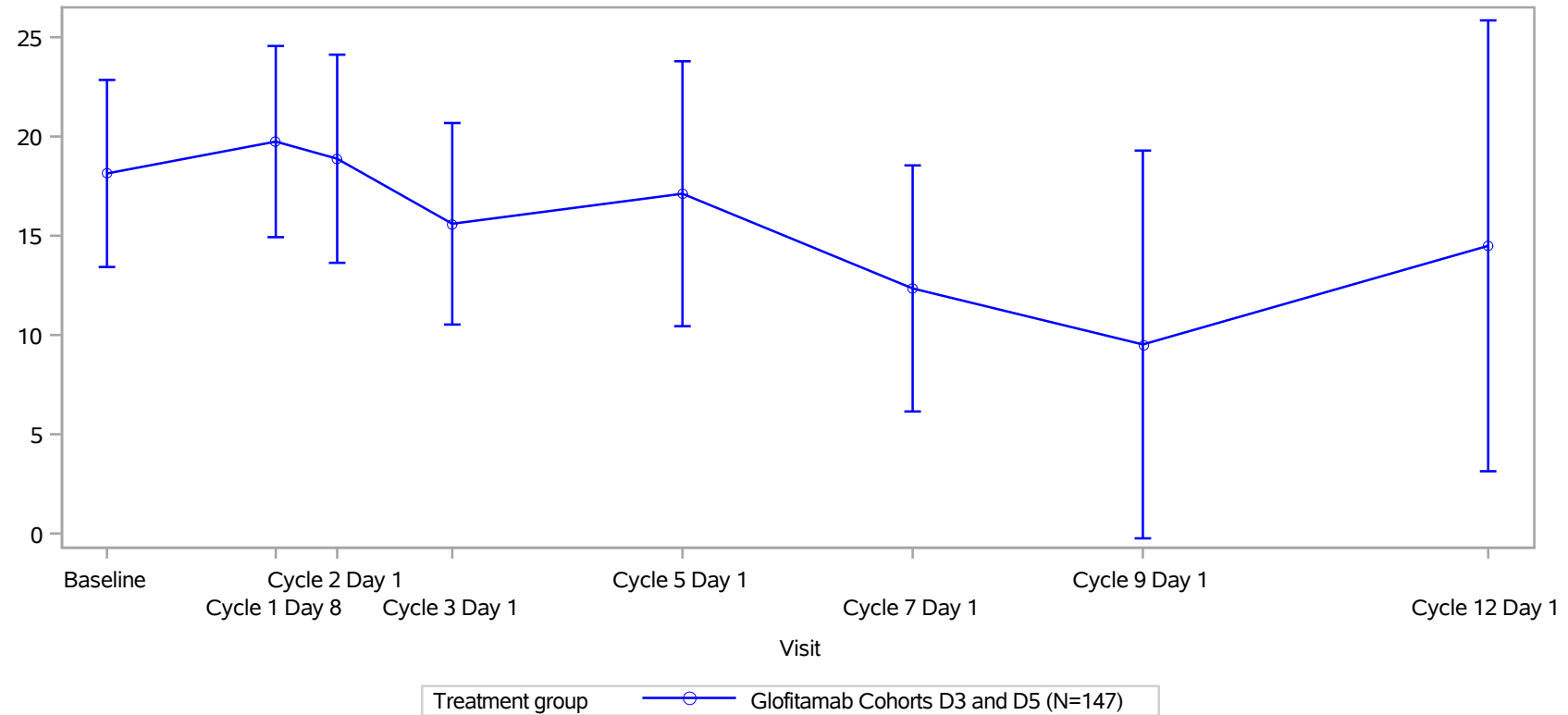
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D35_C30CO.xls

27FEB2023 10:31

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Constipation
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D35_C30CO.pdf
27FEB2023 10:39

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Constipation (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab Cohorts D3 and D5 (N=127)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	127	100.0	42	33.1	25.5	41.6

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
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 27FEB2023 10:49

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Diarrhoea

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab Cohorts D3 and D5 (N=147)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	147	100.0	136	92.5	9.07	19.23
Cycle 1 Day 8	n/a	139	94.6	131	94.2	10.18	21.84
Cycle 2 Day 1	n/a	122	83.0	114	93.4	8.19	18.58
Cycle 3 Day 1	n/a	104	70.7	94	90.4	8.51	20.70
Cycle 5 Day 1	n/a	80	54.4	73	91.3	10.50	22.82
Cycle 7 Day 1	n/a	57	38.8	54	94.7	9.26	21.88
Cycle 9 Day 1	n/a	43	29.3	21	48.8	6.35	13.41
Cycle 12 Day 1	n/a	41	27.9	23	56.1	8.70	18.03

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

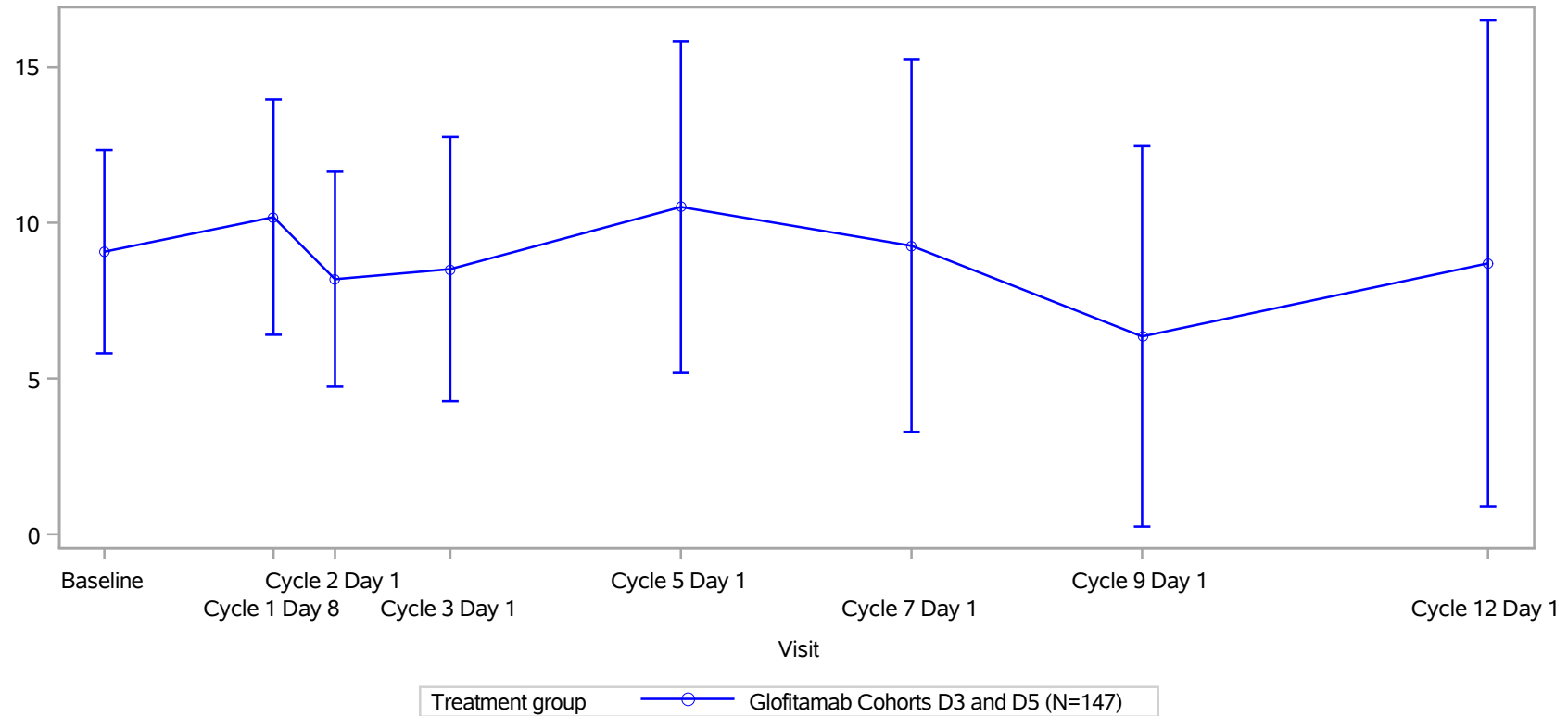
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D35_C30DI.xls

27FEB2023 10:30

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Diarrhoea
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D35_C30D1.pdf
27FEB2023 10:38

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Diarrhoea (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab Cohorts D3 and D5 (N=127)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	127	100.0	31	24.4	17.8	32.6

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D35_M10C30DI.xls
 27FEB2023 10:48

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Dyspnoea

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab Cohorts D3 and D5 (N=147)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	147	100.0	135	91.8	20.49	26.39
Cycle 1 Day 8	n/a	139	94.6	130	93.5	16.92	24.29
Cycle 2 Day 1	n/a	122	83.0	114	93.4	16.67	23.15
Cycle 3 Day 1	n/a	104	70.7	94	90.4	16.31	23.82
Cycle 5 Day 1	n/a	80	54.4	74	92.5	15.32	22.87
Cycle 7 Day 1	n/a	57	38.8	54	94.7	16.05	19.14
Cycle 9 Day 1	n/a	43	29.3	21	48.8	19.05	19.92
Cycle 12 Day 1	n/a	41	27.9	23	56.1	15.94	22.18

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

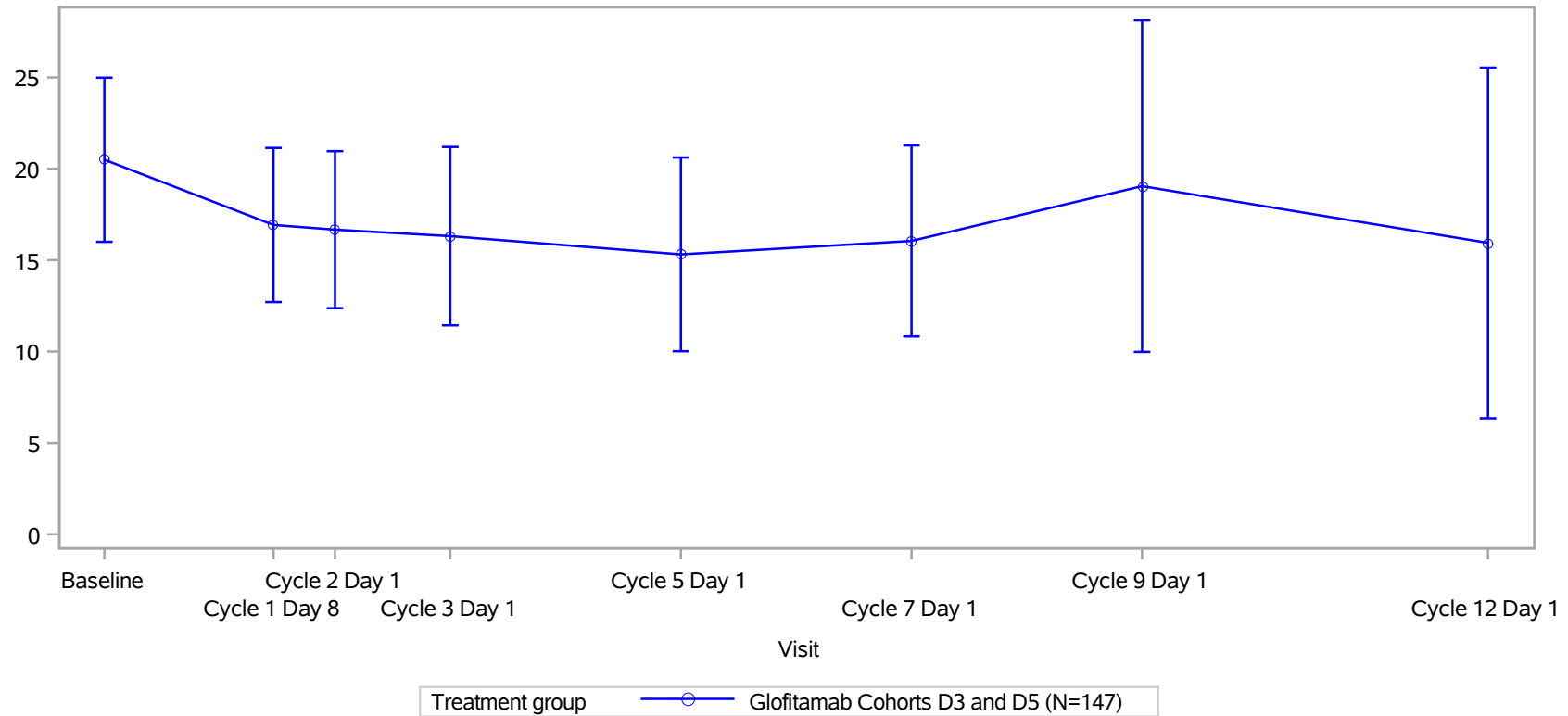
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D35_C30DY.xls

27FEB2023 10:30

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Dyspnoea
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D35_C30DY.pdf
27FEB2023 10:38

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Dyspnoea (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab Cohorts D3 and D5 (N=127)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	127	100.0	34	26.8	19.8	35.1

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D35_M10C30DY.xls
 27FEB2023 10:48

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Fatigue

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab Cohorts D3 and D5 (N=147)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	147	100.0	136	92.5	38.97	26.41
Cycle 1 Day 8	n/a	139	94.6	132	95.0	37.08	27.24
Cycle 2 Day 1	n/a	122	83.0	114	93.4	35.48	24.33
Cycle 3 Day 1	n/a	104	70.7	94	90.4	33.04	22.79
Cycle 5 Day 1	n/a	80	54.4	74	92.5	30.63	21.84
Cycle 7 Day 1	n/a	57	38.8	53	93.0	25.16	20.80
Cycle 9 Day 1	n/a	43	29.3	21	48.8	22.75	21.79
Cycle 12 Day 1	n/a	41	27.9	23	56.1	27.54	25.92

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

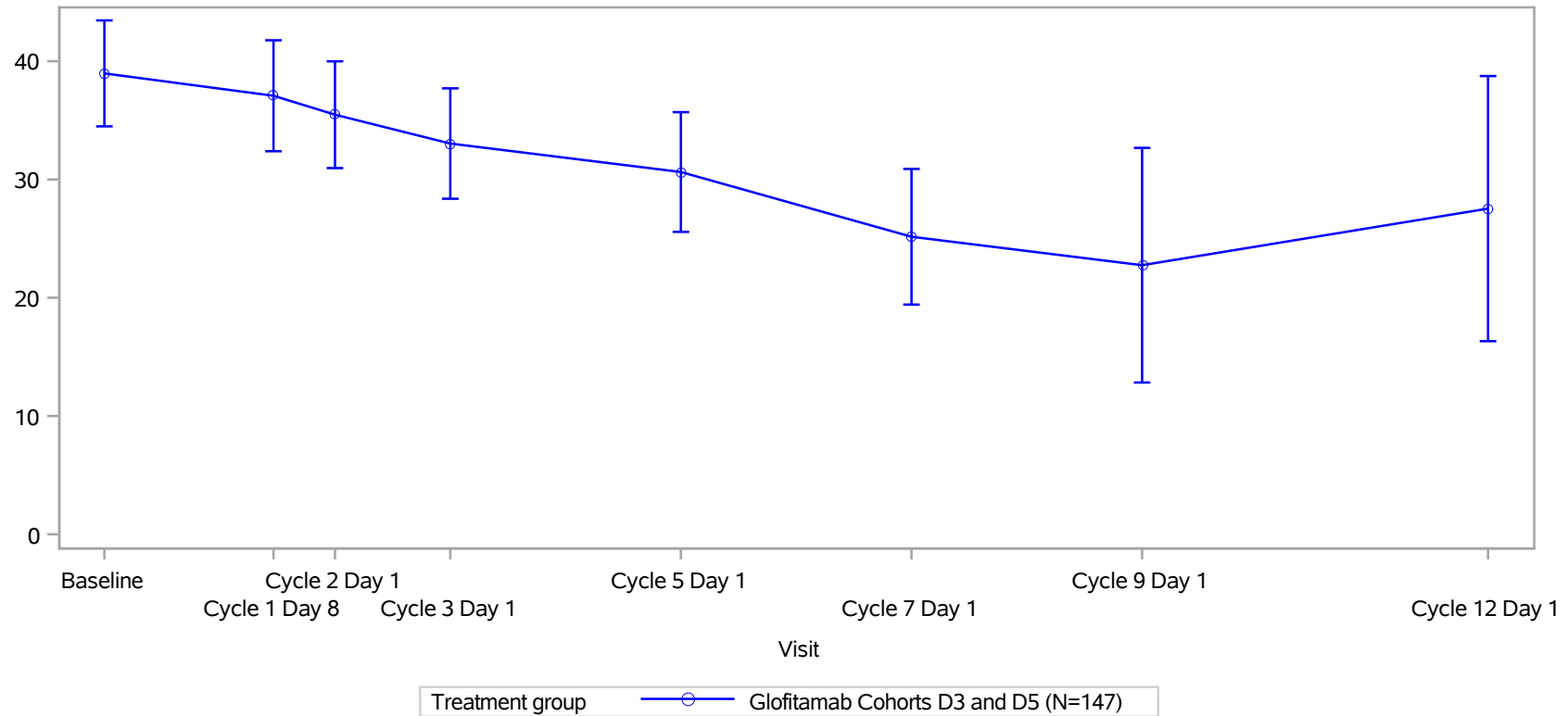
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D35_C30FA.xls

27FEB2023 10:37

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Fatigue
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D35_C30FA.pdf
27FEB2023 10:46

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Fatigue (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab Cohorts D3 and D5 (N=127)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	127	100.0	65	51.2	42.6	59.7

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D35_M10C30FA.xls
 27FEB2023 10:59

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Nausea/Vomiting

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab Cohorts D3 and D5 (N=147)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	147	100.0	136	92.5	4.78	13.89
Cycle 1 Day 8	n/a	139	94.6	132	95.0	6.44	17.43
Cycle 2 Day 1	n/a	122	83.0	114	93.4	4.39	9.68
Cycle 3 Day 1	n/a	104	70.7	94	90.4	4.61	11.82
Cycle 5 Day 1	n/a	80	54.4	74	92.5	3.15	9.82
Cycle 7 Day 1	n/a	57	38.8	54	94.7	2.16	7.27
Cycle 9 Day 1	n/a	43	29.3	21	48.8	3.17	8.53
Cycle 12 Day 1	n/a	41	27.9	23	56.1	4.35	11.48

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

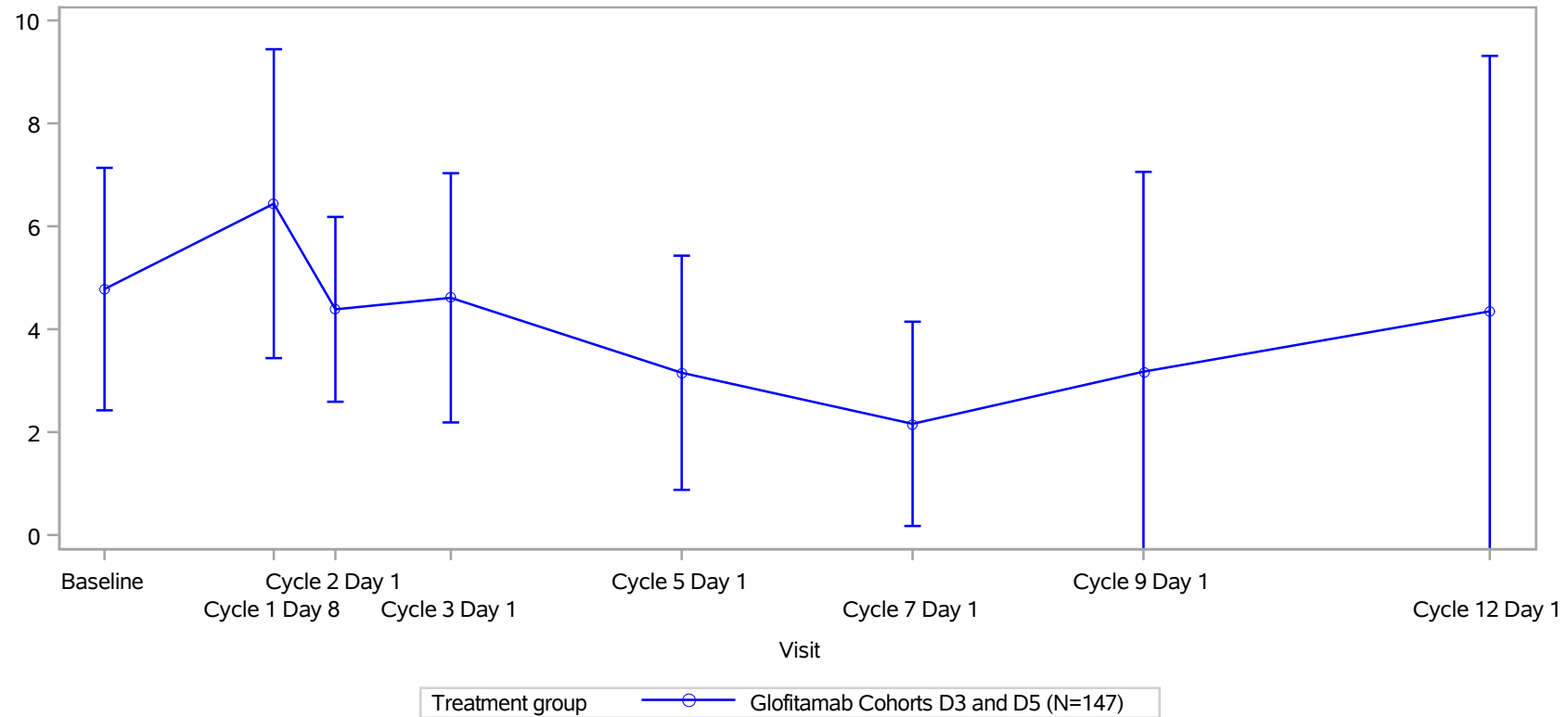
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D35_C30NV.xls

27FEB2023 10:29

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Nausea/Vomiting
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D35_C30NV.pdf
27FEB2023 10:37

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Nausea/Vomiting (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab Cohorts D3 and D5 (N=127)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	127	100.0	37	29.1	21.9	37.6

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D35_M10C30NV.xls
 27FEB2023 10:47

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Pain

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab Cohorts D3 and D5 (N=147)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	147	100.0	136	92.5	31.37	28.40
Cycle 1 Day 8	n/a	139	94.6	132	95.0	27.40	26.30
Cycle 2 Day 1	n/a	122	83.0	114	93.4	23.10	26.93
Cycle 3 Day 1	n/a	104	70.7	94	90.4	19.50	24.64
Cycle 5 Day 1	n/a	80	54.4	74	92.5	19.59	22.30
Cycle 7 Day 1	n/a	57	38.8	52	91.2	16.67	20.61
Cycle 9 Day 1	n/a	43	29.3	21	48.8	16.67	25.82
Cycle 12 Day 1	n/a	41	27.9	23	56.1	17.39	27.74

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

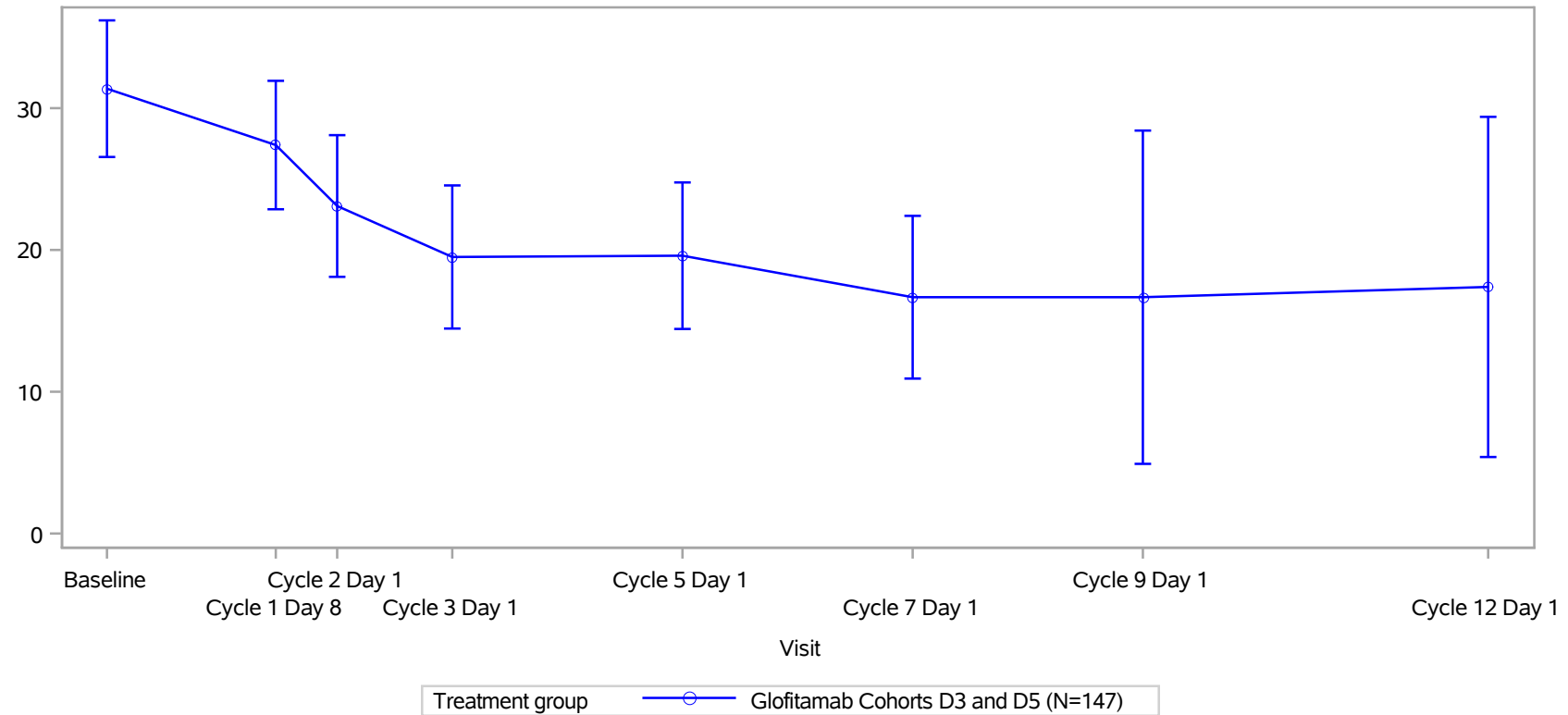
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D35_C30PA.xls

27FEB2023 10:33

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Pain
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D35_C30PA.pdf
27FEB2023 10:41

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Pain (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab Cohorts D3 and D5 (N=127)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	127	100.0	59	46.5	38.0	55.1

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D35_M10C30PA.xls
 27FEB2023 10:53

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Insomnia

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab Cohorts D3 and D5 (N=147)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	147	100.0	135	91.8	31.11	29.70
Cycle 1 Day 8	n/a	139	94.6	132	95.0	30.56	27.64
Cycle 2 Day 1	n/a	122	83.0	113	92.6	28.61	29.16
Cycle 3 Day 1	n/a	104	70.7	93	89.4	24.37	28.72
Cycle 5 Day 1	n/a	80	54.4	74	92.5	28.38	28.50
Cycle 7 Day 1	n/a	57	38.8	53	93.0	25.16	26.07
Cycle 9 Day 1	n/a	43	29.3	21	48.8	25.40	27.70
Cycle 12 Day 1	n/a	41	27.9	23	56.1	26.09	28.35

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

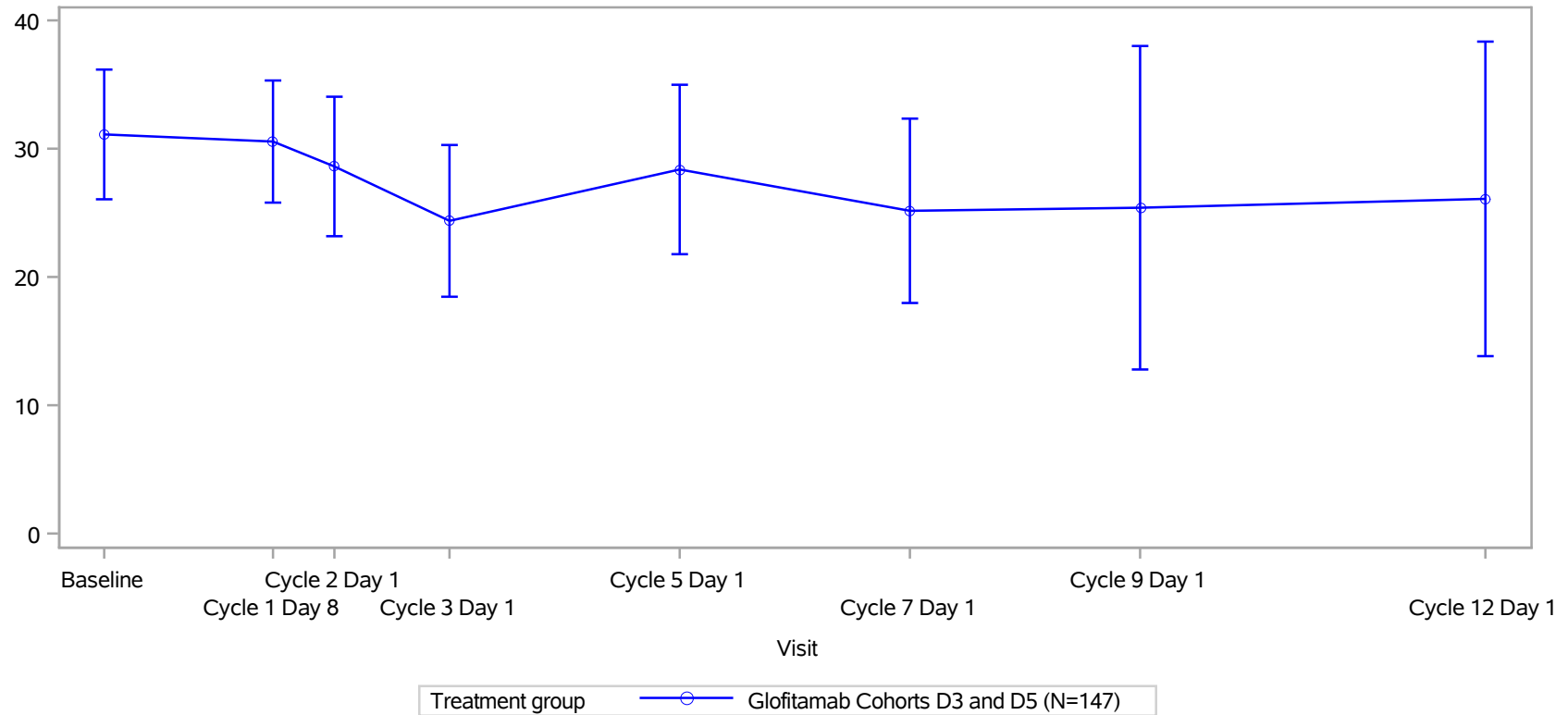
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D35_C30SL.xls

27FEB2023 10:36

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Insomnia
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D35_C30SL.pdf
27FEB2023 10:46

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Insomnia (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab Cohorts D3 and D5 (N=127)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	126	99.2	48	37.8	29.8	46.5

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D35_M10C30SL.xls
 27FEB2023 10:58

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Cognitive Functioning

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab Cohorts D3 and D5 (N=147)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	147	100.0	136	92.5	84.80	22.45
Cycle 1 Day 8	n/a	139	94.6	132	95.0	88.26	17.80
Cycle 2 Day 1	n/a	122	83.0	114	93.4	87.13	19.21
Cycle 3 Day 1	n/a	104	70.7	94	90.4	88.83	15.53
Cycle 5 Day 1	n/a	80	54.4	73	91.3	87.44	15.41
Cycle 7 Day 1	n/a	57	38.8	54	94.7	86.42	15.89
Cycle 9 Day 1	n/a	43	29.3	21	48.8	87.30	19.65
Cycle 12 Day 1	n/a	41	27.9	23	56.1	81.16	23.19

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

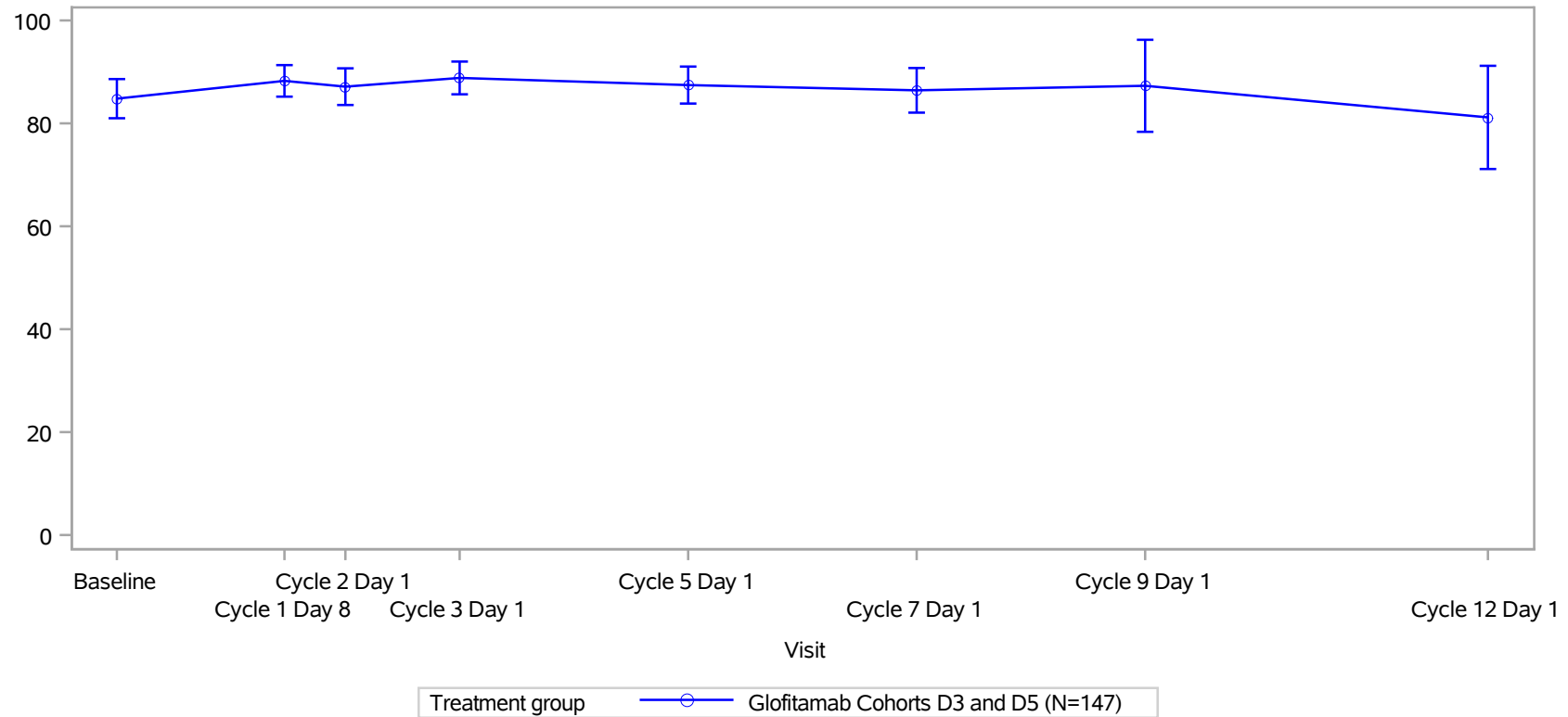
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D35_C30CF.xls

27FEB2023 10:35

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Cognitive Functioning
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D35_C30CF.pdf
27FEB2023 10:44

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Cognitive Functioning (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab Cohorts D3 and D5 (N=127)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	127	100.0	50	39.4	31.3	48.1

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D35_M10C30CF.xls
 27FEB2023 10:56

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Emotional Functioning

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab Cohorts D3 and D5 (N=147)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	147	100.0	136	92.5	75.18	21.73
Cycle 1 Day 8	n/a	139	94.6	132	95.0	78.96	19.81
Cycle 2 Day 1	n/a	122	83.0	114	93.4	79.63	20.81
Cycle 3 Day 1	n/a	104	70.7	93	89.4	80.11	20.78
Cycle 5 Day 1	n/a	80	54.4	73	91.3	81.32	18.35
Cycle 7 Day 1	n/a	57	38.8	54	94.7	80.56	21.96
Cycle 9 Day 1	n/a	43	29.3	21	48.8	83.73	19.80
Cycle 12 Day 1	n/a	41	27.9	23	56.1	78.14	25.16

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

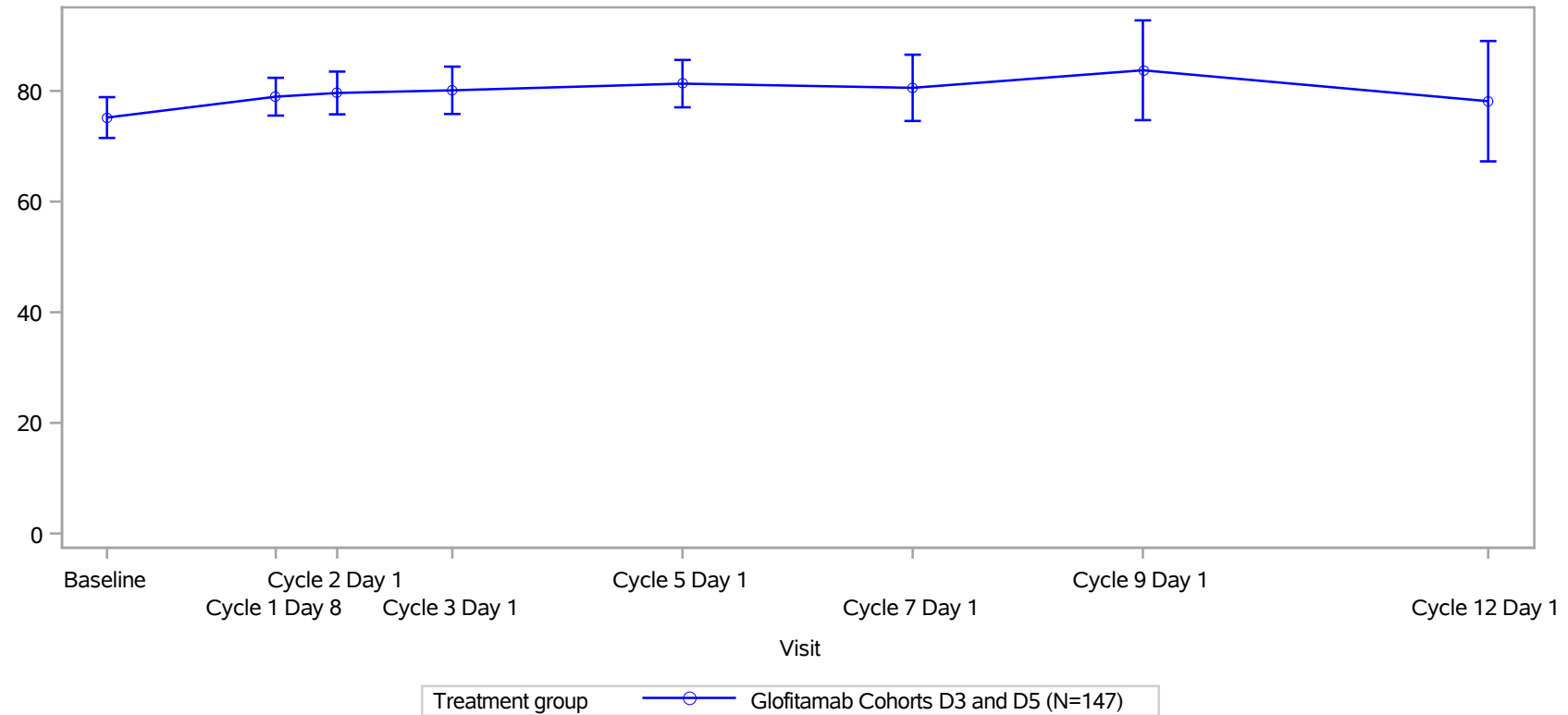
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D35_C30EF.xls

27FEB2023 10:34

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Emotional Functioning
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D35_C30EF.pdf
27FEB2023 10:43

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Emotional Functioning (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab Cohorts D3 and D5 (N=127)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	127	100.0	29	22.8	16.4	30.9

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D35_M10C30EF.xls
 27FEB2023 10:55

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Physical Functioning

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab Cohorts D3 and D5 (N=147)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	147	100.0	136	92.5	75.78	22.92
Cycle 1 Day 8	n/a	139	94.6	132	95.0	75.98	22.02
Cycle 2 Day 1	n/a	122	83.0	114	93.4	77.73	19.55
Cycle 3 Day 1	n/a	104	70.7	94	90.4	79.49	19.20
Cycle 5 Day 1	n/a	80	54.4	74	92.5	82.93	16.73
Cycle 7 Day 1	n/a	57	38.8	54	94.7	84.66	15.73
Cycle 9 Day 1	n/a	43	29.3	21	48.8	83.17	15.29
Cycle 12 Day 1	n/a	41	27.9	23	56.1	83.19	16.80

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

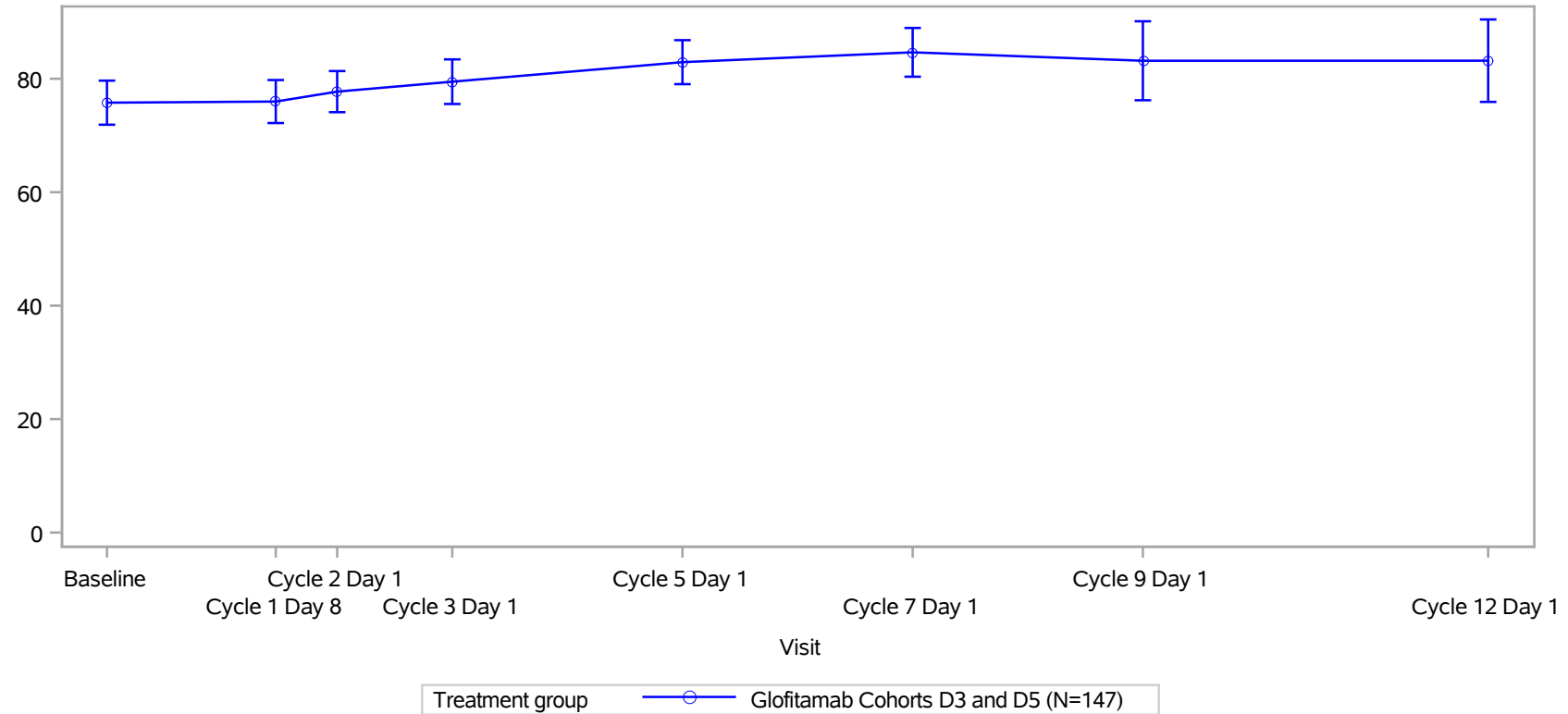
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D35_C30PF.xls

27FEB2023 10:32

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Physical Functioning
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D35_C30PF.pdf
27FEB2023 10:41

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Physical Functioning (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab Cohorts D3 and D5 (N=127)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	127	100.0	51	40.2	32.0	48.9

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D35_M10C30PF.xls
 27FEB2023 10:52

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Global Health Status

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab Cohorts D3 and D5 (N=147)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	147	100.0	136	92.5	56.43	23.46
Cycle 1 Day 8	n/a	139	94.6	132	95.0	57.01	22.18
Cycle 2 Day 1	n/a	122	83.0	114	93.4	60.53	21.24
Cycle 3 Day 1	n/a	104	70.7	93	89.4	63.35	21.71
Cycle 5 Day 1	n/a	80	54.4	73	91.3	65.07	19.53
Cycle 7 Day 1	n/a	57	38.8	53	93.0	66.67	21.56
Cycle 9 Day 1	n/a	43	29.3	21	48.8	71.03	21.18
Cycle 12 Day 1	n/a	41	27.9	23	56.1	67.03	27.69

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

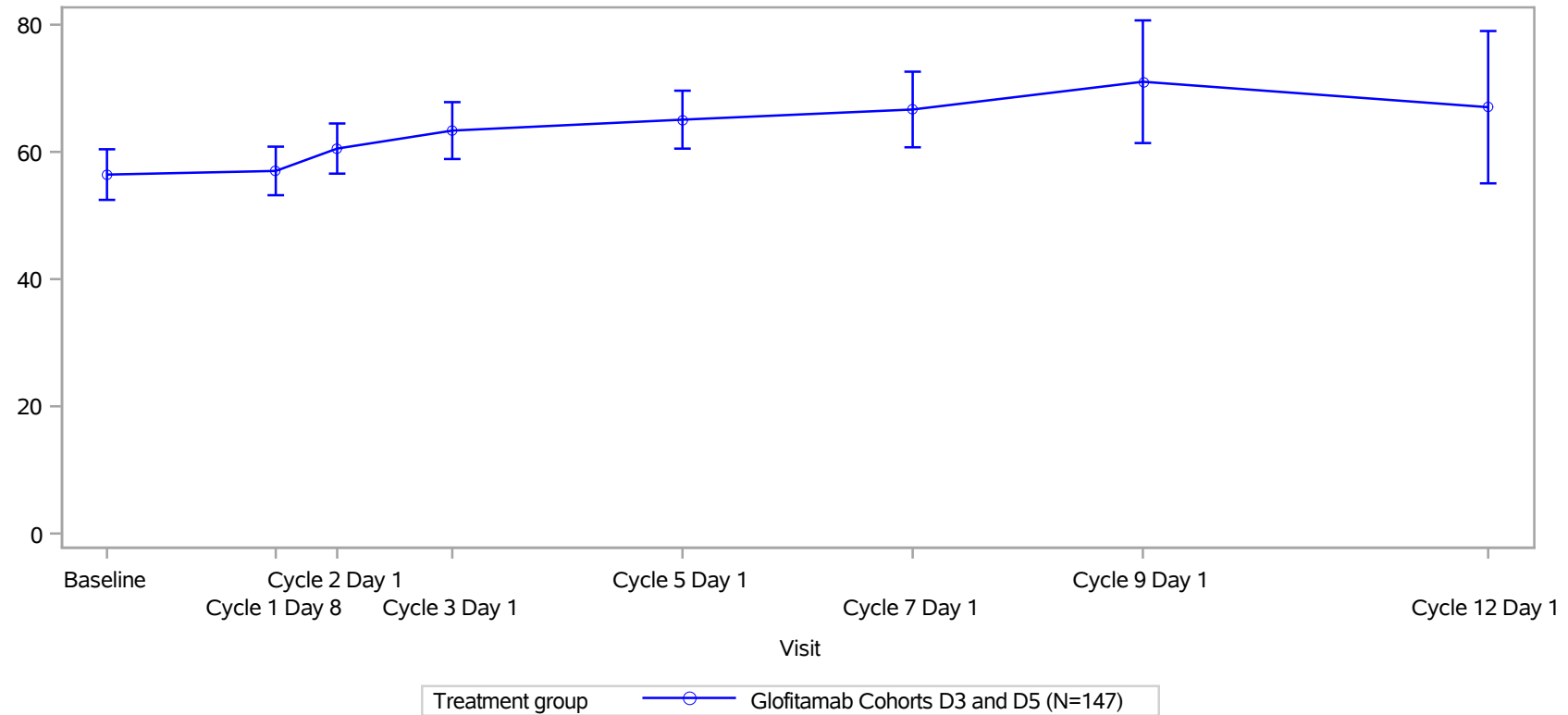
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D35_C30QL.xls

27FEB2023 10:31

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Global Health Status
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D35_C30QL.pdf
27FEB2023 10:39

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Global Health Status (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab Cohorts D3 and D5 (N=127)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	127	100.0	49	38.6	30.6	47.3

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D35_M10C30QL.xls
 27FEB2023 10:50

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Role Functioning

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab Cohorts D3 and D5 (N=147)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	147	100.0	136	92.5	72.92	30.63
Cycle 1 Day 8	n/a	139	94.6	132	95.0	71.84	29.21
Cycle 2 Day 1	n/a	122	83.0	114	93.4	74.56	27.80
Cycle 3 Day 1	n/a	104	70.7	94	90.4	79.26	25.60
Cycle 5 Day 1	n/a	80	54.4	73	91.3	84.70	19.20
Cycle 7 Day 1	n/a	57	38.8	54	94.7	83.95	23.78
Cycle 9 Day 1	n/a	43	29.3	21	48.8	88.89	19.95
Cycle 12 Day 1	n/a	41	27.9	23	56.1	89.13	22.25

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

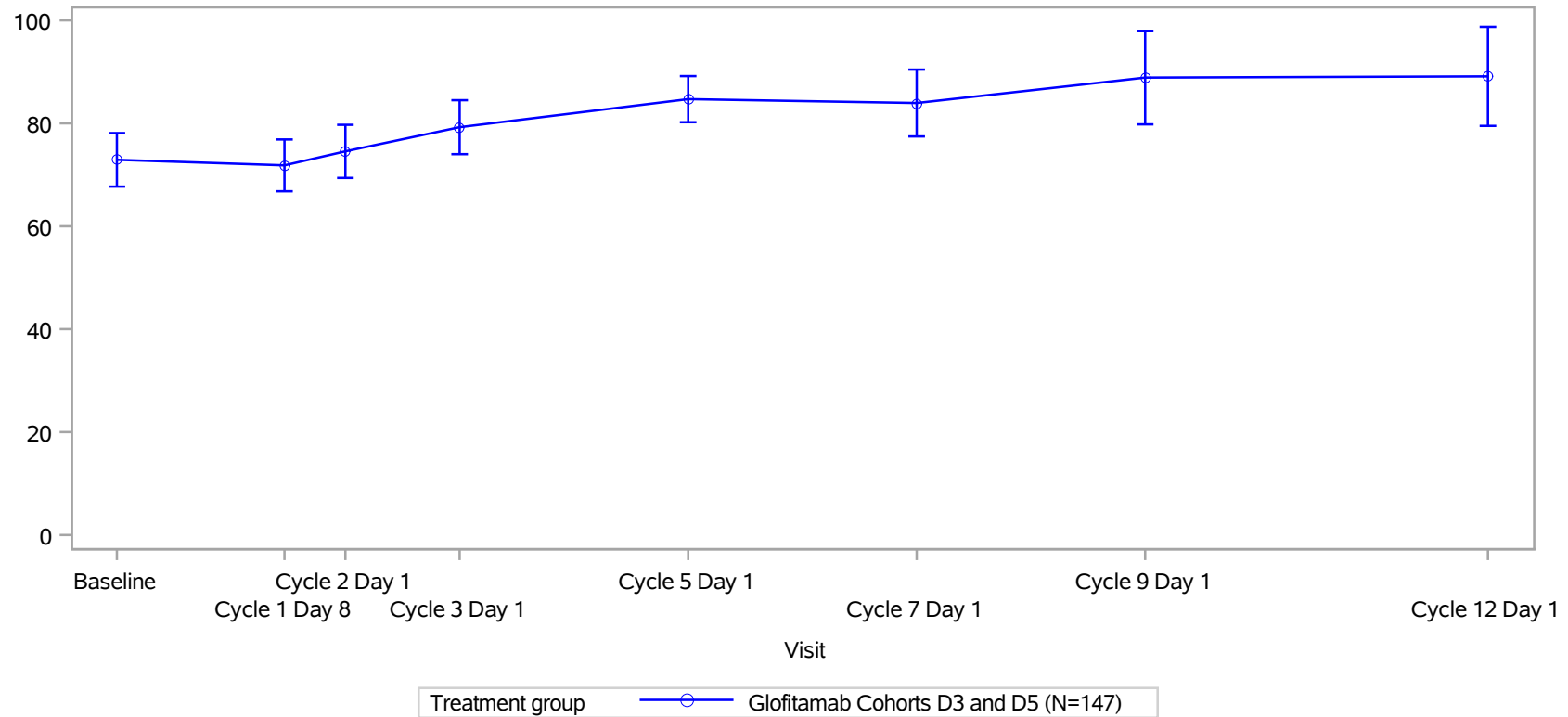
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D35_C30RF.xls

27FEB2023 10:34

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Role Functioning
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D35_C30RF.pdf
27FEB2023 10:43

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Role Functioning (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab Cohorts D3 and D5 (N=127)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	127	100.0	61	48.0	39.5	56.7

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D35_M10C30RF.xls
 27FEB2023 10:54

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: EORTC QLQ-C30: Scale Social Functioning

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab Cohorts D3 and D5 (N=147)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	147	100.0	136	92.5	76.72	27.54
Cycle 1 Day 8	n/a	139	94.6	132	95.0	77.90	25.18
Cycle 2 Day 1	n/a	122	83.0	114	93.4	79.53	26.89
Cycle 3 Day 1	n/a	104	70.7	94	90.4	81.56	23.63
Cycle 5 Day 1	n/a	80	54.4	73	91.3	84.93	21.00
Cycle 7 Day 1	n/a	57	38.8	54	94.7	84.57	24.41
Cycle 9 Day 1	n/a	43	29.3	21	48.8	86.51	18.72
Cycle 12 Day 1	n/a	41	27.9	23	56.1	85.51	24.26

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

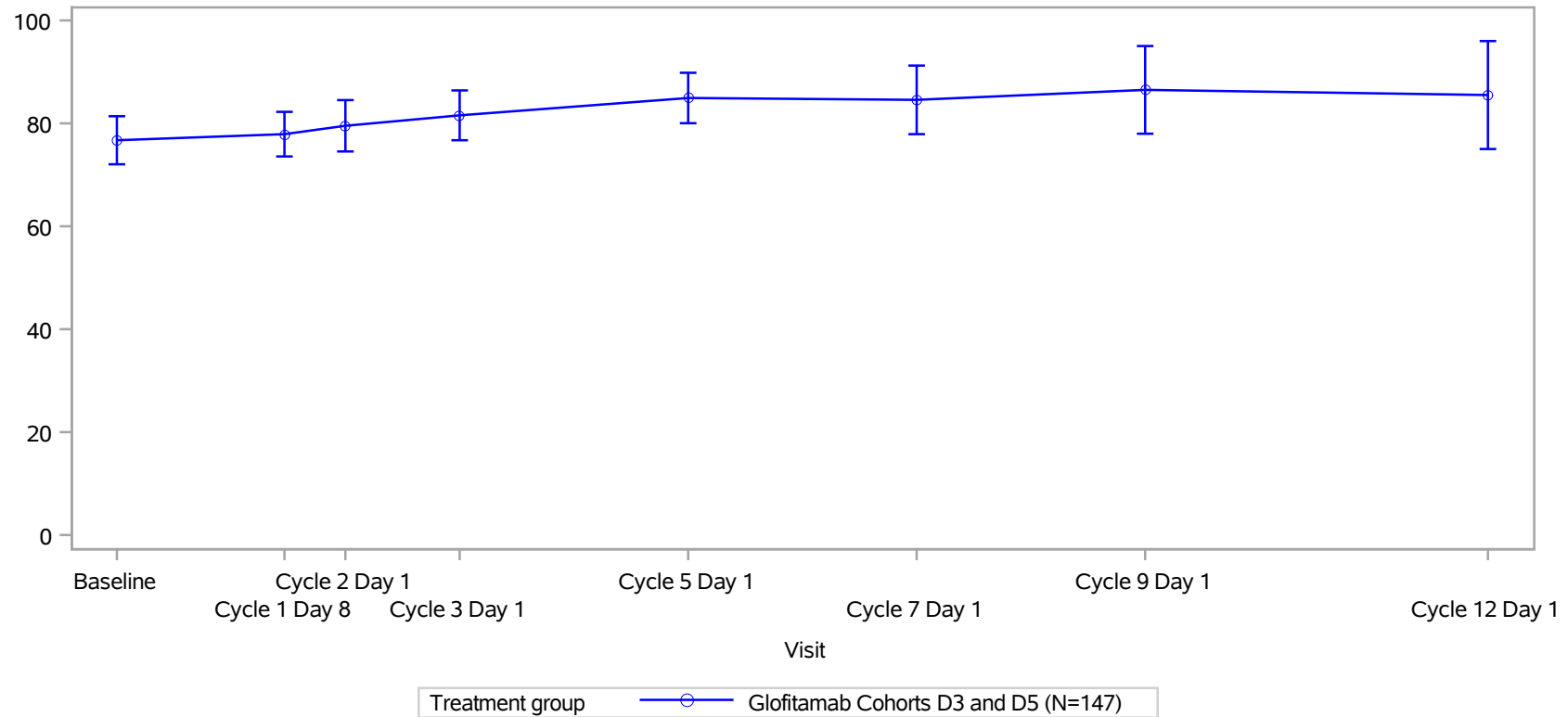
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D35_C30SF.xls

27FEB2023 10:35

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: EORTC QLQ-C30: Scale Social Functioning
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D35_C30SF.pdf
27FEB2023 10:44

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: EORTC QLQ-C30: Scale Social Functioning (MID 10, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab Cohorts D3 and D5 (N=127)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	127	100.0	53	41.7	33.5	50.4

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D35_M10C30SF.xls
 27FEB2023 10:57

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients

ENDPOINT: FACT-Lym Subscale Score

MODEL: --

STUDY: NP30179

Compliance/Mean

		Glofitamab Cohorts D3 and D5 (N=147)					
		Patients				Statistics	
Name Visit	Level	in study ¹	%	with value ¹	%	mean ²	SD
All							
BASELINE	n/a	147	100.0	134	91.2	12.04	9.35
Cycle 1 Day 8	n/a	139	94.6	131	94.2	13.54	8.77
Cycle 2 Day 1	n/a	122	83.0	113	92.6	12.31	8.76
Cycle 3 Day 1	n/a	104	70.7	93	89.4	10.83	7.80
Cycle 5 Day 1	n/a	80	54.4	74	92.5	10.18	8.05
Cycle 7 Day 1	n/a	57	38.8	52	91.2	10.07	7.85
Cycle 9 Day 1	n/a	43	29.3	20	46.5	8.41	8.15
Cycle 12 Day 1	n/a	41	27.9	22	53.7	10.35	10.01

¹ in study: number of subjects in study at respective visit; % based on baseline.

with value: number of subjects in study and with value at respective visit - used for the calculation of the mean and SD; % based on patients in study at respective visit.

² mean: descriptive statistics - absolute values

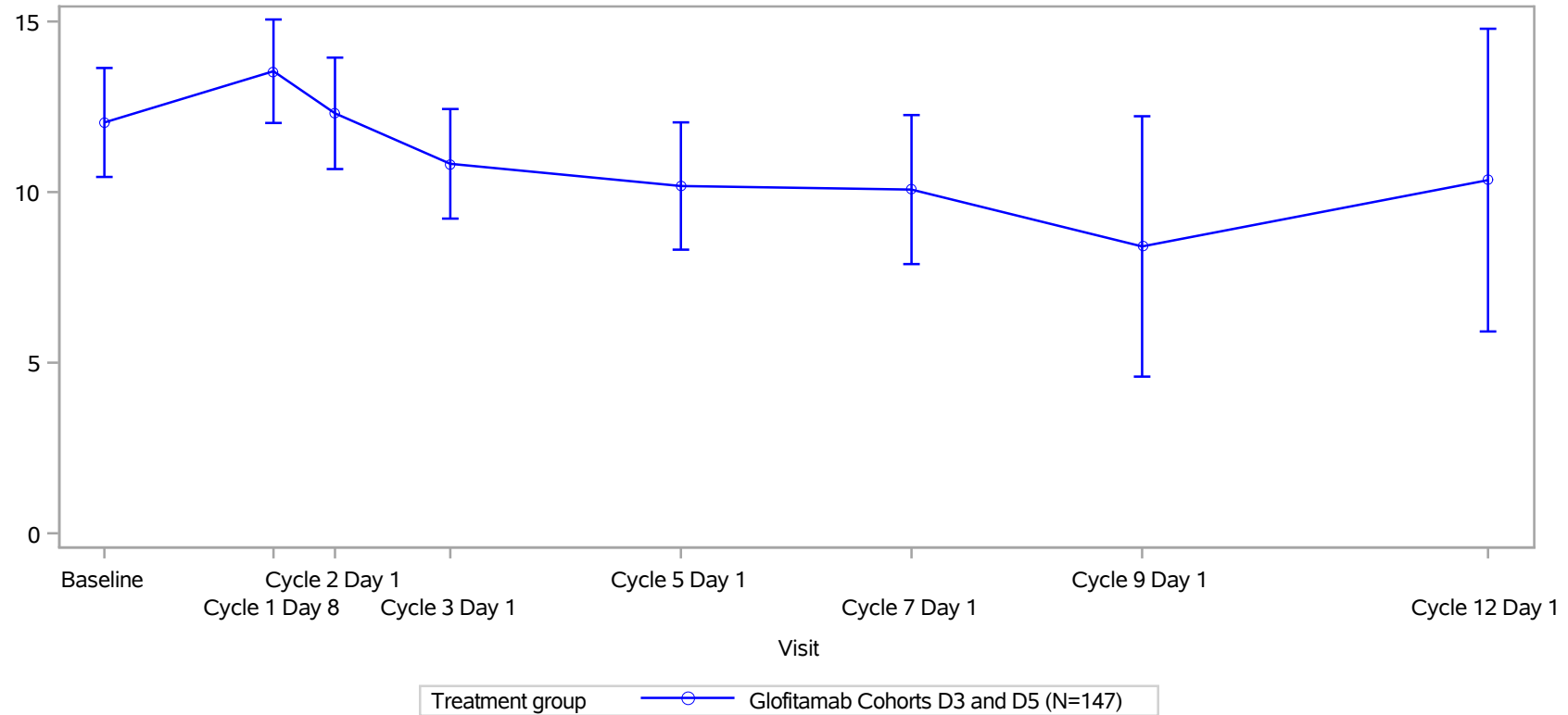
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_mean.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_mean_JUN22_EE_D35_FLYM.xls

27FEB2023 10:36

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), Efficacy-Evaluable Patients
ENDPOINT: FACT-Lym Subscale Score
MODEL: --
STUDY: NP30179
Plot of Mean and 95% CI by Visit



Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_g_mean.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_g_mean_JUN22_EE_D35_FLYM.pdf
27FEB2023 10:45

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: FACT-Lym Subscale Score (MID 3, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab Cohorts D3 and D5 (N=126)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	124	98.4	67	53.2	44.5	61.7

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D35_M3FLYM.xls
 27FEB2023 10:59

POPULATION: Cohorts D3 and D5 (R/R DLBCL Patients), PRO-Evaluable Patients
 ENDPOINT: FACT-Lym Subscale Score (MID 9, worsening)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (efficacy)

		Glofitamab Cohorts D3 and D5 (N=126)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	124	98.4	18	14.3	9.2	21.5

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/eff_resp.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/eff_resp_JUN22_PPOP_D35_M9FLYM.xls
 27FEB2023 11:01

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: Any AEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	152	98.7	95.4	99.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_AEANY.xls

28FEB2023 14:33

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: Any AEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
Name	SOC	PT	Level	Patients		Patients with Event			
				n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	154	100.0	86	55.8	48.0	63.4
		Anaemia	n/a	154	100.0	47	30.5	23.8	38.2
		Anaemia of malignant disease	n/a	154	100.0	1	0.6	0.1	3.6
		Febrile neutropenia	n/a	154	100.0	4	2.6	1.0	6.5
		Hypofibrinogenaemia	n/a	154	100.0	1	0.6	0.1	3.6
		Iron deficiency anaemia	n/a	154	100.0	1	0.6	0.1	3.6
		Leukocytosis	n/a	154	100.0	1	0.6	0.1	3.6
		Lymphopenia	n/a	154	100.0	6	3.9	1.8	8.2
		Monocytosis	n/a	154	100.0	1	0.6	0.1	3.6
		Neutropenia	n/a	154	100.0	55	35.7	28.6	43.5
		Polycythaemia	n/a	154	100.0	1	0.6	0.1	3.6
		Thrombocytopenia	n/a	154	100.0	33	21.4	15.7	28.6
	Cardiac disorders	-Total	n/a	154	100.0	15	9.7	6.0	15.4
		Atrial fibrillation	n/a	154	100.0	3	1.9	0.7	5.6
		Cardiac failure	n/a	154	100.0	2	1.3	0.4	4.6
		Sinus bradycardia	n/a	154	100.0	1	0.6	0.1	3.6
		Sinus node dysfunction	n/a	154	100.0	1	0.6	0.1	3.6

		Sinus tachycardia	n/a	154	100.0	2	1.3	0.4	4.6
		Tachycardia	n/a	154	100.0	6	3.9	1.8	8.2
		Ventricular extrasystoles	n/a	154	100.0	1	0.6	0.1	3.6
	Ear and labyrinth disorders	-Total	n/a	154	100.0	4	2.6	1.0	6.5
		Ear congestion	n/a	154	100.0	1	0.6	0.1	3.6
		Ear pain	n/a	154	100.0	2	1.3	0.4	4.6
		Vertigo	n/a	154	100.0	2	1.3	0.4	4.6
	Endocrine disorders	-Total	n/a	154	100.0	1	0.6	0.1	3.6
		Hypothyroidism	n/a	154	100.0	1	0.6	0.1	3.6
	Eye disorders	-Total	n/a	154	100.0	5	3.2	1.4	7.4
		Conjunctival haemorrhage	n/a	154	100.0	1	0.6	0.1	3.6
		Conjunctivitis allergic	n/a	154	100.0	1	0.6	0.1	3.6
		Eye pain	n/a	154	100.0	1	0.6	0.1	3.6
		Periorbital pain	n/a	154	100.0	1	0.6	0.1	3.6
		Periorbital swelling	n/a	154	100.0	1	0.6	0.1	3.6
		Vision blurred	n/a	154	100.0	1	0.6	0.1	3.6
	Gastrointestinal disorders	-Total	n/a	154	100.0	73	47.4	39.7	55.3
		Abdominal discomfort	n/a	154	100.0	2	1.3	0.4	4.6
		Abdominal distension	n/a	154	100.0	2	1.3	0.4	4.6
		Abdominal pain	n/a	154	100.0	13	8.4	5.0	13.9
		Abdominal pain upper	n/a	154	100.0	3	1.9	0.7	5.6
		Anorectal discomfort	n/a	154	100.0	1	0.6	0.1	3.6
		Ascites	n/a	154	100.0	1	0.6	0.1	3.6
		Colitis	n/a	154	100.0	1	0.6	0.1	3.6

		Constipation	n/a	154	100.0	21	13.6	9.1	19.9
		Dental caries	n/a	154	100.0	1	0.6	0.1	3.6
		Diaphragmatic hernia	n/a	154	100.0	1	0.6	0.1	3.6
		Diarrhoea	n/a	154	100.0	20	13.0	8.6	19.2
		Dry mouth	n/a	154	100.0	1	0.6	0.1	3.6
		Duodenal obstruction	n/a	154	100.0	1	0.6	0.1	3.6
		Dyspepsia	n/a	154	100.0	1	0.6	0.1	3.6
		Dysphagia	n/a	154	100.0	1	0.6	0.1	3.6
		Faeces discoloured	n/a	154	100.0	1	0.6	0.1	3.6
		Gastric haemorrhage	n/a	154	100.0	1	0.6	0.1	3.6
		Gastritis	n/a	154	100.0	3	1.9	0.7	5.6
		Gastrointestinal haemorrhage	n/a	154	100.0	2	1.3	0.4	4.6
		Haemorrhoids	n/a	154	100.0	1	0.6	0.1	3.6
		Intestinal perforation	n/a	154	100.0	1	0.6	0.1	3.6
		Large intestinal haemorrhage	n/a	154	100.0	1	0.6	0.1	3.6
		Nausea	n/a	154	100.0	16	10.4	6.5	16.2
		Stomatitis	n/a	154	100.0	2	1.3	0.4	4.6
		Toothache	n/a	154	100.0	4	2.6	1.0	6.5
		Umbilical hernia	n/a	154	100.0	1	0.6	0.1	3.6
		Vomiting	n/a	154	100.0	7	4.5	2.2	9.1
	General disorders and administration site conditions	-Total	n/a	154	100.0	65	42.2	34.7	50.1
		Asthenia	n/a	154	100.0	13	8.4	5.0	13.9
		Catheter site pain	n/a	154	100.0	1	0.6	0.1	3.6

		Catheter site pruritus	n/a	154	100.0	1	0.6	0.1	3.6
		Chest discomfort	n/a	154	100.0	1	0.6	0.1	3.6
		Chills	n/a	154	100.0	2	1.3	0.4	4.6
		Face oedema	n/a	154	100.0	1	0.6	0.1	3.6
		Facial pain	n/a	154	100.0	1	0.6	0.1	3.6
		Fatigue	n/a	154	100.0	18	11.7	7.5	17.7
		Gait disturbance	n/a	154	100.0	2	1.3	0.4	4.6
		General physical health deterioration	n/a	154	100.0	1	0.6	0.1	3.6
		Inflammation	n/a	154	100.0	1	0.6	0.1	3.6
		Injection site phlebitis	n/a	154	100.0	1	0.6	0.1	3.6
		Injection site reaction	n/a	154	100.0	1	0.6	0.1	3.6
		Localised oedema	n/a	154	100.0	1	0.6	0.1	3.6
		Malaise	n/a	154	100.0	2	1.3	0.4	4.6
		Oedema	n/a	154	100.0	4	2.6	1.0	6.5
		Oedema peripheral	n/a	154	100.0	9	5.8	3.1	10.7
		Pain	n/a	154	100.0	4	2.6	1.0	6.5
		Peripheral swelling	n/a	154	100.0	2	1.3	0.4	4.6
		Pyrexia	n/a	154	100.0	25	16.2	11.2	22.9
		Swelling	n/a	154	100.0	2	1.3	0.4	4.6
		Swelling face	n/a	154	100.0	2	1.3	0.4	4.6
	Hepatobiliary disorders	-Total	n/a	154	100.0	3	1.9	0.7	5.6
		Biliary colic	n/a	154	100.0	2	1.3	0.4	4.6
		Cholestasis	n/a	154	100.0	1	0.6	0.1	3.6

		Folliculitis	n/a	154	100.0	1	0.6	0.1	3.6
		Gastroenteritis	n/a	154	100.0	1	0.6	0.1	3.6
		Herpes zoster	n/a	154	100.0	3	1.9	0.7	5.6
		Infection	n/a	154	100.0	2	1.3	0.4	4.6
		Influenza	n/a	154	100.0	1	0.6	0.1	3.6
		Localised infection	n/a	154	100.0	1	0.6	0.1	3.6
		Myelitis	n/a	154	100.0	1	0.6	0.1	3.6
		Nail infection	n/a	154	100.0	1	0.6	0.1	3.6
		Nasopharyngitis	n/a	154	100.0	2	1.3	0.4	4.6
		Neutropenic infection	n/a	154	100.0	1	0.6	0.1	3.6
		Oesophageal candidiasis	n/a	154	100.0	1	0.6	0.1	3.6
		Ophthalmic herpes zoster	n/a	154	100.0	1	0.6	0.1	3.6
		Oral candidiasis	n/a	154	100.0	1	0.6	0.1	3.6
		Paronychia	n/a	154	100.0	1	0.6	0.1	3.6
		Periodontitis	n/a	154	100.0	1	0.6	0.1	3.6
		Peritonitis	n/a	154	100.0	1	0.6	0.1	3.6
		Pneumococcal infection	n/a	154	100.0	1	0.6	0.1	3.6
		Pneumonia	n/a	154	100.0	7	4.5	2.2	9.1
		Respiratory tract infection	n/a	154	100.0	2	1.3	0.4	4.6
		Rhinitis	n/a	154	100.0	2	1.3	0.4	4.6
		Sepsis	n/a	154	100.0	6	3.9	1.8	8.2
		Sinusitis	n/a	154	100.0	3	1.9	0.7	5.6
		Skin infection	n/a	154	100.0	1	0.6	0.1	3.6

		Tooth abscess	n/a	154	100.0	1	0.6	0.1	3.6
		Tooth infection	n/a	154	100.0	2	1.3	0.4	4.6
		Upper respiratory tract infection	n/a	154	100.0	3	1.9	0.7	5.6
		Urinary tract infection	n/a	154	100.0	4	2.6	1.0	6.5
		Urinary tract infection bacterial	n/a	154	100.0	1	0.6	0.1	3.6
		Vascular device infection	n/a	154	100.0	3	1.9	0.7	5.6
		Viral upper respiratory tract infection	n/a	154	100.0	1	0.6	0.1	3.6
	Injury, poisoning and procedural complications	-Total	n/a	154	100.0	20	13.0	8.6	19.2
		Clavicle fracture	n/a	154	100.0	1	0.6	0.1	3.6
		Fall	n/a	154	100.0	3	1.9	0.7	5.6
		Humerus fracture	n/a	154	100.0	1	0.6	0.1	3.6
		Infusion related reaction	n/a	154	100.0	10	6.5	3.6	11.5
		Joint dislocation	n/a	154	100.0	1	0.6	0.1	3.6
		Muscle rupture	n/a	154	100.0	1	0.6	0.1	3.6
		Thermal burn	n/a	154	100.0	1	0.6	0.1	3.6
		Toxicity to various agents	n/a	154	100.0	1	0.6	0.1	3.6
		Wound complication	n/a	154	100.0	1	0.6	0.1	3.6
	Investigations	-Total	n/a	154	100.0	46	29.9	23.2	37.5
		Alanine aminotransferase increased	n/a	154	100.0	13	8.4	5.0	13.9
		Aspartate aminotransferase increased	n/a	154	100.0	12	7.8	4.5	13.1

		Blood alkaline phosphatase increased	n/a	154	100.0	13	8.4	5.0	13.9
		Blood bilirubin increased	n/a	154	100.0	6	3.9	1.8	8.2
		Blood creatinine increased	n/a	154	100.0	8	5.2	2.7	9.9
		Blood fibrinogen decreased	n/a	154	100.0	1	0.6	0.1	3.6
		Blood iron decreased	n/a	154	100.0	1	0.6	0.1	3.6
		Blood lactate dehydrogenase increased	n/a	154	100.0	3	1.9	0.7	5.6
		Blood lactic acid increased	n/a	154	100.0	1	0.6	0.1	3.6
		Blood urea increased	n/a	154	100.0	1	0.6	0.1	3.6
		Blood uric acid increased	n/a	154	100.0	1	0.6	0.1	3.6
		C-reactive protein increased	n/a	154	100.0	6	3.9	1.8	8.2
		Cardiac murmur	n/a	154	100.0	1	0.6	0.1	3.6
		Ejection fraction decreased	n/a	154	100.0	2	1.3	0.4	4.6
		Fibrin D dimer increased	n/a	154	100.0	2	1.3	0.4	4.6
		Gamma-glutamyltransferase increased	n/a	154	100.0	10	6.5	3.6	11.5
		Hepatic enzyme increased	n/a	154	100.0	2	1.3	0.4	4.6
		Lymphocyte count decreased	n/a	154	100.0	1	0.6	0.1	3.6
		Neutrophil count decreased	n/a	154	100.0	3	1.9	0.7	5.6

		Hyperuricaemia	n/a	154	100.0	6	3.9	1.8	8.2
		Hypoalbuminaemia	n/a	154	100.0	2	1.3	0.4	4.6
		Hypocalcaemia	n/a	154	100.0	19	12.3	8.0	18.5
		Hypochloraemia	n/a	154	100.0	9	5.8	3.1	10.7
		Hypoglycaemia	n/a	154	100.0	1	0.6	0.1	3.6
		Hypokalaemia	n/a	154	100.0	17	11.0	7.0	17.0
		Hypomagnesaemia	n/a	154	100.0	22	14.3	9.6	20.7
		Hyponatraemia	n/a	154	100.0	12	7.8	4.5	13.1
		Hypophosphataemia	n/a	154	100.0	27	17.5	12.3	24.3
		Hypovolaemia	n/a	154	100.0	1	0.6	0.1	3.6
		Tumour lysis syndrome	n/a	154	100.0	2	1.3	0.4	4.6
	Musculoskeletal and connective tissue disorders	-Total	n/a	154	100.0	43	27.9	21.4	35.5
		Arthralgia	n/a	154	100.0	9	5.8	3.1	10.7
		Back pain	n/a	154	100.0	16	10.4	6.5	16.2
		Bone pain	n/a	154	100.0	3	1.9	0.7	5.6
		Bone swelling	n/a	154	100.0	1	0.6	0.1	3.6
		Flank pain	n/a	154	100.0	3	1.9	0.7	5.6
		Joint swelling	n/a	154	100.0	1	0.6	0.1	3.6
		Limb mass	n/a	154	100.0	1	0.6	0.1	3.6
		Muscle spasms	n/a	154	100.0	2	1.3	0.4	4.6
		Muscular weakness	n/a	154	100.0	3	1.9	0.7	5.6
		Musculoskeletal pain	n/a	154	100.0	1	0.6	0.1	3.6
		Myalgia	n/a	154	100.0	6	3.9	1.8	8.2
		Myofascial pain syndrome	n/a	154	100.0	1	0.6	0.1	3.6

		Neck pain	n/a	154	100.0	3	1.9	0.7	5.6
		Osteoarthritis	n/a	154	100.0	1	0.6	0.1	3.6
		Pain in extremity	n/a	154	100.0	4	2.6	1.0	6.5
		Pain in jaw	n/a	154	100.0	3	1.9	0.7	5.6
		Spinal osteoarthritis	n/a	154	100.0	1	0.6	0.1	3.6
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	154	100.0	26	16.9	11.8	23.6
		Benign neoplasm of thyroid gland	n/a	154	100.0	1	0.6	0.1	3.6
		Melanoma recurrent	n/a	154	100.0	1	0.6	0.1	3.6
		Squamous cell carcinoma	n/a	154	100.0	1	0.6	0.1	3.6
		Transitional cell carcinoma	n/a	154	100.0	1	0.6	0.1	3.6
		Tumour associated fever	n/a	154	100.0	2	1.3	0.4	4.6
		Tumour flare	n/a	154	100.0	17	11.0	7.0	17.0
		Tumour pain	n/a	154	100.0	3	1.9	0.7	5.6
	Nervous system disorders	-Total	n/a	154	100.0	39	25.3	19.1	32.7
		Ageusia	n/a	154	100.0	1	0.6	0.1	3.6
		Cognitive disorder	n/a	154	100.0	1	0.6	0.1	3.6
		Dizziness	n/a	154	100.0	8	5.2	2.7	9.9
		Dysaesthesia	n/a	154	100.0	1	0.6	0.1	3.6
		Headache	n/a	154	100.0	15	9.7	6.0	15.4
		Hemiparaesthesia	n/a	154	100.0	1	0.6	0.1	3.6
		Myoclonus	n/a	154	100.0	1	0.6	0.1	3.6
		Neuropathy peripheral	n/a	154	100.0	3	1.9	0.7	5.6
		Paraesthesia	n/a	154	100.0	5	3.2	1.4	7.4

		Peripheral sensory neuropathy	n/a	154	100.0	2	1.3	0.4	4.6
		Presyncope	n/a	154	100.0	1	0.6	0.1	3.6
		Seizure	n/a	154	100.0	1	0.6	0.1	3.6
		Somnolence	n/a	154	100.0	2	1.3	0.4	4.6
		Transient ischaemic attack	n/a	154	100.0	1	0.6	0.1	3.6
		Tremor	n/a	154	100.0	2	1.3	0.4	4.6
	Psychiatric disorders	-Total	n/a	154	100.0	18	11.7	7.5	17.7
		Agitation	n/a	154	100.0	1	0.6	0.1	3.6
		Anxiety	n/a	154	100.0	6	3.9	1.8	8.2
		Confusional state	n/a	154	100.0	3	1.9	0.7	5.6
		Delirium	n/a	154	100.0	2	1.3	0.4	4.6
		Depression	n/a	154	100.0	1	0.6	0.1	3.6
		Disorientation	n/a	154	100.0	1	0.6	0.1	3.6
		Insomnia	n/a	154	100.0	3	1.9	0.7	5.6
		Mood altered	n/a	154	100.0	1	0.6	0.1	3.6
		Nervousness	n/a	154	100.0	1	0.6	0.1	3.6
	Renal and urinary disorders	-Total	n/a	154	100.0	8	5.2	2.7	9.9
		Acute kidney injury	n/a	154	100.0	1	0.6	0.1	3.6
		Cystitis noninfective	n/a	154	100.0	1	0.6	0.1	3.6
		Dysuria	n/a	154	100.0	2	1.3	0.4	4.6
		Hydronephrosis	n/a	154	100.0	1	0.6	0.1	3.6
		Nocturia	n/a	154	100.0	1	0.6	0.1	3.6
		Oliguria	n/a	154	100.0	2	1.3	0.4	4.6
		Pollakiuria	n/a	154	100.0	1	0.6	0.1	3.6

		Renal impairment	n/a	154	100.0	1	0.6	0.1	3.6
	Reproductive system and breast disorders	-Total	n/a	154	100.0	5	3.2	1.4	7.4
		Benign prostatic hyperplasia	n/a	154	100.0	1	0.6	0.1	3.6
		Erectile dysfunction	n/a	154	100.0	1	0.6	0.1	3.6
		Orchitis noninfective	n/a	154	100.0	1	0.6	0.1	3.6
		Prostatitis	n/a	154	100.0	2	1.3	0.4	4.6
	Respiratory, thoracic and mediastinal disorders	-Total	n/a	154	100.0	30	19.5	14.0	26.4
		Bronchopneumopathy	n/a	154	100.0	1	0.6	0.1	3.6
		Cough	n/a	154	100.0	6	3.9	1.8	8.2
		Cough variant asthma	n/a	154	100.0	1	0.6	0.1	3.6
		Dysphonia	n/a	154	100.0	2	1.3	0.4	4.6
		Dyspnoea	n/a	154	100.0	4	2.6	1.0	6.5
		Hiccups	n/a	154	100.0	1	0.6	0.1	3.6
		Hyperventilation	n/a	154	100.0	1	0.6	0.1	3.6
		Hypoxia	n/a	154	100.0	1	0.6	0.1	3.6
		Lung disorder	n/a	154	100.0	1	0.6	0.1	3.6
		Lung opacity	n/a	154	100.0	1	0.6	0.1	3.6
		Nasal congestion	n/a	154	100.0	1	0.6	0.1	3.6
		Oropharyngeal pain	n/a	154	100.0	2	1.3	0.4	4.6
		Orthopnoea	n/a	154	100.0	1	0.6	0.1	3.6
		Pleural effusion	n/a	154	100.0	4	2.6	1.0	6.5
		Pneumonitis	n/a	154	100.0	1	0.6	0.1	3.6
		Productive cough	n/a	154	100.0	2	1.3	0.4	4.6
		Pulmonary embolism	n/a	154	100.0	1	0.6	0.1	3.6

		Rales	n/a	154	100.0	1	0.6	0.1	3.6
		Rhinitis allergic	n/a	154	100.0	1	0.6	0.1	3.6
		Rhinorrhoea	n/a	154	100.0	2	1.3	0.4	4.6
		Sinus congestion	n/a	154	100.0	1	0.6	0.1	3.6
		Upper-airway cough syndrome	n/a	154	100.0	1	0.6	0.1	3.6
		Wheezing	n/a	154	100.0	1	0.6	0.1	3.6
	Skin and subcutaneous tissue disorders	-Total	n/a	154	100.0	36	23.4	17.4	30.7
		Actinic keratosis	n/a	154	100.0	1	0.6	0.1	3.6
		Dermatitis	n/a	154	100.0	1	0.6	0.1	3.6
		Dermatitis acneiform	n/a	154	100.0	1	0.6	0.1	3.6
		Dermatitis exfoliative	n/a	154	100.0	1	0.6	0.1	3.6
		Dry skin	n/a	154	100.0	1	0.6	0.1	3.6
		Eczema	n/a	154	100.0	2	1.3	0.4	4.6
		Erythema	n/a	154	100.0	8	5.2	2.7	9.9
		Hyperhidrosis	n/a	154	100.0	1	0.6	0.1	3.6
		Hyperkeratosis	n/a	154	100.0	1	0.6	0.1	3.6
		Night sweats	n/a	154	100.0	2	1.3	0.4	4.6
		Palmar erythema	n/a	154	100.0	1	0.6	0.1	3.6
		Pruritus	n/a	154	100.0	8	5.2	2.7	9.9
		Rash	n/a	154	100.0	8	5.2	2.7	9.9
		Rash erythematous	n/a	154	100.0	1	0.6	0.1	3.6
		Rash maculo-papular	n/a	154	100.0	4	2.6	1.0	6.5
		Rash pruritic	n/a	154	100.0	2	1.3	0.4	4.6

		Skin ulcer	n/a	154	100.0	2	1.3	0.4	4.6
		Urticaria	n/a	154	100.0	2	1.3	0.4	4.6
	Vascular disorders	-Total	n/a	154	100.0	15	9.7	6.0	15.4
		Embolism	n/a	154	100.0	1	0.6	0.1	3.6
		Hot flush	n/a	154	100.0	1	0.6	0.1	3.6
		Hypertension	n/a	154	100.0	3	1.9	0.7	5.6
		Hypotension	n/a	154	100.0	8	5.2	2.7	9.9
		Jugular vein thrombosis	n/a	154	100.0	1	0.6	0.1	3.6
		Phlebitis	n/a	154	100.0	2	1.3	0.4	4.6
		Phlebitis superficial	n/a	154	100.0	1	0.6	0.1	3.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_soc_JUN22_SE_D235_AEANY.xls

28FEB2023 14:59

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	60	39.0	31.6	46.8

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_AEGR3.xls

28FEB2023 14:34

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
				Patients		Patients with Event			
Name	SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	154	100.0	43	27.9	21.4	35.5
		Anaemia	n/a	154	100.0	12	7.8	4.5	13.1
		Anaemia of malignant disease	n/a	154	100.0	1	0.6	0.1	3.6
		Febrile neutropenia	n/a	154	100.0	2	1.3	0.4	4.6
		Hypofibrinogenaemia	n/a	154	100.0	1	0.6	0.1	3.6
		Lymphopenia	n/a	154	100.0	2	1.3	0.4	4.6
		Neutropenia	n/a	154	100.0	26	16.9	11.8	23.6
		Thrombocytopenia	n/a	154	100.0	8	5.2	2.7	9.9
	Cardiac disorders	-Total	n/a	154	100.0	2	1.3	0.4	4.6
		Cardiac failure	n/a	154	100.0	2	1.3	0.4	4.6
	Eye disorders	-Total	n/a	154	100.0	1	0.6	0.1	3.6
		Periorbital swelling	n/a	154	100.0	1	0.6	0.1	3.6
	Gastrointestinal disorders	-Total	n/a	154	100.0	3	1.9	0.7	5.6
		Ascites	n/a	154	100.0	1	0.6	0.1	3.6
		Gastric haemorrhage	n/a	154	100.0	1	0.6	0.1	3.6
		Gastrointestinal haemorrhage	n/a	154	100.0	1	0.6	0.1	3.6
	General disorders and administration site conditions	-Total	n/a	154	100.0	4	2.6	1.0	6.5
		Asthenia	n/a	154	100.0	1	0.6	0.1	3.6

		Fatigue	n/a	154	100.0	1	0.6	0.1	3.6
		General physical health deterioration	n/a	154	100.0	1	0.6	0.1	3.6
		Pain	n/a	154	100.0	1	0.6	0.1	3.6
		Swelling	n/a	154	100.0	1	0.6	0.1	3.6
	Immune system disorders	-Total	n/a	154	100.0	4	2.6	1.0	6.5
		Cytokine release syndrome by ASTCT grade	n/a	154	100.0	4	2.6	1.0	6.5
		Cytokine release syndrome by Lee grade	n/a	154	100.0	3	1.9	0.7	5.6
	Infections and infestations	-Total	n/a	154	100.0	13	8.4	5.0	13.9
		Abscess neck	n/a	154	100.0	1	0.6	0.1	3.6
		Appendicitis	n/a	154	100.0	1	0.6	0.1	3.6
		Biliary tract infection bacterial	n/a	154	100.0	1	0.6	0.1	3.6
		COVID-19	n/a	154	100.0	2	1.3	0.4	4.6
		COVID-19 pneumonia	n/a	154	100.0	2	1.3	0.4	4.6
		Clostridium difficile infection	n/a	154	100.0	1	0.6	0.1	3.6
		Gastroenteritis	n/a	154	100.0	1	0.6	0.1	3.6
		Influenza	n/a	154	100.0	1	0.6	0.1	3.6
		Neutropenic infection	n/a	154	100.0	1	0.6	0.1	3.6
		Peritonitis	n/a	154	100.0	1	0.6	0.1	3.6
		Pneumococcal infection	n/a	154	100.0	1	0.6	0.1	3.6
		Pneumonia	n/a	154	100.0	1	0.6	0.1	3.6
		Sepsis	n/a	154	100.0	1	0.6	0.1	3.6

	White blood cell count decreased	n/a	154	100.0	1	0.6	0.1	3.6
Metabolism and nutrition disorders	-Total	n/a	154	100.0	16	10.4	6.5	16.2
	Hypercalcaemia	n/a	154	100.0	3	1.9	0.7	5.6
	Hypoalbuminaemia	n/a	154	100.0	1	0.6	0.1	3.6
	Hypokalaemia	n/a	154	100.0	2	1.3	0.4	4.6
	Hyponatraemia	n/a	154	100.0	2	1.3	0.4	4.6
	Hypophosphataemia	n/a	154	100.0	8	5.2	2.7	9.9
	Tumour lysis syndrome	n/a	154	100.0	2	1.3	0.4	4.6
Musculoskeletal and connective tissue disorders	-Total	n/a	154	100.0	4	2.6	1.0	6.5
	Back pain	n/a	154	100.0	2	1.3	0.4	4.6
	Pain in extremity	n/a	154	100.0	1	0.6	0.1	3.6
	Pain in jaw	n/a	154	100.0	1	0.6	0.1	3.6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	154	100.0	6	3.9	1.8	8.2
	Tumour flare	n/a	154	100.0	4	2.6	1.0	6.5
	Tumour pain	n/a	154	100.0	2	1.3	0.4	4.6
Nervous system disorders	-Total	n/a	154	100.0	1	0.6	0.1	3.6
	Somnolence	n/a	154	100.0	1	0.6	0.1	3.6
Psychiatric disorders	-Total	n/a	154	100.0	1	0.6	0.1	3.6
	Delirium	n/a	154	100.0	1	0.6	0.1	3.6
Renal and urinary disorders	-Total	n/a	154	100.0	1	0.6	0.1	3.6
	Oliguria	n/a	154	100.0	1	0.6	0.1	3.6
Respiratory, thoracic and mediastinal disorders	-Total	n/a	154	100.0	7	4.5	2.2	9.1
	Lung opacity	n/a	154	100.0	1	0.6	0.1	3.6
	Pleural effusion	n/a	154	100.0	4	2.6	1.0	6.5

		Pulmonary embolism	n/a	154	100.0	1	0.6	0.1	3.6
		Wheezing	n/a	154	100.0	1	0.6	0.1	3.6
	Skin and subcutaneous tissue disorders	-Total	n/a	154	100.0	2	1.3	0.4	4.6
		Rash	n/a	154	100.0	1	0.6	0.1	3.6
		Rash pruritic	n/a	154	100.0	1	0.6	0.1	3.6
	Vascular disorders	-Total	n/a	154	100.0	1	0.6	0.1	3.6
		Hypertension	n/a	154	100.0	1	0.6	0.1	3.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_soc_JUN22_SE_D235_AEGR3.xls

28FEB2023 15:00

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 4

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	29	18.8	13.4	25.7

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_AEGR4.xls

28FEB2023 14:35

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 4

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
				Patients		Patients with Event			
Name	SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	154	100.0	20	13.0	8.6	19.2
		Febrile neutropenia	n/a	154	100.0	2	1.3	0.4	4.6
		Lymphopenia	n/a	154	100.0	4	2.6	1.0	6.5
		Neutropenia	n/a	154	100.0	13	8.4	5.0	13.9
		Thrombocytopenia	n/a	154	100.0	2	1.3	0.4	4.6
	Gastrointestinal disorders	-Total	n/a	154	100.0	3	1.9	0.7	5.6
		Colitis	n/a	154	100.0	1	0.6	0.1	3.6
		Duodenal obstruction	n/a	154	100.0	1	0.6	0.1	3.6
		Gastrointestinal haemorrhage	n/a	154	100.0	1	0.6	0.1	3.6
		Large intestinal haemorrhage	n/a	154	100.0	1	0.6	0.1	3.6
	Immune system disorders	-Total	n/a	154	100.0	2	1.3	0.4	4.6
		Cytokine release syndrome by ASTCT grade	n/a	154	100.0	2	1.3	0.4	4.6
		Cytokine release syndrome by Lee grade	n/a	154	100.0	2	1.3	0.4	4.6

	Infections and infestations	-Total	n/a	154	100.0	6	3.9	1.8	8.2
		COVID-19	n/a	154	100.0	1	0.6	0.1	3.6
		Myelitis	n/a	154	100.0	1	0.6	0.1	3.6
		Pneumonia	n/a	154	100.0	1	0.6	0.1	3.6
		Sepsis	n/a	154	100.0	3	1.9	0.7	5.6
	Investigations	-Total	n/a	154	100.0	5	3.2	1.4	7.4
		Gamma-glutamyltransferase increased	n/a	154	100.0	1	0.6	0.1	3.6
		Neutrophil count decreased	n/a	154	100.0	2	1.3	0.4	4.6
		Platelet count decreased	n/a	154	100.0	1	0.6	0.1	3.6
		White blood cell count decreased	n/a	154	100.0	1	0.6	0.1	3.6
	Metabolism and nutrition disorders	-Total	n/a	154	100.0	1	0.6	0.1	3.6
		Hypophosphataemia	n/a	154	100.0	1	0.6	0.1	3.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/R07082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/R07082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_soc_JUN22_SE_D235_AEGR4.xls

28FEB2023 15:01

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 5 (AEs leading to death)

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	9	5.8	3.1	10.7

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_AEGR5.xls

28FEB2023 14:35

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AEs Grade 5 (AEs leading to death)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
				Patients		Patients with Event			
Name	SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	Infections and infestations	-Total	n/a	154	100,0	8	5,2	2,7	9,9
		COVID-19	n/a	154	100,0	3	1,9	0,7	5,6
		COVID-19 pneumonia	n/a	154	100,0	3	1,9	0,7	5,6
		Sepsis	n/a	154	100,0	2	1,3	0,4	4,6
	Psychiatric disorders	-Total	n/a	154	100,0	1	0,6	0,1	3,6
		Delirium	n/a	154	100,0	1	0,6	0,1	3,6

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_soc_JUN22_SE_D235_AEGR5.xls
 28FEB2023 15:01

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AEs Grade >=3
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	98	63.6	55.8	70.8

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_AEGR345.xls

28FEB2023 14:36

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade >=3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
Name	SOC	PT	Level	Patients		Patients with Event			
				n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	154	100.0	54	35.1	28.0	42.9
		Anaemia	n/a	154	100.0	12	7.8	4.5	13.1
		Anaemia of malignant disease	n/a	154	100.0	1	0.6	0.1	3.6
		Febrile neutropenia	n/a	154	100.0	4	2.6	1.0	6.5
		Hypofibrinogenaemia	n/a	154	100.0	1	0.6	0.1	3.6
		Lymphopenia	n/a	154	100.0	6	3.9	1.8	8.2
		Neutropenia	n/a	154	100.0	39	25.3	19.1	32.7
		Thrombocytopenia	n/a	154	100.0	10	6.5	3.6	11.5
	Cardiac disorders	-Total	n/a	154	100.0	2	1.3	0.4	4.6
		Cardiac failure	n/a	154	100.0	2	1.3	0.4	4.6
	Eye disorders	-Total	n/a	154	100.0	1	0.6	0.1	3.6
		Periorbital swelling	n/a	154	100.0	1	0.6	0.1	3.6
	Gastrointestinal disorders	-Total	n/a	154	100.0	5	3.2	1.4	7.4
		Ascites	n/a	154	100.0	1	0.6	0.1	3.6
		Colitis	n/a	154	100.0	1	0.6	0.1	3.6
		Duodenal obstruction	n/a	154	100.0	1	0.6	0.1	3.6
		Gastric haemorrhage	n/a	154	100.0	1	0.6	0.1	3.6
		Gastrointestinal haemorrhage	n/a	154	100.0	2	1.3	0.4	4.6

		Large intestinal haemorrhage	n/a	154	100.0	1	0.6	0.1	3.6
	General disorders and administration site conditions	-Total	n/a	154	100.0	4	2.6	1.0	6.5
		Asthenia	n/a	154	100.0	1	0.6	0.1	3.6
		Fatigue	n/a	154	100.0	1	0.6	0.1	3.6
		General physical health deterioration	n/a	154	100.0	1	0.6	0.1	3.6
		Pain	n/a	154	100.0	1	0.6	0.1	3.6
		Swelling	n/a	154	100.0	1	0.6	0.1	3.6
	Immune system disorders	-Total	n/a	154	100.0	6	3.9	1.8	8.2
		Cytokine release syndrome by ASTCT grade	n/a	154	100.0	6	3.9	1.8	8.2
		Cytokine release syndrome by Lee grade	n/a	154	100.0	5	3.2	1.4	7.4
	Infections and infestations	-Total	n/a	154	100.0	26	16.9	11.8	23.6
		Abscess neck	n/a	154	100.0	1	0.6	0.1	3.6
		Appendicitis	n/a	154	100.0	1	0.6	0.1	3.6
		Biliary tract infection bacterial	n/a	154	100.0	1	0.6	0.1	3.6
		COVID-19	n/a	154	100.0	6	3.9	1.8	8.2
		COVID-19 pneumonia	n/a	154	100.0	5	3.2	1.4	7.4
		Clostridium difficile infection	n/a	154	100.0	1	0.6	0.1	3.6
		Gastroenteritis	n/a	154	100.0	1	0.6	0.1	3.6
		Influenza	n/a	154	100.0	1	0.6	0.1	3.6
		Myelitis	n/a	154	100.0	1	0.6	0.1	3.6
		Neutropenic infection	n/a	154	100.0	1	0.6	0.1	3.6

		Neutrophil count decreased	n/a	154	100.0	3	1.9	0.7	5.6
		Platelet count decreased	n/a	154	100.0	2	1.3	0.4	4.6
		Weight decreased	n/a	154	100.0	1	0.6	0.1	3.6
		White blood cell count decreased	n/a	154	100.0	2	1.3	0.4	4.6
	Metabolism and nutrition disorders	-Total	n/a	154	100.0	17	11.0	7.0	17.0
		Hypercalcaemia	n/a	154	100.0	3	1.9	0.7	5.6
		Hypoalbuminaemia	n/a	154	100.0	1	0.6	0.1	3.6
		Hypokalaemia	n/a	154	100.0	2	1.3	0.4	4.6
		Hyponatraemia	n/a	154	100.0	2	1.3	0.4	4.6
		Hypophosphataemia	n/a	154	100.0	9	5.8	3.1	10.7
		Tumour lysis syndrome	n/a	154	100.0	2	1.3	0.4	4.6
	Musculoskeletal and connective tissue disorders	-Total	n/a	154	100.0	4	2.6	1.0	6.5
		Back pain	n/a	154	100.0	2	1.3	0.4	4.6
		Pain in extremity	n/a	154	100.0	1	0.6	0.1	3.6
		Pain in jaw	n/a	154	100.0	1	0.6	0.1	3.6
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	154	100.0	6	3.9	1.8	8.2
		Tumour flare	n/a	154	100.0	4	2.6	1.0	6.5
		Tumour pain	n/a	154	100.0	2	1.3	0.4	4.6
	Nervous system disorders	-Total	n/a	154	100.0	1	0.6	0.1	3.6
		Somnolence	n/a	154	100.0	1	0.6	0.1	3.6
	Psychiatric disorders	-Total	n/a	154	100.0	2	1.3	0.4	4.6
		Delirium	n/a	154	100.0	2	1.3	0.4	4.6
	Renal and urinary disorders	-Total	n/a	154	100.0	1	0.6	0.1	3.6
		Oliguria	n/a	154	100.0	1	0.6	0.1	3.6

	Respiratory, thoracic and mediastinal disorders	-Total	n/a	154	100.0	7	4.5	2.2	9.1
		Lung opacity	n/a	154	100.0	1	0.6	0.1	3.6
		Pleural effusion	n/a	154	100.0	4	2.6	1.0	6.5
		Pulmonary embolism	n/a	154	100.0	1	0.6	0.1	3.6
		Wheezing	n/a	154	100.0	1	0.6	0.1	3.6
	Skin and subcutaneous tissue disorders	-Total	n/a	154	100.0	2	1.3	0.4	4.6
		Rash	n/a	154	100.0	1	0.6	0.1	3.6
		Rash pruritic	n/a	154	100.0	1	0.6	0.1	3.6
	Vascular disorders	-Total	n/a	154	100.0	1	0.6	0.1	3.6
		Hypertension	n/a	154	100.0	1	0.6	0.1	3.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_soc_JUN22_SE_D235_AEGR345.xls

28FEB2023 15:02

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: Any SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	75	48.7	40.9	56.5

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_AESAE.xls

28FEB2023 14:36

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: Any SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
Name	SOC	PT	Level	Patients		Patients with Event			
				n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	154	100.0	10	6.5	3.6	11.5
		Anaemia	n/a	154	100.0	3	1.9	0.7	5.6
		Febrile neutropenia	n/a	154	100.0	3	1.9	0.7	5.6
		Lymphopenia	n/a	154	100.0	1	0.6	0.1	3.6
		Neutropenia	n/a	154	100.0	3	1.9	0.7	5.6
		Thrombocytopenia	n/a	154	100.0	1	0.6	0.1	3.6
	Cardiac disorders	-Total	n/a	154	100.0	2	1.3	0.4	4.6
		Cardiac failure	n/a	154	100.0	1	0.6	0.1	3.6
		Sinus node dysfunction	n/a	154	100.0	1	0.6	0.1	3.6
	Eye disorders	-Total	n/a	154	100.0	1	0.6	0.1	3.6
		Vision blurred	n/a	154	100.0	1	0.6	0.1	3.6
	Gastrointestinal disorders	-Total	n/a	154	100.0	7	4.5	2.2	9.1
		Colitis	n/a	154	100.0	1	0.6	0.1	3.6
		Constipation	n/a	154	100.0	1	0.6	0.1	3.6
		Duodenal obstruction	n/a	154	100.0	1	0.6	0.1	3.6
		Gastric haemorrhage	n/a	154	100.0	1	0.6	0.1	3.6
		Gastrointestinal haemorrhage	n/a	154	100.0	2	1.3	0.4	4.6

		Intestinal perforation	n/a	154	100.0	1	0.6	0.1	3.6
		Large intestinal haemorrhage	n/a	154	100.0	1	0.6	0.1	3.6
		Nausea	n/a	154	100.0	1	0.6	0.1	3.6
		Vomiting	n/a	154	100.0	1	0.6	0.1	3.6
	General disorders and administration site conditions	-Total	n/a	154	100.0	4	2.6	1.0	6.5
		Asthenia	n/a	154	100.0	1	0.6	0.1	3.6
		Gait disturbance	n/a	154	100.0	1	0.6	0.1	3.6
		General physical health deterioration	n/a	154	100.0	1	0.6	0.1	3.6
		Pyrexia	n/a	154	100.0	2	1.3	0.4	4.6
	Immune system disorders	-Total	n/a	154	100.0	34	22.1	16.3	29.3
		Cytokine release syndrome by ASTCT grade	n/a	154	100.0	16	10.4	6.5	16.2
		Cytokine release syndrome by Lee grade	n/a	154	100.0	34	22.1	16.3	29.3
	Infections and infestations	-Total	n/a	154	100.0	28	18.2	12.9	25.0
		Abscess	n/a	154	100.0	1	0.6	0.1	3.6
		Abscess neck	n/a	154	100.0	1	0.6	0.1	3.6
		Appendicitis	n/a	154	100.0	1	0.6	0.1	3.6
		Biliary tract infection bacterial	n/a	154	100.0	1	0.6	0.1	3.6
		COVID-19	n/a	154	100.0	5	3.2	1.4	7.4
		COVID-19 pneumonia	n/a	154	100.0	5	3.2	1.4	7.4
		Campylobacter infection	n/a	154	100.0	1	0.6	0.1	3.6
		Clostridium difficile colitis	n/a	154	100.0	1	0.6	0.1	3.6

		Infection	n/a	154	100.0	2	1.3	0.4	4.6
		Myelitis	n/a	154	100.0	1	0.6	0.1	3.6
		Neutropenic infection	n/a	154	100.0	1	0.6	0.1	3.6
		Peritonitis	n/a	154	100.0	1	0.6	0.1	3.6
		Pneumococcal infection	n/a	154	100.0	1	0.6	0.1	3.6
		Pneumonia	n/a	154	100.0	2	1.3	0.4	4.6
		Sepsis	n/a	154	100.0	6	3.9	1.8	8.2
		Urinary tract infection	n/a	154	100.0	1	0.6	0.1	3.6
		Vascular device infection	n/a	154	100.0	2	1.3	0.4	4.6
	Injury, poisoning and procedural complications	-Total	n/a	154	100.0	3	1.9	0.7	5.6
		Infusion related reaction	n/a	154	100.0	1	0.6	0.1	3.6
		Joint dislocation	n/a	154	100.0	1	0.6	0.1	3.6
		Toxicity to various agents	n/a	154	100.0	1	0.6	0.1	3.6
	Investigations	-Total	n/a	154	100.0	2	1.3	0.4	4.6
		C-reactive protein increased	n/a	154	100.0	1	0.6	0.1	3.6
		Weight decreased	n/a	154	100.0	1	0.6	0.1	3.6
	Metabolism and nutrition disorders	-Total	n/a	154	100.0	1	0.6	0.1	3.6
		Hyponatraemia	n/a	154	100.0	1	0.6	0.1	3.6
	Musculoskeletal and connective tissue disorders	-Total	n/a	154	100.0	2	1.3	0.4	4.6
		Back pain	n/a	154	100.0	2	1.3	0.4	4.6
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	154	100.0	8	5.2	2.7	9.9
		Transitional cell carcinoma	n/a	154	100.0	1	0.6	0.1	3.6

		Tumour associated fever	n/a	154	100.0	1	0.6	0.1	3.6
		Tumour flare	n/a	154	100.0	5	3.2	1.4	7.4
		Tumour pain	n/a	154	100.0	1	0.6	0.1	3.6
	Nervous system disorders	-Total	n/a	154	100.0	2	1.3	0.4	4.6
		Dizziness	n/a	154	100.0	1	0.6	0.1	3.6
		Transient ischaemic attack	n/a	154	100.0	1	0.6	0.1	3.6
	Psychiatric disorders	-Total	n/a	154	100.0	2	1.3	0.4	4.6
		Delirium	n/a	154	100.0	2	1.3	0.4	4.6
	Renal and urinary disorders	-Total	n/a	154	100.0	1	0.6	0.1	3.6
		Acute kidney injury	n/a	154	100.0	1	0.6	0.1	3.6
	Respiratory, thoracic and mediastinal disorders	-Total	n/a	154	100.0	4	2.6	1.0	6.5
		Pleural effusion	n/a	154	100.0	3	1.9	0.7	5.6
		Pulmonary embolism	n/a	154	100.0	1	0.6	0.1	3.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_soc_JUN22_SE_D235_AESAE.xls

28FEB2023 15:03

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AEs leading to treatment discontinuation
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	14	9.1	5.5	14.7

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_AEDISC.xls
 28FEB2023 14:37

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs leading to treatment discontinuation

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)						
Name	SOC	PT	Level	Patients		Patients with Event				
				n	%	n	%	95% CI (LL)	95% CI (UL)	
All	Blood and lymphatic system disorders	-Total	n/a	154	100.0	2	1.3		0.4	4.6
		Neutropenia	n/a	154	100.0	2	1.3		0.4	4.6
	Gastrointestinal disorders	-Total	n/a	154	100.0	1	0.6		0.1	3.6
		Gastrointestinal haemorrhage	n/a	154	100.0	1	0.6		0.1	3.6
	Hepatobiliary disorders	-Total	n/a	154	100.0	1	0.6		0.1	3.6
		Cholestasis	n/a	154	100.0	1	0.6		0.1	3.6
		Hepatic cytolysis	n/a	154	100.0	1	0.6		0.1	3.6
	Immune system disorders	-Total	n/a	154	100.0	1	0.6		0.1	3.6
		Cytokine release syndrome by ASTCT grade	n/a	154	100.0	1	0.6		0.1	3.6
		Cytokine release syndrome by Lee grade	n/a	154	100.0	1	0.6		0.1	3.6
	Infections and infestations	-Total	n/a	154	100.0	6	3.9		1.8	8.2
		Biliary tract infection bacterial	n/a	154	100.0	1	0.6		0.1	3.6
		COVID-19	n/a	154	100.0	2	1.3		0.4	4.6
		COVID-19 pneumonia	n/a	154	100.0	1	0.6		0.1	3.6
		Myelitis	n/a	154	100.0	1	0.6		0.1	3.6
		Sepsis	n/a	154	100.0	1	0.6		0.1	3.6
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	154	100.0	1	0.6		0.1	3.6

		Melanoma recurrent	n/a	154	100.0	1	0.6	0.1	3.6
	Psychiatric disorders	-Total	n/a	154	100.0	2	1.3	0.4	4.6
		Delirium	n/a	154	100.0	2	1.3	0.4	4.6

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_soc_JUN22_SE_D235_AEDISC.xls
28FEB2023 15:04

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: AST, ALT, or total bilirubin elevation - Grade >= 2
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	11	7.1	4.0	12.3

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ABIL.xls

28FEB2023 14:48

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: AST, ALT, or total bilirubin elevation - Grade >= 3
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	6	3.9	1.8	8.2

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ABIL345.xls
 28FEB2023 14:48

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: AST, ALT, or total bilirubin elevation - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ABILSAE.xls
28FEB2023 14:49

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Colitis

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	1	0.6	0.1	3.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ACOL.xls

28FEB2023 14:54

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: Colitis - Grade \geq 3
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	1	0.6	0.1	3.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ACOL345.xls

28FEB2023 14:55

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Colitis - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	1	0.6	0.1	3.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ACOLSAE.xls

28FEB2023 14:55

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: Cytokine release syndrome by ASTCT grade - Grade \geq 2
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	25	16.2	11.2	22.9

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ACRS.xls

28FEB2023 14:38

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: Cytokine release syndrome by ASTCT grade - Grade 2
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	19	12.3	8.0	18.5

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ACRS2.xls

28FEB2023 14:38

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: Cytokine release syndrome by ASTCT grade - Grade \geq 3
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	6	3.9	1.8	8.2

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ACRS345.xls

28FEB2023 14:39

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by ASTCT grade - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	16	10.4	6.5	16.2

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ACRSSAE.xls

28FEB2023 14:40

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: Cytokine release syndrome by Lee grade - Grade \geq 2
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	29	18.8	13.4	25.7

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ACRSL.xls
 28FEB2023 14:40

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by Lee grade - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	5	3.2	1.4	7.4

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ACRSL345.xls

28FEB2023 14:41

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: Cytokine release syndrome by Lee grade - SAEs
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	18	11.7	7.5	17.7

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ACRSLSAE.xls
 28FEB2023 14:42

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Disseminated Intravascular Coagulation - Grade \geq 2
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ADIC.xls
28FEB2023 14:50

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Disseminated Intravascular Coagulation - Grade \geq 3
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ADIC345.xls
28FEB2023 14:50

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Disseminated Intravascular Coagulation - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ADICSAE.xls
28FEB2023 14:50

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: Febrile Neutropenia - Grade >= 3
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	4	2.6	1.0	6.5

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_AFEF.xls
 28FEB2023 14:46

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Febrile Neutropenia - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	3	1.9	0.7	5.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_AFEBSAE.xls

28FEB2023 14:47

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Hemophagocytic lymphohistiocytosis
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_AHEMA.xls
28FEB2023 14:44

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Hemophagocytic lymphohistiocytosis - Grade \geq 3
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_AHEMA345.xls
28FEB2023 14:45

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Hemophagocytic lymphohistiocytosis - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_AHEMASAE.xls

28FEB2023 14:45

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Secondary malignancies

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	1	0.6	0.1	3.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_AMAL.xls

28FEB2023 14:56

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Secondary malignancies - Grade \geq 3
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_AMAL345.xls
28FEB2023 14:57

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Secondary malignancies - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_AMALSAE.xls
28FEB2023 14:57

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Neurologic AEs - Grade \geq 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	22	14.3	9.6	20.7

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ANAE.xls

28FEB2023 14:42

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Neurologic AEs - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	4	2.6	1.0	6.5

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ANAE345.xls

28FEB2023 14:43

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Neurologic AEs - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	3	1.9	0.7	5.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ANAESAE.xls

28FEB2023 14:44

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: Pneumonitis or interstitial lung disease
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	2	1.3	0.4	4.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_APILD.xls

28FEB2023 14:53

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Pneumonitis or interstitial lung disease - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	1	0.6	0.1	3.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_APILD345.xls

28FEB2023 14:53

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Pneumonitis or interstitial lung disease - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_APILDSAE.xls
28FEB2023 14:54

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: Tumor flare - Grade \geq 2
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)							
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	11	7.1	4.0	12.3

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ATF.xls
 28FEB2023 14:51

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Tumor flare - Grade \geq 3
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	4	2.6	1.0	6.5

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ATF345.xls
28FEB2023 14:51

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Tumor flare - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	4	2.6	1.0	6.5

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ATFSAE.xls

28FEB2023 14:52

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: Tumor lysis syndrome - Grade >= 3
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	2	1.3	0.4	4.6

95% CI based on Wilson Scores.
 Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ATLS.xls
 28FEB2023 14:45

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Tumor lysis syndrome - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ATLSSAE.xls
28FEB2023 14:46

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: Obinutuzumab: Tumor lysis syndrome
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	2	1.3	0.4	4.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ATLSO.xls

28FEB2023 14:57

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: Obinutuzumab: Tumor lysis syndrome - Grade \geq 3
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100.0	2	1.3	0.4	4.6

95% CI based on Wilson Scores.

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ATLSO345.xls
 28FEB2023 14:58

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Obinutuzumab: Tumor lysis syndrome - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_raw_JUN22_SE_D235_ATLSOSAE.xls
28FEB2023 14:59

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: All patients
 MODEL: --
 STUDY: NP30179
 Outcome of Adverse Events

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)															
		Total		RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
Category of Adverse Events		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Any AEs																	
	All	1449	100.0	1082	74.7	5	0.3	336	23.2	10	0.7	16	1.1	0	0.0	0	0.0
	Grade 1	762	100.0	596	78.2	1	0.1	155	20.3	0	0.0	10	1.3	0	0.0	0	0.0
	Grade 2	422	100.0	296	70.1	4	0.9	118	28.0	0	0.0	4	0.9	0	0.0	0	0.0
	Grade 3	206	100.0	157	76.2	0	0.0	49	23.8	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	48	100.0	33	68.8	0	0.0	13	27.1	0	0.0	2	4.2	0	0.0	0	0.0
	Grade 5	10	100.0	0	0.0	0	0.0	0	0.0	10	100.0	0	0.0	0	0.0	0	0.0
	Missing	1	100.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
Any SAEs																	
	All	168	100.0	135	80.4	0	0.0	21	12.5	10	6.0	2	1.2	0	0.0	0	0.0
	Grade 1	35	100.0	32	91.4	0	0.0	3	8.6	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 2	47	100.0	45	95.7	0	0.0	2	4.3	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	51	100.0	43	84.3	0	0.0	8	15.7	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	25	100.0	15	60.0	0	0.0	8	32.0	0	0.0	2	8.0	0	0.0	0	0.0
	Grade 5	10	100.0	0	0.0	0	0.0	0	0.0	10	100.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Any AESI																	
	All	102	100.0	74	72.5	1	1.0	25	24.5	1	1.0	1	1.0	0	0.0	0	0.0
	Grade 1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 2	66	100.0	48	72.7	1	1.5	17	25.8	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	29	100.0	23	79.3	0	0.0	6	20.7	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	6	100.0	3	50.0	0	0.0	2	33.3	0	0.0	1	16.7	0	0.0	0	0.0
	Grade 5	1	100.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_resolved.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_resolved_JUN22_SE_D235_SG.xls
 11APR2023 15:25

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: All patients
 MODEL: --
 STUDY: NP30179
 Outcome of Adverse Events of Special Interest

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)															
Category of Adverse Events		Total		RECOVERED/RESOLVED		RECOVERED/RESOLVED WITH SEQUELAE		NOT RECOVERED/NOT RESOLVED		FATAL		RECOVERING/RESOLVING		UNKNOWN		MISSING	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
AESI: Cytokine release syndrome by Lee grade, Grade >= 2																	
	All	66	100.0	62	93.9	0	0.0	4	6.1	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 2	55	100.0	53	96.4	0	0.0	2	3.6	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	7	100.0	7	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	4	100.0	2	50.0	0	0.0	2	50.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: Cytokine release syndrome by ASTCT grade, Grade >= 2																	
	All	27	100.0	26	96.3	0	0.0	1	3.7	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 2	21	100.0	21	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	4	100.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	2	100.0	1	50.0	0	0.0	1	50.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: Neurologic AEs, Grade >= 2																	
	All	50	100.0	24	48.0	2	4.0	22	44.0	2	4.0	0	0.0	0	0.0	0	0.0
	Grade 2	42	100.0	24	57.1	2	4.8	16	38.1	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	4	100.0	0	0.0	0	0.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	2	100.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	2	100.0	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: Tumor lysis syndrome, Grade >= 3																	
	All	4	100.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	4	100.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: Febrile Neutropenia, Grade >= 3																	
	All	12	100.0	12	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	8	100.0	8	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	4	100.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: AST, ALT, or total bilirubin elevation, Grade >= 2																	
	All	38	100.0	18	47.4	0	0.0	20	52.6	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 2	16	100.0	4	25.0	0	0.0	12	75.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	22	100.0	14	63.6	0	0.0	8	36.4	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: Tumour flare, Grade >= 2																	
	All	22	100.0	20	90.9	0	0.0	2	9.1	0	0.0	0	0.0	0	0.0	0	0.0

	Grade 2	14	100.0	12	85.7	0	0.0	2	14.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	8	100.0	8	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: Pneumonitis or interstitial lung disease																			
	All	4	100.0	4	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 2	2	100.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	2	100.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: Colitis																			
	All	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0
	Grade 1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: Obinutuzumab - Secondary malignancies																			
	All	2	100.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 2	2	100.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
AESI: Obinutuzumab - TLS																			
	All	2	100.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 2	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 3	2	100.0	2	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Grade 5	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Missing	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Clinical cut-off: 15JUN2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_resolved_aes_i.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_FDA_Sub2_EU_RTQ_Aug2022/prod/output/saf_resolved_aes_i_JUN22_SE_D235_SG.xls

11APR2023 15:26

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: Any AEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	113	99,1	95,2	99,8

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_AEANY.xls

03MAR2023 9:17

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: Any AEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
Name	SOC	PT	Level	Patients		Patients with Event			
				n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	114	100,0	61	53,5	44,4	62,4
		Anaemia	n/a	114	100,0	35	30,7	23,0	39,7
		Anaemia of malignant disease	n/a	114	100,0	1	0,9	0,2	4,8
		Febrile neutropenia	n/a	114	100,0	4	3,5	1,4	8,7
		Iron deficiency anaemia	n/a	114	100,0	1	0,9	0,2	4,8
		Leukocytosis	n/a	114	100,0	1	0,9	0,2	4,8
		Lymphopenia	n/a	114	100,0	4	3,5	1,4	8,7
		Monocytosis	n/a	114	100,0	1	0,9	0,2	4,8
		Neutropenia	n/a	114	100,0	43	37,7	29,4	46,9
		Polycythaemia	n/a	114	100,0	1	0,9	0,2	4,8
		Thrombocytopenia	n/a	114	100,0	25	21,9	15,3	30,4
	Cardiac disorders	-Total	n/a	114	100,0	11	9,6	5,5	16,5
		Atrial fibrillation	n/a	114	100,0	3	2,6	0,9	7,5
		Cardiac failure	n/a	114	100,0	1	0,9	0,2	4,8
		Sinus bradycardia	n/a	114	100,0	1	0,9	0,2	4,8
		Sinus node dysfunction	n/a	114	100,0	1	0,9	0,2	4,8
		Sinus tachycardia	n/a	114	100,0	1	0,9	0,2	4,8

		Tachycardia	n/a	114	100,0	4	3,5	1,4	8,7
		Ventricular extrasystoles	n/a	114	100,0	1	0,9	0,2	4,8
	Ear and labyrinth disorders	-Total	n/a	114	100,0	2	1,8	0,5	6,2
		Ear congestion	n/a	114	100,0	1	0,9	0,2	4,8
		Ear pain	n/a	114	100,0	1	0,9	0,2	4,8
		Vertigo	n/a	114	100,0	1	0,9	0,2	4,8
	Endocrine disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Hypothyroidism	n/a	114	100,0	1	0,9	0,2	4,8
	Eye disorders	-Total	n/a	114	100,0	4	3,5	1,4	8,7
		Conjunctival haemorrhage	n/a	114	100,0	1	0,9	0,2	4,8
		Conjunctivitis allergic	n/a	114	100,0	1	0,9	0,2	4,8
		Eye pain	n/a	114	100,0	1	0,9	0,2	4,8
		Periorbital pain	n/a	114	100,0	1	0,9	0,2	4,8
		Periorbital swelling	n/a	114	100,0	1	0,9	0,2	4,8
	Gastrointestinal disorders	-Total	n/a	114	100,0	54	47,4	38,4	56,5
		Abdominal discomfort	n/a	114	100,0	2	1,8	0,5	6,2
		Abdominal distension	n/a	114	100,0	1	0,9	0,2	4,8
		Abdominal pain	n/a	114	100,0	11	9,6	5,5	16,5
		Abdominal pain upper	n/a	114	100,0	1	0,9	0,2	4,8
		Anorectal discomfort	n/a	114	100,0	1	0,9	0,2	4,8
		Ascites	n/a	114	100,0	1	0,9	0,2	4,8
		Colitis	n/a	114	100,0	1	0,9	0,2	4,8
		Constipation	n/a	114	100,0	13	11,4	6,8	18,5
		Dental caries	n/a	114	100,0	1	0,9	0,2	4,8

		Diarrhoea	n/a	114	100,0	14	12,3	7,5	19,6
		Dry mouth	n/a	114	100,0	1	0,9	0,2	4,8
		Dyspepsia	n/a	114	100,0	1	0,9	0,2	4,8
		Dysphagia	n/a	114	100,0	1	0,9	0,2	4,8
		Faeces discoloured	n/a	114	100,0	1	0,9	0,2	4,8
		Gastric haemorrhage	n/a	114	100,0	1	0,9	0,2	4,8
		Gastrointestinal haemorrhage	n/a	114	100,0	2	1,8	0,5	6,2
		Haemorrhoids	n/a	114	100,0	1	0,9	0,2	4,8
		Intestinal perforation	n/a	114	100,0	1	0,9	0,2	4,8
		Large intestinal haemorrhage	n/a	114	100,0	1	0,9	0,2	4,8
		Nausea	n/a	114	100,0	12	10,5	6,1	17,5
		Stomatitis	n/a	114	100,0	1	0,9	0,2	4,8
		Toothache	n/a	114	100,0	3	2,6	0,9	7,5
		Umbilical hernia	n/a	114	100,0	1	0,9	0,2	4,8
		Vomiting	n/a	114	100,0	5	4,4	1,9	9,9
	General disorders and administration site conditions	-Total	n/a	114	100,0	50	43,9	35,1	53,0
		Asthenia	n/a	114	100,0	8	7,0	3,6	13,2
		Catheter site pain	n/a	114	100,0	1	0,9	0,2	4,8
		Catheter site pruritus	n/a	114	100,0	1	0,9	0,2	4,8
		Chest discomfort	n/a	114	100,0	1	0,9	0,2	4,8
		Chills	n/a	114	100,0	1	0,9	0,2	4,8
		Facial pain	n/a	114	100,0	1	0,9	0,2	4,8
		Fatigue	n/a	114	100,0	13	11,4	6,8	18,5

		General physical health deterioration	n/a	114	100,0	1	0,9	0,2	4,8
		Inflammation	n/a	114	100,0	1	0,9	0,2	4,8
		Injection site phlebitis	n/a	114	100,0	1	0,9	0,2	4,8
		Injection site reaction	n/a	114	100,0	1	0,9	0,2	4,8
		Localised oedema	n/a	114	100,0	1	0,9	0,2	4,8
		Malaise	n/a	114	100,0	2	1,8	0,5	6,2
		Oedema	n/a	114	100,0	3	2,6	0,9	7,5
		Oedema peripheral	n/a	114	100,0	6	5,3	2,4	11,0
		Pain	n/a	114	100,0	2	1,8	0,5	6,2
		Pyrexia	n/a	114	100,0	19	16,7	10,9	24,6
		Swelling	n/a	114	100,0	2	1,8	0,5	6,2
		Swelling face	n/a	114	100,0	2	1,8	0,5	6,2
	Hepatobiliary disorders	-Total	n/a	114	100,0	2	1,8	0,5	6,2
		Biliary colic	n/a	114	100,0	2	1,8	0,5	6,2
	Immune system disorders	-Total	n/a	114	100,0	85	74,6	65,9	81,7
		Cytokine release syndrome by ASTCT grade	n/a	114	100,0	21	18,4	12,4	26,5
		Cytokine release syndrome by Lee grade	n/a	114	100,0	83	72,8	64,0	80,1
		Hypogammaglobulinaemia	n/a	114	100,0	2	1,8	0,5	6,2
	Infections and infestations	-Total	n/a	114	100,0	48	42,1	33,4	51,3
		Abscess	n/a	114	100,0	1	0,9	0,2	4,8
		Appendicitis	n/a	114	100,0	1	0,9	0,2	4,8

		Bacterial infection	n/a	114	100,0	1	0,9	0,2	4,8
		Biliary tract infection bacterial	n/a	114	100,0	1	0,9	0,2	4,8
		Bronchitis	n/a	114	100,0	3	2,6	0,9	7,5
		COVID-19	n/a	114	100,0	8	7,0	3,6	13,2
		COVID-19 pneumonia	n/a	114	100,0	5	4,4	1,9	9,9
		Campylobacter infection	n/a	114	100,0	1	0,9	0,2	4,8
		Chronic sinusitis	n/a	114	100,0	1	0,9	0,2	4,8
		Clostridium difficile infection	n/a	114	100,0	2	1,8	0,5	6,2
		Escherichia infection	n/a	114	100,0	2	1,8	0,5	6,2
		Gastroenteritis	n/a	114	100,0	1	0,9	0,2	4,8
		Herpes zoster	n/a	114	100,0	2	1,8	0,5	6,2
		Infection	n/a	114	100,0	1	0,9	0,2	4,8
		Localised infection	n/a	114	100,0	1	0,9	0,2	4,8
		Myelitis	n/a	114	100,0	1	0,9	0,2	4,8
		Nasopharyngitis	n/a	114	100,0	2	1,8	0,5	6,2
		Neutropenic infection	n/a	114	100,0	1	0,9	0,2	4,8
		Oesophageal candidiasis	n/a	114	100,0	1	0,9	0,2	4,8
		Ophthalmic herpes zoster	n/a	114	100,0	1	0,9	0,2	4,8
		Paronychia	n/a	114	100,0	1	0,9	0,2	4,8
		Periodontitis	n/a	114	100,0	1	0,9	0,2	4,8
		Peritonitis	n/a	114	100,0	1	0,9	0,2	4,8
		Pneumococcal infection	n/a	114	100,0	1	0,9	0,2	4,8

		Pneumonia	n/a	114	100,0	6	5,3	2,4	11,0
		Respiratory tract infection	n/a	114	100,0	2	1,8	0,5	6,2
		Rhinitis	n/a	114	100,0	2	1,8	0,5	6,2
		Sepsis	n/a	114	100,0	6	5,3	2,4	11,0
		Sinusitis	n/a	114	100,0	3	2,6	0,9	7,5
		Tooth infection	n/a	114	100,0	2	1,8	0,5	6,2
		Upper respiratory tract infection	n/a	114	100,0	2	1,8	0,5	6,2
		Urinary tract infection	n/a	114	100,0	2	1,8	0,5	6,2
		Urinary tract infection bacterial	n/a	114	100,0	1	0,9	0,2	4,8
		Vascular device infection	n/a	114	100,0	3	2,6	0,9	7,5
		Viral upper respiratory tract infection	n/a	114	100,0	1	0,9	0,2	4,8
	Injury, poisoning and procedural complications	-Total	n/a	114	100,0	12	10,5	6,1	17,5
		Fall	n/a	114	100,0	1	0,9	0,2	4,8
		Infusion related reaction	n/a	114	100,0	7	6,1	3,0	12,1
		Joint dislocation	n/a	114	100,0	1	0,9	0,2	4,8
		Thermal burn	n/a	114	100,0	1	0,9	0,2	4,8
		Toxicity to various agents	n/a	114	100,0	1	0,9	0,2	4,8
		Wound complication	n/a	114	100,0	1	0,9	0,2	4,8
	Investigations	-Total	n/a	114	100,0	35	30,7	23,0	39,7
		Alanine aminotransferase increased	n/a	114	100,0	7	6,1	3,0	12,1

		Aspartate aminotransferase increased	n/a	114	100,0	8	7,0	3,6	13,2
		Blood alkaline phosphatase increased	n/a	114	100,0	7	6,1	3,0	12,1
		Blood bilirubin increased	n/a	114	100,0	3	2,6	0,9	7,5
		Blood creatinine increased	n/a	114	100,0	7	6,1	3,0	12,1
		Blood fibrinogen decreased	n/a	114	100,0	1	0,9	0,2	4,8
		Blood lactate dehydrogenase increased	n/a	114	100,0	3	2,6	0,9	7,5
		Blood urea increased	n/a	114	100,0	1	0,9	0,2	4,8
		Blood uric acid increased	n/a	114	100,0	1	0,9	0,2	4,8
		C-reactive protein increased	n/a	114	100,0	5	4,4	1,9	9,9
		Cardiac murmur	n/a	114	100,0	1	0,9	0,2	4,8
		Ejection fraction decreased	n/a	114	100,0	1	0,9	0,2	4,8
		Fibrin D dimer increased	n/a	114	100,0	1	0,9	0,2	4,8
		Gamma-glutamyltransferase increased	n/a	114	100,0	8	7,0	3,6	13,2
		Hepatic enzyme increased	n/a	114	100,0	2	1,8	0,5	6,2
		Lymphocyte count decreased	n/a	114	100,0	1	0,9	0,2	4,8
		Neutrophil count decreased	n/a	114	100,0	2	1,8	0,5	6,2
		Neutrophil count increased	n/a	114	100,0	1	0,9	0,2	4,8

		Platelet count decreased	n/a	114	100,0	3	2,6	0,9	7,5
		Platelet count increased	n/a	114	100,0	1	0,9	0,2	4,8
		Polymerase chain reaction positive	n/a	114	100,0	2	1,8	0,5	6,2
		Serum ferritin decreased	n/a	114	100,0	1	0,9	0,2	4,8
		Serum ferritin increased	n/a	114	100,0	1	0,9	0,2	4,8
		Weight decreased	n/a	114	100,0	2	1,8	0,5	6,2
		White blood cell count decreased	n/a	114	100,0	2	1,8	0,5	6,2
	Metabolism and nutrition disorders	-Total	n/a	114	100,0	50	43,9	35,1	53,0
		Decreased appetite	n/a	114	100,0	4	3,5	1,4	8,7
		Dehydration	n/a	114	100,0	2	1,8	0,5	6,2
		Fluid retention	n/a	114	100,0	1	0,9	0,2	4,8
		Hypercalcaemia	n/a	114	100,0	3	2,6	0,9	7,5
		Hyperglycaemia	n/a	114	100,0	2	1,8	0,5	6,2
		Hyperkalaemia	n/a	114	100,0	1	0,9	0,2	4,8
		Hypermagnesaemia	n/a	114	100,0	2	1,8	0,5	6,2
		Hyperphosphataemia	n/a	114	100,0	3	2,6	0,9	7,5
		Hyperuricaemia	n/a	114	100,0	5	4,4	1,9	9,9
		Hypoalbuminaemia	n/a	114	100,0	1	0,9	0,2	4,8
		Hypocalcaemia	n/a	114	100,0	13	11,4	6,8	18,5
		Hypochloraemia	n/a	114	100,0	6	5,3	2,4	11,0
		Hypoglycaemia	n/a	114	100,0	1	0,9	0,2	4,8
		Hypokalaemia	n/a	114	100,0	12	10,5	6,1	17,5

		Hypomagnesaemia	n/a	114	100,0	19	16,7	10,9	24,6
		Hyponatraemia	n/a	114	100,0	8	7,0	3,6	13,2
		Hypophosphataemia	n/a	114	100,0	20	17,5	11,7	25,6
		Tumour lysis syndrome	n/a	114	100,0	2	1,8	0,5	6,2
	Musculoskeletal and connective tissue disorders	-Total	n/a	114	100,0	30	26,3	19,1	35,1
		Arthralgia	n/a	114	100,0	7	6,1	3,0	12,1
		Back pain	n/a	114	100,0	11	9,6	5,5	16,5
		Bone pain	n/a	114	100,0	3	2,6	0,9	7,5
		Flank pain	n/a	114	100,0	1	0,9	0,2	4,8
		Joint swelling	n/a	114	100,0	1	0,9	0,2	4,8
		Limb mass	n/a	114	100,0	1	0,9	0,2	4,8
		Muscle spasms	n/a	114	100,0	1	0,9	0,2	4,8
		Muscular weakness	n/a	114	100,0	1	0,9	0,2	4,8
		Musculoskeletal pain	n/a	114	100,0	1	0,9	0,2	4,8
		Myalgia	n/a	114	100,0	3	2,6	0,9	7,5
		Neck pain	n/a	114	100,0	1	0,9	0,2	4,8
		Pain in extremity	n/a	114	100,0	2	1,8	0,5	6,2
		Pain in jaw	n/a	114	100,0	3	2,6	0,9	7,5
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	114	100,0	20	17,5	11,7	25,6
		Acute myeloid leukaemia	n/a	114	100,0	1	0,9	0,2	4,8
		Benign neoplasm of thyroid gland	n/a	114	100,0	1	0,9	0,2	4,8
		Tumour associated fever	n/a	114	100,0	1	0,9	0,2	4,8
		Tumour flare	n/a	114	100,0	14	12,3	7,5	19,6
		Tumour pain	n/a	114	100,0	3	2,6	0,9	7,5

	Nervous system disorders	-Total	n/a	114	100,0	26	22,8	16,1	31,3
		Ageusia	n/a	114	100,0	1	0,9	0,2	4,8
		Dizziness	n/a	114	100,0	3	2,6	0,9	7,5
		Headache	n/a	114	100,0	11	9,6	5,5	16,5
		Hemiparaesthesia	n/a	114	100,0	1	0,9	0,2	4,8
		Myoclonus	n/a	114	100,0	1	0,9	0,2	4,8
		Neuropathy peripheral	n/a	114	100,0	2	1,8	0,5	6,2
		Paraesthesia	n/a	114	100,0	4	3,5	1,4	8,7
		Peripheral sensory neuropathy	n/a	114	100,0	2	1,8	0,5	6,2
		Presyncope	n/a	114	100,0	1	0,9	0,2	4,8
		Seizure	n/a	114	100,0	1	0,9	0,2	4,8
		Somnolence	n/a	114	100,0	2	1,8	0,5	6,2
		Tremor	n/a	114	100,0	1	0,9	0,2	4,8
	Psychiatric disorders	-Total	n/a	114	100,0	14	12,3	7,5	19,6
		Agitation	n/a	114	100,0	1	0,9	0,2	4,8
		Anxiety	n/a	114	100,0	5	4,4	1,9	9,9
		Confusional state	n/a	114	100,0	1	0,9	0,2	4,8
		Delirium	n/a	114	100,0	1	0,9	0,2	4,8
		Depression	n/a	114	100,0	1	0,9	0,2	4,8
		Disorientation	n/a	114	100,0	1	0,9	0,2	4,8
		Insomnia	n/a	114	100,0	2	1,8	0,5	6,2
		Mood altered	n/a	114	100,0	1	0,9	0,2	4,8
		Nervousness	n/a	114	100,0	1	0,9	0,2	4,8
	Renal and urinary disorders	-Total	n/a	114	100,0	6	5,3	2,4	11,0

		Sinus congestion	n/a	114	100,0	1	0,9	0,2	4,8
		Upper-airway cough syndrome	n/a	114	100,0	1	0,9	0,2	4,8
		Wheezing	n/a	114	100,0	1	0,9	0,2	4,8
	Skin and subcutaneous tissue disorders	-Total	n/a	114	100,0	27	23,7	16,8	32,3
		Dermatitis	n/a	114	100,0	1	0,9	0,2	4,8
		Dermatitis acneiform	n/a	114	100,0	1	0,9	0,2	4,8
		Dermatitis exfoliative	n/a	114	100,0	1	0,9	0,2	4,8
		Dry skin	n/a	114	100,0	1	0,9	0,2	4,8
		Eczema	n/a	114	100,0	2	1,8	0,5	6,2
		Erythema	n/a	114	100,0	7	6,1	3,0	12,1
		Hyperhidrosis	n/a	114	100,0	1	0,9	0,2	4,8
		Hyperkeratosis	n/a	114	100,0	1	0,9	0,2	4,8
		Night sweats	n/a	114	100,0	1	0,9	0,2	4,8
		Palmar erythema	n/a	114	100,0	1	0,9	0,2	4,8
		Pruritus	n/a	114	100,0	6	5,3	2,4	11,0
		Rash	n/a	114	100,0	9	7,9	4,2	14,3
		Rash maculo-papular	n/a	114	100,0	2	1,8	0,5	6,2
		Rash pruritic	n/a	114	100,0	2	1,8	0,5	6,2
		Urticaria	n/a	114	100,0	1	0,9	0,2	4,8
	Vascular disorders	-Total	n/a	114	100,0	12	10,5	6,1	17,5
		Embolism	n/a	114	100,0	1	0,9	0,2	4,8
		Hypertension	n/a	114	100,0	3	2,6	0,9	7,5
		Hypotension	n/a	114	100,0	6	5,3	2,4	11,0
		Jugular vein thrombosis	n/a	114	100,0	1	0,9	0,2	4,8

		Phlebitis	n/a	114	100,0	2	1,8	0,5	6,2
		Phlebitis superficial	n/a	114	100,0	1	0,9	0,2	4,8

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_soc_OCT22_SE_D23_AEANY.xls

03MAR2023 9:41

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	44	38,6	30,2	47,8

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_AEGR3.xls

03MAR2023 9:17

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
Name	SOC	PT	Level	Patients		Patients with Event			
				n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	114	100,0	33	28,9	21,4	37,9
		Anaemia	n/a	114	100,0	10	8,8	4,8	15,4
		Anaemia of malignant disease	n/a	114	100,0	1	0,9	0,2	4,8
		Febrile neutropenia	n/a	114	100,0	2	1,8	0,5	6,2
		Lymphopenia	n/a	114	100,0	1	0,9	0,2	4,8
		Neutropenia	n/a	114	100,0	21	18,4	12,4	26,5
		Thrombocytopenia	n/a	114	100,0	5	4,4	1,9	9,9
	Cardiac disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Cardiac failure	n/a	114	100,0	1	0,9	0,2	4,8
	Eye disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Periorbital swelling	n/a	114	100,0	1	0,9	0,2	4,8
	Gastrointestinal disorders	-Total	n/a	114	100,0	3	2,6	0,9	7,5
		Ascites	n/a	114	100,0	1	0,9	0,2	4,8
		Gastric haemorrhage	n/a	114	100,0	1	0,9	0,2	4,8
		Gastrointestinal haemorrhage	n/a	114	100,0	1	0,9	0,2	4,8
	General disorders and administration site conditions	-Total	n/a	114	100,0	4	3,5	1,4	8,7
		Asthenia	n/a	114	100,0	1	0,9	0,2	4,8
		Fatigue	n/a	114	100,0	1	0,9	0,2	4,8

		General physical health deterioration	n/a	114	100,0	1	0,9	0,2	4,8
		Pain	n/a	114	100,0	1	0,9	0,2	4,8
		Swelling	n/a	114	100,0	1	0,9	0,2	4,8
	Immune system disorders	-Total	n/a	114	100,0	3	2,6	0,9	7,5
		Cytokine release syndrome by ASTCT grade	n/a	114	100,0	3	2,6	0,9	7,5
		Cytokine release syndrome by Lee grade	n/a	114	100,0	2	1,8	0,5	6,2
	Infections and infestations	-Total	n/a	114	100,0	10	8,8	4,8	15,4
		Appendicitis	n/a	114	100,0	1	0,9	0,2	4,8
		Biliary tract infection bacterial	n/a	114	100,0	1	0,9	0,2	4,8
		COVID-19	n/a	114	100,0	2	1,8	0,5	6,2
		COVID-19 pneumonia	n/a	114	100,0	2	1,8	0,5	6,2
		Clostridium difficile infection	n/a	114	100,0	1	0,9	0,2	4,8
		Gastroenteritis	n/a	114	100,0	1	0,9	0,2	4,8
		Neutropenic infection	n/a	114	100,0	1	0,9	0,2	4,8
		Peritonitis	n/a	114	100,0	1	0,9	0,2	4,8
		Pneumococcal infection	n/a	114	100,0	1	0,9	0,2	4,8
		Pneumonia	n/a	114	100,0	1	0,9	0,2	4,8
		Sepsis	n/a	114	100,0	1	0,9	0,2	4,8
		Vascular device infection	n/a	114	100,0	2	1,8	0,5	6,2
	Injury, poisoning and procedural complications	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Toxicity to various agents	n/a	114	100,0	1	0,9	0,2	4,8

	Investigations	-Total	n/a	114	100,0	11	9,6	5,5	16,5
		Alanine aminotransferase increased	n/a	114	100,0	2	1,8	0,5	6,2
		Aspartate aminotransferase increased	n/a	114	100,0	2	1,8	0,5	6,2
		Blood alkaline phosphatase increased	n/a	114	100,0	1	0,9	0,2	4,8
		C-reactive protein increased	n/a	114	100,0	1	0,9	0,2	4,8
		Ejection fraction decreased	n/a	114	100,0	1	0,9	0,2	4,8
		Gamma-glutamyltransferase increased	n/a	114	100,0	3	2,6	0,9	7,5
		Hepatic enzyme increased	n/a	114	100,0	2	1,8	0,5	6,2
		Lymphocyte count decreased	n/a	114	100,0	1	0,9	0,2	4,8
		Neutrophil count decreased	n/a	114	100,0	1	0,9	0,2	4,8
		Weight decreased	n/a	114	100,0	1	0,9	0,2	4,8
		White blood cell count decreased	n/a	114	100,0	1	0,9	0,2	4,8
	Metabolism and nutrition disorders	-Total	n/a	114	100,0	11	9,6	5,5	16,5
		Hypercalcaemia	n/a	114	100,0	3	2,6	0,9	7,5
		Hyperglycaemia	n/a	114	100,0	1	0,9	0,2	4,8
		Hypokalaemia	n/a	114	100,0	1	0,9	0,2	4,8
		Hyponatraemia	n/a	114	100,0	1	0,9	0,2	4,8
		Hypophosphataemia	n/a	114	100,0	4	3,5	1,4	8,7
		Tumour lysis syndrome	n/a	114	100,0	2	1,8	0,5	6,2

Musculoskeletal and connective tissue disorders	-Total	n/a	114	100,0	3	2,6	0,9	7,5	
	Back pain	n/a	114	100,0	2	1,8	0,5	6,2	
	Pain in jaw	n/a	114	100,0	1	0,9	0,2	4,8	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	114	100,0	4	3,5	1,4	8,7	
	Tumour flare	n/a	114	100,0	2	1,8	0,5	6,2	
	Tumour pain	n/a	114	100,0	2	1,8	0,5	6,2	
Nervous system disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8	
	Somnolence	n/a	114	100,0	1	0,9	0,2	4,8	
Respiratory, thoracic and mediastinal disorders	-Total	n/a	114	100,0	4	3,5	1,4	8,7	
	Pleural effusion	n/a	114	100,0	3	2,6	0,9	7,5	
	Wheezing	n/a	114	100,0	1	0,9	0,2	4,8	
Skin and subcutaneous tissue disorders	-Total	n/a	114	100,0	2	1,8	0,5	6,2	
	Rash	n/a	114	100,0	1	0,9	0,2	4,8	
	Rash pruritic	n/a	114	100,0	1	0,9	0,2	4,8	
Vascular disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8	
	Hypertension	n/a	114	100,0	1	0,9	0,2	4,8	

95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_soc_OCT22_SE_D23_AEGR3.xls
03MAR2023 9:42

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 4

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	24	21,1	14,6	29,4

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_AEGR4.xls

03MAR2023 9:18

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 4

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
Name	SOC	PT	Level	Patients		Patients with Event			
				n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	114	100,0	16	14,0	8,8	21,6
		Febrile neutropenia	n/a	114	100,0	2	1,8	0,5	6,2
		Lymphopenia	n/a	114	100,0	3	2,6	0,9	7,5
		Neutropenia	n/a	114	100,0	10	8,8	4,8	15,4
		Thrombocytopenia	n/a	114	100,0	2	1,8	0,5	6,2
	Gastrointestinal disorders	-Total	n/a	114	100,0	2	1,8	0,5	6,2
		Colitis	n/a	114	100,0	1	0,9	0,2	4,8
		Gastrointestinal haemorrhage	n/a	114	100,0	1	0,9	0,2	4,8
		Large intestinal haemorrhage	n/a	114	100,0	1	0,9	0,2	4,8
	Immune system disorders	-Total	n/a	114	100,0	2	1,8	0,5	6,2
		Cytokine release syndrome by ASTCT grade	n/a	114	100,0	2	1,8	0,5	6,2
		Cytokine release syndrome by Lee grade	n/a	114	100,0	2	1,8	0,5	6,2
	Infections and infestations	-Total	n/a	114	100,0	6	5,3	2,4	11,0
		COVID-19	n/a	114	100,0	1	0,9	0,2	4,8
		Myelitis	n/a	114	100,0	1	0,9	0,2	4,8
		Pneumonia	n/a	114	100,0	1	0,9	0,2	4,8
		Sepsis	n/a	114	100,0	3	2,6	0,9	7,5

	Investigations	-Total	n/a	114	100,0	3	2,6	0,9	7,5
		Neutrophil count decreased	n/a	114	100,0	1	0,9	0,2	4,8
		Platelet count decreased	n/a	114	100,0	1	0,9	0,2	4,8
		White blood cell count decreased	n/a	114	100,0	1	0,9	0,2	4,8
	Metabolism and nutrition disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Hypophosphataemia	n/a	114	100,0	1	0,9	0,2	4,8
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Acute myeloid leukaemia	n/a	114	100,0	1	0,9	0,2	4,8

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_soc_OCT22_SE_D23_AEGR4.xls

03MAR2023 9:43

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 5 (AEs leading to death)

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	7	6,1	3,0	12,1

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_AEGR5.xls

03MAR2023 9:19

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 5 (AEs leading to death)

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
				Patients		Patients with Event			
Name	SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	Infections and infestations	-Total	n/a	114	100,0	6	5,3	2,4	11,0
		COVID-19	n/a	114	100,0	1	0,9	0,2	4,8
		COVID-19 pneumonia	n/a	114	100,0	3	2,6	0,9	7,5
		Sepsis	n/a	114	100,0	2	1,8	0,5	6,2
	Psychiatric disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Delirium	n/a	114	100,0	1	0,9	0,2	4,8

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_soc_OCT22_SE_D23_AEGR5.xls

03MAR2023 9:44

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade >=3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	75	65,8	56,7	73,9

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_AEGR345.xls

03MAR2023 9:19

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade >=3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
Name	SOC	PT	Level	Patients		Patients with Event			
				n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	114	100,0	40	35,1	26,9	44,2
		Anaemia	n/a	114	100,0	10	8,8	4,8	15,4
		Anaemia of malignant disease	n/a	114	100,0	1	0,9	0,2	4,8
		Febrile neutropenia	n/a	114	100,0	4	3,5	1,4	8,7
		Lymphopenia	n/a	114	100,0	4	3,5	1,4	8,7
		Neutropenia	n/a	114	100,0	31	27,2	19,9	36,0
		Thrombocytopenia	n/a	114	100,0	7	6,1	3,0	12,1
	Cardiac disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Cardiac failure	n/a	114	100,0	1	0,9	0,2	4,8
	Eye disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Periorbital swelling	n/a	114	100,0	1	0,9	0,2	4,8
	Gastrointestinal disorders	-Total	n/a	114	100,0	4	3,5	1,4	8,7
		Ascites	n/a	114	100,0	1	0,9	0,2	4,8
		Colitis	n/a	114	100,0	1	0,9	0,2	4,8
		Gastric haemorrhage	n/a	114	100,0	1	0,9	0,2	4,8
		Gastrointestinal haemorrhage	n/a	114	100,0	2	1,8	0,5	6,2
		Large intestinal haemorrhage	n/a	114	100,0	1	0,9	0,2	4,8

General disorders and administration site conditions	-Total	n/a	114	100,0	4	3,5	1,4	8,7
	Asthenia	n/a	114	100,0	1	0,9	0,2	4,8
	Fatigue	n/a	114	100,0	1	0,9	0,2	4,8
	General physical health deterioration	n/a	114	100,0	1	0,9	0,2	4,8
	Pain	n/a	114	100,0	1	0,9	0,2	4,8
	Swelling	n/a	114	100,0	1	0,9	0,2	4,8
Immune system disorders	-Total	n/a	114	100,0	5	4,4	1,9	9,9
	Cytokine release syndrome by ASTCT grade	n/a	114	100,0	5	4,4	1,9	9,9
	Cytokine release syndrome by Lee grade	n/a	114	100,0	4	3,5	1,4	8,7
Infections and infestations	-Total	n/a	114	100,0	21	18,4	12,4	26,5
	Appendicitis	n/a	114	100,0	1	0,9	0,2	4,8
	Biliary tract infection bacterial	n/a	114	100,0	1	0,9	0,2	4,8
	COVID-19	n/a	114	100,0	4	3,5	1,4	8,7
	COVID-19 pneumonia	n/a	114	100,0	5	4,4	1,9	9,9
	Clostridium difficile infection	n/a	114	100,0	1	0,9	0,2	4,8
	Gastroenteritis	n/a	114	100,0	1	0,9	0,2	4,8
	Myelitis	n/a	114	100,0	1	0,9	0,2	4,8
	Neutropenic infection	n/a	114	100,0	1	0,9	0,2	4,8
	Peritonitis	n/a	114	100,0	1	0,9	0,2	4,8
	Pneumococcal infection	n/a	114	100,0	1	0,9	0,2	4,8
	Pneumonia	n/a	114	100,0	2	1,8	0,5	6,2
	Sepsis	n/a	114	100,0	6	5,3	2,4	11,0

		Vascular device infection	n/a	114	100,0	2	1,8	0,5	6,2
	Injury, poisoning and procedural complications	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Toxicity to various agents	n/a	114	100,0	1	0,9	0,2	4,8
	Investigations	-Total	n/a	114	100,0	13	11,4	6,8	18,5
		Alanine aminotransferase increased	n/a	114	100,0	2	1,8	0,5	6,2
		Aspartate aminotransferase increased	n/a	114	100,0	2	1,8	0,5	6,2
		Blood alkaline phosphatase increased	n/a	114	100,0	1	0,9	0,2	4,8
		C-reactive protein increased	n/a	114	100,0	1	0,9	0,2	4,8
		Ejection fraction decreased	n/a	114	100,0	1	0,9	0,2	4,8
		Gamma-glutamyltransferase increased	n/a	114	100,0	3	2,6	0,9	7,5
		Hepatic enzyme increased	n/a	114	100,0	2	1,8	0,5	6,2
		Lymphocyte count decreased	n/a	114	100,0	1	0,9	0,2	4,8
		Neutrophil count decreased	n/a	114	100,0	2	1,8	0,5	6,2
		Platelet count decreased	n/a	114	100,0	1	0,9	0,2	4,8
		Weight decreased	n/a	114	100,0	1	0,9	0,2	4,8
		White blood cell count decreased	n/a	114	100,0	2	1,8	0,5	6,2
	Metabolism and nutrition disorders	-Total	n/a	114	100,0	12	10,5	6,1	17,5
		Hypercalcaemia	n/a	114	100,0	3	2,6	0,9	7,5

		Hyperglycaemia	n/a	114	100,0	1	0,9	0,2	4,8
		Hypokalaemia	n/a	114	100,0	1	0,9	0,2	4,8
		Hyponatraemia	n/a	114	100,0	1	0,9	0,2	4,8
		Hypophosphataemia	n/a	114	100,0	5	4,4	1,9	9,9
		Tumour lysis syndrome	n/a	114	100,0	2	1,8	0,5	6,2
	Musculoskeletal and connective tissue disorders	-Total	n/a	114	100,0	3	2,6	0,9	7,5
		Back pain	n/a	114	100,0	2	1,8	0,5	6,2
		Pain in jaw	n/a	114	100,0	1	0,9	0,2	4,8
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	114	100,0	5	4,4	1,9	9,9
		Acute myeloid leukaemia	n/a	114	100,0	1	0,9	0,2	4,8
		Tumour flare	n/a	114	100,0	2	1,8	0,5	6,2
		Tumour pain	n/a	114	100,0	2	1,8	0,5	6,2
	Nervous system disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Somnolence	n/a	114	100,0	1	0,9	0,2	4,8
	Psychiatric disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Delirium	n/a	114	100,0	1	0,9	0,2	4,8
	Respiratory, thoracic and mediastinal disorders	-Total	n/a	114	100,0	4	3,5	1,4	8,7
		Pleural effusion	n/a	114	100,0	3	2,6	0,9	7,5
		Wheezing	n/a	114	100,0	1	0,9	0,2	4,8
	Skin and subcutaneous tissue disorders	-Total	n/a	114	100,0	2	1,8	0,5	6,2
		Rash	n/a	114	100,0	1	0,9	0,2	4,8
		Rash pruritic	n/a	114	100,0	1	0,9	0,2	4,8
	Vascular disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Hypertension	n/a	114	100,0	1	0,9	0,2	4,8

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95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_soc_OCT22_SE_D23_AEGR345.xls
03MAR2023 9:45

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: Any SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	60	52,6	43,5	61,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_AESAE.xls

03MAR2023 9:20

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: Any SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
Name	SOC	PT	Level	Patients		Patients with Event			
				n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	114	100,0	8	7,0	3,6	13,2
		Anaemia	n/a	114	100,0	2	1,8	0,5	6,2
		Febrile neutropenia	n/a	114	100,0	3	2,6	0,9	7,5
		Lymphopenia	n/a	114	100,0	1	0,9	0,2	4,8
		Neutropenia	n/a	114	100,0	2	1,8	0,5	6,2
		Thrombocytopenia	n/a	114	100,0	1	0,9	0,2	4,8
	Cardiac disorders	-Total	n/a	114	100,0	2	1,8	0,5	6,2
		Cardiac failure	n/a	114	100,0	1	0,9	0,2	4,8
		Sinus node dysfunction	n/a	114	100,0	1	0,9	0,2	4,8
	Gastrointestinal disorders	-Total	n/a	114	100,0	6	5,3	2,4	11,0
		Colitis	n/a	114	100,0	1	0,9	0,2	4,8
		Constipation	n/a	114	100,0	1	0,9	0,2	4,8
		Gastric haemorrhage	n/a	114	100,0	1	0,9	0,2	4,8
		Gastrointestinal haemorrhage	n/a	114	100,0	2	1,8	0,5	6,2
		Intestinal perforation	n/a	114	100,0	1	0,9	0,2	4,8
		Large intestinal haemorrhage	n/a	114	100,0	1	0,9	0,2	4,8
		Nausea	n/a	114	100,0	1	0,9	0,2	4,8

	Vascular device infection	n/a	114	100,0	2	1,8	0,5	6,2
Injury, poisoning and procedural complications	-Total	n/a	114	100,0	3	2,6	0,9	7,5
	Infusion related reaction	n/a	114	100,0	1	0,9	0,2	4,8
	Joint dislocation	n/a	114	100,0	1	0,9	0,2	4,8
	Toxicity to various agents	n/a	114	100,0	1	0,9	0,2	4,8
Investigations	-Total	n/a	114	100,0	2	1,8	0,5	6,2
	C-reactive protein increased	n/a	114	100,0	1	0,9	0,2	4,8
	Weight decreased	n/a	114	100,0	1	0,9	0,2	4,8
Musculoskeletal and connective tissue disorders	-Total	n/a	114	100,0	2	1,8	0,5	6,2
	Back pain	n/a	114	100,0	2	1,8	0,5	6,2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	114	100,0	8	7,0	3,6	13,2
	Acute myeloid leukaemia	n/a	114	100,0	1	0,9	0,2	4,8
	Tumour associated fever	n/a	114	100,0	1	0,9	0,2	4,8
	Tumour flare	n/a	114	100,0	5	4,4	1,9	9,9
	Tumour pain	n/a	114	100,0	1	0,9	0,2	4,8
Psychiatric disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
	Delirium	n/a	114	100,0	1	0,9	0,2	4,8
Renal and urinary disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
	Acute kidney injury	n/a	114	100,0	1	0,9	0,2	4,8
Respiratory, thoracic and mediastinal disorders	-Total	n/a	114	100,0	2	1,8	0,5	6,2
	Pleural effusion	n/a	114	100,0	2	1,8	0,5	6,2

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_soc_OCT22_SE_D23_AESAE.xls

03MAR2023 9:45

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs leading to treatment discontinuation

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	10	8,8	4,8	15,4

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_AEDISC.xls

03MAR2023 9:21

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs leading to treatment discontinuation

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
				Patients		Patients with Event			
Name	SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Neutropenia	n/a	114	100,0	1	0,9	0,2	4,8
	Gastrointestinal disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Gastrointestinal haemorrhage	n/a	114	100,0	1	0,9	0,2	4,8
	Immune system disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Cytokine release syndrome by ASTCT grade	n/a	114	100,0	1	0,9	0,2	4,8
		Cytokine release syndrome by Lee grade	n/a	114	100,0	1	0,9	0,2	4,8
	Infections and infestations	-Total	n/a	114	100,0	6	5,3	2,4	11,0
		Biliary tract infection bacterial	n/a	114	100,0	1	0,9	0,2	4,8
		COVID-19	n/a	114	100,0	2	1,8	0,5	6,2
		COVID-19 pneumonia	n/a	114	100,0	1	0,9	0,2	4,8
		Myelitis	n/a	114	100,0	1	0,9	0,2	4,8
		Sepsis	n/a	114	100,0	1	0,9	0,2	4,8
	Psychiatric disorders	-Total	n/a	114	100,0	1	0,9	0,2	4,8
		Delirium	n/a	114	100,0	1	0,9	0,2	4,8

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95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_soc_OCT22_SE_D23_AEDISC.xls
03MAR2023 9:46

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: AST, ALT, or total bilirubin elevation - Grade \geq 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	5	4,4	1,9	9,9

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ABIL.xls

03MAR2023 9:31

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: AST, ALT, or total bilirubin elevation - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	3	2,6	0,9	7,5

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ABIL345.xls

03MAR2023 9:32

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: AST, ALT, or total bilirubin elevation - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ABILSAE.xls
03MAR2023 9:32

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Colitis

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	1	0,9	0,2	4,8

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ACOL.xls

03MAR2023 9:36

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Colitis - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	1	0,9	0,2	4,8

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ACOL345.xls

03MAR2023 9:37

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Colitis - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	1	0,9	0,2	4,8

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ACOLSAE.xls

03MAR2023 9:38

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by ASTCT grade - Grade \geq 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	21	18,4	12,4	26,5

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ACRS.xls

03MAR2023 9:22

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by ASTCT grade - Grade 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	16	14,0	8,8	21,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ACRS2.xls

03MAR2023 9:22

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by ASTCT grade - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	5	4,4	1,9	9,9

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ACRS345.xls

03MAR2023 9:23

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by ASTCT grade - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	14	12,3	7,5	19,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ACRSSAE.xls

03MAR2023 9:24

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by Lee grade - Grade \geq 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	25	21,9	15,3	30,4

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ACRSL.xls

03MAR2023 9:24

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by Lee grade - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	4	3,5	1,4	8,7

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ACRSL345.xls

03MAR2023 9:25

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by Lee grade - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	16	14,0	8,8	21,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ACRSISAE.xls

03MAR2023 9:26

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Disseminated Intravascular Coagulation - Grade \geq 2
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ADIC.xls
03MAR2023 9:33

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Disseminated Intravascular Coagulation - Grade \geq 3
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ADIC345.xls
03MAR2023 9:33

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Disseminated Intravascular Coagulation - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ADICSAE.xls

03MAR2023 9:33

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Febrile Neutropenia - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	4	3,5	1,4	8,7

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_AFEB.xls

03MAR2023 9:30

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Febrile Neutropenia - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	3	2,6	0,9	7,5

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_AFEBSAE.xls

03MAR2023 9:30

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Hemophagocytic lymphohistiocytosis
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_AHEMA.xls
03MAR2023 9:28

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Hemophagocytic lymphohistiocytosis - Grade \geq 3
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_AHEMA345.xls
03MAR2023 9:28

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Hemophagocytic lymphohistiocytosis - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_AHEMASAE.xls
03MAR2023 9:29

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Secondary malignancies

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	1	0,9	0,2	4,8

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_AMAL.xls

03MAR2023 9:38

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Secondary malignancies - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	1	0,9	0,2	4,8

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_AMAL345.xls

03MAR2023 9:39

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Secondary malignancies - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	1	0,9	0,2	4,8

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_AMALSAE.xls

03MAR2023 9:39

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Neurologic AEs - Grade \geq 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	18	15,8	10,2	23,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ANAE.xls

03MAR2023 9:26

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Neurologic AEs - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	3	2,6	0,9	7,5

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ANAE345.xls

03MAR2023 9:27

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Neurologic AEs - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	2	1,8	0,5	6,2

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ANAESAE.xls

03MAR2023 9:27

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Pneumonitis or interstitial lung disease
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_APILD.xls
03MAR2023 9:35

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Pneumonitis or interstitial lung disease - Grade \geq 3
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_APILD345.xls
03MAR2023 9:36

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Pneumonitis or interstitial lung disease - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_APILDSAE.xls

03MAR2023 9:36

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Tumor flare - Grade \geq 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	8	7,0	3,6	13,2

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ATF.xls

03MAR2023 9:34

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Tumor flare - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	2	1,8	0,5	6,2

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ATF345.xls

03MAR2023 9:34

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Tumor flare - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	4	3,5	1,4	8,7

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ATFSAE.xls

03MAR2023 9:35

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Tumor lysis syndrome - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	2	1,8	0,5	6,2

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ATLS.xls

03MAR2023 9:29

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Tumor lysis syndrome - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ATLSSAE.xls
03MAR2023 9:30

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Obinutuzumab: Tumor lysis syndrome

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	2	1,8	0,5	6,2

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ATLSO.xls

03MAR2023 9:40

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Obinutuzumab: Tumor lysis syndrome - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2) and D3 (N=114)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	114	100,0	2	1,8	0,5	6,2

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ATLSO345.xls

03MAR2023 9:40

POPULATION: Cohorts D2 (Sub 2) and D3 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Obinutuzumab: Tumor lysis syndrome - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D23_ATLSOSAE.xls
03MAR2023 9:41

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: Any AEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	152	98,7	95,4	99,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_AEANY.xls
02MAR2023 15:33

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: Any AEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
Name	SOC	PT	Level	Patients		Patients with Event			
				n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	154	100,0	85	55,2	47,3	62,8
		Anaemia	n/a	154	100,0	46	29,9	23,2	37,5
		Anaemia of malignant disease	n/a	154	100,0	1	0,6	0,1	3,6
		Febrile neutropenia	n/a	154	100,0	4	2,6	1,0	6,5
		Hypofibrinogenaemia	n/a	154	100,0	1	0,6	0,1	3,6
		Iron deficiency anaemia	n/a	154	100,0	1	0,6	0,1	3,6
		Leukocytosis	n/a	154	100,0	1	0,6	0,1	3,6
		Lymphopenia	n/a	154	100,0	6	3,9	1,8	8,2
		Monocytosis	n/a	154	100,0	1	0,6	0,1	3,6
		Neutropenia	n/a	154	100,0	55	35,7	28,6	43,5
		Polycythaemia	n/a	154	100,0	1	0,6	0,1	3,6
		Thrombocytopenia	n/a	154	100,0	33	21,4	15,7	28,6
	Cardiac disorders	-Total	n/a	154	100,0	15	9,7	6,0	15,4
		Atrial fibrillation	n/a	154	100,0	3	1,9	0,7	5,6
		Cardiac failure	n/a	154	100,0	2	1,3	0,4	4,6
		Sinus bradycardia	n/a	154	100,0	1	0,6	0,1	3,6
		Sinus node dysfunction	n/a	154	100,0	1	0,6	0,1	3,6

		Sinus tachycardia	n/a	154	100,0	2	1,3	0,4	4,6
		Tachycardia	n/a	154	100,0	6	3,9	1,8	8,2
		Ventricular extrasystoles	n/a	154	100,0	1	0,6	0,1	3,6
	Ear and labyrinth disorders	-Total	n/a	154	100,0	4	2,6	1,0	6,5
		Ear congestion	n/a	154	100,0	1	0,6	0,1	3,6
		Ear pain	n/a	154	100,0	2	1,3	0,4	4,6
		Vertigo	n/a	154	100,0	2	1,3	0,4	4,6
	Endocrine disorders	-Total	n/a	154	100,0	1	0,6	0,1	3,6
		Hypothyroidism	n/a	154	100,0	1	0,6	0,1	3,6
	Eye disorders	-Total	n/a	154	100,0	5	3,2	1,4	7,4
		Conjunctival haemorrhage	n/a	154	100,0	1	0,6	0,1	3,6
		Conjunctivitis allergic	n/a	154	100,0	1	0,6	0,1	3,6
		Eye pain	n/a	154	100,0	1	0,6	0,1	3,6
		Periorbital pain	n/a	154	100,0	1	0,6	0,1	3,6
		Periorbital swelling	n/a	154	100,0	1	0,6	0,1	3,6
		Vision blurred	n/a	154	100,0	1	0,6	0,1	3,6
	Gastrointestinal disorders	-Total	n/a	154	100,0	73	47,4	39,7	55,3
		Abdominal discomfort	n/a	154	100,0	2	1,3	0,4	4,6
		Abdominal distension	n/a	154	100,0	2	1,3	0,4	4,6
		Abdominal pain	n/a	154	100,0	14	9,1	5,5	14,7
		Abdominal pain upper	n/a	154	100,0	3	1,9	0,7	5,6
		Anorectal discomfort	n/a	154	100,0	1	0,6	0,1	3,6
		Ascites	n/a	154	100,0	1	0,6	0,1	3,6
		Colitis	n/a	154	100,0	1	0,6	0,1	3,6

		Constipation	n/a	154	100,0	21	13,6	9,1	19,9
		Dental caries	n/a	154	100,0	1	0,6	0,1	3,6
		Diaphragmatic hernia	n/a	154	100,0	1	0,6	0,1	3,6
		Diarrhoea	n/a	154	100,0	20	13,0	8,6	19,2
		Dry mouth	n/a	154	100,0	1	0,6	0,1	3,6
		Duodenal obstruction	n/a	154	100,0	1	0,6	0,1	3,6
		Dyspepsia	n/a	154	100,0	1	0,6	0,1	3,6
		Dysphagia	n/a	154	100,0	1	0,6	0,1	3,6
		Faeces discoloured	n/a	154	100,0	1	0,6	0,1	3,6
		Gastric haemorrhage	n/a	154	100,0	1	0,6	0,1	3,6
		Gastritis	n/a	154	100,0	2	1,3	0,4	4,6
		Gastrointestinal haemorrhage	n/a	154	100,0	2	1,3	0,4	4,6
		Haemorrhoids	n/a	154	100,0	1	0,6	0,1	3,6
		Intestinal perforation	n/a	154	100,0	1	0,6	0,1	3,6
		Large intestinal haemorrhage	n/a	154	100,0	1	0,6	0,1	3,6
		Nausea	n/a	154	100,0	16	10,4	6,5	16,2
		Stomatitis	n/a	154	100,0	2	1,3	0,4	4,6
		Toothache	n/a	154	100,0	4	2,6	1,0	6,5
		Umbilical hernia	n/a	154	100,0	1	0,6	0,1	3,6
		Vomiting	n/a	154	100,0	7	4,5	2,2	9,1
	General disorders and administration site conditions	-Total	n/a	154	100,0	66	42,9	35,3	50,8
		Asthenia	n/a	154	100,0	13	8,4	5,0	13,9
		Catheter site pain	n/a	154	100,0	1	0,6	0,1	3,6

		Catheter site pruritus	n/a	154	100,0	1	0,6	0,1	3,6
		Chest discomfort	n/a	154	100,0	1	0,6	0,1	3,6
		Chills	n/a	154	100,0	2	1,3	0,4	4,6
		Face oedema	n/a	154	100,0	1	0,6	0,1	3,6
		Facial pain	n/a	154	100,0	1	0,6	0,1	3,6
		Fatigue	n/a	154	100,0	18	11,7	7,5	17,7
		Gait disturbance	n/a	154	100,0	2	1,3	0,4	4,6
		General physical health deterioration	n/a	154	100,0	1	0,6	0,1	3,6
		Inflammation	n/a	154	100,0	1	0,6	0,1	3,6
		Injection site phlebitis	n/a	154	100,0	1	0,6	0,1	3,6
		Injection site reaction	n/a	154	100,0	1	0,6	0,1	3,6
		Localised oedema	n/a	154	100,0	1	0,6	0,1	3,6
		Malaise	n/a	154	100,0	3	1,9	0,7	5,6
		Oedema	n/a	154	100,0	4	2,6	1,0	6,5
		Oedema peripheral	n/a	154	100,0	9	5,8	3,1	10,7
		Pain	n/a	154	100,0	4	2,6	1,0	6,5
		Peripheral swelling	n/a	154	100,0	2	1,3	0,4	4,6
		Pyrexia	n/a	154	100,0	25	16,2	11,2	22,9
		Swelling	n/a	154	100,0	2	1,3	0,4	4,6
		Swelling face	n/a	154	100,0	2	1,3	0,4	4,6
	Hepatobiliary disorders	-Total	n/a	154	100,0	3	1,9	0,7	5,6
		Biliary colic	n/a	154	100,0	2	1,3	0,4	4,6
		Cholestasis	n/a	154	100,0	1	0,6	0,1	3,6

		Folliculitis	n/a	154	100,0	1	0,6	0,1	3,6
		Gastroenteritis	n/a	154	100,0	1	0,6	0,1	3,6
		Herpes zoster	n/a	154	100,0	3	1,9	0,7	5,6
		Infection	n/a	154	100,0	2	1,3	0,4	4,6
		Influenza	n/a	154	100,0	1	0,6	0,1	3,6
		Localised infection	n/a	154	100,0	1	0,6	0,1	3,6
		Myelitis	n/a	154	100,0	1	0,6	0,1	3,6
		Nail infection	n/a	154	100,0	1	0,6	0,1	3,6
		Nasopharyngitis	n/a	154	100,0	2	1,3	0,4	4,6
		Neutropenic infection	n/a	154	100,0	1	0,6	0,1	3,6
		Oesophageal candidiasis	n/a	154	100,0	1	0,6	0,1	3,6
		Ophthalmic herpes zoster	n/a	154	100,0	1	0,6	0,1	3,6
		Oral candidiasis	n/a	154	100,0	1	0,6	0,1	3,6
		Paronychia	n/a	154	100,0	1	0,6	0,1	3,6
		Periodontitis	n/a	154	100,0	1	0,6	0,1	3,6
		Peritonitis	n/a	154	100,0	1	0,6	0,1	3,6
		Pneumococcal infection	n/a	154	100,0	1	0,6	0,1	3,6
		Pneumonia	n/a	154	100,0	7	4,5	2,2	9,1
		Respiratory tract infection	n/a	154	100,0	2	1,3	0,4	4,6
		Rhinitis	n/a	154	100,0	2	1,3	0,4	4,6
		Sepsis	n/a	154	100,0	6	3,9	1,8	8,2
		Sinusitis	n/a	154	100,0	3	1,9	0,7	5,6
		Skin infection	n/a	154	100,0	1	0,6	0,1	3,6

		Tooth abscess	n/a	154	100,0	1	0,6	0,1	3,6
		Tooth infection	n/a	154	100,0	2	1,3	0,4	4,6
		Upper respiratory tract infection	n/a	154	100,0	3	1,9	0,7	5,6
		Urinary tract infection	n/a	154	100,0	4	2,6	1,0	6,5
		Urinary tract infection bacterial	n/a	154	100,0	1	0,6	0,1	3,6
		Vascular device infection	n/a	154	100,0	3	1,9	0,7	5,6
		Viral upper respiratory tract infection	n/a	154	100,0	1	0,6	0,1	3,6
	Injury, poisoning and procedural complications	-Total	n/a	154	100,0	20	13,0	8,6	19,2
		Clavicle fracture	n/a	154	100,0	1	0,6	0,1	3,6
		Fall	n/a	154	100,0	3	1,9	0,7	5,6
		Humerus fracture	n/a	154	100,0	1	0,6	0,1	3,6
		Infusion related reaction	n/a	154	100,0	10	6,5	3,6	11,5
		Joint dislocation	n/a	154	100,0	1	0,6	0,1	3,6
		Muscle rupture	n/a	154	100,0	1	0,6	0,1	3,6
		Thermal burn	n/a	154	100,0	1	0,6	0,1	3,6
		Toxicity to various agents	n/a	154	100,0	1	0,6	0,1	3,6
		Wound complication	n/a	154	100,0	1	0,6	0,1	3,6
	Investigations	-Total	n/a	154	100,0	46	29,9	23,2	37,5
		Alanine aminotransferase increased	n/a	154	100,0	13	8,4	5,0	13,9
		Aspartate aminotransferase increased	n/a	154	100,0	12	7,8	4,5	13,1

		Blood alkaline phosphatase increased	n/a	154	100,0	13	8,4	5,0	13,9
		Blood bilirubin increased	n/a	154	100,0	6	3,9	1,8	8,2
		Blood creatinine increased	n/a	154	100,0	8	5,2	2,7	9,9
		Blood fibrinogen decreased	n/a	154	100,0	1	0,6	0,1	3,6
		Blood iron decreased	n/a	154	100,0	1	0,6	0,1	3,6
		Blood lactate dehydrogenase increased	n/a	154	100,0	3	1,9	0,7	5,6
		Blood lactic acid increased	n/a	154	100,0	1	0,6	0,1	3,6
		Blood urea increased	n/a	154	100,0	1	0,6	0,1	3,6
		Blood uric acid increased	n/a	154	100,0	1	0,6	0,1	3,6
		C-reactive protein increased	n/a	154	100,0	6	3,9	1,8	8,2
		Cardiac murmur	n/a	154	100,0	1	0,6	0,1	3,6
		Ejection fraction decreased	n/a	154	100,0	2	1,3	0,4	4,6
		Fibrin D dimer increased	n/a	154	100,0	2	1,3	0,4	4,6
		Gamma-glutamyltransferase increased	n/a	154	100,0	10	6,5	3,6	11,5
		Hepatic enzyme increased	n/a	154	100,0	2	1,3	0,4	4,6
		Lymphocyte count decreased	n/a	154	100,0	1	0,6	0,1	3,6
		Neutrophil count decreased	n/a	154	100,0	3	1,9	0,7	5,6

		Neutrophil count increased	n/a	154	100,0	1	0,6	0,1	3,6
		Platelet count decreased	n/a	154	100,0	5	3,2	1,4	7,4
		Platelet count increased	n/a	154	100,0	1	0,6	0,1	3,6
		Polymerase chain reaction positive	n/a	154	100,0	2	1,3	0,4	4,6
		SARS-CoV-2 test positive	n/a	154	100,0	1	0,6	0,1	3,6
		Serum ferritin decreased	n/a	154	100,0	1	0,6	0,1	3,6
		Serum ferritin increased	n/a	154	100,0	2	1,3	0,4	4,6
		Troponin I increased	n/a	154	100,0	1	0,6	0,1	3,6
		Weight decreased	n/a	154	100,0	2	1,3	0,4	4,6
		White blood cell count decreased	n/a	154	100,0	3	1,9	0,7	5,6
		White blood cells urine positive	n/a	154	100,0	1	0,6	0,1	3,6
	Metabolism and nutrition disorders	-Total	n/a	154	100,0	66	42,9	35,3	50,8
		Decreased appetite	n/a	154	100,0	5	3,2	1,4	7,4
		Dehydration	n/a	154	100,0	2	1,3	0,4	4,6
		Fluid retention	n/a	154	100,0	1	0,6	0,1	3,6
		Hypercalcaemia	n/a	154	100,0	3	1,9	0,7	5,6
		Hyperglycaemia	n/a	154	100,0	4	2,6	1,0	6,5
		Hyperkalaemia	n/a	154	100,0	2	1,3	0,4	4,6
		Hyperlactacidaemia	n/a	154	100,0	1	0,6	0,1	3,6
		Hypermagnesaemia	n/a	154	100,0	2	1,3	0,4	4,6
		Hyperphosphataemia	n/a	154	100,0	3	1,9	0,7	5,6

		Neck pain	n/a	154	100,0	3	1,9	0,7	5,6
		Osteoarthritis	n/a	154	100,0	1	0,6	0,1	3,6
		Pain in extremity	n/a	154	100,0	4	2,6	1,0	6,5
		Pain in jaw	n/a	154	100,0	3	1,9	0,7	5,6
		Spinal osteoarthritis	n/a	154	100,0	1	0,6	0,1	3,6
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	154	100,0	27	17,5	12,3	24,3
		Acute myeloid leukaemia	n/a	154	100,0	1	0,6	0,1	3,6
		Benign neoplasm of thyroid gland	n/a	154	100,0	1	0,6	0,1	3,6
		Melanoma recurrent	n/a	154	100,0	1	0,6	0,1	3,6
		Squamous cell carcinoma	n/a	154	100,0	1	0,6	0,1	3,6
		Transitional cell carcinoma	n/a	154	100,0	1	0,6	0,1	3,6
		Tumour associated fever	n/a	154	100,0	2	1,3	0,4	4,6
		Tumour flare	n/a	154	100,0	17	11,0	7,0	17,0
		Tumour pain	n/a	154	100,0	3	1,9	0,7	5,6
	Nervous system disorders	-Total	n/a	154	100,0	38	24,7	18,5	32,0
		Ageusia	n/a	154	100,0	1	0,6	0,1	3,6
		Cognitive disorder	n/a	154	100,0	1	0,6	0,1	3,6
		Dizziness	n/a	154	100,0	8	5,2	2,7	9,9
		Dysaesthesia	n/a	154	100,0	1	0,6	0,1	3,6
		Headache	n/a	154	100,0	15	9,7	6,0	15,4
		Hemiparaesthesia	n/a	154	100,0	1	0,6	0,1	3,6
		Myoclonus	n/a	154	100,0	1	0,6	0,1	3,6
		Neuropathy peripheral	n/a	154	100,0	3	1,9	0,7	5,6

		Paraesthesia	n/a	154	100,0	4	2,6	1,0	6,5
		Peripheral sensory neuropathy	n/a	154	100,0	2	1,3	0,4	4,6
		Presyncope	n/a	154	100,0	1	0,6	0,1	3,6
		Seizure	n/a	154	100,0	1	0,6	0,1	3,6
		Somnolence	n/a	154	100,0	2	1,3	0,4	4,6
		Transient ischaemic attack	n/a	154	100,0	1	0,6	0,1	3,6
		Tremor	n/a	154	100,0	2	1,3	0,4	4,6
	Psychiatric disorders	-Total	n/a	154	100,0	18	11,7	7,5	17,7
		Agitation	n/a	154	100,0	1	0,6	0,1	3,6
		Anxiety	n/a	154	100,0	6	3,9	1,8	8,2
		Confusional state	n/a	154	100,0	3	1,9	0,7	5,6
		Delirium	n/a	154	100,0	2	1,3	0,4	4,6
		Depression	n/a	154	100,0	1	0,6	0,1	3,6
		Disorientation	n/a	154	100,0	1	0,6	0,1	3,6
		Insomnia	n/a	154	100,0	3	1,9	0,7	5,6
		Mood altered	n/a	154	100,0	1	0,6	0,1	3,6
		Nervousness	n/a	154	100,0	1	0,6	0,1	3,6
	Renal and urinary disorders	-Total	n/a	154	100,0	9	5,8	3,1	10,7
		Acute kidney injury	n/a	154	100,0	2	1,3	0,4	4,6
		Cystitis noninfective	n/a	154	100,0	1	0,6	0,1	3,6
		Dysuria	n/a	154	100,0	2	1,3	0,4	4,6
		Hydronephrosis	n/a	154	100,0	1	0,6	0,1	3,6
		Nocturia	n/a	154	100,0	1	0,6	0,1	3,6

	Oliguria	n/a	154	100,0	2	1,3	0,4	4,6
	Pollakiuria	n/a	154	100,0	1	0,6	0,1	3,6
	Renal impairment	n/a	154	100,0	1	0,6	0,1	3,6
Reproductive system and breast disorders	-Total	n/a	154	100,0	5	3,2	1,4	7,4
	Benign prostatic hyperplasia	n/a	154	100,0	1	0,6	0,1	3,6
	Erectile dysfunction	n/a	154	100,0	1	0,6	0,1	3,6
	Orchitis noninfective	n/a	154	100,0	1	0,6	0,1	3,6
	Prostatitis	n/a	154	100,0	2	1,3	0,4	4,6
Respiratory, thoracic and mediastinal disorders	-Total	n/a	154	100,0	31	20,1	14,6	27,2
	Bronchopneumopathy	n/a	154	100,0	1	0,6	0,1	3,6
	Cough	n/a	154	100,0	7	4,5	2,2	9,1
	Cough variant asthma	n/a	154	100,0	1	0,6	0,1	3,6
	Dysphonia	n/a	154	100,0	2	1,3	0,4	4,6
	Dyspnoea	n/a	154	100,0	4	2,6	1,0	6,5
	Hiccups	n/a	154	100,0	1	0,6	0,1	3,6
	Hyperventilation	n/a	154	100,0	1	0,6	0,1	3,6
	Hypoxia	n/a	154	100,0	1	0,6	0,1	3,6
	Lung disorder	n/a	154	100,0	1	0,6	0,1	3,6
	Lung opacity	n/a	154	100,0	1	0,6	0,1	3,6
	Nasal congestion	n/a	154	100,0	1	0,6	0,1	3,6
	Oropharyngeal pain	n/a	154	100,0	2	1,3	0,4	4,6
	Orthopnoea	n/a	154	100,0	1	0,6	0,1	3,6
	Pleural effusion	n/a	154	100,0	4	2,6	1,0	6,5
	Pneumonitis	n/a	154	100,0	1	0,6	0,1	3,6

		Productive cough	n/a	154	100,0	2	1,3	0,4	4,6
		Pulmonary embolism	n/a	154	100,0	1	0,6	0,1	3,6
		Rales	n/a	154	100,0	1	0,6	0,1	3,6
		Rhinitis allergic	n/a	154	100,0	1	0,6	0,1	3,6
		Rhinorrhoea	n/a	154	100,0	2	1,3	0,4	4,6
		Sinus congestion	n/a	154	100,0	1	0,6	0,1	3,6
		Upper-airway cough syndrome	n/a	154	100,0	1	0,6	0,1	3,6
		Wheezing	n/a	154	100,0	1	0,6	0,1	3,6
	Skin and subcutaneous tissue disorders	-Total	n/a	154	100,0	37	24,0	18,0	31,4
		Actinic keratosis	n/a	154	100,0	1	0,6	0,1	3,6
		Dermatitis	n/a	154	100,0	1	0,6	0,1	3,6
		Dermatitis acneiform	n/a	154	100,0	1	0,6	0,1	3,6
		Dermatitis exfoliative	n/a	154	100,0	1	0,6	0,1	3,6
		Dry skin	n/a	154	100,0	1	0,6	0,1	3,6
		Eczema	n/a	154	100,0	2	1,3	0,4	4,6
		Erythema	n/a	154	100,0	8	5,2	2,7	9,9
		Hyperhidrosis	n/a	154	100,0	1	0,6	0,1	3,6
		Hyperkeratosis	n/a	154	100,0	1	0,6	0,1	3,6
		Night sweats	n/a	154	100,0	2	1,3	0,4	4,6
		Palmar erythema	n/a	154	100,0	1	0,6	0,1	3,6
		Pruritus	n/a	154	100,0	8	5,2	2,7	9,9
		Rash	n/a	154	100,0	9	5,8	3,1	10,7
		Rash erythematous	n/a	154	100,0	1	0,6	0,1	3,6
		Rash maculo-papular	n/a	154	100,0	4	2,6	1,0	6,5

		Rash pruritic	n/a	154	100,0	2	1,3	0,4	4,6
		Skin ulcer	n/a	154	100,0	2	1,3	0,4	4,6
		Urticaria	n/a	154	100,0	2	1,3	0,4	4,6
	Vascular disorders	-Total	n/a	154	100,0	15	9,7	6,0	15,4
		Embolism	n/a	154	100,0	1	0,6	0,1	3,6
		Hot flush	n/a	154	100,0	1	0,6	0,1	3,6
		Hypertension	n/a	154	100,0	3	1,9	0,7	5,6
		Hypotension	n/a	154	100,0	8	5,2	2,7	9,9
		Jugular vein thrombosis	n/a	154	100,0	1	0,6	0,1	3,6
		Phlebitis	n/a	154	100,0	2	1,3	0,4	4,6
		Phlebitis superficial	n/a	154	100,0	1	0,6	0,1	3,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_soc_OCT22_SE_D235_AEANY.xls

02MAR2023 15:58

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	60	39,0	31,6	46,8

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_AEGR3.xls
02MAR2023 15:34

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
Name	SOC	PT	Level	Patients		Patients with Event			
				n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	154	100,0	43	27,9	21,4	35,5
		Anaemia	n/a	154	100,0	12	7,8	4,5	13,1
		Anaemia of malignant disease	n/a	154	100,0	1	0,6	0,1	3,6
		Febrile neutropenia	n/a	154	100,0	2	1,3	0,4	4,6
		Hypofibrinogenaemia	n/a	154	100,0	1	0,6	0,1	3,6
		Lymphopenia	n/a	154	100,0	2	1,3	0,4	4,6
		Neutropenia	n/a	154	100,0	26	16,9	11,8	23,6
		Thrombocytopenia	n/a	154	100,0	8	5,2	2,7	9,9
	Cardiac disorders	-Total	n/a	154	100,0	2	1,3	0,4	4,6
		Cardiac failure	n/a	154	100,0	2	1,3	0,4	4,6
	Eye disorders	-Total	n/a	154	100,0	1	0,6	0,1	3,6
		Periorbital swelling	n/a	154	100,0	1	0,6	0,1	3,6
	Gastrointestinal disorders	-Total	n/a	154	100,0	3	1,9	0,7	5,6
		Ascites	n/a	154	100,0	1	0,6	0,1	3,6
		Gastric haemorrhage	n/a	154	100,0	1	0,6	0,1	3,6
		Gastrointestinal haemorrhage	n/a	154	100,0	1	0,6	0,1	3,6
	General disorders and administration site conditions	-Total	n/a	154	100,0	4	2,6	1,0	6,5
		Asthenia	n/a	154	100,0	1	0,6	0,1	3,6

		Fatigue	n/a	154	100,0	1	0,6	0,1	3,6
		General physical health deterioration	n/a	154	100,0	1	0,6	0,1	3,6
		Pain	n/a	154	100,0	1	0,6	0,1	3,6
		Swelling	n/a	154	100,0	1	0,6	0,1	3,6
	Immune system disorders	-Total	n/a	154	100,0	4	2,6	1,0	6,5
		Cytokine release syndrome by ASTCT grade	n/a	154	100,0	4	2,6	1,0	6,5
		Cytokine release syndrome by Lee grade	n/a	154	100,0	3	1,9	0,7	5,6
	Infections and infestations	-Total	n/a	154	100,0	13	8,4	5,0	13,9
		Abscess neck	n/a	154	100,0	1	0,6	0,1	3,6
		Appendicitis	n/a	154	100,0	1	0,6	0,1	3,6
		Biliary tract infection bacterial	n/a	154	100,0	1	0,6	0,1	3,6
		COVID-19	n/a	154	100,0	2	1,3	0,4	4,6
		COVID-19 pneumonia	n/a	154	100,0	2	1,3	0,4	4,6
		Clostridium difficile infection	n/a	154	100,0	1	0,6	0,1	3,6
		Gastroenteritis	n/a	154	100,0	1	0,6	0,1	3,6
		Influenza	n/a	154	100,0	1	0,6	0,1	3,6
		Neutropenic infection	n/a	154	100,0	1	0,6	0,1	3,6
		Peritonitis	n/a	154	100,0	1	0,6	0,1	3,6
		Pneumococcal infection	n/a	154	100,0	1	0,6	0,1	3,6
		Pneumonia	n/a	154	100,0	1	0,6	0,1	3,6
		Sepsis	n/a	154	100,0	1	0,6	0,1	3,6

	White blood cell count decreased	n/a	154	100,0	1	0,6	0,1	3,6
Metabolism and nutrition disorders	-Total	n/a	154	100,0	16	10,4	6,5	16,2
	Hypercalcaemia	n/a	154	100,0	3	1,9	0,7	5,6
	Hyperglycaemia	n/a	154	100,0	1	0,6	0,1	3,6
	Hypoalbuminaemia	n/a	154	100,0	1	0,6	0,1	3,6
	Hypokalaemia	n/a	154	100,0	2	1,3	0,4	4,6
	Hyponatraemia	n/a	154	100,0	1	0,6	0,1	3,6
	Hypophosphataemia	n/a	154	100,0	8	5,2	2,7	9,9
	Tumour lysis syndrome	n/a	154	100,0	2	1,3	0,4	4,6
Musculoskeletal and connective tissue disorders	-Total	n/a	154	100,0	4	2,6	1,0	6,5
	Back pain	n/a	154	100,0	2	1,3	0,4	4,6
	Pain in extremity	n/a	154	100,0	1	0,6	0,1	3,6
	Pain in jaw	n/a	154	100,0	1	0,6	0,1	3,6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	154	100,0	6	3,9	1,8	8,2
	Tumour flare	n/a	154	100,0	4	2,6	1,0	6,5
	Tumour pain	n/a	154	100,0	2	1,3	0,4	4,6
Nervous system disorders	-Total	n/a	154	100,0	1	0,6	0,1	3,6
	Somnolence	n/a	154	100,0	1	0,6	0,1	3,6
Psychiatric disorders	-Total	n/a	154	100,0	1	0,6	0,1	3,6
	Delirium	n/a	154	100,0	1	0,6	0,1	3,6
Renal and urinary disorders	-Total	n/a	154	100,0	2	1,3	0,4	4,6
	Acute kidney injury	n/a	154	100,0	1	0,6	0,1	3,6
	Oliguria	n/a	154	100,0	1	0,6	0,1	3,6
Respiratory, thoracic and mediastinal disorders	-Total	n/a	154	100,0	7	4,5	2,2	9,1

		Lung opacity	n/a	154	100,0	1	0,6	0,1	3,6
		Pleural effusion	n/a	154	100,0	4	2,6	1,0	6,5
		Pulmonary embolism	n/a	154	100,0	1	0,6	0,1	3,6
		Wheezing	n/a	154	100,0	1	0,6	0,1	3,6
	Skin and subcutaneous tissue disorders	-Total	n/a	154	100,0	2	1,3	0,4	4,6
		Rash	n/a	154	100,0	1	0,6	0,1	3,6
		Rash pruritic	n/a	154	100,0	1	0,6	0,1	3,6
	Vascular disorders	-Total	n/a	154	100,0	1	0,6	0,1	3,6
		Hypertension	n/a	154	100,0	1	0,6	0,1	3,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_soc_OCT22_SE_D235_AEGR3.xls

02MAR2023 15:59

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 4

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	30	19,5	14,0	26,4

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_AEGR4.xls
02MAR2023 15:34

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 4

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
				Patients		Patients with Event			
Name	SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	154	100,0	20	13,0	8,6	19,2
		Febrile neutropenia	n/a	154	100,0	2	1,3	0,4	4,6
		Lymphopenia	n/a	154	100,0	4	2,6	1,0	6,5
		Neutropenia	n/a	154	100,0	13	8,4	5,0	13,9
		Thrombocytopenia	n/a	154	100,0	2	1,3	0,4	4,6
	Gastrointestinal disorders	-Total	n/a	154	100,0	3	1,9	0,7	5,6
		Colitis	n/a	154	100,0	1	0,6	0,1	3,6
		Duodenal obstruction	n/a	154	100,0	1	0,6	0,1	3,6
		Gastrointestinal haemorrhage	n/a	154	100,0	1	0,6	0,1	3,6
		Large intestinal haemorrhage	n/a	154	100,0	1	0,6	0,1	3,6
	Immune system disorders	-Total	n/a	154	100,0	2	1,3	0,4	4,6
		Cytokine release syndrome by ASTCT grade	n/a	154	100,0	2	1,3	0,4	4,6
		Cytokine release syndrome by Lee grade	n/a	154	100,0	2	1,3	0,4	4,6
	Infections and infestations	-Total	n/a	154	100,0	7	4,5	2,2	9,1
		COVID-19	n/a	154	100,0	2	1,3	0,4	4,6
		Myelitis	n/a	154	100,0	1	0,6	0,1	3,6
		Pneumonia	n/a	154	100,0	1	0,6	0,1	3,6

		Sepsis	n/a	154	100,0	3	1,9	0,7	5,6
	Investigations	-Total	n/a	154	100,0	5	3,2	1,4	7,4
		Gamma-glutamyltransferase increased	n/a	154	100,0	1	0,6	0,1	3,6
		Neutrophil count decreased	n/a	154	100,0	2	1,3	0,4	4,6
		Platelet count decreased	n/a	154	100,0	1	0,6	0,1	3,6
		White blood cell count decreased	n/a	154	100,0	1	0,6	0,1	3,6
	Metabolism and nutrition disorders	-Total	n/a	154	100,0	1	0,6	0,1	3,6
		Hypophosphataemia	n/a	154	100,0	1	0,6	0,1	3,6
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	154	100,0	1	0,6	0,1	3,6
		Acute myeloid leukaemia	n/a	154	100,0	1	0,6	0,1	3,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_soc_OCT22_SE_D235_AEGR4.xls

02MAR2023 16:00

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade 5 (AEs leading to death)

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	9	5,8	3,1	10,7

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_AEGR5.xls
02MAR2023 15:35

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AEs Grade 5 (AEs leading to death)
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
				Patients		Patients with Event			
Name	SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	Infections and infestations	-Total	n/a	154	100,0	8	5,2	2,7	9,9
		COVID-19	n/a	154	100,0	3	1,9	0,7	5,6
		COVID-19 pneumonia	n/a	154	100,0	3	1,9	0,7	5,6
		Sepsis	n/a	154	100,0	2	1,3	0,4	4,6
	Psychiatric disorders	-Total	n/a	154	100,0	1	0,6	0,1	3,6
		Delirium	n/a	154	100,0	1	0,6	0,1	3,6

95% CI based on Wilson Scores.
 Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_soc_OCT22_SE_D235_AEGR5.xls
 02MAR2023 16:00

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AEs Grade >=3
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	99	64,3	56,5	71,4

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_AEGR345.xls
02MAR2023 15:35

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs Grade >=3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
Name	SOC	PT	Level	Patients		Patients with Event			
				n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	154	100,0	54	35,1	28,0	42,9
		Anaemia	n/a	154	100,0	12	7,8	4,5	13,1
		Anaemia of malignant disease	n/a	154	100,0	1	0,6	0,1	3,6
		Febrile neutropenia	n/a	154	100,0	4	2,6	1,0	6,5
		Hypofibrinogenaemia	n/a	154	100,0	1	0,6	0,1	3,6
		Lymphopenia	n/a	154	100,0	6	3,9	1,8	8,2
		Neutropenia	n/a	154	100,0	39	25,3	19,1	32,7
		Thrombocytopenia	n/a	154	100,0	10	6,5	3,6	11,5
	Cardiac disorders	-Total	n/a	154	100,0	2	1,3	0,4	4,6
		Cardiac failure	n/a	154	100,0	2	1,3	0,4	4,6
	Eye disorders	-Total	n/a	154	100,0	1	0,6	0,1	3,6
		Periorbital swelling	n/a	154	100,0	1	0,6	0,1	3,6
	Gastrointestinal disorders	-Total	n/a	154	100,0	5	3,2	1,4	7,4
		Ascites	n/a	154	100,0	1	0,6	0,1	3,6
		Colitis	n/a	154	100,0	1	0,6	0,1	3,6
		Duodenal obstruction	n/a	154	100,0	1	0,6	0,1	3,6
		Gastric haemorrhage	n/a	154	100,0	1	0,6	0,1	3,6
		Gastrointestinal haemorrhage	n/a	154	100,0	2	1,3	0,4	4,6

		Large intestinal haemorrhage	n/a	154	100,0	1	0,6	0,1	3,6
	General disorders and administration site conditions	-Total	n/a	154	100,0	4	2,6	1,0	6,5
		Asthenia	n/a	154	100,0	1	0,6	0,1	3,6
		Fatigue	n/a	154	100,0	1	0,6	0,1	3,6
		General physical health deterioration	n/a	154	100,0	1	0,6	0,1	3,6
		Pain	n/a	154	100,0	1	0,6	0,1	3,6
		Swelling	n/a	154	100,0	1	0,6	0,1	3,6
	Immune system disorders	-Total	n/a	154	100,0	6	3,9	1,8	8,2
		Cytokine release syndrome by ASTCT grade	n/a	154	100,0	6	3,9	1,8	8,2
		Cytokine release syndrome by Lee grade	n/a	154	100,0	5	3,2	1,4	7,4
	Infections and infestations	-Total	n/a	154	100,0	27	17,5	12,3	24,3
		Abscess neck	n/a	154	100,0	1	0,6	0,1	3,6
		Appendicitis	n/a	154	100,0	1	0,6	0,1	3,6
		Biliary tract infection bacterial	n/a	154	100,0	1	0,6	0,1	3,6
		COVID-19	n/a	154	100,0	7	4,5	2,2	9,1
		COVID-19 pneumonia	n/a	154	100,0	5	3,2	1,4	7,4
		Clostridium difficile infection	n/a	154	100,0	1	0,6	0,1	3,6
		Gastroenteritis	n/a	154	100,0	1	0,6	0,1	3,6
		Influenza	n/a	154	100,0	1	0,6	0,1	3,6
		Myelitis	n/a	154	100,0	1	0,6	0,1	3,6
		Neutropenic infection	n/a	154	100,0	1	0,6	0,1	3,6

		Delirium	n/a	154	100,0	2	1,3	0,4	4,6
	Renal and urinary disorders	-Total	n/a	154	100,0	2	1,3	0,4	4,6
		Acute kidney injury	n/a	154	100,0	1	0,6	0,1	3,6
		Oliguria	n/a	154	100,0	1	0,6	0,1	3,6
	Respiratory, thoracic and mediastinal disorders	-Total	n/a	154	100,0	7	4,5	2,2	9,1
		Lung opacity	n/a	154	100,0	1	0,6	0,1	3,6
		Pleural effusion	n/a	154	100,0	4	2,6	1,0	6,5
		Pulmonary embolism	n/a	154	100,0	1	0,6	0,1	3,6
		Wheezing	n/a	154	100,0	1	0,6	0,1	3,6
	Skin and subcutaneous tissue disorders	-Total	n/a	154	100,0	2	1,3	0,4	4,6
		Rash	n/a	154	100,0	1	0,6	0,1	3,6
		Rash pruritic	n/a	154	100,0	1	0,6	0,1	3,6
	Vascular disorders	-Total	n/a	154	100,0	1	0,6	0,1	3,6
		Hypertension	n/a	154	100,0	1	0,6	0,1	3,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_soc_OCT22_SE_D235_AEGR345.xls

02MAR2023 16:01

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: Any SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	75	48,7	40,9	56,5

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_AESAE.xls
02MAR2023 15:36

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: Any SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

				Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
Name	SOC	PT	Level	Patients		Patients with Event			
				n	%	n	%	95% CI (LL)	95% CI (UL)
All	Blood and lymphatic system disorders	-Total	n/a	154	100,0	10	6,5	3,6	11,5
		Anaemia	n/a	154	100,0	3	1,9	0,7	5,6
		Febrile neutropenia	n/a	154	100,0	3	1,9	0,7	5,6
		Lymphopenia	n/a	154	100,0	1	0,6	0,1	3,6
		Neutropenia	n/a	154	100,0	3	1,9	0,7	5,6
		Thrombocytopenia	n/a	154	100,0	1	0,6	0,1	3,6
	Cardiac disorders	-Total	n/a	154	100,0	2	1,3	0,4	4,6
		Cardiac failure	n/a	154	100,0	1	0,6	0,1	3,6
		Sinus node dysfunction	n/a	154	100,0	1	0,6	0,1	3,6
	Eye disorders	-Total	n/a	154	100,0	1	0,6	0,1	3,6
		Vision blurred	n/a	154	100,0	1	0,6	0,1	3,6
	Gastrointestinal disorders	-Total	n/a	154	100,0	7	4,5	2,2	9,1
		Colitis	n/a	154	100,0	1	0,6	0,1	3,6
		Constipation	n/a	154	100,0	1	0,6	0,1	3,6
		Duodenal obstruction	n/a	154	100,0	1	0,6	0,1	3,6
		Gastric haemorrhage	n/a	154	100,0	1	0,6	0,1	3,6
		Gastrointestinal haemorrhage	n/a	154	100,0	2	1,3	0,4	4,6

		Intestinal perforation	n/a	154	100,0	1	0,6	0,1	3,6
		Large intestinal haemorrhage	n/a	154	100,0	1	0,6	0,1	3,6
		Nausea	n/a	154	100,0	1	0,6	0,1	3,6
		Vomiting	n/a	154	100,0	1	0,6	0,1	3,6
	General disorders and administration site conditions	-Total	n/a	154	100,0	4	2,6	1,0	6,5
		Asthenia	n/a	154	100,0	1	0,6	0,1	3,6
		Gait disturbance	n/a	154	100,0	1	0,6	0,1	3,6
		General physical health deterioration	n/a	154	100,0	1	0,6	0,1	3,6
		Pyrexia	n/a	154	100,0	2	1,3	0,4	4,6
	Immune system disorders	-Total	n/a	154	100,0	34	22,1	16,3	29,3
		Cytokine release syndrome by ASTCT grade	n/a	154	100,0	16	10,4	6,5	16,2
		Cytokine release syndrome by Lee grade	n/a	154	100,0	34	22,1	16,3	29,3
	Infections and infestations	-Total	n/a	154	100,0	28	18,2	12,9	25,0
		Abscess	n/a	154	100,0	1	0,6	0,1	3,6
		Abscess neck	n/a	154	100,0	1	0,6	0,1	3,6
		Appendicitis	n/a	154	100,0	1	0,6	0,1	3,6
		Biliary tract infection bacterial	n/a	154	100,0	1	0,6	0,1	3,6
		COVID-19	n/a	154	100,0	5	3,2	1,4	7,4
		COVID-19 pneumonia	n/a	154	100,0	5	3,2	1,4	7,4
		Campylobacter infection	n/a	154	100,0	1	0,6	0,1	3,6
		Clostridium difficile colitis	n/a	154	100,0	1	0,6	0,1	3,6

		Infection	n/a	154	100,0	2	1,3	0,4	4,6
		Myelitis	n/a	154	100,0	1	0,6	0,1	3,6
		Neutropenic infection	n/a	154	100,0	1	0,6	0,1	3,6
		Peritonitis	n/a	154	100,0	1	0,6	0,1	3,6
		Pneumococcal infection	n/a	154	100,0	1	0,6	0,1	3,6
		Pneumonia	n/a	154	100,0	2	1,3	0,4	4,6
		Sepsis	n/a	154	100,0	6	3,9	1,8	8,2
		Urinary tract infection	n/a	154	100,0	1	0,6	0,1	3,6
		Vascular device infection	n/a	154	100,0	2	1,3	0,4	4,6
	Injury, poisoning and procedural complications	-Total	n/a	154	100,0	3	1,9	0,7	5,6
		Infusion related reaction	n/a	154	100,0	1	0,6	0,1	3,6
		Joint dislocation	n/a	154	100,0	1	0,6	0,1	3,6
		Toxicity to various agents	n/a	154	100,0	1	0,6	0,1	3,6
	Investigations	-Total	n/a	154	100,0	2	1,3	0,4	4,6
		C-reactive protein increased	n/a	154	100,0	1	0,6	0,1	3,6
		Weight decreased	n/a	154	100,0	1	0,6	0,1	3,6
	Musculoskeletal and connective tissue disorders	-Total	n/a	154	100,0	2	1,3	0,4	4,6
		Back pain	n/a	154	100,0	2	1,3	0,4	4,6
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	154	100,0	9	5,8	3,1	10,7
		Acute myeloid leukaemia	n/a	154	100,0	1	0,6	0,1	3,6
		Transitional cell carcinoma	n/a	154	100,0	1	0,6	0,1	3,6

		Tumour associated fever	n/a	154	100,0	1	0,6	0,1	3,6
		Tumour flare	n/a	154	100,0	5	3,2	1,4	7,4
		Tumour pain	n/a	154	100,0	1	0,6	0,1	3,6
	Nervous system disorders	-Total	n/a	154	100,0	2	1,3	0,4	4,6
		Dizziness	n/a	154	100,0	1	0,6	0,1	3,6
		Transient ischaemic attack	n/a	154	100,0	1	0,6	0,1	3,6
	Psychiatric disorders	-Total	n/a	154	100,0	2	1,3	0,4	4,6
		Delirium	n/a	154	100,0	2	1,3	0,4	4,6
	Renal and urinary disorders	-Total	n/a	154	100,0	2	1,3	0,4	4,6
		Acute kidney injury	n/a	154	100,0	2	1,3	0,4	4,6
	Respiratory, thoracic and mediastinal disorders	-Total	n/a	154	100,0	4	2,6	1,0	6,5
		Pleural effusion	n/a	154	100,0	3	1,9	0,7	5,6
		Pulmonary embolism	n/a	154	100,0	1	0,6	0,1	3,6

95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_soc_OCT22_SE_D235_AESAE.xls
02MAR2023 16:02

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs leading to treatment discontinuation

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	14	9,1	5,5	14,7

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_AEDISC.xls

02MAR2023 15:36

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AEs leading to treatment discontinuation

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

						Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
				Patients		Patients with Event					
Name	SOC	PT	Level	n	%	n	%	95% CI (LL)	95% CI (UL)		
All	Blood and lymphatic system disorders	-Total	n/a	154	100,0	2	1,3	0,4	4,6		
		Neutropenia	n/a	154	100,0	2	1,3	0,4	4,6		
	Gastrointestinal disorders	-Total	n/a	154	100,0	1	0,6	0,1	3,6		
		Gastrointestinal haemorrhage	n/a	154	100,0	1	0,6	0,1	3,6		
	Hepatobiliary disorders	-Total	n/a	154	100,0	1	0,6	0,1	3,6		
		Cholestasis	n/a	154	100,0	1	0,6	0,1	3,6		
		Hepatic cytolysis	n/a	154	100,0	1	0,6	0,1	3,6		
	Immune system disorders	-Total	n/a	154	100,0	1	0,6	0,1	3,6		
		Cytokine release syndrome by ASTCT grade	n/a	154	100,0	1	0,6	0,1	3,6		
		Cytokine release syndrome by Lee grade	n/a	154	100,0	1	0,6	0,1	3,6		
	Infections and infestations	-Total	n/a	154	100,0	6	3,9	1,8	8,2		
		Biliary tract infection bacterial	n/a	154	100,0	1	0,6	0,1	3,6		
		COVID-19	n/a	154	100,0	2	1,3	0,4	4,6		
		COVID-19 pneumonia	n/a	154	100,0	1	0,6	0,1	3,6		
		Myelitis	n/a	154	100,0	1	0,6	0,1	3,6		
		Sepsis	n/a	154	100,0	1	0,6	0,1	3,6		
	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-Total	n/a	154	100,0	1	0,6	0,1	3,6		

		Melanoma recurrent	n/a	154	100,0	1	0,6	0,1	3,6
	Psychiatric disorders	-Total	n/a	154	100,0	2	1,3	0,4	4,6
		Delirium	n/a	154	100,0	2	1,3	0,4	4,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw_soc.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_soc_OCT22_SE_D235_AEDISC.xls

02MAR2023 16:02

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: AST, ALT, or total bilirubin elevation - Grade \geq 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	11	7,1	4,0	12,3

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ABIL.xls

02MAR2023 15:47

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: AST, ALT, or total bilirubin elevation - Grade \geq 3
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	6	3,9	1,8	8,2

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ABIL345.xls
 02MAR2023 15:47

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: AST, ALT, or total bilirubin elevation - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ABILSAE.xls

02MAR2023 15:48

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Colitis

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	1	0,6	0,1	3,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ACOL.xls
02MAR2023 15:53

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Colitis - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	1	0,6	0,1	3,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ACOL345.xls

02MAR2023 15:54

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Colitis - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	1	0,6	0,1	3,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ACOLSAE.xls
02MAR2023 15:54

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by ASTCT grade - Grade \geq 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	25	16,2	11,2	22,9

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ACRS.xls

02MAR2023 15:37

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by ASTCT grade - Grade 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	19	12,3	8,0	18,5

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ACRS2.xls
02MAR2023 15:38

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by ASTCT grade - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	6	3,9	1,8	8,2

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ACRS345.xls
02MAR2023 15:38

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by ASTCT grade - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	16	10,4	6,5	16,2

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ACRSSAE.xls
02MAR2023 15:39

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by Lee grade - Grade \geq 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	29	18,8	13,4	25,7

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ACRSL.xls
02MAR2023 15:40

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Cytokine release syndrome by Lee grade - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	5	3,2	1,4	7,4

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ACRSL345.xls
02MAR2023 15:40

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
 ENDPOINT: AESI: Cytokine release syndrome by Lee grade - SAEs
 MODEL: --
 STUDY: NP30179
 Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	18	11,7	7,5	17,7

95% CI based on Wilson Scores.
 Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
 Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ACRSLSAE.xls
 02MAR2023 15:41

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Disseminated Intravascular Coagulation - Grade \geq 2
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ADIC.xls
02MAR2023 15:48

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Disseminated Intravascular Coagulation - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ADIC345.xls

02MAR2023 15:49

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Disseminated Intravascular Coagulation - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ADICSAE.xls

02MAR2023 15:49

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Febrile Neutropenia - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	4	2,6	1,0	6,5

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_AFEB.xls

02MAR2023 15:45

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Febrile Neutropenia - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	3	1,9	0,7	5,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_AFEBSAE.xls
02MAR2023 15:46

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Hemophagocytic lymphohistiocytosis

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_AHEMA.xls

02MAR2023 15:43

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Hemophagocytic lymphohistiocytosis - Grade \geq 3
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_AHEMA345.xls
02MAR2023 15:44

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Hemophagocytic lymphohistiocytosis - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_AHEMASAE.xls

02MAR2023 15:44

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Secondary malignancies

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	2	1,3	0,4	4,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_AMAL.xls

02MAR2023 15:55

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Secondary malignancies - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	1	0,6	0,1	3,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_AMAL345.xls
02MAR2023 15:55

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Secondary malignancies - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	1	0,6	0,1	3,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_AMALSAE.xls
02MAR2023 15:56

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Neurologic AEs - Grade \geq 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	23	14,9	10,2	21,4

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ANAE.xls

02MAR2023 15:42

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Neurologic AEs - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	4	2,6	1,0	6,5

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ANAE345.xls
02MAR2023 15:42

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Neurologic AEs - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	3	1,9	0,7	5,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ANAESAE.xls
02MAR2023 15:43

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Pneumonitis or interstitial lung disease

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	2	1,3	0,4	4,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_APILD.xls
02MAR2023 15:51

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Pneumonitis or interstitial lung disease - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	1	0,6	0,1	3,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_APILD345.xls

02MAR2023 15:52

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Pneumonitis or interstitial lung disease - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_APILDSAE.xls

02MAR2023 15:53

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Tumor flare - Grade \geq 2

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	11	7,1	4,0	12,3

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ATF.xls
02MAR2023 15:49

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Tumor flare - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	4	2,6	1,0	6,5

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ATF345.xls

02MAR2023 15:50

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Tumor flare - SAEs

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	4	2,6	1,0	6,5

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ATFSAE.xls
02MAR2023 15:51

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Tumor lysis syndrome - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	2	1,3	0,4	4,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ATLS.xls

02MAR2023 15:44

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Tumor lysis syndrome - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ATLSSAE.xls
02MAR2023 15:45

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Obinutuzumab: Tumor lysis syndrome

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	2	1,3	0,4	4,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ATLSO.xls
02MAR2023 15:57

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients

ENDPOINT: AESI: Obinutuzumab: Tumor lysis syndrome - Grade \geq 3

MODEL: --

STUDY: NP30179

Dichotomous analysis (safety)

		Glofitamab Cohorts D2 (Sub 2), D3, D5 (N=154)					
		Patients		Patients with Event			
Name	Level	n	%	n	%	95% CI (LL)	95% CI (UL)
All	n/a	154	100,0	2	1,3	0,4	4,6

95% CI based on Wilson Scores.

Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas

Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ATLS0345.xls

02MAR2023 15:57

POPULATION: Cohorts D2 (Sub 2), D3, D5 (R/R DLBCL Patients), Safety-Evaluable Patients
ENDPOINT: AESI: Obinutuzumab: Tumor lysis syndrome - SAEs
MODEL: --
STUDY: NP30179
Dichotomous analysis (safety)

Null Report: No observations met the reporting criteria for inclusion in this output.

95% CI based on Wilson Scores.
Clinical cut-off: 10OCT2022

Program: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_BASE/prod/program/saf_raw.sas
Output: root/clinical_studies/RO7082859/CDT70029/NP30179/data_analysis/ACE_Adhocs_Interim_10OCT2022/prod/output/saf_raw_OCT22_SE_D235_ATLSOSAE.xls
02MAR2023 15:58