Anhang 4-G: Ergänzende Daten zur Studie FIREFLY-1

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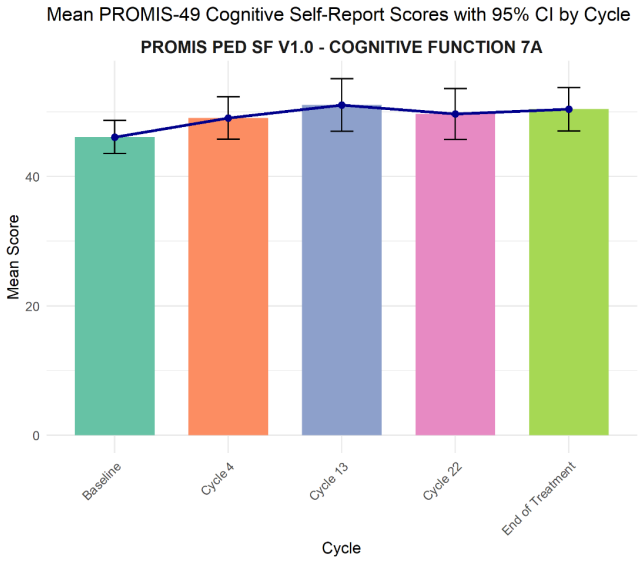
Figure 11. PROMIS Cognitive Function



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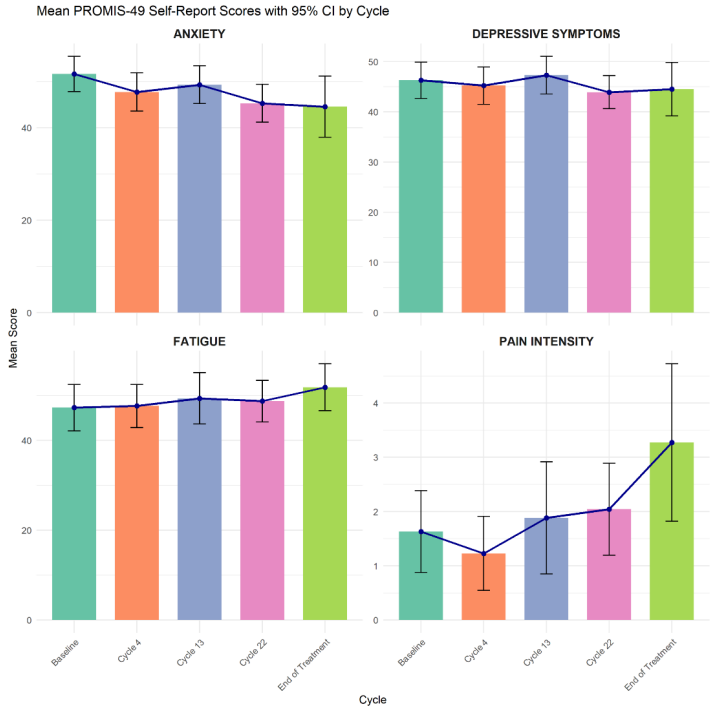
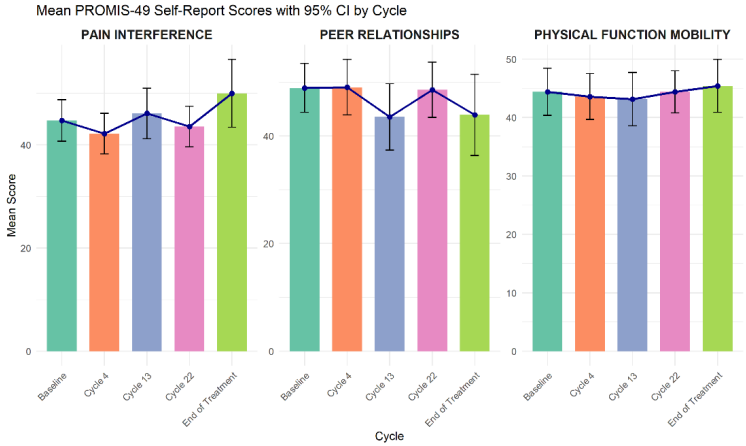


Figure 8. PROMIS-49 (2/2)



Anhang 4-G1.1.3: PROMIS-Parent-Proxy-49 Profile

Figure 9. PROMIS-49 Parent Proxy (1/2)

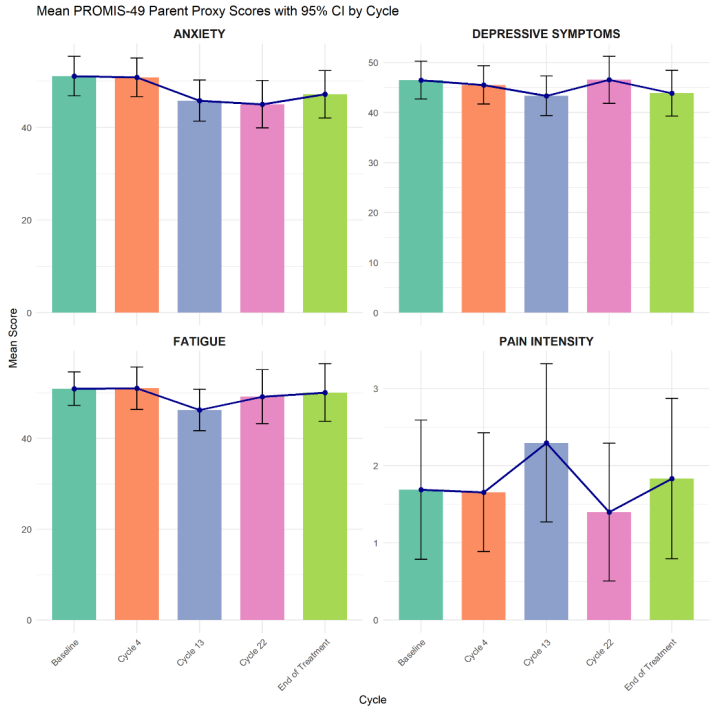
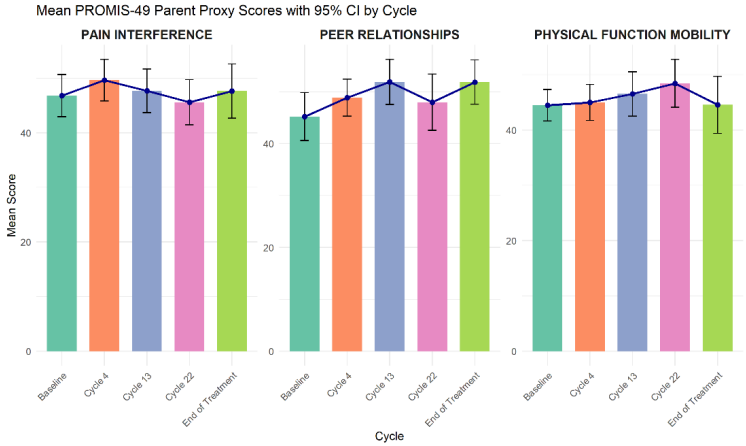
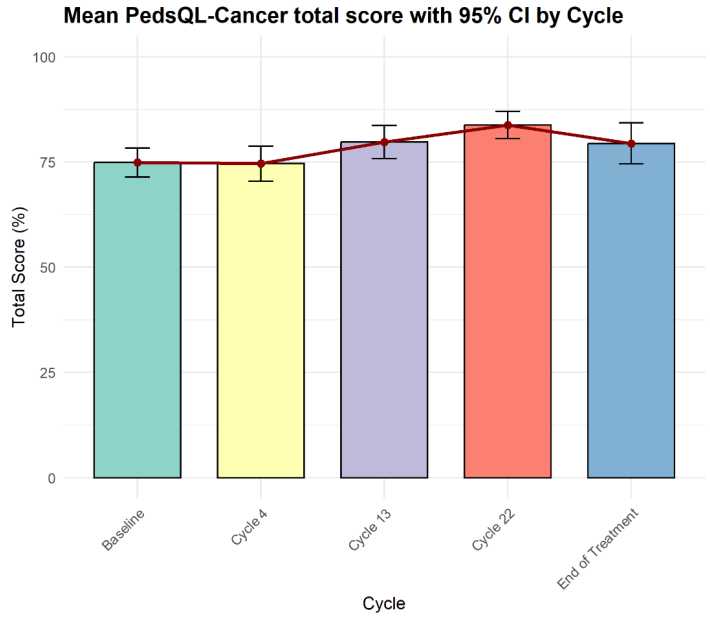


Figure 10. PROMIS-49 Parent Proxy (2/2)



Anhang 4-G1.1.4: PedsQL – Cancer Gesamtscore nach Behandlungsende

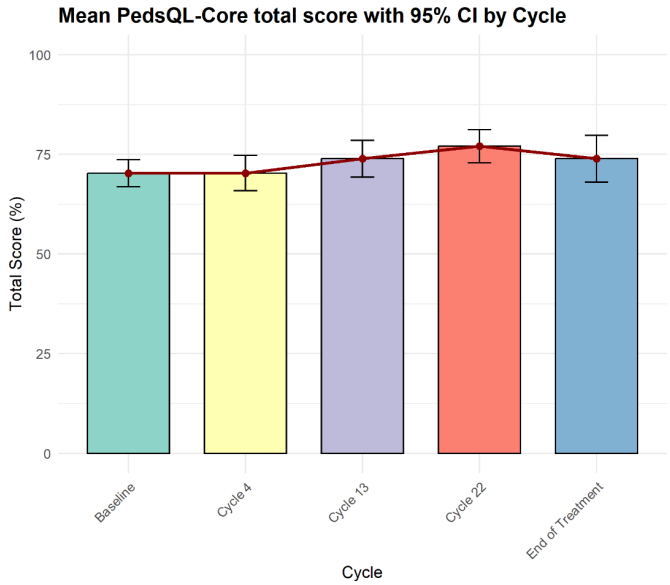
Figure 4. PedsQL - Cancer total score



Anhang 4-G1.2: Verlaufsgrafiken zu Gesundheitsbezogene Lebensqualität

Anhang 4-G1.2.1: PedsQL – Core Gesamtscore nach Behandlungsende

Figure 2. PedsQL - Core total score



Anhang 4-G2: 3-Jahres-Datenschnitt

Anhang 4-G2.1: Gesamtüberleben

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Table 14.2.5 Overall Survival
Full Analysis Set

	Arm 1 (Low-Grade Glioma) (N=69)
Number of patients, n (%)	
Death	3 (4.3)
Alive	66 (95.7)
Overall Survival (months)	
n	69
Mean (StD)	37.73 (9.147)
Median	40.38
Q1, Q3	37.75, 42.61
Min, Max	1.1, 49.0
KM Overall Survival (months) [1]	
25th Percentile (95% CI)	- (-, -)
Median (95% CI)	- (-, -)
75th Percentile (95% CI)	- (-, -)
Overall Survival rate (95% CI)[1]	
3 months	98.551 (90.155, 99.795)
6 months	98.551 (90.155, 99.795)
9 months	98.551 (90.155, 99.795)
12 months	98.551 (90.155, 99.795)
15 months	97.080 (88.823, 99.262)
18 months	97.080 (88.823, 99.262)
24 months	97.080 (88.823, 99.262)
36 months	95.514 (86.721, 98.532)

CI=Confidence Interval, KM=Kaplan-Meier.
[1] Estimated using Kaplan-Meier method.

Program: t0adtte0overall.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:01

Anhang 4-G2.2: Tumoransprechen

Anhang 4-G2.2.1: Gesamtansprechen und Klinische Nutzenrate

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Table 14.2.1.2.1 Overall Response Rate and Clinical Benefit Rate (RAPNO-LGG by IRC)
RAPNO-LGG Evaluable Analysis Set - Arm 1

	Arm 1 (Low-Grade Glioma) (N=76)
Best Overall Response, n (%)	
Complete Response (CR)	0
Partial Response (PR)	30 (39.5)
Minor Response (MR)	10 (13.2)
Stable Disease (SD)	22 (28.9)
Stable Disease >= 12 Months	4 (5.3)
Stable Disease < 12 Months	18 (23.7)
Progressive Disease (PD)	13 (17.1)
Not Evaluable (NE)	1 (1.3)
Number of Patients with Confirmed Response	40
Overall Response Rate (95% CI) [1]	52.632 (40.844, 64.208)
Number of Patients with Confirmed Response or SD >=12 Months	44
Clinical Benefit Rate (95% CI) [1]	57.895 (46.017, 69.138)

CI=Confidence Interval, IRC=Independent Radiology Review Committee, RAPNO=Response Assessment in Pediatric Neuro-Oncology.
[1] The exact 95% confidence intervals (CIs) are calculated using Clopper-Pearson method.

Program: t0bor0orr0rapno.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:04

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Table 14.2.1.5.1 Overall Response Rate and Clinical Benefit Rate (RANO-LGG by IRC)
RANO-LGG Evaluable Analysis Set - Arm 1

	Arm 1 (Low-Grade Glioma) (N=76)
Best Overall Response, n (%)	
Complete Response (CR)	0
Partial Response (PR)	24 (31.6)
Minor Response (MR)	17 (22.4)
Stable Disease (SD)	22 (28.9)
Stable Disease >= 12 Months	5 (6.6)
Stable Disease < 12 Months	17 (22.4)
Progressive Disease (PD)	12 (15.8)
Not Evaluable (NE)	1 (1.3)
Number of Patients with Confirmed Response	41
Overall Response Rate (95% CI) [1]	53.947 (42.125, 65.452)
Number of Patients with Confirmed Response or SD >=12 Months	46
Clinical Benefit Rate (95% CI) [1]	60.526 (48.650, 71.557)

CI=Confidence Interval, IRC=Independent Radiology Review Committee, RANO= Response Assessment in Neuro-Oncology.
[1] The exact 95% confidence intervals (CIs) are calculated using Clopper-Pearson method.

Program: t0bor0lgg.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:03

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Table 14.2.1.1.1 Overall Response Rate and Clinical Benefit Rate (RANO-HGG by IRC)
Full Analysis Set - Arm 1

	Arm 1 (Low-Grade Glioma) (N=69)
Best Overall Response, n (%)	
Complete Response (CR)	16 (23.2)
Partial Response (PR)	33 (47.8)
Stable Disease (SD)	15 (21.7)
Stable Disease >= 12 Months	4 (5.8)
Stable Disease < 12 Months	11 (15.9)
Progressive Disease (PD)	4 (5.8)
Not Evaluable (NE)	1 (1.4)
Number of Patients with Confirmed Response	49
Overall Response Rate (95% CI) [1]	71.014 (58.842, 81.313)
Number of Patients with Confirmed Response or SD >=12 Months	53
Clinical Benefit Rate (95% CI) [1]	76.812 (65.093, 86.126)

CI=Confidence Interval, IRC=Independent Radiology Review Committee, RANO=Response Assessment in Neuro-Oncology.
[1] The exact 95% confidence intervals (CIs) are calculated using Clopper-Pearson method.

Program: t0bor0orr.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:04

Anhang 4-G2.2.2: Zeit bis zum Ansprechen

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Table 14.2.4.2.1 Time to Response (RAPNO-LGG by IRC)
RAPNO-LGG Evaluable Analysis Set - Arm 1

	Arm 1 (Low-Grade Glioma) (N=76)
Number of Patients with Response	40
Time to Response (months)	
n	40
Mean (StD)	5.4324 (3.4081)
Median	5.3717
Q1, Q3	2.7598, 7.1129
Min, Max	1.6099, 17.5441

IRC=Independent Radiology Review Committee, RAPNO=Response Assessment in Pediatric Neuro-Oncology.

Program: t0ttr.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:14

Table 14.2.4.4.1 Time to Response (RANO-LGG by IRC)
RANO-LGG Evaluable Analysis Set - Arm 1

	Arm 1 (Low-Grade Glioma) (N=76)
Number of Patients with Response	41
Time to Response (months)	
n	41
Mean (StD)	5.7206 (3.1727)
Median	5.4867
Q1, Q3	2.7598, 8.1807
Min, Max	1.6099, 13.8973

IRC=Independent Radiology Review Committee, RANO=Response Assessment in Neuro Oncology.

Program: t0ttr0lgg.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:14

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Table 14.2.4.1.1 Time to Response (RANO-HGG by IRC)
Full Analysis Set - Arm 1

	Arm 1 (Low-Grade Glioma) (N=69)
Number of Patients with Response	49
Time to Response (months)	
n	49
Mean (StD)	5.7247 (4.5866)
Median	5.2895
Q1, Q3	2.7269, 5.5852
Min, Max	2.5626, 19.3840

IRC=Independent Radiology Review Committee, RANO=Response Assessment in Neuro Oncology.

Program: t0ttr.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:14

Anhang 4-G2.2.3: Dauer des Ansprechens

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Table 14.2.3.2.1 Duration of Response (RAPNO-LGG by IRC)
RAPNO-LGG Evaluable Analysis Set - Arm 1

	Arm 1 (Low-Grade Glioma) (N=76)
Number of Patients with Response	40
Number of Patients with the Event [1], n (%)	27 (67.5)
Progressive Disease (PD)	27 (67.5)
Death	0
Number of Patients Censored [1], n (%)	13 (32.5)
No Evaluable Post-baseline Efficacy Assessment	0
PD or Death after Missing Two Consecutive Visits	0
Subsequent Anti-cancer Therapy Prior to PD or Death	2 (5.0)
No PD or death at time of analysis	11 (27.5)
Estimated Time to PD or Death after Response (months) [2]	
25th Percentile (95% CI)	11.203 (8.312, 13.996)
Median (95% CI)	19.351 (13.832, 27.170)
75th Percentile (95% CI)	- (22.768, -)
Probability of Continued Response (95% CI) [2]	
3 months	100 (100, 100)
6 months	92.500 (78.522, 97.518)
9 months	87.500 (72.541, 94.597)
12 months	70.000 (53.262, 81.713)
18 months	55.000 (38.463, 68.793)
24 months	37.500 (22.882, 52.085)
36 months	29.847 (15.534, 45.609)

CI=Confidence Interval, IRC=Independent Radiology Review Committee, RAPNO=Response Assessment in Pediatric Neuro-Oncology.
[1] Percentages are based on number of patients with response.
[2] Estimated using Kaplan-Meier method.

Program: t0pfs.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:10

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Table 14.2.3.4.1 Duration of Response (RANO-LGG by IRC)
RANO-LGG Evaluable Analysis Set - Arm 1

	Arm 1 (Low-Grade Glioma) (N=76)
Number of Patients with Response	41
Number of Patients with the Event [1], n (%)	33 (80.5)
Progressive Disease (PD)	33 (80.5)
Death	0
Number of Patients Censored [1], n (%)	8 (19.5)
No Evaluable Post-baseline Efficacy Assessment	0
PD or Death after Missing Two Consecutive Visits	0
Subsequent Anti-cancer Therapy Prior to PD or Death	0
No PD or death at time of analysis	8 (19.5)
Estimated Time to PD or Death after Response (months) [2]	
25th Percentile (95% CI)	8.509 (5.717, 13.897)
Median (95% CI)	18.431 (11.959, 20.435)
75th Percentile (95% CI)	25.791 (19.351, -)
Probability of Continued Response (95% CI) [2]	
3 months	100 (100, 100)
6 months	85.366 (70.294, 93.144)
9 months	73.171 (56.812, 84.149)
12 months	65.763 (49.133, 78.100)
18 months	50.587 (34.409, 64.707)
24 months	25.294 (13.167, 39.377)
36 months	14.939 (5.142, 29.584)

CI=Confidence Interval, IRC=Independent Radiology Review Committee, RANO=Response Assessment in Neuro-Oncology.
[1] Percentages are based on number of patients with response.
[2] Estimated using Kaplan-Meier method.

Program: t0pfsgrp0lgg.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:11

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Table 14.2.3.1.1 Duration of Response (RANO-HGG by IRC)
Full Analysis Set - Arm 1

	Arm 1 (Low-Grade Glioma) (N=69)
Number of Patients with Response	49
Number of Patients with the Event [1], n (%)	32 (65.3)
Progressive Disease (PD)	32 (65.3)
Death	0
Number of Patients Censored [1], n (%)	17 (34.7)
No Evaluable Post-baseline Efficacy Assessment	0
PD or Death after Missing Two Consecutive Visits	0
Subsequent Anti-cancer Therapy Prior to PD or Death	2 (4.1)
No PD or death at time of analysis	15 (30.6)
Estimated Time to PD or Death after Response (months) [2]	
25th Percentile (95% CI)	10.875 (8.345, 13.766)
Median (95% CI)	21.421 (13.733, 29.470)
75th Percentile (95% CI)	- (27.828, -)
Probability of Continued Response (95% CI) [2]	
3 months	100 (100, 100)
6 months	95.918 (84.650, 98.963)
9 months	77.551 (63.141, 86.886)
12 months	65.306 (50.264, 76.803)
18 months	55.102 (40.221, 67.706)
24 months	42.343 (28.328, 55.682)
36 months	31.965 (18.917, 45.784)

CI=Confidence Interval, IRC=Independent Radiology Review Committee, RANO=Response Assessment in Neuro-Oncology.
[1] Percentages are based on number of patients with response.
[2] Estimated using Kaplan-Meier method.

Program: t0pfs.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:10

Anhang 4-G2.3: Progressionsfreies Überleben

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Table 14.2.2.2.1 Progression Free Survival (RAPNO-LGG by IRC)
RAPNO-LGG Evaluable Analysis Set - Arm 1

	Arm 1 (Low-Grade Glioma) (N=76)
Number of Patients with Event, n (%)	59 (77.6)
Progressive Disease (PD)	58 (76.3)
Death	1 (1.3)
Number of Patients Censored, n (%)	17 (22.4)
No Evaluable Post-baseline Efficacy Assessment	0
PD or Death after Missing Two Consecutive Visits	0
Subsequent Anti-cancer Therapy Prior to PD or Death	4 (5.3)
No PD or death at time of analysis	13 (17.1)
Estimated Time to PD or Death (months) [1]	
25th Percentile (95% CI)	5.552 (2.793, 8.279)
Median (95% CI)	16.559 (8.345, 19.121)
75th Percentile (95% CI)	26.710 (22.045, -)
Progression Free Survival Rate (95% CI) [1]	
3 months	81.156 (70.260, 88.381)
6 months	71.569 (59.792, 80.447)
9 months	60.559 (48.435, 70.680)
12 months	59.182 (47.059, 69.417)
18 months	39.914 (28.708, 50.868)
24 months	31.656 (21.387, 42.408)
36 months	20.473 (12.086, 30.408)

CI=Confidence Interval, IRC=Independent Radiology Review Committee, RAPNO=Response Assessment in Pediatric Neuro-Oncology.
[1] Estimated using Kaplan-Meier method.

Program: t0pfs.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:10

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Table 14.2.2.5 Progression Free Survival (RANO-LGG by IRC)
RANO-LGG Evaluable Analysis Set - Arm 1

	Arm 1 (Low-Grade Glioma) (N=76)
Number of Patients with Event, n (%)	65 (85.5)
Progressive Disease (PD)	64 (84.2)
Death	1 (1.3)
Number of Patients Censored, n (%)	11 (14.5)
No Evaluable Post-baseline Efficacy Assessment	0
PD or Death after Missing Two Consecutive Visits	0
Subsequent Anti-cancer Therapy Prior to PD or Death	1 (1.3)
No PD or death at time of analysis	10 (13.2)
Estimated Time to PD or Death (months) [1]	
25th Percentile (95% CI)	6.472 (2.793, 11.006)
Median (95% CI)	13.996 (11.072, 19.055)
75th Percentile (95% CI)	24.871 (19.450, 34.037)
Progression Free Survival Rate (95% CI) [1]	
3 months	83.861 (73.328, 90.496)
6 months	75.746 (64.297, 83.969)
9 months	68.983 (57.110, 78.183)
12 months	59.514 (47.457, 69.675)
18 months	40.206 (28.989, 51.147)
24 months	29.115 (19.204, 39.742)
36 months	12.478 (6.139, 21.177)

CI=Confidence Interval, IRC=Independent Radiology Review Committee.
[1] Estimated using Kaplan-Meier method.

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Table 14.2.2.1.1 Progression Free Survival (RANO-HGG by IRC)
Full Analysis Set - Arm 1

	Arm 1 (Low-Grade Glioma) (N=69)
Number of Patients with Event, n (%)	48 (69.6)
Progressive Disease (PD)	47 (68.1)
Death	1 (1.4)
Number of Patients Censored, n (%)	21 (30.4)
No Evaluable Post-baseline Efficacy Assessment	0
PD or Death after Missing Two Consecutive Visits	0
Subsequent Anti-cancer Therapy Prior to PD or Death	5 (7.2)
No PD or death at time of analysis	16 (23.2)
Estimated Time to PD or Death (months) [1]	
25th Percentile (95% CI)	13.602 (7.392, 14.522)
Median (95% CI)	22.341 (16.526, 26.710)
75th Percentile (95% CI)	- (27.630, -)
Progression Free Survival Rate (95% CI) [1]	
3 months	94.159 (85.180, 97.767)
6 months	86.708 (76.006, 92.854)
9 months	82.223 (70.815, 89.492)
12 months	77.738 (65.809, 85.937)
18 months	55.235 (42.576, 66.191)
24 months	47.563 (35.207, 58.921)
36 months	26.538 (16.378, 37.805)

CI=Confidence Interval, IRC=Independent Radiology Review Committee, RANO=Response Assessment in Neuro-Oncology.
[1] Estimated using Kaplan-Meier method.

Program: t0pfs.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:10

Anhang 4-G2.4: Langfristige Tumorkontrolle nach Behandlungsende

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Table 14.2.8.1.1 Best Overall Response for Patients Off Treatment due to non-PD reasons/Drug Holiday
Off Treatment (due to non-PD reasons)/Drug Holiday Population Set - Arm 1

	RANO-HGG by IRC (N=57)	RANO-HGG by Investigator (N=57)	RAPNO-LGG by IRC (N=63)	RANO-LGG by IRC (N=63)
Best Overall Response, n (%) [1]				
Complete Response (CR)	15 (26.3)	6 (10.5)	0	0
Partial Response (PR)	29 (50.9)	26 (45.6)	27 (42.9)	22 (34.9)
Minor Response (MR)	NA	NA	8 (12.7)	15 (23.8)
Stable Disease (SD)	10 (17.5)	21 (36.8)	17 (27.0)	16 (25.4)
Progressive Disease (PD)	2 (3.5)	3 (5.3)	10 (15.9)	9 (14.3)
Not Evaluable (NE)	1 (1.8)	1 (1.8)	1 (1.6)	1 (1.6)
Number of patients with response and had drug holiday, n (%) [2]	32/34 (94.1)	26/34 (76.5)	27/39 (69.2)	28/39 (71.8)
95% CI [3]	80.323, 99.280	58.829, 89.254	52.431, 82.980	55.126, 84.999

CI=Confidence Interval, IRC=Independent Radiology Review Committee, NA=Not Applicable, RANO=Response Assessment in Neuro-Oncology, RAPNO= Response Assessment in Pediatric Neuro-Oncology.
[1] Percentages are based on patients within each response category.
[2] Percentages are calculated based on patients on drug holiday.
[3] The exact 95% confidence interval (CI) is calculated using Clopper-Pearson method.

Program: t0bor0offdh.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:04

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Table 14.2.8.3 Time from Last Dose to Subsequent Anticancer Therapy
Off Treatment (due to non-PD reasons)/Drug Holiday Population Set - Arm 1 and Arm 2

Arm 1

	Drug Holiday	No-PD Off treatment/Prolonged Dose Hold	Total
Number of Patients Included	39	24	63
Number of Patients with event, n (%)	8 (20.5)	12 (50.0)	20 (31.7)
Received Subsequent Anticancer Therapy After Last Dose	8 (20.5)	9 (37.5)	17 (27.0)
Tovorafenib retreatment	8 (20.5)	0	8 (12.7)
Others	0	9 (37.5)	9 (14.3)
Death	0	3 (12.5)	3 (4.8)
Number of patients censored, n (%)	31 (79.5)	12 (50.0)	43 (68.3)
Follow-up Time From last dose to Subsequent Anticancer Therapy(mo)[1]			
n	39	24	63
Mean	14.69	11.90	13.63
Median (min, max)	16.00 (1.4, 24.5)	5.65 (0.1, 41.0)	15.10 (0.1, 41.0)
>= 3mo	37 (94.9)	12 (50.0)	49 (77.8)
>= 6mo	33 (84.6)	12 (50.0)	45 (71.4)
>= 9mo	31 (79.5)	12 (50.0)	43 (68.3)
>= 12mo	30 (76.9)	10 (41.7)	40 (63.5)
>= 18mo	12 (30.8)	7 (29.2)	19 (30.2)
>= 24mo	1 (2.6)	6 (25.0)	7 (11.1)

[1] Time From last dose to Subsequent Anticancer Therapy is defined as the time from the last dose of primary treatment to one day prior to subsequent anti-cancer therapy/tovorafenib retreatment.
For patients without subsequent anti-cancer therapy/tovorafenib retreatment, Follow-up Time From last dose to Subsequent Anticancer Therapy is defined as the time from the last dose of primary treatment to clinical cut off or end of study day, whichever comes first.
[2] Only includes patients with subsequent anticancer therapy.
[3] Estimated using Kaplan-Meier method.

Program: t0tte0ant0off.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:14

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Table 14.2.8.3 Time from Last Dose to Subsequent Anticancer Therapy
Off Treatment (due to non-PD reasons)/Drug Holiday Population Set - Arm 1 and Arm 2

Arm 1

	Drug Holiday	No-PD Off treatment/Prolonged Dose Hold	Total
Time From last dose to Subsequent Anticancer Therapy(mo)[2]			
n	9	11	20
Mean	6.04	8.53	7.41
Median (min, max)	5.60 (1.4, 12.0)	1.40 (0.4, 41.0)	3.40 (0.4, 41.0)
Kaplan-Meier Estimated TFST (months) [3]			
25th Percentile (95% CI)	- (3.483, -)	1.216 (0.066, 9.528)	9.002 (1.446, -)
Median (95% CI)	-	19.844 (1.216, -)	40.969 (19.844, -)
75th Percentile (95% CI)	-	40.969 (19.844, -)	40.969 (-, -)
Probability of Alive and No Subsequent Anti-Cancer Therapy Since Last Dose (95% CI) [3]			
3 months	94.872 (81.016, 98.692)	58.235 (34.874, 75.767)	81.850 (69.613, 89.517)
6 months	87.024 (71.573, 94.388)	58.235 (34.874, 75.767)	76.765 (63.920, 85.536)
9 months	87.024 (71.573, 94.388)	58.235 (34.874, 75.767)	76.765 (63.920, 85.536)
12 months	77.979 (60.567, 88.392)	53.382 (30.571, 71.716)	69.238 (55.585, 79.443)
15 months	77.979 (60.567, 88.392)	53.382 (30.571, 71.716)	69.238 (55.585, 79.443)
18 months	77.979 (60.567, 88.392)	53.382 (30.571, 71.716)	69.238 (55.585, 79.443)
21 months	77.979 (60.567, 88.392)	45.756 (22.691, 66.223)	64.292 (47.920, 76.701)
24 months	-	45.756 (22.691, 66.223)	64.292 (47.920, 76.701)

[1] Time From last dose to Subsequent Anticancer Therapy is defined as the time from the last dose of primary treatment to one day prior to subsequent anti-cancer therapy/tovorafenib retreatment.
For patients without subsequent anti-cancer therapy/tovorafenib retreatment, Follow-up Time From last dose to Subsequent Anticancer Therapy is defined as the time from the last dose of primary treatment to clinical cut off or end of study day, whichever comes first.
[2] Only includes patients with subsequent anticancer therapy.
[3] Estimated using Kaplan-Meier method.

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Table 14.2.8.3 Time from Last Dose to Subsequent Anticancer Therapy
Off Treatment (due to non-PD reasons)/Drug Holiday Population Set - Arm 1 and Arm 2

Arm 2

	Drug Holiday	No-PD Off treatment/Prolonged Dose Hold	Total
Number of Patients Included	31	16	47
Number of Patients with event, n (%)	7 (22.6)	10 (62.5)	17 (36.2)
Received Subsequent Anticancer Therapy After Last Dose	6 (19.4)	9 (56.3)	15 (31.9)
Tovorafenib retreatment	5 (16.1)	0	5 (10.6)
Others	1 (3.2)	9 (56.3)	10 (21.3)
Death	1 (3.2)	1 (6.3)	2 (4.3)
Number of patients censored, n (%)	24 (77.4)	6 (37.5)	30 (63.8)
Follow-up Time From last dose to Subsequent Anticancer Therapy(mo)[1]			
n	31	16	47
Mean	8.94	5.27	7.69
Median (min, max)	8.40 (0.6, 21.4)	1.95 (0.2, 21.0)	7.20 (0.2, 21.4)
>= 3mo	27 (87.1)	6 (37.5)	33 (70.2)
>= 6mo	26 (83.9)	5 (31.3)	31 (66.0)
>= 9mo	14 (45.2)	4 (25.0)	18 (38.3)
>= 12mo	7 (22.6)	2 (12.5)	9 (19.1)
>= 18mo	2 (6.5)	1 (6.3)	3 (6.4)
>= 24mo	0	0	0

[1] Time From last dose to Subsequent Anticancer Therapy is defined as the time from the last dose of primary treatment to one day prior to subsequent anti-cancer therapy/tovorafenib retreatment.
For patients without subsequent anti-cancer therapy/tovorafenib retreatment, Follow-up Time From last dose to Subsequent Anticancer Therapy is defined as the time from the last dose of primary treatment to clinical cut off or end of study day, whichever comes first.
[2] Only includes patients with subsequent anticancer therapy.
[3] Estimated using Kaplan-Meier method.

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Table 14.2.8.3 Time from Last Dose to Subsequent Anticancer Therapy
Off Treatment (due to non-PD reasons)/Drug Holiday Population Set - Arm 1 and Arm 2

Arm 2

	Drug Holiday	No-PD Off treatment/Prolonged Dose Hold	Total
Time From last dose to Subsequent Anticancer Therapy(mo)[2]			
n	6	9	15
Mean	5.72	1.88	3.41
Median (min, max)	6.40 (1.6, 9.0)	1.10 (0.3, 6.7)	2.30 (0.3, 9.0)
Kaplan-Meier Estimated TFST (months) [3]			
25th Percentile (95% CI)	9.002 (5.618, -)	0.871 (0.197, 2.333)	5.618 (1.084, 9.002)
Median (95% CI)	- (9.002, -)	2.333 (0.854, -)	- (7.195, -)
75th Percentile (95% CI)	-	- (2.333, -)	-
Probability of Alive and No Subsequent Anti-Cancer Therapy Since Last Dose (95% CI) [3]			
3 months	93.103 (75.141, 98.229)	41.667 (17.673, 64.260)	75.416 (59.984, 85.576)
6 months	89.379 (70.539, 96.452)	41.667 (17.673, 64.260)	72.902 (57.168, 83.640)
9 months	78.113 (53.863, 90.609)	33.333 (11.565, 57.150)	62.592 (44.980, 75.976)
12 months	57.861 (26.670, 79.733)	33.333 (11.565, 57.150)	50.555 (29.625, 68.219)
15 months	57.861 (26.670, 79.733)	33.333 (11.565, 57.150)	50.555 (29.625, 68.219)
18 months	57.861 (26.670, 79.733)	33.333 (11.565, 57.150)	50.555 (29.625, 68.219)
21 months	-	-	-
24 months	-	-	-

[1] Time From last dose to Subsequent Anticancer Therapy is defined as the time from the last dose of primary treatment to one day prior to subsequent anti-cancer therapy/tovorafenib retreatment.
For patients without subsequent anti-cancer therapy/tovorafenib retreatment, Follow-up Time From last dose to Subsequent Anticancer Therapy is defined as the time from the last dose of primary treatment to clinical cut off or end of study day, whichever comes first.
[2] Only includes patients with subsequent anticancer therapy.
[3] Estimated using Kaplan-Meier method.

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Table 14.2.8.3 Time from Last Dose to Subsequent Anticancer Therapy
Off Treatment (due to non-PD reasons)/Drug Holiday Population Set - Arm 1 and Arm 2

Total

	Drug Holiday	No-PD Off treatment/Prolonged Dose Hold	Total
Number of Patients Included	70	40	110
Number of Patients with event, n (%)	15 (21.4)	22 (55.0)	37 (33.6)
Received Subsequent Anticancer Therapy After Last Dose	14 (20.0)	18 (45.0)	32 (29.1)
Tovorafenib retreatment	13 (18.6)	0	13 (11.8)
Others	1 (1.4)	18 (45.0)	19 (17.3)
Death	1 (1.4)	4 (10.0)	5 (4.5)
Number of patients censored, n (%)	55 (78.6)	18 (45.0)	73 (66.4)
Follow-up Time From last dose to Subsequent Anticancer Therapy(mo)[1]			
n	70	40	110
Mean	12.14	9.25	11.09
Median (min, max)	12.05 (0.6, 24.5)	2.05 (0.1, 41.0)	10.20 (0.1, 41.0)
>= 3mo	64 (91.4)	18 (45.0)	82 (74.5)
>= 6mo	59 (84.3)	17 (42.5)	76 (69.1)
>= 9mo	45 (64.3)	16 (40.0)	61 (55.5)
>= 12mo	37 (52.9)	12 (30.0)	49 (44.5)
>= 18mo	14 (20.0)	8 (20.0)	22 (20.0)
>= 24mo	1 (1.4)	6 (15.0)	7 (6.4)

[1] Time From last dose to Subsequent Anticancer Therapy is defined as the time from the last dose of primary treatment to one day prior to subsequent anti-cancer therapy/tovorafenib retreatment.
For patients without subsequent anti-cancer therapy/tovorafenib retreatment, Follow-up Time From last dose to Subsequent Anticancer Therapy is defined as the time from the last dose of primary treatment to clinical cut off or end of study day, whichever comes first.
[2] Only includes patients with subsequent anticancer therapy.
[3] Estimated using Kaplan-Meier method.

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Table 14.2.8.3 Time from Last Dose to Subsequent Anticancer Therapy
Off Treatment (due to non-PD reasons)/Drug Holiday Population Set - Arm 1 and Arm 2

Total

	Drug Holiday	No-PD Off treatment/Prolonged Dose Hold	Total
Time From last dose to Subsequent Anticancer Therapy(mo)[2]			
n	15	20	35
Mean	5.91	5.54	5.70
Median (min, max)	5.60 (1.4, 12.0)	1.30 (0.3, 41.0)	2.60 (0.3, 41.0)
Kaplan-Meier Estimated TFST (months) [3]			
25th Percentile (95% CI)	11.992 (8.049, -)	1.084 (0.493, 1.610)	6.702 (1.643, 10.743)
Median (95% CI)	-	6.702 (1.380, -)	40.969 (19.844, -)
75th Percentile (95% CI)	-	40.969 (19.844, -)	40.969 (-, -)
Probability of Alive and No Subsequent Anti-Cancer Therapy Since Last Dose (95% CI) [3]			
3 months	94.118 (85.082, 97.751)	51.433 (34.315, 66.145)	79.134 (70.049, 85.740)
6 months	88.032 (77.474, 93.833)	51.433 (34.315, 66.145)	75.145 (65.662, 82.357)
9 months	84.320 (72.686, 91.285)	48.407 (31.488, 63.412)	71.673 (61.783, 79.426)
12 months	72.687 (58.139, 82.890)	45.382 (28.735, 60.621)	63.285 (52.354, 72.364)
15 months	72.687 (58.139, 82.890)	45.382 (28.735, 60.621)	63.285 (52.354, 72.364)
18 months	72.687 (58.139, 82.890)	45.382 (28.735, 60.621)	63.285 (52.354, 72.364)
21 months	72.687 (58.139, 82.890)	38.899 (21.133, 56.351)	59.066 (45.736, 70.162)
24 months	-	38.899 (21.133, 56.351)	59.066 (45.736, 70.162)

[1] Time From last dose to Subsequent Anticancer Therapy is defined as the time from the last dose of primary treatment to one day prior to subsequent anti-cancer therapy/tovorafenib retreatment.
For patients without subsequent anti-cancer therapy/tovorafenib retreatment, Follow-up Time From last dose to Subsequent Anticancer Therapy is defined as the time from the last dose of primary treatment to clinical cut off or end of study day, whichever comes first.
[2] Only includes patients with subsequent anticancer therapy.
[3] Estimated using Kaplan-Meier method.

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Table 14.3.7 Visual Acuity Outcomes by Visit
Safety Analysis Set - Arm 1 and Arm 2

Visit	Category [1]	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
	Patients with both baseline value and at least one post-baseline assessment	51	54	105
Cycle 3	LogMAR Change from baseline			
	Decline >= 0.2 logMAR	5 (9.8)	9 (16.7)	14 (13.3)
	Increase >= 0.2 logMAR	4 (7.8)	5 (9.3)	9 (8.6)
	Investigator Assessment of Visual Acuity			
	Improved	2 (3.9)	3 (5.6)	5 (4.8)
	Stable	37 (72.5)	33 (61.1)	70 (66.7)
	Visual Progressive Disease	1 (2.0)	0	1 (1.0)
	Unknown/Not Evaluable	5 (9.8)	2 (3.7)	7 (6.7)
	Not Applicable	4 (7.8)	11 (20.4)	15 (14.3)
	Not Done	2 (3.9)	2 (3.7)	4 (3.8)
Cycle 6	LogMAR Change from baseline			
	Decline >= 0.2 logMAR	13 (25.5)	10 (18.5)	23 (21.9)
	Increase >= 0.2 logMAR	7 (13.7)	3 (5.6)	10 (9.5)
	Investigator Assessment of Visual Acuity			
	Improved	8 (15.7)	6 (11.1)	14 (13.3)
	Stable	28 (54.9)	28 (51.9)	56 (53.3)
	Visual Progressive Disease	0	0	0
	Unknown/Not Evaluable	6 (11.8)	1 (1.9)	7 (6.7)
	Not Applicable	4 (7.8)	11 (20.4)	15 (14.3)
	Not Done	4 (7.8)	4 (7.4)	8 (7.6)

Baseline is defined as the last available assessments prior to start of Tovorafenib on Cycle 1 Day 1.
Percentages are based on number of patients with both baseline value and at least one post-baseline assessment.
[1] Patient is counted in 'decline and/or increase >= 0.2 logMAR' if at least one side of eye meets the criteria.

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Table 14.3.7 Visual Acuity Outcomes by Visit
Safety Analysis Set - Arm 1 and Arm 2

Visit	Category [1]	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Cycle 9	LogMAR Change from baseline			
	Decline >= 0.2 logMAR	14 (27.5)	8 (14.8)	22 (21.0)
	Increase >= 0.2 logMAR	4 (7.8)	3 (5.6)	7 (6.7)
	Investigator Assessment of Visual Acuity			
	Improved	5 (9.8)	4 (7.4)	9 (8.6)
	Stable	29 (56.9)	29 (53.7)	58 (55.2)
	Visual Progressive Disease	1 (2.0)	1 (1.9)	2 (1.9)
	Unknown/Not Evaluable	6 (11.8)	1 (1.9)	7 (6.7)
	Not Applicable	3 (5.9)	10 (18.5)	13 (12.4)
	Not Done	2 (3.9)	2 (3.7)	4 (3.8)
Cycle 12	LogMAR Change from baseline			
	Decline >= 0.2 logMAR	13 (25.5)	9 (16.7)	22 (21.0)
	Increase >= 0.2 logMAR	5 (9.8)	2 (3.7)	7 (6.7)
	Investigator Assessment of Visual Acuity			
	Improved	2 (3.9)	5 (9.3)	7 (6.7)
	Stable	33 (64.7)	24 (44.4)	57 (54.3)
	Visual Progressive Disease	2 (3.9)	1 (1.9)	3 (2.9)
	Unknown/Not Evaluable	4 (7.8)	1 (1.9)	5 (4.8)
	Not Applicable	3 (5.9)	10 (18.5)	13 (12.4)
	Not Done	1 (2.0)	6 (11.1)	7 (6.7)

Baseline is defined as the last available assessments prior to start of Tovorafenib on Cycle 1 Day 1.
Percentages are based on number of patients with both baseline value and at least one post-baseline assessment.
[1] Patient is counted in 'decline and/or increase >= 0.2 logMAR' if at least one side of eye meets the criteria.

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Table 14.3.7 Visual Acuity Outcomes by Visit
Safety Analysis Set - Arm 1 and Arm 2

Visit	Category [1]	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Cycle 15	LogMAR Change from baseline			
	Decline >= 0.2 logMAR	13 (25.5)	13 (24.1)	26 (24.8)
	Increase >= 0.2 logMAR	1 (2.0)	3 (5.6)	4 (3.8)
	Investigator Assessment of Visual Acuity			
	Improved	3 (5.9)	9 (16.7)	12 (11.4)
	Stable	25 (49.0)	19 (35.2)	44 (41.9)
	Visual Progressive Disease	1 (2.0)	3 (5.6)	4 (3.8)
	Unknown/Not Evaluable	5 (9.8)	1 (1.9)	6 (5.7)
	Not Applicable	3 (5.9)	10 (18.5)	13 (12.4)
	Not Done	4 (7.8)	3 (5.6)	7 (6.7)
Cycle 18	LogMAR Change from baseline			
	Decline >= 0.2 logMAR	14 (27.5)	12 (22.2)	26 (24.8)
	Increase >= 0.2 logMAR	1 (2.0)	2 (3.7)	3 (2.9)
	Investigator Assessment of Visual Acuity			
	Improved	2 (3.9)	6 (11.1)	8 (7.6)
	Stable	26 (51.0)	20 (37.0)	46 (43.8)
	Visual Progressive Disease	0	2 (3.7)	2 (1.9)
	Unknown/Not Evaluable	5 (9.8)	2 (3.7)	7 (6.7)
	Not Applicable	3 (5.9)	9 (16.7)	12 (11.4)
	Not Done	3 (5.9)	3 (5.6)	6 (5.7)

Baseline is defined as the last available assessments prior to start of Tovorafenib on Cycle 1 Day 1.
Percentages are based on number of patients with both baseline value and at least one post-baseline assessment.
[1] Patient is counted in 'decline and/or increase >= 0.2 logMAR' if at least one side of eye meets the criteria.

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Table 14.3.7 Visual Acuity Outcomes by Visit
Safety Analysis Set - Arm 1 and Arm 2

Visit	Category [1]	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Cycle 21	LogMAR Change from baseline			
	Decline >= 0.2 logMAR	14 (27.5)	12 (22.2)	26 (24.8)
	Increase >= 0.2 logMAR	0	3 (5.6)	3 (2.9)
	Investigator Assessment of Visual Acuity			
	Improved	4 (7.8)	6 (11.1)	10 (9.5)
	Stable	25 (49.0)	23 (42.6)	48 (45.7)
	Visual Progressive Disease	0	0	0
	Unknown/Not Evaluable	4 (7.8)	1 (1.9)	5 (4.8)
	Not Applicable	2 (3.9)	9 (16.7)	11 (10.5)
	Not Done	1 (2.0)	2 (3.7)	3 (2.9)
Cycle 24	LogMAR Change from baseline			
	Decline >= 0.2 logMAR	14 (27.5)	8 (14.8)	22 (21.0)
	Increase >= 0.2 logMAR	0	2 (3.7)	2 (1.9)
	Investigator Assessment of Visual Acuity			
	Improved	6 (11.8)	3 (5.6)	9 (8.6)
	Stable	19 (37.3)	17 (31.5)	36 (34.3)
	Visual Progressive Disease	1 (2.0)	0	1 (1.0)
	Unknown/Not Evaluable	3 (5.9)	1 (1.9)	4 (3.8)
	Not Applicable	2 (3.9)	8 (14.8)	10 (9.5)
	Not Done	2 (3.9)	5 (9.3)	7 (6.7)

Baseline is defined as the last available assessments prior to start of Tovorafenib on Cycle 1 Day 1.
Percentages are based on number of patients with both baseline value and at least one post-baseline assessment.
[1] Patient is counted in 'decline and/or increase >= 0.2 logMAR' if at least one side of eye meets the criteria.

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Table 14.3.7 Visual Acuity Outcomes by Visit
Safety Analysis Set - Arm 1 and Arm 2

Visit	Category [1]	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Cycle 27	LogMAR Change from baseline			
	Decline >= 0.2 logMAR	3 (5.9)	3 (5.6)	6 (5.7)
	Increase >= 0.2 logMAR	0	0	0
	Investigator Assessment of Visual Acuity			
	Improved	2 (3.9)	2 (3.7)	4 (3.8)
	Stable	5 (9.8)	5 (9.3)	10 (9.5)
	Visual Progressive Disease	0	0	0
	Unknown/Not Evaluable	1 (2.0)	0	1 (1.0)
	Not Applicable	0	7 (13.0)	7 (6.7)
	Not Done	3 (5.9)	3 (5.6)	6 (5.7)
Cycle 30	LogMAR Change from baseline			
	Decline >= 0.2 logMAR	3 (5.9)	2 (3.7)	5 (4.8)
	Increase >= 0.2 logMAR	0	0	0
	Investigator Assessment of Visual Acuity			
	Improved	2 (3.9)	0	2 (1.9)
	Stable	7 (13.7)	3 (5.6)	10 (9.5)
	Visual Progressive Disease	0	0	0
	Unknown/Not Evaluable	1 (2.0)	1 (1.9)	2 (1.9)
	Not Applicable	0	2 (3.7)	2 (1.9)
	Not Done	3 (5.9)	1 (1.9)	4 (3.8)

Baseline is defined as the last available assessments prior to start of Tovorafenib on Cycle 1 Day 1.
Percentages are based on number of patients with both baseline value and at least one post-baseline assessment.
[1] Patient is counted in 'decline and/or increase >= 0.2 logMAR' if at least one side of eye meets the criteria.

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Table 14.3.7 Visual Acuity Outcomes by Visit
Safety Analysis Set - Arm 1 and Arm 2

Visit	Category [1]	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Cycle 33	LogMAR Change from baseline			
	Decline >= 0.2 logMAR	3 (5.9)	1 (1.9)	4 (3.8)
	Increase >= 0.2 logMAR	0	0	0
	Investigator Assessment of Visual Acuity			
	Improved	1 (2.0)	0	1 (1.0)
	Stable	6 (11.8)	5 (9.3)	11 (10.5)
	Visual Progressive Disease	0	0	0
	Unknown/Not Evaluable	0	0	0
	Not Applicable	0	2 (3.7)	2 (1.9)
	Not Done	2 (3.9)	0	2 (1.9)
Cycle 36	LogMAR Change from baseline			
	Decline >= 0.2 logMAR	2 (3.9)	2 (3.7)	4 (3.8)
	Increase >= 0.2 logMAR	0	0	0
	Investigator Assessment of Visual Acuity			
	Improved	1 (2.0)	0	1 (1.0)
	Stable	4 (7.8)	5 (9.3)	9 (8.6)
	Visual Progressive Disease	0	0	0
	Unknown/Not Evaluable	1 (2.0)	0	1 (1.0)
	Not Applicable	0	2 (3.7)	2 (1.9)
	Not Done	1 (2.0)	0	1 (1.0)

Baseline is defined as the last available assessments prior to start of Tovorafenib on Cycle 1 Day 1.
Percentages are based on number of patients with both baseline value and at least one post-baseline assessment.
[1] Patient is counted in 'decline and/or increase >= 0.2 logMAR' if at least one side of eye meets the criteria.

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Table 14.3.7 Visual Acuity Outcomes by Visit
Safety Analysis Set - Arm 1 and Arm 2

Visit	Category [1]	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Cycle 39	LogMAR Change from baseline			
	Decline >= 0.2 logMAR	2 (3.9)	1 (1.9)	3 (2.9)
	Increase >= 0.2 logMAR	0	0	0
	Investigator Assessment of Visual Acuity			
	Improved	0	0	0
	Stable	1 (2.0)	1 (1.9)	2 (1.9)
	Visual Progressive Disease	1 (2.0)	0	1 (1.0)
	Unknown/Not Evaluable	0	0	0
	Not Applicable	0	2 (3.7)	2 (1.9)
	Not Done	1 (2.0)	0	1 (1.0)
Cycle 42	LogMAR Change from baseline			
	Decline >= 0.2 logMAR	2 (3.9)	0	2 (1.9)
	Increase >= 0.2 logMAR	1 (2.0)	0	1 (1.0)
	Investigator Assessment of Visual Acuity			
	Improved	0	0	0
	Stable	3 (5.9)	0	3 (2.9)
	Visual Progressive Disease	0	0	0
	Unknown/Not Evaluable	0	0	0
	Not Applicable	0	0	0
	Not Done	0	0	0

Baseline is defined as the last available assessments prior to start of Tovorafenib on Cycle 1 Day 1.
Percentages are based on number of patients with both baseline value and at least one post-baseline assessment.
[1] Patient is counted in 'decline and/or increase >= 0.2 logMAR' if at least one side of eye meets the criteria.

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Table 14.3.7 Visual Acuity Outcomes by Visit
Safety Analysis Set - Arm 1 and Arm 2

Visit	Category [1]	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Cycle 45	LogMAR Change from baseline			
	Decline >= 0.2 logMAR	1 (2.0)	0	1 (1.0)
	Increase >= 0.2 logMAR	0	0	0
	Investigator Assessment of Visual Acuity			
	Improved	1 (2.0)	0	1 (1.0)
	Stable	0	0	0
	Visual Progressive Disease	0	0	0
	Unknown/Not Evaluable	0	0	0
	Not Applicable	0	0	0
	Not Done	0	0	0
End of Treatment	LogMAR Change from baseline			
	Decline >= 0.2 logMAR	10 (19.6)	10 (18.5)	20 (19.0)
	Increase >= 0.2 logMAR	3 (5.9)	5 (9.3)	8 (7.6)
	Investigator Assessment of Visual Acuity			
	Improved	0	4 (7.4)	4 (3.8)
	Stable	23 (45.1)	17 (31.5)	40 (38.1)
	Visual Progressive Disease	1 (2.0)	1 (1.9)	2 (1.9)
	Unknown/Not Evaluable	4 (7.8)	1 (1.9)	5 (4.8)
	Not Applicable	2 (3.9)	8 (14.8)	10 (9.5)
	Not Done	2 (3.9)	2 (3.7)	4 (3.8)

Baseline is defined as the last available assessments prior to start of Tovorafenib on Cycle 1 Day 1.
Percentages are based on number of patients with both baseline value and at least one post-baseline assessment.
[1] Patient is counted in 'decline and/or increase >= 0.2 logMAR' if at least one side of eye meets the criteria.

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Anhang 4-G2.6: Sicherheit

Anhang 4-G2.6.1: Gesamtraten

Day One Biopharmaceuticals
Protocol: DAY101-001

Table 14.3.2.1.1 Overall Summary of Treatment Emergent Adverse Events
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
All Treatment Emergent Adverse Events (TEAEs)	77 (100)	60 (100)	137 (100)
TEAEs Related to Study Drug	76 (98.7)	60 (100)	136 (99.3)
TEAEs with Severity Grade 3 or Higher	64 (83.1)	49 (81.7)	113 (82.5)
TEAEs Related to Study Drug with Severity Grade 3 or Higher	49 (63.6)	42 (70.0)	91 (66.4)
TEAEs Leading to Death	2 (2.6)	3 (5.0)	5 (3.6)
TEAEs Related to Study Drug Leading to Death	0	0	0
TEAEs Leading to Study Drug Dose Reduction	25 (32.5)	20 (33.3)	45 (32.8)
TEAEs Related to Study Drug leading to Dose Reduction	25 (32.5)	20 (33.3)	45 (32.8)
TEAEs Leading to Study Drug Dose Interruption	50 (64.9)	39 (65.0)	89 (65.0)
TEAEs Related to Study Drug leading to Dose Interruption	32 (41.6)	26 (43.3)	58 (42.3)
TEAEs Leading to Study Drug Modification	56 (72.7)	41 (68.3)	97 (70.8)
TEAEs Related to Study Drug leading to Dose Modification	39 (50.6)	30 (50.0)	69 (50.4)
TEAEs Leading to Study Drug Discontinuation	8 (10.4)	11 (18.3)	19 (13.9)
TEAEs Related to Study Drug Leading to Study Drug Discontinuation	7 (9.1)	11 (18.3)	18 (13.1)

TEAE is defined as an AE that starts on or after the first administration of study drug until 30 days after the last dose of Tovorafenib in the primary treatment period.
Treatment related adverse events are those where relationship to study drug is marked as related or missing.
TEAEs leading to drug modification is defined as TEAEs leading to dose reduction or dose interruption.
Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories. Patients with multiple severities for AE are counted only once under the AE with the maximum severity.
MedDRA version 23.1.

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Protocol: DAY101-001

Table 14.3.2.1.1 Overall Summary of Treatment Emergent Adverse Events
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
TEAEs by Severity			
Grade 1: Mild	0	0	0
Grade 2: Moderate	13 (16.9)	11 (18.3)	24 (17.5)
Grade 3: Severe	54 (70.1)	37 (61.7)	91 (66.4)
Grade 4: Life-Threatening	8 (10.4)	9 (15.0)	17 (12.4)
Grade 5: Fatal	2 (2.6)	3 (5.0)	5 (3.6)
All Serious Treatment Emergent Adverse Events	42 (54.5)	35 (58.3)	77 (56.2)
Serious TEAEs Related to Study Drug	18 (23.4)	11 (18.3)	29 (21.2)

TEAE is defined as an AE that starts on or after the first administration of study drug until 30 days after the last dose of Tovorafenib in the primary treatment period.
Treatment related adverse events are those where relationship to study drug is marked as related or missing.
TEAEs leading to drug modification is defined as TEAEs leading to dose reduction or dose interruption.
Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories. Patients with multiple severities for AE are counted only once under the AE with the maximum severity.
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Anhang 4-G2.6.2: UE nach SOC und PT

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Protocol: DAY101-001

Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Patients with Any Treatment Emergent Adverse Event (TEAE)	77 (100)	60 (100)	137 (100)
Skin and subcutaneous tissue disorders	74 (96.1)	59 (98.3)	133 (97.1)
Hair colour changes	64 (83.1)	42 (70.0)	106 (77.4)
Rash maculo-papular	40 (51.9)	29 (48.3)	69 (50.4)
Dry skin	30 (39.0)	26 (43.3)	56 (40.9)
Dermatitis acneiform	24 (31.2)	24 (40.0)	48 (35.0)
Pruritus	25 (32.5)	13 (21.7)	38 (27.7)
Eczema	18 (23.4)	16 (26.7)	34 (24.8)
Alopecia	18 (23.4)	11 (18.3)	29 (21.2)
Erythema	14 (18.2)	9 (15.0)	23 (16.8)
Rash	15 (19.5)	8 (13.3)	23 (16.8)
Photosensitivity reaction	8 (10.4)	13 (21.7)	21 (15.3)
Rash erythematous	9 (11.7)	6 (10.0)	15 (10.9)
Rash papular	6 (7.8)	5 (8.3)	11 (8.0)
Skin hypopigmentation	3 (3.9)	5 (8.3)	8 (5.8)
Hair texture abnormal	5 (6.5)	2 (3.3)	7 (5.1)
Skin discolouration	4 (5.2)	3 (5.0)	7 (5.1)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Skin and subcutaneous tissue disorders (continued)			
Acne	4 (5.2)	2 (3.3)	6 (4.4)
Skin hyperpigmentation	4 (5.2)	2 (3.3)	6 (4.4)
Dermatitis	3 (3.9)	2 (3.3)	5 (3.6)
Papule	4 (5.2)	1 (1.7)	5 (3.6)
Blister	2 (2.6)	2 (3.3)	4 (2.9)
Drug eruption	4 (5.2)	0	4 (2.9)
Onychoclasis	3 (3.9)	1 (1.7)	4 (2.9)
Skin exfoliation	4 (5.2)	0	4 (2.9)
Dermatitis atopic	2 (2.6)	1 (1.7)	3 (2.2)
Dermatitis bullous	2 (2.6)	1 (1.7)	3 (2.2)
Dermatitis diaper	0	3 (5.0)	3 (2.2)
Hand dermatitis	2 (2.6)	1 (1.7)	3 (2.2)
Ingrowing nail	2 (2.6)	1 (1.7)	3 (2.2)
Seborrhoeic dermatitis	3 (3.9)	0	3 (2.2)
Skin lesion	1 (1.3)	2 (3.3)	3 (2.2)
Urticaria	1 (1.3)	2 (3.3)	3 (2.2)
Xeroderma	2 (2.6)	1 (1.7)	3 (2.2)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Skin and subcutaneous tissue disorders (continued)			
Blood blister	1 (1.3)	1 (1.7)	2 (1.5)
Dermatitis allergic	1 (1.3)	1 (1.7)	2 (1.5)
Ephelides	2 (2.6)	0	2 (1.5)
Erythema multiforme	0	2 (3.3)	2 (1.5)
Keratosis pilaris	2 (2.6)	0	2 (1.5)
Onychomadesis	1 (1.3)	1 (1.7)	2 (1.5)
Petechiae	1 (1.3)	1 (1.7)	2 (1.5)
Psoriasis	0	2 (3.3)	2 (1.5)
Rash follicular	2 (2.6)	0	2 (1.5)
Rash macular	2 (2.6)	0	2 (1.5)
Rash pruritic	0	2 (3.3)	2 (1.5)
Skin fissures	2 (2.6)	0	2 (1.5)
Skin ulcer	2 (2.6)	0	2 (1.5)
Achromotrichia acquired	1 (1.3)	0	1 (0.7)
Androgenetic alopecia	1 (1.3)	0	1 (0.7)
Erythema nodosum	1 (1.3)	0	1 (0.7)
Hyperhidrosis	1 (1.3)	0	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Skin and subcutaneous tissue disorders (continued)			
Hyperkeratosis	0	1 (1.7)	1 (0.7)
Intertrigo	1 (1.3)	0	1 (0.7)
Macule	1 (1.3)	0	1 (0.7)
Miliaria	0	1 (1.7)	1 (0.7)
Nail disorder	1 (1.3)	0	1 (0.7)
Nail ridging	0	1 (1.7)	1 (0.7)
Night sweats	1 (1.3)	0	1 (0.7)
Pain of skin	1 (1.3)	0	1 (0.7)
Palmar-plantar erythrodysaesthesia syndrome	0	1 (1.7)	1 (0.7)
Purpura	0	1 (1.7)	1 (0.7)
Rash vesicular	1 (1.3)	0	1 (0.7)
Scab	0	1 (1.7)	1 (0.7)
Sensitive skin	1 (1.3)	0	1 (0.7)
Skin depigmentation	1 (1.3)	0	1 (0.7)
Skin fragility	1 (1.3)	0	1 (0.7)
Skin hypertrophy	1 (1.3)	0	1 (0.7)
Skin irritation	0	1 (1.7)	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Skin and subcutaneous tissue disorders (continued)			
Skin odour abnormal	1 (1.3)	0	1 (0.7)
Skin toxicity	0	1 (1.7)	1 (0.7)
Telangiectasia	1 (1.3)	0	1 (0.7)
Gastrointestinal disorders	70 (90.9)	53 (88.3)	123 (89.8)
Vomiting	42 (54.5)	36 (60.0)	78 (56.9)
Nausea	30 (39.0)	21 (35.0)	51 (37.2)
Constipation	24 (31.2)	26 (43.3)	50 (36.5)
Diarrhoea	18 (23.4)	18 (30.0)	36 (26.3)
Abdominal pain	18 (23.4)	12 (20.0)	30 (21.9)
Stomatitis	8 (10.4)	10 (16.7)	18 (13.1)
Abdominal pain upper	11 (14.3)	5 (8.3)	16 (11.7)
Cheilitis	8 (10.4)	4 (6.7)	12 (8.8)
Lip dry	7 (9.1)	5 (8.3)	12 (8.8)
Angular cheilitis	7 (9.1)	4 (6.7)	11 (8.0)
Gastrooesophageal reflux disease	5 (6.5)	5 (8.3)	10 (7.3)
Gingival bleeding	6 (7.8)	3 (5.0)	9 (6.6)
Dental caries	4 (5.2)	3 (5.0)	7 (5.1)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Gastrointestinal disorders (continued)			
Dyspepsia	2 (2.6)	4 (6.7)	6 (4.4)
Enterocolitis	1 (1.3)	2 (3.3)	3 (2.2)
Tooth development disorder	1 (1.3)	2 (3.3)	3 (2.2)
Abdominal distension	0	2 (3.3)	2 (1.5)
Anal incontinence	2 (2.6)	0	2 (1.5)
Aphthous ulcer	2 (2.6)	0	2 (1.5)
Ascites	2 (2.6)	0	2 (1.5)
Chapped lips	1 (1.3)	1 (1.7)	2 (1.5)
Lip ulceration	2 (2.6)	0	2 (1.5)
Mouth ulceration	1 (1.3)	1 (1.7)	2 (1.5)
Oral pain	1 (1.3)	1 (1.7)	2 (1.5)
Periodontal disease	0	2 (3.3)	2 (1.5)
Toothache	1 (1.3)	1 (1.7)	2 (1.5)
Anal fissure	1 (1.3)	0	1 (0.7)
Dental cyst	1 (1.3)	0	1 (0.7)
Dysphagia	0	1 (1.7)	1 (0.7)
Enteritis	1 (1.3)	0	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Gastrointestinal disorders (continued)			
Eructation	0	1 (1.7)	1 (0.7)
Food poisoning	0	1 (1.7)	1 (0.7)
Gastritis	1 (1.3)	0	1 (0.7)
Gastrointestinal haemorrhage	0	1 (1.7)	1 (0.7)
Gastrointestinal pain	1 (1.3)	0	1 (0.7)
Gingival pain	1 (1.3)	0	1 (0.7)
Haematemesis	1 (1.3)	0	1 (0.7)
Haematochezia	1 (1.3)	0	1 (0.7)
Haemorrhoids	1 (1.3)	0	1 (0.7)
Hypoaesthesia oral	1 (1.3)	0	1 (0.7)
Impaired gastric emptying	0	1 (1.7)	1 (0.7)
Lip disorder	1 (1.3)	0	1 (0.7)
Lip oedema	0	1 (1.7)	1 (0.7)
Lip pain	1 (1.3)	0	1 (0.7)
Lower gastrointestinal haemorrhage	0	1 (1.7)	1 (0.7)
Odynophagia	1 (1.3)	0	1 (0.7)
Proctitis	1 (1.3)	0	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Gastrointestinal disorders (continued)			
Salivary hypersecretion	1 (1.3)	0	1 (0.7)
Tongue eruption	1 (1.3)	0	1 (0.7)
Tooth discolouration	1 (1.3)	0	1 (0.7)
Investigations	72 (93.5)	50 (83.3)	122 (89.1)
Blood creatine phosphokinase increased	52 (67.5)	33 (55.0)	85 (62.0)
Aspartate aminotransferase increased	32 (41.6)	21 (35.0)	53 (38.7)
Blood lactate dehydrogenase increased	30 (39.0)	23 (38.3)	53 (38.7)
Weight decreased	20 (26.0)	15 (25.0)	35 (25.5)
Alanine aminotransferase increased	15 (19.5)	18 (30.0)	33 (24.1)
Lymphocyte count decreased	11 (14.3)	13 (21.7)	24 (17.5)
Blood bilirubin increased	15 (19.5)	5 (8.3)	20 (14.6)
Neutrophil count decreased	10 (13.0)	9 (15.0)	19 (13.9)
White blood cell count decreased	9 (11.7)	7 (11.7)	16 (11.7)
Weight increased	6 (7.8)	8 (13.3)	14 (10.2)
Platelet count decreased	6 (7.8)	5 (8.3)	11 (8.0)
SARS-CoV-2 test positive	8 (10.4)	0	8 (5.8)
Blood phosphorus decreased	4 (5.2)	3 (5.0)	7 (5.1)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Investigations (continued)			
Blood bicarbonate decreased	2 (2.6)	4 (6.7)	6 (4.4)
Blood cholesterol increased	3 (3.9)	2 (3.3)	5 (3.6)
Activated partial thromboplastin time prolonged	3 (3.9)	1 (1.7)	4 (2.9)
Blood potassium decreased	4 (5.2)	0	4 (2.9)
Blood thyroid stimulating hormone increased	2 (2.6)	2 (3.3)	4 (2.9)
Vitamin D decreased	2 (2.6)	2 (3.3)	4 (2.9)
Blood creatinine increased	1 (1.3)	2 (3.3)	3 (2.2)
Blood thyroid stimulating hormone decreased	2 (2.6)	1 (1.7)	3 (2.2)
Gamma-glutamyltransferase increased	2 (2.6)	1 (1.7)	3 (2.2)
Haemoglobin decreased	3 (3.9)	0	3 (2.2)
International normalised ratio increased	3 (3.9)	0	3 (2.2)
Blood alkaline phosphatase decreased	1 (1.3)	1 (1.7)	2 (1.5)
Blood chloride increased	0	2 (3.3)	2 (1.5)
Blood glucose increased	1 (1.3)	1 (1.7)	2 (1.5)
Blood growth hormone abnormal	0	2 (3.3)	2 (1.5)
Blood iron decreased	2 (2.6)	0	2 (1.5)
Blood magnesium decreased	2 (2.6)	0	2 (1.5)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Investigations (continued)			
Blood sodium increased	0	2 (3.3)	2 (1.5)
Blood urea increased	1 (1.3)	1 (1.7)	2 (1.5)
C-reactive protein increased	1 (1.3)	1 (1.7)	2 (1.5)
Electrocardiogram QT prolonged	1 (1.3)	1 (1.7)	2 (1.5)
Haematocrit decreased	2 (2.6)	0	2 (1.5)
Lymphocyte count increased	1 (1.3)	1 (1.7)	2 (1.5)
Mean cell volume increased	2 (2.6)	0	2 (1.5)
Platelet count increased	0	2 (3.3)	2 (1.5)
Red blood cell count decreased	2 (2.6)	0	2 (1.5)
Serum ferritin increased	1 (1.3)	1 (1.7)	2 (1.5)
Thyroxine increased	1 (1.3)	1 (1.7)	2 (1.5)
Urine output increased	2 (2.6)	0	2 (1.5)
White blood cell count increased	2 (2.6)	0	2 (1.5)
Adenovirus test positive	0	1 (1.7)	1 (0.7)
Blood alkaline phosphatase increased	0	1 (1.7)	1 (0.7)
Blood bicarbonate increased	0	1 (1.7)	1 (0.7)
Blood calcium decreased	1 (1.3)	0	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Investigations (continued)			
Blood chloride decreased	1 (1.3)	0	1 (0.7)
Blood creatine increased	0	1 (1.7)	1 (0.7)
Blood creatinine decreased	1 (1.3)	0	1 (0.7)
Blood prolactin abnormal	1 (1.3)	0	1 (0.7)
Bordetella test positive	0	1 (1.7)	1 (0.7)
Cardiac murmur	0	1 (1.7)	1 (0.7)
Clostridium test positive	1 (1.3)	0	1 (0.7)
Electrocardiogram T wave amplitude decreased	1 (1.3)	0	1 (0.7)
Haptoglobin decreased	0	1 (1.7)	1 (0.7)
Hepatic enzyme increased	0	1 (1.7)	1 (0.7)
Human metapneumovirus test positive	1 (1.3)	0	1 (0.7)
Influenza A virus test positive	1 (1.3)	0	1 (0.7)
Insulin C-peptide increased	0	1 (1.7)	1 (0.7)
Intraocular pressure increased	1 (1.3)	0	1 (0.7)
Lipase increased	0	1 (1.7)	1 (0.7)
Protein total decreased	0	1 (1.7)	1 (0.7)
Protein total increased	1 (1.3)	0	1 (0.7)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Investigations (continued)			
Thyroid function test abnormal	1 (1.3)	0	1 (0.7)
Tri-iodothyronine decreased	1 (1.3)	0	1 (0.7)
Tri-iodothyronine free increased	1 (1.3)	0	1 (0.7)
Tri-iodothyronine increased	1 (1.3)	0	1 (0.7)
Troponin T increased	0	1 (1.7)	1 (0.7)
Urobilinogen urine increased	1 (1.3)	0	1 (0.7)
Vital capacity abnormal	0	1 (1.7)	1 (0.7)
Yersinia test positive	1 (1.3)	0	1 (0.7)
General disorders and administration site conditions	66 (85.7)	53 (88.3)	119 (86.9)
Fatigue	47 (61.0)	37 (61.7)	84 (61.3)
Pyrexia	35 (45.5)	30 (50.0)	65 (47.4)
Face oedema	14 (18.2)	13 (21.7)	27 (19.7)
Influenza like illness	9 (11.7)	5 (8.3)	14 (10.2)
Chills	3 (3.9)	4 (6.7)	7 (5.1)
Non-cardiac chest pain	4 (5.2)	1 (1.7)	5 (3.6)
Hypothermia	0	4 (6.7)	4 (2.9)
Oedema peripheral	1 (1.3)	3 (5.0)	4 (2.9)

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MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
General disorders and administration site conditions (continued)			
Swelling face	2 (2.6)	2 (3.3)	4 (2.9)
Chest discomfort	2 (2.6)	1 (1.7)	3 (2.2)
Pain	1 (1.3)	2 (3.3)	3 (2.2)
Gait disturbance	1 (1.3)	1 (1.7)	2 (1.5)
Malaise	1 (1.3)	1 (1.7)	2 (1.5)
Peripheral swelling	2 (2.6)	0	2 (1.5)
Thirst	1 (1.3)	1 (1.7)	2 (1.5)
Asthenia	0	1 (1.7)	1 (0.7)
Axillary pain	1 (1.3)	0	1 (0.7)
Brain death	1 (1.3)	0	1 (0.7)
Catheter site eczema	0	1 (1.7)	1 (0.7)
Catheter site erythema	0	1 (1.7)	1 (0.7)
Catheter site swelling	1 (1.3)	0	1 (0.7)
Complication associated with device	1 (1.3)	0	1 (0.7)
Death	1 (1.3)	0	1 (0.7)
Facial pain	1 (1.3)	0	1 (0.7)
Gait inability	1 (1.3)	0	1 (0.7)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
General disorders and administration site conditions (continued)			
Generalised oedema	0	1 (1.7)	1 (0.7)
Injection site erythema	1 (1.3)	0	1 (0.7)
Injection site papule	1 (1.3)	0	1 (0.7)
Medical device site irritation	0	1 (1.7)	1 (0.7)
Medical device site pain	1 (1.3)	0	1 (0.7)
Oedema	0	1 (1.7)	1 (0.7)
Pseudocyst	1 (1.3)	0	1 (0.7)
Screaming	0	1 (1.7)	1 (0.7)
Infections and infestations	67 (87.0)	51 (85.0)	118 (86.1)
Upper respiratory tract infection	24 (31.2)	28 (46.7)	52 (38.0)
Paronychia	25 (32.5)	17 (28.3)	42 (30.7)
COVID-19	24 (31.2)	13 (21.7)	37 (27.0)
Nasopharyngitis	13 (16.9)	13 (21.7)	26 (19.0)
Conjunctivitis	8 (10.4)	10 (16.7)	18 (13.1)
Viral infection	10 (13.0)	6 (10.0)	16 (11.7)
Otitis media	5 (6.5)	9 (15.0)	14 (10.2)
Influenza	6 (7.8)	7 (11.7)	13 (9.5)

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MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Infections and infestations (continued)			
Skin infection	7 (9.1)	6 (10.0)	13 (9.5)
Gastroenteritis	6 (7.8)	5 (8.3)	11 (8.0)
Rash pustular	5 (6.5)	6 (10.0)	11 (8.0)
Gastroenteritis viral	5 (6.5)	5 (8.3)	10 (7.3)
Viral upper respiratory tract infection	5 (6.5)	5 (8.3)	10 (7.3)
Pneumonia	2 (2.6)	7 (11.7)	9 (6.6)
Rhinovirus infection	5 (6.5)	4 (6.7)	9 (6.6)
Folliculitis	3 (3.9)	5 (8.3)	8 (5.8)
Impetigo	4 (5.2)	4 (6.7)	8 (5.8)
Respiratory syncytial virus infection	3 (3.9)	5 (8.3)	8 (5.8)
Ear infection	3 (3.9)	4 (6.7)	7 (5.1)
Hand-foot-and-mouth disease	3 (3.9)	3 (5.0)	6 (4.4)
Hordeolum	4 (5.2)	2 (3.3)	6 (4.4)
Sepsis	4 (5.2)	2 (3.3)	6 (4.4)
Tonsillitis	3 (3.9)	3 (5.0)	6 (4.4)
Appendicitis	3 (3.9)	2 (3.3)	5 (3.6)
Cellulitis	1 (1.3)	4 (6.7)	5 (3.6)

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MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Infections and infestations (continued)			
Device related infection	3 (3.9)	2 (3.3)	5 (3.6)
Pharyngitis	5 (6.5)	0	5 (3.6)
Pharyngitis streptococcal	3 (3.9)	2 (3.3)	5 (3.6)
Urinary tract infection	2 (2.6)	3 (5.0)	5 (3.6)
Coronavirus infection	0	4 (6.7)	4 (2.9)
Enterovirus infection	2 (2.6)	2 (3.3)	4 (2.9)
Eye infection	1 (1.3)	3 (5.0)	4 (2.9)
Otitis externa	1 (1.3)	3 (5.0)	4 (2.9)
Rhinitis	3 (3.9)	1 (1.7)	4 (2.9)
Sinusitis	3 (3.9)	1 (1.7)	4 (2.9)
Erysipelas	2 (2.6)	1 (1.7)	3 (2.2)
Molluscum contagiosum	2 (2.6)	1 (1.7)	3 (2.2)
Parainfluenzae virus infection	2 (2.6)	1 (1.7)	3 (2.2)
Postoperative wound infection	2 (2.6)	1 (1.7)	3 (2.2)
Respiratory tract infection viral	2 (2.6)	1 (1.7)	3 (2.2)
Shunt infection	0	3 (5.0)	3 (2.2)
Varicella	2 (2.6)	1 (1.7)	3 (2.2)

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MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Infections and infestations (continued)			
Vascular device infection	2 (2.6)	1 (1.7)	3 (2.2)
Viraemia	1 (1.3)	2 (3.3)	3 (2.2)
Adenovirus infection	2 (2.6)	0	2 (1.5)
Bronchitis	1 (1.3)	1 (1.7)	2 (1.5)
Cystitis	1 (1.3)	1 (1.7)	2 (1.5)
Enterocolitis infectious	1 (1.3)	1 (1.7)	2 (1.5)
Eyelid infection	1 (1.3)	1 (1.7)	2 (1.5)
Fungal infection	1 (1.3)	1 (1.7)	2 (1.5)
Fungal skin infection	0	2 (3.3)	2 (1.5)
Herpes simplex	2 (2.6)	0	2 (1.5)
Infected bite	1 (1.3)	1 (1.7)	2 (1.5)
Injection site infection	0	2 (3.3)	2 (1.5)
Lip infection	1 (1.3)	1 (1.7)	2 (1.5)
Localised infection	1 (1.3)	1 (1.7)	2 (1.5)
Lower respiratory tract infection	2 (2.6)	0	2 (1.5)
Oral candidiasis	0	2 (3.3)	2 (1.5)
Oral herpes	2 (2.6)	0	2 (1.5)

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MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Infections and infestations (continued)			
Otitis media acute	1 (1.3)	1 (1.7)	2 (1.5)
Scarlet fever	2 (2.6)	0	2 (1.5)
Tooth infection	0	2 (3.3)	2 (1.5)
Viral rash	1 (1.3)	1 (1.7)	2 (1.5)
Vulvovaginal candidiasis	0	2 (3.3)	2 (1.5)
Adenoviral upper respiratory infection	0	1 (1.7)	1 (0.7)
Anorectal cellulitis	1 (1.3)	0	1 (0.7)
Bacteraemia	0	1 (1.7)	1 (0.7)
COVID-19 pneumonia	1 (1.3)	0	1 (0.7)
Campylobacter infection	1 (1.3)	0	1 (0.7)
Candida infection	1 (1.3)	0	1 (0.7)
Catheter site cellulitis	1 (1.3)	0	1 (0.7)
Clostridial sepsis	1 (1.3)	0	1 (0.7)
Clostridium difficile colitis	0	1 (1.7)	1 (0.7)
Conjunctivitis bacterial	1 (1.3)	0	1 (0.7)
Conjunctivitis viral	0	1 (1.7)	1 (0.7)
Coxsackie viral infection	0	1 (1.7)	1 (0.7)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Infections and infestations (continued)			
Dental fistula	1 (1.3)	0	1 (0.7)
Dermatitis infected	1 (1.3)	0	1 (0.7)
Ear lobe infection	1 (1.3)	0	1 (0.7)
Extradural abscess	1 (1.3)	0	1 (0.7)
Eye infection viral	1 (1.3)	0	1 (0.7)
Febrile infection	1 (1.3)	0	1 (0.7)
Fungaemia	0	1 (1.7)	1 (0.7)
Furuncle	1 (1.3)	0	1 (0.7)
Gastrointestinal infection	1 (1.3)	0	1 (0.7)
Genital infection bacterial	0	1 (1.7)	1 (0.7)
Gingivitis	0	1 (1.7)	1 (0.7)
Groin infection	0	1 (1.7)	1 (0.7)
Helminthic infection	1 (1.3)	0	1 (0.7)
Herpes simplex reactivation	1 (1.3)	0	1 (0.7)
Herpes zoster	0	1 (1.7)	1 (0.7)
Infection	1 (1.3)	0	1 (0.7)
Meningitis	0	1 (1.7)	1 (0.7)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Infections and infestations (continued)			
Metapneumovirus infection	0	1 (1.7)	1 (0.7)
Nail infection	1 (1.3)	0	1 (0.7)
Onychomycosis	1 (1.3)	0	1 (0.7)
Osteomyelitis	0	1 (1.7)	1 (0.7)
Otitis externa fungal	0	1 (1.7)	1 (0.7)
Parvovirus infection	1 (1.3)	0	1 (0.7)
Penile infection	1 (1.3)	0	1 (0.7)
Periorbital cellulitis	0	1 (1.7)	1 (0.7)
Peritonitis	0	1 (1.7)	1 (0.7)
Pneumococcal sepsis	1 (1.3)	0	1 (0.7)
Pneumonia haemophilus	1 (1.3)	0	1 (0.7)
Pneumonia influenzal	1 (1.3)	0	1 (0.7)
Respiratory syncytial virus bronchiolitis	0	1 (1.7)	1 (0.7)
Respiratory tract infection	1 (1.3)	0	1 (0.7)
Septic shock	1 (1.3)	0	1 (0.7)
Skin bacterial infection	0	1 (1.7)	1 (0.7)
Skin candida	0	1 (1.7)	1 (0.7)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Infections and infestations (continued)			
Staphylococcal infection	1 (1.3)	0	1 (0.7)
Staphylococcal skin infection	0	1 (1.7)	1 (0.7)
Streptococcal infection	1 (1.3)	0	1 (0.7)
Streptococcal sepsis	0	1 (1.7)	1 (0.7)
Suspected COVID-19	1 (1.3)	0	1 (0.7)
Systemic infection	0	1 (1.7)	1 (0.7)
Tinea infection	0	1 (1.7)	1 (0.7)
Urethritis	0	1 (1.7)	1 (0.7)
Viral pharyngitis	0	1 (1.7)	1 (0.7)
Viral rhinitis	1 (1.3)	0	1 (0.7)
Viral tonsillitis	1 (1.3)	0	1 (0.7)
Vulvovaginal mycotic infection	1 (1.3)	0	1 (0.7)
Vulvovaginitis	1 (1.3)	0	1 (0.7)
Musculoskeletal and connective tissue disorders	61 (79.2)	46 (76.7)	107 (78.1)
Growth retardation	33 (42.9)	28 (46.7)	61 (44.5)
Pain in extremity	21 (27.3)	7 (11.7)	28 (20.4)
Arthralgia	11 (14.3)	11 (18.3)	22 (16.1)

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MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Musculoskeletal and connective tissue disorders (continued)			
Myalgia	16 (20.8)	6 (10.0)	22 (16.1)
Muscle spasms	14 (18.2)	4 (6.7)	18 (13.1)
Back pain	8 (10.4)	4 (6.7)	12 (8.8)
Neck pain	6 (7.8)	4 (6.7)	10 (7.3)
Muscular weakness	3 (3.9)	4 (6.7)	7 (5.1)
Growth failure	1 (1.3)	2 (3.3)	3 (2.2)
Bone pain	1 (1.3)	1 (1.7)	2 (1.5)
Flank pain	2 (2.6)	0	2 (1.5)
Groin pain	2 (2.6)	0	2 (1.5)
Joint swelling	1 (1.3)	1 (1.7)	2 (1.5)
Musculoskeletal pain	2 (2.6)	0	2 (1.5)
Arthritis reactive	1 (1.3)	0	1 (0.7)
Coccydynia	1 (1.3)	0	1 (0.7)
Facial asymmetry	0	1 (1.7)	1 (0.7)
Jaw cyst	0	1 (1.7)	1 (0.7)
Joint effusion	1 (1.3)	0	1 (0.7)
Joint range of motion decreased	0	1 (1.7)	1 (0.7)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Musculoskeletal and connective tissue disorders (continued)			
Joint stiffness	1 (1.3)	0	1 (0.7)
Limb deformity	0	1 (1.7)	1 (0.7)
Muscle fatigue	1 (1.3)	0	1 (0.7)
Muscle tightness	1 (1.3)	0	1 (0.7)
Musculoskeletal chest pain	1 (1.3)	0	1 (0.7)
Osteoarthritis	0	1 (1.7)	1 (0.7)
Plantar fasciitis	1 (1.3)	0	1 (0.7)
Scoliosis	0	1 (1.7)	1 (0.7)
Soft tissue mass	1 (1.3)	0	1 (0.7)
Synovial cyst	1 (1.3)	0	1 (0.7)
Systemic lupus erythematosus	1 (1.3)	0	1 (0.7)
Tenosynovitis	1 (1.3)	0	1 (0.7)
Metabolism and nutrition disorders	60 (77.9)	46 (76.7)	106 (77.4)
Hypophosphataemia	33 (42.9)	40 (66.7)	73 (53.3)
Decreased appetite	27 (35.1)	15 (25.0)	42 (30.7)
Hypokalaemia	21 (27.3)	19 (31.7)	40 (29.2)
Hypocalcaemia	16 (20.8)	8 (13.3)	24 (17.5)

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MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Metabolism and nutrition disorders (continued)			
Hypoalbuminaemia	12 (15.6)	9 (15.0)	21 (15.3)
Hyponatraemia	8 (10.4)	12 (20.0)	20 (14.6)
Hypernatraemia	9 (11.7)	8 (13.3)	17 (12.4)
Hyperglycaemia	7 (9.1)	7 (11.7)	14 (10.2)
Hypoglycaemia	4 (5.2)	6 (10.0)	10 (7.3)
Hypomagnesaemia	5 (6.5)	2 (3.3)	7 (5.1)
Dehydration	2 (2.6)	3 (5.0)	5 (3.6)
Hyperkalaemia	4 (5.2)	1 (1.7)	5 (3.6)
Vitamin D deficiency	1 (1.3)	4 (6.7)	5 (3.6)
Hypermagnesaemia	3 (3.9)	1 (1.7)	4 (2.9)
Cerebral salt-wasting syndrome	1 (1.3)	1 (1.7)	2 (1.5)
Hyperphosphataemia	2 (2.6)	0	2 (1.5)
Obesity	1 (1.3)	1 (1.7)	2 (1.5)
Polydipsia	1 (1.3)	1 (1.7)	2 (1.5)
Acidosis	1 (1.3)	0	1 (0.7)
Alkalosis	1 (1.3)	0	1 (0.7)
Electrolyte imbalance	1 (1.3)	0	1 (0.7)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Metabolism and nutrition disorders (continued)			
Hypercalcaemia	1 (1.3)	0	1 (0.7)
Hypercholesterolaemia	0	1 (1.7)	1 (0.7)
Hypertriglyceridaemia	0	1 (1.7)	1 (0.7)
Hypochloraemia	1 (1.3)	0	1 (0.7)
Hypoproteinaemia	1 (1.3)	0	1 (0.7)
Increased appetite	0	1 (1.7)	1 (0.7)
Iron deficiency	1 (1.3)	0	1 (0.7)
Lactic acidosis	1 (1.3)	0	1 (0.7)
Metabolic acidosis	0	1 (1.7)	1 (0.7)
Metabolic disorder	1 (1.3)	0	1 (0.7)
Nervous system disorders	59 (76.6)	43 (71.7)	102 (74.5)
Headache	44 (57.1)	33 (55.0)	77 (56.2)
Dizziness	7 (9.1)	11 (18.3)	18 (13.1)
Hydrocephalus	9 (11.7)	7 (11.7)	16 (11.7)
Seizure	5 (6.5)	10 (16.7)	15 (10.9)
Lethargy	7 (9.1)	2 (3.3)	9 (6.6)
Paraesthesia	7 (9.1)	2 (3.3)	9 (6.6)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Nervous system disorders (continued)			
Visual field defect	5 (6.5)	2 (3.3)	7 (5.1)
Somnolence	2 (2.6)	3 (5.0)	5 (3.6)
Ataxia	1 (1.3)	3 (5.0)	4 (2.9)
Memory impairment	1 (1.3)	3 (5.0)	4 (2.9)
Dysgeusia	2 (2.6)	1 (1.7)	3 (2.2)
Hemiparesis	0	3 (5.0)	3 (2.2)
Hypoaesthesia	3 (3.9)	0	3 (2.2)
Amnesia	1 (1.3)	1 (1.7)	2 (1.5)
Depressed level of consciousness	0	2 (3.3)	2 (1.5)
Disturbance in attention	0	2 (3.3)	2 (1.5)
Dysarthria	1 (1.3)	1 (1.7)	2 (1.5)
Dystonia	2 (2.6)	0	2 (1.5)
Hypersomnia	2 (2.6)	0	2 (1.5)
Syncope	0	2 (3.3)	2 (1.5)
Tremor	2 (2.6)	0	2 (1.5)
Anosmia	0	1 (1.7)	1 (0.7)
Aphasia	1 (1.3)	0	1 (0.7)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Nervous system disorders (continued)			
Cerebral ventricle dilatation	1 (1.3)	0	1 (0.7)
Cerebrospinal fluid circulation disorder	0	1 (1.7)	1 (0.7)
Cognitive disorder	1 (1.3)	0	1 (0.7)
Coordination abnormal	0	1 (1.7)	1 (0.7)
Dysaesthesia	0	1 (1.7)	1 (0.7)
Facial nerve disorder	0	1 (1.7)	1 (0.7)
Facial paresis	0	1 (1.7)	1 (0.7)
Hemianopia homonymous	0	1 (1.7)	1 (0.7)
Intracranial pressure increased	1 (1.3)	0	1 (0.7)
Migraine	0	1 (1.7)	1 (0.7)
Migraine with aura	0	1 (1.7)	1 (0.7)
Nervous system disorder	1 (1.3)	0	1 (0.7)
Neuralgia	1 (1.3)	0	1 (0.7)
Neurological decompensation	1 (1.3)	0	1 (0.7)
Nystagmus	1 (1.3)	0	1 (0.7)
Peripheral motor neuropathy	1 (1.3)	0	1 (0.7)
Serotonin syndrome	0	1 (1.7)	1 (0.7)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Nervous system disorders (continued)			
Slow response to stimuli	1 (1.3)	0	1 (0.7)
Status epilepticus	0	1 (1.7)	1 (0.7)
Transient ischaemic attack	1 (1.3)	0	1 (0.7)
Respiratory, thoracic and mediastinal disorders	51 (66.2)	40 (66.7)	91 (66.4)
Epistaxis	30 (39.0)	14 (23.3)	44 (32.1)
Cough	17 (22.1)	19 (31.7)	36 (26.3)
Rhinorrhoea	6 (7.8)	14 (23.3)	20 (14.6)
Nasal congestion	10 (13.0)	8 (13.3)	18 (13.1)
Oropharyngeal pain	12 (15.6)	5 (8.3)	17 (12.4)
Rhinitis allergic	9 (11.7)	5 (8.3)	14 (10.2)
Dyspnoea	4 (5.2)	3 (5.0)	7 (5.1)
Hypoxia	2 (2.6)	1 (1.7)	3 (2.2)
Productive cough	2 (2.6)	1 (1.7)	3 (2.2)
Sleep apnoea syndrome	2 (2.6)	1 (1.7)	3 (2.2)
Tachypnoea	0	3 (5.0)	3 (2.2)
Atelectasis	0	2 (3.3)	2 (1.5)
Dysphonia	1 (1.3)	1 (1.7)	2 (1.5)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Respiratory, thoracic and mediastinal disorders (continued)			
Pulmonary hypertension	1 (1.3)	1 (1.7)	2 (1.5)
Respiratory failure	0	2 (3.3)	2 (1.5)
Sneezing	1 (1.3)	1 (1.7)	2 (1.5)
Tonsillar hypertrophy	1 (1.3)	1 (1.7)	2 (1.5)
Adenoidal hypertrophy	1 (1.3)	0	1 (0.7)
Bronchospasm	0	1 (1.7)	1 (0.7)
Bronchostenosis	0	1 (1.7)	1 (0.7)
Choking	0	1 (1.7)	1 (0.7)
Hypopnoea	0	1 (1.7)	1 (0.7)
Laryngeal inflammation	0	1 (1.7)	1 (0.7)
Nasal discomfort	1 (1.3)	0	1 (0.7)
Nasal dryness	0	1 (1.7)	1 (0.7)
Nasal inflammation	1 (1.3)	0	1 (0.7)
Nasal ulcer	1 (1.3)	0	1 (0.7)
Pharyngeal erythema	0	1 (1.7)	1 (0.7)
Pleural effusion	0	1 (1.7)	1 (0.7)
Pulmonary congestion	0	1 (1.7)	1 (0.7)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Respiratory, thoracic and mediastinal disorders (continued)			
Snoring	1 (1.3)	0	1 (0.7)
Throat clearing	1 (1.3)	0	1 (0.7)
Throat irritation	1 (1.3)	0	1 (0.7)
Wheezing	1 (1.3)	0	1 (0.7)
Blood and lymphatic system disorders	53 (68.8)	36 (60.0)	89 (65.0)
Anaemia	50 (64.9)	33 (55.0)	83 (60.6)
Eosinophilia	8 (10.4)	3 (5.0)	11 (8.0)
Neutropenia	2 (2.6)	0	2 (1.5)
Thrombocytosis	1 (1.3)	1 (1.7)	2 (1.5)
Anaemia macrocytic	0	1 (1.7)	1 (0.7)
Autoimmune haemolytic anaemia	1 (1.3)	0	1 (0.7)
Bone marrow failure	0	1 (1.7)	1 (0.7)
Disseminated intravascular coagulation	1 (1.3)	0	1 (0.7)
Febrile neutropenia	0	1 (1.7)	1 (0.7)
Haemolysis	0	1 (1.7)	1 (0.7)
Iron deficiency anaemia	1 (1.3)	0	1 (0.7)
Leukocytosis	0	1 (1.7)	1 (0.7)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Blood and lymphatic system disorders (continued)			
Leukopenia	1 (1.3)	0	1 (0.7)
Lymphadenitis	0	1 (1.7)	1 (0.7)
Lymphadenopathy	1 (1.3)	0	1 (0.7)
Lymphocytosis	0	1 (1.7)	1 (0.7)
Lymphopenia	1 (1.3)	0	1 (0.7)
Macrocytosis	1 (1.3)	0	1 (0.7)
Thrombocytopenia	0	1 (1.7)	1 (0.7)
Eye disorders	36 (46.8)	30 (50.0)	66 (48.2)
Periorbital oedema	8 (10.4)	4 (6.7)	12 (8.8)
Blepharitis	4 (5.2)	7 (11.7)	11 (8.0)
Vision blurred	7 (9.1)	3 (5.0)	10 (7.3)
Dry eye	4 (5.2)	3 (5.0)	7 (5.1)
Photophobia	2 (2.6)	3 (5.0)	5 (3.6)
Visual impairment	2 (2.6)	3 (5.0)	5 (3.6)
Dyschromatopsia	3 (3.9)	1 (1.7)	4 (2.9)
Ocular hyperaemia	2 (2.6)	2 (3.3)	4 (2.9)
Conjunctivitis allergic	2 (2.6)	1 (1.7)	3 (2.2)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Eye disorders (continued)			
Diplopia	1 (1.3)	2 (3.3)	3 (2.2)
Erythema of eyelid	0	3 (5.0)	3 (2.2)
Eye discharge	2 (2.6)	1 (1.7)	3 (2.2)
Eye pain	3 (3.9)	0	3 (2.2)
Eye pruritus	3 (3.9)	0	3 (2.2)
Eye swelling	2 (2.6)	1 (1.7)	3 (2.2)
Strabismus	2 (2.6)	1 (1.7)	3 (2.2)
Chalazion	1 (1.3)	1 (1.7)	2 (1.5)
Eyelash discolouration	2 (2.6)	0	2 (1.5)
Eyelid margin crusting	0	2 (3.3)	2 (1.5)
Eyelid ptosis	0	2 (3.3)	2 (1.5)
Optic nerve disorder	1 (1.3)	1 (1.7)	2 (1.5)
Asthenopia	0	1 (1.7)	1 (0.7)
Astigmatism	1 (1.3)	0	1 (0.7)
Blepharospasm	1 (1.3)	0	1 (0.7)
Conjunctival papillae	0	1 (1.7)	1 (0.7)
Corneal oedema	1 (1.3)	0	1 (0.7)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Eye disorders (continued)			
Eczema eyelids	1 (1.3)	0	1 (0.7)
Episcleritis	1 (1.3)	0	1 (0.7)
Extraocular muscle paresis	0	1 (1.7)	1 (0.7)
Eye irritation	0	1 (1.7)	1 (0.7)
Eye movement disorder	1 (1.3)	0	1 (0.7)
Eyelash hypopigmentation	0	1 (1.7)	1 (0.7)
Eyelid disorder	0	1 (1.7)	1 (0.7)
Glaucoma	1 (1.3)	0	1 (0.7)
Optic atrophy	1 (1.3)	0	1 (0.7)
Papilloedema	1 (1.3)	0	1 (0.7)
Periorbital swelling	1 (1.3)	0	1 (0.7)
Photopsia	1 (1.3)	0	1 (0.7)
Scleral discolouration	1 (1.3)	0	1 (0.7)
Swelling of eyelid	0	1 (1.7)	1 (0.7)
Visual acuity reduced	0	1 (1.7)	1 (0.7)
Vitreous floaters	1 (1.3)	0	1 (0.7)
Injury, poisoning and procedural complications	26 (33.8)	25 (41.7)	51 (37.2)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Injury, poisoning and procedural complications (continued)			
Contusion	6 (7.8)	5 (8.3)	11 (8.0)
Arthropod bite	3 (3.9)	6 (10.0)	9 (6.6)
Procedural pain	4 (5.2)	2 (3.3)	6 (4.4)
Shunt malfunction	3 (3.9)	3 (5.0)	6 (4.4)
Fall	1 (1.3)	4 (6.7)	5 (3.6)
Skin abrasion	1 (1.3)	2 (3.3)	3 (2.2)
Skin laceration	2 (2.6)	1 (1.7)	3 (2.2)
Limb injury	0	2 (3.3)	2 (1.5)
Oral contusion	2 (2.6)	0	2 (1.5)
Thermal burn	1 (1.3)	1 (1.7)	2 (1.5)
Ankle fracture	1 (1.3)	0	1 (0.7)
Arthropod sting	1 (1.3)	0	1 (0.7)
Burns second degree	0	1 (1.7)	1 (0.7)
Eyelid injury	0	1 (1.7)	1 (0.7)
Foot fracture	0	1 (1.7)	1 (0.7)
Humerus fracture	1 (1.3)	0	1 (0.7)
Infusion related reaction	0	1 (1.7)	1 (0.7)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Injury, poisoning and procedural complications (continued)			
Joint dislocation	0	1 (1.7)	1 (0.7)
Ligament sprain	1 (1.3)	0	1 (0.7)
Lip injury	1 (1.3)	0	1 (0.7)
Muscle strain	0	1 (1.7)	1 (0.7)
Postoperative wound complication	1 (1.3)	0	1 (0.7)
Procedural headache	1 (1.3)	0	1 (0.7)
Skin injury	0	1 (1.7)	1 (0.7)
Subdural haemorrhage	1 (1.3)	0	1 (0.7)
Sunburn	1 (1.3)	0	1 (0.7)
Tibia fracture	1 (1.3)	0	1 (0.7)
Tooth fracture	1 (1.3)	0	1 (0.7)
Traumatic fracture	0	1 (1.7)	1 (0.7)
Vaccination complication	0	1 (1.7)	1 (0.7)
Wound complication	1 (1.3)	0	1 (0.7)
Wound dehiscence	1 (1.3)	0	1 (0.7)
Psychiatric disorders	21 (27.3)	22 (36.7)	43 (31.4)
Insomnia	8 (10.4)	4 (6.7)	12 (8.8)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Psychiatric disorders (continued)			
Anxiety	6 (7.8)	5 (8.3)	11 (8.0)
Depression	2 (2.6)	4 (6.7)	6 (4.4)
Irritability	2 (2.6)	2 (3.3)	4 (2.9)
Agitation	0	2 (3.3)	2 (1.5)
Enuresis	1 (1.3)	1 (1.7)	2 (1.5)
Hallucination	1 (1.3)	1 (1.7)	2 (1.5)
Attention deficit hyperactivity disorder	0	1 (1.7)	1 (0.7)
Confusional state	1 (1.3)	0	1 (0.7)
Delirium	0	1 (1.7)	1 (0.7)
Depressed mood	0	1 (1.7)	1 (0.7)
Flat affect	1 (1.3)	0	1 (0.7)
Initial insomnia	1 (1.3)	0	1 (0.7)
Intentional self-injury	1 (1.3)	0	1 (0.7)
Mood altered	1 (1.3)	0	1 (0.7)
Personality change	1 (1.3)	0	1 (0.7)
Restlessness	0	1 (1.7)	1 (0.7)
Sleep disorder	1 (1.3)	0	1 (0.7)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Psychiatric disorders (continued)			
Staring	0	1 (1.7)	1 (0.7)
Suicidal ideation	0	1 (1.7)	1 (0.7)
Cardiac disorders	20 (26.0)	19 (31.7)	39 (28.5)
Pericardial effusion	9 (11.7)	8 (13.3)	17 (12.4)
Sinus tachycardia	2 (2.6)	6 (10.0)	8 (5.8)
Bradycardia	0	3 (5.0)	3 (2.2)
Tachycardia	2 (2.6)	1 (1.7)	3 (2.2)
Left atrial dilatation	2 (2.6)	0	2 (1.5)
Left ventricular hypertrophy	1 (1.3)	1 (1.7)	2 (1.5)
Palpitations	1 (1.3)	1 (1.7)	2 (1.5)
Ventricular arrhythmia	2 (2.6)	0	2 (1.5)
Aortic valve incompetence	0	1 (1.7)	1 (0.7)
Atrioventricular block	1 (1.3)	0	1 (0.7)
Cardiac dysfunction	0	1 (1.7)	1 (0.7)
Cardiac failure	1 (1.3)	0	1 (0.7)
Cardiac ventricular disorder	1 (1.3)	0	1 (0.7)
Cardiomegaly	0	1 (1.7)	1 (0.7)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Cardiac disorders (continued)			
Hyperdynamic left ventricle	1 (1.3)	0	1 (0.7)
Left ventricular dysfunction	0	1 (1.7)	1 (0.7)
Sinus bradycardia	0	1 (1.7)	1 (0.7)
Ventricular extrasystoles	1 (1.3)	0	1 (0.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	13 (16.9)	19 (31.7)	32 (23.4)
Tumour haemorrhage	8 (10.4)	9 (15.0)	17 (12.4)
Melanocytic naevus	3 (3.9)	7 (11.7)	10 (7.3)
Intracranial tumour haemorrhage	2 (2.6)	2 (3.3)	4 (2.9)
Fibroma	1 (1.3)	0	1 (0.7)
Haemangioma of bone	0	1 (1.7)	1 (0.7)
Skin papilloma	0	1 (1.7)	1 (0.7)
Vascular disorders	19 (24.7)	12 (20.0)	31 (22.6)
Flushing	10 (13.0)	4 (6.7)	14 (10.2)
Hypertension	5 (6.5)	3 (5.0)	8 (5.8)
Haematoma	3 (3.9)	0	3 (2.2)
Hot flush	2 (2.6)	0	2 (1.5)
Hypotension	0	2 (3.3)	2 (1.5)

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Vascular disorders (continued)			
Pallor	1 (1.3)	1 (1.7)	2 (1.5)
Angiopathy	0	1 (1.7)	1 (0.7)
Diastolic hypotension	1 (1.3)	0	1 (0.7)
Hypovolaemic shock	1 (1.3)	0	1 (0.7)
Thrombophlebitis superficial	0	1 (1.7)	1 (0.7)
Vasculitis	1 (1.3)	0	1 (0.7)
Vena cava thrombosis	1 (1.3)	0	1 (0.7)
Ear and labyrinth disorders	16 (20.8)	7 (11.7)	23 (16.8)
Ear pain	6 (7.8)	1 (1.7)	7 (5.1)
Tinnitus	6 (7.8)	1 (1.7)	7 (5.1)
Vertigo	1 (1.3)	3 (5.0)	4 (2.9)
Ear congestion	2 (2.6)	0	2 (1.5)
Hypoacusis	1 (1.3)	1 (1.7)	2 (1.5)
Conductive deafness	1 (1.3)	0	1 (0.7)
Deafness	0	1 (1.7)	1 (0.7)
Deafness unilateral	1 (1.3)	0	1 (0.7)
Excessive cerumen production	0	1 (1.7)	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

Program: t0ae0soc.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:01

Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Ear and labyrinth disorders (continued)			
External ear inflammation	1 (1.3)	0	1 (0.7)
Hyperacusis	0	1 (1.7)	1 (0.7)
Motion sickness	0	1 (1.7)	1 (0.7)
Otorrhoea	1 (1.3)	0	1 (0.7)
Tympanosclerosis	1 (1.3)	0	1 (0.7)
Endocrine disorders	8 (10.4)	10 (16.7)	18 (13.1)
Precocious puberty	4 (5.2)	3 (5.0)	7 (5.1)
Adrenal insufficiency	2 (2.6)	2 (3.3)	4 (2.9)
Diabetes insipidus	2 (2.6)	2 (3.3)	4 (2.9)
Hyperthyroidism	1 (1.3)	1 (1.7)	2 (1.5)
Glucocorticoid deficiency	0	1 (1.7)	1 (0.7)
Growth hormone deficiency	0	1 (1.7)	1 (0.7)
Hyperparathyroidism	0	1 (1.7)	1 (0.7)
Hypothyroidism	0	1 (1.7)	1 (0.7)
Renal and urinary disorders	11 (14.3)	6 (10.0)	17 (12.4)
Dysuria	4 (5.2)	1 (1.7)	5 (3.6)
Urinary incontinence	5 (6.5)	0	5 (3.6)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

Program: t0ae0soc.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:01

Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Renal and urinary disorders (continued)			
Pollakiuria	3 (3.9)	0	3 (2.2)
Acute kidney injury	1 (1.3)	1 (1.7)	2 (1.5)
Haematuria	1 (1.3)	0	1 (0.7)
Micturition urgency	1 (1.3)	0	1 (0.7)
Polyuria	0	1 (1.7)	1 (0.7)
Proteinuria	1 (1.3)	0	1 (0.7)
Renal impairment	0	1 (1.7)	1 (0.7)
Urge incontinence	0	1 (1.7)	1 (0.7)
Urinary retention	0	1 (1.7)	1 (0.7)
Reproductive system and breast disorders	8 (10.4)	7 (11.7)	15 (10.9)
Amenorrhoea	2 (2.6)	5 (8.3)	7 (5.1)
Menstruation irregular	4 (5.2)	1 (1.7)	5 (3.6)
Acquired phimosis	0	1 (1.7)	1 (0.7)
Breast discolouration	1 (1.3)	0	1 (0.7)
Menstruation delayed	1 (1.3)	0	1 (0.7)
Vaginal haemorrhage	1 (1.3)	0	1 (0.7)
Vulval oedema	1 (1.3)	0	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

Program: t0ae0soc.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:01

Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Reproductive system and breast disorders (continued)			
Vulvovaginal erythema	0	1 (1.7)	1 (0.7)
Vulvovaginal pain	1 (1.3)	0	1 (0.7)
Vulvovaginal pruritus	1 (1.3)	0	1 (0.7)
Product issues	3 (3.9)	4 (6.7)	7 (5.1)
Device malfunction	0	2 (3.3)	2 (1.5)
Device occlusion	2 (2.6)	0	2 (1.5)
Device breakage	1 (1.3)	0	1 (0.7)
Device failure	0	1 (1.7)	1 (0.7)
Device leakage	0	1 (1.7)	1 (0.7)
Hepatobiliary disorders	2 (2.6)	4 (6.7)	6 (4.4)
Cholelithiasis	0	2 (3.3)	2 (1.5)
Jaundice	2 (2.6)	0	2 (1.5)
Ocular icterus	2 (2.6)	0	2 (1.5)
Cholecystitis	0	1 (1.7)	1 (0.7)
Hepatomegaly	0	1 (1.7)	1 (0.7)
Congenital, familial and genetic disorders	1 (1.3)	3 (5.0)	4 (2.9)
Birth mark	1 (1.3)	2 (3.3)	3 (2.2)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Table 14.3.2.2.1 Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set – Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Congenital, familial and genetic disorders (continued)			
Gilbert's syndrome	0	1 (1.7)	1 (0.7)
Immune system disorders	3 (3.9)	1 (1.7)	4 (2.9)
Seasonal allergy	2 (2.6)	0	2 (1.5)
Allergy to arthropod sting	1 (1.3)	0	1 (0.7)
Hypersensitivity	0	1 (1.7)	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Anhang 4-G2.6.3: Schwere UE nach SOC und PT

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Table 14.3.2.4.1 Treatment Emergent Adverse Events with Severity Grade 3 or Higher by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Patients with Any Treatment Emergent Adverse Event (TEAE) with Severity Grade 3 or Higher	64 (83.1)	49 (81.7)	113 (82.5)
Infections and infestations	21 (27.3)	27 (45.0)	48 (35.0)
Pneumonia	1 (1.3)	5 (8.3)	6 (4.4)
Sepsis	4 (5.2)	2 (3.3)	6 (4.4)
Appendicitis	3 (3.9)	2 (3.3)	5 (3.6)
Device related infection	3 (3.9)	2 (3.3)	5 (3.6)
Viral infection	4 (5.2)	0	4 (2.9)
Cellulitis	0	3 (5.0)	3 (2.2)
Otitis media	1 (1.3)	2 (3.3)	3 (2.2)
Shunt infection	0	3 (5.0)	3 (2.2)
Vascular device infection	2 (2.6)	1 (1.7)	3 (2.2)
Viral upper respiratory tract infection	2 (2.6)	1 (1.7)	3 (2.2)
Erysipelas	1 (1.3)	1 (1.7)	2 (1.5)
Gastroenteritis viral	1 (1.3)	1 (1.7)	2 (1.5)
Paronychia	1 (1.3)	1 (1.7)	2 (1.5)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

Program: t0ae0socpoly.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:02

Table 14.3.2.4.1 Treatment Emergent Adverse Events with Severity Grade 3 or Higher by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Infections and infestations (continued)			
Respiratory syncytial virus infection	1 (1.3)	1 (1.7)	2 (1.5)
Tooth infection	0	2 (3.3)	2 (1.5)
Upper respiratory tract infection	0	2 (3.3)	2 (1.5)
Bacteraemia	0	1 (1.7)	1 (0.7)
Bronchitis	1 (1.3)	0	1 (0.7)
COVID-19 pneumonia	1 (1.3)	0	1 (0.7)
Clostridial sepsis	1 (1.3)	0	1 (0.7)
Clostridium difficile colitis	0	1 (1.7)	1 (0.7)
Coronavirus infection	0	1 (1.7)	1 (0.7)
Enterovirus infection	0	1 (1.7)	1 (0.7)
Extradural abscess	1 (1.3)	0	1 (0.7)
Eye infection viral	1 (1.3)	0	1 (0.7)
Folliculitis	0	1 (1.7)	1 (0.7)
Gastroenteritis	0	1 (1.7)	1 (0.7)
Herpes simplex reactivation	1 (1.3)	0	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

Program: t0ae0socpoly.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:02

Table 14.3.2.4.1 Treatment Emergent Adverse Events with Severity Grade 3 or Higher by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Infections and infestations (continued)			
Infection	1 (1.3)	0	1 (0.7)
Meningitis	0	1 (1.7)	1 (0.7)
Oral herpes	1 (1.3)	0	1 (0.7)
Osteomyelitis	0	1 (1.7)	1 (0.7)
Otitis externa	1 (1.3)	0	1 (0.7)
Periorbital cellulitis	0	1 (1.7)	1 (0.7)
Peritonitis	0	1 (1.7)	1 (0.7)
Pneumococcal sepsis	1 (1.3)	0	1 (0.7)
Pneumonia haemophilus	1 (1.3)	0	1 (0.7)
Pneumonia influenzal	1 (1.3)	0	1 (0.7)
Respiratory tract infection viral	0	1 (1.7)	1 (0.7)
Rhinovirus infection	0	1 (1.7)	1 (0.7)
Septic shock	1 (1.3)	0	1 (0.7)
Skin infection	0	1 (1.7)	1 (0.7)
Streptococcal sepsis	0	1 (1.7)	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

Program: t0ae0socpoly.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:02

Table 14.3.2.4.1 Treatment Emergent Adverse Events with Severity Grade 3 or Higher by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Infections and infestations (continued)			
Systemic infection	0	1 (1.7)	1 (0.7)
Tonsillitis	1 (1.3)	0	1 (0.7)
Musculoskeletal and connective tissue disorders	24 (31.2)	24 (40.0)	48 (35.0)
Growth retardation	24 (31.2)	22 (36.7)	46 (33.6)
Growth failure	0	2 (3.3)	2 (1.5)
Pain in extremity	1 (1.3)	0	1 (0.7)
Investigations	17 (22.1)	18 (30.0)	35 (25.5)
Blood creatine phosphokinase increased	9 (11.7)	7 (11.7)	16 (11.7)
Alanine aminotransferase increased	3 (3.9)	5 (8.3)	8 (5.8)
Neutrophil count decreased	2 (2.6)	4 (6.7)	6 (4.4)
Weight increased	2 (2.6)	3 (5.0)	5 (3.6)
Aspartate aminotransferase increased	2 (2.6)	2 (3.3)	4 (2.9)
Weight decreased	2 (2.6)	0	2 (1.5)
Activated partial thromboplastin time prolonged	1 (1.3)	0	1 (0.7)
Blood bilirubin increased	1 (1.3)	0	1 (0.7)

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MedDRA version 23.1.

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Table 14.3.2.4.1 Treatment Emergent Adverse Events with Severity Grade 3 or Higher by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Investigations (continued)			
Blood phosphorus decreased	0	1 (1.7)	1 (0.7)
Gamma-glutamyltransferase increased	0	1 (1.7)	1 (0.7)
Lipase increased	0	1 (1.7)	1 (0.7)
Lymphocyte count decreased	1 (1.3)	0	1 (0.7)
White blood cell count decreased	1 (1.3)	0	1 (0.7)
Nervous system disorders	13 (16.9)	13 (21.7)	26 (19.0)
Hydrocephalus	8 (10.4)	6 (10.0)	14 (10.2)
Seizure	2 (2.6)	5 (8.3)	7 (5.1)
Headache	3 (3.9)	2 (3.3)	5 (3.6)
Cerebral ventricle dilatation	1 (1.3)	0	1 (0.7)
Cerebrospinal fluid circulation disorder	0	1 (1.7)	1 (0.7)
Depressed level of consciousness	0	1 (1.7)	1 (0.7)
Intracranial pressure increased	1 (1.3)	0	1 (0.7)
Neurological decompensation	1 (1.3)	0	1 (0.7)
Status epilepticus	0	1 (1.7)	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Table 14.3.2.4.1 Treatment Emergent Adverse Events with Severity Grade 3 or Higher by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Nervous system disorders (continued)			
Syncope	0	1 (1.7)	1 (0.7)
Blood and lymphatic system disorders	11 (14.3)	13 (21.7)	24 (17.5)
Anaemia	9 (11.7)	11 (18.3)	20 (14.6)
Autoimmune haemolytic anaemia	1 (1.3)	0	1 (0.7)
Disseminated intravascular coagulation	1 (1.3)	0	1 (0.7)
Febrile neutropenia	0	1 (1.7)	1 (0.7)
Iron deficiency anaemia	1 (1.3)	0	1 (0.7)
Leukocytosis	0	1 (1.7)	1 (0.7)
Neutropenia	1 (1.3)	0	1 (0.7)
Metabolism and nutrition disorders	13 (16.9)	9 (15.0)	22 (16.1)
Hypokalaemia	6 (7.8)	2 (3.3)	8 (5.8)
Decreased appetite	3 (3.9)	2 (3.3)	5 (3.6)
Hypernatraemia	1 (1.3)	4 (6.7)	5 (3.6)
Hyponatraemia	1 (1.3)	3 (5.0)	4 (2.9)
Hypocalcaemia	1 (1.3)	1 (1.7)	2 (1.5)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Table 14.3.2.4.1 Treatment Emergent Adverse Events with Severity Grade 3 or Higher by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Metabolism and nutrition disorders (continued)			
Acidosis	1 (1.3)	0	1 (0.7)
Electrolyte imbalance	1 (1.3)	0	1 (0.7)
Hyperglycaemia	0	1 (1.7)	1 (0.7)
Hypoalbuminaemia	0	1 (1.7)	1 (0.7)
Hypoglycaemia	0	1 (1.7)	1 (0.7)
Hypophosphataemia	1 (1.3)	0	1 (0.7)
Metabolic acidosis	0	1 (1.7)	1 (0.7)
Obesity	0	1 (1.7)	1 (0.7)
Vitamin D deficiency	0	1 (1.7)	1 (0.7)
Skin and subcutaneous tissue disorders	13 (16.9)	8 (13.3)	21 (15.3)
Rash maculo-papular	8 (10.4)	3 (5.0)	11 (8.0)
Eczema	2 (2.6)	1 (1.7)	3 (2.2)
Erythema	0	2 (3.3)	2 (1.5)
Pruritus	2 (2.6)	0	2 (1.5)
Dermatitis acneiform	1 (1.3)	0	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

Program: t0ae0socpoly.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:02

Table 14.3.2.4.1 Treatment Emergent Adverse Events with Severity Grade 3 or Higher by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Skin and subcutaneous tissue disorders (continued)			
Photosensitivity reaction	0	1 (1.7)	1 (0.7)
Rash erythematous	1 (1.3)	0	1 (0.7)
Rash follicular	1 (1.3)	0	1 (0.7)
Rash pruritic	0	1 (1.7)	1 (0.7)
Gastrointestinal disorders	11 (14.3)	8 (13.3)	19 (13.9)
Vomiting	6 (7.8)	3 (5.0)	9 (6.6)
Ascites	2 (2.6)	0	2 (1.5)
Dental caries	2 (2.6)	0	2 (1.5)
Diarrhoea	1 (1.3)	1 (1.7)	2 (1.5)
Abdominal pain	0	1 (1.7)	1 (0.7)
Constipation	0	1 (1.7)	1 (0.7)
Gastrointestinal haemorrhage	0	1 (1.7)	1 (0.7)
Impaired gastric emptying	0	1 (1.7)	1 (0.7)
General disorders and administration site conditions	12 (15.6)	7 (11.7)	19 (13.9)
Pyrexia	5 (6.5)	4 (6.7)	9 (6.6)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Table 14.3.2.4.1 Treatment Emergent Adverse Events with Severity Grade 3 or Higher by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
General disorders and administration site conditions (continued)			
Fatigue	3 (3.9)	3 (5.0)	6 (4.4)
Brain death	1 (1.3)	0	1 (0.7)
Complication associated with device	1 (1.3)	0	1 (0.7)
Death	1 (1.3)	0	1 (0.7)
Hypothermia	0	1 (1.7)	1 (0.7)
Pseudocyst	1 (1.3)	0	1 (0.7)
Respiratory, thoracic and mediastinal disorders	4 (5.2)	5 (8.3)	9 (6.6)
Hypoxia	2 (2.6)	1 (1.7)	3 (2.2)
Respiratory failure	0	2 (3.3)	2 (1.5)
Adenoidal hypertrophy	1 (1.3)	0	1 (0.7)
Cough	1 (1.3)	0	1 (0.7)
Dyspnoea	0	1 (1.7)	1 (0.7)
Epistaxis	0	1 (1.7)	1 (0.7)
Sleep apnoea syndrome	1 (1.3)	0	1 (0.7)
Tonsillar hypertrophy	1 (1.3)	0	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
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Table 14.3.2.4.1 Treatment Emergent Adverse Events with Severity Grade 3 or Higher by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Respiratory, thoracic and mediastinal disorders (continued)			
Wheezing	1 (1.3)	0	1 (0.7)
Injury, poisoning and procedural complications	4 (5.2)	4 (6.7)	8 (5.8)
Shunt malfunction	3 (3.9)	3 (5.0)	6 (4.4)
Subdural haemorrhage	1 (1.3)	0	1 (0.7)
Traumatic fracture	0	1 (1.7)	1 (0.7)
Eye disorders	1 (1.3)	5 (8.3)	6 (4.4)
Visual impairment	1 (1.3)	1 (1.7)	2 (1.5)
Blepharitis	0	1 (1.7)	1 (0.7)
Extraocular muscle paresis	0	1 (1.7)	1 (0.7)
Optic nerve disorder	0	1 (1.7)	1 (0.7)
Visual acuity reduced	0	1 (1.7)	1 (0.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (2.6)	3 (5.0)	5 (3.6)
Tumour haemorrhage	2 (2.6)	2 (3.3)	4 (2.9)
Intracranial tumour haemorrhage	0	1 (1.7)	1 (0.7)
Product issues	2 (2.6)	2 (3.3)	4 (2.9)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Table 14.3.2.4.1 Treatment Emergent Adverse Events with Severity Grade 3 or Higher by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Product issues (continued)			
Device malfunction	0	2 (3.3)	2 (1.5)
Device breakage	1 (1.3)	0	1 (0.7)
Device occlusion	1 (1.3)	0	1 (0.7)
Endocrine disorders	0	3 (5.0)	3 (2.2)
Adrenal insufficiency	0	2 (3.3)	2 (1.5)
Growth hormone deficiency	0	1 (1.7)	1 (0.7)
Psychiatric disorders	1 (1.3)	2 (3.3)	3 (2.2)
Anxiety	1 (1.3)	1 (1.7)	2 (1.5)
Depression	0	1 (1.7)	1 (0.7)
Vascular disorders	1 (1.3)	2 (3.3)	3 (2.2)
Hypertension	0	2 (3.3)	2 (1.5)
Hypovolaemic shock	1 (1.3)	0	1 (0.7)
Renal and urinary disorders	1 (1.3)	1 (1.7)	2 (1.5)
Acute kidney injury	1 (1.3)	1 (1.7)	2 (1.5)
Cardiac disorders	1 (1.3)	0	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

Program: t0ae0socpoly.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:02

Table 14.3.2.4.1 Treatment Emergent Adverse Events with Severity Grade 3 or Higher by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Cardiac disorders (continued)			
Pericardial effusion	1 (1.3)	0	1 (0.7)
Hepatobiliary disorders	0	1 (1.7)	1 (0.7)
Cholecystitis	0	1 (1.7)	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

Program: t0ae0socpoly.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:02

Anhang 4-G2.6.4: UE mit CTCAE Grad = 5 nach SOC und PT

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Table 14.3.2.12.1 Treatment Emergent Adverse Events with Outcome of Death by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Patients with Any Treatment Emergent Adverse Event (TEAE) with Outcome of Death	2 (2.6)	3 (5.0)	5 (3.6)
General disorders and administration site conditions	2 (2.6)	0	2 (1.5)
Brain death	1 (1.3)	0	1 (0.7)
Death	1 (1.3)	0	1 (0.7)
Infections and infestations	0	2 (3.3)	2 (1.5)
Pneumonia	0	1 (1.7)	1 (0.7)
Sepsis	0	1 (1.7)	1 (0.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0	1 (1.7)	1 (0.7)
Tumour haemorrhage	0	1 (1.7)	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

Program: t0ae0socpoly.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:02

Anhang 4-G2.6.5: SUE nach SOC und PT

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Table 14.3.2.6.1 Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Patients with Any Serious Treatment Emergent Adverse Event (TEAE)	42 (54.5)	35 (58.3)	77 (56.2)
Infections and infestations	23 (29.9)	23 (38.3)	46 (33.6)
Pneumonia	1 (1.3)	5 (8.3)	6 (4.4)
Sepsis	4 (5.2)	2 (3.3)	6 (4.4)
Viral infection	4 (5.2)	2 (3.3)	6 (4.4)
Appendicitis	3 (3.9)	2 (3.3)	5 (3.6)
Device related infection	3 (3.9)	2 (3.3)	5 (3.6)
Cellulitis	0	3 (5.0)	3 (2.2)
Erysipelas	2 (2.6)	1 (1.7)	3 (2.2)
Otitis media	2 (2.6)	1 (1.7)	3 (2.2)
Rhinovirus infection	2 (2.6)	1 (1.7)	3 (2.2)
Shunt infection	0	3 (5.0)	3 (2.2)
Vascular device infection	2 (2.6)	1 (1.7)	3 (2.2)
Enterovirus infection	1 (1.3)	1 (1.7)	2 (1.5)
Gastroenteritis viral	1 (1.3)	1 (1.7)	2 (1.5)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Table 14.3.2.6.1 Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Infections and infestations (continued)			
Respiratory syncytial virus infection	1 (1.3)	1 (1.7)	2 (1.5)
Upper respiratory tract infection	0	2 (3.3)	2 (1.5)
Viral upper respiratory tract infection	2 (2.6)	0	2 (1.5)
Bacteraemia	0	1 (1.7)	1 (0.7)
Bronchitis	1 (1.3)	0	1 (0.7)
COVID-19 pneumonia	1 (1.3)	0	1 (0.7)
Clostridial sepsis	1 (1.3)	0	1 (0.7)
Clostridium difficile colitis	0	1 (1.7)	1 (0.7)
Coronavirus infection	0	1 (1.7)	1 (0.7)
Enterocolitis infectious	0	1 (1.7)	1 (0.7)
Extradural abscess	1 (1.3)	0	1 (0.7)
Herpes simplex reactivation	1 (1.3)	0	1 (0.7)
Infection	1 (1.3)	0	1 (0.7)
Meningitis	0	1 (1.7)	1 (0.7)
Oral herpes	1 (1.3)	0	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

Program: t0ae0socpoly.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:02

Table 14.3.2.6.1 Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Infections and infestations (continued)			
Osteomyelitis	0	1 (1.7)	1 (0.7)
Otitis externa	1 (1.3)	0	1 (0.7)
Periorbital cellulitis	0	1 (1.7)	1 (0.7)
Peritonitis	0	1 (1.7)	1 (0.7)
Pneumococcal sepsis	1 (1.3)	0	1 (0.7)
Pneumonia haemophilus	1 (1.3)	0	1 (0.7)
Pneumonia influenzal	1 (1.3)	0	1 (0.7)
Septic shock	1 (1.3)	0	1 (0.7)
Streptococcal sepsis	0	1 (1.7)	1 (0.7)
Systemic infection	0	1 (1.7)	1 (0.7)
Tonsillitis	1 (1.3)	0	1 (0.7)
Nervous system disorders	13 (16.9)	13 (21.7)	26 (19.0)
Hydrocephalus	6 (7.8)	5 (8.3)	11 (8.0)
Headache	5 (6.5)	3 (5.0)	8 (5.8)
Seizure	2 (2.6)	6 (10.0)	8 (5.8)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

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Table 14.3.2.6.1 Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Nervous system disorders (continued)			
Somnolence	1 (1.3)	1 (1.7)	2 (1.5)
Ataxia	0	1 (1.7)	1 (0.7)
Cerebral ventricle dilatation	1 (1.3)	0	1 (0.7)
Cerebrospinal fluid circulation disorder	0	1 (1.7)	1 (0.7)
Depressed level of consciousness	0	1 (1.7)	1 (0.7)
Dizziness	0	1 (1.7)	1 (0.7)
Intracranial pressure increased	1 (1.3)	0	1 (0.7)
Lethargy	0	1 (1.7)	1 (0.7)
Neurological decompensation	1 (1.3)	0	1 (0.7)
Status epilepticus	0	1 (1.7)	1 (0.7)
Syncope	0	1 (1.7)	1 (0.7)
Transient ischaemic attack	1 (1.3)	0	1 (0.7)
General disorders and administration site conditions	11 (14.3)	11 (18.3)	22 (16.1)
Pyrexia	7 (9.1)	8 (13.3)	15 (10.9)
Hypothermia	0	3 (5.0)	3 (2.2)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

Program: t0ae0socpoly.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:02

Table 14.3.2.6.1 Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
General disorders and administration site conditions (continued)			
Brain death	1 (1.3)	0	1 (0.7)
Complication associated with device	1 (1.3)	0	1 (0.7)
Death	1 (1.3)	0	1 (0.7)
Face oedema	1 (1.3)	0	1 (0.7)
Fatigue	0	1 (1.7)	1 (0.7)
Pseudocyst	1 (1.3)	0	1 (0.7)
Gastrointestinal disorders	8 (10.4)	8 (13.3)	16 (11.7)
Vomiting	5 (6.5)	4 (6.7)	9 (6.6)
Constipation	1 (1.3)	2 (3.3)	3 (2.2)
Abdominal pain	1 (1.3)	1 (1.7)	2 (1.5)
Ascites	2 (2.6)	0	2 (1.5)
Diarrhoea	0	1 (1.7)	1 (0.7)
Enterocolitis	0	1 (1.7)	1 (0.7)
Gastrointestinal haemorrhage	0	1 (1.7)	1 (0.7)
Tooth development disorder	0	1 (1.7)	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

Program: t0ae0socpoly.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:02

Table 14.3.2.6.1 Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Metabolism and nutrition disorders	6 (7.8)	8 (13.3)	14 (10.2)
Hypernatraemia	1 (1.3)	4 (6.7)	5 (3.6)
Hyponatraemia	2 (2.6)	3 (5.0)	5 (3.6)
Decreased appetite	2 (2.6)	1 (1.7)	3 (2.2)
Dehydration	1 (1.3)	1 (1.7)	2 (1.5)
Electrolyte imbalance	1 (1.3)	0	1 (0.7)
Hyperglycaemia	0	1 (1.7)	1 (0.7)
Hypoglycaemia	0	1 (1.7)	1 (0.7)
Hypophosphataemia	0	1 (1.7)	1 (0.7)
Metabolic acidosis	0	1 (1.7)	1 (0.7)
Musculoskeletal and connective tissue disorders	8 (10.4)	2 (3.3)	10 (7.3)
Growth retardation	7 (9.1)	2 (3.3)	9 (6.6)
Arthritis reactive	1 (1.3)	0	1 (0.7)
Blood and lymphatic system disorders	3 (3.9)	5 (8.3)	8 (5.8)
Anaemia	0	2 (3.3)	2 (1.5)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

Program: t0ae0socpoly.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:02

Table 14.3.2.6.1 Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Blood and lymphatic system disorders (continued)			
Autoimmune haemolytic anaemia	1 (1.3)	0	1 (0.7)
Disseminated intravascular coagulation	1 (1.3)	0	1 (0.7)
Febrile neutropenia	0	1 (1.7)	1 (0.7)
Haemolysis	0	1 (1.7)	1 (0.7)
Iron deficiency anaemia	1 (1.3)	0	1 (0.7)
Leukocytosis	0	1 (1.7)	1 (0.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	4 (5.2)	4 (6.7)	8 (5.8)
Tumour haemorrhage	3 (3.9)	3 (5.0)	6 (4.4)
Intracranial tumour haemorrhage	1 (1.3)	1 (1.7)	2 (1.5)
Injury, poisoning and procedural complications	3 (3.9)	4 (6.7)	7 (5.1)
Shunt malfunction	2 (2.6)	3 (5.0)	5 (3.6)
Subdural haemorrhage	1 (1.3)	0	1 (0.7)
Traumatic fracture	0	1 (1.7)	1 (0.7)
Product issues	2 (2.6)	2 (3.3)	4 (2.9)
Device malfunction	0	2 (3.3)	2 (1.5)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

Program: t0ae0socpoly.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:02

Table 14.3.2.6.1 Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Product issues (continued)			
Device breakage	1 (1.3)	0	1 (0.7)
Device occlusion	1 (1.3)	0	1 (0.7)
Respiratory, thoracic and mediastinal disorders	1 (1.3)	3 (5.0)	4 (2.9)
Hypoxia	1 (1.3)	1 (1.7)	2 (1.5)
Respiratory failure	0	2 (3.3)	2 (1.5)
Skin and subcutaneous tissue disorders	3 (3.9)	1 (1.7)	4 (2.9)
Erythema nodosum	1 (1.3)	0	1 (0.7)
Rash erythematous	1 (1.3)	0	1 (0.7)
Rash maculo-papular	1 (1.3)	0	1 (0.7)
Rash pruritic	0	1 (1.7)	1 (0.7)
Eye disorders	2 (2.6)	1 (1.7)	3 (2.2)
Dyschromatopsia	1 (1.3)	0	1 (0.7)
Extraocular muscle paresis	0	1 (1.7)	1 (0.7)
Vision blurred	1 (1.3)	0	1 (0.7)
Visual impairment	1 (1.3)	0	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
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Table 14.3.2.6.1 Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Cardiac disorders	1 (1.3)	1 (1.7)	2 (1.5)
Bradycardia	0	1 (1.7)	1 (0.7)
Ventricular extrasystoles	1 (1.3)	0	1 (0.7)
Endocrine disorders	0	2 (3.3)	2 (1.5)
Adrenal insufficiency	0	2 (3.3)	2 (1.5)
Hepatobiliary disorders	0	2 (3.3)	2 (1.5)
Cholecystitis	0	1 (1.7)	1 (0.7)
Cholelithiasis	0	1 (1.7)	1 (0.7)
Psychiatric disorders	1 (1.3)	1 (1.7)	2 (1.5)
Anxiety	1 (1.3)	1 (1.7)	2 (1.5)
Renal and urinary disorders	1 (1.3)	1 (1.7)	2 (1.5)
Acute kidney injury	1 (1.3)	1 (1.7)	2 (1.5)
Vascular disorders	1 (1.3)	1 (1.7)	2 (1.5)
Hypotension	0	1 (1.7)	1 (0.7)
Hypovolaemic shock	1 (1.3)	0	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
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Table 14.3.2.6.1 Serious Treatment Emergent Adverse Events by System Organ Class and Preferred Term
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Vascular disorders (continued)			
Vasculitis	1 (1.3)	0	1 (0.7)
Investigations	1 (1.3)	0	1 (0.7)
Weight decreased	1 (1.3)	0	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
MedDRA version 23.1.

Program: t0ae0socpoly.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:02

Anhang 4-G2.6.6: UE, die zum Therapieabbruch führten, nach SOC und PT

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Table 14.3.2.11.1 Treatment Emergent Adverse Events Leading to Discontinuation of Treatment
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
Patients with Any Treatment Emergent Adverse Event (TEAE) Leading to Discontinuation of Treatment	8 (10.4)	11 (18.3)	19 (13.9)
Musculoskeletal and connective tissue disorders	3 (3.9)	4 (6.7)	7 (5.1)
Growth retardation	3 (3.9)	3 (5.0)	6 (4.4)
Growth failure	0	1 (1.7)	1 (0.7)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	3 (3.9)	2 (3.3)	5 (3.6)
Tumour haemorrhage	3 (3.9)	2 (3.3)	5 (3.6)
Blood and lymphatic system disorders	1 (1.3)	2 (3.3)	3 (2.2)
Autoimmune haemolytic anaemia	1 (1.3)	0	1 (0.7)
Bone marrow failure	0	1 (1.7)	1 (0.7)
Haemolysis	0	1 (1.7)	1 (0.7)
Skin and subcutaneous tissue disorders	0	2 (3.3)	2 (1.5)
Dermatitis acneiform	0	1 (1.7)	1 (0.7)
Rash pruritic	0	1 (1.7)	1 (0.7)
Cardiac disorders	1 (1.3)	0	1 (0.7)
Ventricular extrasystoles	1 (1.3)	0	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
AE leading to discontinuation of treatment based on both primary and other action taken.
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Table 14.3.2.11.1 Treatment Emergent Adverse Events Leading to Discontinuation of Treatment
Safety Analysis Set - Arm 1 and Arm 2

	Arm 1 (Low-Grade Glioma) (N=77)	Arm 2 (Low-Grade Glioma Extension) (N=60)	Total (N=137)
General disorders and administration site conditions	0	1 (1.7)	1 (0.7)
Fatigue	0	1 (1.7)	1 (0.7)
Injury, poisoning and procedural complications	1 (1.3)	0	1 (0.7)
Shunt malfunction	1 (1.3)	0	1 (0.7)
Nervous system disorders	0	1 (1.7)	1 (0.7)
Cerebrospinal fluid circulation disorder	0	1 (1.7)	1 (0.7)

Patients with multiple events in the same category are counted only once in that category. Patients with events in more than one category are counted once in each of those categories.
AE leading to discontinuation of treatment based on both primary and other action taken.
MedDRA version 23.1.

Program: t0ae0socpoly.sas; Data extract date: 12SEP2025; Data cutoff date: 06JUN2025. 30OCT2025 21:02